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Pregledni članak
Review article

GENERAL REQUIREMENTS FOR THE COMPETENCE OF TESTING LABORATORIES AND THEIR IMPLEMENTATION

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Summary: This paper explains general requirements that testing laboratories should fulfill in order to confirm their competence in the certain field of testing according to the international standard ISO/IEC 17025. The requirements of the standard are separated in two main groups: management requirements and technical requirements. Management requirements can be implemented in the similar way in many testing laboratories, since they consider elements, common for all business systems. A laboratory should pay special attention to the fulfillment of technical requirements. In addition to the requirements of the standard, within each test area exist other applicable legislation. Each laboratory should establish its own goals and needs taking into account the requirements of business environment and legislative that has to be implemented.

Key words: testing laboratory, requirements for the competency

Introduction

Demonstration of technical competence, impartiality and independence of testing laboratories is an important part of the process of consumer protection against nonconforming products or services. It strengthens the confidence in objectivity of laboratories and exactness of test results. Demonstration of competence is an integral part of accreditation process. Accreditation is the official recognition, performed by an authorized organization that a laboratory is competent to perform testing activities within defined scope of accreditation. Organization, performing accreditation in our country is called Yugoslav Accreditation Body. Any testing laboratory, seeking accreditation, should align its internal organization and system of work with the requirements of the standard JUS ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories, which has been adopted and issued in our country in the March, 2001.

Unfortunately, official data of the Yugoslav Accreditation Body show that till December, 2001. only one testing laboratory was accredited according to the requirements of this standard. Other testing laboratories were accredited according to canceled JUS ISO/IEC Guide 25 and/or standard JUS EN 45001 (21 regular certificate of accreditation and 56 temporary certificates). These data show that testing laboratories in our country very slowly move toward new requirements. Whatever the reasons for this situation, testing laboratories should anticipate the future trends and take timely measures to demonstrate their technical competence according to the standard JUS ISO/IEC 17025. Current year shoves greater interest of laboratories for implementation of the standard and accreditation.

Requirements for competence

Standard ISO/IEC 17025 defines general requirements for the competence of the testing and calibration laboratories regardless of the main field of testing and calibration. Standard contains all requirements that testing laboratories should fulfill in order to prove that they have quality system, that they are technically competent and that they can deliver technically valid results. Accreditation bodies that perform recognition of the laboratories competence use this international standard as the basis for the accreditation.

Acceptance of the testing results among countries would be enabled if laboratories fulfill this international standard, and if they are accredited by bodies that have signed agreements of mutual recognition with other equivalent bodies in other countries that use

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standard ISO/IEC 17025. Application of this international standard will enable cooperation between laboratories and other bodies in exchange of information and experience, as well as harmonization of the standards and procedures.

ISO/IEC 17025 is the standard that requires regulation of the working processes in the way that enables:

Better surveillance of the processes for the management of the laboratory,

Clear assignments, responsibilities and authorities for the personnel,

Confidence in the quality of work and testing results for the laboratory clients.

The requirements of the standard are separated in two main groups. Chapter four specifies requirements related to the management of the laboratory. Chapter five defines requirements for technical competency of the laboratory related to the certain field of testing.

In addition to the requirements of the standard, within each testing area exist other applicable legislation, e.g. law, principles of good laboratory practice, technical standards which have to be studied and implemented.

Management requirements

Management requirements relate to organizational, managerial, administrative and commercial aspects of work, including requirements for the quality system. These requirements are very similar to the requirements for quality management system defined in the standard JUS ISO 9001, but also adopted for the particularities of the laboratories.

These requirements can be implemented in the similar way in testing laboratories, since they consider elements, common for all business systems and states specifications that each laboratory seeking accreditation should fulfill. Requirements are grouped into fourteen elements that are considered important for management of any laboratory. They are:

Organization of the laboratory,

Quality system,

Control of the documentation,

Activities related to the contracting with the client and contract revives,

Subcontracting of testing (if applicable),

Purchasing of supplies and services,

Relationship with the clients,

Complaints,

Control of the nonconforming testing,

Corrective measures,

Preventive measures,

Control of records,

Internal audits,

Management reviews.

These requirements, among other measures, expect laboratory to develop policies and procedures for processes stated in this part of the standard.

For the laboratories which are part of the organizations that have implemented standard ISO 9001, several remarks on the particularities for the management system of the laboratory should be useful:

Organization of the laboratory and its place in the larger organization should be stated clearly;

Organization, responsibilities and communication in the laboratory should be established in the way that independence, impartiality and integrity are assured;

Laboratory should not conduct any activities that could create conflict of interest regarding process of testing;

Laboratory should conduct appropriate surveillance for personal involved in testing process;

Laboratory should appoint technical management and quality management (these are not necessary tasks separated from other assignments, specially in the small laboratories where one person have several assignments);

Subcontracting of testing is activity specific for the testing process and should not be mixed with the purchasing process in the organization;

Responsibilities and communication in the laboratory should be defined in the way that enables and assures efficient communication with client;

Complaints consideration and solving is specific for laboratory and separate procedure should be developed for this process;

Control of nonconforming testing requires separate procedure and should not be considered and established in the same manner as control of the nonconforming product of the organization;

Procedure(s) for the corrective and preventive actions developed according to the ISO 9001 could be applicable in the laboratory, but recommendation is to review them carefully because potential and existing causes of the nonconformities in the laboratory can vary from those in the other parts of the organization (depending of the product, services and processes);

Internal auditors should be trained to implement standard ISO/IEC 17025 in the audit process. Training for the internal audits according to ISO 9001 standard is not enough;

Procedure for the control of records should include control of the records regarding testing process,

Procedure for management review and review itself should include all elements of the review stated in the requirement 4.14 of the standard ISO/IEC 17025. Standard ISO 9001 does not require the same list of elements for review.

Technical requirements

A laboratory should pay special attention to the fulfillment of technical requirements. For the defined field and scope of testing, laboratory should assure and demonstrate the following:

- competence of personnel for testing activities and other activities they are assigned,
- adequacy of the equipment,
- adequacy of environmental conditions regarding people, samples, equipment and testing methods,
- adequacy of testing methods whose validity has been confirmed,
- adequacy of procedures with test samples which provide confidence in the test results,
- use of procedures and measures that provide confidence in the testing results,
- adequacy of the procedure for issuing test report.

Technical requirements are specified through ten groups of elements that should enable laboratory to implement it's testing procedures in the manner that provides confidence into validity of the testing results. These requirements include:

- general requirements,
- requirements for personnel,
- requirements for testing methods,
- requirements for working space and environment,
- requirements for the laboratory equipment,
- requirements for traceability of measurement,
- sampling (if laboratory itself performs these activities),
- requirements for handling of testing samples,
- recommendation for use of methods to provide confidence in testing results,
- requirements for testing report.

These requirements are generally stated and should be implemented in each laboratory regarding particularities of the certain field of testing. Standard does not require strictly documented procedures for implementation of these requirements. Even so, laboratory should consider each requirement in detail. If there should be changes in laboratory practice in order to fulfill requirement of the standard, it is recommended to document procedure or instruction. It has been noticed that changes are implemented more efficient with documented procedures.

Implementation of the requirements for the competence

Each laboratory should establish its own goals and needs taking into account the requirements of business environment and legislative that has to be implemented. If requirements for accreditation are part of these requirement, testing laboratory should focus towards fulfillment of these requirements too.

Standard procedure for the implementation of the standard into laboratory practice should include:

- Study of the standard's requirements establish what have to be, what should be and what can be implemented;
- Establish particularities in implementation regarding field of testing, organization, position in the larger organization, number of employees, specially if there are difficulties in the application of certain requirements;
- Specify additional requirements for operation of the particular testing laboratory, such as law, standards, testing methods and other legislative with obligatory application;
- Conduct first audit of the laboratory according to the standard and other applicable requirements;
- Establish specification and scope of measures and activities to be implemented in order to fulfill requirements of the standard;
- Develop the implementation plan that includes: what, who, when, how should be done, what are priorities and how should results be measured;
- Implement the plan and perform periodical review of the accomplishments.

Implementation plan usually includes following elements:

- Training,
- Systematization of the legislative (law, regulations, standards),
- Preparation, review and approval of quality system documents required by the standard and needed by the laboratory,
- Systematization of the testing methods,
- Systematization of the instructions for the testing equipment (where is appropriate),
- Implementation of the quality system documentation and gathering evidence that prove fulfillment of the standards requirements,
- Perform periodical internal audit in order to regularly review fulfillment of the standard requirements, policy and goals of the laboratory.

Content and extent of each group of the activities should be tailored according to the laboratories goals, needs and particularities.

OPŠTI ZAHTEVI ZA KOMPETENTNOST LABORATORIJA ZA ISPITIVANJE I NJIHOVA PRIMENA

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Kratak sadržaj: Rad prikazuje opšte zahteve koje laboratorije za ispitivanje treba da ispune, kako bi mogle potvrditi svoju kompetentnost prema međunarodnom standardu ISO/IEC 17025. Zahtevi su svrstani u dve osnovne grupe: menadžment zahtevi i tehnički zahtevi. Zahtevi koji se odnose na menadžment mogu se primeniti na vrlo sličan način u mnogim laboratorijama za ispitivanja. U njima su definisani elementi, zajednički za sve poslovne sisteme. Ono što je specifično za pojedinačne oblasti ispitivanja su tehnički zahtevi. Pored standarda, u svakoj oblasti ispitivanja primenjuje se i regulativa koja se odnosi na tu oblast. Laboratorija treba da utvrdi sopstvene ciljeve i potrebe, kao i zahteve okruženja i važeće regulative koju mora u svom radu ispunjavati.

Ključne reči: laboratorija za ispitivanje, zahtevi za kompetentnost.

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