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White Paper

March 2021

Keywords:
Accredited calibration, ISO/IEC 17025, ILAC, Traceability, calibration laboratory, calibration certificate

Calibration certificates from accredited providers

What benefits do our accreditations offer the user?

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Abstract

This white paper will deal with the basic concepts of accredited calibration and the advantage of certificates from accredited providers will be explained. The focus here is on the accreditation for calibration laboratories as per ISO/IEC 17025.

Introduction

The Sartorius Group can look back on 150 years of expertise in the field of manufacturing balances. Sartorius laboratory balances have always been known for their quality and reliability.

Sartorius Service offers a comprehensive range of services in order to ensure the reproducibility and reliability of measurement results throughout the entire product life cycle. One extremely important aspect in this context are accredited calibration services.

This white paper will show the advantages of calibration certificates from accredited providers and will explain key terms that are used in relation to calibrations.

Calibration

Calibration is defined as an *"operation that [...] establishes a relation between the quantity values [...] provided by measurement standards and corresponding indications [...]"* (1). During a calibration, the known value of a quantity to be measured (e.g. the conventional weighing value of a test weight) is compared to the indicated value of a corresponding measurement instrument (e.g. that of a laboratory balance) under set conditions while taking account of the associated measurement uncertainties.

The specific implementation of this definition can take different forms, which means that different calibration guidelines | calibration procedures may exist for one and the same measured quantity. For example, there are various different national and international calibration guidelines for calibrating balances. That is why the scope of accreditation of a calibration guideline is decisive for the accreditation of the calibration results and ultimately for the acceptance of the measurement results.

In this context, the EURAMET Calibration Guide No. 18 (for short: "cg-18"), which is not only broadly recognized in Europe, but also worldwide, is of significant importance for the calibration of balances (14).

The calibration itself is always a snapshot establishing a relationship between the measured quantity and a reference value at the time of calibration. Strictly speaking, the results of a calibration alone do not mean a statement can be made about the quality of the measurement results in the past, or about future measurement results. Nevertheless, calibrations are recognized as an important evaluation criterion of measurement devices and are required in all common quality management systems for test equipment.

Traceability

Traceability is the *"property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty"* (1).

Traceability makes it possible to compare measurement results from different measurement devices across the world, because they are related to a national or international standard due to an unbroken chain of comparison measurements.

Traceability is ensured in the context of accredited calibrations, i.e. calibration certificates from accredited providers are recognized as proof of traceability. Non-accredited calibrations may also be recognized as proof of traceability, but this requires actions and documentation of the calibration service provider and/or the user (2).

The ISO 10012 standard illustrates this as follows: *"Traceability is usually achieved through reliable calibration laboratories having their own traceability to national measurement standards. For example, a laboratory complying with the requirements of ISO/IEC 17025 could be considered reliable."* (3).

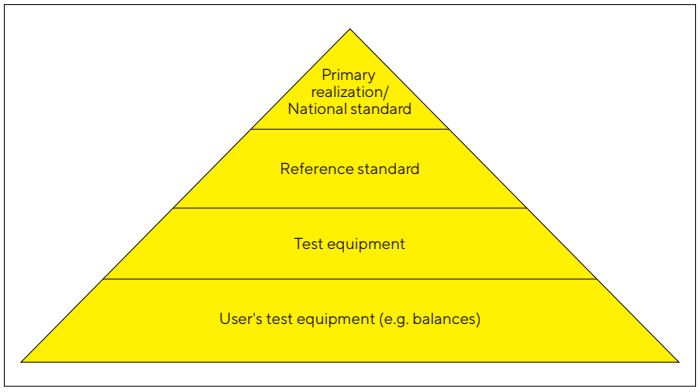

Figure 1: Traceability of measured quantities.

Figure 1 shows a traceability hierarchy. The customer of an accredited calibration laboratory has his test equipment (his balances, for example) calibrated with the laboratory's test equipment (test weights with accredited calibration certificates, for example). Staying with the examples, the weights are recalibrated at regular intervals at Sartorius in an accredited manner using reference standards. The reference standards in turn are recalibrated against the primary standard (the national standard at a national metrology institute). In this way, the customer's balance can be traced back to the national standard. This ensures a seamless verification and comparability of measurement results. In reality, the process described above occurs over a few additional intermediate stages, which are not listed in further detail here for simplicity's sake.

Conformity assessments and conformity assessment bodies

The DAkkS (German Accreditation Body) defines the term of conformity assessment as follows: *"Systematic procedure to assess whether specific requirements for a product, a process, a service, a system, a person or a body are met. The requirements may be defined in laws, standards or otherwise."* (4). Even if a calibration initially does not constitute an assessment, calibrations are also to be understood in this context as conformity assessments.

Conformity assessments can be performed by conformity assessment bodies (CABs). The DAkkS defines these as follows: *"A body that performs conformity assessment activities, including calibrations, tests, certifications and inspections."* (4).

In many countries, Sartorius operates calibration laboratories accredited by the respective national accreditation bodies – typically for balances, mass and volumetric measuring devices, but also for other measured variables.

Accreditation

The standard ISO/IEC 17011 defines the term accreditation as follows: *"Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks"* (5).

The term "accredit" comes from Latin and roughly translates as "to give credence." This credence can only be formed after trust is built over many years and it can be lost quickly if the service provider does not have the competencies to provide an assessment service. Conformity assessment bodies can be accredited in order to prove to the customer the conformity of their work.

Accreditation bodies and the ILAC

The third party described in the section above can, for example, be UKAS (the UK's National Accreditation Body), COFRAC (Comité français d'accréditation – French accreditation body), or DAkkS (German accreditation body). These organizations are tasked under the law with accrediting conformity assessment bodies. The national accreditation bodies are internationally organized within the ILAC (International Laboratory Accreditation Cooperation).

ILAC *"is the international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration laboratories (using ISO/IEC 17025), (...)."* (6).

The ILAC Mutual Recognition Arrangement (ILAC MRA) is an agreement that can be accepted and signed by national accreditation bodies. This means that the results for goods and products that were calibrated, tested or inspected by an accredited laboratory are accepted by all ILAC MRA signatories (7). In other words, for example, calibration certificates of an accredited laboratory that was accredited by an accreditation body, which has signed the ILAC MRA, must be accepted by other signatories of the agreement, which leads to a high acceptance at an international level. The signatories of the ILAC MRA are listed on the ILAC website.

Conformity assessment bodies and accreditation

The increasing globalization and liberalization of global trade requires framework conditions in which economic actors can rely on the goods and services they require. The quality requirements and standards can only be ensured through objective assessments, such as an accredited calibration.

In an accreditation process, the conformity assessment body must prove to an independent accreditation body that it is complying with the corresponding national and international standards, laws and guidelines and therefore is operating at a globally comparable level. The conformity assessment body is then regularly monitored, inspected and verified by the independent accreditation body.

All of this serves to build trust, to maintain trust and support the quality system and an international comparability within and between the conformity assessment bodies and their services.

Another advantage of accreditations is the recognition of the independent accreditation bodies and the associated mutual recognition of certificates, provided the competent accreditation bodies are signatories of the ILAC MRA. This makes duplicate checking of products in different regions or countries redundant. This means a tremendous cost reduction – both for the user as well as for the conformity assessment bodies. This also facilitates goods traffic for all members of the ILAC agreement (8).

Figure 2: Highly accurate weighing on an analytical balance.

ISO | IEC 17025

One prerequisite for conformity assessment bodies to be accredited is that they meet the quality management requirements as they are described in ISO/IEC 17025. The accreditation body verifies this through quality audits. The ISO/IEC 17025 describes "General requirements for the competence of testing and calibration laboratories" and therefore defines which requirements a laboratory must meet to be able to prove that it is working competently and is capable of achieving valid results. It defines general and structural requirements as well as requirements for resources, processes and management (13).

One point within the ISO/IEC 17025 describes the traceability of the test equipment. This means that all test equipment that is used for calibration or as part of a calibration must be traceable to international standards. This ensures that an accredited calibration certificate alone is always recognized as proof of traceability – no further documentation of the test equipment used is required for this purpose.

Effects of accreditation on the laboratory's processes

In addition to the general requirements for the laboratory's quality management, the ISO/IEC 17025 requires that the laboratory plans and implements measures to handle risks and opportunities. Handling both risks and opportunities forms a basis to increase the effectiveness of the management system, to achieve high quality work and results, and to avoid negative effects. The responsible laboratory personnel (typically the laboratory management) is responsible for deciding which risks and opportunities must be addressed.

In addition, the laboratory must ensure that the activities are performed impartially and that impartiality is ensured in general. The laboratory management must expressly undertake to do this. Among other things, this means avoiding commercial or financial pressure. Impartiality must be included in the consideration of risks and opportunities and any risk is to be minimized here.

Impartiality on the part of the laboratory staff must be ensured through trainings from a training system, which the laboratory must provide to ensure the competence of its employees. All of this can only be done in accordance with the laboratory's management system. Employees must be aware of the competencies they need for the respective roles and they must be clearly defined in advance - the same goes for the significance of deviations.

Another important point of the ISO/IEC 17025 is the traceability of the test equipment. This means that the test equipment that is used for calibration or as part of a calibration must be traceable to international standards.

User benefits of an accredited laboratory's service

Compared to non-accredited calibrations, accredited calibrations offer many advantages to the user. As already mentioned in the section above, accredited calibrations prove traceability of the test equipment to the user. This proves without interruption that the test instruments (balances, volumetric measuring devices, ...) are internationally comparable. The calibration certificates also need to be recognized by accreditation bodies of other countries that have also signed the ILAC agreement. This leads to time and financial savings, as multiple calibrations are no longer necessary. Regular calibration of the test equipment must be ensured here, of course.

In the case of the company being audited, calibration certificates from an accredited laboratory are the means of choice to legitimize the use of test equipment and the results of the test equipment. The laboratory's accreditation serves as a proof of competence in this situation, since the laboratory is required to regularly demonstrate its capabilities to an independent appointed body (accreditation body). This in turn happens through audits of the accredited laboratory. Accredited providers are therefore regularly verified and monitored, which provides an *"objective proof of their quality"* (9). This makes it easier to choose a competent laboratory.

The user also saves time and money as a result of the fact that accredited providers rarely have product failures and recalls. (9)

Calibrations – DAkkS | DKD | ISO | Factory calibration | FAT?

Generally, only the actual condition of the balance is recorded when calibrating a balance. Known weights are placed on the balance in different measuring processes and the measurement instrument's display is recorded. The differences between the value of the known weights and the balance display, however, also make it possible to reach conclusions about the functionality of the instrument. The environmental influences on the balance and the measurement sequence also need to be taken into consideration to be able to make the most accurate assessment possible (see (10) and (11)). Calibrations can be done based on an accreditation, but do not necessarily have to be done that way. For some sectors, non-accredited processes are sufficient or the combination of accredited and non-accredited processes is necessary. This depends on the user's quality management system and applicable regulations and laws.

One example of the necessity of an accredited calibration is a quality management system according to ISO 9001. In section 7.6, this requires: *"(...) If the metrological traceability is a requirement, or the organization considers it a key contribution to establishing trust in the validity of the measurement results, the measurement equipment: a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; (...)"* (16).

Other guidelines, standards and laws have similar requirements. A calibration certificate from an accredited provider fulfills the requirement for proof of traceability in full.

In the application areas of expert reports, health, and areas that are directly related to money (such as when weighing at the supermarket checkout), compliance with the calibration law may be required (17), which, depending on the national law, is either checked by a sovereign body or by a company accredited/authorized for this purpose.

There are currently some colloquial terms in used for calibration certificates, which will be covered in detail here. One country-specific example of the order of an accredited calibration is the "DKD certificate". Note that the accreditation body of the German Calibration Service (DKD) was transferred to the Deutsche Akkreditierungsstelle GmbH (DAkkS) with effect from December 17, 2009 (12). There are accordingly no more calibration laboratories accredited by DKD, but rather only those accredited by DAkkS. The laboratories that want to offer this service need to be accredited by DAkkS in the context of the corresponding standard.

The DKD, on the other hand, is now a committee for the professional forum for its members, over 400 laboratories and companies in the calibration industry (15). This collaboration does, for example, produce calibration process-related proposals.

Another term is "ISO calibration". Some calibration service providers use this to offer a non-accredited calibration. The "ISO calibration" is not an accredited calibration, but rather a service that can be based on a standard. This also applies to a factory calibration, which in most cases is also based on national or international guidelines, but does not necessarily fulfill the aspect of traceability. Sartorius offers the "Factory Acceptance Test (FAT)" as a factory calibration.

Figure 3: Calibration service from an accredited provider.

Advantages of a calibration service from a provider accredited according to ISO/IEC 17025.

The advantages of an accredited calibration certificate for the balance user are summarized again below.

- The accredited balance calibration is used for the purpose of tracing user test equipment/products to national/international standards.
- If the calibrating laboratory is accredited according to ISO/IEC 17025, this is considered as proof of traceability for the entire test equipment chain of the calibration. This also means that the user does not need to keep any calibration certificates of the test equipment used for the accredited calibration.
- The test equipment used by the accredited calibration laboratory is inspected and monitored in regular audits performed by the competent accreditation body, since the traceability of the test equipment is explicitly required.
- If a balance has been calibrated by an accredited calibration laboratory, the calibration certificate must be accepted by all accreditation bodies that have signed the ILAC agreement. Of course, the instrument must be regularly calibrated.
- Accredited calibrations offer audit certainty and should be a fixed component of any test equipment management.
- The accreditation serves as *"proof of competence (and) makes it easier to choose a suitable service provider for the conformity assessment"* (9) of balances.
- The accreditation is *"objective proof of the quality and competence of the activity of a conformity assessment body according to international standards"* (9).
- Accredited calibration laboratories prove the necessary competence to an appointed independent body.
- Accredited providers are regularly monitored and verified.
- There are *"fewer product failures or recalls"* from accredited service providers (9).

Sartorius recommendation

- A balance should be regularly tested with traceable weights, regardless of regulatory requirements.
- A calibration certificate from an accredited laboratory is the first choice internationally in order to meet regulatory quality requirements.
- Adhere to an appropriate calibration cycle. As the user, you are responsible for ensuring that your balance is suitable for use every time it is used.
- Document the calibration history of your test equipment using the calibration certificates of an accredited calibration laboratory.
- An accredited calibration certificate saves you from having to answer questions about service provider qualifications and traceability during audits.

This white paper is part of the white paper series "Best Practice Guide: Lab Weighing". To be able to dynamically add updates and corrections and at the same time giving users as clear a reference as possible, for example in their QM documentation, versions are provided.

Version history

Version	Date	Changes
1.0	March 2021	Initial version

Literature

1. Brinkmann B: International Dictionary of Metrology: Grundlegende und allgemeine Begriffe und zugeordnete Benennungen (VIM) Deutsch-englische Fassung ISO/IEC-Leitfaden 99:2007, [Basic and General Terms and Associated Designations (VIM) German-English Version ISO/IEC Guide 99:2007] Beuth Verlag
2. ILAC P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results
3. EN ISO 10012:2003 – Measurement management systems – Requirements for measurement processes and measuring equipment (ISO 10012:2003)
4. https://www.dakks.de/content/glossar. Accessed on July 27, 2020
5. DIN EN ISO/IEC 17011:2018 - Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies
6. https://www.dakks.de/content/was-ist-akkreditierung. Accessed on: 25.05.2020
7. https://ilac.org/language-pages/german/. Accessed on: 27.07.2020
8. https://www.dakks.de/content/kombiniertes-zeichen-von-ilac-und-iaf. Accessed on: 25.05.2020
9. https://www.dakks.de/content/welche-vorteile-bieten-akkreditierungen. Accessed on: 27.05.2020
10. Sartorius white paper: Reliable Weighing Results (How to Correctly Handle Laboratory Balances and Samples), 2020.
11. Sartorius white paper: Calibration According to EURAMET cg-18 (Understanding Calibration Certificates and Applying Results in Practice), 2021 (planned).
12. https://www.dkd.eu/. Accessed on: 23.07.2020.
13. DIN EN ISO/IEC 17025:2018 - General Requirements for the Competence of Testing and Calibration Laboratories
14. EURAMET Calibration Guide No. 18, Version 4.0. "Guidelines on the Calibration of Non-Automatic Weighing Instruments" (11/2015).
15. https://www.ptb.de/cms/de/metrologische-dienstleistungen/dkd.html. Accessed on: 26.05.2020
16. ISO 9001:2015; Quality management systems – Requirements
17. Sartorius white paper: Working in Legal Metrology (Use and Testing of Laboratory Balances in a Legally Regulated Environment), 2020

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Status: 02 | 2021