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Foreword (ILAC)

The ILAC Secretariat will provide the current text for the ILAC forward prior to the document being distributed for ballot.

Foreword (OIML)

The International ~~Organization~~-Organisation of Legal Metrology (OIML) is a worldwide, intergovernmental ~~organization~~-organisation whose primary aim is to ~~harmonize~~-harmonise the regulations and metrological controls applied by the national metrological services, or related ~~organizations~~organisations, of its Member States. The main categories of OIML publications are:

- **International Recommendations (OIML R)**, which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity. OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and which are intended to ~~harmonize~~-harmonise and improve work in the field of legal metrology;
- **International Guides (OIML G)**, which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology;
- **International Basic Publications (OIML B)**, which define the operating rules of the various OIML structures and systems; and

OIML Draft Recommendations, Documents and Guides are developed by Project Groups linked to Technical Committees or Subcommittees which comprise representatives from OIML Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements have been established between the OIML and certain institutions, such as ISO and the IEC, with the objective of avoiding contradictory requirements. Consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

International Recommendations, Documents, Guides and Basic Publications are published in English (E) and translated into French (F) and are subject to periodic revision.

Additionally, the OIML publishes or participates in the publication of **Vocabularies (OIML V)** and periodically commissions legal metrology experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus, they do not necessarily represent the views of the OIML.

This publication - reference ILAC-G24 / OIML D 10, Edition 20XX - was developed by the ILAC Accreditation Committee and by OIML TC 4 *Measurement standards and calibration and verification devices*. ~~This version supersedes OIML D 10 (Edition 2007).~~ It was approved for final publication by ILAC in 20XX and by the International Committee of Legal Metrology at its xx meeting in xxxxxx 20xx and will be submitted to the International Conference on Legal Metrology in 20xx for formal sanction~~International Committee of Legal Metrology in 20XX~~. This edition of D 10 supersedes the previous edition dated 2007.

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1 Introduction

- 1.1** This ~~Guidance~~ ~~Document~~ ~~Document~~ is a revision of OIML D 10. It was developed by the OIML (International Organization of Legal Metrology) and ILAC (International Laboratory Accreditation Cooperation) as a joint venture and is published as such.
- 1.2** It is important to point out that:
- ~~a) it is not the responsibility of accreditation bodies to teach testing laboratories how to run their business;~~
 - ~~b)~~ a) it is the responsibility of each ~~individual testing~~ laboratory to choose to implement any or none of the methods described in this ~~Document~~ ~~Document~~ based on its individual needs and its individual assessment of risks, and
 - ~~e)~~ b) it is also ~~the~~ responsibility of each ~~testing~~ laboratory to evaluate the effectiveness of ~~implemented~~ the method(s) ~~implemented~~ and to take responsibility for the consequences of the decisions taken as a result of the method(s) chosen.

2 Scope

- 2.1** The purpose of this ~~Document~~ ~~Document~~ is to give ~~testing~~ laboratories ~~guidance or any other relevant parties, particularly while setting up their calibration system, guidance~~ on how to determine the recalibration intervals of ~~a~~ measuring equipment while setting up their calibration program. ~~This~~ ~~The~~ ~~is~~ ~~Document~~ is also applicable ~~also~~ to other Conformity Assessment Bodies (e.g. Inspection Bodies and Certification Bodies) and other parties (e.g. manufacturers) ~~who that utilize a measuring equipment. Document identifies and describes the methods that are available and generally accepted for the evaluation of recalibration intervals.~~

3 Terms and definitions

Unless otherwise stated in the following sub-clauses, the terminology used in this ~~Document~~ conforms to the VIM [1], ISO 10012 [5], ISO/IEC 17000 [14], ISO/IEC 17020 [15], ISO/IEC 17025 [3], ISO/IEC 17065 [19] and CIPM MRA-D-04 [2].

For the purpose of this ~~Document~~, the definitions and abbreviations given below apply. ~~The terms and definitions listed below apply to this publication.~~

3.1 measurement uncertainty (VIM, 2.26)

uncertainty of measurement

uncertainty

non-negative parameter characterising the dispersion of the quantity values being attributed to a measurand, based on the information used

Note 1: Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

Note 2: The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

Note 3: Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from

the statistical distribution of the quantity values from series of measurements and can be characterised by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.

3.1 ~~Note 4:~~ In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty. ~~measurement uncertainty, uncertainty of measurement, uncertainty-~~
~~non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used-~~

~~Note 1~~ Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

~~Note 2~~ The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half width of an interval, having a stated coverage probability.

~~Note 3~~ Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.

~~Note 4~~ In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

(OIML V2-200, 2.26 [1])

3.2 combined standard measurement uncertainty (VIM, 2.31)

combined standard uncertainty
 standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model

Note: In the case of correlations of input quantities in a measurement model, covariances must also be taken into account when calculating the combined standard measurement uncertainty; see also GUM:1995, 2.3.4.

3.2.3 calibration (VIM, 2.39)

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

- Note 1:* A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.
- Note 2:* Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, nor with verification of calibration.
- Note 3:–* Often, the first step alone in the above definition is perceived as being calibration.

(OIML V2-200, 2.39 [1])

3.4 measurement result (VIM, 2.9)

~~3.3~~ ~~–~~result of measurement

set of quantity values being attributed to a measurand together with any other available relevant information

- Note 1:* A measurement result generally contains “relevant information” about the set of quantity values, such that some may be more representative of the measurand than others. This may be expressed in the form of a probability density function (PDF).
- Note 2:* A measurement result is generally expressed as a single measured quantity value and a measurement uncertainty. If the measurement uncertainty is considered to be negligible for some purpose, the measurement result may be expressed as a single measured quantity value. In many fields, this is the common way of expressing a measurement result.
- Note 3:* In the traditional literature and in the previous edition of the VIM, the measurement result was defined as a value attributed to a measurand and explained to mean an indication, or an uncorrected result, or a corrected result, according to the context.

(OIML V2-200, 2.9 [1])

3.5 material measure (VIM, 3.6)

measuring instrument reproducing or supplying, in a permanent manner during its use, quantities of one or more given kinds, each with an assigned quantity value

Examples: Standard weight, volume measure (supplying one or several quantity values, with or without a quantity-value scale), standard electric resistor, line scale (ruler), gauge block, standard signal generator, certified reference material.

Note 1: The indication of a material measure is its assigned quantity value.

Note 2: A material measure can be a measurement standard.

3.6 adjustment of a measuring system (VIM, 3.11)

adjustment

set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of a quantity to be measured

Note 1: Types of adjustment of a measuring system include zero adjustment of a measuring system, offset adjustment, and span adjustment (sometimes called gain adjustment).

Note 2: Adjustment of a measuring system should not be confused with calibration, which is a prerequisite for adjustment.

Note 3: After an adjustment of a measuring system, the measuring system must usually be recalibrated.

3.43.7 instrumental drift (VIM, 4.21)

continuous or incremental change over time in indication, due to changes in ~~metrological~~ properties of a measuring instrument

Note:— Instrumental drift is related neither to a change in a quantity being measured nor to a change of any ~~recognized~~ ~~recognised~~ influence quantity.

~~(OIML V2-200, 4.21 [1])~~

3.8 maximum permissible measurement error (VIM, 4.26)

~~maximum permissible error~~

3.5 ~~limit of error~~

extreme value of measurement error, with respect to a known reference quantity value, permitted by specifications or regulations for a given measurement, measuring instrument, or measuring system

Note 1: Usually, the term “maximum permissible errors” or “limits of error” is used where there are two extreme values.

Note 2: The term “tolerance” should not be used to designate ‘maximum permissible error’.

~~(OIML V2-200, 4.26 [1])~~

3.9 reference measurement standard (VIM, 5.6)

reference standard

measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organisation or at a given location

3.10 reference quantity value (VIM, 5.18)

3.6 ~~reference value~~

quantity value used as a basis for comparison with values of quantities of the same kind

Note 1: A reference quantity value can be a true quantity value of a measurand, in which case it is unknown, or a conventional quantity value, in which case it is known.

Note 2: A reference quantity value with associated measurement uncertainty is usually provided with reference to

- a) a material, e.g. a certified reference material,
- b) a device, e.g. a ~~stabilized~~ ~~stabilised~~ laser,
- c) a reference measurement procedure,
- d) a comparison of measurement standards.

—

~~(OIML V2-200, 5.18 [1])~~

3.73.11 measuring instrument (VIM, 3.1)

device used for making measurements, alone or in conjunction with one or more supplementary devices

Note 1: A measuring instrument that can be used alone is a measuring system.

Note 2: A measuring instrument may be an indicating measuring instrument or a material measure.

~~(OIML V2-200, 3.1 [1])~~

3.12 measuring system (VIM, 3.2)

set of one or more measuring instruments and often other devices, including any reagent and supply, assembled and adapted to give information used to generate measured quantity values within specified intervals for quantities of specified kinds

Note: A measuring system may consist of only one measuring instrument.

3.83.13 measuring equipment (ISO 10012, 3.3)

measuring instrument, software, measurement standard, reference material or auxiliary apparatus, or a combination thereof, necessary to realize a measurement process

~~(ISO 10012: 2003, 3.3 [5])~~

Note 1: A measuring instrument is a component of a the measuring equipment which plays an important role for measurement. Some measuring instruments can be used independently to complete a measurement process or realize a physical quantity.

Note 2: The measuring equipment is equal to the measuring system.

3.14 calibration and measurement capability (CIPM MRA-D-04)

~~3.9~~ (CMC)

~~is a~~ calibration and measurement capability available to customers under normal conditions:

- a) as published in the BIPM key comparison database (KCDB) of the CIPM MRA; or
- b) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement.

~~(CIPM MRA-D-04 [2])~~

3.15 laboratory (ISO/IEC 17025, 3.6)

body that performs one or more of the following activities:

- testing;
- calibration;
- sampling, associated with subsequent testing or calibration

Note: In the context of this dDocument, “laboratory activities” refer to the three above-mentioned activities.

~~**3.10 testing laboratory**~~

~~body that performs determination one or more characteristics of testing object~~

~~*Note*——Testing typically applies to materials, products or processes.~~

3.16 conformity assessment body (ISO/IEC 17000, 2.5)

body that performs conformity assessment services

Note: An accreditation body is not a conformity assessment body.

3.17 certification body (ISO/IEC 17065, 3.12)

third-party conformity assessment body operating certification schemes

Note: A certification body can be non-governmental or governmental (with or without a regulatory authority)

3.18 inspection body (ISO/IEC 17020, 3.5)

body that performs inspection

Note: An inspection body can be an organization, or part of an organization.

4 General aspects

- 4.1 An important aspect for maintaining the capability of ~~testing~~ a laboratory to produce traceable and reliable measurement results is a determination of the maximum period that should be permitted between successive calibrations (recalibrations) of the measuring equipment used. Various international standards dealing with measurement activities take this aspect into account, e.g. ISO/IEC 17025 [3] or ISO 15189 [17]. In addition, this aspect is also included in international standards applicable to conformity assessment bodies and other parties operating according to e.g. ISO/IEC 17020 [15], ISO/IEC 17043 [16], ISO/IEC 17065 [19], ISO 9001 [13], ISO 10012 [5], ISO 17034 [18] or ISO 22870 [20]. ~~Various international standards take this aspect into account, e.g.:~~

- ~~ISO/IEC 17025:2017 [3] contains the following requirements:~~
- ~~Subclause 6.4.6: "Measuring equipment shall be calibrated when:~~
 - ~~the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or~~
 - ~~calibration of the equipment is required to establish the metrological traceability of the reported results.~~
- ~~NOTE Types of equipment having an effect on the validity of the reported results can include:~~
 - ~~those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;~~
 - ~~those used to make corrections to the measured value, e.g. temperature measurements;~~
 - ~~those used to obtain a measurement result calculated from multiple quantities".~~
- ~~Subclause 6.4.7: "The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration".~~
- ~~Subclause 6.4.8: "All equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity".~~
- ~~Subclause 6.4.10: "When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure".~~
- ~~Subclause 6.4.13: "Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:~~
 - ~~e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;"~~
- ~~Subclause 6.5.1: "The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.~~
- ~~NOTE 1 In ISO/IEC Guide 99 [14], metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty".~~
- ~~NOTE 2 See Annex A for additional information on metrological traceability".~~
- ~~Subclause 6.5.2: "The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:~~

~~_____ a) calibration provided by a competent laboratory; or~~

~~_____ NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent."~~

~~_____ Subclause 7.7.1: "The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:~~

~~_____ e) intermediate checks on measuring equipment;~~

~~_____ f) replicate tests or calibrations using the same or different methods;~~

~~_____ g) retesting or recalibration of retained items;"~~

~~_____ ISO 9001:2015 [13] contains the following requirement:~~

~~_____ Subclause 7.1.5.2: "When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:~~

~~_____ a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;"~~

~~_____ ISO/IEC 17020:2012 [15] contains the following requirements:~~

~~_____ Subclause 6.2.6: "Where appropriate, measurement equipment having a significant influence on the results of the inspection shall be calibrated before being put into service, and thereafter calibrated according to an established programme".~~

~~_____ Subclause 6.2.8: "Reference standards of measurement held by the inspection body shall be used for calibration only and for no other purpose. Reference standards of measurement shall be calibrated providing traceability to a national or international standard of measurement".~~

~~_____ Subclause 6.2.9: "Where relevant, equipment shall be subjected to in service checks between regular recalibrations".~~

~~_____ Subclause 6.2.15: "Relevant information on the equipment, including software, shall be recorded. This shall include identification and where appropriate, information on calibration and maintenance".~~

~~_____ ISO/IEC 17043:2010 [16] contains the following requirements:~~

~~_____ Subclause 3.11: "proficiency testing scheme~~

~~_____ proficiency testing designed and operated in one or more rounds for a specified area of testing, measurement, calibration or inspection"~~

~~_____ NOTE A proficiency testing scheme might cover a particular type of test, calibration, inspection or a number of tests, calibrations or inspections on proficiency test items".~~

~~_____ Subclause 4.4.5.2: "Proficiency testing schemes in the area of calibration shall have assigned values with metrological traceability including measurement uncertainty".~~

~~_____ ISO 15189:2012 [17] contains the requirement:~~

~~_____ Subclause 5.3.1.4: „The laboratory shall have a documented procedure for the calibration of~~

equipment that directly or indirectly affects examination results. This procedure includes:

- b) recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment;
- d) recording the calibration status and date of recalibration;
- e) ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated”.

— ISO 17034: 2016 [18] contains the following requirements:

— Subclause 6.3.3: “The RMP shall ensure that equipment and consumable materials are not used until they have been inspected, calibrated or otherwise verified as complying with the specifications or requirements defined for the RM production activities.”.

— Subclause 6.4.1 “The RMP shall ensure that all laboratory facilities, calibration and testing areas (if applicable), material handling, storage, processing and packaging areas, energy sources, lighting, humidity, temperature, pressure and ventilation are such as to facilitate proper material handling, storage, processing and packaging, as well as proper performance of calibration and testing activities (if applicable)”.

— Subclause 6.4.2 “When the environmental conditions could have an adverse effect on the RM, the environmental conditions in which the RM production activities are undertaken shall be monitored with appropriately calibrated equipment, and shall be controlled and recorded, such that results and processes are not adversely affected”.

— Subclause 7.2.3 “The RMP shall address, during the planning stage, the following:

- g) verification and calibration of measuring equipment;

— Subclause 7.7 “The RMP shall ensure that measuring equipment used in RM production is used in compliance with the relevant requirements of ISO/IEC 17025.

— NOTE Additional information on the management of measurement systems, including information on equipment that is found to drift outside acceptable limits, can be found in ISO 10012”.

— Subclause 7.9.5 “For studies in which the values need to be traceable to a higher order reference system (e.g. characterization studies with measurements under reproducibility conditions), it shall be ensured that the measurements are calibrated with standards with metrologically traceable values”.

— ISO 10012:2003 [5] contains the following requirements:

— Subclause 6.3.1: “All measuring equipment necessary to satisfy the specified metrological requirements shall be available and identified in the measurement management system. Measuring equipment shall have a valid calibration status prior to being confirmed”.

— Subclause 7.1.2: “The methods used to determine or change the intervals between metrological confirmation shall be described in documented procedures. These intervals shall be reviewed and adjusted when necessary to ensure continuous compliance with the specified metrological requirements”.

— Each time nonconforming measuring equipment is repaired, adjusted or modified, the interval for its metrological confirmation shall be reviewed”.

~~Subclause 7.3.2: “The management of the metrological function shall ensure that all measurement results are traceable to SI unit standards”.~~

~~“Traceability to SI units of measurement shall be achieved by reference to an appropriate primary standard or by reference to a natural constant, the value of which in terms of the relevant SI units is known and recommended by the General Conference on Weights and Measures and the International Committee for Weights and Measures”.~~

~~“Where agreed to, consensus standards used in contractual situations shall only be used when SI unit standards or recognized natural constants do not exist”.~~

~~“Records of traceability of measurement results shall be maintained for as long as required by the measurement management system, the customer, or by statutory and regulatory requirements”.~~

~~ISO/IEC 17065:2012 [19] contains the following requirements:~~

~~Subclause 6.2.1: “For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; ...”~~

~~Subclause 6.2.2.1 “For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; ...”~~

4.2 The purposes of periodic calibration of measuring equipment are:

~~— to improve the estimation of the deviation between a reference value and the value obtained using a the measuring equipment, and the uncertainty in this deviation, at the time the measuring equipment is actually used;~~

a)

~~— b) to support the validation of the stated least uncertainty to validate the stated least uncertainty that can be achieved with the measuring equipment; and~~

~~— c) to confirm whether or not there has been any alteration of the measuring equipment which could introduce doubt about the results delivered in the elapsed period.~~

4.3 One of the most significant decisions regarding the calibration is “When to do it” and “How often to do it”. A large number of factors influence the time interval that should be allowed between calibrations and should be taken into account by the testing laboratory. For t The most important factors are see clause 5.1 of this document.:

~~— uncertainty of measurement required or declared by the testing laboratory;~~

~~— risk of a measuring equipment exceeding the limits of the maximum permissible error when in use;~~

~~— trend data obtained from previous calibration records;~~

~~— recorded history of maintenance and servicing;~~

~~— risk assessment analysis regarding the consequences if the measuring equipment is out of calibration (it is not traceable anymore);~~

~~— type of measuring equipment and its inner components;~~

~~— manufacturer’s recommendation;~~

~~— tendency to wear and drift;~~

~~— extent and severity of use;~~

~~— significance of the measuring equipment to the quality of the test, measurement or calibration result;~~

~~— environmental conditions (climatic conditions, vibration, ionizing radiation, etc.);~~

~~— frequency of cross checking against other reference standards or measuring instruments;~~

~~— frequency and quality of intermediate checks;~~

~~— transportation arrangements and risk; and~~

- ~~degree to which the operating staff are trained and implementing the established procedures.~~
- 4.4** ~~The previous calibration records can be used for determination of the recalibration interval when subsequent calibration is to be performed by a laboratory with appropriate CMC and/or several different laboratories with similar CMC.~~ The calibration records may be used for determination of the recalibration interval, when the calibrations are performed at, but not limited to, the following conditions:
- a) calibration and measurement capabilities are provided by national metrology institutes and designated institutes that have been subject to suitable peer review processes. Such peer review is conducted under the CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement); or
 - 4.4b)** calibration and measurement capabilities are provided by the laboratories that have been accredited by an accreditation body subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC have demonstrated metrological traceability.
- 4.5** When determining the recalibration intervals, the costs of recalibrations can normally not be ignored. However, these costs need to be balanced against increased measurement uncertainties or a higher risk in terms of measurement quality and services which arise from longer recalibration intervals. ~~Although the cost of calibration cannot normally be ignored in determining the recalibration intervals, the increased measurement uncertainties or a higher risk in terms of measurement quality and services arising from longer intervals may mitigate against the apparently high cost of a calibration.~~
- 4.6** ~~The process of determining recalibration intervals is a complex mathematical and statistical process requiring accurate and sufficient data taken during the calibration process.~~ There appears to be no universally applicable single best practice for establishing and adjusting the recalibration intervals. This has created a need for better understanding of the recalibration interval determination. As no single method is ideally suited for the whole range of measuring equipment, some of the simpler methods of assigning and reviewing the recalibration interval and their suitability for different types of measuring equipment are covered in this ~~Document~~ Document. The methods have been published in more detail in certain standards (e.g. ISO 10012-1:1992 [4] is a standard containing useful details, which have been amended by standard ISO 10012:2003 [5], which however contains only general information related to confirmation intervals), or by reputable technical organizations (e.g. [8], [9], [10]), or in relevant scientific journals.
- 4.7** Methods for determining recalibration intervals developed by ~~a laboratory or adopted by the laboratory~~ may also be used if they are appropriate and validated. ~~The methods can be used for the initial selection of recalibration intervals and the readjustment of these intervals on the basis of calibration trend and experience. Testing laboratory developed methods or methods adopted by the testing laboratory may also be used if they are appropriate and if they are validated.~~
- 4.8** The ~~testing~~ laboratory should select appropriate methods and should document those used. Calibration results should be collected and retained as the historical data, in order to form the basis of future decisions for recalibration intervals of the measuring equipment.
- 4.8** *Note:* For some kinds of measuring equipment, each device or measuring instrument which composes the equipment may be calibrated separately. In this case, a combined standard measurement uncertainty of the measuring equipment is calculated from the uncertainties arising from all the devices and measuring instruments.
- 4.9** Independently ~~from~~ of the determined recalibration intervals, the ~~testing~~ laboratory should have an appropriate system of intermediate checks to ensure the proper functioning and calibration status of the measuring equipment used between calibrations (e.g. see- ISO/IEC 17025:2017 [3];

~~6.4.10 and 7.7.1).~~

- 4.10** The laboratory should check whether the results from external calibration and/or internal tests fall within predetermined set limits prior to approving the measuring equipment for further use.

5 Initial choice of recalibration intervals

- 5.1** The initial decision in determining the recalibration interval is based mainly on, but not limited to, ~~on~~ the following factors:

- a) uncertainty of measurement required or declared by the laboratory;
- b) risk of the measuring equipment exceeding the limits of the maximum permissible error when in use;
- c) risk assessment analysis, e.g. regarding the consequences in the case of incorrect determining of the recalibration interval, measuring equipment is out of calibration (it is not traceable anymore) or significant drift of the measuring equipment;
- d) type of measuring equipment and its inner components;
- e) manufacturer's recommendation regarding the measuring equipment (e.g. suggestions from the manufacturer when the uncertainty of measurement is required or declared by the laboratory based on the accuracy of the instrument);
- f) tendency to wear and drift;
- g) expected extent and severity of use;
- h) significance of the measuring equipment to the quality of the test, measurement or calibration result;
- i) environmental conditions (climatic conditions, vibration, ionizing radiation, etc.);
- j) influence of the measured quantity (e.g. high temperature effect on thermocouples);
- k) pooled or published data about the same or similar devices;
- l) frequency of cross-checking against other reference standards or measuring instruments;
- m) frequency, quality and results of intermediate checks;
- n) transportation arrangements and risk;
- o) degree to which the operating staff are trained and extent to which ~~implementing~~ the established procedures are implemented; and
- p) legal requirements.

~~— the required uncertainty of measurement;~~

~~— the measuring equipment manufacturer's recommendation (e.g. when the uncertainty of measurement required or declared by the testing laboratory is based on the accuracy of instrument);~~

~~— maximum permissible errors (e.g. by legal metrology authorities);~~

~~— expected extent and severity of use;~~

~~— influence of the environment;~~

~~— adjustment of (or change in) the individual measuring equipment;~~

~~— influence of the measured quantity (e.g. high temperature effect on thermocouples);~~

~~— risk assessment analysis in relation to consequences in incorrect determining of the recalibration interval;~~

~~— pooled or published data about the same or similar devices; and~~

~~— legal requirements.~~

- 5.2** The decision should be made by a person or by persons having the relevant technical competence with general experience of measurements, or knowledge of the particular measuring equipment to be calibrated, and preferably also with knowledge of the intervals used by other laboratories. An estimate should be made for each piece of measuring equipment or group of pieces of measuring equipment as to the length of time the measuring equipment ~~instrument~~ is likely to remain within ~~set~~ the prescribed limits (i.e. maximum permissible error, accuracy requirements) after calibration.

6 Methods of reviewing recalibration intervals

6.1 General principles

6.1.1 Once calibration ~~on a routine basis~~ has been established ~~on a routine basis~~ (based on a defined number of consecutive results), adjustment of the recalibration intervals should be possible in order to ~~optimize~~ ~~optimise~~ the balance of risks and costs as stated in the introduction. It will probably be found that the intervals initially selected do not give the desired optimum results due to a number of reasons, for example:

- a) measuring equipment may be less reliable than expected;
- b) the extent of usage and care in maintenance may not be as anticipated;
- c) for certain measuring equipment it may be sufficient to carry out a limited calibration instead of a full calibration; and
- d) the instrumental drift determined by the recalibration of the measuring equipment may show that longer calibration intervals may be possible without increasing risks, etc.

6.1.2 A range of methods is available for reviewing the recalibration intervals. The method chosen differs according to whether:

- a) measuring equipment is treated individually or as groups (e.g. by ~~the~~ manufacturer's model or by ~~the~~ type);
- b) the measuring equipment's performance exceeds ~~set~~ ~~the~~ prescribed limits (e.g. ~~i.e.~~ maximum permissible error, accuracy requirements) due to drift over time or by usage;
- c) ~~the~~ measuring equipment shows different types of instabilities;
- ~~the~~ measuring equipment undergoes adjustments; and
- d)
- e) data are available and importance is attached to the history of calibration of the measuring equipment (e.g. ~~trend data obtained from previous calibration records or recorded history of maintenance and servicing of the measuring instrument~~).

6.1.3 ~~It is recommended for~~ For new measuring equipment, ~~it is recommended to~~ be calibrated more frequently at the beginning of its operational lifetime in order to ~~know~~ quickly become aware of a trend ~~of indicating a change in its characteristics. , so as to establish behavioural trends.~~ After analysis of this ~~the behavioural trend,~~ the ~~periodicities of~~ recalibration intervals may be re-evaluated.

Note: ~~It is~~ For ~~recommended for~~ new measuring equipment, ~~it is recommended~~ to collect calibration data ~~from~~ at least ~~from~~ three successive ~~periodical~~ calibrations ~~periodicities~~ to establish ~~behavioural~~ ~~the~~ trend.

6.1.4 The so-called “engineering intuition” which fixed the initial recalibration intervals, and a system which maintains fixed intervals without review, are not considered as being sufficiently reliable and are therefore not recommended.

6.2 Method 1: Automatic adjustment or “staircase” (calendar-time)

6.2.1 Each time a piece of measuring equipment is calibrated on a routine basis, the subsequent recalibration interval is extended (or unchanged) if the deviation from the reference value is found to be within an appropriately defined percentage of the range between the maximum permissible errors (MPEs). Otherwise, the recalibration interval is reduced when the deviation from the reference value is outside this percentage of the range. The MPEs may be replaced with

any other set of limits as required. It is recommended that appropriate decision criteria for extension or reduction of the recalibration interval of measuring equipment are specified for typical individual cases. ~~Each time a measuring equipment is calibrated on a routine basis, the subsequent recalibration interval is extended if it is found to be within an appropriate defined percentage of the maximum permissible error (or any other set of limits as required) that is required for measurement, or reduced if it is found to be outside this percentage of maximum permissible error (or any other set of limits as required). It is recommended that appropriate decision criteria for extension or reduction of the recalibration interval of measuring equipment are specified for individual cases (e.g. the subsequent recalibration interval may be extended or unchanged if it is found to be within 80 % of the maximum permissible error that is required for measurement, or reduced if it is found to be outside 80 % of the maximum permissible error).~~ This “staircase” response may produce a rapid adjustment of intervals and is easily carried out without administrative effort. When the records of calibration are maintained and utilised, future troubles with a group of measuring equipment will be predicted because the records indicate needs for technical modifications or preventive maintenance. ~~When records are maintained and used, possible trouble with a group of measuring equipment indicating the need for a technical modification, or preventive maintenance, will be known.~~

Note:– NCSL Recommended Practice RP-1 [9] describes the similar Simple Response Method (Method A1). Although this method is inexpensive to implement, random measurement results (with errors falling within or outside the ~~set~~ prescribed limits) essentially drive the calibration interval to change, thus the user shall compromise the results. ~~As other problems~~ Another problem is that, the calibration interval approaches the correct interval slowly and the correct interval may not be maintained even after it has been achieved. ~~RP-1 [9] describes the similar Simple Response Method (Method A1). Although inexpensive to implement, essentially random events (errors falling within or outside the set limits) drive the interval changes, thus compromising the results. Among other problems, the assigned interval approaches the correct interval slowly and may not maintain the correct interval once achieved.~~ A similar point of view may therefore also apply to Method 1 ~~herein~~ the present Document.

6.2.2 A disadvantage of systems ~~treating-dealing with~~ measuring equipment individually may be that it is difficult to keep the calibration workload smooth and balanced ~~between risks and costs~~, and that it requires detailed advanced planning.

6.2.3 It would be inappropriate to ~~take-set an extremely long or short a~~ recalibration interval ~~to extremes~~ using this method. ~~Such a case may lead to~~ The risks associated with withdrawing large numbers of certificates issued, or repeating a lot of work, ~~and such risks~~ may ultimately become unacceptable.

6.3 Method 2: Control chart (calendar-time)

6.3.1 Control charting is one of the most important tools of Statistical Quality Control (SQC) and is well- described in various publications (e.g. [6], [7], [11]). In principle, it works as follows: Significant calibration points are chosen and the results are plotted against time. From these plots, both the dispersion of the results and the instrumental drift are calculated. ~~–The~~ the instrumental drift ~~is the being-either-the~~ mean drift normally over one recalibration interval, although several intervals may be taken into account in the calculation for ~~–or in the case of~~ very stable measuring ~~equipmentinstruments. –the drift over several intervals.~~ From these figures, the optimum interval may be calculated.

6.3.2 ~~This method is difficult to apply (in fact it is very difficult to apply in the case of complex measuring equipment) and can virtually only be used with automatic data processing.~~ Before calculations can commence, considerable knowledge of the variability properties of the measuring equipment is required. Again, it is difficult to achieve the balanced workload between

risks and costs a balanced workload. However, a The considerable variation of the recalibration intervals from those prescribed is permissible possible without invalidating the calculations, because by reason that the reliability can be calculated and in theory at least gives the efficient recalibration interval. Furthermore, the calculation of the dispersion of the results will indicate whether the manufacturer's specification limits are reasonable and the analysis of the instrumental drift found may help in indicating the cause of the drift.

Note: This method is not suitable for calibrations of measuring equipment without an instrumental drift. This method is suitable for for measurand a material measure with a single assigned quantity value, value e.g. , for example calibration of a gauge blocks or a standard resistance.

6.4 Method 3: "In-use" time

6.4.1 This is a variant on the previous methods. The basic method remains unchanged but the recalibration interval is expressed in hours of use, rather than in calendar time, e.g. months. The measuring equipment is equipped with a device which indicates the elapsed time and is returned for calibration when the indication reaches a specified value. Examples of such measuring instruments equipment are for example thermocouples, used at extreme temperatures, dead weight testers for gas pressure, and or length gauges (i.e. measuring equipment instruments that may be subject to mechanical wear). The major advantage in principle of this method is that the number of calibrations performed and therefore the cost of the calibration varies directly with the length of time that the measuring equipment is used. Other Another advantage of this method is that there is the automatic check on the measuring equipment utilization.

6.4.2 Nevertheless, this method has also following practical disadvantages: Furthermore, there is an automatic check on measuring equipment utilization. However, there are many practical disadvantages in using an automatic check, including when:

- it is not suitable for measuring equipment containing passive measuring instrument (e.g. attenuators) or standards (e.g. resistance, capacitance) it is difficult to use the method with passive instruments (e.g. attenuators) or standards (resistance, capacitance, etc.);
- a)
- it is not suitable for measuring equipment known to have a drift or deteriorate when it is not in use (e.g. it is on the shelf) or when it is handled or subjected to a number of short on-off cycles; it should not be used providing that a measuring equipment is known to drift or deteriorate when it is on the shelf, or handled, or subjected to a number of short on-off cycles;;
- b)
- the initial cost is high for providing and installing suitable timers for measuring the elapsed time. Since users may interfere with the installation of timers, additional supervision may be required which will increase the costs 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; and
- c)
- d) the planning of recalibration works is more difficult in comparison with the principle of the methods 1 and 2 since the laboratory has no knowledge of the date on which the recalibration interval will terminate. it is even more difficult to achieve a smooth flow of work than with the methods mentioned above, since the testing laboratory has no knowledge of the date on which the recalibration interval will terminate.

6.5 Method 4: In service checking, or "black-box" testing

6.5.1 This method is a variant on of methods 1 and 2 and may prove to be more effective than the

method of evaluating a recalibration interval of the original measuring equipment. ~~and~~ It is particularly suitable when the part, which provides a reference standard of the measuring equipment, is calibrated ~~an easily~~ and quickly. ~~by calibration of a reference part of measuring equipment is possible.~~ Critical parameters are checked frequently (once a day or even more often) by portable calibration gear, or preferably, by a “black box” designed specifically to check the selected parameters. If the measuring equipment is found to be outside the maximum permissible error (or any other set of limits as required) by the “black box”, it is returned for a full calibration.

Note: Measuring ~~equipment~~~~instruments~~ suitable for this method ~~are~~ ~~is for example~~ ~~e.g.~~ density meters (resonance type), Pt-resistance thermometers (in combination with calendar-time methods), dosimeters (source included) ~~and~~ ~~or~~ sound level meters (source included).

6.5.2 The major advantage of this method is that it provides maximum availability for the ~~user~~ ~~of measuring equipment~~ ~~user~~. It is very suitable for ~~the~~ measuring equipment which are geographically distant from the ~~testing~~ ~~laboratory~~, since a complete calibration is only ~~performed~~ ~~done~~ when it is known to be required. The difficulty is in deciding on the critical parameters and designing the “black box”.

6.5.3 Although the method is in principle very reliable, this is slightly ambiguous, since the measuring equipment may be failing on some parameter that is not measured by the “black box”. In addition, the characteristics of the “black box” itself may not remain constant, thus requiring a choice and periodic review of the ~~recalibration interval of the~~ black box ~~interval~~. ~~This may or may not prove more effective than evaluating the original measuring equipment’s interval.~~

6.6 Method 5: Other statistical approaches

6.6.1 Methods based on statistical analysis of an individual measuring equipment or measuring instrument ~~type~~ can also be a possible approach. These methods are gaining more and more interest, especially when used in combination with adequate software tools. An example of such a software tool and its mathematical background is described by A. Lepek [12].

6.6.2 When large numbers of identical measuring ~~equipment~~~~instruments~~ (i.e. groups of measuring ~~equipment~~~~instruments~~) are to be calibrated, the recalibration intervals can be reviewed with the help of statistical methods (see e.g. [10]). Detailed examples are presented for example in ~~NCSL Recommended Practice RP-1~~ ~~RP-1~~ [9].

6.7 Comparison of methods

~~6.7.1~~ No one method is ideally suited for the full range of measuring equipment encountered (see Table 1). ~~and a~~ ~~The~~ ~~testing~~ ~~laboratory~~ may choose to use different methods using different measuring ~~equipment~~~~instruments~~ ~~depending on the location of use~~ ~~or on different locations~~. Furthermore, it should be noted that the method chosen will be affected by whether the laboratory intends to introduce planned maintenance. There may be other factors which will affect the laboratory’s choice of method. The method chosen will, in turn, affect the form of records to be kept.

6.7.2 For comparison of methods, see Table 1.

Table 1 - Comparison of methods of reviewing recalibration intervals

Performance	Method				
	Method 1 “staircase”	Method 2 control chart	Method 3 “in-use” time	Method 4 “black box”	Method 5 ¹⁾ other statistical approaches
Reliability	medium	high	medium	high	medium
Effort of application	low	high	medium	low	high
Work-load balanced between risks and	medium	medium	badlow	medium	badlow
Applicability with respect to particular devices	medium	low	high	high	low
Availability of measuring equipment	medium	medium	medium	high	medium

----- ¹⁾ Better grading is achieved when an appropriate software tool is used.

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