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Metrological requirements for accredited laboratories

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Abstract. Metrological traceability is considered of high importance in all fields and types of measurements. It facilitates the comparability of measurements "in time and space" and enhances their reliability. The accreditation standards used in the assessment of laboratories, namely ISO 17025 applying to all testing and calibration laboratories and ISO 15189 applying to medical laboratories, introduce specific metrological requirements. In this paper, these metrological requirements are analysed and discussed. Reference is made to basic aspects and frequently occurring problems. The need to increase the awareness of both laboratories and their customers and the efficient communication between laboratories and calibration services suppliers is underlined. Recent developments, mainly new editions of standards and other documents published by competent European and international bodies are taken into consideration.

1 Introduction

The basis for the accreditation of testing and calibration laboratories is the International Standard ISO/IEC 17025[1]. The said standard specifies all management and technical requirements for the competence of laboratories. In the case of medical laboratories, the International Standard ISO 15189 [2] is the most appropriate; although it specifies both management and technical requirements in a similar way like ISO 17025 [1], it addresses more efficiently the particular features and needs of medical laboratories. Both standards underline the need for metrological traceability which can be established with the implementation of an appropriate calibration programme for all equipment which may have a significant effect on the results. Metrological traceability is required to facilitate the comparability of measurements "in time and space" and enhance their reliability [3]. The meaning of metrological traceability is different to traceability referring to the "ability to trace the history, application or location of that which is under consideration", as defined in ISO 9000 [4].

2 Basic definitions

Among a number of definitions relevant to the scope of this paper, the most important ones are given in the International Vocabulary of Metrology-ISO/IEC Guide 99/ VIM 3 [5] and ISO 17000 [6].

Accreditation: third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks [6].

Calibration: 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 [5].

Certified reference material: reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures [5].

Measurement uncertainty: non-negative parameter characterizing the dispersion of the quantity values being attributed to a measure and, based on the information used [5].

Metrological traceability, henceforth referred to as traceability: 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 [5].

Quantity: property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a reference [5].

Reference material: material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in measurement or in examination of nominal properties [5].

Reference measurement 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 [5].

3 Metrological requirements

Testing and calibration laboratories shall demonstrate that they have established traceability. This is provided in both accreditation standards, namely ISO/IEC 17025 [1] and ISO 15189 [2]. The relevant provisions in the standards are referred to below.

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3.1 The provisions of ISO/IEC 17025

Clause 5.6 of ISO/IEC 17025 [1] provides for the measurement traceability. Clause 5.6.1 in particular refers to the need that all equipment used in tests and/or calibrations having a significant effect on the accuracy or the validity of the result shall be calibrated prior to being put into service; it also provides (as does clause 5.5.2) for suitable calibration programmes which shall be prepared to confirm that the equipment continues to be capable of achieving the accuracy required. These provisions refer also to subsidiary equipment e.g. equipment used to monitor environmental conditions.

3.2 The provisions of ISO 15189

Medical laboratories are expected to comply with the requirements of ISO 15189 [2] which is the basis of their assessment and accreditation by the national accreditation body. Following clause 5.3 of the said standard, the term laboratory equipment includes hardware and software of instruments, measuring instruments and laboratory information systems. Clause 5.3.1.4 in particular, specifies that the laboratory shall have a documented procedure for the calibration of all equipment that directly or indirectly may affect examination results. It also states that metrological traceability shall be to a reference material or reference procedure of the highest metrological order available.

3.3 Other normative and guidance documents

The provisions of the accreditation standards are written in a general way. Further information, often required, can be found in a number of normative and guidance documents covering various aspects e.g. measurement uncertainty and frequency of calibration [7-10]. In each case, the laboratory has to comply with the requirements of the accreditation body; according to clause 8.2.2 of ISO 17011 [11] the accreditation body has to provide laboratories with information about suitable ways to obtain traceability of measurement results. This is expected to reflect the situation in a country, its particular problems and needs. However, it has to be in line with the provisions of ILAC P10 [12] which describes the hierarchy of alternative approaches when trying to demonstrate metrological traceability.

4 How traceability is established

4.1 Consideration by the laboratory

Traceability can be established by the use either of services provided by calibration laboratories, or of certified reference materials which are traceable to the International System of Units (SI).

Calibration services are purchased from a competent calibration laboratory fulfilling the requirements referred to above. A testing or a calibration laboratory may decide to carry out in-house calibrations for some of its needs. Considering the prerequisites to be met for such a task, in most of the cases this might not be realistic.

4.2 Are calibration services adequate?

Both testing and calibration laboratories need to confirm that the calibration services they purchase are adequate with regard to the specific task; following clause 5.6.2.1.1 of ISO 17025 [1], this means that the calibration laboratories providing the service can demonstrate competence, measurement capability and traceability. According to ILAC P 10 [12], equipment and reference standard shall be calibrated by either a National Metrology Institute (NMI) whose service is suitable for the intended need and is covered by the Mutual Recognition Arrangement of the International Committee of Weights and Measures (CIPM MRA), or an accredited calibration laboratory whose service is suitable for the intended need where the accreditation body is covered by the Mutual Recognition Arrangement of the International Laboratory Accreditation Cooperation (ILAC MRA).

In case either the NMI or the accreditation body is not covered by CIPM MRA or ILAC MRA respectively, the accreditation body shall establish a policy on how to ensure that the services provided meet the relevant criteria for traceability. This is the case usually of small countries where, even though there is an operational NMI, it does not cover all quantities for which there is frequently a demand.

Clause 5.6.2.1.2 of ISO 17025 [1] provides for those calibrations that currently cannot be strictly made in SI units; in these cases, traceability can be established by the use of certified reference materials or specified methods and/or consensus standards clearly described and agreed by all parties concerned.

4.3 Communication with the calibration services supplier

As a first step, the laboratory should clearly specify its requirements, considering the method requirements as well as the specifications of the particular piece of equipment. It is then up to the calibration laboratory to confirm that it can provide the service required.

The certificate shall contain the measurement result including the uncertainty and/or a statement of compliance with the relevant measurement specification. The laboratory needs to review the certificate to confirm that the equipment calibrated is still fit for purpose. If this is not the case, appropriate corrective actions have to be decided and implemented. Measurement uncertainty should also be taken into account by the laboratory to introduce relevant adjustments to its uncertainty budget, if necessary. In the case of a testing laboratory, this will depend on the relative contribution of the calibration uncertainty to the total uncertainty. This needs to be adequately documented [12].

Although there is no requirement for the calibration services supplier to be accredited, this is preferable with a scope of accreditation including the particular quantity. In this case the accreditation symbol is expected to be

displayed on the calibration certificate, thus illustrating the traceability of the calibration laboratory. In the case where an accredited calibration laboratory does not display the accreditation symbol on the certificates it issues, a question may arise whether the calibration was carried out as specified in the accredited procedure.

4.4 The use of reference materials

Certified reference materials can also be used to establish traceability. To this end, the laboratory should preferably look for an accredited reference material producer (RMP). ISO Guide 34 [13] is used as the accreditation document for RMPs. It is worth mentioning that, in medical laboratories, the instruments, the equipment, the reagents, the control materials, the calibrators and the diagnostic kits are covered by the Directive 98/79/EC on *in vitro* diagnostic medical devices [14]. The said Directive provides that all these devices have to be CE marked while calibrators and control materials need to be traceable to SI units, although in practice this is not always possible. This use of (certified) reference materials must not to be confused with their use in the internal quality control [3].

5 Concluding remarks

Training and increase of awareness of the personnel of laboratories on quality assurance issues is of high importance when implementing a quality management system [15]. Adequate understanding of traceability is a prerequisite in realising the needs, in making best use of calibration certificates as well as in using reference materials to demonstrate traceability. This is also necessary for efficient communication with the suppliers of these services, using appropriate documentation. Furthermore, it is an important part of the quality assurance applied in the laboratory.

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