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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

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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.