

NIST HB 150-2-2016

**NVLAP
Calibration
Laboratories**

Barbara Belzer
Kari K. Harper
Thomas Hettenhouser
Warren Merkel

<http://dx.doi.org/10.6028/NIST.HB.150-2-2016>

NIST
**National Institute of
Standards and Technology**
U.S. Department of Commerce

This page is intentionally left blank.

NIST HB 150-2-2016

**NVLAP
Calibration
Laboratories**

Barbara Belzer
Kari K. Harper
Thomas Hettenhouser
*National Voluntary Laboratory Accreditation Program
Standards Coordination Office
Laboratory Programs*

Warren Merkel
*Standards Services
Standards Coordination Office
Laboratory Programs*

<http://dx.doi.org/10.6028/NIST.HB.150-2-2016>

October 2016



U.S. Department of Commerce
Penny Pritzker, Secretary

National Institute of Standards and Technology
Willie May, Under Secretary of Commerce for Standards and Technology and Director

NVLAP AND THE NVLAP LOGO

The term *NVLAP* and the NVLAP logo are registered marks of the Federal Government, which retains exclusive rights to control the use thereof. Permission to use the term and symbol (NVLAP logo with approved caption) is granted to NVLAP-accredited laboratories for the limited purpose of announcing their accredited status, and for use on reports that describe only testing and calibration within the scope of accreditation. NVLAP reserves the right to control the quality of the use of the NVLAP term, logo, and symbol

National Institute of Standards and Technology Handbook 150-2-2016
Natl. Inst. Stand. Technol. Handb. 150-2-2016, 27 pages (January 2016)
CODEN: NIHAЕ2

This publication is available free of charge from:
<http://dx.doi.org/10.6028/NIST.HB.150-2-2016>

Contents

Foreword.....	v
Introduction and acknowledgments	vii
1 General information	1
1.1 Scope.....	1
1.2 Organization of handbook.....	1
1.3 Program description	1
1.4 References	2
1.5 Terms and definitions.....	2
1.6 Program documentation	3
2 Laboratory Accreditation Program (LAP) establishment, development, and implementation.....	3
3 Accreditation process.....	3
3.1 General	3
3.2 Management system review	4
3.3 On-site assessment	4
3.4 Proficiency testing.....	5
3.5 Laboratories seeking accreditation for calibrations with uncertainties near those provided by a national metrology institute (NMI)	7
3.6 Policy on scopes of accreditation of calibration laboratories.....	7
4 Management requirements for accreditation.....	8
4.1 Organization.....	8
4.2 Management system.....	8
4.3 Document control.....	8
4.4 Review of requests, tenders and contracts.....	8
4.5 Subcontracting of tests and calibrations.....	9
4.6 Purchasing services and supplies	9
4.7 Service to the customer	9
4.8 Complaints	9
4.9 Control of nonconforming testing and/or calibration work.....	9
4.10 Improvement	9
4.11 Corrective action	9
4.12 Preventive action.....	9
4.13 Control of records.....	9
4.14 Internal audits.....	9

4.15 Management reviews.....	9
5 Technical requirements for accreditation.....	10
5.1 General	10
5.2 Personnel	10
5.3 Accommodation and environmental conditions.....	10
5.4 Calibration methods and method validation.....	10
5.5 Equipment	10
5.6 Measurement traceability	10
5.7 Sampling	10
5.8 Handling of calibration items	10
5.9 Assuring the quality of calibration results.....	11
5.10 Reporting the results.....	11
6 Additional requirements.....	12
Annex A (normative) Optional addition to scope of compliance with ANSI/NCSL Z540-1-1994, Part I.....	13
Annex B (normative) Dimensional measurements	14
Annex C (normative) Time and frequency measurements	16

Foreword

The NIST Handbook 150 publication series sets forth the procedures, requirements, and guidance for the accreditation of testing and calibration laboratories by the National Voluntary Laboratory Accreditation Program (NVLAP). The series is comprised of the following publications:

- NIST Handbook 150, NVLAP Procedures and General Requirements, which contains the general procedures and requirements under which NVLAP operates as an unbiased third-party accreditation body;
- NIST Handbook 150-xx program-specific handbooks, which supplement NIST Handbook 150 by providing additional requirements, guidance, and interpretive information applicable to specific NVLAP laboratory accreditation programs (LAPs).

The program-specific handbooks are not stand-alone documents, but rather are companion documents to NIST Handbook 150. They tailor the general criteria found in NIST Handbook 150 to the specific tests, calibrations, or types of tests or calibrations covered by a LAP.

NIST Handbook 150-2, *NVLAP Calibration Laboratories*, presents the technical requirements and guidance for the accreditation of laboratories under the NVLAP Calibration Laboratories LAP. The 2016 edition of NIST Handbook 150-2 supersedes and replaces the following handbooks: 150-2A:2004, 150-2B:2004, 150-2C:2001, 150-2D:2004, 150-2E:2001, 150-2F:2003, 150-2G:2004, and 150-2H:2004.

The handbook was revised with the participation of technical experts in the eight fields of calibration: dimensional, electromagnetics – dc/low frequency, electromagnetics – rf/microwave frequency, time and frequency, ionizing radiation, mechanical, optical radiation, and thermodynamic.

The 2016 edition consolidates several technical guidance documents in the NIST Handbook 150-2 series into one document with a set of normative annexes:

- Annex A addresses the general accreditation requirements prescribed in ANSI/NCSL Z540-1-1994, *Calibration Laboratories and Measuring and Test Equipment – General Requirements, Part I* that are not directly addressed in ISO/IEC 17025:2005.
- Annex B sets out technical requirements not covered in NIST Handbook 150 that are applicable to a laboratory recognized as competent to carry out dimensional calibrations.
- Annex C sets out technical requirements not covered in NIST Handbook 150 that are applicable to a laboratory recognized as competent to carry out time and frequency calibrations.

Additional annexes covering the remaining fields of calibration will be published upon the completion of their review and updating. For areas where additional annexes have not yet been developed, it is suggested that laboratories follow best practices for those measurement areas.

Previously issued NVLAP lab bulletins pertaining to the Calibration Laboratories LAP have been incorporated into the appropriate clauses of the handbook. References and definitions have been updated, where necessary.

This handbook is also available on the NVLAP website (<http://www.nist.gov/nvlap>).

Questions or comments concerning this handbook should be submitted to NVLAP, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2140, Gaithersburg, MD, 20899-2140; phone: 301-975-4016; fax: 301-926-2884; e-mail: nvlap@nist.gov.

Introduction and acknowledgments

The Calibration Laboratories Accreditation Program was developed by the National Voluntary Laboratory Accreditation Program (NVLAP) at the National Institute of Standards and Technology (NIST) at the request of the National Conference of Standards Laboratories (now NCSL International). The goal of the program is to provide a means by which calibration laboratories can be assessed for competency. This voluntary program is not designed to impose specific calibration procedures or minimum uncertainties on applicant laboratories; instead, the program allows for all scientifically valid calibration schemes and requires that laboratories derive and document their calibration and measurement capabilities (CMCs).

In order to streamline program documentation, this handbook consolidates and replaces the previous technical guidance documents in the NIST Handbook 150-2 series. Clauses 4 and 5 of this handbook and the normative annexes include requirements for accreditation that are in addition to those found in ISO/IEC 17025. Annexes for the fields of calibration will be published as they are completed. Relevant guidance information that was contained in the previous NIST Handbook 150-2 series will be retained on the NVLAP website (<http://www.nist.gov/nvlap>).

The authors wish to thank the many NIST colleagues who provided numerous reviews and contributions to the revision of this handbook.

1 General information

1.1 Scope

1.1.1 This handbook specifies the technical requirements and provides guidance for the accreditation of laboratories under the NVLAP Calibration Laboratories Accreditation Program (Calibration LAP). It supplements the NVLAP procedures and general requirements found in NIST Handbook 150, by tailoring the general criteria found in NIST Handbook 150 to the specific calibrations and types of calibrations covered by the Calibration LAP.

1.1.2 NIST Handbook 150 and this handbook constitute the collective body of requirements that must be met by a laboratory seeking NVLAP accreditation for the Calibration LAP.

1.1.3 This handbook is intended for information and use by accredited calibration laboratories, assessors conducting on-site assessments, laboratories seeking accreditation, other laboratory accreditation systems, users of laboratory services, and others needing information on the requirements for accreditation under the Calibration LAP.

1.2 Organization of handbook

1.2.1 The numbering scheme used in clauses 4 and 5 of this handbook corresponds to that used in ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*. In some cases upper-level headings have been included with no additional text and refer the reader to ISO/IEC 17025 or to a specific annex.

1.2.2 The following annexes form a normative part of this handbook, meaning they contain provisions that laboratories must meet in order to conform to the requirements for accreditation:

- Annex A, Optional addition to scope of compliance with ANSI/NCSL Z540-1-1994, Part I;
- Annex B, Dimensional measurements;
- Annex C, Time and frequency measurements.

1.2.3 The word *shall* is used throughout this handbook and describes mandatory requirements for accreditation. The word *should* is used where guidance is provided but does not preclude other acceptable practices.

1.2.4 A note (shown as NOTE in a smaller font) contains additional information intended to assist the understanding or use of the document. Notes may provide clarification of the text, examples, and guidance; they do not contain requirements.

1.3 Program description

1.3.1 In 1994 the Calibration LAP officially began accepting applications for accreditation. Presently, the LAP encompasses eight fields of calibration covering a wide variety of parameters and includes accreditation in multifunction measuring and test equipment calibrations. Depending on the breadth of its calibration capabilities, a laboratory may seek accreditation for all or only selected parameters and/or calibrations offered in the Calibration LAP.

1.3.2 A laboratory may request to have parameters or calibrations added to the scope of the Calibration LAP. Any additions will be handled in accordance with NVLAP procedures for adding to or modifying an established LAP (see NIST Handbook 150, clause 2).

1.4 References

The following documents are referenced in this handbook and pertain to the overall calibration laboratories accreditation program. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) shall apply within one year of publication or within another time limit specified by regulations or other requirement documents.

References that are specific to a measurement field are listed in the appropriate annex of this handbook. Additional references are posted on the Calibration LAP webpage on the NVLAP website, <http://www.nist.gov/nvlap>.

- ANSI/NCCLI Z540.1-1994 (R2002), *Calibration Laboratories and Measuring and Test Equipment – General Requirements*
- BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML, *Guide to the Expression of Uncertainty in Measurement* (GUM)
- ILAC-P14:01/2013, *ILAC Policy for Uncertainty in Calibration*
- ISO/IEC 17043:2010, *Conformity assessment – General requirements for proficiency testing*
- ISO 80000-1:2009, *Quantities and units – Part 1: General laboratories*
- NIST Handbook 150, *NVLAP Procedures and General Requirements*

1.5 Terms and definitions

For the purposes of this handbook, the terms and definitions given in NIST Handbook 150 and the following apply.

1.5.1 measuring and test equipment (M & TE)

All of the measuring instruments, measurement standards, reference materials, auxiliary apparatus, and instructions that are necessary to perform a measurement. This term includes measuring equipment used in the course of testing and inspection, as well as that used in calibration.

NOTE In the context of this handbook, the term *measuring and test equipment* is taken to encompass *measurement instruments* and *measurement standards*. Moreover, a *reference material* is considered to be a type of *measurement standard*.

1.5.2 precision

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

1.5.3

uncertainty, Type A (evaluation of)

Method of evaluation of uncertainty by the statistical analysis of a series of observations.

1.5.4

uncertainty, Type B (evaluation of)

Method of evaluation of uncertainty by means other than the statistical analysis of a series of observations.

1.6 Program documentation

1.6.1 General

Assessors use NVLAP checklists to ensure that each laboratory receives an assessment comparable to that received by others. Checklists assist assessors in documenting the assessment to the NVLAP requirements found in NIST Handbook 150, ISO/IEC 17025, and this handbook. Checklists contain definitive statements or questions about all aspects of the NVLAP requirements for accreditation and form part of the on-site assessment report (see NIST Handbook 150). The current version of each checklist is available on the NVLAP website, <http://www.nist.gov/nvlap>.

1.6.2 NIST Handbook 150 Checklist

All NVLAP programs use the NIST Handbook 150 Checklist, which contains the requirements published in NIST Handbook 150 and ISO/IEC 17025. The checklist items are numbered to correspond to ISO/IEC 17025, clauses 4 and 5, and to NIST Handbook 150, annexes A, B, and E.

1.6.3 NIST Handbook 150-2 Checklist

The NIST Handbook 150-2 Checklist addresses the requirements specific to the Calibration LAP (also referred to as the Calibration LAP Program-Specific Checklist).

1.6.4 NVLAP Lab Bulletins

NVLAP Lab Bulletins are issued to laboratories and assessors, when needed, to clarify program-specific requirements and to provide information about program additions and changes.

2 LAP establishment, development, and implementation

This clause contains no information additional to that provided in NIST Handbook 150, clause 2.

3 Accreditation process

3.1 General

An overview of the laboratory accreditation process is provided in NIST Handbook 150, clause 3, and includes information pertaining to application for accreditation; on-site assessment; proficiency testing; accreditation decision; granting accreditation; renewal of accreditation; changes to scope of accreditation; monitoring visits; and suspension, denial, revocation, and voluntary termination of accreditation.

3.2 Management system review

There are no requirements additional to those set forth in NIST Handbook 150, 3.2.

3.3 On-site assessment

3.3.1 Overview

The on-site assessment process is described in NIST Handbook 150, 3.3. In most cases, the assessment of a calibration laboratory's full scope of accreditation requires several days at the laboratory's site with a team of assessors. The assigned team leader will coordinate activities with the laboratory and the assessment team.

3.3.2 Assessment of field locations

3.3.2.1 Many NVLAP-accredited laboratories provide calibrations in the field by sending a calibration technician from their main laboratory (the facility listed on the scope of accreditation) to a customer's site. When such a service is available for a given calibration, it is indicated on the scope of accreditation.

NOTE The additional requirements in this subclause do not apply to field service calibrations performed by staff based at the main laboratory.

3.3.2.2 When a laboratory has technical aspects of its accredited work being performed at a field location by staff not based at the laboratory's main facility, the following requirements for NVLAP accreditation in a) through g) shall apply.

- a) The laboratory shall demonstrate that all requirements of NIST Handbook 150 (other than the calibration) are being managed, performed, or otherwise controlled at the main facility. The management system documentation shall clearly cover the processes for managing the field operations and identify the personnel specifically authorized to perform calibrations at the field locations.
- b) For an initial accreditation of a calibration laboratory having one or more field locations, at least one field location will be visited by NVLAP. In addition, all field representatives shall be present at the initial assessment of the main facility.
- c) The laboratory shall have field representatives available at the main facility for renewal assessments. In advance of the assessment, NVLAP will notify the laboratory which, or how many, of the field representatives are to be present.
- d) During non-assessment renewal years, an assessment of a field representative shall be done at his or her usual location.
- e) The laboratory shall demonstrate that field personnel are trained at the main facility, by staff from the main facility, or by field-based training staff specifically trained at the main facility. The manner in which field personnel are trained shall be included in the training system documentation.
- f) Calibration reports shall be issued by the main facility, indicate the physical locations of the calibrations, and be signed by approved signatories.

- g) The laboratory shall have a defined interlaboratory comparison program between its headquarters and field locations.

3.4 Proficiency testing

3.4.1 General

Proficiency testing (PT) is an important tool to demonstrate laboratory competence and to assist with maintaining the quality of a laboratory's performance. When NVLAP determines that testing is available and relevant to the proposed scope of accreditation, applicant laboratories are required to successfully complete proficiency testing prior to accreditation.

Current information about the proficiency testing requirements for the Calibration LAP is available on the NVLAP website at <http://www.nist.gov/nvlap>.

3.4.2 Laboratory PT plans

3.4.2.1 Accredited calibration laboratories shall develop a proficiency testing participation plan, describing how the laboratory will meet requirements for minimum participation in PT as defined below. This plan shall reflect the laboratories' planned activities that provide continuing evidence that technical competence is being maintained through inter- or intra-laboratory measurement comparisons. Determining the frequency of performing proficiency testing is dependent upon the measurement field, uncertainty, parameter, and the level of risk associated with those parameters.

3.4.2.2 With each renewal of accreditation, an accredited calibration laboratory shall provide an updated PT participation plan, including evidence that planned activities have been completed. NVLAP reviews the plan and works with the laboratory to ensure that it adequately covers the scope of accreditation.

3.4.2.3 The laboratory shall regularly review the PT plan in response to changes in scope, staffing, methodology, instrumentation, etc. The review shall include a review the Calibration LAP webpage (see <http://www.nist.gov/nvlap>) for up-to-date PT activity information and requirements.

NOTE Review of the PT plan can occur as part of the management review process.

3.4.3 Acceptable PT activities

3.4.3.1 Calibration proficiency tests may be organized by NVLAP in consultation with NIST experts for parameters where laboratories are operating at or near NIST uncertainties. Where laboratory uncertainties do not warrant this level of proficiency testing, NVLAP may accept proficiency testing provided by third-party vendors or organized by the laboratory itself where such tests are commensurate with the laboratory's stated level of uncertainty.

3.4.3.2 NVLAP accepts results from laboratories that have participated in proficiency tests not arranged by NVLAP when:

- a) PT providers are accredited to ISO/IEC 17043 for the parameter being tested at the uncertainty level of that test, and
- b) that accreditation to ISO/IEC 17043 is issued by a body which is signatory to a mutual recognition arrangement (MRA) for proficiency testing accreditation in a regional body recognized by the International Laboratory Accreditation Cooperation (ILAC).

3.4.3.3 PT providers that are not accredited should meet the requirements of ISO/IEC 17043, where applicable. Acceptability of such providers and proficiency tests will be determined by NVLAP in consultation with the laboratory.

3.4.4 NVLAP PT requirements

Unless it has been determined by NVLAP that other planned PT activities (e.g., ILC) are acceptable, laboratories shall meet the following requirements:

- a) Where NVLAP provides coordination for PT, a laboratory accredited for the parameter and range within the specified uncertainty for the test shall participate.
- b) When an ISO/IEC 17043-accredited proficiency test exists, or NVLAP has identified and accepts an independent PT program, for a given parameter and range of uncertainties, NVLAP may require participation if the parameter and range are on the laboratory's scope of accreditation.
- c) A laboratory shall meet any additional PT requirements stated in the annexes in this handbook related to the parameter(s) for which it is accredited.
- d) The E-normal value (E_n) shall be reported for each measurement result, where applicable.

E_n numbers are calculated using the equation:

$$E_n = \frac{x - X}{\sqrt{U_{lab}^2 + U_{ref}^2}}$$

where:

x is the participant's result;

X is the reference value;

U_{lab} is the expanded uncertainty of the participant's result; and

U_{ref} is the expanded uncertainty of the reference value.

$|E_n| \leq 1.0$ indicates "satisfactory" performance

$|E_n| > 1.0$ indicates "unsatisfactory" performance

NOTE Reports of PT activities that NVLAP coordinates may be shared with other parties. In such cases, the identity and performance of individual laboratories are kept confidential.

NOTE Where the proficiency test has multiple E_n values for a range of measurements, allowance for a number of individual measurement E_n to be greater than 1 may be applied. This allowance is based on the coverage probability of 95 % as long as sufficient (typically 10 or more) measurement points are taken for determination.

3.5 Laboratories seeking accreditation for calibrations with uncertainties near those provided by a national metrology institute (NMI)

There are additional requirements in cases where laboratories are seeking accreditation for calibrations with uncertainties deemed by NVLAP to be near those provided by an NMI. These requirements include assessment by an NMI expert, detailed review of uncertainty budgets by NIST technical experts, and proficiency testing of rigor comparable to an NMI key comparison.

3.6 Policy on scopes of accreditation of calibration laboratories¹

3.6.1 The scope of accreditation of an accredited calibration laboratory shall include the calibration and measurement capability (CMC) expressed in terms of:

- a) measurand;
- b) calibration/measurement method/procedure and/or type of instrument to be calibrated/measured;
- c) measurement range and additional parameters where applicable, e.g., frequency of applied voltage;
- d) uncertainty of measurement.

3.6.2 There shall be no ambiguity on the expression of the CMC on the scopes of accreditation and, consequently, on the smallest uncertainty of measurement that can be expected to be achieved by a laboratory during a calibration or a measurement. Particular care should be taken when the measurand covers a range of values. This is generally achieved through employing one or more of the following methods for expression of the uncertainty:

- a) a single value, which is valid throughout the measurement range;
- b) a range, in which case a calibration laboratory should have proper assumptions for the interpolation to find the uncertainty at intermediate values;
- c) an explicit function of the measurand or a parameter;
- d) a matrix where the values of the uncertainty depend on the values of the measurand and additional parameters;
- e) a graphical form, providing there is sufficient resolution on each axis to obtain at least two significant figures for the uncertainty.

Open intervals (e.g., “ $U < x$ ”) are not allowed in the specification of uncertainties.

NOTE In order to harmonize scopes within NVLAP, NVLAP may require a specific form of expressing range and/or uncertainty of measurement for any given parameter.

3.6.3 The uncertainty covered by the CMC shall be expressed as the expanded uncertainty having a specific coverage probability of approximately 95 %. The unit of the uncertainty shall always be the same

¹ ILAC-P14:01/2013, *ILAC Policy for Uncertainty in Calibration*.

as that of the measurand or in a term relative to the measurand, e.g., percent. Usually the inclusion of the relevant unit gives the necessary explanation. This is excepted where U.S. industry practice dictates a specific expression of uncertainty.

3.6.4 Calibration laboratories shall provide evidence that they can provide calibrations to customers in compliance with 3.6.1 b) so that measurement uncertainties equal those covered by the CMC. In the formulation of CMC, laboratories shall take notice of the performance of the “best existing device” that is available for a specific category of calibrations.

A reasonable amount of contribution to uncertainty from repeatability shall be included and contributions due to reproducibility should be included in the CMC uncertainty component, when available. There should, on the other hand, be no significant contribution to the CMC uncertainty component attributable to physical effects that can be ascribed to imperfections of even the best existing device under calibration or measurement.

It is recognized that for some calibrations a “best existing device” does not exist and/or contributions to the uncertainty attributed to the device significantly affect the uncertainty. If such contributions to uncertainty from the device can be separated from other contributions, then the contributions from the device may be excluded from the CMC statement. For such a case, however, the scope of accreditation shall clearly identify that the contributions to the uncertainty from the device are not included.

NOTE 1 The term “best existing device” is understood as a device to be calibrated that is commercially or otherwise available for customers, even if it has a special performance (stability) or has a long history of calibration.

4 Management requirements for accreditation

4.1 Organization

There are no requirements additional to those set forth in ISO/IEC 17025.

4.2 Management system

There are no requirements additional to those set forth in ISO/IEC 17025.

4.3 Document control

There are no requirements additional to those set forth in ISO/IEC 17025.

4.4 Review of requests, tenders and contracts

When a calibration certificate contains a statement of compliance with a metrological specification, with or without the measurement result(s) and uncertainty (see section 5.10.3 of this Handbook), the calibration laboratory shall notify the customer in writing:

- a) that the uncertainty of measurement will be taken into account when issuing the statement of compliance;
- b) of the laboratory’s procedure for measurement uncertainty in statements of compliance (see section 5.4.1 of this Handbook); and

- c) that, when measurement results and associated uncertainties are not reported, the item calibrated is not intended for further dissemination of traceability (i.e., to calibrate another device), and the measurement results and associated uncertainties are available upon request.

4.5 Subcontracting of tests and calibrations

There are no requirements additional to those set forth in ISO/IEC 17025.

4.6 Purchasing services and supplies

There are no requirements additional to those set forth in ISO/IEC 17025.

4.7 Service to the customer

There are no requirements additional to those set forth in ISO/IEC 17025.

4.8 Complaints

There are no requirements additional to those set forth in ISO/IEC 17025.

4.9 Control of nonconforming testing and/or calibration work

There are no requirements additional to those set forth in ISO/IEC 17025.

4.10 Improvement

There are no requirements additional to those set forth in ISO/IEC 17025.

4.11 Corrective action

There are no requirements additional to those set forth in ISO/IEC 17025.

4.12 Preventive action

There are no requirements additional to those set forth in ISO/IEC 17025.

4.13 Control of records

There are no requirements additional to those set forth in ISO/IEC 17025.

4.14 Internal audits

There are no requirements additional to those set forth in ISO/IEC 17025.

4.15 Management reviews

There are no requirements additional to those set forth in ISO/IEC 17025.

5 Technical requirements for accreditation

5.1 General

There are no requirements additional to those set forth in ISO/IEC 17025.

5.2 Personnel

For information regarding personnel requirements in a specific technical area, see the annex associated with that area.

5.3 Accommodation and environmental conditions

For information regarding accommodation and environmental conditions requirements in a specific technical area, see the annex associated with that area.

5.4 Calibration methods and method validation

5.4.1 When a laboratory offers calibration certificates that contain a statement of compliance with a metrological specification, the laboratory shall have a procedure describing how uncertainty is taken into account in the compliance determination.

NOTE The procedure should convey possible level(s) of risk associated with determination of compliance. The procedure may point to current national or international standards or guidance documents on this subject to meet this requirement.

5.4.2 For information regarding the requirements for calibration methods and their selection in a specific technical area, see the annex associated with that area.

5.5 Equipment

For information regarding equipment requirements in a specific technical area, see the annex associated with that area.

5.6 Measurement traceability

For information regarding measurement traceability requirements in a specific technical area, see the annex associated with that area.

5.7 Sampling

There are no requirements additional to those set forth in ISO/IEC 17025.

5.8 Handling of calibration items

For information regarding requirements for the handling of calibration items in a specific technical area, see the annex associated with that area.

5.9 Assuring the quality of calibration results

For information regarding requirements for the assurance of the quality of calibration results in a specific technical area, see the annex associated with that area.

NOTE Actions taken to investigate proficiency testing nonconformities should be commensurate with the number and nature of outlying results. For example, if less than 5 % of all measurements made for a given PT have an $|E_n| > 1$, extensive corrective action may not be required. If the PT results cast doubt on calibration certificates issued by the laboratory, not only would root cause analysis and corrective action be required, but also evidence that the laboratory implemented its procedures for control of nonconforming work.

5.10 Reporting the results²

5.10.1 All content of certificates or reports of calibration shall conform to the requirements of ISO/IEC 17025.

5.10.2 All certificates or reports of calibration shall contain an uncertainty statement which is scientifically determined from measurement data and which agrees with the laboratory's stated definition, except as described in 5.10.3.

5.10.3 By exception, and where it has been established during contract review that only a statement of compliance with a specification is required, then the measured quantity value and/or the measurement uncertainty may be omitted on the calibration certificate. In such cases, the laboratory shall meet the requirements in 4.4. Additional requirements may be in the annexes of this handbook. In addition, the following information shall be included on the certificate:

- a) a statement that the item calibrated is not intended for further dissemination of traceability (i.e., used to calibrate another device), thereby meeting the requirements of ILAC P14:01/2013, 6.1; and
- b) a statement that the measurement results, uncertainties, and procedure for applying uncertainty to the statement of compliance are available upon request.

5.10.4 Uncertainty shall be reported in accordance with the following:

- a) The measurement result shall normally include the measured quantity value y and the associated expanded uncertainty U . In calibration certificates the measurement result should be reported as $y \pm U$ associated with the units of y and U . Tabular presentation of the measurement result may be used and the relative expanded uncertainty $U / |y|$ may also be provided if appropriate. The coverage factor and the coverage probability shall be stated on the calibration certificate. To this an explanatory note shall be added, which may have the following content:

“The reported expanded uncertainty of measurement (U) is stated as the standard uncertainty of measurement multiplied by the coverage factor k such that the coverage probability corresponds to approximately 95 %.”

² ILAC-P14:01/2013, *ILAC Policy for Uncertainty in Calibration*.

NOTE For asymmetrical uncertainties other presentations than $y \pm U$ may be needed. This concerns also cases when uncertainty is determined by Monte Carlo simulations (propagation of distributions) or with logarithmic units.

- b) The numerical value of the expanded uncertainty shall be given to, at most, two significant figures. Further the following applies:
 - 1) The numerical value of the measurement result shall in the final statement be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result.
 - 2) For the process of rounding, the usual rules for rounding of numbers shall be used, subject to the guidance on rounding provided in Section 7 of the GUM.

NOTE For further details on rounding, see ISO 80000-1:2009.

- c) Contributions to the uncertainty stated on the calibration certificate shall include relevant short-term contributions during calibration and contributions that can reasonably be attributed to the customer's device. Where applicable, the uncertainty shall cover the same contributions to uncertainty that were included in evaluation of the CMC uncertainty component, except that uncertainty components evaluated for the best existing device shall be replaced with those of the customer's device. Therefore, reported uncertainties tend to be larger than the uncertainty covered by the CMC. Random contributions that cannot be known by the laboratory, such as transport uncertainties, should normally be excluded in the uncertainty statement. If, however, a laboratory anticipates that such contributions will have significant impact on the uncertainties attributed by the laboratory, the customer should be notified according to the general clauses regarding tenders and reviews of contracts in ISO/IEC 17025.
- d) As the definition of CMC implies, accredited calibration laboratories shall not report a smaller uncertainty of measurement than the uncertainty of the CMC for which the laboratory is accredited.

5.10.5 For information regarding requirements on reporting of results in a specific technical area, see the annex associated with that area.

6 Additional requirements

The following annexes contain requirements that are specific to each technical program area and its associated calibration methods.

Annex A

(normative)

Optional addition to scope of compliance with ANSI/NCSL Z540-1-1994, Part I

A.1 General

This annex addresses the general accreditation requirements prescribed in ANSI/NCSL Z540-1-1994, *Calibration Laboratories and Measuring and Test Equipment – General Requirements, Part I* that are not directly addressed in ISO/IEC 17025:2005. Laboratories wishing to be recognized for compliance with the requirements of ANSI/NCSL Z540-1-1994, Part I shall meet the requirements listed below, in addition to those found in NIST Handbook 150 and this handbook.

A.2 Management requirements for accreditation

A.2.1 The quality manual and/or related documentation shall contain the laboratory's scope of calibrations and/or verifications.

A.2.2 The quality system adopted to satisfy the requirements of ANSI/NCSL Z540-1-1994 shall be reviewed at least once a year by the management to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements.

A.3 Calibration methods and method validation

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

A.4 Equipment

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

A.5 Reporting the results

In addition to the list of required items in 5.10.2 of ISO/IEC 17025, each certificate or report shall include a statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.

Annex B **(normative)**

Dimensional measurements

B.1 General

This annex contains specific technical requirements not covered in NIST Handbook 150 that are applicable to a laboratory recognized as competent to carry out dimensional calibrations.

The dimensional calibration areas currently included in the accreditation program are:

- a) Angular
- b) Ring Gages
- c) Gage Blocks
- d) Laser Frequency/Wavelength
- e) Length & Diameter
- f) Step Gages
- g) Line Standards
- h) Measuring Wires
- i) Optical Reference Planes
- j) Roundness, Sieves
- k) Spherical Diameter
- l) Plug/Ring Gages
- m) Surface Texture
- n) Surveying Rods and Tapes
- o) Threaded Plug & Ring Gages
- p) Two Dimensional Gages
- q) Coordinate Measuring Machines
- r) Film Thickness Standards
- s) Gears

t) Angle of Optical Rotation.

B.2 Accommodation and environmental conditions

B.2.1 Measurement results are generally reported as the length at 20 °C. If measurements are made at temperatures other than 20 °C, the uncertainties of the appropriate thermal corrections for the artifacts shall be included in the total uncertainty. For comparison measurements, the uncertainty component shall reflect the uncertainty in the thermal corrections of both the master and unknown artifacts, as well as the temperature difference between them, and the uncertainty of the temperature sensor used.

B.2.2 The temperature stability of the environment shall be sufficient for the gage and measurement system to be in thermal equilibrium. If measurements are made in slowly changing environments, a suitable measurement model, which includes the effects of the drift, shall be used. Theoretical and experimental verification of the model should be available.

B.2.3 For typical gages made of well-characterized materials (steel, carbide, or ceramic), $\pm 10\%$ shall be used as the standard uncertainty of the thermal expansion coefficient unless there is documentation of a lower value.

B.2.4 The laboratory shall have a documented policy regarding responses to environmental conditions outside of specified range.

B.3 Equipment

B.3.1 The laboratory shall have temperature-measuring capabilities suitable for the calibration procedure and the desired measurement uncertainty.

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

B.3.2 A laboratory that makes mechanical comparisons of masters and test pieces of dissimilar materials shall have force measuring equipment to determine the force on the probe or probes. A correction for differential probe penetration should be applied as long as the probe has maintained its desired geometry.

Annex C

(normative)

Time and frequency measurements

C.1 General

This annex contains specific technical requirements not covered in NIST Handbook 150 that are applicable to a laboratory recognized as competent to carry out time and frequency calibrations.

The time and frequency calibration areas currently included in the accreditation program are:

a) Frequency dissemination

- 1) Information regarding assessment of the quality system used by the calibration service provider;
- 2) Frequency standards
- 3) Frequency accuracy of signal generators, counters, spectrum and network analyzers
- 4) Time accuracy of data loggers and recorders
- 5) Time base of oscilloscopes
- 6) Any other measurement that tests accuracy of frequency measured or generated
- 7) Any other device that creates or reads time difference except stop watches and timers

b) Time dissemination

Devices that accurately read time of day

NOTE Differential timing devices are under frequency.

c) Oscillator characterization

- 1) AM, FM, PM, or any other type of modulation's accuracy of modulation magnitude
- 2) Residual modulation of any modulation type
- 3) Various noise measurements of phase or amplitude
- 4) Various forms of distortion such as harmonic and intermodulation.

d) Pulse waveform

- 1) Rise and Fall Time
- 2) Aberrations

- e) Stopwatches and timers.

C.2 Measurement traceability

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

NOTE This is normally demonstrated by calibration of a high-speed oscilloscope or calibration of a fast-rise generator by an external source meeting the requirements in NIST Handbook 150, Annex B.

C.2.2 Laboratories that utilize a Global Positioning System Disciplined Oscillator (GPSDO) to establish traceability shall:

- a) have procedures in place to ensure GPS is locked and working properly;
- b) consider the internal oscillator's short-term stability and measurement time in the laboratory's reported uncertainty.