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QUALITY MANAGEMENT IN A CALIBRATION LABORATORY IN ACCORDANCE WITH THE REQUIREMENTS OF THE INTERNATIONAL STANDARD ISO/IEC 17025

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ABSTRACT
Standard ISO/IEC 17025 defines quality management as well as technical requirements for testing and calibration laboratories. This standard serves particularly accreditation bodies as a reference according to which laboratories are assessed during the accreditation process. Accreditation is formal recognition of technical competence and serves as a tool by which an accredited body gains confidence on market.
This article describes all necessary measures to be taken by a calibration laboratory in order to comply with the management and technical requirements of the standard ISO/IEC 17025. Special attention is paid to the technical requirements like traceability, uncertainty, calibration methods and procedures etc.
Keywords: calibration laboratory, quality management, standard ISO/IEC 17025

1. INTRODUCTION

If a laboratory offers services like testing and calibration on market, it shall offer their potential clients some kind of proof that it has technical competence for the services it is offering [2]. The most powerful tool for proving such competence is accreditation. Accreditation is performed by an accreditation body recognized in particular country. Accreditation bodies in Europe are operating under an umbrella of European Accreditation (EA). EA is setting rules for the operation of accreditation bodies in order to assure comparable accreditation processes in all member countries. Basic rules for accreditation bodies are however laid down in ISO/IEC 17011. EA MLA is a multilateral agreement between accreditation bodies about recognizing accreditation granted from one body in all signatory countries.
In accreditation process, an accreditation body is checking and monitoring the laboratory in order to ensure that it meets all managerial and technical requirements [1,4] laid down in the standard ISO/IEC 17025. Last issue of this standard dates in 2005 [1].

2. REQUIREMENTS OF ISO/IEC 17025

Standard ISO/IEC17025 is titled General requirements for the competence of testing and calibration laboratories. The requirements are divided into two main groups [1,3]:

- Management requirements, and
- Technical requirements.

Managerial requirements define measures to be taken in order to establish a reliable quality measurement system that will be able to produce stable level of confidence in quality. This part can be very well compared with ISO 9001 and is also based on this standard.
Technical requirements [1, 2] are laid down for technical resources and processes in order to assure defined quality of a test or calibration that is offered to the clients. These requirements are, however, still general. Specific requirements for different fields of testing and calibration like chemistry testing, calibration of electrical quantities, mechanical tests etc. are not defined in the standard because it is designed for general use in all laboratories. A laboratory shall follow general requirements and shall incorporate specific technical procedures and resources in compliance with those requirements [3]. Specific professional performance is than checked by a technical expert/assessor appointed by the accreditation body.

2.1. Management requirements

Table 1. Management requirements of ISO/IEC 17025 [1]

Chapter	Requirement	Short explanation
4.1	Organization	Legal status, organigrams, relation to parent organization, technical management, quality management, communications, impartiality, responsibilities, …
4.2	Management system	Documented policies, systems, programmes, procedures, instructions; quality manual
4.3	Document control	Policy and procedures for issuing and maintaining documents, responsibilities, documentation structure
4.3.1	General	
4.3.2	Document approval and issue	Responsibilities, duties, authorization, distribution
4.3.3	Document changes	New issues, obsolete versions, distribution
4.4	Review of requests, tenders and contracts	Contents and quality of a service, capacity check, possible changes, information exchange, records
4.5	Subcontracting of tests and calibrations	Approval of subcontractors, lists, agreements, documentation, reports, contents and quality of work
4.6	Purchasing services and supplies	Suppliers check, ranking, selection, criteria
4.7	Service to the customer	Policy, communication, inquiry, feedback analysis
4.8	Complaints	Receipt, analysis, corrective actions, documentation
4.9	Control of nonconforming testing and/or calibration work	Responsibilities, analysis, influence on results, corrective actions, informing clients, repeating work
4.10	Improvement	Stimulation, actions, evaluation
4.11	Corrective actions	Non-conformity control, defining corrective actions, responsibilities for performing CA, procedure
4.11.1	General	
4.11.2	Cause analysis	Non-conformance source, involved resources
4.11.3	Selection and implementation of corrective actions	Analysis team, definition of CA, responsible person(s), term, acceptance criteria, records
4.11.4	Monitoring of corrective actions	Responsible management member, records
4.11.5	Additional audits	If necessary, for critical non-conformities
4.12	Preventive actions	QS efficiency improvement, decisions, rcords
4.13	Control of records	QS operation records, technical records
4.13.1	General	Defining records, form, filing, changes
4.13.2	Technical records	Form, contents, electronic records, filing, changes
4.14	Internal audits	Qualified auditors, procedure, records
4.15	Management reviews	Top level management, QS analysis, records

Management requirements are comprised in Table 1. This table is showing all points from the standard that shall be met by all laboratories regardless to the field of activity they are performing. A short explanation for each item is given in the table and some extensive explanations of the most important approaches in the laboratory are given in later chapters.

2.2. Technical requirements

Technical requirements concern technical resources necessary for performing tests or calibrations at an appropriate quality level. These resources are:

- Personnel
- Equipment
- Premises with installations
- Procedures.

Table 2. Technical requirements of ISO/IEC 17025 [1]

Chapter	Requirement	Short explanation
5.1	General	Technical reources
5.2	Personnel	Education, skills, selection, supervision, training
5.3	Accommodation and environmental conditions	Premises, installations, rules for entering, protection, defining and monitoring environmental parameters
5.4	Test and calibration methods and method validation	Selecting methods, documenting, written procedures, validation of non-standard methods, approval
5.4.1	General	
5.4.2	Selection of methods	Best fit for offered services, technical approval
5.4.3	Laboratory-developed methods	Policy, decision, documentation, validation
5.4.4	Non-standard methods	Policy, decision, documentation, validation
5.4.5	Validation of methods	Rules of validation, responsibilities, technical resources, documentation
5.4.6	Estimation of uncertainty of measurement	Following GUM and EA-4/02, decision on necessity, documentation
5.4.7	Control of data	Procedures for checking, records, approval
5.5	Equipment	Function, records, marking, monitoring, servicing
5.6	Measurement traceability	Assuring comparison with national or international standards through unbroken chain of calibration
5.6.1	General	
5.6.2	Specific requirements	Who can calibrate, calibrated parameters, period
5.6.3	Reference standards and reference materials	Special instructions on calibration, maintenance, storage conditions, instructions for use
5.7	Sampling	Procedures (if relevant), records, sample storage
5.8	Handling of test and calibration items	Procedures for safety handling, protection, storage.
5.9	Assuring the quality of test and calibration results	Procedures, supervision, interlaboratory comparisons, replicate tests, retesting, …
5.10	Reporting the results	Procedures, forms, records, reponsibilities
5.10.1	General	
5.10.2	Test reports and calibration certificates	Report form, contents, results, approval, sending, keeping copies, accreditation mark
5.10.3	Test reports	Specific requirements for test reports
5.10.4	Calibration certificates	Specific requirements for calibration certificates
5.10.5	Opinions and interpretations	Policy and procedures for attaching opin. and interp.
5.10.6	Testing and calibration results obtained from subcontractors	Policy and procedure, information to client, requirements to subcontractor
5.10.7	Electronic transmission of results	Policy and procedures for approving such documents, protection, validity, copies.
5.10.8	Format of reports and certificates	Unique recognized format
5.10.9	Amendments to test reports and calibration certificates	Policy and procedures for amending or issuing new certificates, communication with client.

Detailed technical requirements are shown in Table 2. As it can be seen in the table, technical part also covers reports as the basic product of an accredited testing/calibration laboratory. This is the most significant difference to ISO 9001, which is only focused into process quality and is no defining anything about products.

3. CALIBRATION LABORATORY

Calibration laboratory is an important link in a traceability chain [2]. It can be positioned in different level of such chain. An example is shown in Fig. 1. In the second level of presented traceability chain it is possible to see 2 calibration laboratories, which offer their service on market and are therefore accredited. However, company 1 also performs in-house calibration and therefore also has a calibration laboratory. If such laboratory performs only internal calibrations, it is usually not accredited. Bat it can of course also offer calibrations for other companies. In that case it has sense to be accredited in order to prove competence to its clients.

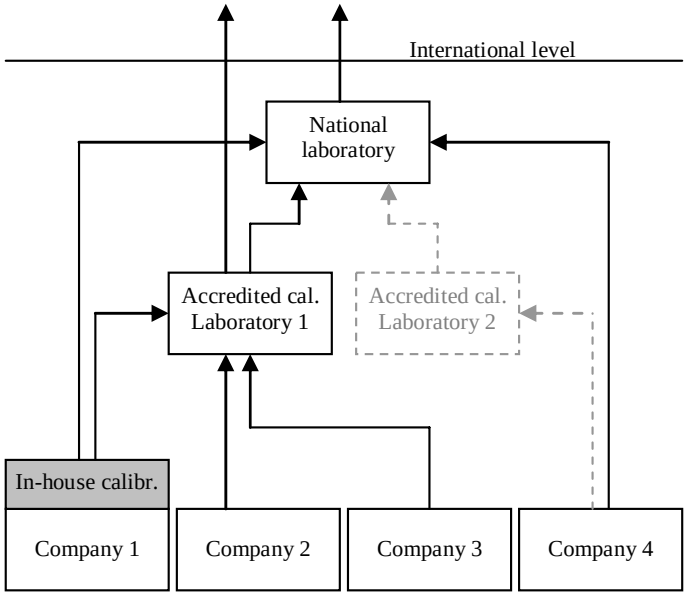

Figure 1. Example of a traceability chain with calibration laboratories at three levels

A national metrology laboratory usually also serves as a calibration laboratory. Its accreditation depends on national metrology policy. Slovenian national laboratories are accredited as well as British, French and some others, while e.g. German, Austrian Dutch and some other are not accredited and assure their competence through BIPM metrological database, Euromet QS Forum etc. In any case, calibration laboratories are very important for assuring traceability and through it international comparability of industrial measurements and are base link of international metrology.

4. QUALITY MANAGEMENT IN A CALIBRATION LABORATORY

If a calibration laboratory intends to apply for accreditation, it shall of course fulfill both managerial and technical requirements of ISO/IEC 17025 [1]. Non-experienced managerial staff usually thinks that a quality manual with supporting documentation is solving all managerial requirements and that it is the first and the only think to do. In fact, legal status, quality policy, organization, responsibilities and duties are the most important things and shall be defined by top management before writing quality documentation. Diagram of activities for establishing quality management system is shown in Fig. 2.

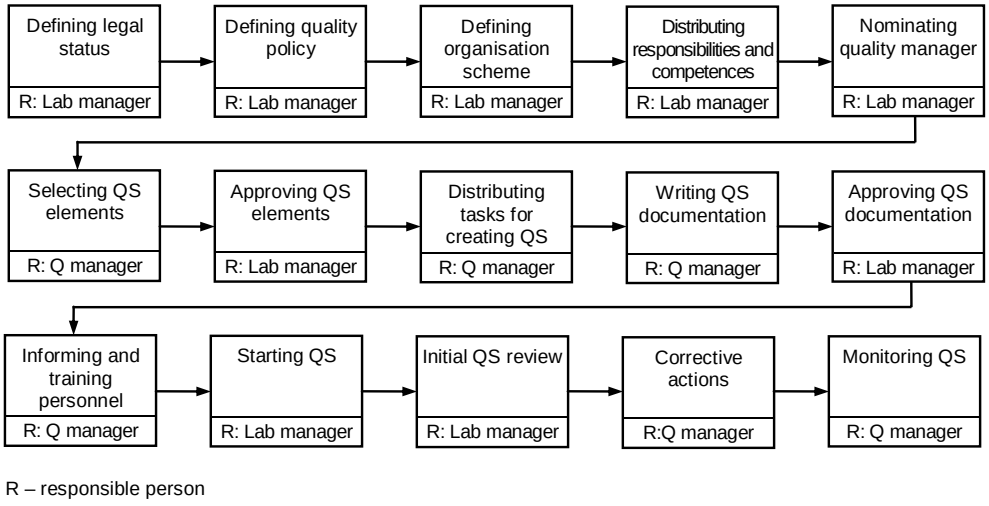

Figure 2. Approach of introducing a quality system into laboratory

4.1. Quality system documentation

Documentation structure is shown in Fig. 3. Top document is Quality manual documenting general quality policy, laboratory identification, activities and structure, as well as policies regarding all quality system elements (personnel, equipment, premises, processes, supervision, …). The manual is followed by system procedures defining organizational activities related to quality like training personnel, performing internal audits, reviews etc. Operating instructions serve for performing technical work and producing appropriate quality.

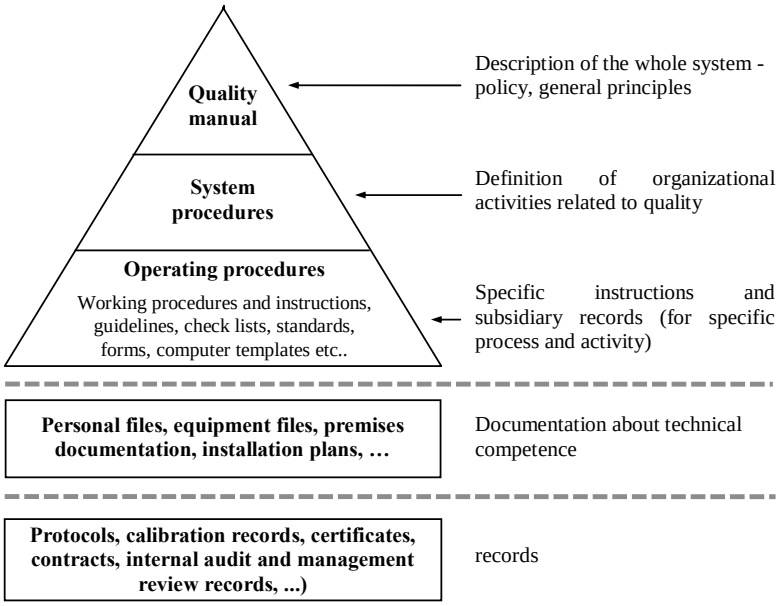

Figure 3. Quality system documentation

The bottom two levels represent records about technical competence and performed activities. These documents are not giving instructions like those in the triangular structure, but are indicating proofs of technical status and status of performed work.

4.2. Technical resources

Technical resources are the most important part of a calibration laboratory. They are already listed in chapter 3. The most important and critical issues concerning those resources are the following [1, 2, 3, 4]:

- selection and supervision of staff (criteria, procedures, approval),
- staff training (plans, performance, analysis),
- traceability of equipment (criteria for calibration, selection of performers of calibrations),
- selection and validation of calibration methods,
- uncertainty of measurement,
- calibration software (selection, validation, updating, management of obsolete versions, records, protection against lost and misuse),
- environmental conditions and protection of calibration rooms.

4.3. Calibration reports and use of the accreditation sign

Calibration report is the main product of a calibration laboratory. An accredited laboratory shall consider all requirements of the accreditation body regarding the use of the accreditation sign and statements about accreditation on the calibration reports/certificates. The standard [2] is defining the contents of calibration reports in detail. Special attention shall be paid to measurement results and corresponding uncertainty of measurement. All technical records must be traceable to the report and kept in technical files. The report shall be approved by a technical competent person.

5. CONCLUSIONS

In order to be prepared for accreditation, a calibration laboratory shall fulfill both managerial and technical requirements of ISO/IEC 17025:2005. Quality management system must be well defined and documented, legal and organizational arrangements shall be performed and technical competence assured. In addition, supplementary requirements of the accreditation body shall be considered. It is of great importance, that the laboratory keeps continuity of the system during its operation and that a system of permanent improvements is adopted. The operation shall be periodically checked through internal audits and the efficiency of the system monitored through management reviews. Al non-conformities shall be effectively eliminated by corrective actions and potential new non-conformities prevented by systematic preventive actions. All changes in the system shall be reported to the accreditation body. Such system requires full engagement of the management as well as all technical staff of the laboratory.

6. REFERENCES

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