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Review Paper

IMPROVING THE QUALITY OF ENVIRONMENTAL TESTING THROUGH THE IMPLEMENTATION OF ISO 17025 STANDARDS

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Abstract. *Contemporary tendencies of standardization and accreditation of business entities are reflected through the intensive implementation of standards, which refer to different management systems: quality, environmental protection, occupational safety and health business continuity, laboratory competence, etc. Quality management in laboratories specialized for environmental testing is one of the most important requirements of modern practice. Accordingly, the standard ISO/IEC 17025 was adopted, the requirements of which confirm the technical competence of testing and calibration of laboratories. This paper discusses the implementation and maintenance of the ISO/IEC 17025 standard, as a tool for improving the quality of environmental testing, as well as the accreditation procedure, which confirms the technical competence of a laboratory.*

Key words: *laboratories, testing of environmental elements, quality, ISO/IEC 17025*

1. INTRODUCTION

Compliance assessment refers to processes proving that a product, process and service, or management system or body that assesses it meets the defined requirements. Accreditation in a broader sense is a certification carried out by a third party, and refers to the compliance assessment body, which provides formal proof of its ability to perform certain tasks according to predefined standards. The Accreditation Body of Serbia is a national accreditation body entrusted with the tasks of determining the competence of compliance assessment

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bodies to perform testing, calibration, control, product certification, management system certification and certification of persons [1].

Technical competence requirements are defined in international ISO and IEC standards as well as other documents of relevant organizations. [1]. The basis of the environmental quality assurance system is accredited laboratories that have implemented the ISO/IEC 17025. The mentioned standard consists of requirements for laboratories that enable them to demonstrate that they operate competently and can provide valid results. This is because the main objective of these systems and compliance assessment procedures is to ensure that products are objectively, impartially and reliably presented, and acceptable to all stakeholders, whereas processes and services constantly meet the requirements defined by this standard, technical regulations and specifications. Establishing and maintaining a competent, impartial and independent accreditation system is a strategic national task. The accreditation body is the holder of these activities, so that the interested parties have confidence in the services provided by accredited organizations and economic entities. Obtaining an accreditation certificate means that the compliance assessment body is competent to perform the work [2]. The paper describes the implementation of the standard SRPS ISO/IEC 17025: 2017 in testing the elements of environmental quality, which assesses the technical competence of accredited laboratories.

2. ACCREDITATION OF ENVIRONMENTAL TESTING LABORATORIES

A laboratory is a body that performs one or more of the following activities: testing, calibration or sampling [3]. Examination and analysis of samples is a daily practice of the laboratory with the obligatory assurance of the reliability of the results. Over the past years, the standard ISO/IEC 17025 - General Competency Requirements for Testing Laboratories and Calibration Laboratories has become an international reference for laboratories determined to demonstrate their ability to issue reliable results. This international standard, which was jointly prepared and revised by the International Organization for Standardization - ISO and the International Electrotechnical Commission - IEC, contains a number of requirements that allow laboratories to improve their ability to provide valid results consistently.

The advantages of laboratory accreditation are: improved internal organization of the laboratory (reduction of empty runs, simplification of certain procedures, setting clear requirements, etc.); preservation of knowledge and experience; easier preparation of references and promotional materials; faster introduction of new employees; employee motivation and development of awareness of one's own abilities; encouraging teamwork and communication; development of cooperation with competing laboratories on the exchange of knowledge and defining common requirements for service users, suppliers, legislators, society, etc.; an increase of customer confidence; internationally recognized results [4]. On the other hand, the disadvantages of laboratory accreditation are: increased material costs; regular supervisory audits; increased staff engagement; a greater volume of documented information; increased prices of services; accreditation must be maintained and renewed [5].

However, regardless of the shortcomings of the accreditation of the environmental testing laboratories, it is necessary and expedient to prove and confirm the technical competence of the laboratory, as well as the validity of test results which are often crucial in expertise and decisions of inspection bodies.

The accreditation procedure, as well as the rights and obligations of participants in the process of obtaining and maintaining accreditation, are determined by the rules of accreditation, Figure 1.

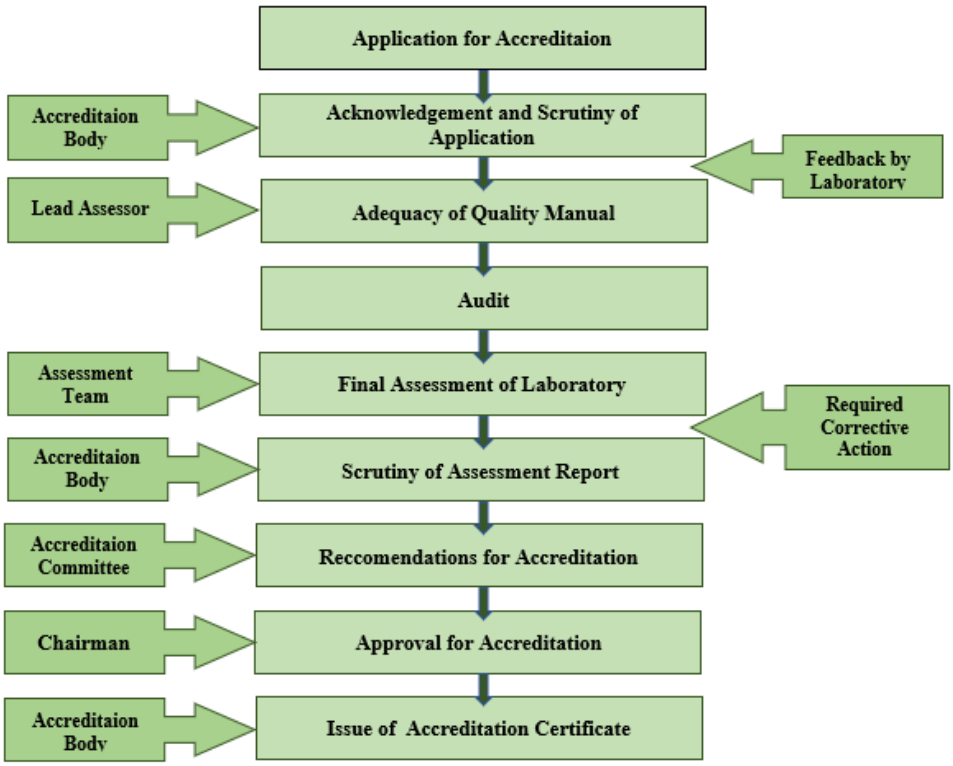

Fig. 1 Accreditation procedure

The accreditation process mainly includes the following activities: submission of an application for accreditation; review of the application for accreditation; preparation for evaluation; assessment; making a decision on accreditation; conformity assessment bodies for compliance assessment in the accreditation cycle.

3. STANDARD REQUIREMENTS SRPS ISO/IEC 17025: 2017

The latest version of the standard has 8 points with 219 requirements that laboratories must meet in order to be accredited. The most significant innovation besides the structure is in the risk-based thinking that requires: that the laboratory plans and implements measures related to risks and opportunities; that dealing with risks and opportunities forms the basis for increasing the effectiveness of the management system; achieving improved results and preventing negative effects. The laboratory is responsible for deciding what risks and opportunities it should address.

Documented information serves as objective evidence that the laboratory meets the requirements of the standard. A hierarchy of documents that are most often used in practice was established, Figure 2.

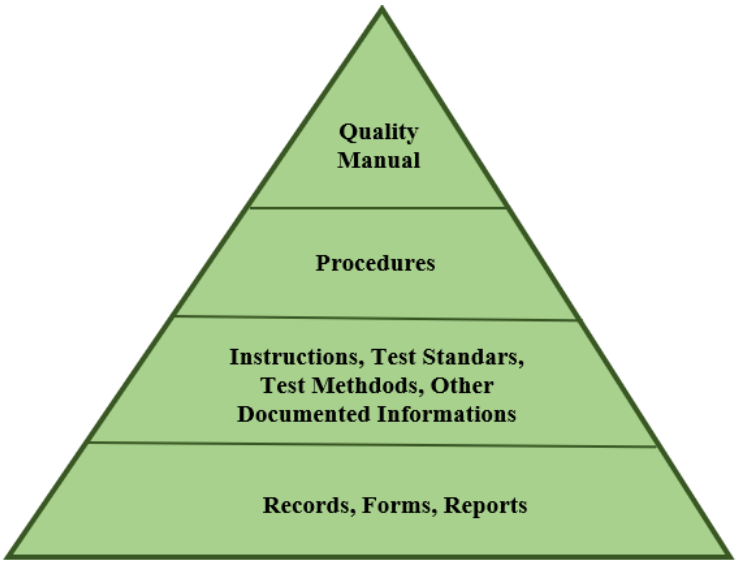

Fig. 2 Hierarchical structure of documented information

The structure of the standard is shown in Table 1.

Table 1 Structure of the standard ISO/IEC 17025

Points	Standard requirement
1.	**Scope**
2.	**Normative references**: reference to ISO/IEC Guide 99 and ISO/IEC 17000
3.	**Terms and definitions**
4.	**General requirements:** Impartiality; Confidentiality
5.	**Structural requirements**
6.	**Resource requirements:** General; Personnel; Facilities and environmental conditions; Equipment; Metrological traceability; Externally provided products and services
7.	**Process requirements:** Review of requests, tenders and contracts; Selection, verification and validation of methods; Sampling; Handling of test or calibration items; Technical records; Evaluation of measurement uncertainty; Ensuring the validity of results; Reporting of results; Complaints; Nonconforming work; Control of data and information management
8.	**Management system requirements:** Option A; Option B (the laboratory is certified ISO 9001)

General requirements include impartiality and confidentiality, whereby laboratory activities should take into account impartiality and keep the confidentiality of all information obtained during the performance of laboratory activities. Risks related to impartiality based on the relationship between service users and laboratory personnel may be: kinship in the sense that a member of the laboratory personnel is in blood or

similarly related to the service user; ownership relations in the sense that the legal entity has a connection with the service user; in a technical sense if laboratory activity is conducted by before one's turn; presenting the results of sampling, testing or calibration in the sense that the result of the laboratory activity is as requested by the user; financial nature in the sense that laboratory personnel takes money from service users, in the form of bribes and corruption; management character in the sense that the laboratory personnel is pressured by an employee who is in one of the management positions; commercial, financial or any other impact that could have adverse effects on the quality of work during the performance of laboratory activities; taking or requesting gifts or other benefits [6].

Risks related to laboratory activities may be: insufficient level of trust in the operation of equipment; calibration standard malfunction; incompetent personnel; inadequate procedure for reviewing bids, contracts, orders; incompetent personnel conducting internal audits; negligent and irresponsible review of performance and success; an approach to management review which is not objective [6].

Structural requirements identify management, laboratory activities, organizational and management structure, responsibilities, authorities, and interpersonal relationships of personnel. They are most often defined through procedures on resource management and the implementation of laboratory tests and documented information that further defines each request individually. The organizational structure is represented through organizational schemes and responsibility matrices, and the leadership or management structure through the objectives and policy statement of the laboratory, i.e. the legal entity.

Resource requirements emphasize the importance of providing resources such as personnel, facilities and environmental conditions, equipment, metrological traceability, and external products and services used to support the work of the laboratory. All laboratory personnel, whether internal or external, who may influence laboratory activities must act impartially, be competent and must work in accordance with the laboratory management system. The laboratory must document competency requirements for each function that affects the results of laboratory activities, including requirements for education, qualifications, training, technical knowledge, skills and experience. The laboratory must obtain and keep the records on: determining competency requirements; personnel selection; personnel training; staff supervision; personnel authorization; monitoring personnel competence. Also, facilities and environmental conditions must be appropriate for laboratory activities and must not adversely affect the validity of the results. Requirements for facilities and environmental conditions necessary to perform laboratory activities must be documented. The laboratory must monitor, manage and record environmental conditions in accordance with relevant specifications, methods or procedures. Therefore, the laboratory must define instructions for the maintenance of working premises and for the conditions of accommodation and preventive maintenance of measuring equipment. Moreover, laboratory personnel must have access to the equipment (measuring instruments, software, standards, reference materials, reference data, reagents, consumables, auxiliary apparatus, etc.) necessary to perform laboratory activities. The laboratory must verify that the equipment complies with the defined requirements before it is put into service or put back into use. The equipment used for measurement must be able to achieve measurement accuracy and must be calibrated when measurement accuracy or measurement uncertainty affects the validity of the reported results and when calibration is required to establish the metrological traceability of the reported results. Also, the laboratory must establish a calibration program, which is reviewed and adjusted to maintain confidence in the calibration status. [3]. Finally, the laboratory must

establish and maintain the metrological traceability of its measurement results using a documented continuous calibration chain, where each of the results contributes to the measurement uncertainty [7].

Process requests relate to: a review of requests, bids and contracts; selection, verification and validation of methods; sampling; handling test or calibration items; technical records; valuation of measurement uncertainty; ensuring the validity of the results; reporting on results; objections; non-compliant work; data management and information management. This point of the standard is the most important for the realization of operational activities. A possible schematic representation of the process of realization of operational activities in the laboratory is shown in Figure 3.

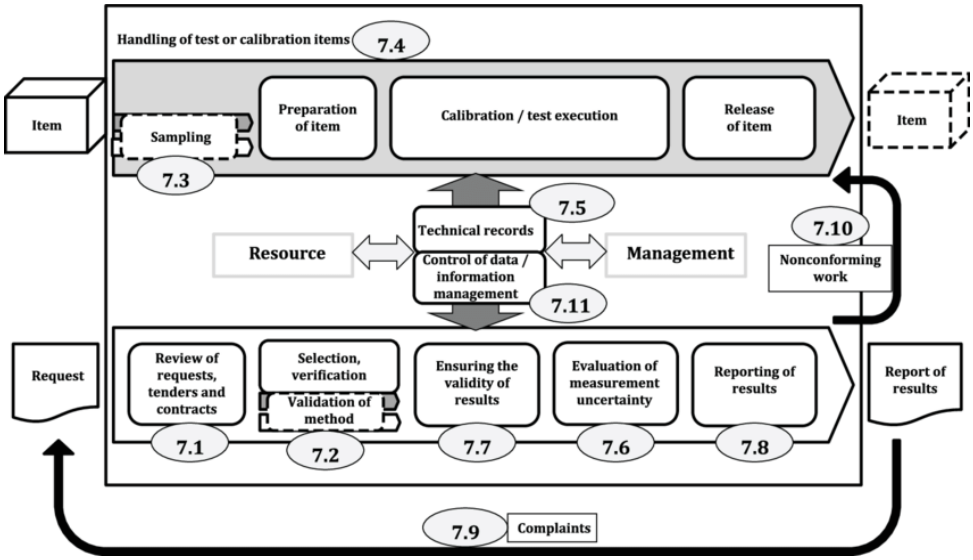

Fig. 3 Possible schematic representation of the process of realization of operational activities in the laboratory [3]

The requirements of the management system define that the laboratory has two options when applying the management system/option A or option B. Option A lists the main requirements for the application of the management system, which means that the laboratory can directly implement the management system based on ISO/IEC 17025. In addition, the laboratory may choose to include ISO 9001 requirements that are relevant to the performance of laboratory activities. Option B is when the laboratory operates in accordance with the requirements of ISO 9001 in a manner that meets the requirements of points 4 to 7 of ISO/IEC 17025, to demonstrate the ability of the laboratory to realize technically valid data and results [8]. It is recommended that laboratories that operate independently as legal entities choose option A, while laboratories that are an integral part of a legal entity that is certified according to the requirements of the ISO 9001 standard choose option B.

4. CONCLUSION

According to the valid legal norms of the Republic of Serbia, monitoring of the state of the environment can be done only by accredited organizations and for that reason, all laboratories providing environmental testing must be accredited according to the latest version of ISO/IEC 17025. Accreditation, as an element of a country's quality infrastructure, is an internationally recognized tool for ensuring trust in the work of laboratories in order to protect the public interest and increase reliability in making appropriate decisions. Accreditation establishes trust in the market and cooperation with the European and international community because it ensures the recognition, acceptance and recognition of the assessment of compliance with the requirements outside the country's borders. Accordingly, on the basis of the certificate of accreditation issued by the Accreditation Body of Serbia, the technical competence of laboratories dealing with environmental issues is confirmed.

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UNAPREĐENJE KVALITETA ISPITIVANJA ELEMENATA ŽIVOTNE SREDINE KROZ PRIMENU STANDARDA ISO 17025

Današnje tendencije standardizacije i akreditacije privrednih subjekata ogledaju se kroz intenzivnu primenu standarda, koji se odnose na različite menadžment sisteme: kvalitet, zaštita životne sredine, bezbednost i zdravlje na radu, kontinuitet u poslovanju, kompetentnost laboratorija i dr. Upravljanje kvalitetom u laboratorijama koje se bave ispitivanjima elemenata životne sredine je jedan od najbitnijih zahteva moderne prakse. Shodno tome, usvojen je standard ISO/IEC 17025 čiji zahtevi potvrđuju tehničku kompetentnost laboratorija za ispitivanje i etaloniranje. U ovom radu se razmatra implementacija i održavanje standarda ISO/IEC 17025, kao alata za unapređenje kvaliteta ispitivanja elemenata životne sredine, kao i postupak akreditacije čime se potvrđuje tehnička kompetentnost laboratorija.

Ključne reči: *laboratorije, ispitivanje elemenata životne sredine, kvalitet, ISO/IEC 17025.*