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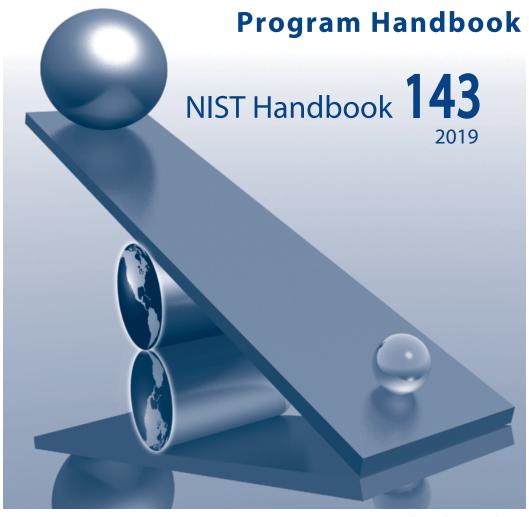
Withdrawn Publication					
Series/Number	NIST HB 143-2019				
Title	State Weights and Measures Laboratories Program Handbook				
<b>Publication Date(s)</b>	May 6, 2019				
Withdrawal Date	December 11, 2023				
Withdrawal Note	Replaced by updated version				
Superseding Publication(s) (if applicable)					
The attached publication has been <b>superseded by</b> the following publication(s):					
Series/Number	NIST HB 143-2023				
Title	NIST Office of Weights and Measures (OWM) Recognition Program				
	Handbook, 7th Edition				
Author(s)	Micheal M. Hicks; Georgia L. Harris; Isabel Chavez Baucom;				
	Elizabeth A. Koncki; Katrice A. Lippa				
<b>Publication Date(s)</b>	December 11, 2023				
URL/DOI	https://doi.org/10.6028/NIST.HB.143-2023				
Additional Information (if applicable)					
Contact					
Latest revision of the					
attached publication					
Related Information					
Withdrawal					
Announcement Link					

Date Updated: December 11, 2023





## State Weights and Measures Laboratories



This publication is available free of charge from: https://doi.org/10.6028/NIST.HB.143-2019 INSIDE FRONT COVER - BLANK

## NIST Handbook 143

2019 Edition Supersedes 2007 Edition

# State Weights and Measures Laboratories Program Handbook, 6<sup>th</sup> Edition

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This publication is available free of charge from: https://doi.org/10.6028/NIST.HB.143-2019

**May 2019** 



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National Institute of Standards and Technology Handbook 143, 2019 Edition, 52 pages (May 2019)

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#### **Preface**

The National Institute of Standards and Technology (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 are conveyed 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 recognition program for the States and to this Program Handbook since the first edition was published in 1985.

Although the program is operated independently from the National Voluntary Laboratory Accreditation Program (NVLAP), the general and technical criteria used in both programs are nearly identical. OWM does not provide formal accreditation according to International Organization for Standardization (ISO) standards.

**Regarding SI Units.** This publication conforms to the concept of primary use of the International System of Units (SI) recommended in the Omnibus Trade and Competitiveness Act of 1988 by citing SI units before U.S. Customary units where both units appear together and placing separate sections containing requirements for SI units before corresponding sections containing requirements for U.S. Customary units.

SI units are used where practical and where use or potential conversion errors will not likely impact the quality of laboratory measurement results. However, in some cases, laboratory standards and/or trade practice are currently restricted to the use of U.S. Customary units. Therefore, some sections in this publication will specify only U.S. Customary units. Non-SI units are commonly used in State legal metrology laboratories and the U.S. petroleum industry for many volumetric measurements. Therefore, non-SI units have been used to reflect the practical needs of the laboratories performing these measurements, as appropriate.

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### **Acknowledgments and History**

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

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

In 1992, the National Conference on Weights and Measures (NCWM) established an ISO 9000 Task Force. After review of the 1985 version of the Program 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:

- Reduce the number of redundant laboratory audits;
- Improve measurement compatibility and acceptance of measurement results between laboratories in the United States and internationally; and
- Comply with the ISO-series standards for quality and management.

The NCSL TQM Committee became an official American National Standards Institute (ANSI) documentary standard writing body (ANSI Committee Z 540) in 1994 and published the U.S. standard as Z540-1-1994, which incorporated ISO Guide 25 and Mil-Std-45662A. When NCSL published the standard in 1994:

- Mil-Std-45662A was rescinded by the Department of Defense in favor of the Z540-1-1994 standard;
- The NIST National Voluntary Laboratory Accreditation Program (NVLAP) and other national private accrediting bodies adopted and referenced ANSI/NCSL Z540-1-1994; and
- The Weights and Measures Division "WMD" abbreviation was incorporated into the standard into Parts 5 and 6 of the 1996 and 1997 editions of the Program Handbook. Additional requirements consistent with NVLAP requirements and with the needs of the legal metrology system were included.

In 1997, NIST management made the decision that NIST would operate only one formal accreditation program, the National Voluntary Laboratory Accreditation Program (NVLAP). Therefore, all references in the Program Handbook to accreditation by OWM were changed to

recognition and OWM ceased issuing *Certificates of Accreditation*. OWM continued to monitor the level of State compliance to the Program Handbook to ensure that adequate accuracy, traceability, and uniformity are maintained in State legal metrology laboratories.

In 1999, ISO/IEC Guide 25 was revised and became the international standard ISO/IEC 17025. The 2003 edition of the Program Handbook incorporated revisions to the procedures and general requirements of the NIST Office of Weights and Measures (OWM) *Measurement Assurance Program for State Laboratory Recognition*. The OWM procedures were revised to ensure continued consistency with international standards and guidelines, specifically those found in ISO/IEC 17025:1999.

In 2003, the requirements in Sections 4 and 5 of the Program Handbook were updated to contain clauses 4 and 5 of ISO/IEC 17025:1999 to ensure a recognized laboratory was competent to perform calibrations. Major changes included:

- In Section 4, *Management Requirements*, included additional or changed requirements in the areas of document control; requests, tenders, and contracts; purchasing; non-conforming work; corrective action; preventive action; and records. Those modifications incorporated changes that were consistent with ISO 9001:1994 requirements. A new clause, *Service to the Customer* was added; and
- In Section 5, Technical Requirements, were described in greater detail with continued recognition of customer needs and greater emphasis and detailed requirements on method validation; estimation of measurement uncertainty and traceability for testing laboratories; and provision for inclusion of interpretations and opinions on calibration certificates. A sampling plan was required where methods or specifications did not specify sampling procedures.

In 2007, Sections 4 and 5 were updated to incorporate ISO/IEC 17025:2005 updates.

This 2019 edition supersedes the 2007 edition of the Program Handbook. Editorial updates and clarifications ensure continued acceptance of measurement results from State legal metrology laboratories and ensure consistency with the NVLAP Program and other accreditation bodies. Major reorganization and updates were made.

- Each participating State legal metrology laboratory shall have an official copy of ISO/IEC 17025:2017 and agrees to comply with these handbook requirements under the conditions for recognition.
- Refinements to Section 2 and 3 include policy and procedure information specific to OWM operations and recognition process. Additional policy or requirements are outlined in Section 2 and apply generally to all State legal metrology laboratories without regard to recognition level.
- Section 2 describes how OWM considers requests for the recognition of remote facilities to be considered as being under one recognition.
- Section 2 includes multiple requirements for a participant laboratory that is concurrently recognized by OWM and accredited by NVLAP. Requirements are related to application for accreditation, adjustment of an accreditation scope, and the annual submission of NVLAP assessment letters and reports to OWM.
- Added emphasis is placed in Section 2 and 3 on the authorized representative(s)

- responsibility to respond in writing to an onsite assessment within 30 calendar days of receiving a final report.
- Figure 1, a flow chart that illustrates major steps of the recognition process, has been updated.
- Recognition Submission Requirements (Table 1) and Training Requirements (Table 2)
  are included in the Program Handbook as examples. Because the tables are periodically
  updated, current versions are maintained on the OWM website
  (www.nist.gov/labmetrology).
- The nature of *Conditional* (limited) recognition has been clarified to emphasize the restricted nature of this rarely used level.
- Certificate of Metrological Traceability effective date ranges have been modified to typically begin between January 1 and February 1 and expire on the subsequent December 31 or January 31 based on the recognition level.
- The annual submission period for laboratories from RMAPs that meet in the Fall has been extended to November 15.
- Sections 4 (Management) and Section 5 (Technical) requirements of ISO/IEC 17025:2005 were eliminated and replaced with a reference to ISO/IEC 17025:2017.
- Section 4 now contains supplemental requirements for weights and measures laboratories, including a reference to technical requirements published in NIST HB 150-2 Annexes for legal metrology, mass, and volume.
- Section 6 (Technical Guidelines) was eliminated and replaced with reference to the technical requirements published in NIST HB 150-2 Annexes for legal metrology, mass, and volume.
- Section 7 (References) and Section 8 (Glossary) were incorporated in Section 1.
- Appendix A (List of NIST Services) has been revised to focus on only OWM services.
- Appendix B (Request for Recognition) and D (Summary of Services) have been replaced
  with a *Recognition Application* form that is available online
  (www.nist.gov/labmetrology).
- Appendix B now contains the summary of legal metrology recognition parameters. Grain Moisture was eliminated from Typical Legal Metrology Recognition Parameters (Table 3).
- Appendix C (Laboratory Assessment Checklist) has been eliminated and replaced with internal audit job aids that are available online (www.nist.gov/labmetrology).
- Appendix E (Uncertainties) has been eliminated. Laboratories must submit their measurement scope, including parameters, ranges, uncertainties, and methods to OWM in a separate file that is submitted with the *Recognition Application*.

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## 1. Program Summary

1.1. Description. State legal metrology laboratories are custodians of measurement standards at the State level that serve as the basis for ensuring equity in the marketplace and as reference standards for calibration services for indigenous industry. The National Institute of Standards and Technology (NIST) Office of Weights and Measures (OWM) has developed performance standards and formalized procedures for the voluntary recognition of State legal metrology laboratories to encourage a high degree of technical and professional competence in calibration activities.

It is the objective of NIST to encourage all State legal metrology laboratories to seek full recognition and formal accreditation. Technical assistance and consultation services are provided to State legal metrology laboratories to help achieve this goal (Appendix A). *Certificates of Metrological Traceability* detail the recognized measurement scope that is issued upon evaluation of a laboratory's ability to reliably make metrologically traceable measurements related to legal metrology, principally the parameters of mass, volume, length, and temperature (Appendix B). The OWM organizational chart and primary State legal metrology laboratory recognition contacts are available on the *Staff and Technical Experts Directory* (www.nist.gov/owm).

OWM adopts ISO/IEC 17025:2017 and the technical criteria and requirements in NIST Handbook (HB) 150-2 Annexes, which amplify ISO/IEC 17025 general criteria for each specific measurement parameter and policies of the International Laboratory Accreditation Cooperation (ILAC). To effectively implement this handbook, each applicant State laboratory shall have an official copy of ISO/IEC 17025:2017. OWM does not comply with ISO/IEC 17011 or sign international agreements of ILAC because it does not operate a formal accreditation program.

The OWM Laboratory Metrology Program interfaces with the NIST National Voluntary Laboratory Accreditation Program (NVLAP) for participating State laboratories that concurrently maintain accreditation. Contact information for NVLAP personnel and calibration program management responsibilities are available on the NIST website (www.nist.go/nvlap).

**1.2 Impact of Recognition.** The NIST Handbook 130, *Uniform Laws and Regulations in the Areas of Legal Metrology and Engine Fuel Quality*, model weights and measures laws, or alternative laws adopted by jurisdictions, frequently affirm that weights and measures programs are required to ensure metrological traceability to NIST or the International System of Units (SI). Current model laws indicate that laboratory recognition or accreditation provides demonstrated evidence of metrological traceability.

An impact of the OWM State legal metrology laboratory recognition over accreditation alone is demonstrated by annual targeted evaluations that focus on specific technical areas throughout all participating laboratories, especially when and where problems have been identified. The discovery of national or regional trends provides unique information that is not analyzed by accreditation programs. Findings help identify metrology training and program needs that are used as inputs in the OWM training program, proficiency testing, and publication updates.

Annual national level analyses are conducted to evaluate system-wide trends from laboratory quality management system documentation, management reviews, internal audits, measurement assurance data, and proficiency testing participation. Analysis resources and job aids are developed for annual assessments and are available on the OWM website (www.nist.gov/labmetrology). Past national level evaluations have included: facility assessment, software verification and validation, succession planning, measurement assurance, uncertainties, and metrological traceability.

State legal metrology laboratories are custodians at the State level of measurement standards that serve as the basis for ensuring equity in the marketplace and as reference standards for calibration services for domestic industry. Over 400 000 calibrations are provided each year for nearly 20 000 customers throughout the United States. About 50 percent of these measurements are in support of regulatory weights and measures activities. The other 50 percent of the measurements provide accessibility to reference measurement standards for local government, educational institutions, and a wide variety of industries. This nationwide availability of measurement services forms a valuable link in the U.S. national measurement infrastructure.

**1.3 State Legal Metrology Laboratory Recognition.** This Program Handbook describes the process and procedures followed in evaluating 55 State and approved jurisdictional legal metrology laboratories for competence. This program is managed by the OWM. Each State legal metrology laboratory shall carefully study this Handbook and apply for recognition in all areas in which it provides measurement services. To be formally recognized, a laboratory must satisfy general, management, and technical requirements for each measurement parameter in which recognition is desired (Appendix B).

Under this voluntary recognition program, State legal metrology laboratories self-appraise compliance with the requirements of this Program Handbook, complete appropriate forms, meet established deadlines, and undergo an annual external evaluation by OWM. Recognition program requirements in Section 2 and Section 4 of this Program Handbook and the management and technical requirements in ISO/IEC 17025:2017 address internationally accepted quality management practices for calibration laboratories.

Following annual external review and evaluation, OWM may issue a *Certificate of Metrological Traceability* that indicates recognized competence areas and defined measurement parameters that establish the scope of recognition. Recognition may be granted for a period up to 2 years as described in Section 3 of this Program Handbook. Each laboratory shall annually review its status, comply with all submission requirements, and inform OWM in writing of any significant changes when they occur.

OWM reserves the right to deny or suspend recognition. In such cases, OWM will notify the State legal metrology laboratory authorized representative(s) in writing of nonconformities and will provide guidelines for corrective action. In the case where full recognition has not been demonstrated, OWM will attempt to reach agreement with and commitment by the State legal metrology laboratory to schedule and achieve corrective action. In these rare cases, OWM may grant a *Conditional* (limited) recognition level that permits operations that only meet the legal requirements of that jurisdiction alone.

In this document, the following verbal forms are used:

- "Shall" indicates a requirement;
- "Should" indicates a recommendation;
- "May" indicates a permission; and
- "Can" indicates a possibility or a capability.

#### 1.4 Abbreviations and Acronyms.

AB Accreditation Body

CMC Calibration and Measurement Capability

IACET International Association for Continuing Education and Training

IEC International Electrotechnical Commission

ILAC International Laboratory Accreditation Cooperation

ILC Interlaboratory Comparison

ISO International Organization for Standardization

LAP Laboratory Auditing Program

MRA Mutual Recognition Arrangement

NCSLI National Conference of Standards Laboratories International

NCWM National Conference on Weights and Measures

NIST National Institute of Standards and Technology

NISTIR NIST Interagency or Internal Report

NVLAP National Voluntary Laboratory Accreditation Program

OWM Office of Weights and Measures

PT Proficiency Test

RMAP Regional Measurement Assurance Program

TE Technical Expert

VIM International Vocabulary of Metrology

**1.5 Terms and Definitions.** For the purposes of this Program Handbook, the relevant terms and definitions given in ISO/IEC 17000 and the VIM apply. General definitions related to quality are given in ISO 9000, whereas ISO/IEC 17000 gives definitions specifically related to certification and laboratory accreditation. Where different definitions are given in ISO 9000, the definitions in ISO/IEC 17000 and the VIM are used.

**Accreditation:** A formal process of determining the technical competence of a laboratory to carry out specific types of testing, measurement and calibration. It provides formal acknowledgement that the laboratory is competent, impartial, and independent. Regular

evaluation occurs to ensure continued compliance with requirements and to check that standards of operation are being maintained.

NOTE - NVLAP accredited state laboratories must maintain concurrent recognition. A State legal metrology laboratory must seek OWM approval before submitting an accreditation application to NVLAP.

**Accredited Laboratory:** A laboratory accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA). Accreditation bodies that are signatories to the ILAC MRA have been peer evaluated in accordance with the requirements of ISO/IEC 17011 to demonstrate their competence.

**Approved Signatory:** An individual who is designated by a laboratory and deemed competent by OWM to sign recognized laboratory calibration certificates. Is responsible for the technical content of the certificate and is the contact person for questions or problems with the certificate. Has responsibility, authority, and technical capability within the organization for the results produced. A recognized State legal metrology laboratory shall maintain an approved signatory(ies) list and make the list available for review during onsite assessments and to OWM upon request. The list is an integral part of the annual *Recognition Application*.

**Assessment, Onsite:** Systematic and documented process for determining laboratory competence and for obtaining records, statements of fact or other relevant information by OWM assessors at the laboratory facilities and other places where calibration services are provided with the objective of determining the extent to which OWM requirements are fulfilled.

**Authorized Representative(s):** An individual or individuals who is approved by the parent organization or laboratory top management to commit the laboratory to fulfill the OWM recognition conditions. Permitted to change the scope or nature of the laboratory's *Recognition Application* and is responsible for reporting changes to OWM that may affect the laboratory's capability, scope, or compliance with recognition requirements. Is the only designate party to receive official OWM administrative correspondence. Multiple individuals may be designated.

**Calibration:** A set of operations which, under specified conditions, in a first step, establishes the relationship between values with measurement uncertainties provide by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

Calibration and Measurement Capability: A calibration and measurement capability available to customers under normal conditions as described in the laboratory recognition scope granted by OWM, where the calibration is 1) performed according to a documented procedure and has an established uncertainty budget under the management system of the recognized laboratory; 2) performed on a regular basis (including on demand or scheduled for convenience at specific times in the year); and 3) available to all customers.

**Certificate of Metrological Traceability:** A document issued by OWM to a participating state legal metrology laboratory that has been granted recognition according to the requirements of this Program Handbook. Is always issued with a Measurement Scope and characterizes the recognition, either *full* (normal) or *Conditional* (limited).

**Competence:** Ability of a laboratory to perform calibrations in accordance with the specified standards and to produce accurate, proper, fit for purpose, technically valid data and calibration results.

**Corrective Action:** An action taken to eliminate the causes of an existing nonconformity or other undesirable situation to prevent recurrence.

**Customer:** Any person or organization that engages the services of a State legal metrology calibration laboratory.

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.

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.

**Headquarters:** A calibration laboratory facility established in a dedicated location where recognized measurements are performed.

**Interlaboratory Comparisons:** Organization, performance, and evaluation of measurements on the same or similar items *between/among* two or more laboratories in accordance with predetermined conditions. In some circumstances, one of the laboratories involved in the intercomparison may be the laboratory that provided the assigned measurement value for the calibration item.

**Internal Audit:** The self-appraisal process used by a calibration laboratory to evaluate compliance to recognition (or accreditation), organization operational requirements, and quality activities that are based on specified general, quality management, and technical criteria through analyzing objective evidence such as records, observations, and interviews. The ongoing process is operated according to planned arrangements to ensure the effective implementation of resulting actions and the achievement of objectives.

**Intralaboratory Comparison:** The organization, performance, and evaluation of measurements or tests on the same or similar items between multiple personnel working *within* the same laboratory in accordance with predetermined schedule.

**Laboratory:** Organization that performs one or more of the following activities: testing, calibrations, or sampling associated with subsequent testing or calibration. When a laboratory is part of an organization that carries out activities additional to calibration, the term laboratory

refers only to those parts of that organization that are involved in the calibration process. A laboratory's activities may be carried out at a permanent, temporary, or remote location.

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

**Laboratory Metrology Program:** A NIST OWM program that provides guidance, technical support, and assistance to State legal metrology laboratories to ensure accurate and traceable measurements are made within each participating jurisdiction.

**Length Laboratory:** Specific area within a metrology laboratory that is used for the calibration of length standards.

**Management System:** Set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives.

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

**Mass Laboratory:** Specific area within a metrology laboratory that is used for calibration of mass standards or field weights, generally divided into specific areas that avoid incompatible activities.

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

**Measurement Procedure:** A detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result. Synonymous with the term method.

**Measurement Scope:** A range of approved measurements issued by OWM to a participating State legal metrology laboratory that has been granted OWM recognition. The measurement scope is found on the *Certificate of Metrological Traceability* and details calibration services for which the laboratory is recognized. See also: *Calibration and Measurement Capability*.

**Measurement Uncertainty:** Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

- NOTE 1 Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.
- NOTE 2 The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.
- NOTE 3 Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.
- NOTE 4 In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty. [JCGM 200:2012 2.26]

**Method:** Defined technical procedure to determine one or more specified characteristics of a material or product. Synonymous with the term measurement procedure.

**Metrological Traceability:** Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty. [JCGM 200:2012 2.41]

- NOTE 1 For this definition, a "reference" can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.
- NOTE 2 Metrological traceability requires an established calibration hierarchy.
- NOTE 3 Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.
- NOTE 4 For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.

NOTE 5 - Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

NOTE 6 - A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

NOTE 7 - The ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC P-10:2002).

NOTE 8 - The abbreviated term "traceability" is sometimes used to mean "metrological traceability" as well as other concepts, such as "sample traceability" or "document traceability" or "instrument traceability" or "material traceability", where the history ("trace") of an item is meant. Therefore, the full term of "metrological traceability" is preferred if there is any risk of confusion.

NOTE 9 (OWM) - A measurement quality assurance system and periodic verification are required for State legal metrology laboratories to ensure that the accuracy of the measurement is within the stated limits of uncertainty.

**Metrologist**: A measurement scientist. Qualifications for a metrologist working in a recognized State laboratory include completing the level of training required for the recognized measurement scope, successful proficiency testing results aligned to meet the recognized measurement scope, and ongoing professional development, including required annual RMAP training.

**Metrology:** The science of measurement and its application, including all theoretical and practical aspects of measurement, whatever the measurement uncertainty and field of application.

**Nonconformity:** Nonfulfillment of OWM recognition requirements.

**Objective Evidence:** Data supporting the existence or verity of something. Objective evidence may be obtained through observation, interview, measurement, or other means. [ISO 9000:2015, 3.8.3]

**Proficiency Test:** The determination of the calibration or testing performance of a laboratory or the testing performance of an inspection body against pre-established criteria by means of interlaboratory comparison.

NOTE 1 - For the purposes of this Program Handbook, the term "proficiency testing" is taken in its widest sense and includes, but is not limited to:

- a) Quantitative scheme, where the objective is to quantify one or more measurands of the proficiency test item;
- b) Qualitative scheme, where the objective is to identify or describe one or more characteristics of the proficiency test item;
- c) Sequential scheme, where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the proficiency testing provider at intervals;
- d) Simultaneous scheme, where proficiency test items are distributed for concurrent testing or measurement within a defined time period;
- e) Single occasion exercise, where proficiency test items are provided on a single occasion;
- f) Continuous scheme, where proficiency test items are provided at regular intervals;
- g) Sampling, where samples are taken from a larger sample for subsequent analysis; and
- h) Data transformation and interpretation, where sets of data or other information are furnished and the information is processed to provide an interpretation (or other outcome). [ISO/IEC 17043:2010, 3.7]

**Quality Management System:** Part of a management system with regard to quality. [ISO 9000:2015, 3.5.4]

**Quality Manual:** Specification for an organization quality management system that often references other laboratory documentation.

NOTE 1 - Quality manuals can vary in detail and format to suit the size and complexity of an individual organization. [ISO 9000:2015, 3.8.8]

**Recognition:** A formal evaluation process of determining the technical competence of a State legal metrology laboratory to carry out specific calibration types and fulfill the requirements of NIST HB 143 (not a formal accreditation). The issuance of a *Certificate of Metrological Traceability* by OWM provides acknowledgement that the laboratory is competent, impartial, and independent. Regular evaluation occurs to ensure continued compliance with requirements and to check that standards of operation are being maintained. Training and assistance provided by OWM to State legal metrology laboratories supports the achievement and maintenance of ISO/IEC 17025 compliance as well as technical training.

NOTE - OWM recognized State legal metrology laboratories may also maintain concurrent accreditation.

**Regional Measurement Assurance Program (RMAP):** A regional approach to ensuring measurement assurance through periodic gathering to conduct training, interlaboratory comparisons, proficiency testing, and continuous improvement activities. OWM jointly operates six regions in cooperation with the State legal metrology laboratories.

**Remote Site:** A location outside calibration laboratory headquarters facility where calibrations are performed by laboratory personnel or by laboratory personnel assigned to the location. Any alternative location other than the headquarters authorized to perform recognized measurements shall be designated on the *Certificate of Metrological Traceability*.

**Requirement:** Provision that conveys criteria to be fulfilled. OWM requirements are mandatory and must be fulfilled to achieve and maintain recognition. OWM requirements are described in this Program Handbook.

**Revocation:** Removal of the recognition status of a laboratory if the laboratory is found to have violated the conditions for recognition.

**Standard, Check:** A standard that is used as part of a process measurement assurance program to evaluate the process and standards to ensure that the standards, measurement results, and measurement processes are within acceptable statistical limits.

**Standard, Intrinsic:** A standard based on well-characterized laws of physics, fundamental constants, or invariant properties of materials; they make ideal stable, precise, and accurate measurement standards when properly designed, characterized, operated, monitored and maintained.

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

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

**Standard, Secondary:** A standard whose value is assigned by comparison with a reference [or primary] standard of the same quantity.

**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.

**Standard Operating Procedure (SOP):** A technical procedure adopted for repetitive use when performing a specific measurement. It may be a nationally or internationally accepted method or one developed, verified, and validated by the user.

**Suspension:** Temporary removal by OWM of the recognition status of a State legal metrology laboratory for all or part of its measurement scope it is determined (by the laboratory or by OWM) that the laboratory does not meet recognition conditions.

**Temperature Laboratory:** Specific area within a metrology laboratory that is used for the calibration of temperature standards.

**Traceability:** See Metrological Traceability.

**Volume Laboratory:** Specific area within a metrology laboratory that is used for the calibration or tolerance testing of volume standards, generally divided into specific areas that avoid incompatible activities.

**1.6. References.** The following documents are referred to in this Program Handbook so that all or some of the content constitutes requirements of this program. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced documents (including any amendments) apply.

#### General

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

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

ILAC-G21, Cross-Frontier Accreditation - Principles for Cooperation.

ILAC-P10:01/2013, ILAC Policy on Traceability of Measurement Results.

ILAC-P14, ILAC Policy ILAC Policy for Uncertainty in Calibration.

ILAC-R7:05/2015, Rules for the Use of the ILAC MRA Mark.

ISO 9000:2015, Quality Management Systems - Fundamentals and Vocabulary.

ISO 9001, Quality Management Systems – Requirements.

ISO/IEC 17000:2004, Conformity Assessment - Vocabulary and General Principles.

ISO/IEC 17011, Conformity Assessment - General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies.

ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories.

ISO/IEC 17043:2010, Conformity Assessment - General Requirements for Proficiency Testing.

ISO/IEC Guide 2:2004, Standardization and Related Activities - General Vocabulary.

National Conference of Standards Laboratories International (NCSL International) LM-14:2010, *Metrology Human Resources Handbook*.

NCSL International RP-7:2000, Laboratory Design.

NCSL International RP-20:2010, Laboratory Workforce Planning.

NIST Handbook (HB) 150, National Voluntary Laboratory Accreditation Program (NVLAP) NVLAP Procedures and General Requirements.

NIST HB 150-2, NVLAP Calibration Laboratories.

NISTIR 7854:2012, Guidelines for NIST Staff Participating in Documentary Standards Developing Organizations' Activities.

NIST Special Publication (SP) 330, The International System of Units (SI).

NIST SP 811, Guide for the Use of the International System of Units (SI).

#### **Technical**

Technical requirements for recognition, additional resources, job aids, and records to support the State legal metrology laboratories are maintained and published by OWM. Individual procedures are periodically updated and available for download from the OWM website (www.nist.gov/labmetrology). Participant laboratories shall periodically verify the version status of each procedure to ensure the laboratory uses the current edition.

Publications that include the general and technical requirements for State legal metrology laboratory recognition include:

NIST HB 145:1986, Handbook for the Quality Assurance of Metrological Measurements.

Note - This publication is out of print. Most sections have been replaced with NISTIRs. A limited number of archive sections are available on the OWM website.

NISTIR 5672, Advanced Mass Measurements and Measurement Assurance Program for State Calibration Laboratories.

NISTIR 6969, Selected Laboratory and Measurement Practices, and Procedures, to Support Basic Mass Calibrations.

NISTR 7082, Proficiency Test Policy and Plan (for State Weights & Measures Laboratories).

NISTIR 7214, Weights and Measures Quality Manual for Proficiency Testing and Interlaboratory Comparisons.

NISTIR 7383, Selected Procedures for Volumetric Calibrations.

NISTIR 8028, Selected Laboratory and Measurement Practices and Procedures for Length Calibrations.

## 2. General Information and Operational Requirements

**2.1 Purpose.** OWM is a United States Government entity administered by NIST, an agency of the U.S. Department of Commerce. 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 recognize qualifying 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 criteria contained in this Program Handbook is the most effective means for ensuring accurate measurements consistent with national standards.

As part of NIST's continuing support to the States, OWM manages the Laboratory Metrology Program, which is 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 (Appendix A). The program operates through continued partnership with the State legal metrology laboratories to manage numerous activities within the program.

**2.2 Description.** 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 legal metrology laboratories and increase their measurement capabilities. The program also provided the laboratory equipment necessary for the States to use the standards to provide 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 that met specifications established under the State Standards Program and to maintain acceptable staffing. The laboratory metrologist was required to complete training at NIST to ensure proper use of the standards and equipment.

- **2.3 Quality Policy.** It is the policy of the Laboratory Metrology Program to help all State legal metrology laboratories achieve and maintain recognition and to enable State legal metrology laboratories to provide their customers accurate and traceable measurement services in an atmosphere of continual quality improvement.
- **2.4 Objectives.** The objectives of the State Laboratory Program are to:
  - Support the basic level of measurement services required for legal metrology enforcement and oversight activities;
  - Provide technical support for the accuracy and traceability of State legal metrology laboratories to the International System of Units (SI) through development, training, publication of, and use of standard procedures, protocols, proficiency testing, and measurement assurance programs;
  - Provide and maintain the recognition program for State legal metrology laboratories as evidence of continuing measurement traceability to include auditing of the use and care of the physical artifact standards of mass, length, and volume; and
  - Assist the States to upgrade and expand laboratory measurement services to satisfy the changing needs of the legal metrology system and laboratory customers.

**2.5 Description and Scope.** This Program Handbook sets forth the general requirements under which OWM operates a recognition program for State legal metrology laboratories. The Program Handbook shall be used to develop laboratory management and technical systems that govern participant laboratory operations. State legal metrology laboratories that fulfill Program Handbook requirements meet both the management system and technical competence requirements necessary to consistently deliver technically valid calibration results.

**Voluntary, Non-contractual, and Fees.** The recognition function for participating State legal metrology laboratories is a voluntary and non-regulated program of support to the States. It provides a cost-effective means for providing evidence of measurement accuracy and traceability.

Responsibility for measurement accuracy and traceability used in trade and commerce is cooperatively shared by a group of Federal and State agencies. An excellent working partnership exists between the State legal metrology laboratories and OWM. The State legal metrology laboratories provide payment-in-kind through voluntary efforts for many of the activities needed to maintain the recognition process, procedure development, instruction at training seminars, and the coordination and analysis of proficiency testing in partnership with OWM. Because of this partnership and shared responsibilities, fees are not charged to participant laboratories to support the recognition process.

**Measurement Scope.** Each State legal metrology laboratory must define the measurement scope, which includes the specific range and metrological uncertainty level for each recognized measurement parameter. Uncertainties shall be defined at each level. For example, each laboratory must maintain a document that reports each nominal mass, each nominal volume, and so on, with the associated uncertainty. The OWM recognition program measurement parameters are limited to legal metrology (Appendix B).

**Legal Compliance Requirements.** Although there are currently no Federal recognition requirements, some States have weights and measures laws that require continued formal accreditation, certification, approval, or other forms of recognition by NIST as evidence of maintaining metrological traceability for reference [primary] standards used in the enforcement of weights and measures laws.

**Limitations.** The OWM recognition program is limited in scope. It is provided only for government legal metrology laboratories. Eligible program participants include each State legal metrology laboratory, plus those of Puerto Rico, the District of Columbia, the Virgin Islands, Los Angeles County, and the U.S. Department of Agriculture, Agricultural Marketing Service, Federal Grain Inspection Service (USDA, AMS, FGIS). In contrast, NVLAP offers accreditation services to all laboratories and is not limited in the audience or scope of whom may be accredited.

**Liability.** NIST recognition does not certify individual measurements made by a State, but formally recognizes that the State legal metrology laboratory has traceable standards, the capability to perform reliable measurements, and that approved signatory(ies) performing

measurements have been trained in the proper implementation of procedures to provide traceable measurements and has demonstrated competence and proficiency. Recognition also indicates that the authorized representative(s) has submitted technical data, records, and documentation requested by NIST. NIST assumes no liability for the accuracy and traceability of individual measurement results provided by a recognized laboratory.

**2.6 Services.** OWM offers consultative and technical support through informal and formal means to all State legal metrology laboratories regardless of their recognition status (Appendix A). Informal assistance may be in the form of telephone, e-mail, mailed responses, or courtesy onsite laboratory visits. Formal support and assistance are available through the OWM training program and the Regional Measurement Assurance Program (RMAP) of the Laboratory Metrology Program.

**Recognition of Remote Facilities.** In limited situations, a State legal metrology laboratory organization may request that remote facility sites be considered as being under one recognition. For two or more locations to be considered as one recognition, the following shall be considered:

- If the headquarters has oversight of the quality management system of the remote facility, including but not limited to development of policies, procedures, and document control; and
- If the headquarters has oversight of the technical operations of the remote (field) site.

If OWM determines that two or more locations fall under the same recognition scope, the remote facility site will be designated on the *Certificate of Metrological Traceability* and the following shall be considered in the *Recognition Application* review and onsite assessment:

- How proficiency testing (PT) is distributed between personnel and sites; and
- How traceability requirements are met.

All requirements in this Program Handbook apply to remote sites. OWM reserves the right to not recognize a remote facility.

**Subcontracting.** OWM generally does not subcontract activities related to determining recognition status and issuing a *Certificate of Metrological Traceability*. OWM may contract with technical experts (TEs) to perform onsite training, onsite assessments, or proficiency tests.

**2.7 Confidentiality.** To the extent permitted by applicable laws, OWM seeks to ensure the confidentiality of all information obtained relating to the application, evaluation, onsite assessment, and recognition of State legal metrology laboratories, unless the laboratory provides permission to share such information. For example, best practices may be shared in training.

An exception is the implementation of Proficiency Testing, described in *NISTIR 7082 Proficiency Test Policy and Plan for State Weights & Measures* Laboratories. All OWM PTs are considered OPEN and anonymity is not implied or guaranteed.

**2.8 Requirements Development.** When national or international standards accreditation requirements for calibration laboratories are available, OWM adopts such standards as program criteria after suitable review. This includes ISO/IEC 17025:2017, ILAC policies, NVLAP

handbooks, and other suitable publications. OWM has supplemental requirements that are detailed later in this Program Handbook (Section 4).

The National Technology Transfer and Advancement Act (NTTAA) directs federal agencies to use voluntary standards whenever they are available and applicable in lieu of developing their own standards, thereby reducing the number of government unique standards for regulatory and procurement activities. OWM adopts national or international standards whenever feasible and appropriate.

**Solicitation of Comment and Review by Affected Laboratories.** Draft laboratory publications are reviewed by affected laboratories prior to publication. This edition of the Program Handbook was posted and open for comment from April 2018 to October 2018.

- **2.9 Records.** OWM maintains recognition records related to the accuracy and traceability of standards and measurements for each State according to NIST record retention policies. Records include, but are not limited to, the following:
  - 1) Management review and internal audit reports;
  - 2) Quality manual, administrative procedures, and associated appendices latest version;
  - 3) Traceability records for reference [primary] standards, working standards, and check standards, including traceability hierarchies and calibration certificates;
  - 4) Measurement assurance data (control charts and surveillance tests) latest year as submitted;
  - 5) Uncertainty tables latest year;
  - 6) Personnel training and Laboratory Auditing Program (LAP) problem completion;
  - 7) RMAP proficiency test reports; and
  - 8) Onsite assessment reports.
- **2.10 Recognition Status Notification.** OWM reserves the right to notify State and Federal agencies as well as any indigenous industry of a State regarding recognition and/or accreditation status. This is generally accomplished through the periodic publication of State legal metrology laboratory status information online and may include periodic memoranda to affected parties. Copies of current *Certificate of Metrological Traceability* (PDF) for each recognized laboratory are posted on the OWM website (www.nist.gov/owm). A downloaded *Certificate of Metrological Traceability* (PDF) is sufficient evidence to demonstrate and verify laboratory recognition status.
- **2.11 Complaints.** Any person or organization may submit a complaint regarding the activities of a recognized State legal metrology laboratory by sending a written description of the complaint and supporting documentation to OWM. A complaint concerning a recognized laboratory should first be addressed by the laboratory against which the complaint is lodged. OWM will evaluate each complaint, including determining the complaint validity, taking appropriate and effective actions, responding to complainants, and recordkeeping.
- **2.12. Recognized Laboratory Duties and Responsibilities.** To effectively implement this Program Handbook, each applicant State laboratory shall have an official copy of ISO/IEC 17025:2017.

Certificate of Metrological Traceability Display. Each Certificate of Metrological Traceability issued to a recognized laboratory details the approved measurement scope and effective dates. The State legal metrology laboratory should display the current Certificate of Metrological Traceability in the laboratory facility, post to the organization webpage, and link to the OWM State Laboratory Contacts webpage (www.nist.gov/owm). A Certificate of Metrological Traceability may be copied and distributed to laboratory customers to use as evidence of traceability.

**Referencing Recognition Status**. A State legal metrology laboratory may reference the *Certificate of Metrological Traceability* or recognition status only if it is consistent with NIST legal policy (15 CFR Ch. 11, 200.113) on the use of the NIST name. Permitted materials include: letterhead, brochures, websites, and other communication media. The NIST name may not be used for endorsement purposes, but may be used to make factual statements regarding recognition, accreditation, or metrological traceability. A participant laboratory may not use the recognition status in a manner that brings NIST into disrepute or misrepresent the laboratory's scope of recognition or recognition status.

Reference is only permitted for State legal metrology laboratories with full or *Conditional* (limited) recognition. Recognition status must be clearly communicated to laboratory customers by using appropriate terms to represent the recognition level and only for measurement parameters and scope that are specifically recognized: Recognized or *Conditionally* (limited) recognized. Reference is prohibited for laboratories with suspended or voluntarily withdrawn recognition. A State legal metrology laboratory shall discontinue reference immediately upon the suspension, revocation, voluntary termination, or scope modifications of recognition as applicable. An applicant laboratory that has not yet achieved recognition may not reference its applicant status.

For State legal metrology laboratories that have both recognized and unrecognized sites, the laboratory shall ensure that promotional materials do not imply that recognition is held for sites that are not recognized and does not misrepresent the scope of recognition at recognized sites.

For State laboratories that concurrently maintain NVLAP accreditation, compliance with NIST Handbook 150 and NVLAP policies on the use of the NVLAP name and logo is required.

**Recognition Status Use on Calibration Certificates**. The use of the recognition status on a participating laboratory calibration certificate issued to a customer shall be limited to the specific recognized scope as detailed on the *Certificate of Metrological Traceability*, recognized facility location(s), site(s), or field activity(ies). The name and signature of at least one approved signatory shall appear on a calibration certificate that references recognition.

Any measurement made OUTSIDE of the recognized parameters listed on the *Certificate of Metrological Traceability* measurement scope shall be clearly identified on any calibration certificate issued by the laboratory. A calibration certificate that contains BOTH data covered by recognition and data not covered by recognition shall clearly identify the data that are NOT covered by recognition. The calibration certificate shall prominently display the following

statement at the beginning of the document: *This calibration certificate contains data that are not covered by recognition*. A participant laboratory shall not reference recognition on a calibration certificate that contains data from a calibration not performed by the laboratory.

A *Conditionally* (limited) recognized State legal metrology laboratory shall prominently display the following statement within calibration certificates: "*Conditional* (limited) recognition only meets legal weights and measures requirements within this state (or jurisdiction)."

Violations of this policy shall include a corrective action request and/or recognition suspension, as necessary.

**Notification of Change.** The State legal metrology laboratory authorized representative(s) is responsible for notifying OWM in writing when laboratory circumstances change significantly during a recognition cycle.

Changes include both improvements and adverse changes that might affect the quality of measurement services provided to customers. Any change that might adversely affect the quality of measurement results is particularly important and must be reported immediately. Applicable changes require the submission of an updated *Recognition Application* form, which is available online (www.nist.gov/labmetrology).

Changes may include, but are not limited to: changes in personnel, relocation and renovation of the laboratory facility, damage to or loss of facility environmental controls (and monitoring instruments), damage or change of laboratory equipment used to provide measurement services, and damage, replacement, or recalibration of reference [primary] standards used to provide measurement services.

**Timely and Complete Submissions.** OWM solicits information from all State legal metrology laboratories each year as a reminder of the recognition requirements. The *Recognition Application* submission shall be made within the annual submission period (Section 3.3) and must include those items specifically requested but is not limited to the items listed in the *Recognition Submission Requirements* (Table 1).

Failure of a laboratory to provide a complete packet of requested material in a timely manner will prevent full 2-year recognition and may result in a 1-year or *Conditional* (limited) recognition. Requests for technical assistance and scope modifications by the laboratory may be made at any time.

Management System Requirements. Each State legal metrology laboratory is required to implement and maintain a quality management system, including an organizational chart and a quality manual that fulfills the requirements of ISO/IEC 17025:2017 and this Program Handbook (Table 1). The quality management system must be aligned with the laboratory measurement scope and specific program services and customized to reflect laboratory operations. Periodic quality manual updates shall be submitted for review during the annual submission process. At minimum, the quality management system implementation shall be evaluated and documented in an annual internal audit. Top management shall systematically evaluate laboratory operations in

a documented management review within six months of submitting the *Recognition Application*.

Table 1. Recognition Submission Requirements (Example)						
ISO/IEC 17025:2017 Section or Reference	Item	Guidance	Submitted Annually by all Laboratories, as Appropriate			
Application	HB 143, Recognition Application (Current version available online)	Requested Measurement Scope, Contacts, Approved Signatory(ies), Authorized Representative(s). Information is used to update the OWM Contacts System and online laboratory directory. Use when reporting changes or amendment requests.	Yes			
ALL	Previous Non-conformities	Review and complete action items related to prior year OWM recognition feedback, onsite assessments, and internal audits.	Yes			
ALL	NVLAP Assessment Letters and Reports	Submit all NVLAP Assessments since the last Recognition Application.	Yes			
6	Special Technical Assessment	Guidance will be provided in the Annual Solicitation Memo when requests are made.	Yes, when requested			
6.2	Laboratory Auditing Program (LAP) Problems	Current version available online.	If applicable			
6.6	Calibration Certificates for all Standards Calibrated by Other Laboratories	Shall include supplier evaluations and certificate assessment.	If applicable			
7.2	Laboratory Developed Calibration Procedures	Shall include validation procedure and evidence of validation.	New procedures only			
7.6	Uncertainties for all Measurement Parameters		Yes			
7.7	PT Participation Plan and Follow-up Forms (one per PT, not one per staff member)	Only for PTs completed by the applicant lab. Template job aid available online. Alternative formats acceptable when they include the required elements and required actions. Include evidence of action plan, corrective actions. Multi-year assessments may be requested to determine completion of previous corrective action and compliance to the OWM PT Policy.	Yes			
7.7	Control Chart and Measurement Assurance Assessments	Uncertainties shall match the Recognition Application. Excel versions preferred. Ensure components match applicable SOP uncertainty budget tables. Update all standard deviations consistent with control charts. Evaluate all uncertainties with appropriate precision assessment ( $P_n$ ) and if there are any $P_n$ failures, include appropriate comments and evidence of corrective action or pending corrective action.	Yes, when requested			

ISO/IEC 17025:2017 Section or Reference	Item	Guidance	Submitted Annually by all Laboratories, as Appropriate
8.2	Quality Management System	Submit the complete system including the Quality Manual, Appendices, Administrative Procedures, Forms, and Lab Developed Methods. Internal assessment to include QMS cross-references, observations, interviews and other implementation objective evidence.	Yes
8.8	Internal Quality Management System Assessment	A complete annual audit report shall include supporting documentation, such as related forms and the action plan.	Yes
8.9	Management Review	Shall be within 6 months from the application date. A template outline is available online.	Yes

**NVLAP Accreditation.** A NVLAP accredited State legal metrology laboratory shall maintain concurrent recognition. If recognition is denied, suspended, or withdrawn, the NVLAP accreditation must also be similarly modified to align with the OWM recognition scope. A State legal metrology laboratory must seek OWM approval before submitting an accreditation application to NVLAP or modifying an accredited scope (parameter, range, uncertainty, and/or method), or amending uncertainties. A State legal metrology laboratory that is concurrently recognized by OWM and accredited by NVLAP shall submit all NVLAP assessment records to OWM, preferably when received but is required to accompany each annual *Recognition Application* if not already submitted.

**Reciprocity.** Recognized State legal metrology laboratories may have reciprocity with other recognized or accredited State legal metrology laboratories as a part of the voluntary registration program for service agents. Reciprocal acceptance of calibration certificates should be limited to laboratories that have maintained full (not *Conditional*) recognition by OWM or accreditation from an accreditation body (that is also an ILAC signatory). Verification of ILAC signatory status may be made by reviewing the directory available on the ILAC website (www.ILAC.org).

Calibration certificates from laboratories that have failed to maintain recognition or accreditation should be refused. Calibration certificates from *Conditionally* (limited) recognized laboratories are also unacceptable for any legal metrology application outside that jurisdiction and should be refused.

Response to Nonconformities and Corrective Action Requests. A State legal metrology laboratory will have a specified amount of time to respond to nonconformities addressed through annual review, internal management review, OWM review, or through an onsite assessment. When nonconformities are found during the onsite assessment, the authorized representative(s) must submit a satisfactory response to OWM in writing within 30 calendar days of receiving a final onsite assessment report.

At the end of the specified time interval, the State legal metrology laboratory may be granted a *Conditional* (limited) recognition detailed later in this publication. When a laboratory fails to

respond, or fails to respond adequately, it will not be recognized in the area under question until it responds or corrects nonconformities. The laboratory has the right to appeal a recognition decision, according to the process described later in the Program Handbook.

**Failure to Maintain Recognition.** Any State legal metrology laboratory that fails to maintain recognition will be encouraged to correct nonconformities and be given an opportunity to submit evidence of corrective action for each documented nonconformity. A participant laboratory that has lost recognition status may subsequently comply with the recognition criteria. Laboratories are encouraged to work closely with the OWM to reestablish recognition as soon as possible. OWM is committed to assisting each participating laboratory as much as possible based on need and available resources.

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## 3. Recognition Process

The annual evaluation of a participant laboratory *Recognition Application* and the required submission materials (Table 1) is conducted by OWM. Recognition process elements include (Figure 1):

- 1) Annual *Recognition Solicitation* memorandum published by OWM;
- 2) Laboratory internal assessment and preparation;
- 3) Laboratory *Recognition Application* (or lack of request);
- 4) Submission receipt by OWM;
- 5) Submission review and technical evaluation by OWM; and
- 6) Recognition decision by OWM.
- **3.1 Annual Recognition Solicitation.** The recognition process is initiated when the annual *Recognition Solicitation* memorandum is published online between July 1 and September 1 (www.nist.gov/labmetrology). The annual memorandum details all required submission components and materials. The information to be submitted annually depends on the circumstances of a laboratory's recognition and will be detailed in the solicitation memo. Requested information is always related to specific criteria in this Handbook. The *Recognition Submission Requirements* (Table 1) are an example of requirements and guidelines. The exact requirements and associated guidelines are annually updated and contained in the current *Recognition Solicitation* memorandum.
- **3.2 Internal Assessment and Preparation.** A State legal metrology laboratory seeking recognition shall prepare for submitting the *Recognition Application* by:
  - Reviewing the required materials (*Recognition Solicitation* memo);
  - Ensure the requested measurement scope and uncertainties align with the information presented in the *Recognition Application*;
  - Verify that the requested measurement scope is aligned with the NVLAP measurement scope (if applicable);
  - Review and complete action items related to the prior year OWM feedback, including any unresolved recognition (or accreditation) and onsite assessment findings;
  - Review and complete action items related to internal audits, which provides the State legal metrology laboratory with the opportunity to verify their achievement of all Program Handbook requirements and confirm the successfully integrated into the operations;
  - Conduct an annual internal assessment, prepare a report, develop an action plan, and implement appropriate corrective and improvement actions.
  - Conduct a management review within six months of submitting the *Recognition Application* to ensure current information is communicated to OWM; and
  - Ensure that all submitted materials use document control best practices, including file names.
- **3.3 Recognition Application.** To initiate or renew recognition, the applicant laboratory shall submit a completed *Recognition Application* form that details the requested measurement scope, along with required documentation during the annual submission period, prior to the established deadline. The *Recognition Application* form is posted online (www.nist.gov/labmetrology).

**Submission Method.** All required items shall be submitted electronically according to the submission methods detailed in the annual *Recognition Solicitation* memorandum.

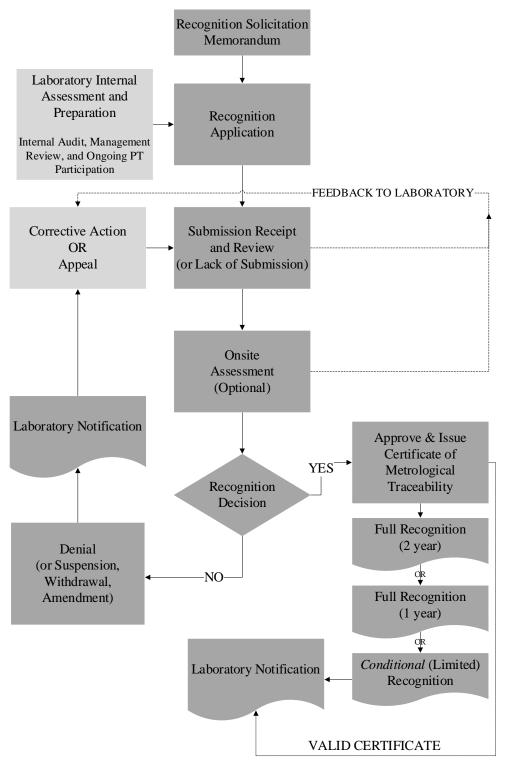


Figure 1. Recognition Process Flowchart

**Annual Submission Period.** The *Recognition Application* and required supporting materials are accepted each year for laboratories from RMAPs that meet in the Spring during the annual submission period between October 1 to November 1. The deadline is November 1. Laboratories from RMAPs that meet in the Fall are authorized an extension to November 15.

By submitting the *Recognition Application*, the laboratory's authorized representative(s) attest that the information in the application is correct and commits the laboratory to fulfill the conditions for recognition contained in the Program Handbook, including attestation that the laboratory has an official copy of ISO/IEC 17025:2017. *Recognition Application* categories include:

- **New (Lapsed).** Any participant laboratory that seeks to initiate recognition and receive a *Certificate of Metrological Traceability* must submit the *Recognition Application* and required submission materials during the annual submission period (Table 1). When recognition and the associated *Certificate of Metrological Traceability* lapses for any reason or time frame, it is treated as a new application;
- **Renewal (Expiring)**. Any participant laboratory wishing to renew an expiring *Certificate of Metrological Traceability* shall submit a *Recognition Application* and the required recognition materials annually for review by OWM during the annual submission period (Table 1);
- **Maintenance** (**Current**). Any participant laboratory wishing to maintain a current *Certificate of Metrological Traceability* shall submit a *Recognition Application* and the required recognition materials annually for review by OWM during the annual submission period (Table 1); and
- **Amendment.** Requests to expand, reduce, or withdrawal recognition may be submitted at any time. Changes are initiated when an authorized representative(s) submits a *Recognition Application* and supporting submission materials detailing amendments to the approved measurement scope and/or approved signatory(ies) list.

**Measurement Scope.** The information provided on the *Recognition Application* will be used to define the approved recognition measurement scope on the *Certificate of Metrological Traceability*. The Measurement parameters and ranges shall match the submitted uncertainties.

OWM permits special measurement scope designation requests, such as "internal only" calibrations, that support measurement traceability hierarchy, where appropriate. Participant laboratories must designate any special measurement scope designation request on the *Recognition Application* form. OWM will not make special measurement scope designations on the *Certificate of Metrological Traceability*. OWM will stringently evaluate these requests and supporting submission evidence to ensure participant laboratories have all necessary elements in place to support metrological traceability.

**3.4 Submission Receipt.** OWM will inform the authorized representative(s) upon the receipt of the *Recognition Application* and supporting submission materials. If further information is required, OWM will contact the applicant. The date of receipt is recorded for all submissions.

A recognition decision may be delayed when OWM does not receive a *Recognition Application* because the laboratory fails to submit the request, meet the deadline, or submit a complete set of required materials.

Materials received past the application deadline or that are incomplete may not be reviewed prior to the expiration of the current *Certificate of Metrological Traceability*.

**3.5 Submission Review and Technical Evaluation.** An annual submission review and technical evaluation is conducted prior to making a recognition decision or awarding a *Certificate of Metrological Traceability*. Timely reviews of late and incomplete submissions are not guaranteed. Preference is given first to State legal metrology laboratories with complete and on time applications, then to laboratories without current recognition. OWM will review late and incomplete submissions as time is available. Items that are significantly late may not be reviewed until the next review cycle.

The evaluation includes a full review of all available technical information regarding the laboratory, which may include prior recognition findings, current submission materials, quality management system (e.g., quality manual, associated appendices, and administrative procedures), assigned training problems, onsite assessment reports, proficiency test results, training records, RMAP attendance and participation, accreditation status or assessment findings, control charts, or any other relevant information affecting the quality and traceability of laboratory measurement results.

**3.5.1 Recognition Scoring Model**. The recognition scoring model is used to assign a numerical value to each State legal metrology laboratory to provide a quality index to the overall OWM Laboratory Metrology Program. OWM's goal is to observe stable model scores for each laboratory and increasing model scores for all laboratories over time until all State legal metrology laboratories attain concurrent recognition and accreditation.

OWM shall not publish specific coding that identifies an individual State legal metrology laboratory. A self-evaluation shall be conducted, documented, and submitted by the State legal metrology laboratory authorized signatory in writing to OWM before receiving an individual recognition scoring model ranking.

The following general criteria categories describe what OWM typically observes when State legal metrology laboratory operations successfully implement this Program Handbook.

**Documentation and Operations.** OWM observes that internal and external assessments demonstrate a robust and functioning Quality Management System and a ISO/IEC 17025:2017 compliant Quality Manual. Policies, administrative processes, and technical procedures are documented, implemented, and maintained with ongoing improvements. OWM observes that laboratory management is highly engaged through regular interactions with personnel, exhibits support for laboratory operations by providing adequate resources and funding, participates in regular management reviews, and supports recognition and/or accreditation. Resources for facilities, equipment, and standards upgrades, as well as personnel training are made available as needs are demonstrated. OWM observes that laboratory management gains additional insights into calibration operations through their participation in training workshops and/or webinars. *Recognition Application* and submission materials are consistently submitted on time and are complete.

**Staffing.** OWM observes that a training plan and succession plan are in place and have been implemented for all State legal metrology laboratory personnel. Laboratory personnel have completed the level of training required for the recognized measurement scope and engage in professional development by attending the required annual RMAP training. Personnel frequently exceed minimum training requirements.

Facilities and Accommodations. OWM observes that exceptional controls of facility and environment exist, detects no deficiencies or negative impacts to calibration services. Available equipment used by the State legal metrology laboratory is aligned with the recognized measurement scope and well maintained in functioning order. Laboratory personnel have identified no risks related to the use of older equipment. Complete control charts are maintained and demonstrate appropriate standard deviations and no noticeable weaknesses. OWM discerns that PT uncertainties reflect acceptable  $P_n$  values for all measurement areas and ranges on the recognized scope.

**Equipment and Standards.** The State legal metrology laboratory demonstrates that appropriate reference, working, and check standards are in service with no demonstrated gaps. OWM observes that current and appropriate calibrations are available for all standards. The calibration system traceability hierarchy is fully implemented to ensure regular calibrations take place at suitable intervals.

Competency Demonstration. OWM observes that personnel competence is demonstrated through a program of ongoing and successful PT participation, including the maintenance of PT Participation Plan requirements (Section 4). State legal metrology laboratory approved signatory(ies) achieve excellent PT results, with limited failures and immediate corrective action, where needed. The State legal metrology laboratory maintains up-to-date records.

**Submission Timeliness.** OWM observes that the State legal metrology laboratory's annual recognition submissions consistently meet the *Recognition Application* deadline and that the contents completely meet the required materials (Table 1).

Once the observation scores are assigned to each State legal metrology laboratory, a multiplier is used to further refine the laboratory model hierarchy based on recognition level:

- NVLAP accreditation with 2-year OWM recognition;
- NVLAP accreditation with 1-year OWM recognition;
- OWM recognition (2-year);
- OWM recognition (1-year);
- OWM Conditional (limited) recognition;
- No OWM recognition; and
- Closed Laboratory.

**3.5.2 Competency Demonstration.** Metrological traceability depends on the competency of all personnel responsible for performing laboratory measurements and approved to sign calibration certificates. Training, Laboratory Auditing Program (LAP) problems, Proficiency tests (PT), and procedure observation during onsite assessment are methods that shall be used to assess technical competence, where available.

Training and Laboratory Auditing Program (LAP) Problems. The successful completion of LAP problems following specific OWM training seminars shall be used to evaluate laboratory application of training and provide evidence of competency. LAP problems have been developed to provide a new metrologist in a mechanism for recognition of approved signatory status once they have successfully completed the associated training seminars. These problems are an auditing activity that shall include observations, findings, and necessary recommended improvement and corrective actions that are combined into a written summary that flow into the normal laboratory internal audit and management reviews. The LAP problems shall include an action plan, implementation, and monitoring of any corrective and improvement action that resulted from the problem analysis. Although the new metrologist may not have the authority to assign and complete action items within the State legal metrology laboratory, they are responsible for coordinating the process with the laboratory management to fully accomplish the problems.

**Proficiency Testing.** PTs are conducted nationally and regionally within the Regional Measurement Assurance Program (RMAP) according to NISTIR 7082 (Policies and Plan) and NISTIR 7214 (Quality Manual). A PT Participation Plan is developed according to NISTIR 7082 within each RMAP to support laboratory compliance with recognition and accreditation policies that require ongoing proficiency testing. Annual planning, analysis, and reporting takes place at each RMAP meeting, where State legal metrology laboratories develop a plan to meet the needs of their measurement scopes. Overall program costs are minimized through volunteer coordination and data analysis by participant laboratories.

All OWM PTs are considered OPEN and anonymity is not implied or guaranteed. Results of proficiency tests are discussed openly at annual RMAP meetings in the spirit of continual improvement and teamwork. PT participants will not use any PT report for any purpose other than internal measurement assurance or recognition (accreditation) activities. The use of OWM PTs in sales, marketing, or the advertising of the results of any participating laboratory are strictly prohibited.

PT results shall be analyzed against accepted and/or standardized data analysis methods according to NISTIR 7214. PT nonconformities are defined as, but not limited to, one or more of the following:

- 1) Failure to meet specified PT performance requirements or objectives prescribed at the outset of the interlaboratory comparison;
- 2) Failure to participate in a regularly scheduled round of PT for which the laboratory has received instructions and/or materials and for which the laboratory is seeking recognition;
- 3) Failure to submit laboratory control data as required specific to each interlaboratory comparison;
- 4) Performance as a statistically outlying laboratory in two successive rounds of PT or showing a general pattern of outlying results over three or more rounds;
- 5) Failure to produce acceptable calibration results when using special artifacts whose properties are well characterized and known to OWM; and
- 6) Failure to complete corrective action after a PT failure.

Acceptable PT results are required for recognition to be granted, where available. Further investigation is required to resolve any nonconformities. As with onsite assessments and recognition decisions, the laboratory may submit feedback or complaints to OWM regarding proficiency test results if they believe an analysis was incorrect or if insufficient information was available for a complete evaluation.

**Procedure Observation.** When a PT is not suitable or unavailable, observation of a technical procedure, recalibration of a retained item, or calibration of artifacts submitted to the State legal metrology laboratory shall be conducted and documented during an onsite assessment to demonstrate competency.

**3.5.3 Onsite Assessment.** All onsite assessments initiated by OWM are technical monitoring assessments or assistance visits. Essential monitoring assessments are conducted periodically, generally in conjunction with training or regional meetings. Additional onsite assessments may be requested in writing by a participant laboratory and will be conducted as feasible.

The primary objectives of onsite assessments are to: 1) ensure that the laboratories maintain calibration quality by complying with the Program Handbook and 2) assist the laboratories to improve their overall operations, including facilities, equipment, standards, and personnel to ensure adequate accuracy and traceability to meet State legal requirements.

**Preparation.** Adequate advanced notice of the assessment date(s) is provided to State legal metrology laboratories for scheduling purposes. An onsite assessment typically requires between one and three business days and is conducted to minimize disruption of normal laboratory operations.

**Assessor Assignment.** Onsite assessments may be conducted by OWM personnel, other technical experts (TE), and/or NVLAP personnel (when the participant laboratory has applied to or is accredited by NVLAP). It is essential that assessors possess the required professional knowledge, experience, and familiarity with the recognition criteria in the Program Handbook and are adequately trained in assessment techniques. OWM selects onsite assessors based on

their education, work experience, technical knowledge, training, assessment experience, communication and interpersonal skills, and discretion. OWM may provide additional auditing techniques to onsite assessors. OWM maintains TE qualifications and prior onsite assessment records.

OWM strives to ensure fairness and impartiality during onsite assessments. A participant laboratory should notify OWM of any concerns or conflicts of interest regarding an assigned assessor.

An onsite assessor evaluates all information provided by OWM and collected from a participant laboratory to conduct the assessment on OWM's behalf at the laboratory facility and at any other facility locations where recognized calibration activities are performed. Records include the quality management system (e.g., quality manual, administrative procedures, associated appendices, and forms), training records, uncertainty tables, internal and external audit results, management review reports, PT and ILC results, control charts, NIST calibration certificates, internal and external calibration certificates, and laboratory correspondence.

**Conduct.** During the onsite assessment, the assessor(s) interact with management and laboratory personnel, discuss any safety considerations and precautions, by examination of facility, equipment, standards, calibration certificates, quality management system documents, processes and procedures, operational records, and by observation of procedure performance. An assessor(s) shall use the Program Handbook, checklists, and template forms to review records, observe operations and measurements, and conduct interviews. The assessor(s) need not be provided with any personnel information that violates individual privacy such as salary, medical information, or performance reviews outside the scope of the recognition program.

The authorized representative(s) and laboratory personnel may be provided with either the assessor(s) notes or a draft report at the close of the onsite assessment.

**Assessment Report.** Assessors shall provide input to the onsite assessment report. All final onsite assessment reports are prepared, reviewed, and finalized by OWM personnel, detailing observations, identified nonconformities, and improvement opportunities. All onsite assessment reports follow the same general format to ensure consistency. As a minimum, an onsite assessment report shall contain the following information:

- 1) Laboratory name and address;
- 2) Assessment date;
- 3) Criteria used;
- 4) Parameters and scope of recognition evaluated;
- 5) Assessor name(s) and affiliation(s);
- 6) Laboratory management and personnel name(s) contacted during assessment;
- 7) List of records reviewed during the onsite assessment (e.g., quality management system documents, training records, control charts, proficiency test results, customer feedback etc.);
- 8) Discussions related to observations and findings; and
- 9) Findings aligned with Program Handbook references for each nonconformity identified during onsite record reviews, observations, and interviews.

**Response.** The State legal metrology laboratory is given an opportunity to respond to or appeal onsite assessment nonconformities. When nonconformities are found during the onsite assessment, the authorized representative(s) must submit a satisfactory written response to OWM within 30 calendar days of receiving a final onsite assessment report.

The response shall include an action plan that details the necessary corrective actions to resolve onsite assessment findings and appropriate deadlines and be signed by the authorized representative(s). Because an assessor(s) may not be fully aware of specific laboratory conditions, clarification may be appropriate. Laboratory response may include clarification.

Nonconformities do not necessarily need to be corrected within the 30-day response period, but an action plan must be developed and submitted. The authorized representative(s) may communicate any steps that have already been taken to address the nonconformities as well as planned actions to resolve any outstanding action items.

The laboratory is expected to correct nonconformities as soon as possible and to implement improvement actions as a normal course of operations. OWM will respond in writing to the authorized representative(s) regarding the acceptability of the laboratory action plan response.

**3.6 Recognition Decision.** Recognition decisions are determined by OWM and based on the degree to which the State metrology laboratory meets criteria in this Program Handbook and the pattern of submission timeliness and completeness. OWM evaluates the information gathered during the recognition process, including:

- Information provided on the *Recognition Application*;
- Information provided in the required submission materials;
- Onsite assessment reports;
- Proficiency testing results; and
- Actions taken by the laboratory to correct nonconformities.

All nonconformities and resolutions will be subject to thorough review and evaluation prior to the recognition decision.

**Feedback.** Improvement action will be recommended and corrective action shall be required for noted nonconformities. Minor nonconformities may not affect a laboratory's ability to receive recognition. Minor nonconformities often result in a shorter recognition period due to the necessity of additional OWM management oversight and to facilitate and encourage the timely implementation of all necessary corrective action. If substantial nonconformities are cited, OWM may require an additional onsite assessment or corrective action evidence prior to making a recognition decision.

Any State legal metrology laboratory that cannot meet the criteria in this Program Handbook should not apply for NVLAP accreditation.

Recognition decisions and feedback are typically provided to the applicant laboratory between November 1 and December 31. A *Certificate of Metrological Traceability* is typically issued for

effective dates beginning between January 1 and February 1, and expiring on subsequent December 31 or January 31, based on the recognition level. Recognition denial may be modified based on the laboratory response or resolution of an appeal. Recognition is not granted when a *Recognition Application* is not submitted.

The current *Certificate of Metrological Traceability* for each participating State legal metrology laboratory is posted on the OWM State Laboratory Contact website (www.nist.gov/owm) at the end of the annual recognition cycle and updated throughout the year, as needed.

**Recognition Approval.** Recognition approval, status, and submission evaluation findings will be communicated to the authorized representative(s) through written correspondence. Recognition approval involves the issuance of a *Certificate of Metrological Traceability* that includes the approved measurement scope.

- **Maintenance.** When a laboratory recognition has not expired, a new *Certificate of Metrological Traceability* will not be issued because the current document continues to be valid unless a measurement scope expansion or reduction was requested.
- **Two-year Recognition.** A two-year *Certificate of Metrological Traceability* may be issued to those laboratories fully meeting the requirements of this Program Handbook. Additional supporting information and data must be submitted annually for review, as requested. Accreditation is often recommended to laboratories consistently achieving this level of recognition.
- One-year Recognition. A one-year Certificate of Metrological Traceability may be
  issued when OWM personnel are confident that continuing acceptable traceable
  measurements are being provided to laboratory customers. However, it is limited to one
  year because additional oversight by OWM management is required when minor
  nonconformities exist that prevent fully meeting the Program Handbook criteria.
- Conditional (Limited) Recognition. This limited status restricts a State legal metrology laboratory measurement scope to only meet legal weights and measures requirements within that jurisdiction and granted for a period of one year or less. Conditional (limited) recognition approval will not be continued indefinitely. Restrictions shall be stated in writing on the Certificate of Metrological Traceability to clearly communicate the limited status. The laboratory shall communicate the Conditional (limited status) to customers during the contract review process. This limited status is granted on an infrequent basis in situations when a participant laboratory would otherwise be denied recognition because multiple nonconformities exist in the personnel, facilities, equipment, standards, or overall laboratory operations. The State legal metrology laboratory shall provide evidence and management commitment to OWM that demonstrates ongoing efforts to meet Program Handbook criteria.

**Recognition Denial**. Recognition is not granted when significant nonconformities to the Program Handbook criteria are identified. Recognition denial and supporting submission evaluation findings will be communicated to the authorized representative(s) through written correspondence.

Other Decisions (Suspension, Withdrawal, or Amendment). Recognition suspension or withdrawal may result from information noting changes in circumstances provided by the

authorized representative(s), annual submission assessment, onsite assessment, proficiency test, document review, or other evaluation. Recognition suspension or withdrawal decisions will be communicated with supporting evaluation findings to the authorized representative(s) through written correspondence.

- **Suspension.** Any situation that critically affects the laboratory's ability to provide accurate and traceable measurements may be cause for temporary suspension of the *Certificate of Metrological Traceability* until the Program Handbook criteria are met. OWM will suspend recognition and await a new *Recognition Application* when a State legal metrology laboratory is relocated to a facility that differs from a recognized location.
- **Withdrawal.** A participant laboratory may choose to withdraw entirely or from specific levels of recognition (e.g., reduced scope) based on laboratory circumstances. The laboratory shall advise OWM of the request in writing. Recognition may be reinstated when it has demonstrated that it fully meets criteria in this Program Handbook.
- Amendment. A participant laboratory may request a reduction or expansion in scope at any time by submitting an updated *Recognition Application* and supporting documentation for evaluation. OWM reserves the right to amend a *Certificate of Metrological Traceability* at any time to correct an error or omission. A description of updated information is noted on an amended *Certificate of Metrological Traceability*.
- **3.7 Appeal.** An applicant laboratory has the right to appeal any adverse decision related to its recognition status in writing to OWM. The appeal response will likely include a full independent onsite laboratory assessment according to the Program Handbook criteria. The State legal metrology laboratory requesting an appeal will be given every opportunity to provide input to OWM for evaluation in response to recognition evaluations and onsite assessments. OWM personnel assigned to investigate the appeal decide on the validity of the appeal and, if appropriate, render a recommendation. OWM will advise the authorized representative(s) in writing of the appeal outcome.
- **3.8 Feedback and Complaints.** Feedback and complaints regarding recognition program operation, technical evaluation, onsite assessment, or decision shall be submitted in writing to the OWM Laboratory Metrology Program.

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# 4. OWM Supplemental Requirements

A State legal metrology laboratory recognition scope is limited to align with the completion of various levels of demonstrated competency, training requirements, and demonstrated compliance to all Program Handbook requirements. In addition, OWM uses technical requirements found in NVLAP HB 150-2 Annexes for evaluation of traceability as part of a recognition decision. Any deviation from these supplemental criteria must have a technical basis, data, and technical analysis to support variances.

Regional Measurement Assurance Program (RMAP) Requirements. State legal metrology laboratory personnel involved in calibrations covered by recognition shall attend the annual RMAP to participate in the training and PT activities provided by OWM (Figure 2). Annual RMAP participation is required to achieve and maintain ongoing recognition (or concurrent recognition and accreditation). Coordination of national legal metrology issues, distribution of updated procedures, and ongoing professional development are provided. PTs are coordinated through one of the six RMAP regions or through a national plan coordinated by OWM. PT planning and reporting are a key activity of the annual RMAP. Each RMAP maintains a PT Performance Plan to support recognition and accreditation requirements. The State legal metrology laboratory is required to submit the PT Performance Plan with each *Recognition Application*.

# U.S. State Legal Metrology Laboratories NEMAP MidMAP

WRAP USDA/AMS/FGIS North Dakota Michigan New Hampshire Montana Massachusetts South Dakota Rhode Island Oregon Connecticut Idaho New Jersey Nevada Utah Virginia Maryland Washington, DC Colorado Missouri California North Carolina South Los Angeles Oklahoma County Arkan Arizona SEMAP Hawaii Texas CaMAP WRAP - Western Louisiana) Mississippi U.S. Virgin MidMap - MidAmerican Islands **NEMAP - Northeast** SWAP Puerto SWAP - Southwest Rico **SEMAP - Southeast** CaMap - Caribbean

Figure 2. U.S. State Legal Metrology Laboratories Organized into RMAP Groups.

The six regions include:

- Caribbean Measurement Assurance Program (CaMAP);
- Southeast Measurement Assurance Program (SEMAP);
- Northeast Measurement Assurance Program (NEMAP);
- Southwest Assurance Program (SWAP);
- Western Regional Assurance Program (WRAP); and
- MidAmerican Measurement Assurance Program (MidMAP).

**Training Requirements.** OWM publishes training requirements for State legal metrology laboratory personnel to ensure that standardized procedures and methods are used to support uniformity of measurements that ensure measurement traceability. These training requirements shall be met by State legal metrology laboratories who are recognized, accredited by NVLAP, or seeking accreditation by NVLAP. Training requirements are published in Table 2 and updates posted on the OWM website (www.nist.gov/labmetrology). The completion of Laboratory Auditing Program (LAP) problems following specific OWM training seminars are required as they serve as a significant method used to evaluate competency.

NIST recommends that States develop minimum qualifications for metrologists. Working knowledge of algebra, basic statistics, and computer software is essential. A suitable technical degree, such as Engineering, Physics, Mathematics, or Chemistry, is highly recommended. OWM expects that metrologists will have spent time in their State legal metrology laboratory familiarizing themselves with the laboratory quality management system, procedures, and equipment prior to attending a seminar.

Mass and Volume courses must be successfully completed by at least one person in each recognized laboratory. In some situations, management has assigned only one person to perform calibration duties. In such cases, recognition will only be granted to the State legal metrology laboratory when the sole metrologist has successfully completed the Mass and Volume seminars and associated Laboratory Auditing Program (LAP) problems.

**Approved Signatory.** Personnel in State legal metrology laboratories who hold an approved signatory status for signing and issuing a calibration certificate shall comply with the OWM training requirements published in this Program Handbook. An approved signatory is required to complete the appropriate level of training as indicated in Table 2 for the participant laboratory to be recognized at the designated level. Information regarding the training program is described in Appendix A. Authorization and confirmation of competence records for all technical personnel are maintained, such as education, qualifications, training, and experience.

**Table 2. Training Requirements** 

Recognition Level	Training Required	For Whom	How Often
All Measurement Parameters	Regional Measurement Assurance Program (RMAP)Training, Ongoing Professional Development	At Least One Personnel	Annually
Legal Metrology  Mass Echelon III  Volume Echelon II	<ol> <li>Fundamentals of Metrology Seminar (1-week)</li> <li>Introduction and Orientation to Mass and Volume Procedures</li> <li>Fundamentals of Metrology and Laboratory Auditing Program (LAP) Problems</li> <li>Successful Proficiency Testing (PT) Completion</li> </ol>	Usually all Personnel, at Least One Personnel	Once Initially  Refresher  Portions  Covered During  RMAP Training
Mass Calibration  Mass Echelon II and III	All of the Above, Plus:  1. Mass Seminar (2-week)  2. Successful PT Completion for Each Area on the Laboratory Scope	Usually all Personnel At Least One Personnel	Once Initially Refresher Recommended Every 10 year
Mass Calibration  Mass Echelon I	All of the Above, Plus:  1. Advanced Mass Seminar (2-week)  2. Advanced Laboratory Auditing Program (LAP) Problems  3. Successful PT Completion Using Weighing Designs  4. Optional: Advanced Hands-on Mass Seminar (If Available)	At Least One Personnel	Once Initially  Refresher  Recommended  Every 10 year
Volume Calibration  Volume Echelon I and II	<ol> <li>Legal Metrology and Mass Calibration Requirements (Above)</li> <li>Volume Calibration Course (1-week)</li> <li>Successful PT Completion of for Each Area on the Laboratory Scope Using Gravimetric Calibrations</li> </ol>	ments (Above) Calibration Course (1-week) Ful PT Completion of for Each the Laboratory Scope Using Personnel At Least One	
All Measurement Parameters in Addition to Mass and Volume	Documented Training     Successful PT Completion in Each     Area of the Laboratory Scope	At Least One Personnel, As Needed	At Least Once Refresher, As Needed

**Procedures.** Use of uniform technical procedures is critical for maintaining the integrity of the legal measurement system. The OWM publishes and maintains legal metrology laboratory procedures (e.g., good measurement practices, good laboratory practices, standard operating procedures, and associated job aids). States must reference and use NIST procedures for all applicable measurement procedures unless data or other evidence is available to support acceptable results using another procedure. Internally developed procedures with associated verification and validation data, as well as any other non-NIST procedures must be submitted to OWM for review and approval.

Legal metrology procedures are used by OWM for seminar and webinar training, proficiency testing, and during onsite laboratory assessments. Any on-the-job training provided to new personnel will use NIST OWM procedures and shall be conducted by a qualified approved signatory who has successfully met all requirements at the designated scope level, including the successful completion of all Laboratory Auditing Program (LAP) problems and proficiency testing at that level.

**Equipment Requirements.** Equipment shall be listed on the uncertainty table with the current performance evaluation. Equipment information is requested during onsite assessments and annually with measurement control records (Table 1).

**Standards Requirements.** Copies of calibration certificates for reference [primary] standards used in the laboratory are maintained and archived by the OWM. The State legal metrology laboratory must submit new calibration certificates annually (Table 1). When calibration certificates are not obtained from NIST, they shall be obtained from a laboratory accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Council, Mutual Recognition Arrangement (ILAC MRA) or a NIST recognized laboratory. A *Conditionally* (limited) recognized State legal metrology laboratory is unacceptable.

**Demonstrating Metrological Traceability.** OWM requires that the essential elements of metrological traceability are demonstrated by State legal metrology laboratories according to GMP 11, *Assignment and Adjustment of Calibration Intervals for Laboratory Standards* and GMP 13, *Ensuring Traceability*. This requirement is above and beyond the requirements of ISO/IEC 17025:2017, Section 6.5.

**Uncertainty Requirements.** NIST SOP 29, *Assignment of Uncertainty*, is the procedure for evaluating and implementing this requirement and utilizes the *Guide to the Expression of Uncertainty in Measurement* (GUM).

**Integrated Measurement Assurance.** OWM requires the use of formal measurement assurance concepts and procedures that are integrated in such a way as to assist in ensuring measurement traceability, quantifying uncertainties, supporting decisions regarding calibration intervals, and substantiating results of interlaboratory comparisons. Components of an integrated measurement assurance system include:

 Periodic calibration at NIST for direct traceability. Tracking historical data for calibrations provides an assessment of drift rates, stability of standards, system uncertainties, and data that may be used to justify calibration intervals;

- Annual conduct of interlaboratory comparisons using artifacts with accepted reference values. Evaluation of bias in the results of interlaboratory comparisons or proficiency tests provides a data point for correlation with NIST calibration results and surveillance testing of laboratory standards;
- Surveillance testing of State legal metrology laboratory reference standards with external check standards. This is a special test in a single laboratory using check standards that belong to NIST or another laboratory with NIST reference values and specific procedures to evaluate the ongoing stability and traceability of laboratory standards;
- Surveillance testing of State legal metrology laboratory reference standards with internal check standards. This is a special test in a single laboratory using check standards from within the laboratory that have NIST reference values and using specific surveillance procedures to evaluate the ongoing stability and traceability of laboratory standards;
- Periodic calibration of working standards within the State legal metrology laboratory
  using standard procedures and check standards. The history of calibration values for
  working standards and the data for the check standards both provide valid points of
  reference in ensuring accurate measurements or in identifying problem areas; and
- Measurement assurance control charts and check standards used for the routine work of the laboratory. The data obtained from these charts provides ongoing assurance of the stability of working standards, justification for calibration intervals of working standards, and a way to measure the actual uncertainty of the measurements.

The State legal metrology laboratory shall maintain a list of control charts, standard deviation charts, surveillance activities, and proficiency tests participated in by the laboratory. Measurement control requirements shall be in place for each measurement service provided by the laboratory. This documentation shall be available during onsite assessments and submitted to the OWM as requested.

**Software Requirements.** Software tools such as spreadsheets have historically been used to gather and analyze many types of the data generated within the State legal metrology laboratory. Validation and verification of measurement software is required.

**Conformity Assessment and Calibration Intervals.** State legal metrology laboratories often have regulatory requirements, in addition to ISO/IEC 17025:2017 compliance, for assessing customer standards submitted for calibration for conformity against specified documentary standards. Examples include NIST Handbook 44, *Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices* and the NIST Handbook 105 Series of documentary standards.

Depending on the local regulations, a State legal metrology laboratory may require compliance statements for weights and measures field standards to be expressed on an issued calibration certificate. Compliance statements shall assess field standards for full compliance to the reference documents except where exemptions are noted according to ISO/IEC 17025:2017 and the documentary standards themselves.

Initial inspections and suitable calibration intervals are often required and defined by State and local regulations. The purpose of these technical requirements is to eliminate from use weights

and measures and weighing and measuring devices that give readings that are false, that are of such construction that they are faulty (that is, that are not reasonably permanent in their adjustment or will not repeat their indications correctly), or that facilitate the perpetration of fraud, without prejudice to apparatus that conforms as closely as practicable to the official standards.

# **Appendix A. OWM Services**

The primary objective of NIST is to ensure nationally consistent measurement results, acceptable accuracy and metrological traceability, and the credibility and acceptance of State legal metrology laboratory measurements. OWM encourages all State legal metrology laboratories to seek full recognition and formal accreditation.

Services and technical assistance includes the following:

**Onsite Assessment.** Evaluation of participating State legal metrology laboratory facilities by onsite visit and guidance on the construction of new facilities.

**Training.** International Association for Continuing Education and Training (IACET) accredited training program that is authorized to offer Continuing Education Units (CEU). Course descriptions and prerequisites, the current schedule, and enrollment links for the OWM Contacts System are available online (www.nist.gov/labmetrology).

**Seminar Series.** OWM offers a number of laboratory metrology seminars. The current schedule, course descriptions, and enrollment links are available on the website (www.nist.gov/owm).

- Fundamentals of Metrology (1week course) and evaluation of Laboratory Auditing Program (LAP) problems;
- Mass Seminar (2-week course);
- Volume Seminar (1-week course);
- Advanced Mass Seminar (2-week course) and evaluation of LAP problems; and
- Other Measurement Seminars on special measurement techniques (2 day to 5 day). Examples: Length Seminar, Balance and Scale Calibration and Uncertainties Seminar, Precision Thermometry Seminar, and Laboratory Administration Seminar.

**Webinar Series.** Webinars are typically 2-hour sessions with specific learning objectives and activities designed to engage participants in an online environment. Quality and technical topics include:

- Assessment of Traceability;
- Basic Uncertainty Calculations;
- Calibration Method Validation;
- Calibration Certificate Evaluation:
- Conducting an Effective Management Review;
- Document Control and Record Keeping;
- Documenting Traceability and Calibration Intervals;
- Internal Auditing Best Practices;
- Proficiency Testing Follow-up and Analysis;
- Software Verification and Validation;
- State Lab Annual Submission Process: and
- Supplier Evaluation.

Laboratory Metrology Info Hour (LMIH) sessions are 1-hour events that provide updated news and current events to State legal metrology laboratory personnel only. These events require enrollment but do not involve pre-work or post-work. Training certificates are not issued to participants.

**Self-study Resources.** NIST SP 1001 and 1001-S, Basic Mass Metrology CD-ROM training course (English & Spanish) and technical demonstration videos are available online (www.nist.gov/labmetrology).

**Regional Training.** Ongoing regional training is coordinated annually through 6 national regions (Figure 2):

- Caribbean Measurement Assurance Program (CaMAP);
- Southeast Measurement Assurance Program (SEMAP);
- Northeast Measurement Assurance Program (NEMAP);
- Southwest Assurance Program (SWAP);
- Western Regional Assurance Program (WRAP); and
- MidAmerican Measurement Assurance Program (MidMAP).

**Nationally Accepted Procedures.** Standard Operating Procedures (SOP), Good Laboratory Practices (GLP), and Good Measurement Practices (GMP) that support typical measurement areas used in trade and commerce are available online (www.nist.gov/labmetrology):

### Mass Calibration

- Three Echelons:
- Weighing designs and comparison procedures; and
- Mass standards, field standards, weight carts, wheel-load weigher, and railroad test car.

## Volume Calibration

- Two Echelons; and
- Gravimetric, volume transfer, and dynamic small volume provers.

# Length Calibration

- Tape (length bench, tape-to-tape); and
- Rigid rule (direct comparison).

### Additional Measurement Areas

- Temperature;
- Time and Frequency; and
- Hydrometer.

**Proficiency Testing and Interlaboratory Comparisons (PT/ILC).** The NIST OWM proficiency testing program participation audience is limited to only those calibration laboratories who participate in the OWM U.S. Regional Measurement Assurance Program (Figure 2). Ongoing PTs are coordinated through these 6 regions:

• Caribbean Measurement Assurance Program (CaMAP);

- Southeast Measurement Assurance Program (SEMAP);
- Northeast Measurement Assurance Program (NEMAP);
- Southwest Assurance Program (SWAP);
- Western Regional Assurance Program (WRAP); and
- MidAmerican Measurement Assurance Program (MidMAP)

This measurement assurance program operates in selected legal metrology scope areas, including mass, volume, and length (steel tapes and rules) calibration. While most interlaboratory comparisons are also proficiency tests, some are not.

The proficiency testing (PT) program operates according to NISTIR 7082, *Proficiency Test Policy Plan* and NISTIR 7214, *Weights and Measures Quality Manual for Proficiency Testing and Interlaboratory Comparisons*. Tools and job aids have been developed to plan, coordinate, and analyzing PTs. These resources are available online (www.nist.gov/labmetrology).

The PT program requires each participating laboratory to complete a minimum level of proficiency testing that is established to meet international accreditation requirements. Laboratories formulate a PT participation plan that defines involvement in PT for each measurement parameter included in the laboratory's recognition and/or accreditation scope. A greater frequency may be required for some parameters. Each Regional Measurement Assurance Program (RMAP) develops plans and schedules annually so that PTs can be organized and implemented on a regional and/or national level.

**Additional Assistance.** 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, please contact:

Office of Weights and Measures National Institute of Standards and Technology 100 Bureau Dr, Mail Stop 2600 Gaithersburg, MD 20899-2600 Phone: 301-975-4004

www.nist.gov/labmetrology

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# **Appendix B. Recognition Parameter Summary**

State legal metrology laboratories providing calibrations under a recognized measurement scope have evaluated and declared measurement capabilities in terms of uncertainties for each nominal value and each type of procedure. A participant laboratory specifies the nominal ranges requested in the annual *Recognition Application*. The approved recognition Scope is documented on the *Certificate of Metrological Traceability*.

Other Areas. In addition to the recognized measurement areas that have been described, many State legal metrology laboratories perform measurements for which the NIST Office of Weights and Measures has either not developed specific technical criteria or not established guidelines for recognition. State legal metrology laboratories are recognized for these areas in a limited number of cases, where validated and verified procedures are available. These areas include tuning forks used in testing radar speed devices, testing of wheel-load weighers used in testing large trucks for road weight restrictions, and the testing of hydrometers for testing sugar content of syrup. Areas without established recognition guidelines include the calibration of dial gauges used to test polyethylene sheeting (an extension of dimensional measurements), lottery balls for State lottery programs, or entire programs, such as watthour meter and petroleum quality testing.

Table 3. Typical Legal Metrology Recognition Parameters

Parameter	Typical Recognition Scope Range	Class/Application	Typical Expanded Uncertainty
Mass Echelon I (Extra Fine Accuracy)	30 kg to 1 mg 50 lb to 0.001 lb 8 oz to 0.03125 oz	OIML Class E <sub>1</sub> , E <sub>2</sub> ASTM Class 0, 1	
Mass Echelon II	1200 kg to 1 mg 2500 lb to 0.001 lb 8 oz to 0.0125625 oz	OIML Class F <sub>1</sub> , F <sub>2</sub> ASTM Class 2, 3	
Mass Echelon III	2500 kg to 1 mg 2500 lb to 0.001 lb 8 oz to 0.0125625 oz	NIST Handbook 105-1, Class F (Legal/regulatory enforcement) OIML Class M <sub>1</sub> , M <sub>1-2</sub> , M <sub>2</sub> , M <sub>2-3</sub> , M <sub>3</sub> ASTM Class 4, 5, 6, 7	Less than 1/3 of stated tolerance
Mass Echelon III Weight Cart	≤ 10 000 lb	NIST Handbook 105-8	
Mass Echelon III Wheel-Load Weigher Railroad Test Car	≤ 40 000 lb ≤ 115 000 lb	NIST Handbook 44	
Volume Echelon I Gravimetric	500 L to 100 mL 1 mL to 1 µL 100 gal to 1 gal	Syringe, micropipette, glassware, slicker, and metal prover	0.000 10 mL/L
Volume Echelon II Volume Transfer	5000 L to 100 mL 2000 gal to 1 gal 1 qt to 1 gill	Prover and glassware	< 0.001 mL/L

Parameter	Typical Recognition Scope Range	Class/Application	Typical Expanded Uncertainty
Volume Echelon II Volume Transfer LPG	2000 L to 100 L 500 gal to 25 gal	Prover	< 0.001 mL/L
Length Tape, Bench Method	Up to 30 m Up to 200 ft	Up to 25 m (100 ft)	0.0001 m to 0.000 14 m
Length Tape, Tape Method	Up to 30 m Up to 200 ft	Up to 25 m (100 ft)	0.000 15 m to 0.000 25 m
Length Rule, Direct Comparison	Up to 1 m Up to 24 in	Up to 0.5 cm (18 in)	< 0.000 05 m
Temperature Echelon I	230 °C to - 30 °C 450 °F to - 25 °F	Standard Platinum Resistance Thermometer (SPRT)	≤± 0.005 °C
Temperature Echelon II	230 °C to - 30 °C 450 °F to - 25 °F	Thermistor and thermocouple	> ± 0.005 °C to ≤ ± 0.05 °C
Temperature Echelon III	230 °C to - 30 °C 450 °F to - 25 °F	Liquid-in-glass thermometer	> ± 0.05 °C to ≤ ± 0.20 °C
Temperature Echelon IV	230 °C to - 30 °C 450 °F to - 25 °F	Liquid-in-glass, dial type, and pyrometer	> ± 0.20 °C to ≤ ± 1.0 °C
Temperature Echelon V	230 °C to - 30 °C 450 °F to - 25 °F	Infrared sensor and thermograph	> ± 1.0 °C to ≤ ± 5.0 °C
Frequency	10 kHz to 1 kHz	Tuning fork used for law enforcement	Estimate based on interlaboratory comparison
Time	≤ 24 h	Stopwatch used for law enforcement	Significantly less than tolerances. Estimated at 2 s for a 24 h test
Hydrometer	Degree Baumé Degree Brix	Sugar, syrup, and petroleum	Estimates from control chart measurement assurance

NOTE - Mass Echelon I, II, and III correspond directly related to OIML R111:2004 weight classes. Echelon I:  $E_1$  and  $E_2$ . Echelon II:  $F_1$  and  $F_2$ . Echelon III:  $M_1$ ,  $M_2$ ,  $M_3$  (etc.). The ASTM E617:2013 classes correspond to those of OIML R111. NIST Handbook 105-1, Class F weights correspond to Echelon III. Volume Echelon I is related to gravimetric volume calibration measurement procedures. Volume Echelon II is related to volume transfer calibration procedures. Temperature accuracy classes are related to requirements published in NVLAP 150-2 Annexes.