



Third Committee Draft (CD)

Project: Review of OIML D10
Title: Guidelines for the determination of recalibration intervals of measuring equipment
Date: 2021-08-30
Document number: TC4/P9/N022
Supersedes document: (2 CD) TC4/P9/N017
Project Group: OIML TC 4/p 9
Convenership: Slovakia
Convener: Mr. Stephan Kral

Circulated to P- and O-members and liaison international bodies and external organisations for:

☐ ☐ Information:

☐ ☐ Comments by:

☐ ☒ Vote (P-members only) and comments by 1 December 2021, 17:00 CEST

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Foreword (ILAC)

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Foreword (OIML)

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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*. 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. This edition of D 10 supersedes the previous edition dated 2007.

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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

1 Introduction

- 1.1** This guidance Document 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 the responsibility of each laboratory to choose to implement any or none of the methods described in this Document based on its individual needs and risk assessments, and
 - b) it is also the responsibility of each laboratory to evaluate the effectiveness of the implemented method(s). The laboratory should also take responsibility for the consequences of the choice of the method(s).

2 Scope

The purpose of this Document is to give laboratories guidance on how to determine the recalibration intervals of measuring equipment under their control while setting up their calibration program. This Document is also applicable to other Conformity Assessment Bodies (e.g. Inspection Bodies and Certification Bodies) and other parties (e.g. manufacturers) that utilise measuring equipment.

3 Terms and definitions

Unless otherwise stated in the following subclauses, 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-G-13 [2].

For the purpose of this Document, the definitions and abbreviations given below apply. Some of the terms are listed with alternative terms which are considered to have the same definition. Text “for D10” marks text which is not part of original wording of terms as defined in referenced document (e.g. additional explanatory notes specific for this Document).

3.1 **measurement uncertainty** (VIM, 2.26)

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.

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.

3.3 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.

3.4 measurement result (VIM, 2.9)

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, 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.

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: for D 10: After an adjustment of a measuring system, the measuring system must usually be recalibrated.

3.7 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 influence quantity.

3.8 maximum permissible measurement error (VIM, 4.26)

maximum permissible error

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 terms “maximum permissible errors” or “limits of error” are used where there are two extreme values.

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

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 organization or at a given location

3.10 reference quantity value (VIM, 5.18)

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 laser,
- c) a reference measurement procedure,
- d) a comparison of measurement standards.

3.11 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.

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.

3.13 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

Note 1: for D 10: A measuring instrument is a component of the measuring equipment which plays an important role for measurement. Some measuring instruments can be used independently to complete a measurement process or realise a physical quantity.

Note 2: for D 10: The measuring equipment may be considered equivalent with measuring system.

3.14 calibration and measurement capability (CIPM MRA-G-13) (CMC)

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.

3.15 conformity assessment body (ISO/IEC 17000, 4.6)

body that performs conformity assessment activities, excluding accreditation

3.16 inspection body (ISO/IEC 17020, 3.5)

body that performs inspection

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

3.17 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: For D 10: In the context of this Document, “laboratory activities” refer to the three above-mentioned activities.

3.18 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).

4 General aspects

4.1 An important aspect for maintaining the capability of a laboratory to produce traceable 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].

4.2 The purposes of periodic calibration of measuring equipment as a measure of maintaining metrological traceability are:

- a) to improve the estimation of the deviation between a reference value and the value obtained using the measuring equipment, and the uncertainty in this deviation, at the time the measuring equipment is actually used;
- b) to support the validation of the required or declared measurement 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 are those related to timing and frequency of implementation. Many factors influence the time interval that should be allowed between calibrations and they should be taken into account by the laboratory. For the most important factors see 5.1.

4.4 The calibration records may be used for determining the recalibration interval, when the following conditions are met:

- 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
- b) calibration and measurement capabilities are provided by the laboratories that have been accredited by an accreditation body subject to the ILAC MRA (International Laboratory Accreditation Cooperation Mutual Recognition Arrangement) or by an accreditation body under regional arrangements recognised by ILAC; or
- c) calibration and measurement capabilities are provided by national metrological institutes, designated institutes or laboratories not fulfilling conditions a) or b) and which services are suitable for the intended use, provided that conditions a) or b) could not be met for other than economic reasons (i.e. are not available).

Abovementioned requirements do not preclude application of other methods providing sufficient evidence of metrological traceability of calibration records, as metrological traceability requirements are subject to change. Such methods shall be considered to be acceptable for this purpose by ILAC or other relevant international organisations.

- 4.5** When determining the recalibration intervals, the costs of recalibrations normally cannot be ignored. The costs need to be balanced against risks in terms of quality of measurement which arise from increased measurement uncertainties under longer recalibration intervals.
- 4.6** 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. The methods have been published in more detail in certain standards (e.g. ISO 10012-1 [4] is a withdrawn standard containing useful details, which have been revised by standard ISO 10012 [5], containing only general information related to confirmation intervals), or by reputable technical organisations (e.g. [8], [9], [10]), or in relevant scientific journals.
- 4.7** Methods for determining recalibration intervals developed by or adapted by the laboratory may also be used if they are appropriate and validated.
- 4.8** The laboratory should select appropriate methods for determining recalibration intervals 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.
- 4.9** The 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 [3]).
- 4.10** The laboratory should check whether the results from external calibration and/or internal tests fall within predetermined limits prior to approving the measuring equipment for further use.

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. It may be necessary to reevaluate calibration intervals of whole measuring equipment or its constituent parts based on data obtained from calibrations of measuring equipment or its constituent parts.

5 Initial choice of recalibration intervals

- 5.1** The initial decision in determining the recalibration interval is based mainly on, but not limited to, the following factors:
- a) measurement uncertainty required and evaluated by the laboratory;
 - b) risk of the measuring equipment exceeding the predetermined limits (e.g. maximum permissible error, accuracy requirements) when in use;
 - c) risk assessment analysis, taking into account risks related to e.g. incorrect determination of the recalibration interval, use of measuring equipment after calibration due date or with significant drift, or other situations which might negatively influence traceability;
 - d) type of measuring equipment and its components;
 - e) manufacturer's recommendation regarding the measuring equipment (e.g. suggestions from the manufacturer when the measurement uncertainty is required and evaluated by the laboratory based on the accuracy of the instrument);
 - f) tendency to wear and drift;
 - g) expected extent and severity of use;
 - h) environmental conditions (climatic conditions, vibration, ionising radiation, etc.);

- i) influence of the measured quantity (e.g. high temperature effect on thermocouples) on measuring equipment;
- j) pooled or published data about the same or similar devices;
- k) frequency of comparisons with other reference standards or measuring instruments;
- l) frequency, quality and results of intermediate checks;
- m) transportation arrangements of the measuring equipment and associated risks;
- n) degree to which the operating staff are trained and extent to which the established procedures are implemented; and
- o) legal requirements.

5.2 The decision should be made by personnel having the relevant technical competence. An estimate should be made for each piece (or a group of pieces) of measuring equipment as to the time period in which the piece(s) is (are) likely to remain within the prescribed limits (i.e. maximum permissible error, accuracy requirements) after a calibration.

6 Methods of reviewing recalibration intervals

Note: The methods described in this section may also be used to review the type and frequency of intermediate checks or components of the calibration program.

6.1 General principles

6.1.1 Once calibration has been conducted on a routine basis (based on a defined number of consecutive results), adjustment of the recalibration intervals should be possible in order to optimise the balance of risks and costs as stated in the general aspects. 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 more or 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 shorter calibration intervals are required or 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 fails to meet prescribed limits (e.g. maximum permissible error, accuracy requirements) due to drift over time or by usage,
- c) the measuring equipment shows different types of instabilities,
- d) the measuring equipment undergoes adjustments, and
- e) data are available and 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) is considered to be important.

6.1.3 For new measuring equipment, it is recommended that they are calibrated more frequently at the beginning of its operational lifetime in order to allow the laboratory to quickly become aware of a trend indicating a change in its characteristics. After analysis of this trend, the recalibration intervals may be re-evaluated.

- 6.1.4** A system based on so-called “engineering intuition” in which a fixed recalibration interval is maintained without review is generally not considered as being sufficiently reliable and it is 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. 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.

Note: National Conference of Standards Laboratories International (NCSL) in its publication Establishment and Adjustment of Calibration Intervals [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 prescribed limits) essentially drive the calibration interval to change as due to decision rules of this method each new calibration should lead to either expansion or reduction of calibration interval (without possibility to maintain current interval). Another drawback is that the calibration interval approaches the correct interval slowly. A similar point of view may therefore also apply to Method 1 explained in first paragraph of this subclause.

- 6.2.2** A disadvantage of systems dealing with measuring equipment individually may be that it is difficult to keep the calibration workload smooth, relatively stable and balanced between risks and costs, and that it requires detailed advanced planning.
- 6.2.3** It would be inappropriate to set an extremely long recalibration interval using this method. Such a case may lead to risks associated with withdrawing large numbers of reported measurement results, or repeating a significant amount 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 instrumental drift is the mean drift normally over one recalibration interval, although several intervals may be taken into account in the calculation for very stable measuring equipment. From these figures, the optimum interval may be calculated.
- 6.3.2** Before calculations can commence, considerable knowledge of the variability properties of the measuring equipment is required. Again, it is difficult to achieve the smooth workload balanced between risks and costs. A considerable variation of the recalibration intervals from those prescribed is possible without invalidating the calculation results, because the reliability of interval 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 indicate 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 a material measure with a single assigned quantity value, e.g. calibration of a gauge block 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. Such measuring equipment are for example thermocouples, used at extreme temperatures, standard lamps of which the drift is subject to their burning time, dead weight testers for gas pressure or length gauges (i.e. measuring equipment 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. Another advantage of this method is that on the automatic timer for the hours of use of the measuring equipment may be available.

6.4.2 Nevertheless, this method also has the following practical disadvantages:

- a) it is not suitable for measuring equipment containing passive (not requiring additional energy input source for providing output) measuring instruments (e.g. attenuators) or passive standards (e.g. resistance, capacitance);
- b) 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;
- c) the initial cost may be high for providing and installing suitable timers for measuring the elapsed time, if the time is not recorded manually. Since users may interfere with the timers, additional supervision may be required which will increase the costs; and
- d) the planning of recalibration work is more difficult in comparison with the procedures of the methods 1 and 2 since it is not possible to predict precise date when the next calibration is required.

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

6.5.1 This method of evaluating of a recalibration interval is a variant of methods 1 and 2 and is particularly suitable when easy and quick calibration of measuring equipment or its part(s) 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" or portable calibration gear, it is returned for a full calibration. Method 4 may prove to be more effective than evaluating the original measuring equipment's interval.

Note: Measuring equipment suitable for this method are for example density meters (resonance type), Pt-resistance thermometers (in combination with calendar-time methods), dosimeters (source included) 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. It is very suitable for measuring equipment which is geographically distant from the laboratory, since a complete calibration is only performed 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.

6.6 Method 5: Other statistical approaches

- 6.6.1** Methods based on statistical analysis of individual measuring equipment or groups of measuring instrument 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 (i.e. groups of measuring equipment) 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 publication of National Conference of Standards Laboratories International NCSL Recommended Practice RP-1 Establishment and Adjustment of Calibration [9].

6.7 Comparison of methods of reviewing recalibration intervals

- 6.7.1** No one method described in 6.2 to 6.6 is ideally suited for the full range of measuring equipment encountered (see Table 1). The laboratory may choose the most appropriate reviewing methods for different measuring equipment considering a variety of factors discussed in Clauses 4, 5 and 6.1. Furthermore, it should be noted that the choice will be affected by whether the laboratory intends to introduce planned maintenance schedule. 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 costs	medium	medium	low	medium	low
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.

7 Bibliography

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