

NIST Handbook NIST HB 143-2023

NIST Office of Weights and Measures (OWM) Recognition Program Handbook, 7th Edition

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Abstract

NIST Handbook 143 provides the National Institute of Standards and Technology (NIST) Office of Weights and Measures (OWM) performance standards and formalized procedures for the voluntary recognition of state legal metrology laboratories. This 2023 edition supersedes the 2019 edition.

Keywords

Calibration; ISO/IEC 17025; laboratory recognition; state laboratory program; weights and measures; legal metrology; metrological traceability; accreditation; RMAP

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Preface

The National Institute of Standards and Technology (NIST) Office of Weights and Measures (OWM) manages the NIST Handbook 143 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 NIST 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 NIST Handbook 143 since the first edition was published in 1985.

Although the program is operated independently from the National Voluntary Laboratory Accreditation Program (NVLAP), the general (ISO/IEC 17025:2017) and technical criteria (Annexes) 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 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.

The Digital Object Identifier (DOI) allows this publication to be easily retrieved through scientific/technical databases and internet search engines. Please use the current <u>DOI</u> when citing this publication.

Acknowledgments and History

NIST Handbook 143, 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 NIST OWM issued *Certificates of Participation* to States participating in the program. In 1985, NIST OWM began evaluating laboratories against the criteria in Handbook 143, OWM Recognition 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*.

Beginning in 1991, updates to the program and this document were facilitated by Georgia L. Harris who was the Laboratory Metrology Program leader from 1990 to 2019. 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, U.S. Department of Defense, U.S. Department of Energy, U.S. Nuclear Regulatory Commission, U.S. 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 NIST Handbook 143 and ISO/IEC Guide 25 to determine the conformance status of state laboratories, the task force recommended the use of one standard in the U.S. (consistent with the NCSL International 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 NIST Handbook 143.

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 to accreditation in the NIST Handbook 143 were changed to recognition and NIST OWM ceased issuing *Certificates of Accreditation*. NIST OWM continued to monitor the level of state compliance to NIST Handbook 143 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 NIST Handbook 143 incorporated revisions to the procedures and general requirements of the NIST 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 2003 NIST Handbook 143 were updated to reflect Sections 4 and 5 of ISO/IEC 17025:1999 to ensure a recognized laboratory was competent to perform calibrations. Major changes in 2003 included:

- in Section 4, Management Requirements, included additional or changed requirements in the areas of document control; requests, tenders, and contracts; purchasing; nonconforming 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 updates to ISO/IEC 17025:2005.

The 2019 edition was updated by Elizabeth Gentry (Benham) and superseded the 2007 edition of NIST Handbook 143. Editorial updates and clarifications ensured continued acceptance of measurement results from state legal metrology laboratories and ensured consistency with the NVLAP Program and other accreditation bodies. Major reorganization and updates were made.

- Each participating state legal metrology laboratory was required to have an official copy of ISO/IEC 17025:2017 and agree to comply with these handbook requirements under the conditions for recognition.
- Refinements to Section 2 and 3 included policy and procedure information specific to OWM operations and recognition processes. Additional policy or requirements were

- outlined in Section 2 and applied generally to all state legal metrology laboratories without regard to recognition level.
- Section 2 described how OWM considers requests for the recognition of remote facilities to be considered as being under one recognition.
- Section 2 included multiple requirements for a participant laboratory that is concurrently recognized by OWM and accredited by NVLAP. Requirements were related to application for accreditation, adjustment of an accreditation scope, and the annual submission of NVLAP assessment letters and reports to OWM.
- Added emphasis was placed in Section 2 and 3 on the laboratory authorized representative(s) (LAR) responsibility to respond in writing to an onsite assessment within 30 calendar days of receiving a final report.
- Fig. 1, a flow chart that illustrates major steps of the recognition process, was updated.
- Recognition Submission Requirements (<u>Table 1</u>) and Training Requirements (<u>Table 2</u>)
 are included in the NIST Handbook 143 as examples. Because the tables are periodically
 updated, current versions are maintained on the OWM Laboratory Metrology webpage
 (www.nist.gov/labmetrology).
- The nature of *Conditional* (limited) recognition was clarified to emphasize the restricted nature of this rarely used level.
- Certificate of Metrological Traceability effective date ranges were 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 was 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 included 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) was revised to focus on only OWM services.
- The prior Appendix B (Request for Recognition) and Appendix D (Summary of Services)
 were replaced with a *Recognition Application* form that is available online and may be
 periodically updated (www.nist.gov/labmetrology).

- <u>Appendix B</u> now contains the summary of typical legal metrology recognition parameters. Grain Moisture was eliminated from Typical Legal Metrology Recognition Parameters (Table 3).
- Appendix C (Laboratory Assessment Checklist) was eliminated and replaced with internal audit job aids that are available upon request after demonstrating availability of a laboratory copy of ISO/IEC 17025:2017.
- Appendix E (Uncertainties) was 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* (See <u>Table</u> <u>1</u>).

This 2023 edition was updated by Micheal Hicks, Laboratory Metrology Program Leader, Georgia L. Harris (retired), Isabel Chavez Baucom, and Elizabeth Koncki and supersedes the 2019 edition of NIST Handbook 143. 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.

- What was in the 2007 version of NIST Handbook 143 as Section 6 (Technical Guidelines) was eliminated in the 2019 version. It was replaced with reference to the technical requirements published in NIST Handbook 150-2 Annexes for legal metrology, mass, and volume. The technical sections have been restored as a part of this edition of the NIST Handbook 143, NIST OWM Recognition Program Handbook as normative Annexes (i.e., mandatory technical requirements) and are based on the 2019 NVLAP Handbook 150-2 publication as much as possible to ensure consistent program evaluations among laboratories providing comparable calibrations. These Annexes appear as 59.
- OWM training requirements were clarified with additional footnotes in Table 2. Training Requirements.
- Formatting and numbering were added throughout the document to improve document references.
- Documentary standards were added to <u>Appendix B</u>. Recognition Parameters were added to assist in providing appropriate references for conformity statements and decision rules in legal metrology calibrations.
- Numerical values used to evaluate criteria for the Recognition Scoring Model were provided in Section 3.5.1.

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 domestic 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 OWM Staff and Technical Experts Directory.

OWM adopts ISO/IEC 17025:2017 and the technical criteria and requirements in Appendix E, which amplifies ISO/IEC 17025 general criteria for each specific measurement parameter and implements policies of the International Laboratory Accreditation Cooperation (ILAC). NIST National Voluntary Laboratory Accreditation Program (NVLAP) Handbook 150-2 Annexes were edited for OWM applications and are incorporated in this Program Handbook as Annexes in Appendix E for user convenience and for consistency (except where noted). To effectively implement this Program 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 NVLAP for participating state laboratories that concurrently maintain accreditation. Contact information for NVLAP personnel and calibration program management responsibilities are available here.

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 NIST 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 Laboratory Metrology webpage (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 300 000 calibrations are provided each year for nearly 10 000 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

The NIST Handbook 143 recognition program 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 Handbook, complete appropriate forms, meet established deadlines, and undergo an annual external evaluation by OWM. Recognition program requirements in Section 4, 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 <u>Section 3</u>. 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. References

The following documents are referred to in this NIST OWM Recognition 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) applies.

1.4.1. General

- BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML, Guide to the Expression of Uncertainty in Measurement (GUM). (Note: ISO/IEC Guide 98-3:2008, Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995). ISO/IEC Guide 98-3:2008 is a reissue of the 1995 version of the Guide to the Expression of Uncertainty in Measurement (GUM), with minor corrections. Also known as JCGM 100.)
- BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML, International Vocabulary of Basic and General Terms in Metrology (VIM). (Note: ISO/IEC Guide 99, International vocabulary of metrology — Basic and general concepts and associated terms (VIM). Also known as JCGM 200.)
- ILAC-G21, Cross-Frontier Accreditation Principles for Cooperation.
- ILAC-P10:2020, ILAC Policy on Traceability of Measurement Results.
- ILAC-P14:2020, ILAC Policy for Uncertainty in Calibration.
- ILAC-R7:2015, 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 17000:2020, 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 17043:2023, Conformity Assessment General Requirements for the competence of proficiency testing providers.
- 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) 150:2020, National Voluntary Laboratory Accreditation Program (NVLAP) NVLAP Procedures and General Requirements.
- NIST HB 150-2:2019, NVLAP Calibration Laboratories.
- NISTIR 7854:2012, Guidelines for NIST Staff Participating in Documentary Standards Developing Organizations' Activities.
- NIST Special Publication (SP) 330:2019, The International System of Units (SI).
- NIST SP 811:2008, Guide for the Use of the International System of Units (SI).

1.4.2. 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 Laboratory Metrology webpage (www.nist.gov/labmetrology). Participant laboratories shall periodically verify the version status of each procedure to ensure the laboratory uses the current edition according to ISO/IEC 17025:2017, section 7.2.1.3.

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 NIST Handbook 145 procedures have been replaced with NISTIRs. A limited number of archive sections are available on the OWM Laboratory Program webpage.

- 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.
- NISTIR 8250, Calibration Procedures for Weights and Measures Laboratories.

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 NIST 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 (<u>Appendix A</u>). 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 all 50 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 OWM 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 OWM Laboratory Metrology 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.

2.5.1. 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.

2.5.2. 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 and minimally reviewed and updated (where appropriate) on an annual basis. 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).

2.5.3. 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.

2.5.4. 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.

2.5.5. 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 (<u>Appendix A</u>). Informal assistance may be in the form of telephone, e-mail, mailed responses, virtual meeting, 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.

2.6.1. 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 satisfied:

• 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 the headquarters has oversight of the technical operations of the remote

facility. If OWM determines that two or more locations fall under the same recognition scope, the remote facility site is 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.

2.6.2. Field Calibrations

Field calibrations shall require assessment of the environment to ensure the location is suitable and complies with the standard operating procedure (SOP) requirements. The laboratory shall maintain access controls for all equipment and standard used for the calibration to ensure the integrity of the calibration. Field calibrations must ensure the metrological traceability and validity of the calibration through the implementation of policies, procedures, and implementation of standard operating procedures, measurement assurance, and full traceability and uncertainty assessments to ensure compliance. State laboratories shall submit separate uncertainty evaluations for all field calibrations and submit data for facility environmental evaluations, measurement assurance (control charts, calibration for check standards), and traceability assessments as requested.

2.6.3. Subcontracting

OWM does not subcontract activities related to making final decision on recognition status and issuing a *Certificate of Metrological Traceability*. OWM may contract with technical experts to provide input on the recognition determination and process, 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 events.

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, latest ILAC policies, latest NVLAP handbooks, and other suitable publications. OWM has supplemental requirements that are detailed in this Program Handbook (See 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.

2.8.1. Solicitation of Comment and Review by Program Laboratories

OWM publications are reviewed by laboratories recognized as a part of this program prior to publication. This edition of the NIST Handbook 143, NIST OWM Recognition Program Handbook was posted and open for comment from July 2021 to December 2021.

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. Historical records and inventories may be retained to aid in ongoing NIST evaluation of traceability of standards and equipment. 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 year as submitted;
- 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 as submitted and scope;
- 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 domestic 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 webpage (www.nist.gov/labmetrology). 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.

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. Objective evidence of a laboratory copy is required to obtain OWM internal auditing forms that contain language of the standard.

2.12.1. 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 <u>State Metrology Laboratory Contacts webpage</u>. A *Certificate of Metrological Traceability* may be copied and distributed to laboratory customers to use as evidence of traceability.

2.12.2. 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 CA2. 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.

2.12.3. 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.

2.12.4. Notification of Change

The state legal metrology laboratory authorized representative(s) is responsible for notifying OWM in writing when laboratory circumstances change significantly.

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.

2.12.5. Timely and Complete Submissions

OWM solicits information from state legal metrology laboratories each year as part 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 may prevent full 2-year recognition and may result in a 1-year or *Conditional* (limited) recognition. Requests by the laboratory for technical assistance and scope modifications may be made at any time.

2.12.6. 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
ALL	NIST 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 submit the status of 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.	If applicable
ALL	Special Technical Assessment	Guidance is provided in the Recognition solicitation memorandum when requests are made.	As appropriate
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

ISO/IEC 17025:2017 Section or Reference	Item	Guidance	Submitted Annually
7.6	Uncertainties for all Measurement Parameters	Uncertainties shall match the Recognition Application and be reviewed and updated annually. 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
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	Update all standard deviations of process consistent with control charts in uncertainty budgets. Ensure surveillance of measurement process is routinely done and reviewed.	As appropriate
Quality 8.2 Managemen System		Updates of quality system documents shall be submitted, including the Quality Manual, Appendices, Administrative Procedures, and Forms.	As appropriate
8.8	Internal Quality Management System Assessment	A complete annual audit report shall include supporting documentation such as related forms, executive summary of findings, action plan, and objective evidence examples that prove compliance with this Program Handbook and ISO/IEC 17025:2017.	As appropriate

ISO/IEC 17025:2017 Section or Reference	Item	Guidance	Submitted Annually
8.9	Management Review	Shall be within 6 months from the Recognition application due date. A template outline is available online.	Yes

2.12.6.1. NVLAP Accreditation

A NVLAP accredited state legal metrology laboratory shall maintain concurrent recognition. If recognition is denied, suspended, withdrawn, or changed in scope, the NVLAP accreditation must also be similarly modified to align with the OWM recognition scope. The state metrology laboratory is responsible for providing NVLAP with its latest OWM recognition scope to allow the alignment of OWM and NVLAP scopes to the extent possible. A state legal metrology laboratory must have OWM approval before submitting an accreditation application to NVLAP. The state metrology laboratory must notify OWM when modifying an accredited scope (parameter, range, uncertainty, and/or method), or amending uncertainties to NVLAP accreditation. 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.

2.12.7. 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 the issuing jurisdiction and should be refused.

2.12.8. Response to Nonconformities and Corrective Action Requests

A state legal metrology laboratory is provided specified amount of time to respond to nonconformities addressed through OWM or other third party annual audits, management reviews, other OWM technical reviews, or during onsite assessments. When nonconformities are found during OWM assessments, the authorized representative(s) must submit a

satisfactory response to OWM in writing within 30 calendar days of receiving final assessment report or other documented feedback.

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 is not 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 this Program Handbook.

2.12.9. Failure to Maintain Recognition

Any state legal metrology laboratory that fails to maintain recognition is encouraged to correct nonconformities and resubmit 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.

3. Recognition Process

The annual evaluation of a participant laboratory's *Recognition Application* and the required submission materials (<u>Table 1</u>) is conducted by OWM. Recognition process elements include (<u>Fig. 1</u>):

- 1) annual *Recognition Solicitation* memorandum published online (www.nist.gov/labmetrology).
- 2) laboratory internal assessment and preparation;
- 3) laboratory Recognition Application (or lack of request);
- 4) submission receipt;
- 5) submission review and technical evaluation; 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 prior to September (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 is detailed in the solicitation memo. Requested information is always related to specific criteria in this Program Handbook. The *Recognition Submission Requirements* (Table 1) are an example of requirements and guidelines. The exact requirements and associated guidelines are updated annually and contained in the current *Recognition Solicitation* memorandum. In addition, OWM holds an annual webinar to review the submission criteria of the Recognition Solicitation memorandum prior to September.

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);
- ensuring the requested measurement scope and uncertainties align with the information presented in the Recognition Application;
- verifying that the requested measurement scope is aligned with the NVLAP measurement scope (if applicable);
- reviewing the status of action items related to the prior year OWM feedback, including any unresolved recognition (or accreditation) and onsite assessment findings;
- reviewing the status of action items related to internal audits, which provides the state legal metrology laboratory with the opportunity to verify their achievement of all NIST Handbook 143 requirements and confirm that they are successfully integrated into the operations;

- conducting an annual internal assessment, preparing a report, developing an action plan, and implementing appropriate corrective and improvement actions;
- conducting a management review within six months immediately prior to submitting the Recognition Application and ensuring current information is communicated to OWM; and
- ensuring that all submitted materials use document control best practices, including file naming practices.

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 on the OWM webpage (www.nist.gov/labmetrology).

3.3.1. Submission Method

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

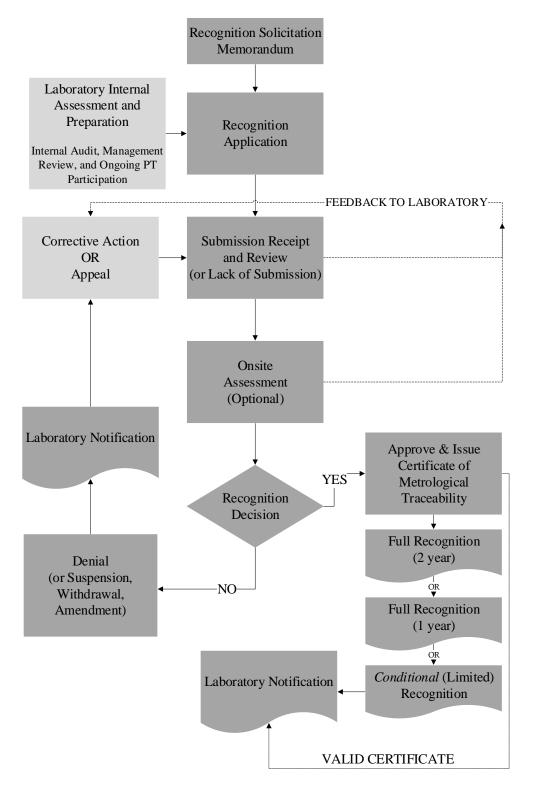


Fig. 1. Recognition Process Flowchart.

3.3.2. Annual Submission Period

The *Recognition Application* and required supporting materials are accepted each year for laboratories from RMAPs that meet prior to the Fall season between October 1 to November 1. The deadline is November 1. Laboratories from RMAPs that meet in the Fall are allowed an optional extension to November 15.

By submitting the *Recognition Application*, the laboratory authorized representative(s) (LAR) attest that the information in the application is correct and commits the laboratory to fulfill the conditions for recognition contained in the NIST Handbook 143, 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 may submit the Recognition Application and
 required submission materials during the annual submission period (<u>Table 1</u>) or any time
 throughout the year if OWM has time to process and review the submission. 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 change recognition scope or withdraw recognition may be submitted at any time during the year. 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.

3.3.3. Measurement Scope

The information provided on the *Recognition Application* is 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 does not include special measurement scope designations

on the *Certificate of Metrological Traceability*. OWM stringently evaluates 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 informs the laboratory authorized representative(s) (LARs) upon the receipt of the *Recognition Application* and supporting submission materials. If further information is required, OWM contacts the LARs. 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, fails to meet deadlines, or fails to 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 reviews 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 related tasks and 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.

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

• a 2.5 multiplier is used for laboratories with a 2-year recognition and accreditation;

- a 2.25 multiplier is used for laboratories with a 1-year recognition and accreditation;
- a 2 multiplier is used for laboratories with a 2-year recognition;
- a 1.5 multiplier is used for laboratories with a 1-year recognition;
- a 1 multiplier is used for laboratories with Conditional (limited) recognition;
- a 0 multiplier is used for laboratories with no recognition or closed.

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 its recognition scoring model score. OWM can be contacted to provide more guidance on how to perform the self-evaluation.

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

3.5.1.1. Documentation and Operations

The score for this criterion ranges from 0 to 55 points. The laboratory demonstrates a robust, well-aligned, and fully functioning and implemented ISO/IEC 17025:2017 compliant Quality Management System through internal and external assessments; policies, administrative processes, and technical procedures are documented, implemented, and maintained with ongoing improvements; 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; and management gains additional insights into calibration operations through their participation in training workshops and/or webinars.

3.5.1.2. Staffing

The score for this criterion ranges from 0 to 10 points. The laboratory demonstrates a training plan and succession plan for all personnel and positions; 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; where formal training programs are not available, structured on-the-job training is used to document competency (See <u>Table 2</u> requirements); and records of authorization and confirmation of competence for all technical personnel are maintained, such as education, qualifications, training, and experience.

3.5.1.3. Facilities and Accommodations

The score for this criterion ranges from 0 to 5 points. The laboratory demonstrates exceptional controls of facility and environment that results in minimum deficiencies or negative impacts to calibration services; available equipment used by the laboratory aligns with the recognized measurement scope and is maintained in functioning order; personnel have identified no risks related to the use of equipment and instrumentation that have been in service for extended periods of time; complete control charts and other measurement assurance methods are maintained which demonstrate appropriate standard deviations with no noticeable weaknesses; and PT uncertainties reflect acceptable normalized precision assessments (P_n) values for all measurement areas and ranges on the recognized scope to ensure that the laboratory is capable of meeting decision rules as published in applicable legal metrology documentary standards.

3.5.1.4. Equipment and Standards

The score for this criterion ranges from 0 to 10 points. The laboratory maintains appropriate reference, working, and check standards in service with no deficiencies; current and appropriate calibrations are available for all standards and proper maintenance plans and records are available for all equipment used in calibration procedures; and the calibration system and program traceability hierarchy are fully implemented to ensure regular calibrations take place at suitable intervals.

3.5.1.5. Competency Demonstration

The score for this criterion ranges from -5 to 10 points. The competence of the laboratory personnel is demonstrated through a program of ongoing and successful PT participation, including the maintenance of PT Participation Plan requirements (Section 4); approved signatory(ies) achieve excellent PT results, with limited failures and immediate corrective action, where needed; and up-to-date records are maintained (See also Section 3.5.1.2.).

3.5.1.6. Management Support

The score for this criterion ranges from -5 to 5 points. The management support is demonstrated through ongoing efforts to meet ISO/IEC 17025:2017 and this Program Handbook requirements through adequate resources for competent staff, facility, equipment, and standards.

3.5.1.7. Submission Completeness and Timeliness

The score for this criterion ranges from -10 to 10 points. The timeliness of the laboratory's annual recognition submission material consistently meets the *Recognition Application* deadline, and its contents satisfy the requirements of the submittal (<u>Table 1</u>).

3.5.2. Competency Evaluation

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, PTs, and procedure observation during onsite assessment are methods that shall be used to assess technical competence, where available (See <u>Table 2</u> – latest version is posted on the OWM Laboratory Program webpage).

3.5.2.1. 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 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.

There are two types of problems assigned by OWM following the completion of the associated training seminar necessary to receive Approved Signatory Status. These include the Fundamental of Metrology LAP problems and the Advanced Mass LAP problems. The Fundamentals of Metrology LAP problems are due within one year of completing the Fundamentals of Metrology seminar. The Advanced Mass LAP problems are due within two years of completing the Advanced Mass seminar.

3.5.2.2. Proficiency Tests

Proficiency Tests (PTs) are conducted nationally and regionally through 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 shall 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 is 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;
- 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/surveillance 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;
- 6) Failure to complete corrective action after a PT failure;
- 7) Failure to submit valid calibration or test certificates that are fully compliant with ISO/IEC 17025:2017.

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.

3.5.2.3. 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, assistance visits, or courtesy visits to review portions of a laboratory facility, equipment, staff, and operations. 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 conducted as feasible. Unlike accreditation body assessments which follow ILAC policies regarding independence, it is the responsibility of the NIST OWM to provide assistance, training, and guidance as a part of this OWM program.

The primary objectives of onsite assessments are to: 1) ensure that the laboratories maintain calibration quality by complying with ISO/IEC 17025:2017 and this 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. Non-conformities to this Program Handbook or ISO/IEC 17025:2017 may be identified and communicated to the laboratory as observed during onsite assessments. Courtesy visits are often conducted during OWM program staff travel, laboratory tours, and laboratory construction and renovation site visits. Courtesy visits may or may not result in formal onsite assessment reports depending on the purpose and outcomes of the laboratory visit.

3.5.3.1. Preparation for Onsite Assessment

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. OWM staff may contact a laboratory prior to arrival and request oral and/or written reviews of the safety considerations and precautions at the laboratory.

3.5.3.2. Assessor Assignment

Onsite assessments may be conducted by OWM staff and/or technical experts. It is essential that assessors possess the required professional knowledge, experience, and familiarity with ISO/IEC 17205:2017, recognition criteria in this Program Handbook, relevant sections of the technical criteria in Appendix E of this 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 technique instructions to onsite assessors. OWM maintains technical experts' 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 may include (but are not limited to) 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.

3.5.3.3. Conduct of Onsite Assessment

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 NIST Handbook 143, checklists, and template forms to review records, observe operations and measurements, and conduct interviews. The assessors(s) needs 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.

3.5.3.4. 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;
- assessment date;
- 3) criteria used;
- 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) references for each finding aligned with the NIST Handbook 143 during onsite record reviews, observations, and interviews.

3.5.3.5. Laboratory Response

The state legal metrology laboratory is given an opportunity to respond to or appeal (<u>Section 3.6.5</u>) 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 responds 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 are subject to thorough review and evaluation prior to the recognition decision.

3.6.1. Laboratory Feedback

Improvement actions are often recommended, and corrective action shall be required for identified 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 fully meet all criteria in this Program Handbook should not apply for NVLAP accreditation.

Recognition decisions and feedback are typically provided to the applicant laboratory between January 1 and February 15. A *Certificate of Metrological Traceability* is typically issued for

effective dates beginning on February 1 and expiring on subsequent 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 State Laboratory Contact website (www.nist.gov/owm) at the end of the annual recognition cycle and updated throughout the year, as needed.

3.6.2. Recognition Approval

Recognition approval, status, and submission evaluation findings are communicated to the laboratory 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* is not issued because the current certificate 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 criteria of this Program Handbook.
- 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 is not 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) recognition 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 the NIST Handbook 143, NIST OWM Recognition Program Handbook criteria.

3.6.3. Recognition Denial

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

3.6.4. 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 are 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 NIST Handbook 143 criteria are met.
 OWM suspends recognition and awaits a new Recognition Application when a state legal
 metrology laboratory is relocated to a facility that differs from a recognized location or if
 significant nonconformities are identified (e.g., loss of all qualified staff, damage to all
 laboratory equipment or standards).
- **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*.

3.6.5. Laboratory Appeal

An applicant laboratory has the right to appeal any adverse decision related to its recognition status in writing to OWM. The OWM response to an appeal will likely include a full independent onsite laboratory assessment according to all NIST Handbook 143 criteria. The state legal metrology laboratory requesting an appeal is 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 shall advise the laboratory authorized representative(s) in writing of the appeal outcome.

3.7. 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. All feedback and complaints will be archived and used for continuous improvement of the OWM Laboratory Metrology Program.

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 NIST Handbook 143 requirements. In addition, OWM uses technical requirements included in the Annexes in Appendix E that are based on those found in NVLAP HB 150-2 Annexes for evaluation of technical requirements and traceability as part of a recognition decisions. Any deviation from these supplemental criteria must have a technical basis, data, and technical analysis to support variances.

4.1. 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 as shown Fig. 2 and as designated in Table 2 (i.e., at least one staff member shall represent the laboratory and all staff should participate when event is held within the state or virtually). 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 Participation Plan to support recognition and accreditation requirements. The state legal metrology laboratory is required to submit the PT Participation Plan with each *Recognition Application*.



U.S. State Legal Metrology Laboratories

Fig. 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).

4.2. 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 Laboratory Metrology webpage (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.

OWM recommends that states develop minimum qualifications for metrologists. Working knowledge of algebra, basic statistics, and computer software is essential. A suitable technical degree as found in the field of physical science (such as physics, chemistry, and Earth science), mathematical science (such as statistics and computational science) and applied science (such as engineering), is highly recommended. OWM recommends metrologists to spend time in their state legal metrology laboratory familiarizing themselves with the laboratory quality management system, procedures, and equipment prior to attending a training seminar.

NIST OWM Mass and Volume seminars 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, full recognition may only be granted to the state legal metrology laboratory when the sole metrologist has successfully completed the NIST OWM Mass and Volume seminars and associated Laboratory Auditing Program (LAP) problems.

4.3. 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 (or as updated and posted online). An approved signatory is required to complete the appropriate level of training as indicated in <u>Table 2</u> for the participant laboratory to be recognized at the designated level. Information regarding the training program is described in <u>Appendix A</u>.

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 staff member for RMAP training and all staff are recommended when RMAP training is conducted virtually or when lab is the local host for the training (no outof-state travel required).	Annually

Recognition Level	Training Required	For Whom	How Often
Legal Metrology Limited: Conditional Recognition. Conditional Approved Signatory Waiver.	 NIST OWM Fundamentals of Metrology (1 week laboratory seminar) Introduction and orientation to mass and volume procedures (SOP 8, SOP 19)ⁱⁱⁱ Fundamentals of Metrology, Laboratory Auditing Program (LAP) problems Successful proficiency testing (PT) completion 	Usually all staff, at least one staff member	Once initially Refresher portions covered during RMAP training
Mass Calibration Mass Echelon II and III	 All of the above, plus: NIST OWM Mass Seminar (2-week) Successful PT completion for each area on the laboratory scope using mass calibrations 	Usually all staff, At least one staff member	Once initially Refresher recommended every 10 year
Volume Calibration Volume Echelon I and II	 Legal Metrology and Mass Calibration requirements NIST OWM Volume Seminar (1-week) Successful PT completion for each area on the laboratory scope using volume transfer and/or gravimetric calibrations 	Usually, all staff At least one staff member	Once Initially Refresher recommended every 10 year
Mass Calibration Mass Echelon I	 All of the above, plus: NIST OWM Advanced Mass Seminar (2-week) Advanced Laboratory Auditing Program (LAP) Problems Successful PT completion using weighing designs 	At least one staff member	Once initially Refresher recommended every 10 year

Recognition Level	Training Required	For Whom	How Often
All Measurement Parameters in addition to Mass and Volume	 Documented training Successful PT completion in each area of the laboratory scope where PT is available 	At least one staff member, as needed	At least once Refresher, as needed

Staff are not granted full Signatory Status unless they have completed three core seminars: Fundamentals of Metrology, Mass Calibration Seminar, Volume Calibration Seminar provided by NIST OWM. The "Legal Metrology" designation is an exception to full training requirements and may be approved by OWM to grant *Conditional Recognition* only when the laboratory has one staff available and who has completed this level of training. If there is only one staff member in the laboratory, the laboratory will only be fully Recognized if they have also successfully completed the NIST OWM Mass Calibration and NIST OWM Volume Calibration courses. It is possible under limited situations for a laboratory with only one staff member to obtain Conditional Signatory Status and gain Conditional Recognition pending completion of all training requirements.

Scope. A waiver for Conditional Signatory Status may be issued to students whether they have completed the full NIST

OWM Fundamentals of Metrology seminar or an on-line interim course at OWM's discretion.

4.4. Procedures

Use of uniform technical procedures is critical for maintaining the integrity of the legal measurement system. 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 OWM procedures for all applicable measurement procedures unless data or other evidence is available to support acceptable results using another validated 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, where available, 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.

ii Waivers for *Conditional Signatory Status* of staff may be provided and approved by OWM personnel under unique circumstances. Conditional waivers for signatory authority require completion of stated level of training and include submitting a waiver request with objective evidence of mass/volume orientation as noted in Endnote iii, successful completion of Mass and Volume PTs, and successful completion of Laboratory Auditing Program (LAP) problems. Waiver approvals are limited to SOP 8 and SOP 19 calibrations. The intent of interim orientation is to enable completion of proficiency testing and NIST OWM Fundamentals of Metrology course, Laboratory Auditing Program (LAP) problems only. Waivers include an expiration date and may be extended by OWM with appropriate justification, if/as applicable.
iii Orientation for Mass (SOP 8) and Volume (SOP 19) may be provided by OWM during other seminars, during onsite laboratory visits, via web-based training (recorded or live with applicable evidence) or may be approved by OWM for onthe-job training by qualified staff who have successfully met all other requirements at the designated level. NIST OWM Mass and Volume Calibration courses must be successfully completed by at least one person in each laboratory to achieve full (non-Conditional) Recognition and by all staff who have full Signatory Authority for the applicable procedures and

4.5. Equipment Requirements

Equipment and/or standards shall be listed on the uncertainty table and/or the calibration database/inventory with the current performance evaluation (i.e., precision assessment). Equipment information is requested during onsite assessments and annually with measurement control records (Table 1).

4.6. Standards Requirements

Copies of calibration certificates for standards (i.e., reference, secondary, working, etc. standards) used in the laboratory are maintained and archived by the OWM. The state legal metrology laboratory must submit new calibration certificates obtained during the year to OWM during the following annual submission period (Table 1). When calibration services are not obtained from NIST, they shall be obtained from an equivalent National Metrology Institute, laboratory accredited by an accreditation body that is a signatory to the International Laboratory Accreditation Council, Mutual Recognition Arrangement (ILAC MRA) or a NIST OWM recognized laboratory. A *Conditionally* (limited) recognized state legal metrology laboratory is unacceptable as a calibration provider for other laboratories.

4.7. Demonstrating Metrological Traceability

State laboratories shall demonstrate the essential elements of metrological traceability according to NISTIR 6969, Good Measurement Practice (GMP) 13, Ensuring Metrological Traceability. This requirement is above and beyond the requirements of ISO/IEC 17025:2017, Section 6.5. Resources for conducting internal audits to assess metrological traceability are published with GMP 13 on the OWM webpage (www.nist.gov/labmetrology).

4.8. Uncertainty Requirements

State laboratories shall achieve compliance to the *Guide to the Expression of Uncertainty in Measurement* (GUM) either directly and/or by adoption and use of Standard Operating Procedure (SOP) 29, Assignment of Uncertainty (NISTIR 6969). Laboratories shall update standard uncertainties as calibrations occur and update measurement assurance standard deviations at least during annual reviews or whenever there is a change in the measurement process (e.g., new or service of equipment causing a change, moving a laboratory).

4.9. 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. Good Laboratory Practice (GLP) 1 (NISTIR 6969) provides an outline of approaches used to ensure validity of laboratory measurement results and includes a

table of reference resources. 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 interlaboratory comparisons conducted using artifacts with accepted reference values and the evaluation of bias in the results of interlaboratory comparisons or proficiency tests that 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;
- 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; and
- Measurement assurance data shall be reviewed annually (as a minimum), with calibrations of standards obtained when problematic data is observed; along with uncertainties updated at least annually or updated when significant changes are observed such as the uncertainty values exceeding 10 % variability of prior values.

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 (e.g., for annual submission).

4.10. 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. NISTIR 8250, Good Laboratory Practice (GLP) 15, Software Quality Assurance shall be used unless an equivalent or more rigorous procedure is available in the laboratory.

4.11. 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,* the NIST Handbook 105 series of documentary standards, and several ASTM and OIML 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 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. NIST OWM Services

The NIST OWM vision is to lead the advancement of legal metrology documentary standards and practices to promote U.S. economic growth and fair trade. We aim to achieve this through our mission to establish uniformity, equity, SI use, and traceability in weights and measures by advancing national and international legal metrology standards, procedures, capabilities, and training.

Integral to <u>OWM's current strategic plan</u>, a primary objective is to promote uniformity of measurement approaches, acceptable accuracy, and metrological traceability of results made through state legal metrology laboratory measurements. OWM thus encourages all state legal metrology laboratories to seek OWM recognition (2 or 1 year) and NVLAP accreditation.

Services and technical assistance include the following:

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

Training. The OWM Training Program is an International Association for Continuing Education and Training (IACET) accredited provider that is authorized to offer Continuing Education Units (CEUs). Course descriptions and prerequisites, the current schedule, and enrollment links for the OWM training courses are available online (www.nist.gov/owm). Students are awarded the CEUs a course is assigned as well as a training certificate after successful completion.

Seminar Series. NIST 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 (1-week course)
- Mass Seminar (2-weeks course);
- Volume Seminar (1-week course);
- Advanced Mass Seminar (2-weeks course); and
- other Measurement Seminars on special measurement techniques (2 days to 5 days). Examples: Length Seminar, Balance and Scale Calibration and Uncertainties Seminar, Precision Thermometry Seminar, and Laboratory Administration Workshop.

Webinar Series. Webinars are typically 2-hour sessions with specific learning objectives and activities designed to engage participants in an online setting. 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;
- Fundamental of Metrology Overview (series of 4 webinars);
- Internal Auditing Best Practices;
- Laboratory Administration Workshop (series of 8 webinars);
- Laboratory Audit Program problems;
- Proficiency Testing Follow-up and Analysis;
- Software Verification and Validation;
- State Laboratory Annual Submission Process for Recognition; and
- Supplier Evaluation.

Laboratory Metrology Info Hour (LMIH) sessions. These 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 and CEUs are not issued to participants for the LMIH sessions.

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 as listed below (see also Fig. 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. SOP, GLP, and GMP that support typical measurement areas used in trade and commerce are available online (www.nist.gov/labmetrology):

Mass Calibration

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

Volume Calibration

• Gravimetric, volume transfer, and dynamic small volume provers.

Length Calibration

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

Additional Measurement Areas

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

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 Regional Measurement Assurance Program (RMAP) (Fig. 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 on the Laboratory Metrology webpage (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 a 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 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/owm

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 listed in Table 3, many state legal metrology laboratories perform measurements for which the NIST Office of Weights and Measures (OWM) 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 calibration, test, or verification of tuning forks used in testing radar speed devices, wheel-load weighers used in testing large trucks for road weight restrictions, and hydrometers for testing sugar content of syrup. Areas without established recognition criteria include the calibration of dial gauges used to test polyethylene sheeting (an extension of dimensional measurements), lottery balls for state lottery programs (which may be recognized for mass and/or dimensional measurements), or entire programs, such as grain moisture and petroleum quality testing.

Table 3. Typical Legal Metrology Recognition Parameters

Parameter	Typical Recognition Scope Range	Class/Application and Documentary Standard	Typical Expanded Uncertainty	
Mass Echelon I (Extra Fine Accuracy)	30 kg to 1 mg 50 lb to 0.001 lb 8 oz to 0.031 25 oz	OIML Class E ₁ , E ₂ ASTM Class 000, 00, 0, 1	OIML R111	
Mass Echelon II (Fine Accuracy)	1200 kg to 1 mg 2500 lb to 0.001 lb 8 oz to 0.015 625 oz	OIML Class F ₁ , F ₂ ASTM Class 2, 3	ASTM E617	
Mass Echelon III (Medium Accuracy)	2500 kg to 1 mg 2500 lb to 0.001 lb 8 oz to 0.015 625 oz	NIST Handbook 105-1, Class F (1990) Legal/regulatory enforcement) OIML Class M ₁ , M ₁₋₂ , M ₂ , M ₂₋₃ , M ₃ ASTM Class 4, 5, 6, 7	Require compliance to specifications and maximum permissible errors (m.p.e.); uncertainty	
Mass Echelon III Weight Cart	≤ 10 000 lb	NIST Handbook 105-8	must be less than 1/3 m.p.e.	

Parameter	Typical Recognition Scope Range	Class/Application and Documentary Standard	Typical Expanded Uncertainty
Mass Echelon III Wheel-Load Weigher Railroad Test Car	≤ 40 000 lb ≤ 115 000 lb	NIST Handbook 44 ASTM E74	
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 ASTM Standards OIML Standards NIST Handbook 105-2	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 NIST Handbook 105-2 NIST Handbook 105-3	< 0.001 mL/L
Volume Echelon II Volume Transfer LPG	2000 L to 100 L 500 gal to 25 gal	Prover NIST Handbook 105-4	< 0.001 mL/L
Length Tape, Bench Method	Up to 30 m Up to 200 ft	NIST Handbook 44 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	NIST Handbook 44 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	NIST Handbook 44 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 NIST Handbook 105-6	> ± 0.005 °C to ≤ ± 0.05 °C
Temperature Echelon III	230 °C to - 30 °C 450 °F to - 25 °F	Liquid-in-glass thermometer NIST Handbook 105-6	> ± 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 $\pm 0.20 ^{\circ}\text{C}$ NIST Handbook 105-6 $\pm 1.0 ^{\circ}\text{C}$	
Temperature Echelon V	230 °C to - 30 °C 450 °F to - 25 °F	Infrared sensor and thermograph	> ± 1.0 °C to ≤ ± 5.0 °C

Parameter	Typical Recognition Scope Range	Class/Application and Documentary Standard	Typical Expanded Uncertainty
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 NIST Handbook 105-5 NIST Handbook 44	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 1 – See Annexes in Appendix E of this OWM Recognition Program Handbook for detailed technical criteria used for evaluation of traceability and competency.

NOTE 2 – Typical Uncertainties are not the sole limiting factor for assigning Recognition for Echelons listed in this table. See additional technical criteria in the applicable documentary standards and procedures regarding standards, equipment, environmental requirements, design, and decision rules.

Table 4. Summary of Environmental Facility Limits Specified in the NISTIR¹ Procedures

Parameter, Echelon	Temperature Range (°C)	Temperature variability from set point (± °C / h)	Max change per calibration (°C/h)	Relative Humidity (RH) Range (%)	RH variability from set point (± % / h)
Mass, I (OIML E ₁)	18 to 23	0.5 °C / 12 h	0.3	40 to 60	5 % / 4 h
Mass, I (OIML E ₂)	18 to 23	1.0 °C / 12 h	0.7	40 to 60	5 % / 4 h
Mass, II	18 to 23	2 °C / 12 h	1.5	40 to 60	10 % / 4 h
Mass, III	18 to 27	5 °C / 12 h	3.0	40 to 60	20 % / 4 h
Force ²	23	NS	0.2	NS	NS
Force ³	18 to 27	5 °C / 12 h	3.0	40 to 60	20 % / 4 h
Volume, I Gravimetric	18 to 23	NS	1.0	40 to 60	10 % / 4 h
Volume, II Transfer	18 to 27	NS	2.0	35 to 65	20 % / 4 h
Dimensional	18 to 22	1 °C / 24 h	0.5	40 to 60	10 % / 4 h
Time	General laboratory conditions; record conditions from laboratory observations				
Tuning Forks	18 to 25	NS	NS	40 to 60	NS
Thermometry	NS	2 °C / 24 h	NS	40 to 60	10 % / 4 h
Hydrometers	Stable	NS	NS	NS	NS
Watthour Meters ⁴	23	NS	1.0	30 to 50	NS

NS = Not Specified.

NOTE: <u>Table 4</u> is provided with the intent to be a useful summary at a glance; the applicable documentary standard and laboratory procedures take precedence in the case of conflicts

¹ NISTIR 6969, Selected Laboratory and Measurement Practices, and Procedures to Support Basic Mass Calibrations, 2019. NISTIR 5672, Advanced Mass Calibrations and Measurements Assurance Program for the State Calibration Laboratories, 2019. NISTIR 7383, Selected Procedures for Volumetric Calibrations, 2019.

NISTIR 8028, Selected Laboratory and Measurement Practices and Procedures for Length Calibrations, 2014.

NISTIR 8250, Calibration Procedures for Weights and Measures Laboratories, 2019.
² See Appendix E, Annex D. Mechanical Calibrations Technical Criteria.

³ Unpublished SOP from Pennsylvania Laboratory, specifies Mass Echelon III environmental conditions.

⁴ See Appendix E, Annex A. Unique Legal Metrology Technical Criteria

Appendix C. I	List of Symbols	, Abbreviations	, and Acronyms
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AB

Accreditation Body

ANSI

American National Standards Institute

CEU

Continuing Education Units

CMC

Calibration and Measurement Capability

DOI

Digital Object Identifier

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

LAR

Laboratory Authorize Representative

LMIH

Laboratory Metrology Info Hour

m.p.e.

maximum permissible error

MRA

Mutual Recognition Arrangement

NBS

National Bureau of Standards (former name of NIST)

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

NTTAA

National Technology Transfer and Advancement Act

NVLAP

National Voluntary Laboratory Accreditation Program

OWM

Office of Weights and Measures

SI

International System of Unites

PT

Proficiency Test

RMAP

Regional Measurement Assurance Program

USDA, AMS, FGIS

U.S. Department of Agriculture, Agricultural Marketing Service, Federal Grain Inspection Service

VIM

International Vocabulary of Metrology

Appendix D. Glossary

For the purposes of this Program Handbook, the relevant terms and definitions given in ISO/IEC 17000 and the International Vocabulary of Metrology (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 –An accredited state legal metrology laboratory must maintain concurrent OWM recognition.

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 provided 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 handbook. It is always issued with a Measurement Scope and characterizes the recognition, either *full* (normal) or *Conditional* (limited).

Competence

The 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).

Length Laboratory

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

Management Review

A planned, formal review of the management system by the parties in the organization. To include a high-level overview and a review of the organization structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives, and processes to achieve organizational goals.

NOTE: OWM requires at least one management review annually less than 6 months prior to Recognition Application submissions.

NOTE: Documented management review results feed into the laboratory planning system and include the goals, objectives, and action plans for the coming year.

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. Alternative documentary standards may apply to these different management systems, e.g., ISO/IEC 17025:2017 for the General Requirements for the Competence of Testing and Calibration Laboratories, ISO 14001 for Environmental Management Systems — Requirements with Guidance for Use, etc.

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) – Notes 1 to 8 are taken directly from the International Vocabulary of Metrology. Note 9 is added as an additional OWM requirement per Good Measurement Practice 13, Ensuring Traceability. A measurement assurance system and periodic verification are required for state legal metrology laboratories to ensure the validity of the measurement results and 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]

OWM Program

The NIST OWM Laboratory Metrology program provides guidance, technical support, and assistance to state legal metrology laboratories to ensure accurate and traceable measurements are made within each participating jurisdiction.

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. [ISO/IEC 17043:2023, 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 Handbook 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 17025:2017 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 under the same quality management system. 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.

Appendix E. Additional Technical Requirements

The following annexes included in this appendix provide additional technical requirements for attaining traceable measurement results in the specified measurement areas.

Annex A. Unique Legal Metrology Technical Criteria

A.1. Electrical Watt-Hour Meter Calibrations

A.1.1. Scope

This section contains specific technical criteria that a laboratory shall meet to be competent to calibrate power frequency wattmeters (WMs) and watthour meters (WHMs).

A.1.2. References

- a) "Code for Electricity Metering," ANSI C-12.
- b) Oldham, N. M., Laug, O. B., Waltrip, B. C., and Palm, R. A2.,"The NIST Digitally Synthesized Power Calibration Source," NIST Technical Note 1281, 1990.
- c) Ramboz, J. D., and McAuliff, R. C., "A Calibration Service for Wattmeters and Watthour Meters," NBS Technical Note 1179, 1983.
- d) U. S. Department of the Interior Bureau of Reclamation, "Watt-hour Meter Maintenance and Testing, Facilities Instructions, Standards, and Techniques," Volume 3-10, 2000.

A.1.3. Equipment

The laboratory shall have the necessary power/energy calibrator to calibrate all the ranges of the test WMs and WHMs. The calibrator shall be calibrated to an uncertainty smaller (by a factor of 2 or more) than the desired test WM/WHM uncertainty. The test WM/WHM shall be connected to the calibrator in accordance with the calibrator or test WM/WHM specifications.

A.1.4. Assuring the Validity of Test and Calibration Results

The laboratory shall periodically calibrate at least one control WM/WHM over the range normally used by the laboratory to calibrate test WMs/WHMs. Data analysis of drift, trends, and shifts in measurement assurance data must be periodically assessed and incorporated into the uncertainty evaluations.

A.1.5. Accommodation and Environmental Conditions

A.1.5.1. Calibrations shall be performed under the following conditions:

- a) Ambient temperature of (20 to 23, with a set point \pm 1) °C.
- b) Ambient relative humidity between 30 % and 60 %.
- c) Mains voltage within ± 10 % of nominal, with less than 3 % Total Harmonic Distortion

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(THD).

A.1.5.2. These requirements may be relaxed to the point that their combined influence will not exceed 25 % of the uncertainty budget.

A.1.6. Reporting the Results

In addition to the requirements of ISO/IEC 17025:2017 section 7.8, the calibration report shall include the following:

- a) Test parameters (function, amplitude [range and applied], and frequency);
- b) WM/WHM correction;
- c) Calibration uncertainty and description of how the uncertainty was calculated;
- d) Ambient (or instrument) temperature and humidity;
- e) Applicable tolerances and conformity assessments; and
- f) Brief description of the standard used to perform the calibration.

A.2. Thermometry Calibrations

A.2.1. Scope

- A.2.1.1. This section contains the specific technical criteria in accordance with which a laboratory shall demonstrate that it operates, if it is to be accredited or recognized as competent to carry out thermometer calibrations.
- A.2.1.2. This section may also be used as a guide by thermometer calibration laboratories in the development and implementation of their quality systems.

Echelon: Level of performance associated with the level of expanded uncertainty, according to the following <u>Table 5</u>:

Echelon	Example Expanded Uncertainties
I	≤ ± 0.005 °C
II	> ± 0.005 °C to ≤ ± 0.05 °C
III	> ± 0.05 °C to ≤ ± 0.20 °C
IV	> ± 0.20 °C to ≤ ± 1.0 °C
V	> ± 1.0 °C to ≤ ± 5.0 °C

Table 5. Typical uncertainties in thermometry

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

A.2.2. References

- 1. ASTM VOLUME 14.03:2022, ASTM Book of Standards Volume 14.03 Temperature Measurement.
- BIPM "Supplementary Information for the International Temperature Scale of 1990," Bureau International Des Poids et Mesures, Pavilion de Breteuil, F-92310 Sevres, France, 1990.
- 3. BIPM "Techniques for Approximating the ITS-90," Bureau International Des Poids et Mesures, Pavilion de Breteuil, F-92310 Sevres, France, 1990.
- 4. Burns, G.W., Scroger, "The Calibration of Thermocouples and Thermocouple Materials," NIST SP 250-35, 1989.
- 5. Mangum, B. W., Furukawa, G. T., "Guidelines for Realizing the International Temperature Scale of 1990 (ITS-90)," NIST Technical Note 1265, 1990.
- 6. Mangum, B. W., "Reproducibility of the Temperature of the Ice Point in Routine

- Measurements," NIST Technical Note 1411, 1995.
- 7. Meyer, C. W., Strouse, G. F., Tew, W. L., "A Revised Assessment of Calibration Uncertainties for Capsule Type Standard Platinum and Rhodium-Iron Resistance Thermometers," NISTIR 6138, 1998.
- 8. NIST Handbook 105-6, Specifications and Tolerances for Field Standard Thermometers, 1997.
- 9. Ripple, D., Burns, G.W., Scroger, M.G., "Assessment of Uncertainties of Thermocouple Calibrations at National Institute of Standards and Technology," NISTIR 5340,1994.
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- 11. Wise, J., "Liquid-In-Glass Thermometer Calibration Service," NIST SP 250-23, 1988.
- 12. Wise, J.A., "Assessment of Uncertainties of Liquid-in-Glass Thermometer Calibrations at the National Institute of Standards and Technology," NISTIR 5341, 1994.
- 13. Wise, J.A., Soulen, R.J., "Thermometer Calibration, A Model for State Calibration Laboratories (Appendix A: NBS Monograph 150, Liquid-In-Glass Thermometry)," NBS Monograph 174, 1986.

A.2.3. Ensuring the Validity of Calibration Results

A.2.3.1. Fixed-point Cell as the Reference Standards

When the reference standard used by the laboratory is a fixed-point cell, the three action items described below are required as indicated by the application table, <u>Table 6</u>, that follows their description.

- A.2.3.1.1. Records of complete phase equilibrium plateaus obtained for each cell upon receipt and every six months thereafter shall be maintained. This shall include either manually recorded temperatures at consistent intervals, or a graphical representation of the equilibrium plateau, as measured by the monitoring sensor.
- A.2.3.1.2. A separate check thermometer shall be used for each cell and control charts shall be maintained.
- A.2.3.1.3. The triple point of water shall be measured after every measurement at another temperature.

Table 6. Requirements for fixed-point cell reference standards

ltom	Echelon					
Item	I	II	III	IV	V	
A.2.3.1.1.	Х	Х	Х	Х		
A.2.3.1.2.	Х	Х	Х	Х		
A.2.3.1.3.	Х					

A.2.3.2. SPRT or RIRT as the Reference Standard

When the reference standard used by the laboratory is a standard platinum resistance thermometer (SPRT) or a rhodium-iron resistance thermometer (RIRT), the two action items described below are required as indicated by the application table, <u>Table 7</u>.

A.2.3.2.1. There shall be documentation (i.e., control charts) to show that the resistance of the instrument at the triple point of water has not changed since its last calibration by more than the equivalent shown in the table below.

A.2.3.2.2. If a digital voltmeter (DVM), digital multi-meter (DMM), or digital temperature indicator is used, the calibration of the temperature indicating system (indicator and sensor) shall be checked periodically at either the water triple point or at the ice point.

Table 7. Requirements for SPRT and RIRT reference standards per Echelon

Itom	Echelon					
Item	I	Η	III	IV	V	
A.2.3.2.1.	2 mK	2 mK	5 mK	10 mK	10 mK	
A.2.3.2.2.	X	X	X	X	Х	

A.2.3.3. Thermistor thermometer as the Reference Standard

When the reference standard used by the laboratory is a thermistor thermometer, the two action items described below are required as indicated by the application table, Table 8.

- A.2.3.3.1. The calibration of the thermistor thermometer shall be checked frequently (monthly or weekly) depending on the application, and control charts shall be kept.
- A.2.3.3.2. If, since the last calibration, the resistance of the thermistor thermometer has changed at a reference check point (fixed-point, preferably) by the equivalent shown in <u>Table 8</u>, a new calibration shall be done.

Table 8. Requirements for Thermistor thermometer reference standards

lt oue	Echelon					
Item	I	=	II	IV	V	
A.2.3.3.1.		Х	Х	Х	Х	
A.2.3.3.2.		2 mK	5 mK	10 mK		

A.2.3.4. Thermocouple as the Reference Standard

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

A.2.3.5. Liquid-in-glass Thermometer as the Reference Standard

When the reference standard used by the laboratory is a liquid-in-glass thermometer, the two action items described below are required as indicated by the application table, Table 9.

A.2.3.5.1. The total-immersion mercury-in-glass thermometer shall be checked according to good laboratory practice. One method is to check at the ice point on a regular basis after use and maintain records.

A.2.3.5.2. The total-immersion liquid-in-glass thermometer shall be checked according to good laboratory practice. One method is to check at the ice point regularly and maintain applicable control charts.

Table 9. Requirements for liquid-in-glass thermometer reference standards

ltom	Echelon				
Item	I	П	Ш	IV	V
A.2.3.5.1.			Х	Х	
A.2.3.5.2.					Х

A.2.4. Accommodation and Environment

- A.2.4.1. For all echelons, the environmental conditions of the laboratory shall be controlled.
- A.2.4.2. The temperature of the laboratory shall be controlled to \pm 2 °C.
- A.2.4.3. The relative humidity shall be controlled between 40 % and 60 %.
- A.2.4.4. Vibrations in the laboratory shall be minimized.

A.2.5. Equipment and Reference Materials

A.2.5.1. Reference Standards

The following <u>Table 10</u> indicates which reference standard is acceptable for each echelon.

Table 10. Thermometry reference standards

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

A.2.5.2. Fixed-point Cell as the Reference Standard

- A.2.5.2.1. The purity of the fixed-point material shall be at least 99.999 9 % and the other starting materials of construction of the cells shall be of ultra-high purity also. If the cells are unsealed, they shall be filled at all times with an inert gas such as argon.
- A.2.5.2.2. The cells shall be of the defining fixed points of the ITS 90, or well-characterized, stable, and reproducible secondary fixed points.

A.2.5.3. SPRT or RIRT as the Reference Standard

- A.2.5.3.1. A system having adequate resolution and uncertainty shall be used to measure a reference SPRT or RIRT. Recommendations for specific situations are given below in <u>Table 11</u>.
- A.2.5.3.2. A resistance bridge having at least the resolution shown below, <u>Table 11</u>, as a function of claimed total uncertainty is essential. A ratio bridge and standard resistors may be used:

Table 11. Thermometry resolution and uncertainty requirements for SPRT and RIRT systems

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

A.2.5.3.3. Alternatively, a DVM or DMM with the resolution shown below in <u>Table 12</u>, and a constant-current source with provision for reversing the current, may be used. The current shall be known to the same accuracy as the DVM or DMM.

Table 12. Conditions for a digital voltmeter or multimeter application in thermometry

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

A.2.5.4. Thermocouple as the Reference Standard

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

A.2.6. Measurement Traceability and Calibration

A.2.6.1. Fixed-point Cell as the Reference Standard

When the reference standard is a fixed-point cell, the four action items described below are required as indicated by the application table, Table 13.

- A.2.6.1.1. The cell shall be evaluated by NIST.
- A.2.6.1.2. The cell may have been evaluated by the supplier, if the supplier documented in detail the preparation and evaluation, showing direct traceability to the SI, or is accredited.
- A.2.6.1.3. The cell shall have been evaluated by an accredited supplier.
- A.2.6.1.4. The maximum uncertainty of the temperature of the cell shall be as indicated in Table 13.

Table 13. Fixed-point cell maximum uncertainty allowed

Itom	Echelon					
ltem	I	II	II	IV		
A.2.6.1.1.	Х	X*				
A.2.6.1.2.		X**				
A.2.6.1.3.			X	Х		
A.2.6.1.4.	± 0.001 °C	≤ ± 0.005 °C	0.01 °C	± 0.02 °C		

^{*} for total uncertainties ≤ ± 0.01 °C

A.2.6.2. SPRT or RIRT as the Reference Standard

When the reference standard is an SPRT or RIRT, the four action items described below are required as indicated by the application table, Table 14.

^{**} for total uncertainties in range \pm 0.01 °C to \pm 0.05 °C

- A.2.6.2.1. The SPRT or RIRT shall be calibrated by NIST or an accredited laboratory every 2 years but may be calibrated by NIST every 2 to 5 years if adequate measurement process data is evident.
- A.2.6.2.2. The SPRT or RIRT shall be calibrated annually, and all reference resistors used with the bridge shall be calibrated traceable to the SI.
- A.2.6.2.3. If a bridge is used, it shall be calibrated annually, and all reference resistors used with the bridge shall be calibrated traceable to the SI.
- A.2.6.2.4. If a DVM or DMM is used, it shall be calibrated annually.

Χ

ltem		Echelon					
item	I	II	III	IV	V		
A.2.6.2.1.	Х	Х	Х	Х			
A.2.6.2.2.					Х		
A.2.6.2.3.	Х	X	Х	Х			

Χ

Χ

Table 14. Calibration interval requirements for SPRT and RIRT reference standards

- A.2.6.3. If a thermistor thermometer is the reference standard, it shall be calibrated traceable to the SI.
- A.2.6.4. If a thermocouple is the reference standard, documentation shall show that its calibration is traceable to the SI and indicate the annealing procedure used during the thermocouple's use.
- A.2.6.5 . If a liquid-in-glass thermometer is the reference standard, it shall be calibrated traceable to the SI.

A.2.7. Calibration Methods

A.2.6.2.4.

- A.2.7.1. All computer programs used in data logging and analysis shall be documented in detail. Also, all algorithms and equipment shall be correct for the task.
- A.2.7.2. When calibrations are performed by comparison against an SPRT or an RIRT, or a thermistor thermometer, or a liquid-in-glass thermometer, the five action items described below are required as indicated by the application table, Table 15.
- A.2.7.2.1. If a liquid medium is used, it shall be stirred vigorously and a comparison block shall be located in the bath to aid in improving the uniformity.
- A.2.7.2.2. If a liquid medium is used, it shall be adequately stirred and a comparison block shall be located in the bath to aid in improving the uniformity.
- A.2.7.2.3. If the comparison medium is a liquid, it shall be adequately stirred.
- A.2.7.2.4. The uniformity of the comparison medium shall be measured by means of a fast-responding thermometer.

A.2.7.2.5. The temperature stability and uniformity of the comparison medium shall be as shown in Table 15.

Table 15. Comparison medium requirements for comparing thermometers

ltom Echelon						
Item	I	II	III	IV	V	
A.2.7.2.1.	Х	Х				
A.2.7.2.2.			X	Х		
A.2.7.2.3.					X	
A.2.7.2.4.			Х	Х		
A.2.7.2.5.	± 0.0005 °C	± 0.0005 °C*	(a)	(a)	(a)	

^{*}For claimed expanded uncertainty < \pm 0.01 °C. For claimed expanded uncertainty > \pm 0.01 °C, at least 10 times better than the claimed expanded uncertainty.

A.2.7.3. When the reference standard is a total-immersion mercury-in-glass thermometer, corrections obtained from measurements at the ice point shall be made for all temperature measurements.

A.2.7.4. The ice-point bath shall be made according to accepted procedures from ice made from distilled water. This applies to Echelons III, IV and V.

A.2.8. Handling of Calibration Items

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

A.2.9. OWM References and Calibration Procedures

A.2.9.1. Laboratories shall ensure that all legal requirements are met according to specifications, tolerances, conformity assessment, decision rules, and applicable procedures when calibrations are provided and used for legal metrology and commercial applications as specified in local regulations. The following shall be referenced in laboratory documents and on calibration certificates, when and where applicable.

NIST Handbook 44: Specifications, Tolerances, and Other Technical Requirements for Weighing and Measuring Devices - Current Edition⁵.

NIST Handbook 130: Uniform Laws and Regulations in the Areas of Legal Metrology and Fuel Quality - Current Edition^{6.}

NIST Handbook 133: Checking the Net Contents of Packaged Goods - Current Edition⁷.

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

⁵ https://www.nist.gov/pml/owm/publications/nist-handbooks

⁶ https://www.nist.gov/pml/owm/publications/nist-handbooks

⁷ https://www.nist.gov/pml/owm/publications/nist-handbooks

NIST Handbook 105-6: Specifications and Tolerances for Field Standard Thermometers, 19978.

A.3. Hydrometer Calibrations

A.3.1. Scope

This section outlines the specific technical requirements for a laboratory to be recognized as competent to carry out calibrations of hydrometers.

A.3.2. References

- 1. ASTM El 00-19: "Standard Specification for ASTM Hydrometers," 2019.
- 2. ASTM El26-19: "Standard Test Method for Inspection and Verification of ASTM Hydrometers," 2019
- 3. Burgess, G. K., "Standard Density and Volumetric Tables," NBS Circular 19, 6th ed., 1924.
- 4. Hughes, J.C., "Testing of Hydrometers," NBS Circular 555, 1954.

A.3.3. Assuring the Validity of Test and Calibration Results

- A.3.3.1. All sources of variability for the hydrometer calibration shall be appropriately measured and monitored. Check standards shall be used to ensure that the calibrations are carried out under controlled conditions. The laboratory shall maintain measurement assurance commensurate with the level of uncertainty needed for the calibration. The control parameters shall be based on measurements of check standards (or closure parameters) and the repeatability and reproducibility of multiple measurements over time. The frequency and number of process control checks should be appropriate for the level of uncertainty claimed for the calibration.
- A.3.3.2. The laboratory shall have control hydrometers that adequately span the range of hydrometer materials and sizes normally calibrated by the laboratory. Every measured value of each control shall be recorded and compared to its historic value to determine whether the process is in control. Measurement assurance values shall be plotted on a control chart that has upper and lower control limits and be analyzed on a periodic basis to review for the presence of trends, drifts, or shifts.

A.3.4. Accommodation and Environmental Conditions

A.3.4.1. The environmental conditions (i.e., temperature, atmospheric pressure, and relative humidity) in the hydrometer calibration area shall have no more than the maximum variations permitted, depending on the materials and the level of uncertainty needed for the calibration. The reference temperature for a particular hydrometer scale may vary

⁸ https://www.nist.gov/pml/owm/nist-handbook-105-series

- from 15.56 °C (15.56 °C is approximately 60 °F, which is the reference temperature for petroleum products in the U. S.) to 20 °C. The laboratory shall have the appropriate instrumentation required to measure the environmental conditions.
- A.3.4.2. The density of the water used in hydrometer calibrations shall be known to within 0.000 005 g/cm³. Specific gravity is expressed as the ratio of the density of a liquid to the density of water at a specified temperature.
- A.3.4.3. Vibration of equipment used in the hydrometer calibrations shall be reduced to non-influential levels. If an obvious source of vibration exists, it shall not adversely affect the laboratory's claimed uncertainty level.
- A.3.4.4. Any laboratory that makes hydrometer comparisons shall have an appropriate supply of calibration fluids with suitable surface tensions. Hydrometers shall be calibrated in the liquids in which they are to be used or in liquids with comparable density or specific gravity.
- A.3.4.5. Calibration liquids should be stored in an approved safety cabinet. Laboratories that make hydrometer comparisons should abide by all safety requirements set forth by a regulatory counsel (e.g., chemical labeling, EPA, and OSHA guidelines, etc.).

A.3.5. Equipment and Reference Materials

- A.3.5.1. The laboratory shall have the appropriate equipment required to perform hydrometer calibrations at the uncertainty level for which it is accredited. All equipment shall be properly maintained.
- A.3.5.2. The laboratory that performs hydrometer comparisons shall have master hydrometers for which the calibrations are directly traceable to the appropriate national standards laboratory. The appropriate calibration corrections to these master hydrometers shall be applied.
- A.3.5.3. The laboratory shall have the equipment needed to make auxiliary measurements of hydrometers (e.g., balances, mass standards, knowledge of water density, etc.).
- A.3.5.4. Any laboratory that makes hydrometer comparisons shall abide by all safety requirements set forth by a regulatory counsel (e.g., chemical labelling, EPA, and OSHA guidelines, etc.).
- A.3.5.5. The laboratory shall have temperature measuring capabilities suitable for the calibration procedure. In the case of measuring the specific gravity of a liquid with a master hydrometer, temperature measurement of the liquid accurate to \pm 0.01 °C is required.
- A.3.5.6. A laboratory that makes hydrometer comparisons shall have a ventilated chemical hood to exhaust any harmful fumes from the working area.

A.3.6. Test and Calibration Methods and Method Validation

A.3.6.1. The wide use of hydrometers for many different purposes has led to various stem scales for unique applications (e.g., specific gravity, percentage alcohol, degrees API,

degrees Baume and Brix). The appropriate stem scale shall be evaluated so that the appropriate calibration procedure can be selected and performed for the expected use of hydrometer.

- A.3.6.2. Hydrometers being calibrated are compared directly to master hydrometers in the kinds of liquids in which they are to be used. This comparison is performed in a clear, smooth glass cylinder of suitable size. The calibration liquid should be well stirred before each comparison to minimize temperature gradients in the liquid.
- A.3.6.3. The laboratory shall have a document detailing the procedures to be followed for each type of hydrometers being calibrated. This document shall contain all pertinent information needed for calibration to the level of uncertainty for which it is accredited.

A.3.7. Handling of Test and Calibration Items

- A.3.7.1. Hydrometers shall be cleaned and stored in a manner that prevents accidental contact with materials which could damage its surfaces. Since hydrometers are made of glass and can be easily broken, they shall be handled only by an experienced operator.
- A.3.7.2. Inspection shall be made of all hydrometers to be calibrated for bent stems, twisted scales, and loose material inside the body of the hydrometer.
- A.3.7.3. The hydrometer shall be wiped with alcohol and dried to assure a clean surface before it is immersed in the calibration liquid.

A.3.8. Reporting the Results

- A.3.8.1. As required by ISO/IEC 17025:2017, calibration certificates shall describe the hydrometer with sufficient detail to avoid any ambiguity.
- A.3.8.2. The uncertainty for the hydrometer shall be derived from a model of the measurement system that includes, as applicable, the uncertainties due to: master hydrometer, long term reproducibility of the measurement system, thermal expansion, and, other appropriate factors.
- A.3.8.3. A historical registry shall be kept for all control hydrometers.

Annex B. Dimensional Calibrations Technical Criteria

B.1. General

This annex contains specific technical requirements not covered in ISO/IEC 17025:2017 that are applicable to a laboratory recognized as competent to carry out dimensional calibrations.

B.2. Accommodation and Environmental Conditions

B.2.1. Thermal Conditions Affecting Artifacts

- a) Measurement results are generally reported as the length at 20 °C. If measurements are made at temperatures other than 20 °C, the uncertainties of the appropriate thermal corrections for the artifacts shall be included in the total uncertainty.
- b) For comparison measurements, the uncertainty component shall reflect the uncertainty in the thermal corrections of both the master and unknown artifacts, as well as the temperature difference between them, and the uncertainty of the temperature sensor used.
- c) All standards, supporting surfaces, and items submitted for calibration shall be equilibrated in a stable environment according to the applicable procedure.

B.2.2. Ambient Temperature Considerations

- a) The temperature stability of the environment shall be sufficient for the gage and measurement system to be in thermal equilibrium.
- b) If measurements are made in an environment with slowly changing temperature, a suitable measurement model, which includes the effects of the temperature drift, shall be used. Theoretical and experimental verification of the model should be available.
- c) Laboratories shall comply with the environmental requirements for calibrations as specified in the applicable procedures.
- B.2.2.1. For typical gages made of well-characterized materials (steel, carbide, or ceramic), \pm 10 % shall be used as the standard uncertainty of the thermal expansion coefficient unless there is documentation of a lower value.
- B.2.2.2. The laboratory shall have a documented policy regarding responses to environmental conditions outside of specified range.

B.3. Equipment

The laboratory shall have temperature-measuring capabilities suitable for the calibration procedure and the desired measurement uncertainty.

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NOTE: Calibrations involving direct comparisons of artifacts of similar size and materials will, in general, have modest requirements. Absolute calibrations or comparisons between artifacts of different sizes and/or materials will require more accurate temperature measurement or adjustment of the measurement uncertainty.

A laboratory that makes mechanical comparisons of reference standards and test pieces of dissimilar materials shall have force measuring equipment to determine the force on the probe or probes. A correction for differential probe penetration should be applied as long as the probe has maintained its desired geometry.

Annex C. Time and Frequency Calibration Technical Criteria

C.1. General

This annex contains specific technical requirements not covered in ISO/IEC 17025:2017 that are applicable to a laboratory recognized as competent to carry out time and frequency calibrations.

C.2. Measurement Traceability

C.2.1. Because a waveform is a set of ordered pairs (i.e., time, voltage), traceability of both the time and voltage shall be in place.

NOTE This is normally demonstrated by calibration of a high-speed oscilloscope or calibration of a fast-rise generator by an accredited external source.

- C.2.2. Laboratories that utilize a Global Positioning System Disciplined Oscillator (GPSDO) to establish traceability shall:
- a) have procedures in place to ensure the GPS is locked and working properly and
- b) consider the internal oscillator's short-term stability and measurement time in the laboratory's reported uncertainty.

C.3. Accommodation and Environmental Conditions

C.3.1. Thermal Conditions Affecting Artifacts

- a) For comparison measurements, the uncertainty component shall reflect the uncertainty in the thermal corrections of both the standard and unknown artifacts, as well as the temperature difference between them, and the uncertainty of the temperature sensor used.
- b) All standards, supporting surfaces, and items submitted for calibration shall be equilibrated in a stable environment prior to a calibration according to the applicable standard operating procedures. Typical equilibration time is generally not less than 2 hours.

C.3.2. Ambient Temperature Considerations

- a) The temperature stability of the environment shall be sufficient for the standards and measurement system to be in thermal equilibrium.
- b) Laboratories shall comply with the environmental requirements specified in applicable procedures.

Annex D. Mechanical Calibrations Technical Criteria

D.1. Force Calibrations

D.1.1. General

The purpose of this section is to specify the technical criteria that shall be met when performing calibrations of force-measuring instruments.

D.1.2. Procedural Standard Methods

All measurement procedures, accommodation and environmental conditions, instruments and equipment used, and the reporting of results when conducting a force-related calibration, shall comply with one or both of the following documentary standards, except in special circumstances (see below):

- ASTM E74, "Standard Practices of Calibration and Verification of Force-Measuring Instruments"
- ISO 376, "Metallic materials Calibration of force-proving instruments used for the verification of uniaxial testing machines"

Special circumstances: Laboratories may be accredited to other documentary standards methods or laboratory-developed methods once they have been assessed for them.

NOTE: Weights and measures (legal metrology) laboratories may be recognized to other documentary standard methods or laboratory developed methods. Standards calibrated with ASTM E74 or ISO 376 may be used in subsequent comparison calibration methods where suitability for legal metrology has been determined.

D.1.3. Accommodation and Environmental Conditions

- D.1.3.1. All instruments shall be allowed sufficient time to reach room temperature prior to calibration.
- D.1.3.2. The recommended calibration temperature is 23 °C (73.4 °F), however, calibrations shall be conducted within the temperature ranges specified by the procedural method used.
- D.1.3.3. During calibration, the temperature shall be monitored at a location that reflects the temperature of the instrument.
- D.1.3.4. Temperature stability shall be maintained in accordance with the procedural method used.
- D.1.3.5. If the temperature variations exceed \pm 0.2 °C during the calibrations of non-temperature compensated instruments such as proving rings, the calibration data shall be corrected in accordance with the applicable force calibration standard.

D.1.4. Equipment

D.1.4.1. Primary Force Standards (ASTM E74)

- D.1.4.1.1. A laboratory that performs primary force standards calibrations shall directly apply a deadweight force without intervening mechanisms such as levers, hydraulic multipliers, or the like, whose mass has been determined by comparison with mass reference standards traceable to the International System of Units (SI).
- D.1.4.1.2. Primary force standard deadweight machines shall not have any mechanism for amplifying the force such as levers, hydraulic multipliers or the like, or any mechanism that counterbalances the frame (or tare).
- D.1.4.1.3. Weights used as primary standards in deadweight machines shall be made of rolled, forged, or cast metal.
- D.1.4.1.4. The surface roughness of the weights shall meet the requirements of the applicable force calibration standard.
- D.1.4.1.5. If the weights are plated or coated, the finish shall be of a proven design and of a material such as cadmium or nickel-chromium.
- D.1.4.1.6. The forces developed by the weights shall be determined using formula 1,

$$F = mg[1 - (\rho_a/\rho_w)], \tag{1}$$

where

F = force(N),

m = mass (kg),

q = local acceleration due to gravity (m/s²),

 ρ_a = density of air, and

 $\rho_{\rm w}$ = density of the weight (same units as $\rho_{\rm a}$).

- D.1.4.1.7. This requires that the laboratory shall have knowledge of the local gravity, its uncertainty, and the local air buoyancy correction and its uncertainty.
- D.1.4.1.8. The masses of the weights shall be known to within 0.005 % of their nominal values by comparison to reference standards traceable to the International System of Units (SI). The local value of the acceleration due to gravity, calculated within 0.0001 m/s 2 (10 mGal), may be obtained from the National Geodetic Information Center, National Oceanic and Atmospheric Administration.
- D.1.4.1.9. The laboratory shall keep records of the calibration of all weights used as standards.
- D.1.4.1.10. The uncertainty of the vertical component of force applied by the weights shall also be stated in the laboratory records and in reports of calibration.
- D.1.4.1.11. The masses of the weights shall be determined initially and the determination repeated if damage or disassembly of the machine occurs.

D.1.4.1.12. Verification of force realization shall be demonstrated through an intercomparison program as outlined by the laboratory's quality system.

D.1.4.2. Secondary Force Standards (ASTM E74)

- D.1.4.2.1. Secondary force standards shall have been calibrated against primary force standards, with the exception that secondary force standards having capacities exceeding 1 000 000 lbf (4.448 MN) may be calibrated against a combination of several lower-capacity secondary force standards loaded in parallel.
- D.1.4.2.2. If several secondary force standards are combined and loaded in parallel to meet special needs for high capacities exceeding 1 000 000 lbf (4.448 MN), the following conditions shall be met:
- a) those secondary force standards shall have equal compliance, and
- b) forces shall be applied equally to each of those secondary force standards.
- D.1.4.2.3. Secondary force standards used shall have a suitable force calibration frame or mechanism to ensure an axial force application to the unit under test. The secondary system should exhibit no parasitic, frictional or mechanical losses during use.
- D.1.4.2.4. Any perturbations shall have been characterized.

D.1.4.3. Uncertainty of the Applied Forces

The uncertainty of the applied forces generated shall be determined using appropriate methods, such as recommended in ASTM E74 and ISO 376.

D.1.4.4. Overloaded or Repaired Instruments

- D.1.4.4.1. Any force standard or multiplying system that is repaired or modified in a way that may result in changes in the calibration curve shall be recalibrated prior to use.
- D.1.4.4.2. Any instrument that sustains an overload that produces a change in the zero-force output of 1 % or more shall be recalibrated prior to use.

D.1.4.5. Accessory Hardware

All calibration hardware that is subject to calibration forces such as coupling nuts, pull-rods, adapters, etc., shall be clearly labelled with the maximum allowable force they can sustain.

D.1.4.6. Electrical Instruments

The electrical instrumentation used to calibrate force-measuring instrumentation shall comply with the requirements specified by the procedural method used.

D.1.5. Calibration

D.1.5.1. Distribution and Number of Calibration Forces

The calibration forces shall be distributed over the full range of the force-measuring instrument as specified by the procedural method used. Note that the requirements of ASTM E74 and ISO 376 differ.

D.1.5.2. Randomization of Force Application Conditions

Randomization of force application conditions is of primary importance. The instrument undergoing calibration shall be rotated in the calibration machine and subjected to other randomizations in accordance with the procedural method used.

D.1.6. Records

All measurements shall be appropriately recorded and maintained in accordance with the procedural method used where those requirements exceed those of ISO/IEC 17025.

D.1.7. Reporting the Results

- D.1.7.1. In addition to the report requirements of ISO/IEC 17025, the laboratory shall provide calibration reports that conform to the requirements of ASTM E74, ISO, 376 or both.
- D.1.7.2. The calibration report shall state which documentary standard(s) was (were) followed.
- D.1.7.3. In cases where other procedural standards are followed, the calibration report shall, at a minimum, contain the following information:
- a) manufacturer and serial number of the instrument calibrated;
- b) type of reference standard used (i.e., primary standard, secondary standard), including the uncertainty in the applied force;
- c) if critical to transducer performance, identification of the force application fittings used;
- d) temperature at which the calibration was performed, including limits of temperatures variations during the calibrations;
- e) listing of the calibration forces applied and deflections observed;
- the calibration curve, including the method of analysis used to obtain the curve, and the deviations of the experimental data for the fitted curve; and
- g) the uncertainty associated with the calibration results and limits of assigned force ranges if such limits are required.

D.2. Mass Calibrations

D.2.1. General

The purpose of this annex is to specify the criteria needed to assess the competence of a calibration laboratory that performs mass calibrations according to the following Echelons associated with applicable calibration methods and classes of mass standards. When weight classes are not specified by the laboratory or customers, reported uncertainties associated with the nominal mass shall be used to select applicable Echelons for evaluating mass calibration requirements.

Table 16. Echelon Calibration and Measurement Capabilities requirements for Mass Calibrations

Echelon	Methods Specified by Documentary Standards	Applicable Weight Classes Corresponding to Methods (Instrument Type)
	Weighing designs consisting of redundant comparisons with known standards (replicate weighings) with built in buoyancy corrections and statistical process controls for evaluating the standards and measurement process.	
I	Example procedures or equivalents: OIML R111, Annex B; NISTIR 56729, SOP 28 (for calibrated standards used in other mass calibrations) NISTIR 5672, SOP 5 (calibrated standards used for balance calibrations) NBS Technical Notes 952, 844 ¹⁰	OIML R 111: Classes E ₁ , E ₂ ASTM E617: Classes 000, 00, 0, 1
П	Documented comparison (substitution) calibrations with known standards incorporating methods to minimize balance drift, provide buoyancy corrections, and incorporate suitable measurement assurance practices. Example procedures, equivalent or better: OIML R111, Annex B; NISTIR 5672, SOP 5 or NISTIR 6969 ¹¹ , SOP 4	OIML R 111: Classes F ₁ , F ₂ ASTM E617: Classes 2, 3
III	Documented comparison (substitution) calibrations with known standards and incorporated methods for suitable measurement assurance practices. Buoyancy	OIML R 111: Classes M ₁ , M ₁₋₂ , M ₂ , M ₂₋₃ , M ₃ ASTM E617: Classes 4, 5, 6, 7 NIST HB 105-1, Class F (1990)

⁹ NISTIR 5672, "Advanced Mass Calibrations and Measurements Assurance Program for the State Calibration Laboratories," 2019.

¹⁰ "Designs for the Calibration of Small Groups of Standards in the Presence of Drift," NBS Technical Note 844, 1974. "Designs for the Calibration of Standards of Mass," NBS Technical Note 952 1977.

¹¹ NISTIR 6969, "Selected Laboratory and Measurement Practices, and Procedures to Support Basic Mass Calibrations," 2019.

corrections shall be evaluated for significance and incorporated as corrections or as uncertainty components.	
Example procedures, equivalent or better: OIML R111, Annex B; NISTIR 6969, SOP 8	

D.2.2. Accommodation and Environmental Conditions

- D.2.2.1. To be deemed capable of making adequate measurements, calibration laboratories shall provide an environment with adequate environmental controls appropriate for the level of measurements to be made, according to weight classes specified in applicable documentary standards. Laboratory procedures shall specify environmental limitations equal to or better than specified in applicable documentary standards.
- D.2.2.2. The environmental conditions shall be within the specifications of the weighing instruments where applicable.
- D.2.2.3. Instruments measuring environmental conditions shall be used in close proximity to the balance being used. During calibration, the temperature shall be monitored at a location that reflects the temperature of the instrument. For Echelon I, temperature shall be measured inside the weighing chamber when there is a difference between the air temperature in the balance chamber and the surrounding area to ensure compliance with applicable documentary standard and procedure limitations.
- D.2.2.4. The laboratory shall maintain limited access to the calibration area and minimize contamination (maintain a clean surface) for locations where mass standards are being calibrated.
- D.2.2.5. Vibration shall not diminish the performance of precision analytical balances and mass comparators.
- D.2.2.6. Undesirable effects due to static electricity shall be controlled, if needed, with methods such as humidity, anti-static, deionizing radiation devices, the grounding of balances or operators, or with the use of special conductive flooring, and selection of proper clothing for staff.
- D.2.2.7. Laboratories shall evaluate the level of significance for buoyancy corrections for all mass calibrations. For Echelon I and Echelon II, buoyancy corrections shall be made. For Echelon III, if optional buoyancy corrections are not made, an appropriate uncertainty component shall be included in the expanded uncertainty.

D.2.3. Procedures and Method Validation

D.2.3.1. The procedures and formula chosen for the mass measurement, the reference standard(s) to be used, and the equipment to be used for a calibration shall provide acceptable levels of uncertainty for that calibration according to applicable documentary standards.

D.2.3.2. A documented procedure, compliant with the requirements of documentary standards for mass, shall be available in the laboratory to determine the correct algorithm, measurement assurance, and uncertainty budgets to be used for the specific calibration.

D.2.4. Equipment

- D.2.4.1. Due to comparison (substitution) methods and calculations used in mass calibration, the uncertainty of measurement results from auxiliary instruments for Echelons I and II, (e.g., scale, analytical balance, mass comparator) is less important than the precision of the measurement process. However, if such equipment used for comparison are repaired or serviced:
- a) they shall be reevaluated to ascertain the current level of precision prior to use, and
- b) the uncertainty estimate shall reflect the post-repair performance.
- D.2.4.2. The precision of the scale, analytical balance, or mass comparator, as determined through appropriate process control charts, shall be suitable to the echelon class for which it is used.
- D.2.4.3. For an application where external standards are used for comparison, appropriate control charts shall be maintained to evaluate the process standard deviation.

D.2.4.4. Balances

- D.2.4.4.1. Balances used as a direct comparison to the mass unit shall be calibrated prior to use. Direct comparisons of weights to calibrated balances are not permissible for Echelon I and II weight classifications due to procedure requirements in applicable documentary standards.
- D.2.4.4.2. For an application requiring balance accuracy, the laboratory shall choose appropriate and correct calibration procedures and calculations.
- D.2.4.4.3. Balances used as dividers and multipliers of the mass unit shall be capable of providing the appropriate uncertainty and linearity requirements of the classes of weights for which they are used.
- D.2.4.4.4. Calibration of built-in standards if/when used for direct comparison shall be performed periodically and shall be verified prior to use. History from measurement control programs (surveillance analysis) may be used to determine calibration intervals.

D.2.4.5. Environmental Sensors

D.2.4.5.1. Measurement results data from instruments used to monitor environmental conditions and to perform buoyancy corrections in the laboratory shall be traceable to the International System of Units (SI) through a suitable National Metrology Institute laboratory (directly or by way of an accredited laboratory).

- D.2.4.5.2. These instruments shall be recalibrated periodically unless intrinsic (defining) standards are employed. Calibration correction values for environmental sensors used for determining air density shall be evaluated and used for Echelon I and II calibrations unless the calibration errors of those instruments are less than their calibration uncertainties. Accuracy requirements for sensors shall follow the applicable calibration method.
- D.2.4.5.3. Calibration and intercomparison periods shall be documented by the laboratory.
- D.2.4.5.4. For intrinsic standards, data from intercomparison with standards of known measurement values shall be available.
- D.2.4.5.5. Means shall be provided to measure barometric air pressure, air temperature, and relative humidity of the laboratory environment adequate to the method used.
- D.2.4.5.6. Documentation of the uncertainty and traceability of these environmental measurement results shall be maintained.

D.2.5. Standards

- D.2.5.1. Suitable reference standards shall be available at each echelon and range for which the laboratory is accredited. Echelon I mass calibrations require the use of single-piece, highly polished mass standards to enable density testing and with demonstrated stability to comply with applicable documentary standards.
- D.2.5.2. Sufficient historical data, uncertainty analysis, and demonstrated stability shall be available to support the standards used at each level of a traceability hierarchy.
- D.2.5.3. Suitable calibration intervals shall be documented and ensured.
- D.2.5.4. For Echelon I, the laboratory shall state the presence of a possible systematic error in the combined uncertainty associated with the use of an assumed or reported density in the primary or reference standards (additional type B component) or the laboratory shall have appropriate means to measure the density of mass standards.
- D.2.5.5. Each mass standard used as a reference standard by the laboratory shall be calibrated by a National Metrology Institute or by an accredited laboratory with capability adequate to sustain the uncertainty required and maintain traceability to International System of Units (SI).
- D.2.5.6. The laboratory shall provide evidence, such as periodic surveillance, that the mass standards are, in principle, stable and acceptable for providing calibration services at each echelon for which they are used.

D.2.6. Handling of Calibration Items

- D.2.6.1. The laboratory shall have documented procedures to ensure adequate chain-of-custody of calibration items if required by law.
- D.2.6.2. The laboratory shall document appropriate procedures to ensure that cleaning or adjustments of Echelon I and Echelon II reference standards is approved by the customer prior

to calibration, ensures the integrity of the standards, and provides for thermal and other environmental conditioning, as required by the calibration method.

- D.2.6.3. The laboratory shall allow adequate stabilization time for mass standards to ensure environmental and thermal stability prior to calibration. Documentary standards and procedures in this Annex, <u>Table 16</u>, identify stabilization requirements for each Echelon and class of mass standards.
- D.2.6.4. Documented procedures to ensure adequate tracking of calibration items shall be appropriate to the class of mass standard. Strings, tags, or labels fastened to the standard are inappropriate for all types of mass standards.

D.2.7. Assuring the Validity of Calibration Results

- D.2.7.1. Appropriate measurement control programs shall be in place and available for review for each echelon and nominal mass range for which calibration data is provided. Appropriate data including balance standard deviations that represent measurement process variation using well-characterized check standard values.
- D.2.7.2. Measurement control techniques shall exhibit results consistent with the procedures used to perform calibrations and be integrated into the measurement procedures to accurately reflect the measurement process. Documentary standards listed in this Annex and calibration procedures referenced in section D.2.1 incorporate suitable measurement assurance methods and reference additional documented measurement assurance procedures and statistical analysis methods that shall be followed.
- D.2.7.3. For those situations in which statistical information is not inherent to the process, i.e., simple measurements without built-in redundancy checks:
- a) replicate measurements shall be made to provide experimental characterization of the measurement sufficient for an adequate estimation of the process uncertainty and
- b) those data shall be available for review.

D.2.8. Reporting the Results

- D.2.8.1. Calibration reports shall describe the mass standards mentioned in the report with sufficient detail to avoid any ambiguity.
- D.2.8.2. In addition to the general report requirements of ISO/IEC 17025, for Echelon I and II calibrations, additional items to be included on a calibration report, shall comply with reporting requirements of the applicable documentary standard.
- D.2.8.3. Environmental parameters measured during the calibration shall be provided on calibration reports when the customer is using the weights as Echelon I or Echelon II laboratory standards or when the customer requires the specific environmental conditions. Otherwise, ranges can be reported for the environmental conditions. These parameters include: laboratory temperature, barometric pressure, and relative humidity.

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- D.2.8.4. Information regarding cleaning methods, where applicable, shall be provided on the calibration reports.
- D.2.8.5. Calibration reports may include reference to OIML or ASTM classification schemes and maximum permissible errors (tolerances). It is the responsibility of the requestor of the calibration, not the laboratory, to select classifications acceptable for their needs. Regulatory requirements may dictate classifications requirements for legal metrology applications. If conformity is being assessed:
- items being calibrated shall meet appropriate specifications for evaluation as well as maximum permissible errors (tolerances) or shall state which items are or are not evaluated and
- b) in instances where magnetism, surface finish, density, or other requirements of the specifications are not evaluated for Echelon I and II, a statement to that effect shall be included on the calibration report.
- D.2.8.6. The external surface of a mass standard should be free of any sign of abuse or damage. Signs of abuse or misuse include the placement of labels, tags, wires or other material on mass standards. In addition, visible dirt and fingerprints are a sign of misuse for Echelons I and II. It is recommended that the calibration laboratory establish appropriate means for notifying customers regarding any unusual factors, such as signs of abuse regarding the mass standard being calibrated. Any of these indicators of abuse or damage shall be described in the calibration report.
- D.2.8.7. Any out-of-tolerance conditions of the mass standard measurement results identified through the calibration process shall be noted on the calibration report as part of the conformity assessment process.

D.3. Volume Calibrations

D.3.1. General

The purpose of this section is to provide the specific technical requirements to assess the competence of a calibration laboratory that performs volume calibrations. Volumetric measurements are obtained from mass measurements of known-density materials. Volume calibrations are classified by Echelons as determined by either a gravimetric (weighing procedure) or a volume transfer (comparative) procedure. The two types of procedures have different technical requirements, and both are defined here. Note that the type of calibration procedure and design of the instrument being calibrated affects the achievable uncertainty.

Table 17. Echelon Calibration and Measurement Capabilities requirements for Volume Calibrations

Echelon	Method	Typical Type of Instruments and Standards
I	Procedure must include use of calibrated mass standards, balance and environmental sensors with suitable resolution, and verified water quality per section D.3.4. Equilibration and stabilization of standards and water shall be ensured. Water density is calculated using CIPM-adopted ¹² equations or measured using suitable standard reference materials. Air density is calculated using CIPM-adopted ¹³ equations. Examples: ASTM E542 (latest version), NISTIR 7383 (2019), SOP 14, SOP 26, ISO 4787, ISO 8655	Laboratory Ware (glassware, plastic ware like pipettes, flasks, burets) Graduated neck-type provers and test measures Slicker-plate type laboratory standards
II	Procedure must include calibrated volumetric standard(s), environmental sensors with suitable calibration and resolution, and verified water quality per section D.3.4. Equilibration and stabilization of standards and water shall be ensured. Water density calculated using CIPM-adopted equations or measured using suitable standard reference materials. Examples: NISTIR 7383 (2019), SOP 19, EURAMET Calibration Guide No. 21, Version 2.0 (2020), American Petroleum Institute (API) procedures	Graduated neck-type provers and test measures

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¹² M. Tanaka, G. Girard, R. Davis, A. Peuto, and N. Bignell, "Recommended table for the density of water between 0 °C and 40 °C based on recent experimental reports", Metrologia, 38, 2001, 301-309. Also adopted and available in NISTIR 7383, Good Laboratory Procedure 10, 2019.
¹³ Picard, A., Davis, R. S., Glaser, M., and Fujii, K., "Revised formula for the density of moist air (CIPM-2007)," Metrologia, Vol 45, 2008, pp. 149—155. Also adopted and available in NISTIR 6969, Standard Operating Procedure 2, 2019.

D.3.2. Accommodations and Environmental Conditions

- D.3.2.1. Vibration, air currents, rapid temperature fluctuations, and other environmental variations shall be kept to levels such that they do not diminish the validity of the measurement whether by volume transfer methods or the performance of precision balances or scales when gravimetric methods are used. Gravimetric methods typically require environmental limits comparable to mass calibrations due to the use of precision balances or other weighing instruments. Environmental limits shall be specified in applicable laboratory procedures and shall be suitable for achieving the stated uncertainties and operating characteristics of the instruments used.
- D.3.2.2. Relative humidity shall be monitored more closely when evaporation or condensation may be a concern.

D.3.3. Calibration Methods and Method Validation

- D.3.3.1. The algorithm chosen for the measurement, the reference standard to be used, and the equipment to be used for a calibration shall be correct for that calibration.
- D.3.3.2. A documented procedure shall be available in the laboratory as specified in Table 17.

D.3.4. Equipment, Standards and Reference Materials

D.3.4.1. Gravimetric Standards and Equipment

- D.3.4.1.1. Mass standards used as reference standards shall be traceable to the SI through calibrations by a suitable National Metrology Institute (such as NIST) and be available at each class and range for which the laboratory is accredited.
- D.3.4.1.2. When water is used as the medium for gravimetric methods, it shall be deionized or distilled, and meet the water quality requirements of appropriate procedures with outside verification performed as needed. Extreme care shall be used to measure water temperatures. The accuracy of water density calculations is severely degraded by inaccurate water temperature measurements and the presence of thermal gradients.
- D.3.4.1.3. For gravimetric procedures the density shall be calculated/measured to 0.000 001 $\rm g/cm^3$
- D.3.4.1.4. The quality of water used as a calibration medium shall be of adequate purity (potable) and cleanliness and free from excess air entrapment.
- D.3.4.1.5. Gravimetric methods shall be performed using weighing equipment with adequate accuracy and precision for the uncertainty of the measurement procedure.
- D.3.4.1.6. Appropriate control charts shall be maintained to verify the volume measurement process.
- D.3.4.1.7. Mass calibration variability shall not be used to estimate variability for gravimetric volume calibrations.

D.3.4.1.8. Gravimetric methods require the means to adequately measure barometric air pressure, air temperature, water temperature, and relative humidity of the laboratory environment to perform proper buoyancy corrections and calculate or look up accurate water density. Environmental measuring equipment shall be appropriate to support the volume calibration method used.

D.3.4.2. Volumetric Standards

- D.3.4.2.1. Volume standards used as reference standards in the laboratory shall be traceable to the SI through standards maintained by a suitable National Metrology Institute (such as NIST).
- D.3.4.2.2. The laboratory shall have appropriate programs and procedures in place for verification and recalibration of its volume standards.
- D.3.4.2.3. Volumetric methods require accurate temperature measurements. Environmental measuring equipment shall be appropriate to support the volume calibration method used.
- D.3.4.2.4. Extreme care shall be used to measure water temperatures. The accuracy of water density calculations is severely degraded by inaccurate water temperature measurements and the presence of thermal gradients.

D.3.5. Handling of Calibration Items

- D.3.5.1. The volume standard being calibrated shall be free of any sign of abuse or damage, such as dents, chips, improper draining due to lack of cleanliness, and dirty sight gages.
- D.3.5.2. The laboratory shall have documented procedures to ensure adequate chain-of-custody of calibration items if required by law.
- D.3.5.3. Procedures shall be documented to ensure adequate tracking appropriate of glass or metal volumetric standards.

D.3.6. Assuring the Validity of Calibration Results

- D.3.6.1. Measurement control programs shall be in place and available for review for each measurement type (based upon procedures) and nominal volume range for which calibration data is provided. Suitable check standards should be available when possible. Procedure examples listed in <u>Table 17</u> provide measurement assurance methods suitable for volume calibrations.
- D.3.6.2. Measurement control techniques shall be implemented, with the resulting data available for review.
- D.3.6.3. Volume calibrations require replicate measurements to evaluate the measurement results and repeatability of the measurement process. Repeatability data may also be used to ensure suitable operating characteristics of the standards being calibrated. For those situations in which statistical information is not inherent to the process, i.e., simple measurements without built-in redundancy checks using check standards, additional measurements shall be made to provide experimental characterization of the measurement that is sufficient for an adequate estimation of the measurement uncertainty.

D.3.7. Reporting the Results

- D.3.7.1. As required by ISO/IEC 17025, calibration reports shall describe the volume standards with sufficient detail to avoid any ambiguity. In addition to those items required by ISO/IEC 17025, calibration reports shall contain all items specified in applicable documentary standards and laboratory procedures.
- D.3.7.2. Environmental parameters measured during the calibration shall be provided on the calibration report as appropriate. These measurements include laboratory air temperature, volume standard temperature, temperature of the medium, barometric pressure, and relative humidity.
- D.3.7.3. Conformity assessment to a classification scheme is often required for customers using volume standards. If a statement of conformity is being made:
- a) the volume standards being calibrated shall meet the appropriate classifications such as NIST, ASTM, API, or OIML;
- b) the calibration reports shall clearly identify the classification scheme with revision date to which the conformity assessment was made;
- c) conformity statements shall clearly specify to which results they apply and which specifications and tolerances, or parts thereof, are met or not met; and
- d) out-of-tolerance conditions shall be reported.