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Quality assurance requirements for measuring equipment —

Part 1:
Metrological confirmation system for measuring equipment

Exigences d'assurance de la qualité des équipements de mesure — Partie 1: Confirmation métrologique de l'équipement de mesure

Reference number
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Contents

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Annexes

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 10012-1 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Sub-Committee SC 3, *Supporting technologies*.

ISO 10012 consists of the following parts, under the general title *Quality assurance requirements for measuring equipment*:

— *Part 1: Metrological confirmation system for measuring equipment*

— *Part 2: Measurement assurance*

Annex A is based on Organisation Internationale de Métrologie Légale (OIML) International Document No. 10, *Guidelines for the determination of recalibration intervals of measuring equipment used in testing laboratories*.

Annexes A and B of this part of ISO 10012 are for information only.

Introduction

This part of ISO 10012 is written in the context of a Purchaser and 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. Suppliers become Purchasers when procuring supplies and services from vendors or other outside sources. The subject of the negotiations relating to this part of ISO 10012 may be a design, an artefact, a product or a service. This part of ISO 10012 may be applied, by agreement, to other situations.

Reference to this part of ISO 10012 may be made:

— by a Purchaser when specifying products or services required;

— by a Supplier when specifying products or services offered;

— by consumer or employee interests, or by legislative or regulatory bodies;

— in assessment and audit of laboratories.

This part of ISO 10012 includes both requirements and (in clause 4) guidance on the implementation of the requirements.

In order to distinguish clearly between requirements and guidance, in clause 4 the latter appears in italic type-face, in a box, after each corresponding paragraph under the heading "GUIDANCE".

The text under "GUIDANCE" is for information only and contains no requirements. Statements given there are not to be construed as adding to, limiting or modifying any requirement.

NOTE 1 Use of the masculine gender in this part of ISO 10012 is not meant to exclude the feminine gender where applied to persons. Similarly, use of the singular does not exclude the plural (and vice versa) when the sense allows.

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Quality assurance requirements for measuring equipment —

Part 1:
Metrological confirmation system for measuring equipment

1 Scope

1.1 This part of ISO 10012 contains quality assurance requirements for a Supplier to ensure that measurements are made with the intended accuracy. It also contains guidance on the implementation of the requirements.

1.2 This part of ISO 10012 specifies the main features of the confirmation system to be used for a Supplier's measuring equipment.

1.3 This part of ISO 10012 is applicable to measuring equipment used in the demonstration of compliance with a specification: it does not apply to other items of measuring equipment. This part of ISO 10012 does not deal extensively with other elements that may affect measurement results such as methods of measurement, competence of personnel etc.; these are dealt with more specifically in other International Standards, such as those referred to in 1.4.

1.4 This part of ISO 10012 is applicable:

— to testing laboratories, including those providing a calibration service; this includes laboratories operating a quality system in accordance with ISO/IEC Guide 25;

— to Suppliers of products or services who operate a quality system in which measurement results are used to demonstrate compliance with specified requirements; this includes operating systems that meet the requirements of ISO 9001, ISO 9002 and ISO 9003. The guidance given in ISO 9004 is also relevant;

— to other organizations where measurement is used to demonstrate compliance with specified requirements.

1.5 The role of the Purchaser in monitoring a Supplier's compliance with the requirements of this part of ISO 10012 may be fulfilled by a third party, such as an accreditation or certification body.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10012. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10012 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 8402:1986, *Quality — Vocabulary.*

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

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

BIPM/IEC/ISO/OIML, *International vocabulary of basic and general terms in metrology:* 1984.

3 Definitions

For the purposes of this part of ISO 10012, the following definitions apply. Most of them are based on the International vocabulary of basic and general terms in metrology (VIM): 1984, but they are not always identical to the definitions given therein. Terms in ISO 8402 are also relevant. Relevant reference numbers are given in brackets following the definitions.

3.1 metrological confirmation: Set of operations required to ensure that an item of measuring equipment is in a state of compliance with requirements for its intended use.

NOTES

2 Metrological confirmation normally includes, *inter alia*, calibration, any necessary adjustment or repair and subsequent recalibration, as well as any required sealing and labelling.

3 For brevity, in this part of ISO 10012, this term is referred to as "confirmation".

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

NOTE 4 In the context of this part of ISO 10012, the term "measuring equipment" is taken to encompass "measuring instruments" and "measurement standards". Moreover, a "reference material" is considered to be a type of "measurement standard".

3.3 measurement: The set of operations having the object of determining the value of a quantity.

[VIM, 2.01]

3.4 measurand: A quantity subjected to measurement.

NOTE 5 As appropriate, this may be the "measured quantity" or the "quantity to be measured".

[VIM, 2.09]

3.5 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.

[VIM, 2.10]

3.6 accuracy of measurement: The closeness of the agreement between the result of a measurement and the (conventional) true value of the measurand.

NOTES

6 "Accuracy" is a qualitative concept.

7 The use of the term "precision" for "accuracy" should be avoided.

[VIM, 3.05]

3.7 uncertainty of measurement: Result of the evaluation aimed at characterizing the range within which the true value of a measurand is estimated to lie, generally with a given likelihood.

NOTE 8 Uncertainty of measurement comprises, in general, many components. Some of these components may be estimated on the basis of the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. Estimates of other components can only be based on experience or other information.

[VIM, 3.09]

3.8 (absolute) error of measurement: The result of a measurement minus the true value of the measurand.

NOTES

9 See "true value (of a quantity)" and "conventional true value (of a quantity)" in VIM.

10 The term relates equally to

— the indication,
— the uncorrected result,
— the corrected result.

11 The known parts of the error of measurement may be compensated by applying appropriate corrections. The error of the corrected result can only be characterized by an uncertainty.

12 "Absolute error", which has a sign, should not be confused with "absolute value of an error" which is the modulus of an error.

[VIM, 3.10]

3.9 correction: The value which, added algebraically to the uncorrected result of a measurement, compensates for an assumed systematic error.

NOTES

13 The correction is equal to the assumed systematic error, but of opposite sign.

14 Since the systematic error cannot be known exactly, the correction is subject to uncertainty.

[VIM, 3.14]

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

[VIM, 4.01]

3.11 adjustment: The operation intended to bring a measuring instrument into a state of performance and freedom from bias suitable for its use.

[VIM, 4.33]

3.12 specified measuring range: The set of values for a measurand for which the error of a measuring instrument is intended to lie within specified limits.

NOTES

15 The upper and lower limits of the specified measuring range are sometimes called the "maximum capacity" and the "minimum capacity" respectively.

16 In some other fields of knowledge, "range" is used to mean the difference between the greatest and the smallest values.

[VIM, 5.04]

3.13 reference conditions: Conditions of use for a measuring instrument prescribed for performance testing, or to ensure valid intercomparison of results of measurements.

NOTE 17 The reference conditions generally specify "reference values" or "reference ranges" for the influence quantities affecting the measuring instrument.

[VIM, 5.07]

3.14 resolution (of an indicating device): A quantitative expression of the ability of an indicating device to permit distinguishing meaningfully between immediately adjacent values of the quantity indicated.

[VIM, 5.13]

3.15 stability: The ability of a measuring instrument to maintain constant its metrological characteristics.

NOTE 18 It is usual to consider stability with respect to time. Where stability with respect to another quantity is considered, this should be stated explicitly.

[VIM, 5.16]

3.16 drift: The slow variation with time of a metrological characteristic of a measuring instrument.

[VIM, 5.18]

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

[VIM, 5.23]

3.18 (measurement) standard: A material measure, measuring instrument, reference material or system intended to define, realize, conserve or reproduce a unit or one or more values of a quantity in order to transmit them to other measuring instruments by comparison.

EXAMPLES

a) 1 kg mass standard;

b) standard gauge block;

c) 100 Ω standard resistor;

d) Weston standard cell;

e) caesium atomic frequency standard;

f) solution of cortisol in human serum as a standard of concentration.

[VIM, 6.01]

3.19 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.

NOTE 19 This definition is taken from ISO Guide 30, where it has several notes.

[VIM, 6.15]

3.20 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.

[VIM, 6.06]

3.21 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.

NOTE 20 The national standard in a country is often a "primary standard".

[VIM, 6.07]

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

NOTES

21 The unbroken chain of comparisons is called a "traceability chain".

22 (Applicable only to the French text.)

[VIM, 6.12]

3.23 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 or a reference material, and the corresponding values of a quantity realized by a reference standard.

NOTES

23 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.

24 A calibration may also determine other metrological properties.

25 The result of a calibration may be recorded in a document, sometimes called a "calibration certificate" or a "calibration report".

26 The result of a calibration is sometimes expressed as a correction or a "calibration factor", or as a "calibration curve".

[VIM, 6.13]

3.24 (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 27 The quality audit typically applies, 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".

[ISO 8402, 3.10]

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

[ISO 8402, 3.12]

4 Requirements

4.1 General

The Supplier shall document the methods used to implement the provisions of this part of ISO 10012. This documentation shall be an integral part of the Supplier's quality system. It shall be specific in terms of which items of equipment are subject to the provisions of this part of ISO 10012, in terms of the allocation of responsibilities and in terms of the actions to be taken. The Supplier shall make objective evidence available to the Purchaser that the required accuracy is achieved.

4.2 Measuring equipment

Measuring equipment shall have metrological characteristics as required for the intended use (for example accuracy, stability, range and resolution).

Equipment and documentation shall be maintained so as to take account of any corrections, conditions of use (including environmental conditions), etc. that are necessary to achieve the required performance.

The required performance shall be documented.

GUIDANCE

The set of metrological characteristics (specific requirements) is an essential component of the confirmation system. The Supplier is expected to include in his procedures a list of the specified requirements. Usual sources for such requirements include manufacturer's literature, regulations, etc. Wherever the sources are inadequate, the Supplier should himself determine the requirements.

4.3 Confirmation system

The Supplier shall establish and maintain an effective documented system for the managing, confirmation and use of measuring equipment, including measurement standards, used to demonstrate compliance with specified requirements. This system shall be designed to ensure that all such measuring equipment performs as intended. The system shall provide for the prevention of errors outside the specified limits of permissible error, by prompt detection of deficiencies and by timely action for their correction.

The confirmation system shall take full account of all relevant data, including that available from any statistical process control system operated by or for the Supplier.

For each item of measuring equipment, the Supplier shall designate a competent member of his staff as authorized officer to ensure that confirmations are carried out in accordance with the system and that the equipment is in a satisfactory condition.

In cases where any or all of a Supplier's confirmation (including calibration) are replaced or supplemented by services from outside sources, the Supplier shall ensure that these outside sources also comply with the requirements of this part of ISO 10012 to the extent necessary to ensure the Supplier's compliance with the requirements.

GUIDANCE

The intention of a confirmation system is to ensure that the risk of measuring equipment producing results having unacceptable errors remains within acceptable bounds. The use of appropriate statistical methods for analysing the results of preceding calibrations, for assessing the results of calibrations of several similar items of measuring equipment and for predicting cumulative uncertainties is recommended. (See ISO 9004:1987, 13.1.)

The error attributable to calibration should be as small as possible. In most areas of measurement, it should be no more than one third and preferably one tenth of the permissible error of the confirmed equipment when in use.

It is usual to carry out the calibration associated with any confirmation under reference conditions, but where it is known that the operating conditions are significantly different from the reference conditions, calibration under appropriate values of the influence quantities may be carried out. Where this is impractical, due allowance should be made for the difference in the conditions.

For a commercial device, it is usual to take the manufacturer's claimed performance as the criterion of satisfactory performance and accuracy. It is sometimes necessary to modify the manufacturer's claims.

Where no manufacturer's claimed performance is available, criteria for satisfactory performance may have to be determined from experience.

Some instruments, such as null detectors and coincidence detectors, need periodic calibration and confirmation only in the restricted sense of functional checking to assure that they are functioning correctly.

A very useful check that a measuring instrument continues to measure correctly is obtained by the use of a checking measurement standard, applied to the instrument by the user. This will demonstrate if, at the value or values checked and under the conditions of the check, the instrument is still functioning correctly. The checking measurement standard itself needs to be calibrated and confirmed and, in order that the results obtained by its use can with confidence be attributed to the instrument and not to changes in the checking measurement standard, it usually has to be simple and robust. The use of a checking measurement standard is in no way a substitute for regular calibration and confirmation of the instrument, but its use may prevent the use of an instrument which, within the interval between two formal confirmations, ceases to conform to specification.

4.4 Periodic audit and review of the confirmation system

The Supplier shall carry out, or shall arrange to be carried out, periodic and systematic quality auditing of the confirmation system in order to ensure its continuing effective implementation and compliance with the requirements of this part of ISO 10012.

Based on the results of the quality audits and of other relevant factors, such as feedback from Purchasers, the Supplier shall review and modify the system as necessary.

Plans and procedures for the quality audit and review shall be documented. The conduct of the quality audit and review and any subsequent corrective actions shall be recorded.

4.5 Planning

The Supplier shall review any relevant Purchaser's and other technical requirements before commencing work on products or services, and shall ensure that the measuring equipment (including measurement standards) needed for the performance of the work are available and are of the accuracy, stability, range and resolution appropriate for the intended application.