

GUIDANCE
SERIES

ILAC-G24

Edition 2007 (E)

INTERNATIONAL

DOCUMENT

OIML D 10

Edition 2007 (E)

Guidelines for the determination of calibration
intervals of measuring instruments

Guide pour la détermination des intervalles de calibration
des instruments de mesure

INTERNATIONAL
LABORATORY
ACCREDITATION
COOPERATION



ORGANISATION INTERNATIONALE
DE METROLOGIE LEGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

CONTENTS

Copyright – ILAC	3
Foreword – OIML	4
Preamble	5
Purpose	5
Authorship	5
1. Introduction	5
2. Initial choice of calibration intervals	7
3. Methods of reviewing calibration intervals	7
Method 1: Automatic adjustment or “staircase” (calendar-time)	8
Method 2: Control chart (calendar-time)	8
Method 3: “In-use” time	9
Method 4: In service checking, or “black-box” testing	9
Method 5: Other statistical approaches	9
Bibliography	11

Copyright (ILAC)

ILAC-G24:2007

© Copyright ILAC 2007

ILAC encourages the authorized reproduction of its publications, or parts thereof, by organizations wishing to use such material for areas related to education, standardization, accreditation, good laboratory practice or other purposes relevant to ILAC's area of expertise or endeavor.

Organizations seeking permission to reproduce material from ILAC publications must contact the ILAC Chair or Secretariat in writing or via electronic means such as e-mail.

The request for permission should clearly detail:

- 1) the ILAC publication, or part thereof, for which permission is sought;
- 2) where the reproduced material will appear and what it will be used for;
- 3) whether the document containing the ILAC material will be distributed commercially, where it will be distributed or sold, and what quantities will be involved;
- 4) any other background information that may assist ILAC to grant permission.

ILAC reserves the right to refuse permission without disclosing the reasons for such refusal.

The document in which the reproduced material appears must contain a statement acknowledging ILAC's contribution to the document.

ILAC's permission to reproduce its material only extends as far as detailed in the original request. Any variation in the stated use of the ILAC material must be notified in advance in writing to ILAC for additional permission.

ILAC shall not be held liable for any use of its material in another document. Any breach of the above permission to reproduce or any unauthorized use of ILAC material is strictly prohibited and may result in legal action.

To obtain permission or for further assistance, please contact:

The ILAC Secretariat

PO Box 7507

Silverwater NSW 2128

Australia

Fax: +61 2 9736 8373

E-mail: ilac@nata.asn.au

Foreword (OIML)

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, 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 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; and
- **International Basic Publications (OIML B)**, which define the operating rules of the various OIML structures and systems.

OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which comprise representatives from the 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 2007 - 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 1984). It was approved for final publication by ILAC in November 2005 and by the International Committee of Legal Metrology in 2002.

OIML Publications may be downloaded from the OIML web site in the form of PDF files. Additional information on OIML Publications may be obtained from the Organization's headquarters:

Bureau International de Métrologie Légale
11, rue Turgot - 75009 Paris - France
Telephone: 33 (0)1 48 78 12 82
Fax: 33 (0)1 42 82 17 27
E-mail: biml@oiml.org
Internet: www.oiml.org

Guidelines for the determination of calibration intervals of measuring instruments

Preamble

This Guidance Document is a revision of OIML D 10. It was drafted by ILAC (International Laboratory Accreditation Cooperation) and the OIML (International Organization of Legal Metrology) as a joint venture and is published as such.

It is important to point out that:

- It is not the responsibility of accreditation bodies to teach laboratories how to run their business.
- It is the responsibility of each individual laboratory to choose to implement any or none of the methods described in this Document based on its individual needs and its individual assessment of risks.
- It is also the responsibility of the laboratory to evaluate the effectiveness of the method it chooses to implement and take responsibility for the consequences of the decisions taken as a result of the method chosen.

Purpose

The purpose of this Document is to give laboratories, particularly while setting up their calibration system, guidance on how to determine calibration intervals. This Document identifies and describes the methods that are available and known for the evaluation of calibration intervals.

Authorship

This publication was developed by the OIML and ILAC as a joint venture and as a revision of OIML D 10. Within ILAC the focal point has been the Accreditation Committee.

1. Introduction

An important aspect for maintaining the capability of 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 reference or working standards and measuring instruments used. Various international standards take this aspect into account, e.g.:

ISO/IEC 17025:2005 [1] contains the following requirements:

- Clause 5.5.2: “Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results”.*
- Clause 5.5.8: “Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded, or otherwise identified to indicate the status of calibration, including the data when last calibrated and the date or expiration criteria when recalibration is due”.*
- Clause 5.6.1 “All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The*

laboratory shall have an established program and procedure for the calibration of its equipment.”

Note: Such a program should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

ISO 9001:2000 [10] contains the requirement:

Clause 7.6: “Where necessary to ensure valid results, measuring equipment shall:
a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded”.

Note: This Document focuses on the determination of calibration intervals of measuring instruments. The methods described can also be used in an appropriate manner for reference standards, working standards, etc., which are under the control of the laboratory.

In line with the terminology of the VIM [11], the term “measuring instrument” is used instead of “measuring equipment” in this Document.

The general purpose of a periodic calibration is:

- to improve the estimation of the deviation between a reference value and the value obtained using a measuring instrument, and the uncertainty in this deviation, at the time the instrument is actually used;
- to reassure the uncertainty that can be achieved with the measuring instrument; and
- to confirm whether or not there has been any alteration of the measuring instrument which could introduce doubt about the results delivered in the elapsed period.

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 laboratory. The most important factors are:

- uncertainty of measurement required or declared by the laboratory;
- risk of a measuring instrument exceeding the limits of the maximum permissible error when in use;
- cost of necessary correction measures when it is found that the instrument was not appropriate over a long period of time;
- type of instrument;
- tendency to wear and drift;
- manufacturer’s recommendation;
- extent and severity of use;
- environmental conditions (climatic conditions, vibration, ionizing radiation, etc.);
- trend data obtained from previous calibration records;
- recorded history of maintenance and servicing;
- frequency of cross-checking against other reference standards or measuring devices;
- frequency and quality of intermediate checks in the meantime;
- transportation arrangements and risk; and
- degree to which the serving personnel are trained.

Although the cost of calibration cannot normally be ignored in determining the calibration 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.

The process of determining calibration 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 calibration intervals. This has created a need for better understanding of the calibration interval determination. As no single method is ideally suited for the whole range of measuring instruments, some of the simpler methods of assigning and reviewing the calibration interval and their suitability for different types of instruments are covered in this Document. The methods have been published in more detail in certain standards (e.g. [2]), or by reputable technical organizations (e.g. [5], [6], [7]), or in relevant scientific journals.

The methods can be used for the initial selection of calibration intervals and the readjustment of these intervals on the basis of experience. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate and if they are validated.

The laboratory should select appropriate methods and should document those used. Calibration results should be collected as historical data, in order to base future decisions for calibration intervals of the instruments.

Independently from the determined calibration intervals, the laboratory should have an appropriate system to ensure the proper functioning and calibration status of the standards and measuring instruments used between calibrations (see Clauses 5.5.10 and 5.6.3.3 of ISO/IEC 17025:2005).

2. Initial choice of calibration intervals

The initial decision in determining the calibration interval is based on the following factors:

- the instrument manufacturer's recommendation;
- expected extent and severity of use;
- the influence of the environment;
- the required uncertainty in measurement;
- maximum permissible errors (e.g. by legal metrology authorities);
- adjustment of (or change in) the individual instrument;
- influence of the measured quantity (e.g. high temperature effect on thermocouples); and
- pooled or published data about the same or similar devices.

The decision should be made by a person or by persons with general experience of measurements, or of the particular instruments to be calibrated, and preferably also with knowledge of the intervals used by other laboratories. An estimate should be made for each instrument or group of instruments as to the length of time the instrument is likely to remain within the maximum permissible error after calibration.

3. Methods of reviewing calibration intervals

Once calibration on a routine basis has been established, adjustment of the calibration 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 do not give the desired optimum results due to a number of reasons, for example:

- instruments may be less reliable than expected;
- the usage may not be as anticipated;
- it may be sufficient to carry out a limited calibration of certain instruments instead of a full calibration; and

- the drift determined by the recalibration of the instruments may show that longer calibration intervals may be possible without increasing risks, etc.

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

- instruments are treated individually or as groups (e.g. by manufacturer's model or by type);
- instruments exceed the calibration by drift over time or by usage;
- instruments show different types of instabilities;
- instruments undergo adjustments; and
- data are available and importance is attached to the history of calibration of the instruments.

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

Method 1: Automatic adjustment or "staircase" (calendar-time)

Each time an instrument is calibrated on a routine basis, the subsequent interval is extended if it is found to be within e.g. 80 % of the maximum permissible error that is required for measurement, or reduced if it is found to be outside this maximum permissible error. 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 instruments indicating the need for a technical modification, or preventive maintenance, will be known.

A disadvantage of systems treating instruments individually may be that it is difficult to keep the calibration workload smooth and balanced, and that it requires detailed advanced planning.

It would be inappropriate to take an interval to extremes using this method. The risk associated with withdrawing large numbers of certificates issued, or redoing large numbers of jobs may ultimately be unacceptable.

Method 2: Control chart (calendar-time)

Control charting is one of the most important tools of Statistical Quality Control (SQC) and well-described in publications (e.g. [3], [4]). In principle, it works as follows: Significant calibration points are chosen and the results are plotted against time. From these plots, both dispersion of results and drift are calculated, the drift being either the mean drift over one calibration interval, or in the case of very stable instruments, the drift over several intervals. From these figures, the optimum interval may be calculated.

This method is difficult to apply (in fact it is very difficult to apply in the case of complex instruments) and can virtually only be used with automatic data processing. Before calculations can commence, considerable knowledge of the law of variability of the instrument, or similar instruments, is required. Again, it is difficult to achieve a balanced workload. However, a considerable variation of the calibration intervals from those prescribed is permissible without invalidating the calculations; reliability can be calculated and in theory at least gives the efficient calibration interval. Furthermore, the calculation of the dispersion of results will indicate whether the manufacturer's specification limits are reasonable and the analysis of drift found may help in indicating the cause of drift.

Method 3: "In-use" time

This is a variation on the foregoing methods. The basic method remains unchanged but the calibration interval is expressed in hours of use, rather than calendar months. The instrument is fitted with an elapsed time indicator and is returned for calibration when the indicator reaches a specified value. Examples of instruments are thermocouples, used at extreme temperatures, dead weight tester for gas

pressure, length gauges (i.e. instruments that may be subject to mechanical wear). The important theoretical advantage of this method is that the number of calibrations performed and therefore the cost of calibration varies directly with the length of time that the instrument is used.

Furthermore, there is an automatic check on instrument utilization. However, there are many practical disadvantages in using an automatic check, including:

- it cannot be used with passive instruments (e.g. attenuators) or standards (resistance, capacitance, etc.);
- it should not be used when an instrument is known to drift or deteriorate when on the shelf, or when handled, or when subjected to a number of short on-off cycles;
- 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;
- it is even more difficult to achieve a smooth flow of work than with the methods mentioned above, since the (calibration) laboratory has no knowledge of the date on which the calibration interval will terminate.

Method 4: In service checking, or “black-box” testing

This is a variation on methods 1 and 2 and is particularly suitable for complex instruments or test consoles. Critical parameters are checked frequently (once a 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 instrument is found to be outside the maximum permissible error by the “black box”, it is returned for a full calibration.

The major advantage of this method is that it provides maximum availability for the instrument user. It is very suitable for instruments geographically separated from the calibration laboratory, since a complete calibration is only done when it is known to be required. The difficulty is in deciding on the critical parameters and designing the “black box”.

Although theoretically the method is very reliable, this is slightly ambiguous, since the instrument may be failing on some parameter not measured by the “black box”. In addition, the characteristics of the “black box” itself may not remain constant.

Examples of instruments suitable for this method are density meters (resonance type); Pt-resistance thermometers (in combination with calendar-time methods); dosimeters (source included); and sound level meters (source included).

Method 5: Other statistical approaches

Methods based on statistical analysis of an individual instrument or 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 [9].

When large numbers of identical instruments (i.e. groups of instruments) are to be calibrated, the calibration intervals can be reviewed with the help of statistical methods. Detailed examples can be found for example in the work of L.F. Pau [7].

Method comparison

No one method is ideally suited for the full range of instruments encountered (see Table 1). 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.

	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	medium	medium	bad	medium	bad
Applicability with respect to particular devices	medium	low	high	high	low
Availability of instruments	medium	medium	medium	high	medium

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

Table 1: Comparison of methods reviewing calibration intervals

Bibliography

- [1] ISO/IEC 17025:2005
General requirements for the competence of testing and calibration laboratories
- [2] ISO 10012-1, Edition:1992-01
Quality Assurance Requirements for Measuring Equipment;
Management of Measuring Equipment
- [3] Montgomery, D. C.: Introduction to Statistical Quality Control
John Wiley & Sons, 4th ed., 2000
- [4] ANSI/ASQC B1-B3-1996: Quality Control Chart Methodologies
- [5] Methods of reviewing calibration intervals
Electrical Quality Assurance Directorate
Procurement Executive, Ministry of Defense
United Kingdom (1973)
- [6] Establishing and Adjustment of Calibration Intervals
NCSL Recommended Practice RP-1, 1996
- [7] Pau, L.F.: Périodicité des Calibrations
Ecole Nationale Supérieure des Télécommunications, Paris, 1978
- [8] Garfield, F.M.: Quality Assurance Principles for Analytical Laboratories
AOAC Int., 3rd Edition, 2000
- [9] Lepek, A.: Software for the prediction of measurement standards
NCSL International Conference, 2001
- [10] ISO 9001:2000
Quality management systems - Requirements
- [11] International Vocabulary of Basic and General Terms in Metrology (VIM),
BIPM, IEC, IFCC, ISO, IUPAC, OIML. Published by ISO, Geneva, Switzerland, 2nd ed.,
1993