Key points of the ISO/IEC 17025 Norm:

Meaning for the laboratory-supplier relationship

A WhitePaper of BIOMED Labordiagnostik GmbH

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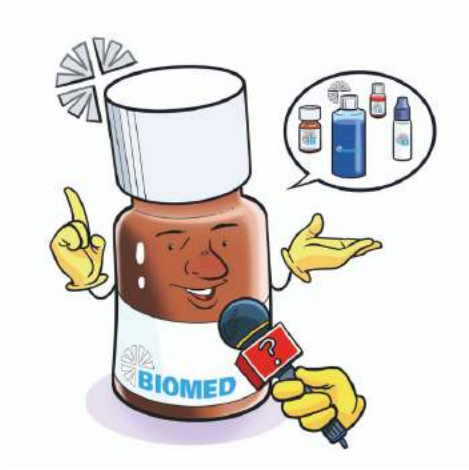
Introduction



ISO/IEC 17025 is the global standard for the accreditation of calibration and testing laboratories. It defines the requirements for the competence of laboratories performing tests and/or calibrations.

But what does accreditation actually mean for the cooperation between laboratories and their suppliers?

During the accreditation process, the laboratory depends on the assistance of its suppliers. Only if they are prepared to provide information on manufacturing processes, their own quality standards, ingredients and compositions, the laboratory can fulfill its documentation obligation as defined by the ISO/IEC 1725 standard and obtain accreditation.

Section 6 of the standard is particularly relevant for the laboratory-supplier relationship. Here, it is defined which evidence and information the laboratory requires from its external partners.

This white paper provides a brief summary of the accreditation process and the most important contents of ISO/IEC 17025, here in the current version of ISO/IEC 17025:2017. It is intended to give suppliers in particular an insight into the subject of accreditation and to make them understand why laboratories rely on the assistance of their suppliers during the accreditation process.

What does accreditation mean?

Accreditation derives from the Latin word "accredere" and means: to give credence to.

It is a legal process in which one generally recognized authority certifies to another the fulfillment of a particular characteristic.

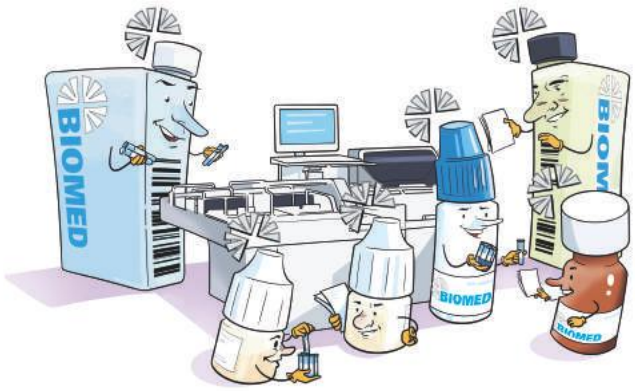
What is laboratory accreditation?

Accreditation is the formal recognition by a competent authority for laboratory competence. This competent authority confirms that the respective laboratory operates according to the applicable standards and performs certain tasks covered by the scope of accreditation.

Within the framework of a so-called accreditation process, the management, quality systems and technical competence of a laboratory for the performance of certain tasks are examined.

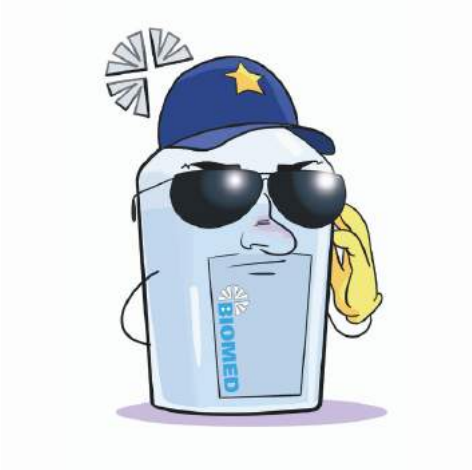
Why does a laboratory get accredited at all?

Both nationally and internationally, laboratory accreditation is regarded as a reliable indicator of professional competence. Accredited laboratories are therefore regarded as particularly reliable and their work is considered to be of high quality.



What are the advantages of accreditation for a laboratory?

- The competence of the laboratory and the quality of the activity are confirmed by an independent authority. This ensures a competitive advantage.
- All operations and processes are accurately described and documented.
- When setting up and maintaining quality management documentation, operational processes are well thought out and streamlined.
- In the quality management manual, all specifications applicable to management and laboratory staff are summarized and easily available.
- Laboratory staff benefit from regular training and continuing education.
- Processes are also made transparent to the outside environment.
- Regular assessments force constant maintenance and improvement of the quality management system.
- Analyses and methods become comparable.
- Results become more precise and reliable, and their acceptance by third parties increases.
- Customer satisfaction increases.
- The quality of patient care increases.



All this leads to potential weaknesses being identified more quickly. An optimization and improvement of processes and operational procedures takes place. As a result, a waste of resources can be avoided, which at the same time goes hand in hand with a quality-related cost reduction.

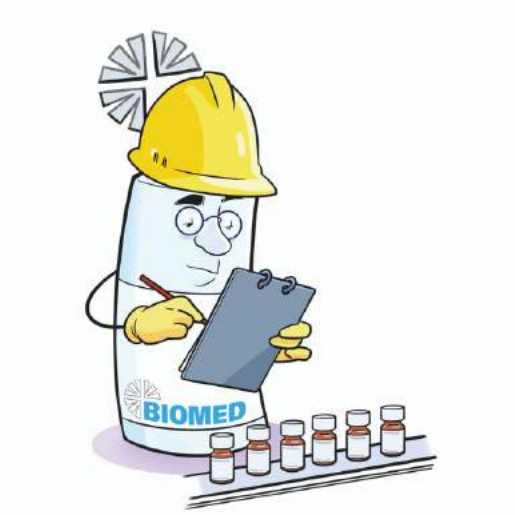
In the event of liability, accreditation or certification offers legal certainty. This is because it confirms compliance with a prescribed duty of care.

What is the difference between an accreditation and a certification?

Accreditation is the confirmation and recognition of the technical competence of a laboratory by a competent authority. This authority verifies whether the laboratory has set up an acceptable quality assurance system and can perform the tasks involved within the scope of accreditation.

In the case of certification, a third party confirms in writing that certain requirements, e.g. international DIN standards, are met. This means that a product, a process or a service fulfills prescribed requirements or that the employees are familiar with the specified requirements.

How to obtain an accreditation?



A certificate of accreditation is obtained after the laboratory's management and quality systems have been reviewed by one or more auditors. The process is very time-consuming for those responsible for the laboratory. This is because for successful accreditation, the laboratory must record detailed, written documentation of all procedures and processes down to the smallest detail, provide it with evidence and submit it to the auditor.

The accreditation is extended after a renewed inspection by the accreditation authority. For this purpose, the laboratory must adapt the documentation and prove that it is up to date.

If there is a change of supplier after the accreditation process has been completed, the new supplier, including the new products, must be included in the documentation instead of the previous one.

ISO/IEC 17025: The standard for laboratory management

ISO/IEC 17025 forms the legal basis for a quality management system implemented in the laboratory. A major advantage of ISO 17025 is that it has some common features with ISO 9001. This means that it is internationally coordinated and internationally accepted. In total, ISO/IEC 17025 (here in the 2017 version) consists of 8 sections and two annexes. Section 6, as already mentioned, is particularly important for a good laboratory-supplier relationship.

Section 6: Resource requirements

Section 6 defines the requirements for resources. In other words, the laboratory must provide all the resources required to perform the laboratory activities.
This means that the employees must have the necessary skills and qualifications. They must be trained regularly to be able to work according to current standards and norms. The premises must meet certain predefined requirements. The furnishings and equipment must also meet the requirements.

All results must be metrologically traceable. The procurement process by third parties must be documented. Neither spatial conditions nor equipment and consumables provided by third parties may have an influence on the validity of the test results.

Therefore, it is essential for accredited laboratories or laboratories currently in the accreditation process to obtain all the information required by ISO/IEC 17025 from their suppliers.

Suppliers who cannot or will not provide this information will sooner or later be replaced by the laboratory. After all, no laboratory wants to risk the accreditation process because of an unreasonable supplier.

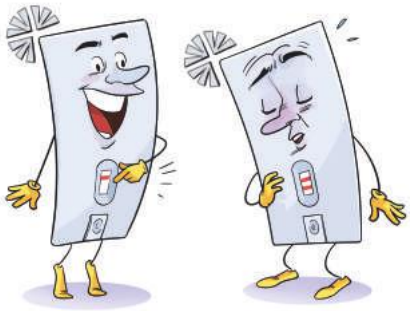
Those responsible for the laboratory must document exactly which device they are working with, how it works, what processes are involved, and where the device was produced. The laboratory must also prove which standards and regulations the supplier has followed in procurement or production. The same applies to control materials, staining solutions, reagents and cleaning products. According to ISO 17025, their composition must also be precisely defined in order to exclude the possibility of the composition having a negative influence on the test results.

Since the laboratory must comply with the latest standard due to the requirements of ISO/IEC 17025 and must prove that it complies with this standard, it is essential for the supplier to always comply with the current standard as well. This means that the supplier must prove to the laboratory that its manufacturing and production processes are based, for example, on the current WHO standard or a current ISO standard.

Anyone planning to work with an accredited laboratory must therefore prove that they adhere to the same current standards as the laboratory. Suppliers who cannot meet this standard or who use outdated versions run the risk of being replaced by the laboratory with a competent competitor.

What do the other sections of ISO/IEC 17025 (2017 version) regulate?

Sections 1 to 3 contain an introduction and definitions of terms.



Section 4 defines general requirements for laboratories. It is subdivided into the sections "Impartiality" and "Confidentiality". Accordingly, the laboratory must ensure and be able to prove that all tests or calibrations are carried out at all times without any influence by third parties. The records and documents of the tests and calibrations must be treated confidentially at all times.

Section 5 deals with structural requirements for laboratories. This section regulates the organization of the laboratory and specifies that a laboratory must be a legal entity that is legally liable for the activities performed. The overall responsibility is carried by the laboratory management. It should have a budget appropriate to the services it provides. In addition, it must be documented which employee has which responsibilities and authorities and what the relationship is between the individual laboratory employees.

Section 7 defines the requirements for the processes in the laboratory. Here, the requirements for the core processes of the laboratory are brought into focus. In detail, this concerns the review of offers, inquiries and contracts, the selection, verification and validation of procedures, sampling, the handling of test and calibration items, and the handling of technical awards. Considerable attention is given to the competence of personnel involved in the final review and approval of test reports and calibration certificates. Section 7 also regulates the control of data and information in an information management system that laboratories must have. Among other things, this should protect against unauthorized access or manipulation of data and results.

Section 8 deals with the requirements for the management system. The topics relate primarily to the quality management system. The requirements include documentation and dealing with opportunities and risks. In addition, a continuous improvement process is required, as well as the implementation of corrective measures and the performance of internal audits.

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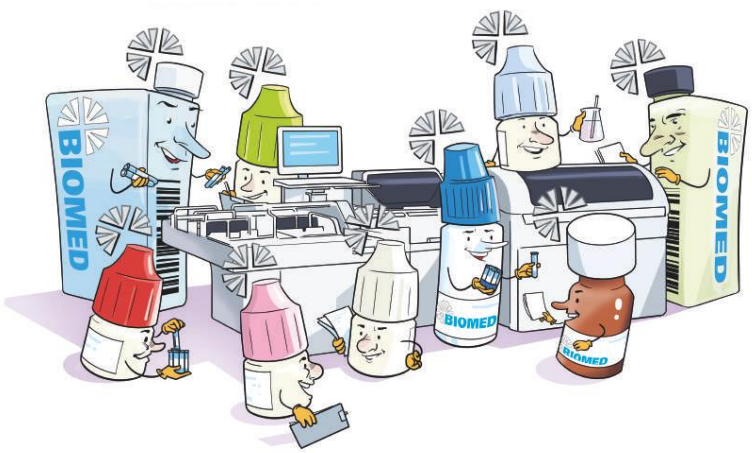

Practical Hints: How to improve the lab-supplier relationship

Hints for the lab:

- Your supplier needs time: let your supplier know at the earliest possible moment when you need the information.
- Create a checklist with all the information and certificates you need from your supplier.
- Explain to your supplier that accreditation has advantages for both sides. After all, as an accredited laboratory, you will receive more orders and consequently need more consumables, more diagnostic equipment, etc…
- Provide your supplier with this white paper and a copy of the current ISO 17025.

Hints for the supplier::

- Familiarize yourself with the requirements of ISO/IEC 17025, especially section 6.
- Inform the laboratory immediately if you yourself obtain new certificates or if the name or composition of a product changes.
- Send product information sheets and safety data sheets to the laboratories without being asked or make them available for download on your website.
- Provide the laboratory with a list of all contact persons including emergency numbers or publish it on your website.
- Always adhere to the current standard for your own documentation (e.g. current requirement of the WHO, current version of the ISO standard, etc.).

Published on: 30.09.2021

Publisher:

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