GUIDE 25

General requirements for the competence of calibration and testing laboratories

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Contents

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) together form a system for worldwide standardization as a whole. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

This third edition of ISO/IEC Guide 25 was drawn up by the ISO Council Committee on conformity assessment (CASCO) in response to a request arising from ILAC '88, the International Laboratory Accreditation Conference held in Auckland (New Zealand) on 17-21 October 1988.

It was approved by the IEC Council in October 1990 and by the ISO Council in December 1990.

The documents produced by CASCO are issued as Guides and follow the general rules for development and promulgation of ISO and IEC standards except that they are the result of a consensus reached within a Council committee, endorsed by the ISO Council and the IEC Council.

The work of ISO/CASCO in preparing Guides, uses as a basis the principle that third party certification systems should, to the extent possible, be based on internationally agreed standards and procedures. While recognizing the major role of manufacturers' declaration of conformity through normal manufacturer/customer relationship, Council resolutions have emphasized the preparation of guidance documents on third party conformity assessment procedures in order that national systems may be compatible with one another so as to facilitate bilateral and multilateral agreements.

Whilst these documents are intended to provide guidance, it is hoped that any changes from the documents made in introducing systems nationally would be minimal. In recognizing that some countries may choose to adopt the Guides directly, they are written to enable this to be done by including words such as "shall" to indicate those aspects which desirably would be mandatory. The overriding basis that the document is intended to provide guidance holds good.

General requirements for the competence of calibration and testing laboratories

Introduction

Since ISO/IEC Guide 25 was last revised in 1982 the use of quality systems in laboratories has greatly increased. Many countries have adopted ISO/IEC Guide 25 as the basis both for establishing quality systems in laboratories and for recognizing their competence, e.g. by accreditation. In recent years there have been many developments in the field of quality assurance which have led to new and improved guides and standards; it was recognized that there was a need to revise ISO/IEC Guide 25 to reflect these changes.

In this revision of the Guide attention is paid to the activities of both calibration and testing laboratories and account is taken of other requirements for laboratory competence such as those laid down in the OECD *Code of Good Laboratory Practice* (GLP) and the ISO 9000 series of quality assurance standards.

This Guide should provide a mechanism for promoting confidence in calibration and testing laboratories that can show that they operate in accordance with its requirements.

Acceptance of calibration and test results between countries will facilitate the removal of non-tariff barriers to trade.

The use of this Guide will facilitate cooperation between laboratories and other bodies to assist in the exchange of information and experience, and in the harmonization of standards and procedures.

This Guide is specific to calibration laboratories and testing laboratories.

Laboratories meeting the requirements of this Guide comply, for calibration and testing activities, with the relevant requirements of the ISO 9000 series of standards, including those of the model described in ISO 9002 when they are acting as suppliers producing calibration and test results.

For laboratories engaged in specific fields of testing such as the chemical field (see for example the OECD *Code of Good Laboratory Practice*) or the information technology field, the requirements of this Guide will need amplification and interpretation, as referred to in clause 4.2 of ISO/IEC Guide 55.

1 Scope

1.1 This Guide sets out the general requirements in accordance with which a laboratory has to demonstrate that it operates, if it is to be recognized as competent to carry out specific calibrations or tests.

1.2 Additional requirements and information which have to be disclosed for assessing competence or for determining compliance with other criteria may be specified by the organization or authority granting the recognition (or approval), depending upon the specific character of the task of the laboratory.

1.3 This Guide is for use by calibration and testing laboratories in the development and implementation of their quality systems. It may also be used by accreditation bodies, certification bodies and others concerned with the competence of laboratories.

2 References

ISO 8402 : 1986, *Quality — Vocabulary.*

ISO 9000 : 1987, *Quality management and quality assurance standards — Guidelines for selection and use.*

ISO 9001 : 1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO 9002 : 1987, *Quality systems — Model for quality assurance in production and installation.*

ISO 9003 : 1987, *Quality systems — Model for quality assurance in final inspection and test.*

ISO 9004 : 1987, *Quality management and quality system elements — Guidelines.*

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) : 1984, issued by BIPM, IEC, ISO and OIML.

3 Definitions

The relevant definitions from ISO/IEC Guide 2, ISO 8402 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 purposes of this Guide.

3.1 laboratory: Body that calibrates and/or tests.

NOTES

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

2 As used herein, the term "laboratory" refers to a body that carries out calibration or testing

— at or from a permanent location,

— at or from a temporary facility, or

— in or from a mobile facility.

3.2 testing laboratory: Laboratory that performs tests.

[ISO/IEC Guide 2 — 12.4]

3.3 calibration laboratory: Laboratory that performs calibration.

3.4 calibration: The 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.

NOTES

1 The result of a calibration permits the estimation of errors of indication of the measuring instrument, measuring system or material measure, 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**.

[VIM — 6.13]

3.5 test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

NOTE — The result of a test is normally recorded in a document sometimes called a **test report** or a **test certificate**.

[ISO/IEC Guide 2 — 12.1, amended]

3.6 calibration method: Defined technical procedure for performing a calibration.

3.7 test method: Defined technical procedure for performing a test.

3.8 verification: Confirmation by examination and provision of evidence that specified requirements have been met.

NOTE — 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 of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment.

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 it is required that a written trace of the verification performed be kept on the measuring instrument's individual record.

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

[ISO 8402 — 3.8, without the notes]

3.10 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.

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

[VIM — 6.08]

3.12 reference material: A material or substance one or more properties of which 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.

[ISO Guide 30 — 2.1]

3.13 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.

[ISO Guide 30 — 2.2]

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

[VIM — 6.12]

[A note given in the VIM to this definition applies to the French text only.]

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

[ISO/IEC Guide 2 — 12.6, amended]

3.16 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.

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 Guide.

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 commercial, financial and other 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 and tests;

e) provide supervision by persons familiar with the calibration or test methods and procedures, the objective of the calibration or test and the assessment of the results. The ratio of supervisory to non-supervisory personnel 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) nominate deputies in case of absence of the technical or quality manager;

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

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

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 and testing 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 or testing 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 quality documentation, shall state the laboratory's policies and operational procedures established in order to meet the requirements of this Guide. the quality manual and related quality 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 relevant 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 tests;

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, verification and/or test procedures used;

k) procedures for handling calibration and test items;

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

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

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

o) procedures to be followed for feedback and corrective action whenever testing 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.

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 or test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

5.4 The quality system adopted to satisfy the requirements of this Guide 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 timescale.

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

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

b) participation in proficiency testing or other inter-laboratory comparisons;

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

d) replicate testings using the same or different methods;

e) re-testing of retained items;

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

6 Personnel

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

6.2 The testing laboratory shall ensure that the training of its personnel is kept up-to-date.

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

7 Accommodation and environment

7.1 Laboratory accommodation, calibration and test areas, energy sources, lighting, heating and ventilation shall be such as to facilitate proper performance of calibrations or tests.

7.2 The environment in which these activities are undertaken shall not invalidate the results or adversely affect the required accuracy 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 provide facilities for the effective monitoring, control and recording of environmental conditions as appropriate. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, humidity, mains voltage, temperature, and sound and vibration levels, as appropriate to the calibrations or tests concerned.

7.4 There shall be effective separation between neighbouring 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 and safety requirements. This aspect, however, is outside the scope of this Guide.

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 and tests. In those cases where the laboratory needs to use equipment outside its permanent control it shall ensure that the relevant requirements of this Guide 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, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

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 or tests 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) date received and date placed in service;

d) current location, where appropriate;

e) condition when received (e.g. new, used, reconditioned);

f) copy of the manufacturer's instructions, where available;

g) dates and results of calibrations and/or verifications and date of next calibration and/or verification;

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

i) history of any damage, malfunction, modification or repair.

9 Measurement traceability and calibration

9.1 All measuring and testing equipment having an effect on the accuracy or validity of calibrations or tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established programme for the calibration and verification of its measuring and test equipment.

9.2 The overall programme of calibration and/or verification and validation of equipment shall be designed and operated so as to ensure that, wherever applicable, measurements made by the laboratory are traceable to national standards of measurement where available. Calibration certificates shall wherever applicable indicate the traceability to national 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.

9.3 Where traceability to national standards of measurement is not applicable, the laboratory shall provide satisfactory evidence of correlation of results, for example by participation in a suitable programme of interlaboratory comparisons or proficiency testing.

9.4 Reference standards of measurement held by the laboratory shall be used for calibration 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 body that can provide traceability to a national standard of measurement. There shall be a programme of calibration and verification for reference standards.

9.6 Where relevant, reference standards and measuring and testing equipment shall be subjected 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 and test 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 and/or testing, where the absence of such instructions could jeopardize the calibrations or tests. 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 and tests and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimation of uncertainty of measurement and analysis of calibration and/or test data). They shall be consistent with the accuracy required, and with any standard specifications relevant to the calibrations or tests concerned.

10.3 Where methods are not specified, the laboratory shall, wherever possible, 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 established as standard, these shall be subject to agreement with the client, be fully documented and validated, and be available to the client and other recipients of the relevant reports.

10.5 Where sampling is carried out as part of the test 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 or test data, the laboratory shall ensure that:

a) the requirements of this Guide 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 and test 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.