American National Standard
for Calibration —

Calibration Laboratories and Measuring and Test Equipment — General Requirements

Secretariat

National Conference of Standards Laboratories

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American National Standard

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Foreword (This foreword is not part of American National Standard ANSI/NCSL Z540-1-1994.

This Standard is written for a Purchaser or a Supplier, both terms being interpreted in the broadest sense. The "Supplier" may be a manufacturer, an installer or a servicing organization responsible for providing a product or a service. The "Purchaser" may be a procurement authority or a customer using a product or service.

Reference to this Standard may be made:

by a Purchaser when specifying products or services required;
by a Supplier when specifying products or services offered;
by agencies as a contractual condition for procurement;
in assessment and audit of laboratories.

This Standard provides a mechanism for promoting confidence in calibration laboratories and measuring and test equipment when it can be shown that they are operated in compliance with its requirements.

This Standard is specific to calibration laboratories and measuring and test equipment

The intent of this Standard is that laboratories meeting its requirements comply, for calibration activities, with the relevant requirements of the ISO 9000 series (ANSI/ASQC Q90 series) of standards, including those of the model described in ISO 9002 (ANSI/ASQC Q92) when they are acting as suppliers producing calibration results. This Standard includes the requirements relevant to calibration laboratories of ISO/IEC Guide 25 (1990) and requirements relevant to the quality assurance of measuring and test equipment derived from Mil-Std 45662A.

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee on General Requirements for Calibration Laboratories and Measuring and Test Equipment, Z540. Committee approval of this standard does not necessarily imply that all committee members voted for its approval. At the time it approved this standard, the Z540 Committee had the following members:

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American National Standard for Calibration —

Calibration Laboratories and Measuring and Test Equipment — General Requirements

Scope

1.1 Part I of this Standard sets out the general requirements in accordance with which a calibration laboratory must demonstrate that it operates, if it is to be recognized as competent to carry out specific calibrations. Part I applies to calibration laboratories in the development and implementation of their quality system.

1.2 Part II of this Standard sets out quality assurance requirements for a Supplier's system to control the accuracy of the measuring and test equipment used to assure that supplies and services comply with prescribed requirements.

1.3 The role of the Purchaser in monitoring a Supplier's compliance with the requirements of this Standard may be fulfilled by a third party, such as an accreditation or certification body.

1.4 This Standard and any procedure or document executed in implementation thereof shall be in addition to and not weaken or detract from other contract requirements.

2 References

ISO 8402 1986, *Quality - Vocabulary*

ISO/IEC Guide 2 : 1986, *General terms and their definitions concerning standardization and related activities.*

International vocabulary of basic and general terms in metrology (VIM) : 1993, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML.

ISO 9000 Series : 1987 (ANSI/ASQC Q90 Series), *Quality management and quality assurance standards.*

ISO/IEC Guide 25 : 1990, *General requirements for the competence of calibration and testing laboratories.*

ISO Guide 30 : 1981, *Terms and definitions used in connection with reference materials.*

MIL-STD 45662A 1988, *Calibration Systems Requirement.*

Guide to the Expression of Uncertainty in Measurement: 1993, issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, and OIML.

3 Definitions

The relevant definitions from ISO/IEC Guide 2, ISO 8402, ISO Guide 30, and the *International vocabulary of basic and general terms in metrology* (VIM) are applicable, the most relevant being quoted below together with further definitions applicable for the purpose of this Standard.

3.1 calibration: The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, and the corresponding standard or known values derived from the standard.

NOTES -

1) The result of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system, or the assignment of values to marks on arbitrary scales.

2) A calibration may also determine other metrological properties.

3) The result of a calibration may be recorded in a document, sometimes called a **calibration certificate** or a **calibration report.**

4) The result of a calibration is sometimes expressed as a **calibration factor**, or as a series of calibration factors in the form of a **calibration curve.**

3.2 calibration certificate or report: Document that presents calibration results and other information relevant to a calibration.

3.3 calibration method: Defined technical procedure for performing a calibration or verification.

3.4 certified reference material (CRM): A reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

3.5 interlaboratory comparisons: Organization, performance and evaluation of calibrations on the same or similar items by two or more laboratories in accordance with predetermined conditions.

3.6 international (measurement) standard: A standard recognized by an international agreement to serve internationally as the basis for fixing the value of all other standards of the quantity concerned.

3.7 influence quantity: A quantity which is not the subject of the measurement but which influences the value of the measurand or the indication of the measuring instrument.

Examples: ambient temperature; frequency of an alternating measured voltage.

3.8 laboratory/calibration laboratory: Body that calibrates or performs calibrations and verifications.

NOTES -

1) In cases where a laboratory forms part of an organization that carries out other activities besides calibration, the term "laboratory" refers only to those parts of that organization that are involved in the calibration process.

2) As used herein, the term "laboratory" refers to a body that carries out calibration at or from a permanent location, at or from a temporary facility, or in or from a mobile facility.

3.9 limits of permissible error (of a measuring instrument): The extreme values of an error permitted by specifications, regulations, etc. for a given measuring instrument.

NOTE - This term is frequently referred to as "tolerance" in the United States.

3.10 measurand A quantity subjected to measurement.

NOTE - As appropriate, this may be the "measured quantity" or the "quantity to be measured."

3.11 measurement: The set of operations having the object of determining the value of a measurand.

3.12 measurement assurance: Measurement assurance is a technique that may include, but is not limited to: 1) use of good experimental design principles so 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.

3.13 measurement standard: A material measure, measuring instrument, reference material or system intended to define, realize, conserve or reproduce a unit or one or more known values of a quantity to serve as a reference.

3.14 measuring and test equipment: All of the measuring instruments, measurement standards, reference materials, and auxiliary apparatus 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 Standard, the term "measuring and test equipment" is taken to encompass "measuring instruments" and "measurement standards". Moreover, a

"reference material" is considered to be a type of "measurement standard".

3.15 measuring instrument: A device intended to make a measurement, alone or in conjunction with supplementary equipment.

3.16 mutual consent standard: An artifact or process that is used as a de facto standard by mutual consent of the supplier and customer when no recognized U.S. national standard is available.

3.17 national (measurement) standard: A standard recognized by an official national decision to serve, in a country, as the basis for fixing the value of all other standards of the quantity concerned.

3.18 proficiency testing: Determination of the laboratory calibration performance by interlaboratory comparisons or other means.

3.19 (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.

NOTE - The quality audit typically applies to, but is not limited to, a quality system or elements thereof, to processes, to products, or to services. Such audits are often called "quality system audit", "process quality audit", "product quality audit", "service quality audit".

3.20 quality manual: A document stating the quality policy, quality system and quality practices of an organization.

NOTE - The quality manual may call up other documentation relating to the laboratory's quality arrangements.

3.21 quality system: The organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

3.22 (quality system) review: A formal evaluation by management of the status and adequacy of the quality system in relation to quality policy and new objectives resulting from changing circumstances.

3.23 reference material: A material or substance of which one or more properties are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

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

3.25 requirement: A translation of the needs into a set of individual quantified or descriptive specifications for the characteristics of an entity in order to enable its realization and examination.

3.26 **traceability:** The property of a result of a measurement whereby it can be related to appropriate standards, generally national or international standards, through an unbroken chain of comparisons.

3.27 uncertainty of measurement: Parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

3.28 **verification:** Evidence by calibration that specified requirements have been met.

NOTES -

1) In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values are consistently smaller than the limits of permissible error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

2) The result of verification leads to a decision either to restore to service, or to perform adjustments, or to repair, or to downgrade, or to declare obsolete. In all cases documentation of the verification performed is kept on the measuring instrument's individual record.

3) The term "verification," as defined in this Standard is frequently referred to as "calibration" in the United States.

PART I GENERAL REQUIREMENTS FOR THE COMPETENCE OF CALIBRATION LABORATORIES

Part I of this Standard applies to calibration laboratories in the development and implementation of their quality system.

4 Organization and management

4.1 The laboratory shall be legally identifiable. It shall be organized and shall operate in such a way that its permanent, temporary and mobile facilities meet the requirements of this Standard.

4.2 The laboratory shall:

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

b) have arrangements to ensure that its personnel are free from any undue pressures which might adversely affect the quality of their work;

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

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

e) provide supervision by persons familiar with the calibration methods and procedures, the objective of the calibration and the assessment of the results. Management practices shall be such as to ensure adequate supervision;

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

g) have a quality manager (however named) who has responsibility for the quality system and its implementation. The quality manager shall have direct access to the highest level of management at which decisions are taken on laboratory policy or resources, and to the technical manager. In some laboratories, the quality manager may also be the technical manager or deputy technical manager;

h) designate alternates in case of absence of the technical or quality manager;

i) where relevant, have documented policy and procedures to ensure the protection of customer's confidential information and proprietary rights;

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

5 Quality system, audit and review

5.1 The laboratory shall establish and maintain a quality system appropriate to the type, range and volume of calibration activities it undertakes. The elements of this system shall be documented. The quality documentation shall be available for use by the laboratory personnel. The laboratory shall define and document its policies and objectives for, and its commitment to, good laboratory practice and quality of calibration services. The laboratory management shall ensure that these policies and objectives are documented in a quality manual and communicated to, understood, and implemented by all laboratory personnel concerned. The quality manual shall be maintained current under the responsibility of the quality manager.

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

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

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

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

d) procedures for control and maintenance of documentation;

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

f) identification of the laboratory's approved signatories (where this concept is appropriate);

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

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

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

j) reference to the calibration and verification procedures used;

k) procedures for handling calibration and verification items;

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

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

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

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

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

q) procedures for dealing with complaints;

r) procedures for protecting confidentiality and proprietary rights;

s) procedures for audit and review;

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

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

5.3 The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such audits shall be carried out by trained and qualified staff who are, wherever possible, independent of the activity to be audited. Where the audit findings cast doubt on the correctness or validity of the laboratory's calibration results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any customer whose work may have been affected.

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

5.5 All audit and review findings and any corrective actions that arise from them shall be documented. The person responsible for quality shall ensure that these actions are discharged within the agreed timeframe.

5.6 In addition to periodic audits the laboratory shall ensure the quality of results provided to customers by implementing checks. These checks shall be reviewed and shall include, as appropriate, but not be limited to:

a) internal quality control using, whenever possible, statistical techniques;

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

b) participation in proficiency testing and other interlaboratory comparisons;

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

d) replicate measurements using the same or different methods;

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

6 Personnel

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

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

6.3 Records on the relevant qualifications, training, skills and experience of the technical personnel shall be maintained and be available to the laboratory.

7 Accommodation and environment

7.1 Laboratory accommodation (facilities), calibration areas, energy sources, lighting, temperature, humidity, and ventilation shall be such as to facilitate proper performance of calibrations/verifications.

7.2 The environment in which these activities are undertaken shall be specified and not invalidate the results or adversely affect the required uncertainty of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

7.3 The laboratory shall effectively monitor, control and record environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, line voltage, temperature, and sound and vibration levels, as appropriate to the calibrations concerned.

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

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

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

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

8 Equipment and reference materials

8.1 The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of calibrations/verifications. In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the relevant requirements of this Standard are met.

8.2 All equipment shall be properly maintained. Maintenance procedures shall be documented. Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration or verification to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations.

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

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

a) the name of the item of equipment;

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

c) current location, where appropriate;

d) where applicable, dates and results of calibration and/or verifications and date or criteria when the calibration and/or verification expires;

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

f) history of any damage, malfunction, modification or repair;

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

9 Measurement traceability and calibration

9.1 All measuring and testing equipment having an effect on the accuracy or validity of calibrations shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment to ensure the recall or removal from service of any standard or equipment which has exceeded its calibration interval or is otherwise judged to be unreliable.

9.2 The overall program of calibration and/or verification of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national, international, or intrinsic standards of measurement where available. Calibration certificates and/or reports shall, wherever applicable, state the traceability to national, international, or intrinsic standards of measurement and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

NOTE - A significant number of intrinsic standards such as the Josephson Array Voltage Standard and the Iodine-Stabilized Helium-Neon Laser Length Standard have been developed and are now being used by many national standards laboratories and some industrial laboratories. These standards are based on well characterized laws of physics, fundamental constants of nature, or invariant properties of materials and make ideal stable, precise, and accurate measurement standards if properly designed, characterized, operated, monitored and maintained. Where intrinsic standards are used, the laboratory should demonstrate by measurement assurance techniques, interlaboratory comparisons, or other suitable means that its intrinsic standard measurement results are correlated with those of national or international standards.

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

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

b) internationally accepted standards in the field concerned;

c) suitable reference materials;

d) ratio or reciprocity-type measurements; or

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

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

9.5 Reference standards of measurement shall be calibrated by a competent body that can provide traceability as described in 9.2 or 9.3. There shall be a program of calibration and verification for reference standards.

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

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

10 Calibration methods

10.1 The laboratory shall have documented instructions on the use and operation of all relevant equipment, on the handling and preparation of items, and for calibration/verification, where the absence of such instructions could jeopardize the calibrations/verifications. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be maintained up-to-date and be readily available to the staff.

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

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

b) The laboratory shall ensure that the calibration uncertainties are sufficiently small so that the adequacy of the measurement is not affected. Well defined and documented measurement assurance techniques or uncertainty analyses may be used to verify the adequacy of a measurement process. If such techniques or analyses are not used, then the collective uncertainty of the measurement standards shall not exceed 25% of the acceptable tolerance (e.g., manufacturer's specification) for each characteristic of the measuring and test equipment being calibrated or verified.

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

10.4 Where it is necessary to employ methods that have not been well established, these shall be subject to agreement with the customer, be fully documented and validated, and be available to the customer or other recipients of the relevant reports.

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

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

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

a) the requirements of this Standard are complied with;

b) computer software is documented and adequate for use;

c) procedures are established and implemented for protecting the integrity of data; such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission and data processing;

d) computer and automated equipment is maintained to ensure proper functioning and provided with the environmental and operating conditions necessary to maintain the integrity of calibration data;

e) it establishes and implements appropriate procedures for the maintenance

of security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

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

Handling of calibration items

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

11.2 Upon receipt of the calibration item, any abnormalities or departures from standard condition as prescribed in the relevant calibration method shall be recorded. Where there is any doubt as to the item's suitability for calibration, where the item does not conform to the description provided, or where the calibration required is not fully specified, the laboratory shall consult the customer for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the customer requires preparation to be undertaken or arranged by the laboratory.

11.3 The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the calibration item, during storage, handling, preparation, and calibration; any relevant instructions provided with the item shall be followed. Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded where necessary. Where a calibration item or portion of an item is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

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

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

12 Records

12.1 The laboratory shall maintain a record system to suit its particular circumstances and comply with any applicable regulations. The records for each calibration shall contain sufficient information to permit the repetition of the calibration. The records shall include the identity of personnel involved in preparation and calibration.

12.2 All records (including those listed in 8.4 pertaining to calibration equipment), certificates and reports shall be safely stored and held secure and in confidence to the customer for the period specified in the quality manual.

13 Certificates and reports

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

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

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

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

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

d) name and address of customer, where appropriate;

e) description and unambiguous identification of the item calibrated;

f) characterization and condition of the calibration item;

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

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

i) reference to sampling procedure, where relevant;

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

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

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

m) a signature and title, or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and date of issue;

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

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

p) special limitations of use; and

q) traceability statement

13.3 Where the certificate or report contains results of calibrations performed by sub-contractors, these results shall be clearly identified.

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

13.5 Material amendments to a calibration report or calibration certificate after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Calibration Report [or Calibration Certificate], serial number... [or as otherwise identified]", or equivalent form of wording. Such amendments shall meet all the relevant requirements of 13.2 of this Standard.

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

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

b) any customer's measuring and test equipment found significantly out-of-tolerance during the calibration/verification process. Measurement data shall be reported so that appropriate action can be taken.

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

14 Sub-contracting of calibration

14.1 Where a laboratory sub-contracts any part of the calibration, this work shall be placed with a laboratory complying with the requirements of this Standard. The laboratory shall ensure and be able

to demonstrate that its sub-contractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory with respect of the work being sub-contracted. The laboratory shall advise the customer of its intention to sub-contract any portion of the calibration to another party.

14.2 The laboratory shall record and retain details of its investigation of the competence and compliance of its sub-contractors and maintain a register of all sub-contracting.

15 Outside support services and supplies that affect calibration results

15.1 Where the laboratory procures outside services and supplies, other than those referred to in this Standard, in support of calibrations, the laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's calibrations.

15.2 Where no independent assurance of the quality of outside support services or supplies is available, the laboratory shall have procedures to ensure that purchased equipment, materials and services comply with specified requirements. The laboratory should, wherever possible, ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with any standard specifications relevant to the calibrations concerned.

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

16 Complaints

16.1 The laboratory shall have documented policy and procedures for the resolution of complaints received from customers or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

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

PART II QUALITY ASSURANCE REQUIREMENTS FOR MEASURING AND TEST EQUIPMENT (M&TE)

Part II of this Standard applies to the control of measuring and test equipment (M&TE) used to assure that supplies and services comply with prescribed customer requirements.

17 General requirements

17.1 The supplier shall establish and document a system to control the calibration/verification of M&TE.

17.2 M&TE used to determine compliance with customer technical specifications shall be calibrated or verified in accordance with Part I of this Standard.

17.3 The supplier shall have a program to recall for calibration or verification, or remove from service, M&TE that has exceeded its calibration interval, has broken calibration seals, or is suspected to be malfunctioning because of mishandling, misuse, or unusual results.

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

17.5 The supplier shall carry out or arrange to be carried out, periodic quality auditing of the calibration and verification system in order to ensure its continuing effective implementation and compliance with the requirements of this Standard.

17.5.1 Based on the results of the audits and any other relevant factors, such as customer feedback, the supplier shall review and modify the system as necessary.

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

18 Detailed requirements

18.1 Calibration system description: The supplier shall provide and maintain a written description of the calibration/verification system covering M&TE and measurement standards. The description shall be sufficient to satisfy each requirement of Part II of this Standard and any deviations shall be submitted with supporting justification to the customer for approval.

18.2 Adequacy of measurement standards: Measurement standards used by the supplier for calibrating M&TE and other measurement standards shall comply with the requirements of 8.1, 9.1 and 10.2 of Part I of this Standard.

18.3 Environmental conditions: M&TE shall be used in an environment controlled to the extent necessary to ensure valid results. Due consideration shall be given to temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference and any other factors affecting the results of measurements. Where pertinent, these factors shall be monitored and recorded and, when appropriate, correcting compensations shall be applied to measurement results.

18.4 Intervals of calibration and verification: M&TE requiring calibration shall be calibrated or verified at periodic intervals established and maintained to assure acceptable reliability, where reliability is defined as the probability that M&TE will remain in-tolerance throughout the interval. Intervals shall be established for all M&TE requiring calibration unless the equipment is regularly monitored through the use of check standards in a documented measurement assurance process. Check standards must closely represent the item parameters normally tested in the process and the check standard must be verified periodically. Where intervals are used to ensure reliability, the interval setting system must be systematically applied and shall have stated reliability goals and a method of verifying that the goals are being attained. Intervals may be based on usage or time since last calibration or verification. All exemptions from periodic calibration or verification shall be documented. The recall system may provide for the temporary extension of the calibration due date for limited periods of time under specified conditions that do not unreasonably impair the satisfaction of the customer's requirements.

18.5 Calibration procedures: Procedures used to calibrate/verify the supplier's M&TE shall comply with the requirements of 10.1 and 10.2 of Part I of this Standard.

18.6 Out-of-tolerance conditions: If any M&TE is found to be significantly out of tolerance during the calibration/verification process, the supplier's system shall provide for notification to the user and to the supplier's quality element, if appropriate, of the out-of-tolerance condition with the associated measurement data so that appropriate action can be taken.

18.7 Adequacy of calibration system: The supplier shall establish and maintain documented procedures to evaluate the adequacy of the calibration system and to ensure compliance with the requirements of this Standard.

18.8 Calibration sources: M&TE requiring calibration shall be calibrated or verified by laboratories meeting the requirements of Part I of this Standard.

18.9 Records: The requirements of this Standard shall be supported by records documenting that established schedules and procedures are followed to maintain the adequacy of all M&TE. The records for M&TE requiring calibration shall include an individual record of calibration or verification, or other means of control, providing a description or identification of the item, calibration interval, date calibrated, identification of the calibration source, calibration results (data and/or condition status) and calibration action taken (adjusted, repaired, new value assigned, derated, etc.).

18.10 Calibration status: M&TE shall be labeled to indicate calibration or verification status. The label shall identify specific date calibrated (day, month, year, Julian date, or equivalent) and the specific calibration due date or usage equivalent. Items not calibrated to their full capability or which have other limitations of use, shall be labeled or otherwise identified as to the limitations. When it is impractical to apply a label directly to an item, the label may be affixed to the instrument container or some other suitable means may be used to reflect calibration status. Tamper-resistant seals are affixed to operator accessible controls or adjustments which if moved will invalidate the calibration. The quality system shall provide instructions for the disposition of equipment with broken tamper-resistant seals.

18.11 Control of subcontractor calibration: The supplier is responsible for assuring that the subcontractor's calibration system conforms to Part I and Part II of this Standard to the degree necessary to assure compliance with contractual requirements. Accreditation of a laboratory to Part I of this Standard by a third party activity acceptable to the customer may serve as the basis for compliance with this requirement.

18.12 Storage and handling: M&TE shall be handled, stored, and transported in a manner which shall not adversely affect the calibration or condition of the equipment.