INTERNATIONAL STANDARD

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Quality assurance for measuring equipment —

Part 2:
Guidelines for control of measurement processes

Assurance de la qualité des équipements de mesure —
Partie 2: Lignes directrices pour la maîtrise des processus de mesure

Reference number
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Contents

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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 10112-2 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies.*

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

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

— *Part 2: Guidelines for control of measurement processes*

Part 1 (now under revision) was published under the title *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment.*

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

Introduction

ISO 10012 is part of the ISO 9000 family of standards.

This part of ISO 10012 is intended to be used as a guidance document for quality management or as a requirement document by agreement between the Supplier and the Customer. It is written in the context of a Customer and a Supplier, both terms being interpreted in the broadest sense. The "Supplier" may be a manufacturer, an installer or a service organization. The "Customer" may be a procurement authority or a customer using a product. Suppliers become customers when procuring products from vendors or other outside sources.

Reference to this International Standard is recommended to be made:

— by a Customer when specifying products required;

— by a Supplier when specifying products offered;

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

— in assessment and audit of the control of measurement systems.

This part of ISO 10012 includes (in clause 4) both recommendations and guidance. It is written in the context of a Customer and a Supplier for a product, all terms being interpreted in the broadest sense given in ISO 8402.

In order to distinguish clearly between recommendations 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.

Part 1 of ISO 10012 contains general quality assurance requirements for the control of measuring equipment. Part 2 provides supplementary guidance on the application statistical process control when this is appropriate for achieving the objectives of part 1.

Measurement should be considered as an overall process. The methods for the control of measurement processes, based on the regular monitoring and analysis of measurement data, are applicable at all levels of measurement, ranging from the calibration of the Supplier's measurement standards by an outside metrology laboratory to the Supplier's own routine measurements. Procedures for the control of measurement processes can be used

— to detect unusual variations in the operation of the measurement process;

— to detect problems with repeatability;

— to identify and quantify the compensations or correction factors for any drift;

— to help in the identification of predictable periodic variations, including cyclic variations;

— to provide some of the documentation required by quality assurance requirements.

This concept of "Measurement Process Control" has also been known as "Measurement Assurance".

In practice, the control of measurement processes is specifically applicable to critical or complex measurement systems (for example for safety or economic purposes). A Supplier may consider that the confirmation system specified in ISO 10012-1 provides adequate control for routine processes, such as the testing of non-critical components.

The Metrological Confirmation System described in ISO 10012-1 is intended to ensure that the measurements (performed using measuring equipment that is within its confirmation interval) are sufficiently accurate for the purpose. However, while the confirmation interval, based on experience, provides a high probability that measuring equipment is still functioning correctly at the expiry of its confirmation interval, it cannot guard against random failure or unsuspected and not easily visible damage. Additionally, the metrological confirmation system does not provide any assurance that the measuring equipment is being used correctly. Even the most accurate measuring equipment will provide incorrect measurement results when used incorrectly. Correctly written measurement procedures should be a safeguard, but it is not always possible to ensure that the procedures are being correctly followed. Controlling measurements as processes, in accordance with part 2 of ISO 10012, reduces the possibilities of problems arising from random failure, damage or misuse. The effectiveness or degree of such reductions is determined by how frequently the checks (process controls) are undertaken. The frequency is a matter of managerial and commercial judgement and, therefore, specific (quantified) recommendations concerning the frequency will not be made in this part of ISO 10012.

Measuring equipment is only one of many factors affecting measurements. The concept of a "Measurement process" views measurement as a complete process starting from analysis of the implications of the scientific basis of the measurement, traceability of the values of measurement standards, calibration and, if necessary, adjustment through verification and metrological confirmation, to the results produced by the measuring equipment at the place of work and under the conditions of use.

The operation of a metrological confirmation system often involves measuring equipment having to be taken from its place of use to a central metrological laboratory for calibration, adjustment or repair and, if necessary, verification and re-confirmation. It is frequently found that such returned equipment is, in fact, operating correctly, no repairs or adjustments being necessary. Indeed, if this were not so for a high proportion of the equipment, there would be a significant chance that incorrect results had been obtained while it was in use, especially towards the end of its confirmation interval. If measuring equipment, returned for confirmation merely because it has reached the end of its confirmation interval, is found to be functioning correctly, it is possible to argue that, with hindsight, it could have been left in use, at a great saving in cost and inconvenience. The risks of producing erroneous measurement results will usually dictate that this argument cannot be accepted.

The combination of metrological confirmation and control of measurement processes that is considered to be adequate depends on economic aspects, safety, fitness for use and other factors.

An overview of the concept of viewing the control of instruments and equipment as continuous processes is given in annex A.

A list of informative references is given in annex B.

Quality assurance for measuring equipment —

Part 2:
Guidelines for control of measurement processes

1 Scope

1.1 This part of ISO 10012 contains quality assurance recommendations that may be used by a Supplier to provide enhanced assurance that measurements are made with the intended accuracy. It also contains guidance on the implementation of the recommendations.

1.2 It is also intended to be used as a guide for quality management or as a requirement document on agreement between the Supplier and the Customer.

1.3 This part of ISO 10012 is applicable to measurement processes. It deals with elements that may affect measurement results, such as measurement procedures, personnel, etc., not extensively covered in ISO 10012-1.

1.4 This part of ISO 10012 is applicable to

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

— suppliers of products 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.

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 8402:1994, *Quality management and quality assurance — Vocabulary.*

ISO 10012-1:1992, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment.*

3 Definitions

For the purposes of this part of ISO 10012, the definitions given in ISO 8402 and the following apply. Most of the definitions are taken from the International vocabulary of basic and general terms in metrology (VIM). Some are taken from ISO 10012-1. Relevant reference numbers are given in square brackets following the definitions. These definitions are included to assist the understanding of the concepts used in this part of ISO 10012 without the need to consult too many other documents.

3.1
accuracy of measurement
closeness of the agreement between the result of a measurement and a true value of the measurand

NOTES

1 "Accuracy" is a qualitative concept.

2 The term precision should not be used for "accuracy".

[VIM:1993, 3.5]

3.2
adjustment (of a measuring instrument)
operation of bringing a measuring instrument into a state of performance suitable for its use

NOTE Adjustment may be automatic, semiautomatic or manual.

[VIM:1993, 4.30]

3.3
calibration
set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards

NOTES

1 The result of a calibration permits either the assignment of values of measurands to the indications or the determination of corrections with respect to indications.

2 A calibration may also determine other metrological properties such as the effect of influence quantities.

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

[VIM:1993, 6.11]

3.4
check standard
measuring equipment, product, or other objects serving to collect a data base for the control of a measurement process, by being measured by that process

NOTES

1 See also VIM:1993, 6.7, note 2.

2 A check standard should only be used as a check standard.

3 An overview of the use of check standards is given in annex A.

3.5
control of measurement processes
monitoring and analysis of data from a measurement process, together with corrective actions, intended to maintain the process of measurement continuously within a specification

NOTE This may include the use of check standards, control charts, or their equivalents.

3.6
limits of permissible error (of a measuring instrument)
maximum permissible errors (of a measuring instrument)
extreme values of error permitted by specifications, regulations, etc. for a given measuring instrument

[VIM:1993, 5.21]

3.7
measurand
particular quantity subject to measurement

EXAMPLE Vapour pressure of a given sample of water at 20 °C.

NOTE The specification of a measurand may require statements about quantities such as time, temperature and pressure.

[VIM:1993, 2.6]

3.8
measurement
set of operations having the object of determining the value of a quantity

NOTE The operations may be performed automatically.

[VIM:1993, 2.1]

3.9
measurement procedure
set of operations, described specifically, used in the performance of particular measurements according to a given method

NOTE A measurement procedure is usually recorded in a document that is sometimes itself called a "measurement procedure" (or a measurement method) and is usually in sufficient detail to enable an operator to carry out a measurement without additional information.

[VIM:1993, 2.5]

3.10
measurement process
set of interrelated resources, activities, and influences which produce a measurement

NOTES

1 The resources concerned include measuring equipment, measurement procedures, operator.

2 "Influences" are all factors such as those caused by the environment which may or may not be controlled or controllable and which add to the variability or the bias of the process.

3 See also definition 1.2 (process) of ISO 8402:1994.

4 A measurement process may consist of measurements made, for example, by:

a) various operators using general purpose measuring equipment in a general plant environment, using informal methods or procedures;

or

b) trained calibration laboratory technicians using a measurement system with a temperature controlled oil bath, reference standard resistors, comparators, and other auxiliary equipment, following a detailed procedure for the purpose of calibrating other standard resistors;

or

c) any variation or combination of or beyond the above two examples.

5 A measurement process may consist of the use of a single measuring instrument.

3.11
measuring equipment
all of the measuring instruments, measurement standards, reference materials, auxiliary apparatus and instructions that are necessary to carry out a measurement

NOTES

1 This term includes measuring equipment used in the course of testing and inspection, as well as that used in calibration.

2 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".

[Adapted from ISO 10012-1:1992, 3.2]

3.12
measuring instrument
device intended to be used to make measurements, alone or in conjunction with supplementary device(s)

[VIM:1993, 4.1]

3.13
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

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

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

[ISO 10012-1:1992, 3.1]

3.14
quality audit
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

NOTES

1 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" or "service quality audit".

2 Quality audits are carried out by staff not having direct responsibility in the areas being audited but, preferably, working in cooperation with the relevant personnel.

3 One purpose of a quality audit is to evaluate the need for improvement or corrective action. An audit should not be confused with quality surveillance or inspection activities performed for the purpose of process control or product acceptance.

4 Quality audits can be conducted for internal or external purposes.

[ISO 8402:1994, 4.9]

3.15
resolution (of a displaying device)
smallest difference between indications of a displaying device that can be meaningfully distinguished

NOTES

1 For a digital displaying device, this is the change in the indication when the least significant digit changes by one step.

2 This concept also applies to a recording device.

[VIM:1993, 5.12]

3.16
stability
ability of a measuring instrument to maintain constant its metrological characteristics with time

NOTES

1 Where stability with respect to a quantity other than time is considered, this should be stated explicitly.

2 Stability may be quantified in several ways, for example:
— in terms of the time over which a metrological characteristic changes by a stated amount, or
— in terms of the change in a characteristic over a stated time.

[VIM:1993, 5.14]

3.17
traceability
property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties

NOTES

1 The concept is often expressed by the adjective "traceable".

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

[VIM:1993, 6.10]

3.18
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

NOTES

1 The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.

2 Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. The other components, which can also be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

3 It is understood that the result of the measurement is the best estimate of the value of the measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.

[VIM:1993, 3.9]

4 This definition is identical with that in the *Guide to the expression of uncertainty in measurement,* in which its rationale is detailed (see, in particular, 2.2.4 and annex D).

3.19
verification
confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

NOTES

1 In design and development, verification concerns the process of examining the result of a given activity to determine conformity with the input requirement for that activity.

2 The term "verified" is used to designate the corresponding status.

[ISO 8402:1994, 2.17]