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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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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.

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.

GUIDANCE

This review should be carried out at as early a stage as practical, so as to permit comprehensive and effective planning of the Supplier's confirmation system.

4.6 Uncertainty of measurement

In performing measurements and in stating and making use of the results, the Supplier shall take into account all significant identified uncertainties in the measurement process including those that are attributable to measuring equipment (including measurement standards) and those contributed by personnel procedures and environment.

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

GUIDANCE

When it has been demonstrated by a calibration that measuring equipment is performing correctly (in accordance with its specification), it is usual to assume that the errors produced while the equipment is in use do not exceed its specified limits of permissible error. This is assumed to hold until the equipment is next calibrated and confirmed. This may not be true under the often more arduous conditions of use as compared with the controlled conditions of the calibration. It may therefore be expedient to compensate for this by tightening the product acceptance limits. The amount of this tightening depends on the particular circumstances and is a matter for judgement based on experience. (See 4.17.)

The use of statistical methods is recommended to monitor and control measurement uncertainty on a continuing basis. (See ISO 9004:1987, 13.1.)

4.7 Documented confirmation procedures

The Supplier shall designate and use documented procedures for all confirmations performed.

The Supplier shall ensure that all procedures are adequate for their purpose. In particular, procedures shall contain sufficient information to ensure their proper implementation, to ensure consistency of application from one application to another, and to ensure valid measurement results.

The procedures shall be available, as necessary, to staff involved in performing confirmations.

GUIDANCE

Procedures may be, but are not necessarily, limited to the compilation of published standard measurement practices and a Purchaser's or an instrument manufacturer's written instructions. The amount of detail in procedures should be commensurate with the complexity of the confirmation process.

These methods may be elaborated using the techniques of statistical process control, whereby measurement standards and measuring instruments are intercompared in-house, drifts and faults are determined, and any necessary corrective action is taken. Statistical process control is complementary to regular calibration and reinforces confidence in measurement results during the intervals between confirmations.

4.8 Records

The Supplier shall maintain records of the make, type and serial number (or other identification) of all relevant measuring equipment (incuding measurement standards). These records shall demonstrate the measurement capability of each item of measuring equipment. Any calibration certificates and other relevant information concerning its functioning shall be available.

GUIDANCE

The records may be in manuscript, typescript or microfilm or may be in an electronic or a magnetic memory or on another data medium.

The minimum time for the retention of records is dependent on many factors, such as the Purchaser's requirements, regulatory or legal requirements, manufacturer's liability, etc.

Records concerned with the principal measurement standards may need to be retained indefinitely.

The calibration results shall be recorded in sufficient detail so that the traceability of all the measurements can be demonstrated and so that any measurement can be reproduced under conditions close to the original conditions, thereby facilitating the resolution of any anomalies.

The recorded information shall include:

a) the description and unique identification of equipment;

b) the date on which each confirmation was completed;

c) the calibration results obtained after and, where relevant, before any adjustment and repair;

> *GUIDANCE*
>
> *In some instances, the calibration result is given as a compliance with or failure to comply with a requirement.*

d) the assigned confirmation interval;

e) identification of the confirmation procedure;

f) the designated limits of permissible error;

g) the source of the calibration used to obtain traceability;

h) the relevant environmental conditions and a statement about any corrections thus necessary;

i) a statement of the uncertainties involved in calibrating the equipment and of their cumulative effect;

j) details of any maintenance such as servicing, adjustment, repairs or modifications carried out;

k) any limitations in use;

l) identification of the person(s) performing the confirmation;

m) identification of person(s) responsible for ensuring the correctness of the recorded information;

n) unique identification (such as serial numbers) of any calibration certificates and other relevant documents concerned.

The Supplier shall maintain clear documented procedures on the retention (including the duration) and safeguarding of records. Records shall be kept until it is no longer probable that they may need to be referred to.

> *GUIDANCE*
>
> *The Supplier should take all reasonable steps to ensure that records cannot inadvertently be destroyed.*

4.9 Nonconforming measuring equipment

Any item of measuring equipment

— that has suffered damage,

— that has been overloaded or mishandled,

— that shows any malfunction,

— whose proper functioning is subject to doubt,

— that has exceeded its designated confirmation interval, or

— the integrity of whose seal has been violated,

shall be removed from service by segregation, prominent labelling or marking.

Such equipment shall not be returned to service until the reasons for its nonconformity have been eliminated and it is again confirmed.

If the results of calibration prior to any adjustment or repair were such as to indicate a risk of significant errors in any of the measurements made with the equipment before the calibration, the Supplier shall take the necessary corrective action.

> *GUIDANCE*
>
> *When measuring equipment is found to be inaccurate or otherwise faulty, it is usual to adjust, overhaul or repair it until it again functions correctly. If this proves to be impractical, consideration should be given to downgrading the equipment or scrapping it. Downgrading should only be used with great care as it may lead to apparently identical equipment having different permissible errors, the fact being only apparent by careful examination of the label referred to in 4.10.*
>
> *Reconfirmation to a relaxed set of requirements is then necessary.*
>
> *In the case of a multi-function or multi-range instrument, where it can be demonstrated that the instrument remains intact on one or more of its functions or ranges, it may continue to be used on the intact functions and/or ranges, provided that it is prominently labelled to indicate the restrictions on its use. All reasonable steps should be taken to prevent the use of the instrument on the faulty functions or ranges.*

4.10 Confirmation labelling

The Supplier shall ensure that all measuring equipment is securely and durably labelled, coded or otherwise identified to indicate its confirmation status. Any limitation on the confirmation, or any restriction of use shall also be indicated on the equipment. When labelling or coding is impracticable or inappropriate, alternative effective procedures shall be established and documented.

GUIDANCE

The labelling may be by a secure self-adhesive stick-on label or by a tie-on label or by durable marking directly on the measuring equipment.

Any confirmation labelling shall clearly indicate when the equipment is next due for confirmation in accordance with the Supplier's system. The labelling shall also permit ready identification of the authorized officer (see 4.3) responsible for the confirmation in question, and the date of the most recent confirmation.

All reasonable measures shall be taken to prevent the intentional or accidental misuse of labels.

Measuring equipment that is deemed not to require confirmation shall be clearly identified as such, so that it may be distinguished from equipment that requires confirmation but whose label has become mislaid or detached.

GUIDANCE

This may be achieved by documentation.

Where a significant part of the total capability of an item of measuring equipment is not covered by a confirmation, this shall be indicated on the confirmation label.

GUIDANCE

An example is a multi-range instrument which is confirmed and used on only some of its ranges.

4.11 Intervals of confirmation

Measuring equipment (including measurement standards) shall be confirmed at appropriate intervals (usually periodic), established on the basis of their stability, purpose and usage. The intervals shall be such that confirmation is again carried out prior to any probable change in accuracy that is of significance in the use of the equipment. Depending on the results of calibrations at preceding confirmations, intervals of confirmation shall be shortened, if necessary, to ensure continued accuracy.

The intervals of confirmation shall not be lengthened unless the results of calibrations at preceding confirmations provide definite indications that such action will not adversely affect confidence in the accuracy of the measuring equipment.

The Supplier shall have specific objective criteria on which to base decisions affecting the choice of intervals of confirmation.

In determining whether the changes in the intervals of confirmation are appropriate, the Supplier shall take account of all relevant data including those available from any statistical process control system operated by or for the Supplier.

GUIDANCE

The purpose of periodically reconfirming measuring equipment is to ensure that the measuring equipment has not suffered a deterioration in accuracy and to prevent it from being used when there is a significant possibility of it producing erroneous results.

It is impossible to determine a confirmation interval so short that there is no possibility of measuring equipment becoming faulty before the end of the assigned confirmation interval.

Frequent confirmation is expensive and takes the equipment out of service, requiring replacement equipment or causing the work on which it was being used to cease. A compromise is therefore necessary.

Until sufficient statistical evidence of nonconformity rates has been acquired by a particular organization, confirmation intervals can only be determined from the experience of others (whose circumstances may be different) or by estimation.

In certain fields of application, the Supplier may have to comply with statutory or technical requirements for confirmation intervals.

Advice on the choice of confirmation intervals is given in annex A.

4.12 Sealing for integrity

Access to adjustable devices on measuring equipment, whose setting affects the performance, shall be sealed or otherwise safeguarded at an appropriate stage of the confirmation, in order to prevent tampering by unauthorized personnel. Seals shall be designed so that tampering is clearly apparent.

The Supplier's confirmation system shall provide instructions for the use of such seals and for the disposition of equipment with damaged or broken seals.

> *GUIDANCE*
>
> *The requirement for sealing does not apply to adjustment devices that are intended to be set by the user without the need for external references; for example, zero adjusters.*
>
> *The decisions about what instruments should be sealed, the controls or adjustments which will be sealed and the sealing material such as labels, solder, wire, paint, etc., are normally left to the Supplier. How the Supplier implements a sealing programme in detail should be documented. Not all measuring equipment lends itself to sealing.*

4.13 Use of outside products and services

The Supplier shall ensure that products and services from outside sources are of the quality level required, where these products and services (including calibration) significantly affect the reliability of the Supplier's measurements.

> *GUIDANCE*
>
> *The Supplier may ensure the quality of outside products and services by using formally accredited sources, where available. (However, the use of such sources does not diminish the Supplier's responsibility to the Purchaser.) Where accredited outside sources are not used and instead the Supplier performs an assessment of the outside source, the Supplier may be called upon to provide formal evidence of his competence to perform such an assessment.*

4.14 Storage and handling

The Supplier shall establish and maintain a system for receiving, handling, transporting, storing and dispatching the Supplier's measuring equipment, in order to prevent abuse, misuse, damage and changes in dimensional and functional characteristics.

Steps shall be taken to prevent confusion between similar items. These steps shall be documented.

> *GUIDANCE*
>
> *While the requirements of this part of ISO 10012 apply specifically to measuring equipment forming a part of the Supplier's own measurement system, it is clearly good practice to exert care also in dealing with any items of measuring equipment that may belong to a Purchaser, such as measuring equipment received for repair, maintenance or calibration by the Supplier. Requirements concerning the handling of items received for testing or calibration by a laboratory are given in ISO/IEC Guide 25.*

4.15 Traceability

All measuring equipment shall be calibrated using measurement standards that are traceable to international measurement standards, or to national measurement standards that are consistent with the recommendations of the General Conference on Weights and Measures (CGPM). In cases where such international or national measurement standards do not exist (for example, for hardness), traceability shall be established to other measurement standards (for example, suitable reference materials, concensus measurement standards or industry measurement standards) that are internationally accepted in the field concerned.

All measurement standards used in the confirmation system shall be supported by certificates, reports or data sheets for the equipment attesting to the source, date, uncertainty, and to the conditions under which the results were obtained. Each such document shall be signed by a person attesting to the correctness of the results.

The Supplier shall maintain documented evidence that each calibration in the chain of traceability has been carried out.

> *GUIDANCE*
>
> *In some countries, the national measurement standards are designated by an official decree in terms of specific artefact measurement standards (or by a group of them), rather than by reference to the technical prescriptions recommended by the CGPM. However, in almost all the situations where this part of ISO 10012 is likely to be used, differences between these two sources of traceability are unlikely to give rise to any problems in practical metrology.*
>
> *Valid traceability may be achieved by the use of accepted values of natural physical constants (for example, phase change temperatures), reference materials, ratio-type self-calibration techniques and build-up scales. The resultant uncertainty may be greater than would be achieved by a direct comparison to an international or national measurement standard.*
>
> *An example of a ratio-type self-calibration at a 1:1 ratio is the use of the Gauss double weighing method using a nominally equal-arm balance. In the field of electrical measurements, many accurate ratios are obtainable by using properly constructed transformers (inductive voltage dividers) and d.c. current comparators.*
>
> *An example of a build-up scale is the production of an accurate scale of masses by intercomparison of unit-value masses, and then using them in appropriate combinations to give a 1, 2, 3, 4, 5 etc. scale. In practice, for economy, a 1-1, 2-2, 5, 10, 20-20, 50 etc. set of masses is often used. Similar methods are used in other fields of measurement, but care has to be taken that the components are truly additive.*
>
> *The Supplier may provide the documented evidence of traceability by obtaining his calibrations from a formally accredited source.*

4.16 Cumulative effect of uncertainties

The cumulative effect of the uncertainties of each successive stage in a chain of calibrations shall be taken into account for each measurement standard and item of equipment that is confirmed. Action shall be taken when the total uncertainty is such that it significantly compromises the ability to make measurements within the limits of permissible error. The details of the significant components of the total uncertainty shall be recorded. The method of combining these components shall also be recorded.

> *GUIDANCE*
>
> *A "chain of calibrations" implies that the value of each measurement standard in the chain has had its value determined using another measurement standard, usually having a smaller uncertainty of measurement, up to an international or national measurement standard.*

4.17 Environmental conditions

Measurement standards and measuring equipment shall be calibrated, adjusted and used in an environment controlled to the extent necessary to ensure valid measurement results. Due consideration shall be given to temperature, rate of change of temperature, humidity, lighting, vibration, dust control, cleanliness, electromagnetic interference and other factors affecting the results of measurements. Where pertinent, these factors shall be continuously monitored and recorded and, when necessary, correcting compensations shall be applied to measurement results. Records shall contain both the original and the corrected data. Corrections, when applied, shall be soundly based.

> *GUIDANCE*
>
> *The manufacturer of a measurement standard or measuring instrument usually provides a specification giving the ranges and maximum loads, together with the limiting environmental conditions for the correct use of the device. When this information is available, it should be used for establishing the conditions of use and to determine if any control is necessary to maintain these conditions.*
>
> *It is permissible to narrow the conditions of use but it is inadvisable to enlarge them.*

4.18 Personnel

The Supplier shall ensure that all confirmations are performed by staff having appropriate qualifications, training, experience, aptitude and supervision.

Annex A
(informative)

Guidelines for the determination of confirmation intervals for measuring equipment

NOTE 28 This annex is based on OIML International Document No. 10.

A.1 Introduction

An important aspect of the efficient operation of a confirmation system is the determination of the maximum period between successive confirmations of measurement standards and measuring equipment. A large number of factors influence the frequency of confirmation. The most important of these factors are the following:

a) type of equipment;

b) manufacturer's recommendation;

c) trend data obtained from previous calibration records;

d) recorded history of maintenance and servicing;

e) extent and severity of use;

f) tendency to wear and drift;

g) frequency of cross-checking against other measuring equipment, particularly measurement standards;

h) frequency and formality of in-house check calibrations;

i) environmental conditions (temperature, humidity, vibration, etc.);

j) accuracy of measurement sought;

k) the penalty of an incorrect measured value being accepted as correct because the measuring equipment has become faulty.

The cost of confirmation cannot normally be ignored in determining the confirmation intervals and this may therefore be a limiting factor. It is obvious from all these stated factors that a list of confirmation intervals which can be universally applied cannot be constructed. It is more useful to present guidelines on how confirmation intervals may be established and then reviewed once confirmation on a routine basis is under way.

There are two basic and opposing criteria which are required to be balanced when deciding on the confirmation intervals for each item of measuring equipment. These are the following:

a) the risk of measuring equipment failing to conform to specification when in use should be as small as possible;

b) the confirmation costs should be kept to a minimum.

Therefore, methods are presented in this annex for the initial selection of confirmation intervals and for the readjustment of these intervals on the basis of experience.

A.2 Initial choice of confirmation intervals

The basis of the initial decision in determining the confirmation interval is invariably the so-called engineering intuition. Someone with experience of measurements in general, or of the measuring equipment to be confirmed in particular, and preferably with knowledge of the intervals used by other laboratories, makes an estimate for each item of equipment or group of items as to the length of time it is likely to remain within tolerance after confirmation.

Factors to be taken into account are:

a) the equipment manufacturer's recommendation;

b) the extent and severity of use;

c) the influence of the environment;

d) the accuracy of measurement sought.

A.3 Methods of reviewing confirmation intervals

A system which maintains confirmation intervals without review, determined only by so-called engineering intuition, is not considered to be sufficiently reliable.

Once confirmation on a routine basis has been established, adjustment of the confirmation intervals should be possible in order to optimize the balance of risks and costs as stated in the Introduction. It will probably be found that the intervals initially selected are not giving the desired optimum results: items of equipment may be less reliable than expected; their usage may not be as expected; it may be sufficient to carry out a limited confirmation of certain items instead of a full confirmation; the drift determined by the regular calibration of the equipment may show that longer confirmation intervals are possible without increasing the risks, and so on.

If shortage of money or shortage of staff means that extended confirmation intervals are necessary, it should not be forgotten that the costs of using inaccurate measuring equipment may be significant. If an estimate of these costs is made, it may well be found to be more economical to spend more money on confirmation and to reduce the confirmation intervals.

A range of methods is available for reviewing the confirmation intervals. These differ according to whether:

— items of equipment are treated individually or as groups (for example, by maker or by type);

— items fail to comply with their specifications due to drift with the lapse of time, or by usage;

— data are available and importance is attached to the history of calibration of the equipment.

No one method is ideally suited for the full range of equipment encountered.

A.3.1 Method 1: Automatic or "staircase" adjustment

Each time an item of equipment is confirmed on a routine basis, the subsequent interval is extended if it is found to be within tolerance, or reduced if it is found to be outside tolerance. This "staircase" response may produce a rapid adjustment of intervals and is easily carried out without clerical effort. When records are maintained and used, possible trouble with a group of items, indicating the desirability of a technical modification or preventive maintenance, will become apparent.

A disadvantage of systems which treat items individually may be that it is difficult to keep the confirmation work-load smooth and balanced, and that it requires detailed advanced planning.

A.3.2 Method 2: Control chart

The same calibration points are chosen from every confirmation and the results are plotted against time. From these plots, both scatter and drift are calculated, the drift being either the mean drift over one confirmation interval or, in the case of very stable equipment, the drift over several intervals. From these figures the effective drift may be calculated.

The method is difficult to apply, in fact very difficult in the case of complicated equipment and can virtually only be used with automatic data processing. Before calculations can commence, considerable knowledge of the law of variability of the equipment, or of similar equipment, is required. Again, it is difficult to achieve a balanced work-load. However, considerable variation of the confirmation intervals from those prescribed is permissible without invalidating the calculations; reliability can be calculated and, in theory at least, it gives the efficient confirmation interval. Furthermore, the calculation of the scatter will indicate if the manufacturer's specification limits are reasonable and the analysis of the drift which is found may help in indicating the cause of the drift.

A.3.3 Method 3: Calendar time

Items of measuring equipment are initially arranged into groups on the basis of their similarity of construction and of their expected similar reliability and stability. A confirmation interval is assigned to the group, initially on the basis of engineering intuition.

In each group, the quantity of items which return at their assigned confirmation interval and are found to have excessive errors or to be otherwise nonconforming is determined and expressed as a proportion of the total quantity of items in that group which are confirmed during a given period. In determining the nonconforming items, those which are obviously damaged or which are returned by the user as suspect or faulty, are not included as they are not likely to cause measurement errors.

If the proportion of nonconforming items of equipment is excessively high, the confirmation interval should be reduced. If it appears that a particular sub-group of items (such as a particular make or type) does not behave like the other members of the group, this sub-group should be removed to a different group with a different confirmation interval.

The period during which the performance is assessed should be as short as possible, compatible with obtaining a statistically meaningful quantity of confirmed items for a given group.

If the proportion of nonconforming items of equipment in a given group proves to be very low, it may be economically justifiable to increase the confirmation interval.

Other statistical methods may be used.

A.3.4 Method 4: "In-use" time

This is a variation on the foregoing methods. The basic method remains unchanged but the confirmation interval is expressed in hours of use rather than in calendar months of elapsed time. An item of equipment may be fitted with an elapsed-time indicator, and is returned for confirmation when this indicator reaches a specified value. The important theoretical advantage of this method is that the number of confirmations performed, and therefore the cost of confirmation, varies directly with the length of time for which the equipment is used. Furthermore, there is an automatic check on equipment utilization.

However, the practical disadvantages are many and include the following:

a) the method cannot be used with passive measuring instruments (for example, attenuators) or with passive measurement standards (resistors, capacitors, etc.);

b) the method should not be used when equipment is known to drift or deteriorate when on the shelf, or when handled, or when subjected to a number of short on/off cycles; it should in any case have a calendar-time back-up;

c) the initial cost of the provision and installation of suitable timers is high and, since users may interfere with them, supervision may be required which again will increase costs;

d) it is even more difficult to achieve a smooth flow of work than with the other methods mentioned, since the calibration laboratory has no knowledge of the date when the confirmation interval will terminate.

A.3.5 Method 5: In-service or "black-box" testing

This method is complementary to a full confirmation. It can provide useful interim information on characteristics of measuring equipment between full confirmations and can give guidance on the appropriateness of the confirmation programme.

This method is a variation on methods 1 and 2 and is particularly suitable for complex instruments and test consoles. Critical parameters are checked frequently (once per day or even more often) by portable calibration gear or, preferably, by a "black-box" made up specifically to check the selected parameters. If the equipment is found to be nonconforming by using the "black-box", it is returned for a full confirmation.

The great advantage of this method is that it provides maximum availability for the equipment user. It is very suitable for equipment which is geographically separated from the calibration laboratory, since a complete confirmation is only done when it is known to be necessary or at extended confirmation intervals. The main difficulty is in deciding on the critical parameters and in designing the "black-box".

Although theoretically the method gives a very high reliability, this is slightly ambiguous since the equipment may be failing on some parameter which is not measured by the "black-box". In addition, the characteristics of the "black-box" itself may not be constant and it also needs to be regularly confirmed.

Annex B
(informative)

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