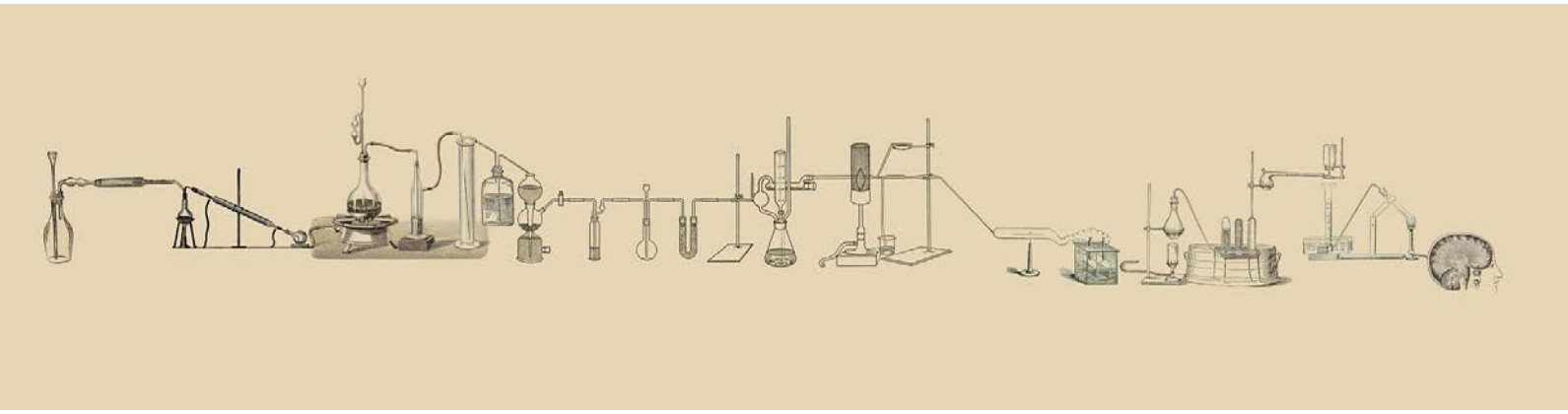
PeRoBa® Unternehmensberatung GmbH
(Management Consultancy LLC)

Introduction of DIN EN ISO/IEC 17025 For Laboratory Accreditation

Special requirements and their implementation



List of contents

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Brief description

- Certifications and accreditations
- Basics for preparing for accreditation
- Process management, procedures and job descriptions
- Connections to DIN EN ISO 9001:2015
- General information on ISO 17025

This edition by PeRoBa® is supposed to provide interested readers with an overview of the requirements according to DIN EN ISO 17025. Regarding this edition, we are not claiming that the statements are complete, detailed or comprehensive and it will not replace any consultations either.
The text of the ISO 17025 standard can be ordered from Beuth Verlag (Publishing House).

Accreditations and certifications

A certification is no accreditation and vice versa. Certification (the word stemming from the Latin word “certus” for “certain”) refers to a procedure for obtaining evidence from a body or organization on conformity to certain requirements.

An accreditation (the word stemming from Latin “accredere“ for “giving credit to“) is defined, as follows, as a “third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks“ [defined in the DIN EN ISO/IEC 17011 standard].

Laboratory standards according to ISO 17025

Laboratory [from Latin “laborare” for “work”] refers to a scientific working place.

The jobs of testing and calibration laboratories can be described through various task areas. Tests and calibrations as well as sampling linked to subsequent calibrations or tests, which are activities during which standardized methods and procedures are used, are focused on. It is a minimum requirement here that not just precise but also timely results be delivered.

Traceable and transparent laboratory procedures, which meet ethical requirements and insure the safety of patients and coworkers, need to provide those results.

ISO 17025 demands quality management systems for laboratories for determining standards for validating and interpreting laboratory tests. Besides, requirements on analyses as well as on the identification and the transportation of samples are defined. Especially with regard to samples from patients, there are increased requirements on storing, safekeeping and securing – even without the GDPR.

Medical laboratories may obtain internationally recognized accreditations for their measures and procedures for performing their services and securing results through DIN EN ISO 17025.

In Germany, the DAkkS is the relevant accreditation body.

ISO 17025 is a recognized standard for medical laboratories and it was developed by the TC212 Technical Committee of the International Organization for Standardization (ISO).

Therefore, ISO 17025 puts in place specific requirements on testing laboratories. Nonetheless, DIN EN ISO 9001:2015 on „Quality management systems – requirements“ can constitute a basis for that. This standard is appropriate for research and / or industrial laboratories, but it is not as profound and far-reaching as ISO 17025 with regard to all the areas concerned.

ISO 17025 is an accreditation standard whereas ISO 9001 is a certification standard.

Save the date: The Accreditation Conference in 2020

The Deutsche Akkreditierungsstelle (DAkkS), the German Accreditation Body, is holding the “AKKKO” in Berlin from September 28 - 29, 2020. During that accreditation conference, experts from the economy, politics, the administration, associations and science will be debating the central issue of what topics are currently popular when it comes down to conformity assessments.
You can obtain further details on the following link:
https://www.dakks.de/content/save-date-akkreditierungskonferenz-2020

First measures for implementation

Some measures need to be taken for enabling a laboratory to apply successfully for an accreditation according to ISO 17025. One measure consists of laboratory management appointing a steering committee. Representatives of laboratory management, the superior and representatives of the departments ought to be working together on the steering committee. Especially persons who work during hours other than the laboratory coworkers or laboratory management and who might often be passed over for that very reason ought to be considered here.

Actively involve affected parties. Changes coworkers have to go along with and actually live will be necessary for a successful ISO 17025 introduction. Yes, there is the IBM saying on “Never change a running system”, to be sure, but the QMS necessitates continual improvements and the changes that go with them.

There are increased requirements, especially on validation of methods, metrological traceability, equipment qualification and evaluation of measurement uncertainty, etc. Topics regarding more comprehensive planning of ring trials might be needed for that as well.

The steering committee will perform a gap analysis and define the basics of a quality policy for the laboratory. A laboratory director who is going to coordinate the respective measures and who will be responsible for the development of a quality manual will be appointed.

The gap analysis:

The steering committee will conduct a gap analysis. That means that all the regulations, processes, procedures and job descriptions already in place will be listed and then, evaluated.
As a supplement to that, they need to be compared to the requirements of ISO 17025 so that they can be supplemented if needed. The documents that won’t meet requirements will be identified and they will constitute the actual results of the gap analysis.

Impartiality:

Contrarily to the past, the current version of 17025:2018-03 contains an entire passage dealing with impartiality, which can be very well derived from general ISO requirements. Therefore, it is now more important for laboratories to set forth how they have been treating the issue of impartiality.

The testing laboratory must be certain that there is no commercial, financial or other pressure that could adversely affect impartiality. If there might be a risk, it will be necessary to try to do away with or minimize such risk.

A practical example:

There are several methods laboratory management can apply to make sure of impartiality. Defining and introducing a specific impartiality policy all the people in the organization need to be aware of is one possible solution.

If a quality policy is existing, a passage on impartiality can be included thereunder.

As a matter of principle, it is advisable to assess impartiality regularly during the management review while including the respective relevant meeting minutes and decisions.

Structural requirements

17025:2018-03 defines that the testing or calibration laboratory needs to be a legal entity.

In order to fulfill the ISO requirement, a laboratory director shall be appointed. Further requirements, like, for instance, the following tasks are specified by the standard:

- Furthering the quality management system and making sure that it be actively further developed
- Selecting and managing suitable suppliers for the scope of the laboratory
- Intermediation between the laboratory and other associated departments

The laboratory director must have the necessary professional and scientific experience for managing and controlling the general laboratory activities.

Furthermore, a manager who assumes the responsibility for

reporting as well as managing resources and making sure that the laboratory be able to perform shall be appointed.

Members of laboratory management should have good verbal and written communication skills and be able to motivate laboratory employees. Negotiations and the coordination of meetings with other departments and their organizations can be other tasks of this group of people.

The continual enhancement of the laboratory and its processes is focused on.

Resource requirements

Laboratory management has the job of creating for the laboratory a quality management manual that is adapted to factual circumstances. The QMM is the central document describing the policy and the purposes of the laboratory, among other things. Employees should be able to find themselves and their jobs in the QMM for the laboratory and to obtain further supplementary guidelines on those areas.

This can include descriptions of further roles and / or responsibilities up to specific requirements on the performance of activities.

Every laboratory coworker needs to know the QMM and be able to access it at any time, of course.

For example

① Guidelines

Laboratory management defines guidelines / rules / specifications, which create basic framework conditions when it comes down to processing and implementing certain requirements.

Possibly, such guidelines may be generalized. For instance, protective measures abc have to be taken while handling substances in hazard classes xyz.

② Process

The process describes the implementation of the guidelines in actually lived practice. In Germany, the “guideline of the German Medical Association on quality assurance for tests in medical laboratories” (Rili-BÄK)” provides an overview of the minimum requirements on laboratory tests for quality assurance.

The process description depicts the necessary activities and the process. Criteria, measures and procedures, which enable an expert to track and evaluate the process, are determined.

③ Procedure

The procedure describes the process step in greater detail and provides information on how it is to be performed. In practice, “procedure” is often used as a synonym to “method”, which should be criticized. In measurement technology, the measurement procedure is a practical interpretation of a measurement principle and the accompanying measurement method.

The procedure describes the implementation that is to be carried out under certain framework conditions, and depicts, for instance, what measures shall be taken if threshold values can’t be or were not conformed to.

Relevant differences of version DIN EN ISO/IEC 17025:2018-03

From our point of view, this version constitutes a reformulation of the standard, compared to 2005. Now key terms that conform to ISO/IEC Guide 99 and ISO/IEC 17000 and which are to be preferred over DIN EN ISO 9000:2015 are defined.

The issue of risks and chances has been more strongly included but no formal risk management methods are demanded.

Requirements on laboratories

The corrected version of DIN EN ISO 17025 dated March, 2018 has 8 standardization sections and 2 annexes. Subsequently, some requirements will be exemplified.

Section 6: Personnel

The laboratory or the organization must be clearly identifiable in a legal sense. Any conflicts of interest with other groups, like, for instance, of a political or financial nature need to be identified or ruled out.

The organization must set up and maintain a laboratory structure, and appoint a manager, a laboratory director and deputies.

In order to develop and preserve the system, it must be made sure of client feedback and complaints, etc. being taken up and processed. The policy that constitutes the framework for the laboratory objectives is the basis for guaranteeing that. The appointment of a steering committee is a measure often implemented in practice.

Section 6.3: Facilities and environmental conditions

In order to develop and maintain the system, it needs to be insured that client feedback and complaints, etc. will be taken up and processed. The guidelines that constitute the framework for the laboratory objectives are the very basis for guaranteeing that. The appointment of a steering committee is a measure that is often implemented in practice.

Laboratory facilities and working conditions need to be defined, maintained according to actual requirements and “monitored”. Requirements result from the activities to be performed and from further, possibly applicable framework conditions. The focus is on making sure of results respectively of their validation.

DIN EN ISO 17025 requires the control of all the documents following DIN EN ISO 9001:2015.

As a matter of principle, you have to set up a system, preferably a document management system in which all your coworkers can access all the documents you require in their most recent, current, valid and actually released versions.

You need to be able to answer the following questions, like, for instance:

- How do you handle outdated documents in order to avoid their inadvertent use?
- How are modified documents released?
- How do you make sure that your documents will still be available after some years?

Documentation is a critical criterion for being able to obtain an accreditation pursuant to an ISO standard.

Section 6.5 et seq.: Metrological traceability

Laboratories require a documented procedure for selecting and assessing the methods and evaluations they use, which must be “traceable to the international system of units (SI)”.

One possibility for meeting this criterion consists in establishing a ring trial for direct or indirect comparisons.

If services or materials from suppliers or clients are used in this context, the traceability requirement will also pertain to such services provided. For example, this can be made sure of through a calibration, depending on framework conditions.

Section 7.9: Complaints

The laboratory requires a documented procedure for dealing with feedback from its different pressure groups in a well-structured and neutral manner. This means that laboratory management must make sure that all feedback is received, assessed, and processed accordingly. Evaluating and testing efficiency is tantamount to another focus, which needs to be reviewed during the entire laboratory operations.

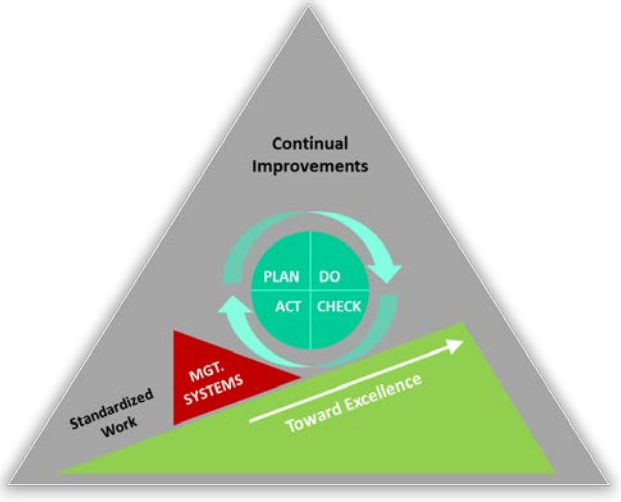
Section 7.10 et seq.: Nonconforming work

A basic attitude of modern error management stating, “Errors are valuable”, and looking for a constructive approach to problems that are occurring is relevant here. DIN EN ISO 17025 requires a provable and implemented procedure here.

If a result is at odds with a specified guideline, a defined process or procedure, such outcome must be defined as an error. Errors need to be documented, the root causes are to be examined and investigated, and corrective measures have to be taken. Depending on the type and relevance of the error, examinations might need to be interrupted or canceled, or results that have already been transmitted might have to be recalled.

Prevention (from Latin praevenire for pre-empt) is also part of error management. Measures and procedures for avoiding undesired results need to be defined. In practice, the fact that an increased number of tests performed does not necessarily avoid the cause of the error but merely guarantees higher statistical detection rates needs to be taken into account.

For basic understanding, we refer to Deming and his PDCA control cycle as well as to the relevant and essential requirements of DIN EN ISO 9001:2015.



Section 8.8: Audits

The laboratory and the organization must undergo internal and external audits. Such audits serve to check whether the laboratory is working in accordance with the guidelines, processes and the policy, among other things. To that end, the development of a corresponding audit program is recommendable for proving the planning of the audits and their suitability at regular intervals.

Management or company management have to appoint internal auditors and make sure they obtain the right qualifications. If they lack skills and competencies, they need to receive the corresponding training in order to become properly qualified at minimum. The guidelines for auditors in DIN EN ISO 19011 provide further requirements on auditors and audits.

This standard was revised in October 2018. One of its focuses is on risk-based auditing.

PeRoBa® Unternehmensberatung GmbH (Management Consultancy LLC) offers plenty of support here, for instance, through our iVision® Remote Audit Solution. Due to that, auditing at any place and time pursuant to standard requirements is possible. The results will be summarized in a digital report and can be mentioned in the management review, as required by ISO 17025.

Section 8.9: Top management review

Management must review the quality management system at least once a year. The assessment includes a list of all the relevant requirements of ISO 17025, like, for instance, all the errors that have occurred during the year, the (preventative and other) measures that have been derived out of them, client feedback and evaluations of internal reporting up to the quality control system and the certificates of the ring trials.

Technical requirements

Laboratory management needs to define qualification requirements for all the relevant activities of the laboratory staff. In case of any deviations, training must be planned and checked for efficiency. Besides, management needs to have regulations in place for personnel evaluation and continual further training. In this context, ISO 17025 provides specific minimum requirements on the evidence that has to be documented.

Facilities must conform to requirements and conditions. The required laboratory equipment and all other factors up to handling patient samples need to be evaluated here, too. In this context, the warehouse and the storage facilities have to be assessed as well. Any cross-contaminations must be avoided at all costs, especially when it comes down to clinical samples.
The maintenance of the aforementioned resources has to be planned and documented also.

Annex A: Metrological traceability

As stated above, laboratory management needs to make sure of the quality of the results, for instance, through ring trials. In order to prove that results are comparable for all the relevant activities, a conception for traceability to standardized guidelines / specifications is necessary. To that end, the entire laboratory personnel needs the corresponding qualification requirements management has to define. In case of any deviations, appropriate training courses must be planned and checked for efficiency. Besides, management has to have regulations in place for staff assessment and continual further training. In this context, ISO 17025 demands that specific minimum requirements on the evidence to be documented be met.

Facilities need to conform to requirements and conditions. To that aim, everything from the necessary laboratory equipment to handling samples has to be evaluated. Warehouses and storage facilities must be assessed in that context as well.
The maintenance of the aforementioned resources needs to be planned and documented as well.

Annex B: Management system options

The laboratory must have a documented procedure in place for insuring the validity of the test results.
To that end, a management system is required. A possible implementation method consists of securing that the minimum requirements on a quality management system according to DIN EN ISO 9001:2015 be met. Many of the requirements are in line with ISO 9001 and therefore, they provide possible and advisable starting points.

Contact details

Suppliers of the ISO 17025 standard

Beuth Verlag GmbH (Beuth Publishing House LLC)

Internet: www.beuth.de

International Organization for Standardization

Internet: www.iso.org

Deutsche Akkreditierungsstelle GmbH (DAkkS) (German Accreditation Body LLC)

Internet: www.dakks.de

International Laboratory Accreditation Organization (ILAC)

Internet: www.ilac.org

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