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STATE WEIGHTS AND MEASURES LABORATORIES

Program Handbook

NIST
Handbook 143
2003

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- Information Access
- Convergent Information Systems
- Information Services and Computing
- Software Diagnostics and Conformance Testing
- Statistical Engineering

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

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Program Handbook

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Preface

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

Significant changes have been made to the program of Recognition for the States and to this Program Handbook since the first edition was published in 1985. The program has incorporated national and international standards; although WMD does not provide formal accreditation according to ISO Guide 58, and although the program is operated independently from the National Voluntary Laboratory Accreditation Program (NVLAP), the general and technical criteria used in both programs are nearly identical.

The following list shows key changes in this edition of the Handbook:

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

- Parts 2 and 3 are policy and procedure information specific to WMD operations and Recognition process; Figure 1 is a flow chart showing the Recognition process.

- Parts 4 and 5 substantially contain ISO/IEC 17025:1999 (previously these sections referenced ANSI/NCSL Z540-1-1994 (parts I and II) with NVLAP additions, WMD Notes, and minor editorial changes for clarity). WMD Notes added to parts 4 and 5 are additional policy or requirements that apply generally to all legal metrology laboratories without regard to Recognition level.

- Part 6 is taken from the NVLAP Calibration Laboratories Draft Technical Guide (1994 Draft, as incorporated in the 1996 and 1997 editions of this Handbook), but edited for this publication. WMD and the National Conference on Weights and Measures (NCWM) ISO 9000 Task Force prepared the mass and volume sections and reviewed them at a special NVLAP workshop in December 1992 (mass criteria only); at a NVLAP workshop in November 1993; at all six regional metrology meetings in 1993 and 1994; and at the 1994 NCWM meeting. Laboratories performing temperature measurements were given the opportunity to review the temperature section. Diane Lee (NIST) prepared the moisture section; it was reviewed at the Southeastern Measurement Assurance Program (SEMAP) regional metrology meeting in 1993. These sections have all been reviewed and updated for this 2003 edition.

- For the 1997 edition, NIST management made changes in the WMD State Laboratory Program. As a result, the 1997 Handbook was revised to delete references to accreditation. References to "accreditation" were replaced with references to "Recognition;" references to a "certificate of accreditation" were replaced with references to a "Certificate of Measurement Traceability;" and references to the WMD State Laboratory Program as an "accreditation program" were replaced with references to a "measurement assurance program."

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

Acknowledgments and History

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

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

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

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

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

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

1) the Department of Defense rescinded Mil-Std-45662A in favor of the Z540-1-1994 standard;
2) the NIST National Voluntary Laboratory Accreditation Program (NVLAP) adopted and referenced ANSI/NCSL Z540-1-1994;
3) the American Association for Laboratory Accreditation (A2LA), a private accrediting body, also adopted the standard; and
4) the NIST/WMD incorporated the standard into Parts 5 and 6 of the 1996 and 1997 editions of this Handbook. Additional requirements consistent with NVLAP requirements and with the needs of the legal metrology system were included.

In 1997, NIST management made the decision that NIST would operate only one formal accreditation program: the National Voluntary Laboratory Accreditation Program (NVLAP). Therefore, all references to accreditation by WMD were changed to Recognition and WMD ceased issuing Certificates of Accreditation. WMD monitors the level of State compliance to this Handbook and other laboratory quality standards to ensure that adequate accuracy, traceability, and uniformity are maintained in State weights and measures laboratories.

In 1999, ISO/IEC Guide 25 was revised and became the international standard ISO/IEC 17025. This 2003 edition of NIST Handbook 143 incorporates revisions to the procedures and general requirements of the NIST Weights and Measures Division (WMD) Measurement Assurance Program for State Laboratory Recognition. The WMD procedures were revised to ensure continued consistency with international standards and guidelines, specifically those currently found in ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories.*

The requirements in Sections 4 and 5 of this edition are nearly identical to those found in clauses 4 and 5 of ISO/IEC 17025:1999. They must be met in order for a laboratory to be Recognized as competent to carry out tests and/or calibrations. Major changes from the previous edition of the handbook include the following:

- In Section 4, *Management requirements*, there are additional or changed requirements in the areas of document control; requests, tenders, and contracts; purchasing; non-conforming work; corrective action; preventive action; and records. These additions and changes incorporate and/or are consistent with ISO 9001:1994 requirements. A new clause, *Service to the client*, prescribes cooperation with clients and provides guidance on such cooperation.

- In Section 5, *Technical requirements*, the requirements are described in greater detail, but most concepts are not "new" for accredited laboratories. There is continued reference to client needs and greater emphasis and/or more detailed requirements on method validation; estimation of measurement uncertainty/traceability for testing laboratories; and provision for inclusion of interpretations and opinions on test reports. A sampling plan will be required where methods or specifications do not specify sampling procedures.

This 2003 edition supersedes and replaces the 1997 edition of NIST Handbook 143.

Table of Contents

1. Program Summary

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

Recognition of State Legal Metrology Laboratories

This Handbook describes the procedures followed in evaluating State (and a few other jurisdictional) legal metrology laboratories for competence. To be Recognized, a laboratory must satisfy general and technical requirements for each measurement area in which recognition is desired (see Appendix B). This program is managed by the NIST/WMD.

The general requirements in sections 4 and 5 incorporate ISO/IEC 17025:1999 (as adopted by the NVLAP Calibration Laboratories Accreditation Program) and address internationally accepted quality practices and good management practices for calibration and testing laboratories. In addition to ISO/IEC 17025 and NVLAP requirements, sections 4 and 5 contain additional general requirements as "notes" that are specific for State legal metrology laboratories. (See Section 7. References.)

The technical criteria in Section 6 amplify general criteria (ISO/IEC 17025) for each specific measurement parameter to be used as needed. Technical requirements of the NIST/WMD recognition program are nearly identical to the NVLAP guidelines published in the draft of NIST/NVLAP Handbook 150-2, Calibration Laboratories Technical Guide; however, WMD does not operate a formal accreditation program. The technical requirements include demonstration that: 1) suitable test equipment, calibration standards, defined test procedures, and the general facilities necessary for good metrological services are available; and 2) that staff have a comprehensive understanding of calibration, measurement, and test requirements and are capable of applying them.

Under this voluntary recognition program, laboratories appraise their compliance with the requirements, completing appropriate checklists that are reviewed and evaluated by NIST/WMD.

Following review and evaluation, which includes an on-site assessment and proficiency testing, NIST/WMD may issue a Certificate of Measurement Traceability indicating recognized competence areas with defined parameters and scope of recognition; a letter describing the quality system in place in each laboratory is also provided. Recognition may be granted for a period up to 2 years, but on an annual basis each laboratory must review its status, complete an internal audit, including

management and quality system review, and submit the evaluation along with a statement that no adverse changes have taken place in order for the Recognition to remain in effect.

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

General

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

2. General Information and Operational Requirements

2.1 Purpose

The NIST Enabling Act (31 Stat. 1449, 15 USC 271, Chapter 6 Weights and Measures), as modified by "authorities and functions pursuant to the Omnibus Trade and Competitiveness Act of 1988," provides the legislative authority to Recognize qualifying State weights and measures (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 Handbook is the most effective means for ensuring accurate measurements consistent with national standards.

2.2 Description, Quality Policy, and Objectives

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

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

State Laboratory Program Quality Policy:

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

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

WMD objectives are to:

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

2. provide technical support for the accuracy and traceability of State legal metrology laboratories to the national standards through development, training, publication of, and use of standard procedures, protocols, and measurement assurance programs;
3. provide and maintain the Recognition program for State legal metrology laboratories as evidence of continuing measurement traceability to include auditing the use and care of the physical standards of mass, length, and volume; and
4. assist the States to upgrade and expand the measurement services of State legal metrology laboratories to satisfy the changing needs of their clients.

2.3 Scope of Recognition

2.3.1 Voluntary and non-contractual

The Recognition function for State legal metrology laboratories is a voluntary, non-regulated program of support to the States. It provides a cost-effective means for providing evidence of measurement accuracy and traceability. (See sections 2.9.8 and 2.9.9.)

2.3.2 Legal compliance requirements

Although there are currently no Federal requirements for Recognition, some States have weights and measures laws that require continued formal accreditation, certification, or other form of Recognition by NIST as evidence of maintaining measurement traceability for primary standards used in the enforcement of weights and measures laws.

2.3.3 Limitations

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

2.3.4 Liability

NIST Recognition does not certify individual measurements made by a State, but formally Recognizes that the State laboratory has traceable standards, the capability to perform reliable measurements, and that the metrologist has been trained in the proper procedures to provide these measurements. Recognition also indicates that the metrologist has submitted technical data, records, and documentation as specifically requested by NIST. NIST assumes no liability for the accuracy and traceability of individual measurement results provided by a Recognized laboratory.

2.4 Technical Support and Assistance

WMD offers consultative and technical support through informal and formal means to all State legal metrology laboratories regardless of their Recognition status. Informal assistance may be in the form of telephone, facsimile, e-mail, or mailed responses. Formal support and assistance are available

through the training program and the Regional Measurement Assurance Program (RMAP) of the State Laboratory Program. (See Appendix A for types of technical assistance available.)

2.5 Confidentiality

To the extent permitted by applicable laws, WMD will seek to ensure the confidentiality of all information obtained relating to the application, on-site assessment, evaluation, and Recognition of laboratories. *Exception: see section 2.9.9*

Results of proficiency tests are generally discussed openly at annual RMAP meetings in the spirit of continuous improvement and teamwork. Proficiency testing may be held confidential if any participating State laboratory requests confidentiality of the results by writing to WMD prior to the beginning of each interlaboratory comparison.

2.6 Development of Requirements

2.6.1 Use of national and international standards wherever available

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

2.6.2 Laboratory review, solicitation of comment by those affected

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

2.7 Documentation

General and technical requirements for Recognition and additional documents and records to support the program for State laboratories are maintained and published by the NIST/WMD.

Other publications that include the general and technical requirements for State laboratory Recognition, are also available:

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

This document contains a general program description and laboratory directory. It is updated periodically and is available on the NIST Internet site.

b) NIST Handbook 145 Handbook for the Quality Assurance of Metrological Measurements

This Handbook contains laboratory procedures that are used in NIST/WMD Training Program and are recommended for use in State laboratories. Adequate data and evidence of measurement impact must be provided by the laboratory to justify deviating from documented procedures. This Handbook includes Good Laboratory Practices, Good Measurement Practices, and Standard Operating Procedures.

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

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

d) NISTIR 5802, Quality Manual Template

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

2.8 Records

Records related to Recognition or accuracy and traceability of measurements and standards for each State are maintained in the NIST/WMD. Procedures regarding record retention are maintained in the WMD. These documents include, but are not limited to, the following:

a) traceability records for primary standards;
b) measurement control/assurance data (control charts and surveillance tests) - latest year;
c) training;
d) quality manuals (latest version);
e) proficiency testing (round robin reports of the RMAPs);
f) internal audits (including management review); and
g) on-site assessment reports.

Letters verifying the status of a laboratory's Recognition level, traceability, and accompanying records will be provided to a State when Certificates of Measurement Traceability are issued, and may also be sent on behalf of the State to customers when formally requested in writing on official letterhead. Facsimile requests are not acceptable.

2.9 Rights, Duties, Responsibilities of the Recognized Laboratory

2.9.1 Display of Certificates of Measurement Traceability

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

2.9.2 Use of Recognition or traceability status on calibration reports

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

2.9.3 Reference to Recognition status

A laboratory may reference its Certificate of Measurement Traceability in promotional literature provided that it is consistent with NIST legal policy (15 CFR Ch. 11, 200.113) on the use of the NIST name (or NVLAP name and logo if applicable and according to NVLAP policies). This policy has been circulated to all State laboratories, and is available in the NIST/WMD as well as most local libraries. A general condition on the use of the NIST name is that it may not be used for endorsement purposes, but may be used to make factual statements regarding Recognition or traceability.

2.9.4 Notification of change

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

2.9.5 Provide timely submissions

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

2.9.6 Reciprocity with other WMD-Recognized laboratories

Recognized State laboratories may have reciprocity with other Recognized or accredited State laboratories as a part of the voluntary registration program for service agents. Reciprocal acceptance of calibration reports should be limited to laboratories that have maintained Recognition with WMD or formal accreditation. Calibration reports from laboratories that have failed to maintain Recognition or formal accreditation should be refused. Information on Recognition status will be made available to States through Special Publication 791, Laboratory Directory and through individual status requests.

2.9.7 Subcontracting

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

2.9.8 Failure to maintain Recognition

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

2.9.9 Notification of status

The NIST/WMD reserves the right to notify State and Federal agencies as well as any indigenous industry of a State regarding Recognition or accreditation status. This is generally accomplished through the periodic publication of a laboratory directory and may include periodic memoranda to affected parties.

2.9.10 Response to deficiencies and corrective action requests

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

3. Recognition Process

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

a) an annual solicitation by WMD;
b) technical review of submitted material (see list in Table 1);
c) review of on-site assessment results;
d) review of proficiency testing results; and
e) issuance of a Certificate of Measurement Traceability, along with a scope of Recognition, and a letter describing the laboratory quality system.

3.1 Request for Recognition and Fees

Each State legal metrology laboratory, plus those of Puerto Rico, the District of Columbia, the Virgin Islands, Los Angeles County, and the Grain Inspection and Packers and Stockyards Administration (GIPSA) Master Scale Depot, may automatically renew its Recognition; however, the annual Request for Recognition must detail the requested Scope of Recognition. An annual evaluation is conducted by WMD.

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

3.2 Annual Solicitation

Material for Recognition and issuance of Certificates of Measurement Traceability is annually solicited by NIST via a detailed memorandum between August 1 and September 15.

3.2.1 Annual submission period

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

3.2.2 Information to be submitted

The information to be submitted annually depends on the particular circumstances of a laboratory's Recognition and will be detailed in the solicitation memorandum. Requested information is always related to specific criteria as described in this Handbook.

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

3.3 On-site Assessments (Monitoring and Requested)

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

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

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

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

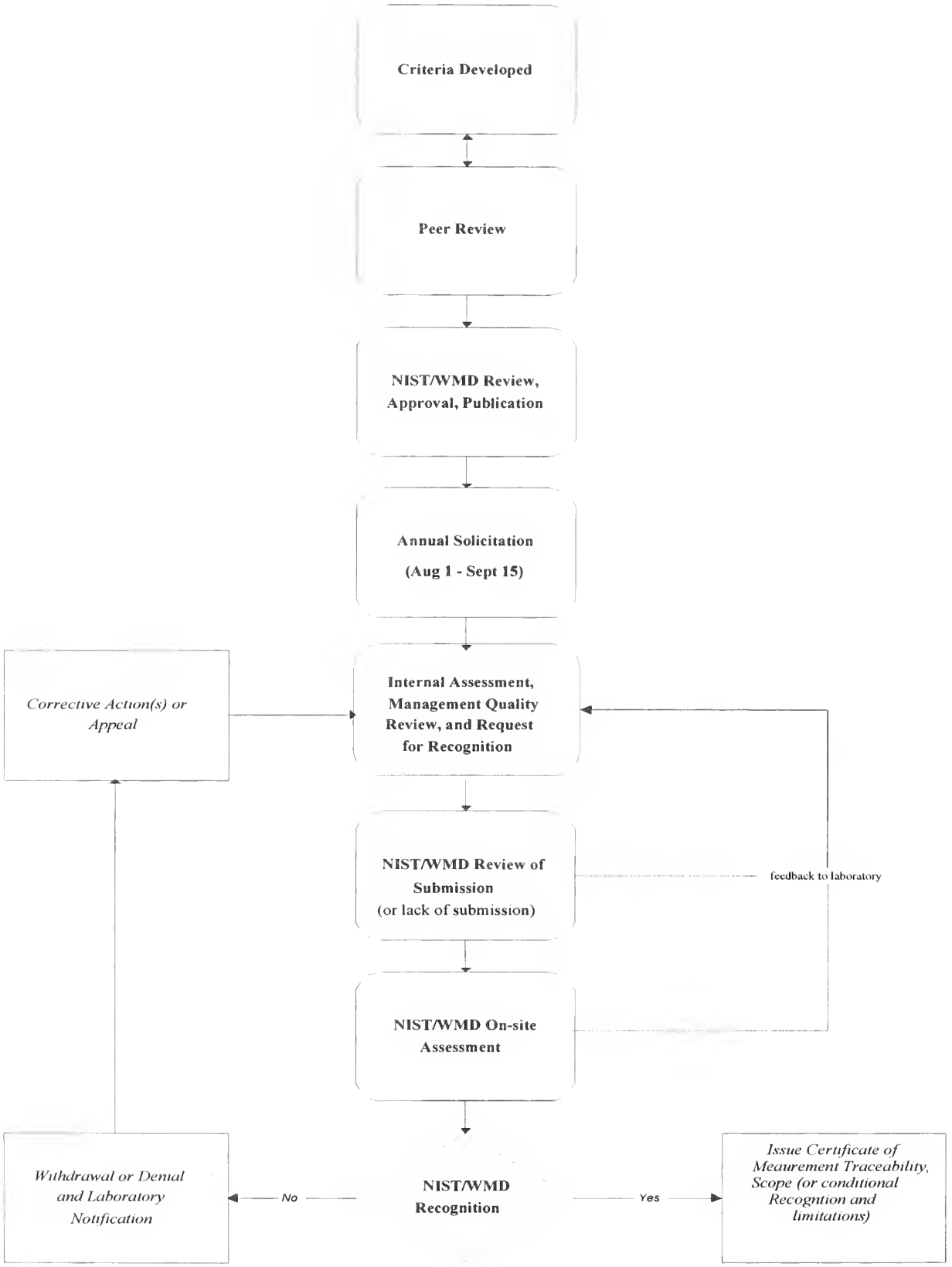

Figure 1. Recognition Process.

3.3.1 NIST staff

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

3.3.2 Technical experts

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

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

3.3.3 Assessment report and invitation to respond

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

3.3.4 Contents of assessment report

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

a) name and address of the laboratory;
b) date of the assessment;
c) criteria used to conduct the assessment;
d) parameters and scope of Recognition for the assessment:

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

k) Proficiency Testing

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

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

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

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

l) NIST Technical Evaluation

Technical evaluation is conducted prior to awarding a Certificate of Measurement Traceability, and includes a full review of all available technical information regarding the laboratory. This may include annual submissions, control charts, quality manuals, assigned training problems, on-site assessment reports, results of proficiency tests, training records, attendance and participation at

RMAPs, formal accreditation, plus any other relevant information affecting the quality of the laboratory's measurement results.

3.5.1 Review of submissions

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

3.5.1.1 New, renewal, or expansion

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

3.5.1.2 Maintenance

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

3.6 Accreditation Periods and Policy

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

Each laboratory will be given every opportunity to provide input to WMD for evaluation and to provide feedback to WMD assessments and evaluations. Any laboratory has the right to appeal Recognition decisions in writing to the NIST/WMD.

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

3.6.1 Full renewal - 2 year

For those laboratories fully meeting criteria in this Handbook, a 2-year Certificate of Measurement Traceability will be issued; however, additional data must continue to be submitted annually for review as requested. Any laboratory that cannot meet the criteria in this Handbook should not apply for NVLAP formal accreditation.

3.6.2 One-year renewal

For laboratories where WMD management and oversight are required, or when minor deficiencies exist, a 1-year Certificate of Measurement Traceability may be issued based on the judgement of WMD staff that acceptable measurements will continue to be provided to laboratory customers. NOTE: Until the new criteria in this Handbook are fully met (including documentation), a laboratory will not be issued a 2-year Certificate of Measurement Traceability.

3.6.3 Conditional renewal

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

3.6.4 Maintenance

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

3.6.5 Suspension, withdrawal, denial

In the event that circumstances change significantly during a Recognition cycle, it is the responsibility of the laboratory to notify WMD. 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 Measurement Traceability until criteria are met.

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

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

Table 1. Submission requirements for Recognition

Reference	Item Description	Annual Review & Submission	Changes or Renewal	Updated
Appendix B	Request for Recognition, Parameters and Scope, Approved Signatories, Authorized Representative	X	Change	
Appendix C	Quality Assessment Checklist and Management Review	X	Change; when requested	
Appendix D	Summary of Services	X	Renewal	X
Appendix E	Uncertainties Charts for all parameters	X		X
	Technical Assessment; Internal Audit Reports; Management Review Reports Note: no checklist is available	X		
	Laboratory Quality Manual and Administrative Procedures			X
	NIST calibration reports for standards			X
	Laboratory Auditing Program (LAP) problems assigned in Training Program			X (completed)
	Measurement control – control charts, surveillance tests	When requested; reviewed during on-site assessments		
	Special Technical Requests	When requested		

4. Management Requirements for Accreditation[1]

4.1 Organization

4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this Handbook and to satisfy the needs of the client, the regulatory authorities or organizations providing Recognition.

4.1.3 The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.

NOTE 1 Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this Handbook.

NOTE 2 If the laboratory wishes to be Recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.

4.1.5. The laboratory shall

a) have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

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1 Section 4 substantially references the text of ISO/IEC 17025:1999, with additional NVLAP notes, WMD notes, and minor editorial changes for clarity. Where "this Handbook" is used in Section 4 it refers to the criteria in ISO/IEC 17025 as applied to this Program Handbook unless otherwise stated. NIST/WMD does not Accredit laboratories; however, WMD assesses State laboratories that participate in the measurement traceability program for conformance to these requirements.

b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;
e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;
f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;
g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;
h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;
i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources; and
j) appoint deputies for key managerial personnel (see note).

NOTE Individuals may have more than one function and it may be impractical to appoint deputies for each function.

4.2 Quality System

4.2.1 The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities. The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2 The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:

a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its clients;

b) the management's statement of the laboratory's standard of service;
c) the objectives of the quality system;

d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and
e) the laboratory management's commitment to compliance with this Handbook.

NOTE The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and clients' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system.

4.2.4 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this Handbook, shall be defined in the quality manual.

WMD NOTE The list of items in this section is not a complete list of all items that must be included in a quality manual. In addition to the items in this section, the laboratory's quality manual must also address each of the requirements in Sections 4 and 5 of this Handbook. The NIST/WMD provides NISTIR 5802, Quality Manual Template for the State laboratories to use as a baseline that complies with the requirements of ISO/IEC Guide 25 and must be sufficiently modified to match specific program details and the requirements of Sections 4 and 5 of this Handbook. All modifications must be evaluated against these criteria. All updates must be submitted for review.

4.3 Document Control

4.3.1 General

The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

NOTE 1 In this context "documents" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc.. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

NOTE 2 The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.12.

4.3.2 Document approval and issue

4.3.2.1 All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The procedure(s) adopted shall ensure that:

a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;
b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;
c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.3 Quality system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

4.3.3 Document changes

4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

4.3.3.3 If the laboratory's documentation control system allows for the amendment of documents by hand pending the reissue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally reissued as soon as practicable.

4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

4.4 Review of Requests, Tenders and Contracts

4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);
b) the laboratory has the capability and resources to meet the requirements; and
c) the appropriate test and/or calibration method is selected and capable of meeting the clients' requirements (see 5.4.2).

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the client.

NOTE 1 The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal clients, reviews of requests, tenders and contracts can be performed in a simplified way.

NOTE 2 The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programs using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

NOTE 3 A contract may be any written or oral agreement to provide a client with testing and/or calibration services.

4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.

NOTE For review of routine and other simple tasks, the date and the identification (e.g., the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for ongoing routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

4.4.3 The review shall also cover any work that is subcontracted by the laboratory.

4.4.4 The client shall be informed of any deviation from the contract.

4.4.5 If a contract is to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

4.5 Subcontracting of Tests and Calibrations

4.5.1 When a laboratory subcontracts work whether due to unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this Handbook for the work in question.

4.5.2 The laboratory shall advise the client of the arrangement in writing and, when appropriate, gain the approval of the client, preferably in writing.

4.5.3 The laboratory is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used.

4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this Handbook for the work in question.

4.6 Purchasing Services and Supplies

4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

NOTE The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the quality system standard under which they were made.

4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.

4.7 Service to the Client

The laboratory shall afford clients or their representatives cooperation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other clients.

NOTE 1 Such cooperation may include:

a) providing the client or the client's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the client; and
b) preparation, packaging, and dispatch of test and/or calibration items needed by the client for verification purposes.

NOTE 2 Clients value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the client, especially in large assignments, should be maintained throughout the work. The laboratory should inform the client of any delays or major deviations in the performance of the tests and/or calibrations.

NOTE 3 Laboratories are encouraged to obtain other feedback, both positive and negative, from their clients (e.g., client surveys). The feedback should be used to improve the quality system, testing and calibration activities and client service.

4.8 Complaints

The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.10).

4.9 Control of Non-conforming Testing and/or Calibration Work

4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. The policy and procedures shall ensure that:

a) the responsibilities and authorities for the management of non-conforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when non-conforming work is identified;
b) an evaluation of the significance of the non-conforming work is made;
c) corrective actions are taken immediately, together with any decision about the acceptability of the non-conforming work;

d) where necessary, the client is notified and work is recalled; and
e) the responsibility for authorizing the resumption of work is defined.

NOTE Identification of non-conforming work or problems with the quality system or with testing and/or calibration activities can occur at various places within the quality system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

4.9.2 Where the evaluation indicates that the non-conforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.10 shall be promptly followed.

4.10 Corrective Action

4.10.1 General

The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when non-conforming work or departures from the policies and procedures in the quality system or technical operations have been identified.

NOTE A problem with the quality system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of non-conforming work, internal or external audits, management reviews, feedback from clients or staff observations.

4.10.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include client requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

4.10.3 Selection and implementation of corrective actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

The laboratory shall document and implement any required changes resulting from corrective action investigations.

4.10.4 Monitoring of corrective actions

The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

4.10.5 Additional audits

Where the identification of non-conformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this Handbook, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.13 as soon as possible.

NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

4.11 Preventive Action

4.11.1 Needed improvements and potential sources of non-conformances, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformances and to take advantage of the opportunities for improvement.

4.11.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

NOTE 1 Preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

NOTE 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency testing results.

4.12 Control of Records

4.12.1 General

4.12.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

4.12.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

NOTE Records may be in any media, such as hard copy or electronic media.

4.12.1.3 All records shall be held secure and in confidence.

4.12.1.4 The laboratory shall have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records.

4.12.2 Technical Records

4.12.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

NOTE 1 In certain fields it may be impossible or impracticable to retain records of all original observations.

NOTE 2 Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, clients' notes, papers and feedback.

4.12.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

4.12.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

4.13 Internal Audits

4.13.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this Handbook. The internal audit program shall address all elements of the quality system, including the testing and/or calibration activities. It is the

responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits will be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

NOTE The cycle for internal auditing should normally be completed in one year.

4.13.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify clients in writing if investigations show that the laboratory results may have been affected.

4.13.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

4.13.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

4.14 Management Reviews

4.14.1 In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

— the suitability of policies and procedures;
— reports from managerial and supervisory personnel;
— the outcome of recent internal audits (see 4.13);
— corrective and preventive actions;
— assessments by external bodies;
— the results of interlaboratory comparisons or proficiency tests;
— changes in the volume and type of the work;
— client feedback;
— complaints; and
— other relevant factors, such as quality control activities, resources and staff training.

NOTE 1 A typical period for conducting a management review is once every 12 months.

NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

4.14.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

5. Technical Requirements for Accreditation[2]

5.1 General

5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

— human factors (5.2);
— accommodation and environmental conditions (5.3);
— test and calibration methods and method validation (5.4);
— equipment (5.5);
— measurement traceability (5.6);
— sampling (5.7); and
— the handling of test and calibration items (5.8).

5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

5.2 Personnel

5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

NOTE 1 In some technical areas (e.g., nondestructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the client.

NOTE 2 The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:

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2 Section 5 substantially references the text of ISO/IEC 17025:1999, with additional NVLAP notes, WMD notes, and minor editorial changes for clarity. Where "this Handbook" is used in Section 4 it refers to the criteria in ISO/IEC 17025 as applied to this Program Handbook unless otherwise stated. NIST/WMD does not Accredit laboratories; however, WMD assesses State laboratories that participate in the measurement traceability program for conformance to these requirements.

— relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;
— knowledge of the general requirements expressed in the legislation and standards; and
— an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc., concerned.

5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.

5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.

5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

NOTE Job descriptions can be defined in many ways. As a minimum, the following should be defined:

— the responsibilities with respect to performing tests and/or calibrations;
— the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;
— the responsibilities for reporting opinions and interpretations;
— the responsibilities with respect to method modification and development and validation of new methods;
— expertise and experience required;
— qualifications and training programs; and
— managerial duties.

5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

WMD NOTE 1: This requirement also applies to Approved Signatories.

WMD NOTE 2: The NIST/WMD provides training to State legal metrology laboratories. State metrologists are required to complete the appropriate level of training as indicated in Table 2 , for the laboratory to be Recognized at designated levels. Information regarding the training program is maintained in the WMD.

5.3 Accommodation and Environmental Conditions

5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.

The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.

5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

5.4 Test and Calibration Methods and Method Validation

5.4.1 General

The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

The laboratory shall have instructions on the use and operation of all relevant equipment, and on the

handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3). Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the client.

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.

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

5.4.2 Selection of methods

The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.

When the client does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The client shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.

The laboratory shall inform the client when the method proposed by the client is considered to be inappropriate or out of date.

5.4.3 Laboratory-developed methods

The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.

Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

5.4.4 Non-standard methods

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.

NOTE For new test and/or calibration methods, procedures should be developed before tests and/or calibrations are performed and should contain at least the following information:

a) appropriate identification;
b) scope;
c) description of the type of item to be tested or calibrated;
d) parameters or quantities and ranges to be determined;
e) apparatus and equipment, including technical performance requirements;
f) reference standards and reference materials required;
g) environmental conditions required and any stabilization period needed;
h) description of the procedure, including:
   — affixing of identification marks, handling, transporting, storing and preparation of items,
   — checks to be made before the work is started,
   — checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,
   — the method of recording the observations and results, and
   — any safety measures to be observed;
i) criteria and/or requirements for approval/rejection;
j) data to be recorded and method of analysis and presentation; and
k) the uncertainty or the procedure for estimating uncertainty.

5.4.5 Validation of methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as

extensive as necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

NOTE 1 Validation may include procedures for sampling, handling and transportation.

NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

— calibration using reference standards or reference materials;
— comparison of results achieved with other methods;
— interlaboratory comparisons;
— systematic assessment of the factors influencing the result; and
— assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

NOTE 3 For changes in the validated non-standard methods, their influence should be documented and, if appropriate, another validation should be carried out.

5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the client needs.

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method development proceeds, regular review should be carried out to verify that the client needs are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

5.4.6 Estimation of uncertainty of measurement

5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

5.4.6.2 Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

— the requirements of the test method;
— the requirements of the client; and
— the existence of narrow limits on which decisions on conformance to a specification are based.

NOTE 2 In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

NOTE 2 The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

NOTE 3 For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see 1.4).

WMD NOTE ANSI/NCSL Z540-2-1997 and NIST Technical Note 1297, 1994 edition, are considered to be equivalent to the Guide to the Expression of Uncertainty in Measurement (GUM).

5.4.7 Control of data

5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;
b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing; and
c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

NOTE Commercial off-the-shelf software (e.g., word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2a).

5.5 Equipment

5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this Handbook are met.

5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).

5.5.3 Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:

a) the identity of the item of equipment and its software;
b) the manufacturer's name, type identification, and serial number or other unique identification;
c) checks that equipment complies with the specification (see 5.5.2);
d) the current location, where appropriate;

e) the manufacturer's instructions, if available, or reference to their location;
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
g) the maintenance plan, where appropriate, and maintenance carried out to date; and
h) any damage, malfunction, modification or repair to the equipment.

5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

NOTE Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.

5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of non-conforming work" procedure (see 4.9).

5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.

5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g., in computer software) are correctly updated.

5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

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

5.6 Measurement Traceability

5.6.1 General

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established program and procedure for the calibration of its equipment.

NOTE Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

5.6.2 Specific requirements

5.6.2.1 Calibration

5.6.2.1.1 For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*).

A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).

NOTE 1 Calibration laboratories fulfilling the requirements of this Handbook are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this Handbook, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

NOTE 2 Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

NOTE 3 Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

NOTE 4 The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

NOTE 5 When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfill the properties of primary standards for the realization of SI units.

NOTE 6 Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located.

NOTE 7 If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

NOTE 8 The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.

5.6.2.1.2 Some calibrations cannot currently be made strictly in SI units. In these cases, calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards, such as:

— the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material; and
— the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

Participation in a suitable program of interlaboratory comparisons is required whenever possible.

5.6.2.2 Testing

5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

NOTE The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the

dominant factor, the requirements should be strictly followed.

5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

The laboratory shall have a program and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

5.6.3.2 Reference materials

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

5.6.3.3 Intermediate checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules

5.6.3.4 Transport and storage

The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

NOTE Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.

WMD NOTE Copies of calibration reports for primary standards used in the laboratory are maintained in the NIST/WMD. The laboratory must submit updated calibration reports as available. If reports are not from NIST, they should be from a NIST-Recognized laboratory or a laboratory with formal accreditation from a recognized accreditation body.

5.7 Sampling

5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.

NOTE 1 Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample may not be representative but is determined by availability.

NOTE 2 Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.

5.7.2 Where the client requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.

5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

5.8 Handling of Test and Calibration Items

5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the client.

5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a subdivision of groups of items and the transfer of items within and from the laboratory.

5.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the discussion.

5.8.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

NOTE 1 Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

NOTE 2 A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples.

NOTE 3 Keeping a test or calibration item secure can be for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.

5.9 Assuring the Quality of Test and Calibration Results

The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of results. This monitoring shall be planned and reviewed and may include, but need not be limited to, the following:

a) regular use of certified reference materials and/or internal quality control using secondary reference materials;
b) participation in interlaboratory comparison or proficiency-testing programs;
c) replicate tests or calibrations using the same or different methods;
d) retesting or recalibration of retained items; and
e) correlation of results for different characteristics of an item.

NOTE The selected methods should be appropriate for the type and volume of the work undertaken.

WMD NOTE The laboratory shall maintain a list of control charts, surveillance activities, and round robins maintained or participated in by the laboratory. Measurement control requirements must be in

place for each measurement service provided by the laboratory. The quality manual template contains forms that may be used by the laboratory to list control charts, surveillance activities, and proficiency tests. This documentation must be available during on-site assessments and submitted to the NIST/WMD as requested.

5.10 Reporting the Results

5.10.1 General

The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

The results shall be reported, usually in a test report or a calibration certificate (see note 1), and shall include all the information requested by the client and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

In the case of tests or calibrations performed for internal clients, or in the case of a written agreement with the client, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the client shall be readily available in the laboratory which carried out the tests and/or calibrations.

NOTE 1 Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.

NOTE 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this Handbook are met.

5.10.2 Test reports and calibration certificates

Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

a) a title (e.g., "Test Report" or "Calibration Certificate");
b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;
c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;
d) the name and address of the client;
e) identification of the method used;

f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;
g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;
h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;
i) the test or calibration results with, where appropriate, the units of measurement;
j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate; and
k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

WMD NOTE WMD defines the person(s) who authorizes the test report or calibration certificate as the Approved Signatory.

NOTE 1 Hard copies of test reports and calibration certificates should also include the page number and total number of pages.

NOTE 2 It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

5.10.3 Test reports

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;
b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;
c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instruction so requires, or when the uncertainty affects compliance to a specification limit;
d) where appropriate and needed, opinions and interpretations (see 5.10.5); and
e) additional information which may be required by specific methods, clients or groups of clients.

5.10.3.2 In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

a) the date of sampling;

b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);
c) the location of sampling, including any diagrams, sketches or photographs;
d) a reference to the sampling plan and procedures used;
e) details of any environmental conditions during sampling that may affect the interpretation of the test results; and
f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.10.4 Calibration certificates

5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

a) the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;
b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof; and
c) evidence that the measurements are traceable (see note 2 in 5.6.2.1.1).

5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.

When statements of compliance are made, the uncertainty of measurement shall be taken into account.

5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

5.10.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations.

5.10.5 Opinions and interpretations

When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

NOTE 1 Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

NOTE 2 Opinions and interpretations included in a test report may comprise, but not be limited to, the following:

— an opinion on the statement of compliance/noncompliance of the results with requirements;
— fulfillment of contractual requirements;
— recommendations on how to use the results; and
— guidance to be used for improvements.

NOTE 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the client. Such dialogue should be written down.

5.10.6 Testing and calibration results obtained from subcontractors

When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.

When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

5.10.7 Electronic transmission of results

In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this Handbook shall be met (see also 5.4.7).

5.10.8 Format of reports and certificates

The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

NOTE 1 Attention should be given to the layout of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

NOTE 2 The headings should be standardized as far as possible.

5.10.9 Amendments to test reports and calibration certificates

Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:

"Supplement to Test Report [or Calibration Certificate], serial number ... [or as otherwise

identified],"

or an equivalent form of wording.

Such amendments shall meet all the requirements of this Handbook.

When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.

Table 2. Training requirements

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

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

6. Specific Technical Guidelines

The material in this section is primarily from the Calibration Laboratories Draft Technical Guide (1994), and is modified and used here as the technical guidelines for evaluation of traceability resulting in the issuance of a Certificate of Measurement Traceability. The following quote, taken from the NVLAP Guide is should be considered in its application.

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

WMD NOTE: Deviation from these recommended criteria must have a technical basis, data, and technical analysis to support the variances.

Recognition Parameter Summary

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

Table 3. Recognition parameter summary

Parameter	Range/Application	Expanded Uncertainty
Mass	laboratory to detail nominal ranges and uncertainties: e.g., 30 kg to 1 mg; Echelon II	
Echelon I	ASTM Class 0, 1, OIML Class E_1, E_2	0.25 mg at 1 kg, and 1 to 5 mg/kg
Echelon II	ASTM Class 2, 3, OIML Class F_1, F_2	1 mg/kg to 20 mg/kg
Echelon III	ASTM Class 4, 5, 6, 7, OIML Class M_1, M_2, M_3 NIST Class F, legal/regulatory enforcement	20 mg/kg to 1 000 mg/kg
Length	laboratory to specify range: e.g., 10 cm to 20 meter tapes	
Tapes, bench method	up to 25 m (100 ft)	0.0 001 m to 0.000 14 m
Tapes, tape method	up to 25 m (100 ft)	0.000 15 m to 0.000 25 m
Rules, direct comparison	up to 0.5 cm (18 in)	< 0.000 05 m
Volume	laboratory to specify ranges: e.g., 2 µL micropipettes to 2000 mL glass flasks	
Gravimetric	syringes, micropipettes, glass standards, and metal provers	0.000 10 mL/L
Volume transfer	glass standards and metal provers	< 0.001 mL/L
Temperature	laboratory to specify type and ranges: e.g., -10 °C to 200 °C; Echelon II	
Echelon I	SPRT's	≤ ± 0.005 °C
Echelon II	Thermistors, thermocouples	> ± 0.005 °C to ≤ ± 0.05 °C
Echelon III	Liquid-in-glass thermometers	> ± 0.05 °C to ≤ ± 0.20 °C
Echelon IV	Liquid-in-glass, dial type, pyrometers	> ± 0.20 °C to ≤ ± 1.0 °C
Echelon V	Infrared sensors, thermographs	> ± 1.0 °C to ≤ ± 5.0 °C
Tuning Forks	as used for law enforcement	0.05 mph, estimate based on interlaboratory tests
Hydrometers	sugar, syrup, petroleum	Estimate
Time	stopwatches used for law enforcement	significantly less than tolerances; estimated at 2 s for a 24 hr test
Grain Moisture	programs for testing grain and commodity moisture	
Oven Methods	laboratory to specify methods and products	0.2 % moisture content
Chemical Methods		0.2 % moisture content

6.1 Technical Criteria for Dimensional Laboratories[3]

6.1.1 Scope

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

a) steel tapes; and
b) rigid rules.

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

6.1.2 References

[1] ANSI/ASME B 89.6.2, Temperature and Humidity Environment for Dimensional Measurements (1973, Reaffirmed 2003).

6.1.3 Statistical Process Control

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

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

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3 This section is adapted from the NVLAP Calibration Laboratories Draft Technical Guide and is modified for WMD application.

6.1.4 Accommodation and Environment

6.1.4.1 The temperature in the calibration area should nominally be 20 °C (degrees Celsius) with a maximum variation and rate of change depending on the materials and the uncertainty level needed for the calibration. Measurements at temperatures other than 20 °C may be made if the proper thermal expansion corrections are applied and the component of uncertainty reflecting the uncertainty in thermal expansion coefficients of the artifacts is calculated and added to the total uncertainty of the calibration. For comparison measurements the uncertainty component should reflect the uncertainty in the thermal expansion of both the master and unknown artifacts.

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

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

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

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

6.1.4.6 The relative humidity in the calibration area should not exceed 50 percent.

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

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

6.1.5 Equipment and Reference Materials

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

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

6.1.5.3 A laboratory that certifies artifacts to tolerance grades should demonstrate a measurement uncertainty which does not exceed 25 % of the tolerance (unless otherwise stated in normative standards). Exceptions to this ratio should be accepted for measurement systems that are documented to be the state-of-the-art and approved by the customer.

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

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

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

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

6.1.6 Calibration Methods

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

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

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

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

a) Bench method for tapes. (SOP 11);
b) Tape to tape method for tapes. (SOP 12);
c) Rigid rule calibration. (SOP 10); and
d) Pi tape calibration (SOP 23 - *draft*).

6.1.7 Handling of Calibration Items

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

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

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

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

6.1.8 Certificates and Reports

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

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

a) master artifact calibration;
b) long term reproducibility of measurement system;
c) thermal expansion correction for gages and measurement scales;
    a. thermometer calibration,
    b. thermal expansion coefficient,
    c. thermal gradients (internal, gage-gage, gage-scale),
d) interferometry;
    a. measurement uncertainty of refractometer,
    b. index of refraction formula,
    c. environmental measurements (air temperature, air pressure, humidity, etc.),

d. calibration of light source frequency,
e. phase correction for reflected light,
f. obliquity and slit corrections

e) instrument geometry;
   a. abbe offset and instrument geometry errors,
   b. scale and gage alignment (cosine errors),
   c. gage support geometry (anvil flatness, block flatness),

f) probe penetration correction;

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

h) analysis algorithms (data fitting, filtering); and

i) other factors as appropriate.

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

6.2 Technical Criteria for Mass Laboratories[4]

6.2.1 Scope

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

6.2.1.1 A laboratory should declare its measurement capability in terms of uncertainties for each mass value. For many laboratories these uncertainties correspond to three arbitrary echelons of measurements that roughly correspond to weight classifications at nominal mass value ranges of measurements. For laboratories seeking Recognition at an uncertainty range that corresponds to a specific echelon, the scope of Recognition should follow the echelons as defined in Table 4 with a declared range of nominal mass values and their associated uncertainties. Recommended ranges of mass values are provided in Table 5. A summary of sections 6.2.3, 6.2.5.1, 6.2.5.6, and 6.2.6.1 are provided in Table 8.

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

Table 4. Mass calibration echelons

Echelon	Verification Levels	Expanded Uncertainty of the Measurements
I, (Extra Fine Accuracy)	OIML Classes E_1, E_2 ASTM Classes 0, 1	The expanded uncertainty must be less than 1/3 of stated tolerances at all levels.
II, (Fine Accuracy)	OIML Classes F_1, F_2 ASTM Classes 2, 3	
III, (Medium Accuracy)	OIML Classes M_1, M_2, M_3 ASTM Classes 4, 5, 6, 7 NIST Class F	

4 This section was originally developed by WMD for adoption in the NVLAP Calibration Laboratories Draft Technical Guide; it is modified here for WMD application.

Table 5. Typical "Ranges of Recognition" for mass calibration

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

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

6.2.2 References

[1] ANSI/ASTM E 617, Standard Specification for Laboratory Weights and Precision Mass Standards, 1997.

[2] OIML R 111, Weights of Classes E_1, E_2, F_1, F_2, M_1, M_2, M_3, 1994 (*under revision* in *2003*).

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

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

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

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

[7] NISTIR 6969, Selected Laboratory and Measurement Practices, and Procedures, to Support Basic Mass Calibrations, Harris, G. L., Torres, J. A., 2003.

6.2.3 Statistical Process Control

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

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

6.2.4 Accommodation and Environment

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

Table 6. Environmental facility guidelines for mass laboratories

Echelon	Temperature	Relative Humidity (maximum per 4 hours)
I	20 °C to 23 °C, a set point ± 1 °C maximum change 0.5 °C/h	40 % to 60 % ± 5 %
II	20 °C to 23 °C, a set point ± 2 °C maximum change 1.0 °C/h	40 % to 60 % ± 10 %
III	18 °C to 27 °C maximum change 2 °C/h	40 % to 60 % ± 20 %

NOTE: The environmental conditions should also be within the specifications of the weighing instruments where applicable.

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

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

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

6.2.5 Equipment and Reference Materials

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

6.2.5.2 The accuracy of auxiliary instruments for Echelons I and II, (e.g., scale, analytical balance, mass comparator) is less important than the precision of the instrument due to algorithms used in mass calibration. However if such equipment is repaired, it should be reevaluated to ascertain its

current level of precision prior to use, and the uncertainty estimate should reflect the post repair performance.

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

6.2.5.4 Means should be provided to measure barometric air pressure, air temperature, and relative humidity of the laboratory environment as indicated in Table 7; documentation of the accuracy and traceability is required. These instruments should be used in close proximity to the balance being used. For Echelon I, temperature may be measured inside the weighing chamber when there is a difference between the air temperature in the balance chamber and the surrounding area. For Echelon III, where buoyancy corrections are generally negligible, recording environmental data is useful in the support of general environmental requirements of the previous section but the accuracy generally does not affect measurement results.

Table 7. Environmental equipment accuracy (expanded uncertainty)

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

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

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

6.2.5.7 Balances used as a direct comparison to the mass unit, should be given a verification test or calibration prior to use. For an application requiring balance accuracy, the laboratory should choose appropriate and correct calibration algorithms. Balances used as dividers and multipliers of the mass unit should be capable of the appropriate accuracy and linearity requirements of the accuracy class for which they are used. Calibration of built-in standards should be performed periodically and

should be verified prior to use. History from measurement control programs (surveillance testing) may be used to determine calibration intervals.

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

6.2.6 Calibration Methods

6.2.6.1 The algorithm chosen for the measurement, the reference standard to be used, and the equipment to be used for a particular calibration should provide acceptable levels of uncertainty for that calibration. A documented procedure should be available in the laboratory to determine the correct algorithm. Note Table 8 for guidelines.

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

6.2.7 Handling of Calibration Items

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

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

6.2.7.3 The laboratory must allow adequate stabilization time for mass standards to ensure environmental and thermal stability prior to calibration.

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

6.2.8 Certificates and Reports

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

6.2.8.2 Environmental parameters measured during the test should be provided on certificates and reports for Echelons I and II. Typical ranges are acceptable for reporting conditions for Echelon III. These include laboratory temperature, barometric pressure and relative humidity.

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

6.2.8.4 Reports may include reference to OIML or ASTM classification schemes and tolerances. Calibration items being tested should meet appropriate specifications for evaluation as well as tolerances. It is the responsibility of the requestor of the calibration to select classifications acceptable for their needs. In the case where magnetism, surface finish, and density are not tested for Echelon I and II, a statement to that effect should be included on the calibration report.

6.2.8.5 The weight surface of a mass standard should be free of any sign of abuse or damage. Signs of abuse or misuse include the placement of labels, tags, wires or other material on mass standards. In addition, visible dirt and fingerprints are a sign of misuse for Echelons I and II. It is recommended that the calibration laboratory establish appropriate means for notifying customers regarding any unusual factors such as signs of abuse regarding the mass standard being tested should be included on the report. Out of tolerance conditions should be reported when significant or when requested.

Table 8. Summary of technical criteria for mass calibration

Echelon	Minimum Measurement Control	Minimum Reference Standards	Minimum Traceability	Minimum Calibration Methods
I (Extra Fine)	• Process control charts • Check standards for each decade, with long term standard deviation • Surveillance of all standards • Proficiency Testing -on-site assessment -round robin participation	• OIML Class E_1, or E_2 or • ASTM Class 0, 1 • single piece, highly polished	• NIST, or other national level calibration every 2 to 5 years based on measurement process data and independent verification, or • NIST Mass MAP, or • User operated mass calibration package, on-site to verify traceability (when available).	• Documented weighing designs consisting of redundant comparisons, with built-in process controls such as those used at the national level. For example: • Technical Notes, 952 and 844, SOP 28
II (Fine)	• Process control charts • Check standards for each decade, with long term standard deviation • Surveillance of selected standards Proficiency Testing -on-site assessment -round robin participation	• OIML Class E_1, or E_2 • ASTM Class 0, 1; or • single piece, highly polished	• NIST calibration every 2 to 5 years based on measurement process data and independent verification, or • Calibration by accredited or Recognized Echelon I laboratory, if uncertainty requirements can be met.	• Documented comparison calibration procedure For example: • NIST Handbook 145, double substitution, or 3-1 weighing design, or equivalent, SOP 4, SOP 5
III (Medium)	• Process control charts • Check standards for each balance Proficiency Testing -on-site assessment -round robin participation	• Working standards such as: • ASTM Class 2, 3 Or • OIML Class F_1 • two piece acceptable, fine finish	• Calibration of all working standards by NIST every 2 to 5 years based on measurement process data and independent verification, or • Calibration of all working standards by an Echelon I or II accredited or Recognized labs every 2 to 5 years based on measurement process data and independent verification	• Use of annually calibrated balance with documented verification procedure prior to each use • Use of modified substitution (NIST Handbook 145) • Other documented and verified procedure

6.3 Technical Criteria for Volume Laboratories[5]

6.3.1 Scope

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

Table 9. Typical "Ranges of Recognition" for volumetric calibration

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

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

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

5 This section was originally developed by WMD for adoption in the NVLAP Calibration Laboratories Draft Technical Guide; it is modified here for WMD application.

6.3.1.3 In the volume transfer procedure, water is delivered from a primary volume standard to the vessel under test. Temperature corrections are made to compensate for the cubical coefficients of thermal expansion of the standard, test vessel, and water to a specified reference temperature. The accuracy and precision will vary considerably depending on the presence of a meniscus, the cleanliness and drain characteristics of the container, the cleanliness and purity of the water, and the ability to make adequate temperature measurements.

6.3.2 References

[1] ANSI/ASTM E 287-02, Standard Specification for Laboratory Glass Graduated Burets (2002).

[2] ANSI/ASTM E 288-94 (1988), Standard Specification for Laboratory Glass Volumetric Flasks.

[3] ANSI/ASTM E 438-92 (2001) e1, Standard Specification for Glasses in Laboratory Apparatus.

[4] ANSI/ASTM E 542-01, Standard Practice for Calibration of Volumetric Apparatus.

[5] ANSI/ASTM E 694-99, Standard Specification for Laboratory Glass Volumetric Apparatus.

[6] ANSI/ASTM E 969-02, Standard Specification for Glass Volumetric (Transfer) Pipets.

[7] OIML R 4 (1972), Volumetric Flasks (one mark) in Glass.

[8] OIML R 40 (1981), Graduated Pipettes for Verification Officers.

[9] OIML R 41 (1977), Standard Burettes for Verification Officers.

[10] OIML R 43 (1977), Standard Graduated Glass Flasks for Verification Officers.

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

[12] API Manual of Petroleum Measurement Standards, Chapter 4 - Proving Systems; Section 3, Small Volume Provers, 1988; Section 4, Tank Provers, 1988; Section 7, Field Standard Test Measures, 1998.

6.3.3 Statistical Process Control

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

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

6.3.4 Accommodation and Environment

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

Table 10. Environmental facility guidelines for volumetric calibration

Procedure	Temperature	Relative Humidity (maximum range per 4 hours)
I Gravimetric	20 °C to 23 °C, set point ± 2 °C maximum change 1.0 °C/h	40 % to 60 % ± 10 %
II Volume Transfer	18 °C to 27 °C maximum change 2.0 °C/h	40 % to 60 % ± 20 %

NOTE: The environmental conditions should also be within the specifications of applicable equipment.

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

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

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

6.3.5 Equipment and reference materials

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

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

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

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

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

Table 11. Environmental equipment accuracy (expanded uncertainty)

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

6.3.6 Calibration methods

6.3.6.1 The algorithm chosen for the measurement, the reference standard to be used, and the equipment to be used for a particular calibration should be correct for that calibration. A

documented procedure should be available in the laboratory to determine the correct algorithm. (Examples are provided in NIST Handbook 145 Standard Operating Procedures, SOPs.)

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

6.3.7 Handling of calibration items

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

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

6.3.8 Certificates and reports

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

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

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

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

Table 12. Summary of technical criteria for volumetric calibration

Procedure	Minimum Measurement Control	Minimum Reference Standard	Minimum Traceability	Minimum Calibration Methods
I Gravimetric	• Process control charts • Check standards • Surveillance of all standards used to provide measurement services • Proficiency testing - On-site assessment - Round robin participation	• Appropriate mass standards - ASTM Class 2 or 3; or - OIML Class F_1 or F_2; or - Calibrated Balance	• NIST, or national level calibration periodically, based on independent historical data verification or • - Test of weighing equipment using correct methods of calibration and adjustment with traceable mass standards	• Documented comparison calibration procedure or • NIST Handbook 145, double substitution (for example) or • - Use of calibrated balance
II Volume Transfer	• Process control charts • Check standards • Surveillance of selected standards • Proficiency testing - On-site assessment - Round robin participation	Primary volume standards with accuracy and repeatability characteristics acceptable for the type of service provided	• Original NIST calibration and periodic independent verification or • Calibration by accredited or Recognized laboratory, if uncertainty requirements can be met	Documented volume transfer (or water draw) procedure recognized by NIST, OIML, ASTM, or API

6.4 Technical Criteria for Hydrometer Laboratories[6]

6.4.1 Scope

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

6.4.2 References

[1] ASTM E 100-95 (2001): Standard Specification for ASTM Hydrometers.

[2] ASTM E 126-92 (1998): Standard Method for Inspection and Verification of Hydrometers.

6.4.3 Statistical process control

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

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

6.4.4 Accommodation and environment

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

6.4.4.2 The density of the water used in hydrometer calibrations should be known to within

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6 This section is adapted from the NVLAP Calibration Laboratories Draft Technical Guide, and modified for WMD application.

0.000005 g/cm^3. Specific gravity is expressed as the ratio of the density of a liquid to the density of water at a specified temperature.

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

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

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

6.4.5 Equipment and reference materials

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

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

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

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

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

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

6.4.6 Calibration methods

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

6.4.6.2 Ideally, hydrometers under test are compared directly to master hydrometers in the kinds of liquids in which they are to be used. This comparison is performed in a clear, smooth glass cylinder of suitable size. The calibration liquid should be well stirred before each comparison to minimize temperature gradient in the liquid.

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

6.4.7 Handling of calibration items

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

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

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

6.4.8 Certificates and reports

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

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

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

6.5 Technical Criteria for Thermometer Laboratories[7]

6.5.1 Scope

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

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

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

Echelon	Expanded Uncertainty
I	$\leq \pm 0.005$ °C
II	$> \pm 0.005$ °C to $\leq \pm 0.05$ °C
III	$> \pm 0.05$ °C to $\leq \pm 0.20$ °C
IV	$> \pm 0.20$ °C to $\leq \pm 1.0$ °C
V	$> \pm 1.0$ °C to $\leq \pm 5.0$ °C

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

6.5.2 References

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

[2] NIST Handbook 105-6, Specifications and Tolerances for Field Standard Thermometers (1997).

[3] NIST SP 250-23, Liquid-In-Glass Thermometer Calibration Service (1988).

7 This section is adapted from the NVLAP Calibration Laboratories Draft Technical Guide, and modified for WMD application.

[4] NBS Monograph 174, Thermometer Calibration, A Model for State Calibration Laboratories (Appendix A: NBS Monograph 150, Liquid-In-Glass Thermometry) (1985).

6.5.3 Statistical process control

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

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

6.5.3.1.1 Records of complete phase equilibrium plateaus obtained for each cell upon receipt and every 6 months thereafter should be maintained. This should include either manually recorded temperatures at consistent intervals, or a graphical representation of the equilibrium plateau, as measured by the monitoring sensor.

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

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

Item	Echelon				
	I	II	III	IV	V
6.5.3.1.1	X	X	X	X	
6.5.3.1.2	X	X	X	X	
6.5.3.1.3	X				

6.5.3.2 SPRT or RIRT as the reference standard

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

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

6.5.3.2.2 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) should be checked periodically at either the water triple point or at the ice point.

Item	Echelon				
	I	II	III	IV	V
6.5.3.2.1	2 mK	2 mK	5 mK	10 mK	10 mK
6.5.3.2.2	X		X	X	X

6.5.3.3 Thermistor thermometer as the reference standard

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

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

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

Item	Echelon				
	I	II	III	IV	V
6.5.3.3.1		x	x	x	x
6.5.3.3.2		2 mK	5 mK	10 mK	

6.5.3.4 Thermocouple as the reference standard

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

6.5.3.4.1 Liquid-in-glass thermometer as the reference standard

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

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

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

Item	Echelon				
	I	II	III	IV	V
6.5.3.4.1.1			X	X	
6.5.3.4.1.2					X

6.5.4 Accommodation and environment

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

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

6.5.4.3 The relative humidity should be controlled between 40 % and 60 %.

6.5.4.4 Vibrations in the laboratory should be minimized.

6.5.5 Equipment and reference materials

6.5.5.1 Reference standards

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

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

6.5.5.2 Fixed-point cell as the reference standard

6.5.5.2.1 The purity of the fixed-point material should be at least 99.999 9 % and the other starting materials of construction of the cells should be of ultra-high purity also. If the cells are unsealed, they should be filled at all times with an inert gas such as argon.

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

6.5.5.3 SPRT or RIRT as the reference standard

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

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

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

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

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

6.5.5.4 Thermocouple as the reference standard

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

6.5.6 Measurement traceability and calibration

6.5.6.1 Fixed-point cell as the reference standard

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

6.5.6.1.1 The cell should be evaluated by NIST; or

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

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

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

Item	Echelon			
	I	II	III	IV
6.5.6.1.1	X	X*		
6.5.6.1.2		X**		
6.5.6.1.3			X	X
6.5.6.1.4	± 1 mK	≤ ± 0.005 °C	0.01 °C	± 0.02 °C

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

6.5.6.2 SPRT or RIRT as the reference standard

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

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

6.5.6.2.2. The SPRT or RIRT should be calibrated annually, and all reference resistors used with the bridge should be calibrated traceable to NIST.

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

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

Item	Echelon				
	I	II	III	IV	V
6.5.6.2.1	X	X	X	X	
6.5.6.2.2					X
6.5.6.2.3	X	X	X	X	
6.5.6.2.4	X	X	X	X	X

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

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

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

6.5.7 Calibration methods

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

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

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

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

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

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

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

Item	Echelon				
	I	II	III	IV	V
6.5.7.2.1	X	X			
6.5.7.2.2			X	X	
6.5.7.2.3					X
6.5.7.2.4			X	X	
6.5.7.2.5	± 0.5 mK	± 0.5 mK*	(a)	(a)	(a)

*For claimed expanded uncertainty < ± 0.01 °C. For claimed expanded uncertainty > ± 0.01 °C, at least 10 times better than the claimed expanded uncertainty.
(a) At least 10 times better than the claimed expanded uncertainty.

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

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

6.5.8 Handling of calibration items

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

6.6 Technical Criteria for Moisture Laboratories[8] - Grain and/or Commodities

6.6.1 Scope

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

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

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

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

Table 13. Moisture determination laboratory classifications

Procedural Category	Moisture Determination Method		Reference Methods
I Oven Methods	Ia	Air Oven	GIPSA, Technical Services Division, Air Oven Moisture Reference Laboratory Working Instructions
	Ib	Vacuum Oven	AOAC Official Methods of Analysis, 17th ed. Revision 1, 2002, vacuum oven methods, Sec. 32
II Chemical Method	IIa	Karl Fischer chemical analysis	AOAC Official Methods of Analysis, 17th ed. Revision 1, 2002, Karl Fischer methods AOAC, Automatic Karl Fischer Titration of Moisture in Grain, (Vol. 64, No. 6, 1981)
	IIb	Basic Reference Method	ISO 711, Cereals and Cereal Products-Determination of Moisture Content

8 This section was originally developed by WMD.

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

6.6.1.5 Important definitions in this section follow:

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

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

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

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

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

6.6.2 References

[1] United States Department of Agriculture, Grain Inspection Packers and Stockyards Administration, (GIPSA), Technical Services Division, Air Oven Moisture Reference Laboratory Working Instructions, April 1998 (Internal Documents).

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

[3] Association of Official Analytical Chemists (AOAC), Official Methods of Analysis, 17th Edition Revision 1, 2002.

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

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

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

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

6.6.3 Statistical Process Control

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

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

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

6.6.4 Accommodation and environment

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

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

Temperature: 20 °C to 23 °C, set point ± 2 °C, maximum change of 1.0 °C/h; and
Humidity: 40 % to 60 % ± 10 %

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

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

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

6.6.4.5 Grains and/or commodities under test should be kept in refrigerated storage areas. The refrigerated storage areas should be maintained between 1.5 °C and 7.0 °C.

6.6.4.6 Excess vibration may adversely affect the performance of precision analytical balances and mass comparators and should be prevented. Proximity to heavy machinery, railways, heavily traveled highways, or similar sources of known vibration is not recommended. Steps should be taken to reduce vibration to an acceptable level of stability with methods such as isolated foundations for balances or elimination of the source.

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

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

6.6.5 Equipment and Reference materials

6.6.5.1 Standard Reference Materials

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

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

6.6.5.2 Primary Equipment - Oven methods

6.6.5.2.1 Category Ia laboratories should have appropriate equipment for the moisture determination of grain and/or commodity moisture: mechanical (forced draft) or gravity convection ovens, desiccator, mill, moisture dishes, and analytical balance. Reference GIPSA Technical Services Division, Air Oven Moisture Reference Laboratory Working Instructions for equipment specifications.

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

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

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

6.6.5.3 Primary Equipment - Karl Fischer chemical analysis

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

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

6.6.5.4 Secondary Equipment

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

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

6.6.6 Measurement traceability and calibration

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

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

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

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

6.6.7 Moisture determination methods

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

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

6.6.8 Handling of grain and/or commodities for moisture determination

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

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

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

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

6.6.9 Test Reports

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

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

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

Table 14. Summary of environmental facility guidelines (as described in Section 6)

Lab	Temperature range °C (set point)	± Temp variability °C	Max change per hour °C	Temp accuracy °C	RH % range	RH % accuracy (change per 4 hours)	Pressure accuracy Pa
Mass I	20 to 23	1.0	0.5	0.1	40 to 60	5	65
Mass II	20 to 23	2.0	1.0	0.5	40 to 60	10	135
Mass III	18 to 27		2.0		40 to 60	20	
Volume - G	20 to 23	2.0	1.0	0.1/0.5 (H_2O, air)	40 to 60	10	
Volume - T	18 to 27	1.0	2.0	0.5	40 to 60		135
Dimensional	20 (18 to 22)	1.0		0.5	> 50	20	
Temperature		2.0			40 to 60	10	
Tuning Forks							
Hydrometers				0.01 (bath)			
Time							
Grain Moisture	20 to 23	2.0	1.0	0.5	40 to 60		

7. References

ANSI/NCSL Z540.1-1994 (R2002), American National Standards Institute, National Conference of Standards Laboratories, American National Standard, *General Requirements for Calibration Laboratories and Measuring and Test Equipment*.

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

ISO/IEC Guide 17025, International Organization for Standardization, *General Requirements for the Competence of Testing and Calibration Laboratories*, 1999.

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

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

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

NIST Handbook 150, National Voluntary Laboratory Accreditation Program, NVLAP, *Procedures and General Requirements*, Alderman, D. F., Faison, C. D., White, V. R., editors, July 2001.

8. Glossary

The following section contains the definitions of a number of terms in the sense in which they are used throughout this Handbook. Where applicable, definitions are taken from: 1) NIST Handbook 150, NVLAP Procedures and General Requirements, 1994, wherever possible; 2) The International Vocabulary of Basic and General Terms in Metrology (VIM:1994); or 3) NIST Handbook 143, Program Handbook, 1997 edition. Many of the NIST Handbook 150 definitions are taken from the VIM:1994.

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

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

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

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

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

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

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

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

Certificate of Measurement Traceability - a certificate issued to a weights and measures laboratory indicating that the laboratory has traceable standards, can make and provide traceable measurements, and complies with the requirements of NIST Handbook 143, Program Handbook.

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

Deficiency - the non-fulfillment of NIST/WMD conditions and/or criteria for Recognition (or accreditation). (HB 150, modified)

Good Laboratory Practices (GLP) - an acceptable way to perform some basic operation or activity in a laboratory, that is known, or believed to influence, the quality of its outputs. GLPs ordinarily are essentially independent of the measurement techniques used. (HB 143, 1997)

Good Measurement Practices (GMP) - an acceptable way to perform some operation associated with a specific measurement technique, and which is known or believed to influence the quality of the measurement. (HB 143, 1997)

Interlaboratory Comparisons - organization, performance and evaluation of calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions. (HB 150)

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

Laboratory - an organization that performs calibrations and/or tests. When a laboratory is part of an organization that carries out activities additional to calibration and testing, the term "laboratory" refers only to those parts of that organization that are involved in the calibration and testing process. The laboratory activities may be carried out at or from a permanent location, at or from a temporary facility, or in or from a mobile facility. (HB 150)

Length Laboratory - a specific area, within a metrology laboratory, that is used solely for calibration or tolerance testing of length standards. (HB 143, 1997)

Mass Laboratory - a specific area, within a metrology laboratory, that is used solely for calibration or tolerance testing of mass standards or test weights; generally divided into small mass ($\leq$ 10 kg) and large mass ($>$ 10 kg) areas. (HB 143, 1997)

Measurement Assurance - a process to ensure adequate measurement results that may include, but is not limited to: 1) use of good experimental design principles so that the entire measurement process, its components, and relevant influence factors can be well characterized, monitored, and controlled; 2) complete experimental characterization of the measurement process uncertainty including

statistical variations, contributions from all known or suspected influence factors, imported uncertainties, and the propagation of uncertainties throughout the measurement process; and 3) continuously monitoring the performance and state of statistical control of the measurement process with proven statistical process control techniques including the measurement of well-characterized check standards along with the normal workload and the use of appropriate control charts. (HB 150)

NVLAP - the NIST National Voluntary Laboratory Accreditation Program.

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

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

Proficiency Testing - the determination of laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions. (HB 150)

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

Quality Audit - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively, and are suitable to achieve objectives. (HB 150)

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

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

Recognition - the evaluation and issuance of a Certificate of Measurement Traceability and letter regarding the laboratory quality system for weights and measures laboratories (not a formal accreditation).

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

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

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

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

Standard, Primary - A standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity. (HB 150)

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

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

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

Standard Operating Procedure (SOP) - a procedure adopted for repetitive use when performing a specific measurement or sampling operation. It may be a standard method or one developed by the user. (HB 143, 1997)

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

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

Tolerance Testing - a measurement operation performed to determine whether the actual value of a standard, artifact, or instrument is within a permitted tolerance of its nominal value. An error and uncertainty value must first be determined before one can assess the tolerance status. (HB 143, 1997)

Traceability - the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties. (VIM:1994)

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

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

Volume Laboratory - a specific area, within a metrology laboratory, that is used solely for calibration or tolerance testing of volume standards; generally divided into small volume ($\leq$ 20 L) and large volume (> 20 L) areas. (HB 143, 1997)

WMD - The NIST Weights and Measures Division. Formerly NIST Office of Weights and Measures (OWM).

Appendix A. List of Services Available from NIST

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

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

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

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

4. Recommended test procedures for:

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

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

6. Measurement assurance information - NBSIR 77-1240 and regional measurement assurance programs.

7. NIST evaluation of laboratory auditing problems.

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

9. Measurement control programs in selected measurement areas.

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

Weights and Measures Division, State Laboratory Program
National Institute of Standards and Technology
Gaithersburg, MD 20899
Phone: 301/975-4004
Fax: 301/926-0647
http://www.nist.gov/owm

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

Name of laboratory

_____

_____

_____

Address of laboratory

_____

_____

_____

Scope of Recognition - complete Appendix D with uncertainty estimates included

_____

_____

_____

_____

Approved Signatories - have assigned responsibility for validity of laboratory reports

_____

_____

_____

Authorized Representative - contact for administration of laboratory Recognition

_____

_____

Appendix C. Laboratory Assessment Checklist

(from NVLAP Handbook 150, 2001)

GENERAL OPERATIONS CHECKLIST

Instructions to the Assessor (or Quality Manager): This checklist addresses the general accreditation criteria prescribed in NIST Handbook 150, *NVLAP Procedures and General Requirements* (2001 edition). The checklist items are numbered to correspond to the requirements found in Sections 4 and 5 of the Handbook. Items marked with a Φ were not sufficiently addressed in the previous version of this Handbook.

Place an "X" beside each checklist item that represents a deficiency. Place a "C" beside each item on which you are commenting for other reasons. Record the item number and written deficiency explanation and/or comment on the comment sheet(s) at the end of the checklist. Write "OK" beside all other items you observed or verified as compliant at the laboratory. Identify policies and procedures where called for.

4 Management requirements for accreditation

4.1 Organization

____ **4.1.1** The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.

Legal name of laboratory ownership: _____

____ **4.1.2** It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this Handbook and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition.

____ **4.1.3** The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

____ **4.1.4** If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.

NOTE 1 Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this Handbook.

NOTE 2 If the laboratory wishes to be Recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgment. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its testing or calibration activities.

4.1.5 The laboratory shall:

____ a) have managerial and technical personnel with the authority and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

____ b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

____ c) have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

____ d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

____ e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

____ f) Specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

____ g) Provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;

____ h) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

Name of person: _____
Area of responsibility: _____
Repeat as necessary: _____

____ i) Appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

Name of person: _____

____ j) appoint deputies for key managerial personnel (see note).

Name(s): _____

NOTE Individuals may have more than one function and it may be impractical to appoint deputies for every function.

4.2 Quality system

4.2.1

____ a) The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities.

____ b) The laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results.

____ c) The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

____ **4.2.2** The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. It shall include at least the following:

____ a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its clients;

___Φ b) the management's statement of the laboratory's standard of service;

____ c) the objectives of the quality system;

____ d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

____ e) the laboratory management's commitment to compliance with this Handbook.

NOTE The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and clients' requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

4.2.3

____ a) The quality manual shall include or make reference to the supporting procedures including technical procedures.

___Φ b) It shall outline the structure of the documentation used in the quality system.

____ **4.2.4** The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this Handbook, shall be defined in the quality manual.

4.3 Document control

4.3.1 General

___ The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

NOTE 1 In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

NOTE 2 The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.12.

4.3.2 Document approval and issue

4.3.2.1

___Φ a) All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue.

___Φ b) A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The procedure(s) adopted shall ensure that:

___Φ a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

___Φ b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

___Φ c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

___Φ d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.3 Quality system documents generated by the laboratory shall be uniquely identified. Such identification shall include:

___Φ a) the date of issue and/or revision identification,

___Φ b) page numbering,

___Φ c) the total number of pages or a mark to signify the end of the document, and

___Φ d) the issuing authority(ies).

4.3.3 Document changes

___Φ **4.3.3.1** Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

___Φ **4.3.3.2** Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

4.3.3.3

___Φ a) If the laboratory's documentation control system allows for the amendment of documents by hand pending the reissue of the documents, the procedures and authorities for such amendments shall be defined.

___Φ b) Amendments shall be clearly marked, initialed and dated. A revised document shall be formally reissued as soon as practicable.

___Φ **4.3.3.4** Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

4.4 Review of requests, tenders and contracts

____ **4.4.1** The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

___Φ a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);

____ b) the laboratory has the capability and resources to meet the requirements;

___Φ c) the appropriate test and/or calibration method is selected and capable of meeting the clients' requirements (see 5.4.2).

___Φ d) Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the client.

NOTE 1 The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal clients, reviews of requests, tenders and contracts can be performed in a simplified way.

NOTE 2 The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in interlaboratory comparisons or proficiency testing and/or the running of trial test or calibration programs using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

NOTE 3 A contract may be any written or oral agreement to provide a client with testing and/or

calibration services.

___Φ **4.4.2** Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.

NOTE For review of routine and other simple tasks, the date and the identification (e.g., the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for ongoing routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

___Φ **4.4.3** The review shall also cover any work that is subcontracted by the laboratory.

___Φ **4.4.4** The client shall be informed of any deviation from the contract.

___Φ **4.4.5** If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

4.5 Subcontracting of tests and calibrations

____ **4.5.1** When a laboratory subcontracts work whether because of unforeseen reasons (e.g., workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g., through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this Handbook for the work in question.

____ **4.5.2** The laboratory shall advise the client of the arrangement in writing and, when appropriate, gain the approval of the client, preferably in writing.

___Φ **4.5.3** The laboratory is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used.

____ **4.5.4** The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this Handbook for the work in question.

4.6 Purchasing services and supplies

____ **4.6.1** The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

4.6.2

____ a) The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the

methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements.

___ b) Records of actions taken to check compliance shall be maintained.

___ **4.6.3** Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

NOTE The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the quality system standard under which they were made.

4.6.4

___ a) The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and

___ b) shall maintain records of these evaluations and list those approved.

4.7 Service to the client

___Φ The laboratory shall afford clients or their representatives cooperation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other clients.

NOTE 1 Such cooperation may include:

a) providing the client or the client's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the client;

b) preparation, packaging, and dispatch of test and/or calibration items needed by the client for verification purposes.

NOTE 2 Such cooperation may include: Clients value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the client, especially in large assignments, should be maintained throughout the work. The laboratory should inform the client of any delays or major deviations in the performance of the tests and/or calibrations.

NOTE 3 Laboratories are encouraged to obtain other feedback, both positive and negative, from their clients (e.g., client surveys). The feedback should be used to improve the quality system, testing and calibration activities and client service.

4.8 Complaints

___ **4.8.1** The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties.

___ **4.8.2** Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.10).

4.9 Control of non-conforming testing and/or calibration work

____ **4.9.1** The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. The policy and procedures shall ensure that:

___Φ a) the responsibilities and authorities for the management of non-conforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when non-conforming work is identified;

____ b) an evaluation of the significance of the non-conforming work is made;

___Φ c) corrective actions are taken immediately, together with any decision about the acceptability of the non-conforming work;

____ d) where necessary, the client is notified and work is recalled;

___Φ e) the responsibility for authorizing the resumption of work is defined.

NOTE Identification of non-conforming work or problems with the quality system or with testing and/or calibration activities can occur at various places within the quality system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

___Φ **4.9.2** Where the evaluation indicates that the non-conforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.10 shall be promptly followed.

4.10 Corrective action

4.10.1 General

____ The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when non-conforming work or departures from the policies and procedures in the quality system or technical operations have been identified.

NOTE A problem with the quality system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of non-conforming work, internal or external audits, management reviews, feedback from clients or staff observations.

4.10.2 Cause analysis

___Φ The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include client requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its

calibration.

4.10.3 Selection and implementation of corrective actions

___Φ a) Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

___Φ b) Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

___Φ c) The laboratory shall document and implement any required changes resulting from corrective action investigations.

4.10.4 Monitoring of corrective actions

___Φ The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

4.10.5 Additional audits

____ Where the identification of non-conformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this Handbook, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.13 as soon as possible.

NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

4.11 Preventive action

4.11.1

___Φ a) Needed improvements and potential sources of non-conformances, either technical or concerning the quality system, shall be identified.

___Φ b) If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformances and to take advantage of the opportunities for improvement.

___Φ **4.11.2** Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.

NOTE 1 Preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.
NOTE 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

4.12 Control of records

4.12.1 General

____ **4.12.1.1** The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

4.12.1.2

____ a) All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

____ b) Retention times of records shall be established.

NOTE Records may be in any media, such as hard copy or electronic media.

____ **4.12.1.3** All records shall be held secure and in confidence.

____ **4.12.1.4** The laboratory shall have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records.

4.12.2 Technical records

4.12.2.1

____ a) The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period.

____ b) The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.

____ c) The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

NOTE 1 In certain fields it may be impossible or impracticable to retain records of all original observations.

NOTE 2 Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, clients' notes, papers and feedback.

___Φ **4.12.2.2** Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

4.12.2.3

___Φ a) When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible

or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction.

____ b) In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

4.13 Internal audits

4.13.1

____ a) The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this Handbook. The internal audit program shall address all elements of the quality system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management.

____ b) Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

NOTE The cycle for internal auditing should normally be completed in one year.

____ **4.13.2** When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify clients in writing if investigations show that the laboratory results may have been affected.

____ **4.13.3** The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

____ **4.13.4** Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

4.14 Management reviews

____ **4.14.1** In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

___Φ a) the suitability of policies and procedures;

___Φ b) reports from managerial and supervisory personnel;

___Φ c) the outcome of recent internal audits;

___Φ d) corrective and preventive actions;

___Φ e) assessments by external bodies;

___Φ f) the results of interlaboratory comparisons or proficiency tests;

___Φ g) changes in the volume and type of the work;

___Φ h) client feedback;

___Φ i) complaints;

___Φ j) other relevant factors, such as quality control activities, resources and staff training.

NOTE 1 A typical period for conducting a management review is once every 12 months.

NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

4.14.2

____ a) Findings from management reviews and the actions that arise from them shall be recorded.

____ b) The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

5 Technical requirements for accreditation

5.1 General

5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:

- human factors (5.2);
- accommodation and environmental conditions (5.3);
- test and calibration methods and method validation (5.4);
- equipment (5.5);
- measurement traceability (5.6 and Annex B);
- sampling (5.7);
- the handling of test and calibration items (5.8).

___Φ **5.1.2** The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

5.2 Personnel

5.2.1

____ a) The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.

____ b) When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

NOTE 1 In some technical areas (e.g., nondestructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirements for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the client.

NOTE 2 The personnel responsible for the opinions and interpretation included in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:

- relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;
- knowledge of the general requirements expressed in the legislation and standards; and
- an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc. concerned.

____ **5.2.2** The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training of personnel. The training program shall be relevant to the present and anticipated tasks of the laboratory.

5.2.3

___Φ a) The laboratory shall use personnel who are employed by, or under contract to, the laboratory.

___Φ b) Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.

____ **5.2.4** The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

NOTE Job descriptions can be defined in many ways. As a minimum, the following should be defined:

- the responsibilities with respect to performing tests and/or calibrations;
- the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;

- the responsibilities for reporting opinions and interpretations;
- the responsibilities with respect to method modification and development and validation of new methods;
- expertise and experience required;
- qualifications and training programs;
- managerial duties.

5.2.5

___Φ a) The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.

____ b) The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.

___Φ c) This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

WMD Note: This requirement also applies to Approved Signatories.

5.3 Accommodation and environmental conditions

5.3.1

____ Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.

The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility.

___Φ b) The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

5.3.2

____ a) The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.

____ b) Tests and calibrations shall be stopped when the environmental conditions jeopardize the

results of the tests and/or calibrations.

____ **5.3.3** There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

____ **5.3.4** Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.

____ **5.3.5** Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

5.4 Test and calibration methods and method validation

5.4.1 General

____ a) The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

____ b) The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations.

____ c) All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3).

____ d) Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the client.

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.

5.4.2 Selection of methods

____ a) The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so.

___Φ b) When necessary, the standard shall be supplemented with additional details to ensure consistent application.

____ c) When the client does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by

the laboratory may also be used if they are appropriate for the intended use and if they are validated.

___Φ d) The client shall be informed as to the method chosen.

___Φ e) The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.

___Φ f) The laboratory shall inform the client when the method proposed by the client is considered to be inappropriate or out of date.

5.4.3 Laboratory-developed methods

___Φ a) The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.

___Φ b) Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

5.4.4 Non-standard methods

____ a) When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the test and/or calibration.

____ b) The method developed shall have been validated appropriately before use.

NOTE For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:

a) appropriate identification;

b) scope;

c) description of the type of item to be tested or calibrated;

d) parameters or quantities and ranges to be determined;

e) apparatus and equipment, including technical performance requirements;

f) reference standards and reference materials required;

g) environmental conditions required and any stabilization period needed;

h) description of the procedure, including:

- affixing of identification marks, handling, transporting, storing and preparation of items,
- checks to be made before the work is started,
- checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,

- the method of recording the observations and results,
- any safety measures to be observed;

i) criteria and/or requirements for approval/rejection;

j) data to be recorded and method of analysis and presentation;

k) the uncertainty or the procedure for estimating uncertainty.

5.4.5 Validation of methods

5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

5.4.5.2

____ a) The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

___Φ b) The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

NOTE 1 Validation may include procedures for sampling, handling and transportation.

NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

- calibration using reference standards or reference materials;
- comparison of results achieved with other methods;
- interlaboratory comparisons;
- systematic assessment of the factors influencing the result;
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

NOTE 3 When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

___Φ **5.4.5.3** The range and accuracy of the values obtainable from validated methods (e.g., the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the clients' needs.

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review should be carried out to verify that the needs of the client are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

5.4.6 Estimation of uncertainty of measurement

____ **5.4.6.1** A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

___Φ **5.4.6.2** Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- the requirements of the test method;
- the requirements of the client;
- the existence of narrow limits on which decisions on conformance to a specification are based.

NOTE 2 In those cases where a well recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

____ **5.4.6.3** When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

NOTE 2 The predicted long-term behavior of the tested and/or calibrated item is not normally taken

into account when estimating the measurement uncertainty.

NOTE 3 For further information, see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see 1.4).

WMD Note: ANSI/NCSL Z540-2-1997 and NIST Technical Note 1297, 1994 edition, are considered to be equivalent to the Guide to the Expression of Uncertainty in Measurement (GUM).

5.4.7 Control of data

____ **5.4.7.1** Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

____ a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;

____ b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

____ c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

NOTE Commercial off-the-shelf software (e.g., word processing, database and statistical programs) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2a).

5.5 Equipment

5.5.1

____ a) The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data).

____ b) In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this Handbook are met.

5.5.2

____ a) Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.

____ b) Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results.

____ c) Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).

____ **5.5.3** Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

____ **5.5.4** Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

____ **5.5.5** Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:

____ a) the identity of the item of equipment and its software;

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

____ c) checks that equipment complies with the specification (see 5.5.2);

____ d) the current location, where appropriate;

____ e) the manufacturer's instructions, if available, or reference to their location;

____ f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;

____ g) the maintenance plan, where appropriate, and maintenance carried out to date;

____ h) any damage, malfunction, modification or repair to the equipment.

____ **5.5.6** The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

NOTE Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.

5.5.7

____ a) Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.

____ b) The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of non-conforming work" procedure (see 4.9).

____ **5.5.8** Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is

due.

____ **5.5.9** When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

___Φ **5.5.10** When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.

___Φ **5.5.11** Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g., in computer software) are correctly updated.

____ **5.5.12** Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

5.6 Measurement traceability

5.6.1 General

____ a) All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g., for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service.

____ b) The laboratory shall have an established program and procedure for the calibration of its equipment.

NOTE Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

5.6.2 Specific requirements

5.6.2.1 Calibration

5.6.2.1.1

____ a) For calibration laboratories, the program for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (*Système international d'unités*).

A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute.

____ b) When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement

capability and traceability.

____ c) The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).

NOTE 1 Calibration laboratories fulfilling the requirements of this Handbook are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this Handbook, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

NOTE 2 Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VIM:1993, 6.4) or by reference to a natural constant, the value of which in terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

NOTE 3 Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

NOTE 4 The term "identified metrological specification" means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

NOTE 5 When the terms "international standard" or "national standard" are used in connection with traceability, it is assumed that these standards fulfill the properties of primary standards for the realization of SI units.

NOTE 6 Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located.

NOTE 7 If a calibration laboratory wishes or needs to obtain traceability from a national metrology institute other than in its own country, this laboratory should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

NOTE 8 The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.

____ **5.6.2.1.2** There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:

____ a) the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;

____ b) the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.

____ c) Participation in a suitable program of interlaboratory comparisons is required where possible.

5.6.2.2 Testing

___Φ **5.6.2.2.1** For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

NOTE The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.

___Φ **5.6.2.2.2** Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

____ a) The laboratory shall have a program and procedure for the calibration of its reference standards.

____ b) Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1.

____ c) Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.

5.6.3.2 Reference materials

____ Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

5.6.3.3 Intermediate checks

____ Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules

5.6.3.4 Transport and storage

___Φ The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

NOTE Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.

5.7 Sampling

5.7.1

____ a) The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration.

___Φ b) The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.

NOTE 1 Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated. In certain cases (e.g., forensic analysis), the sample may not be representative but is determined by availability.

NOTE 2 Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.

___Φ **5.7.2** Where the client requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.

___Φ **5.7.3** The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.

5.8 Handling of test and calibration items

____ **5.8.1** The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the client.

5.8.2

____ a) The laboratory shall have a system for identifying test and/or calibration items.

___Φ b) The identification shall be retained throughout the life of the item in the laboratory.

____ c) The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents.

___Φ d) The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.

5.8.3

____ a) Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded.

____ b) When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the discussion.

5.8.4

____ a) The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation.

____ b) Handling instructions provided with the item shall be followed.

____ c) When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

____ d) Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

NOTE 1 Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

NOTE 2 A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples.

NOTE 3 Reasons for keeping a test or calibration item secure can be for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.

5.9 Assuring the quality of test and calibration results

____ a) The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.

____ b) The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.

____ c) This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

____ 1) regular use of certified reference materials and/or internal quality control using secondary reference materials;

____ 2) participation in interlaboratory comparison or proficiency-testing programs;

____ 3) replicate tests or calibrations using the same or different methods;

____ 4) retesting or recalibration of retained items;

____ 5) correlation of results for different characteristics of an item.

NOTE The selected methods should be appropriate for the type and volume of the work undertaken.

5.10 Reporting the results

5.10.1 General

____ a) The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

____ b) The results shall be reported, usually in a test report or a calibration certificate (see note 1), and shall include all the information requested by the client and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.

____ c) In the case of tests or calibrations performed for internal clients, or in the case of a written agreement with the client, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the client shall be readily available in the laboratory which carried out the tests and/or calibrations.

NOTE 1 Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.

NOTE 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this Handbook are met.

5.10.2 Test reports and calibration certificates

Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

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

____ b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;

____ c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;

____ d) the name and address of the client;

____ e) identification of the method used;

____ f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;

____ g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;

____ h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;

____ i) the test or calibration results with, where appropriate, the units of measurement;

____ j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;

____ k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

WMD Note: WMD defines the person(s) who authorizes the test report or calibration certificate as the Approved Signatory.

NOTE 1 Hard copies of test reports and calibration certificates should also include the page number and total number of pages.

NOTE 2 It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

5.10.3 Test reports

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:

____ a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;

___Φ b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

____ c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instruction so requires, or when the uncertainty affects compliance to a specification limit;

___Φ d) where appropriate and needed, opinions and interpretations (see 5.10.5);

___Φ e) additional information which may be required by specific methods, clients or groups of clients.

5.10.3.2 In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:

___Φ a) the date of sampling;

___Φ b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);

___Φ c) the location of sampling, including any diagrams, sketches or photographs;

___Φ d) a reference to the sampling plan and procedures used;

___Φ e) details of any environmental conditions during sampling that may affect the interpretation of the test results;

___Φ f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned.

5.10.4 Calibration certificates

5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

____ a) the conditions (e.g., environmental) under which the calibrations were made that have an influence on the measurement results;

____ b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

____ c) evidence that the measurements are traceable (see note 2 in 5.6.2.1.1).

5.10.4.2

____ a) The calibration certificate shall relate only to quantities and the results of functional tests.

___Φ b) If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

___Φ c) When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.

___Φ d) When statements of compliance are made, the uncertainty of measurement shall be taken into account.

___Φ **5.10.4.3** When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

___Φ **5.10.4.4** A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations.

5.10.5 Opinions and interpretations

___Φ When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

NOTE 1 Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

NOTE 2 Opinions and interpretations included in a test report may comprise, but not be limited to, the following:

- an opinion on the statement of compliance/noncompliance of the results with requirements;
- fulfillment of contractual requirements;
- recommendations on how to use the results;
- guidance to be used for improvements.

NOTE 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the client. Such dialogue should be written down.

5.10.6 Testing and calibration results obtained from subcontractors

____ a) When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.

___Φ b) The subcontractor shall report the results in writing or electronically.

___Φ c) When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.

5.10.7 Electronic transmission of results

____ In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this Handbook shall be met (see also 5.4.7).

5.10.8 Format of reports and certificates

____ The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

NOTE 1 Attention should be given to the layout of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

NOTE 2 The headings should be standardized as far as possible.

5.10.9 Amendments to test reports and calibration certificates

____ a) Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement:

"Supplement to Test Report [or Calibration Certificate], serial number ... [or as otherwise identified]," or an equivalent form of wording.

____ b) Such amendments shall meet all the requirements of this Handbook.

____ c) When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.

Appendix D. Summary of Services for Laboratory Directory

State

Recognition Period:

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

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

* Uncertainties Chart must be completed for *each* measurement parameter listed.

State

Fees

National Type Evaluation Program (NTEP)	
Address	Telephone Number

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

State

Grain Moisture Testing	
Address	Telephone Number

Petroleum Quality Testing	
Address	Telephone Number

Appendix E. Uncertainties Chart for Measurement Parameter_____
Laboratory_____

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

NIST Technical Publications

Periodical

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

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