

Traceability of Measuring and Test Equipment to National Standards

PURPOSE

To give guidance on the calibration and maintenance of measuring equipment in meeting the requirements of the ISO 9000 series of standards for quality systems, and the EN 45001 standard for the operation of testing laboratories.

EAL-G12 * TRACEABILITY OF MEASUREMENT

Authorship

This publication has been written by EAL Committee 2.

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0 Introduction

- 0.1 The quality of products and services is increasingly dependent on reliable measurements. The importance attached to measurements is reflected in relevant standards by the requirement that measurements must be 'traceable to national or international standards'. Different definitions and explanations of the term 'traceability' exist in standards and literature, giving rise to differing interpretations (and misinterpretations).
- 0.2 There is more to traceability than can be demonstrated in a written declaration, and the objective of this guidance publication is to give a clearer picture of the principles of traceability and how it may be achieved.

1 Scope and field of application

- 1.1 This publication gives guidance and assistance to organisations on how to comply with the traceability requirements in relevant standards, such as those in the EN ISO 9000 and EN 45000 series. It is intended for all organisations where supervision of measuring and test equipment is an important part of quality assurance. It may be used by organisations involved with industrial production processes (development, manufacture, installation, final inspection) and by calibration and testing laboratories.
- 1.2 The publication may also be used by assessors of testing laboratories and inspection bodies and assessors of quality systems of organisations which perform measurements.
- 1.3 Appendix A is a checklist which is intended to be used for internal quality audits or by assessors.

2 Measuring and test equipment in production and in testing laboratories

- 2.1 To meet the ever-increasing expectations of customers, **product quality assurance** is of ever-increasing importance for each company, especially in view of the need to maintain or strengthen its economic position in the European single internal market.
- 2.2 High quality requirements for a product mean that there must be an adequate quality system. Requirements for quality systems are for example laid down in the ISO 9000 series of standards, which are identical to the EN ISO 9000 series of European standards. The **control, calibration and maintenance of measuring and test equipment** is an important part of the content of these standards and provides an assurance that measurements will be made properly during production processes. To this end, all measurement results must be 'traceable to national standards.'
- 2.3 EAL-G12, by explaining the concept of control, calibration and maintenance of measuring and test equipment and what that means in practice, assists

organisations that are building up a quality system. It is therefore addressed primarily to staff members responsible for quality in industry.

- 2.4 However, the calibration of measuring and test equipment, and the traceability of the measurements to national standards, is also an important requirement for the operation of calibration and testing laboratories and is a pre-requisite for their accreditation in accordance with European standards of the EN 45000 series and equivalent international publications. Therefore, EAL-G12 is also addressed to the operators of calibration and testing laboratories and those who assess them as part of the accreditation procedure.

3 Calibration, traceability

- 3.1 **Calibration** means determining and documenting the deviation of the indication of a measuring instrument (or the stated value of a material measure) from the conventional 'true' value of the measurand.
- 3.2 The term **traceability** means a process whereby the indication of a measuring instrument (or a material measure) can be compared, in one or more stages, with a national standard for the measurand in question.
- 3.3 In each of these stages, a calibration has been performed using a standard with a metrological quality already determined by calibration with a higher level standard. There is therefore a **calibration hierarchy**, as shown in Fig. 1. The figure illustrates in particular how an in-house calibration system (right hand side of the diagram) may interact with the existing metrological infrastructure (left hand side of the diagram).
- 3.4 The exact definitions of *calibration* and *traceability* are given in the *International vocabulary of basic and general terms in metrology (VIM)*, BIPM *et al*, 1993.

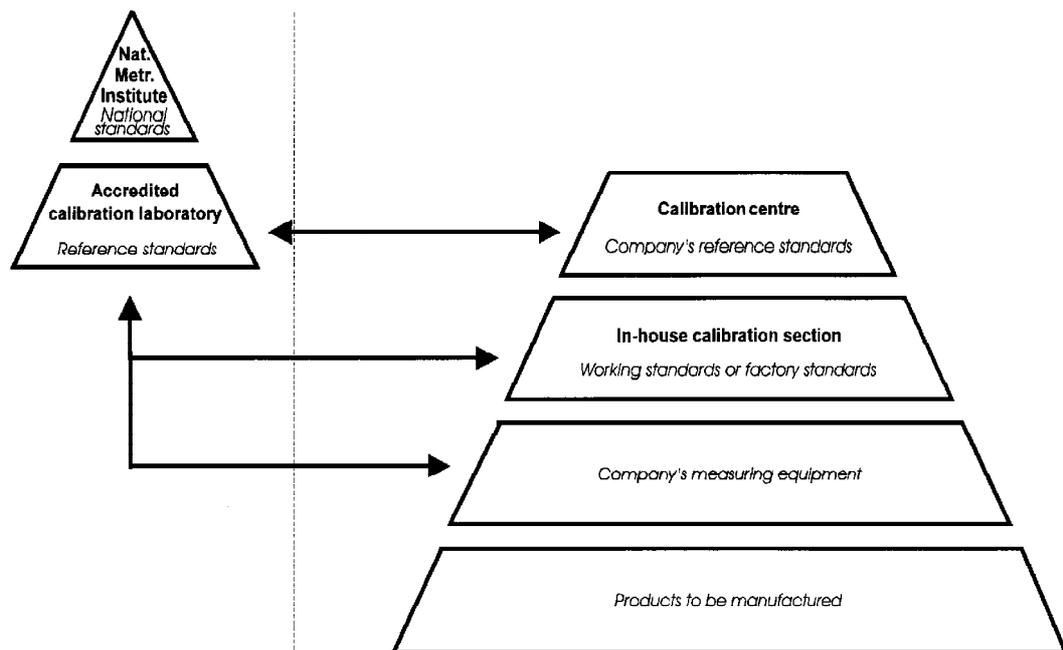


Fig. 1

4 Why are calibrations and traceability necessary?

- 4.1 Traceability of measuring and test equipment to national standards by means of calibration is necessitated by the growing national and international demand that manufactured parts be interchangeable; supplier firms that make products, and customers who install them with other parts, must measure with the 'same measure'.
- 4.2 There are legal as well as technical reasons for traceability of measurement. Relevant laws and regulations have to be complied with just as much as the contractual provisions agreed with the purchaser of the product (guarantee of product quality) and the obligation to put into circulation only products whose safety, if they are used properly, is not affected by defects.
- Note:* If binding requirements for the accuracy of measuring and test equipment have been stipulated, failure to meet these requirements means the absence of a warranted quality with considerable consequent liability.
- 4.3 If it becomes necessary to prove absence of liability, the producer must be able to demonstrate, by reference to a systematic and fully documented system, that adequate measuring and test equipment was chosen, was in proper working order and was used correctly for controlling a product.
- 4.4 There are similar technical and legal reasons why calibration and testing laboratory operators should have consistent control of measuring and test equipment in the manner described.

5 Elements of traceability

- 5.1 Traceability is characterised by a number of essential elements:
- (a) **an unbroken chain of comparisons** going back to a standard acceptable to the parties, usually a national or international standard;
 - (b) **measurement uncertainty**; the measurement uncertainty for each step in the traceability chain must be calculated according to agreed methods and must be stated so that an overall uncertainty for the whole chain may be calculated;
 - (c) **documentation**; each step in the chain must be performed according to documented and generally acknowledged procedures; the results must equally be documented;
 - (d) **competence**; the laboratories or bodies performing one or more steps in the chain must supply evidence for their technical competence, eg by demonstrating that they are accredited;
 - (e) **reference to SI units**; the chain of comparisons must end at primary standards for the realization of the SI units;
 - (f) **re-calibrations**; calibrations must be repeated at appropriate intervals; the length of these intervals will depend on a number of variables, eg uncertainty required, frequency of use, way of use, stability of the equipment.

- 5.2 In many fields, reference materials take the position of physical reference standards. It is equally important that such reference materials are traceable to relevant SI units. Certification of reference materials is a method that is often used to demonstrate traceability to SI units.

6 Calibration hierarchy

6.1 International level

- 6.1.1 At the international level, decisions concerning the International System of Units (SI) and the realization of the primary standards are taken by the Conférence Générale des Poids et Mesures (CGPM). The Bureau International des Poids et Mesures (BIPM) is in charge with coordinating the development and maintenance of primary standards and organises intercomparisons on the highest level.

6.2 National Metrology Institutes

- 6.2.1 The National Metrology Institutes are the highest authorities in metrology in almost all countries. In most cases they maintain the '**national standards**' of the country which are the sources of traceability for the associated physical quantity in that country. If the National Metrology Institute has facilities to realise the corresponding SI unit of measurement (the term SI units includes all derived units), the national standard is identical to or directly traceable to the **primary standard** realising the unit. If the Institute does not have this facility, it has to ensure that the measurements are traceable to a primary standard maintained in another country. The National Metrology Institutes ensure that the primary standards themselves are internationally comparable. They are responsible for disseminating the units of measurement to users, be these scientists, public authorities, laboratories or industrial enterprises and are therefore the top level of the calibration hierarchy in a country. The Western European National Metrology Institutes cooperate in EUROMET.

6.3 Accredited calibration laboratories

- 6.3.1 Calibration Laboratory Accreditation Bodies accredit calibration laboratories in industry and other organisations, according to well established criteria. For Western Europe these criteria are laid down in EN 45001. Internationally, the criteria of ISO/IEC Guide 25 are often used. The publications are almost identical. For some topics EAL has developed application publications. Accreditation is generally given for specified measurands and for the smallest uncertainties that can be achieved with the suitable measuring devices available in the respective calibration laboratory ('best measurement capability').
- 6.3.2 Accredited laboratories are often at the top of a firm's **internal calibration hierarchy**. Their task is then to compare, at appropriate intervals, the firm's own **working standards (factory standards)** with reference standards which are calibrated by a National Metrology Institute or an accredited laboratory with a suitable best measurement capability.

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6.3.3 Many accredited laboratories carry out calibrations for third parties on request, eg for firms that do not have calibration and measurement facilities with suitable equipment, and for private test laboratories working in the field of product certification.

Note: If an accredited laboratory is to be engaged to carry out a particular calibration, the client must ensure that the measurement uncertainty achieved is appropriate for the intended use of the calibrated instrument.

6.3.4 The calibration results are documented in a **calibration certificate**.

6.3.5 The European Calibration Laboratory Accreditation Bodies cooperate in the European cooperation for Accreditation of Laboratories (EAL). One main goal of EAL is to ensure that calibration certificates, issued by any accredited laboratory, are accepted in the other countries. This implies that the laboratories and the Accreditation Bodies have to operate in a compatible way. An evaluation of the Accreditation Bodies and the results of interlaboratory comparisons have resulted in an EAL Multilateral Agreement on the mutual acceptance of calibration certificates. This means that official certificates of calibration (displaying the logo of the accreditation scheme) issued by a calibration laboratory accredited by one of the signatories of the Multilateral Agreement, are equivalent with the certificates issued by laboratories accredited by any of the other signatories.

6.4 In-house calibration (factory calibration)

6.4.1 An in-house calibration system ensures that all measuring and test equipment used in a company is calibrated regularly against its own reference standards. The company reference standards shall have traceability of measurement by being calibrated at an accredited calibration laboratory or a National Metrology Institute. The in-house calibration may be evidenced by a factory calibration certificate, a calibration label, or some other suitable method. The calibration data must be retained for a prescribed period of time.

6.4.2 The nature and scope of the metrological control of in-house calibration are at the discretion of the company concerned. They must be adapted to the particular applications so that the results obtained with the measuring and test equipment are sufficiently accurate and reliable. Accreditation of organisations performing in-house calibration is not necessary to satisfy the requirements of the EN ISO 9000 series of standards applied for internal purposes. However, the use of an in-house calibration certificate by an external body as evidence for traceability should require that the issuing organisation can demonstrate its competence.

6.4.3 The hierarchy of standards and a resulting metrological organisational structure for tracing measurement and test results within a company to national standards are shown in Figs 2 - 5. The user of the standard or the measuring and test equipment is given for each level of the hierarchy, together with his functions within the structure, and the metrological basis and the result of his activity (documentation).

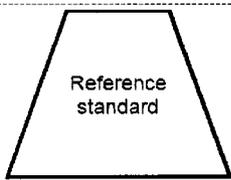
Standard (measuring equipment)	Responsible	Tasks	Basis for the calibration or measurement	Documentation of the calibration or measurement
 National standard	National Metrology Institute	To maintain and disseminate the national standards	Statutory duty to represent SI units and ensure international comparability	Calibration certificate for reference standard
 Reference standard	Accredited calibration laboratories	To safeguard the metrological infrastructure of a country	Calibration certificate from Nat. Metrology Institute or another accredited laboratory	Calibration certificate for working standard or factory standard
 Working standard Factory standard	In-house calibration section	Supervision of test equipment for in-house purposes	Calibration certificate from National Metrology Institute or an accredited laboratory	Factory calibration certificate, calibration mark or the like for test equipment
 Measuring equipment	all sections of a company	Measurements and tests as part of quality assurance measures	Factory calibration certificate, calibration mark or the like	Test mark or the like

Fig. 2

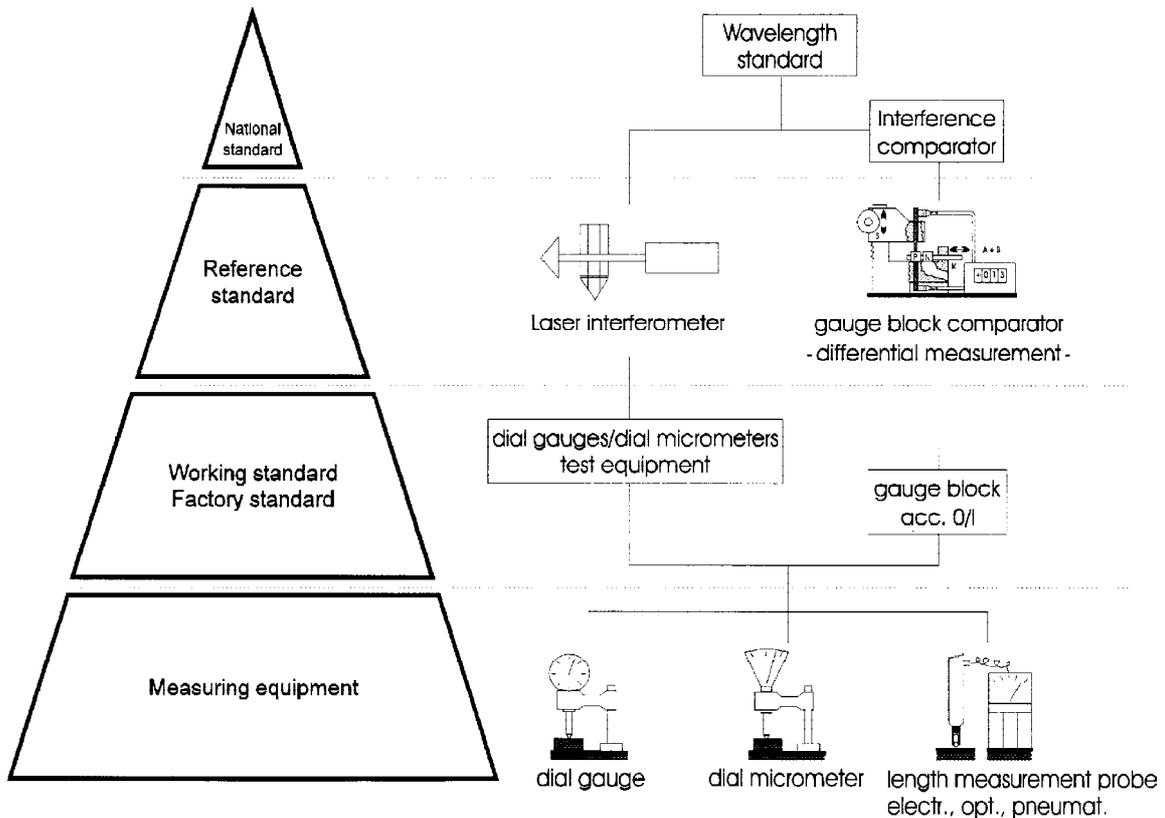


Fig. 3

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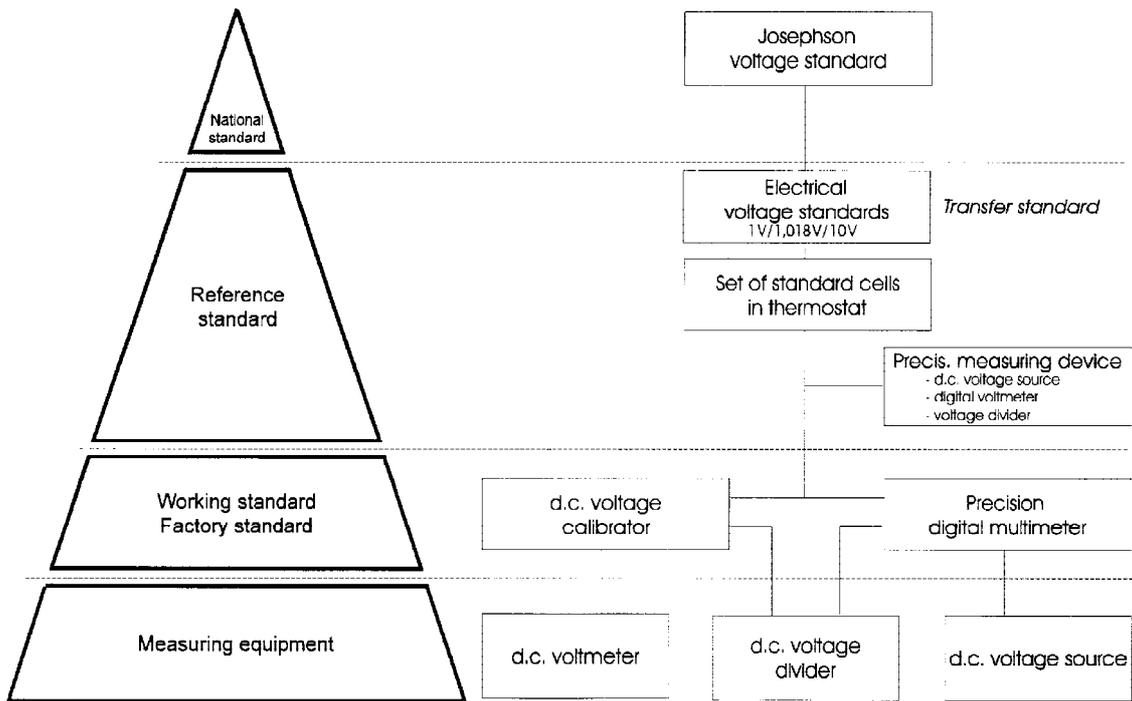


Fig. 4

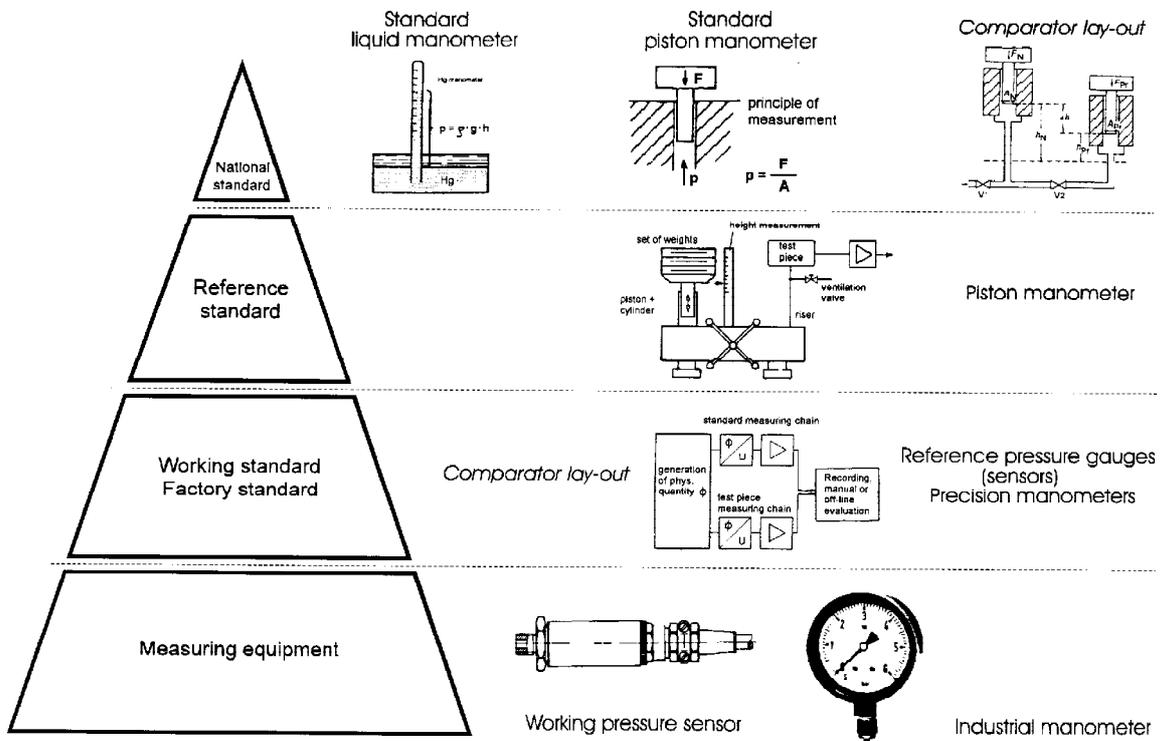


Fig. 5

7 Terminology in the hierarchy of standards

7.1 The following definitions apply to the hierarchy of standards (taken from the *International vocabulary of basic and general terms in metrology (VIM)*, BIPM *et al*, 1993)

Primary standard: Standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity.

International standard: Standard recognised by an international agreement to serve internationally as the basis for assigning values to other standards of the quantity concerned.

National standard: Standard recognised by a national decision to serve, in a country, as the basis for assigning values to other standards of the quantity concerned.

Reference standard: Standard, generally having the highest metrological quality available at a given location or in a given organisation, from which measurements made there are derived.

Transfer standard: A standard used as an intermediary to compare standards.

Travelling standard: Standard, sometimes of special construction, intended for transport between different locations.

Working standard: A standard which, usually calibrated against a reference standard, is used routinely to calibrate or check material measures, measuring instruments or reference materials.

Working standards may also at the same time be reference standards. This is particularly the case for working standards directly calibrated against the standards of a national metrology institute.

Certified reference material (CRM): Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes traceability to an accurate realisation of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

Notes:

- 1 Generally, CRMs are prepared in batches for which the property values are determined within stated uncertainty limits by measurements on samples representative of the whole batch.
- 2 The certified properties of certified reference materials are sometimes conveniently and reliably realised when the material is incorporated into a specially fabricated device, eg a substance of known optical density into a transmission filter, spheres of uniform particle size mounted on a microscope slide. Such devices may also be considered as CRMs.
- 3 All CRMs lie within the definition of 'measurement standards' or 'étalons' given in the *International vocabulary of basic and general terms in metrology (VIM)*.

- 4 Some CRMs and RMs (see below) have properties which, because they cannot be correlated with an established chemical structure or for other reasons, cannot be determined by exactly defined physical and chemical measurement methods. Such materials include certain biological materials such as vaccines to which an International unit has been assigned by the World Health Organisation.

Reference material (RM): Material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

Note:

A RM may be in the form of a pure or mixed gas, liquid or solid. Examples are water for the calibration of viscometers, sapphire as a heat-capacity calibrant in calorimetry, and solutions used for calibration in chemical analysis.

General note:

The value of any standard has an uncertainty. In the calibration hierarchy, the higher ranking standard has a smaller uncertainty. Each additional subordinate level therefore leads to an increase in the uncertainty of measurements.

Appendix A

Checklist for the assessment of the calibration and traceability of measuring and test equipment.

(CAUTION: negative answers may require further questions).

A0 General remarks

- A0.1 The assessor for measuring equipment must have sufficient knowledge in the fields of metrology and calibration.
- A0.2 The assessment refers only to the testing activities for which the laboratory is to be accredited; it does not refer to the operation of a purely calibration laboratory already accredited by another body.

A1 Appropriate calibration of measuring equipment

- A1.1 Is a calibration prescribed for all measuring instruments:
- (a) appropriate with respect to the measurement uncertainty of the measuring equipment;
 - (b) appropriate with respect to the influence of the measured quantity on the test result?
- A1.2 Is an appropriate functional test determined for those measuring instruments that are based on natural constants (eg defined wave lengths)?

A2 Bodies performing calibration of measuring equipment

- A2.1 Is the calibration carried out by an external body that is generally responsible for calibrations or accredited or otherwise accepted for that purpose?
- (a) By a National Metrology Institute?
 - (b) By an accredited calibration laboratory?
- A2.2 Is the calibration carried out internally or externally by a laboratory not falling into the categories mentioned in A2.1(a) and A2.1(b)?
- (a) By a competent internal body of the institute operating the test laboratory?
 - (b) By a competent staff group or single person in the test laboratory?
 - (c) By the user of the measuring equipment himself?
 - (d) By an external body the competence of which is demonstrated by an assessment?

A3 Calibration facilities

(A3 is applicable only if the answer is **'yes'** to one of the questions in A2.2)

- A3.1 Are internal reference standards and, if appropriate, working standards available for all measuring and test instruments, and measured quantities which are relevant for the measurement and test results?
- A3.2 Are the reference standards directly or indirectly linked, in any case by an unbroken chain documented by certificates, to national standards and labelled accordingly by a calibration label?
- A3.3 Are all calibration equipment instruments properly identified?
- A3.4 Is each calibration described in a procedure, eg by *switching diagrams* or *flow charts*?
- A3.5 Is the calibration procedure described step-by-step?
- A3.6 Are defined environmental conditions ensured during calibrations?
- A3.7 Are relevant environmental conditions recorded during calibrations?
- A3.8 Are procedures for the calculation of the measurement uncertainty of the calibration equipment specified and are they followed?
- A3.9 Are re-calibration intervals fixed in accordance with the intended use and the properties of the equipment, and are there programmes for regular re-calibrations?

A4 Evaluation and documentation of results

- A4.1 Are the calibration results and the associated uncertainties documented?
- A4.2 Is the observance of fixed re-calibration intervals supervised?
- A4.3 Where calibrations have to be performed before each measurement, are these cases clearly identified? Are the measuring instruments labelled accordingly?
- A4.4 Are the results of calibrations (including environmental conditions, if applicable) documented and filed? Are they available to the user of the measuring instrument?
- A4.5 Is a calibration label used as a visible indication of an established confirmation system for the measuring equipment?
- A4.6 Is the calibration label supported by a calibration certificate and is the number of the certificate referred to on the label?
- A4.7 Are controls for calibration and adjustment, which should not be adjusted by the user, sealed?

A5 Specified calibration procedures

- A5.1 Is the measuring equipment of a 'self-calibration' type?
- (a) Is the internal reference calibrated?
 - (b) Is the process of 'self-calibration' checked?
- A5.2 Does the measuring equipment include an internal calibration of a less stable component by means of an internal reference?
- (a) Is the internal reference calibrated?
 - (b) Is the procedure of internal calibration checked?
 - (c) Is the internal calibration performed regularly, eg before each use of the measuring equipment?
- A5.3 Is the complete measuring system calibrated as a whole?
- (a) Are the single components of the measuring system adjusted, especially with respect to zero setting?
 - (b) How is the labelling performed for a complete measuring system?
- A5.4 Are single components of a measuring system calibrated?
- (a) Are the calibration parameters for the complete measuring system determined from the values of the single components?
- A5.5 What is done in the case of disposable measuring devices which cannot be calibrated individually (eg strain gauge transducers)?
- (a) Are samples calibrated? Is continuous sample testing practiced?
 - (b) Which body is performing sample testing?
 - (c) Does the body according to A5.5(b) fulfil the requirements of EN 45001 or ISO/IEC Guide 25?
 - (d) Is the body accredited according to EN 45001 or ISO/IEC Guide 25?
- A5.6 Are reference materials used for the calibration?
- (a) Are the reference materials certified?
- A5.7 Are the calibrations computer-aided?
- (a) Is the software validated?
 - (b) By which method?

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A6 Responsibilities; administrative aspects of calibration of measuring equipment

- A6.1 Is each user of measuring equipment aware that he is responsible for the calibration status of his measuring equipment?
- A6.2 Is each new measuring equipment calibrated before use?
- A6.3 Are measuring instruments brought to re-calibration by a confirmation system when the calibration validity period is expired?
- A6.4 Is the responsibility for the working standards, and the internal reference standards and their traceable calibrations clearly defined?
- A6.5 Is the responsibility for the reliability of calibration software clearly defined?