LABORATORY ACCREDITATION – CONFIDENCE IN THE ACTIVITIES OF CONFORMITY ASSESSMENT OF PRODUCTS

LABORATORIJSKA AKREDITACIJA- ZAUPANJE V AKTIVNOST OCENE USTREZNOSTI PROIZVODOV

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The role of accredited laboratories is to verify the quality of products. This is particularly important for those products intended for export. The activities of the laboratories of the Institute of Metallurgy and their significance for industrial activity in Bosnia and Herzegovina are presented.

Key words: accreditation, products quality control, quality management

Naloga akreditiranih laboratorijev je preverjanje kakovosti proizvodov. To je posebno pomemebno za izdelke, namenjene za izvoz. Predstavljena je aktivnost laboratorijev na Institutu za metalurgijo in njegov pomen za industrijsko dejavnost v Bosni in Hercegovini.

Ključne besede: akreditacija, kontrola kakovosti proizvodov, upravljanje kakovosti

1 INTRODUCTION

The prime task of Central and East European Countries is to achieve the required level of quality for products and services that are exported to the countries of the European Union. A considerable amount of work and knowledge are needed to bring the quality of products to a higher level, and much effort is necessary to improve the quality and responsibility of the work of all the people involved in the processes of production, control and quality assurance. The first difficulty to overcome is the barriers related to the conformity of the national legal framework, metrology, standardisation and of quality assessment with EU regulations. This is a major and complex task, since it involves the adoption of rules and processes prescribed in about 200 legal directives and about 7000 European standards related to metrology systems, methods of testing and certification, all necessary in order to have a comparable and transparent system of quality and procedures in all the involved countries, and which are easy to supervise1.

Also, for the placement of products in EU markets in the non-obligatory area of certification, serious barriers exist. First of all, certificates for the quality-management system in accordance with the standard ISO 9001:2000 and for the environmental management systems in accordance with ISO 14000 must be obtained, with the aim to ensure that certificates, accreditations, test and calibration reports are accepted throughout Europe. This means that products intended for export must be tested in accredited laboratories that have a certified system of quality control.

Quality is a characteristic confirming that the product is manufactured according to an approved procedure and that the properties are in agreement with a standard or with a prescription accepted by the manufacturer and the purchaser. The word quality has also a more general significance that may not be defined by a document in the case when it is related to a specific activity, a process or an organisation. With the quality system for companies and laboratories, the rules of behaviour in business are established, and reciprocal relations, tasks and responsibilities of the quality management are put in place. Therefore, good quality control for companies is one of the attributes for survival in a competitive market.

2 QUALITY – A NEW APPROACH TO BUSINESS

Quality is a global requirement valued in developed countries and becoming of essential importance for different industrial companies in Bosnia and Herzegovina, too. The market success of a number of products is more and more dependent on the purchaser's satisfaction and the price of the product. Because of the competition, which may offer the same quality for a lower price or an improved quality for an unchanged price, the quality determines the competitiveness in the market place for companies too³.

For this reason, the concept of quality has radically changed, and at present it is completely oriented towards the purchaser, his or her needs, expectations and preferences. It is not enough for the supplier to have high-quality products/services, it is also necessary to be ready to offer an acceptable price for an increasing level of quality. Therefore, only continuous improvements enable the producer to stay at the front of the general development and to be continuously competitive in the market.

At the beginning of the industrial revolution the sellers controlled the market, and because of the limited range of goods on offer, the purchaser was frequently forced to accept products of insufficient quality. The primary task of manufacturing was to ensure an increasing quantity of goods on the market. The saturation of the market set up the balance between supply and demand and asserted the quality and reliability as being significant for the market value of products. The increased number of suppliers of goods on the market is the cause of decreasing prices for goods of increasing quality. Success in competitive markets forces the producers to ensure not only that their products conform to standards, but also to improve the extent and reliability of the control of quality, including also non-standardised requirements.

The increased market competition and the strengthening of the role of the purchaser led to the development of a quality system involving the control of the quality of products and the inclusion of preventive actions to provide a constant supervision of the manufacturing process as well as the provision of an acceptable level of interference of this process with the environment. All the people involved in the production process have to take part in the activities related in a broad sense to the quality control. This understanding of the broad significance of quality control led to the development of the principles of the system of quality assurance for products.

Rapid changes in the market for products put the producers into a position in which even permanent improvement of the product quality, process and quality system were not sufficient to ensure success. This was the reason for the evolution of quality with new methods of integration and harmonization to predict the customer's behaviour. The processes inside an organization based on standards and internal producer rules were combined with continuous research and development and led to the system of Total Quality Management (TQM).

3 THE IMPORTANCE AND PARTICIPATION OF ACCREDITED LABORATORIES

Frequently, in the business sections of journals in Bosnia and Herzegovina there are reports on the successful operation of companies that have obtained certificates in accordance with standards from the ISO 9000 and ISO 9001 series. However, very rarely, if ever, is the reader informed about organizations with accredited testing and calibration laboratories, in spite of the fact that these organisations are competitive with different services in their domain of activity in accordance with the European standard EN 45001 and the ISO/IEC 17025 standard⁴. The value of the accreditations according to these two standards is equal to the value of the ISO 9000 certificates. The quality of the system involving standards, internal company rules

and metrology and the assessment of the conformity of products depends also on the quality of some basic elements of the country's infrastructure, since the rules, standardization, and metrology for the assessment of the conformity of products and services according to standards are base elements of the infrastructural quality of the country.

The differences in principles and the level of development of the quality of the infrastructure between different countries set up barriers and limited the growth rate of trade on the European and world markets. It is, for this reason, of primary importance that the level of development of the infrastructure, especially in less-developed countries, becomes very fast relative to those in countries that are potential markets for products.

Testing and calibration are base elements for the assessment of conformity and are applied widely for a large range of products and their results are a reliable basis for the inspection and certification of products. In building up the EU market, it was necessary to develop conditions for the acceptance of goods produced in one country to be accepted in other countries without retesting. It was, therefore, necessary to define requirements which can be fulfilled in every certified European laboratory for testing and calibration and make the results of the testing and calibration acceptable in all the countries of the EU². The approach is based on the European standard EN 45001. On the other hand, the countries' governments have a responsibility towards consumers in terms of health, safety, the environment and legal regulations. This requires that all of the testing is carried out in accredited laboratories.

The rules in the standards of the EN 45000 series have been satisfactory for Europe; however, accredited bodies have come to the conclusion that trade is a worldwide process and many countries cannot accept the EU's standards. This was one of the reasons for the development of the new ISO/IEC 17025 standard. This standard includes previous requirements defined in the EN 45001 standard, but also others, which have to be accepted by the testing and calibration laboratories, if these laboratories want their services to be accepted internationally.

It is the policy of the EU to remove trade barriers; one of the basic conditions for a successful functioning of the common market, "a new approach to technical harmonization and standards" is defined. Part of this policy, related to the conformity of assessment, is the goal to abolish technical trade barriers and establish a mutual confidence in producer competence and in the competence of the body for the assessment of conformity (**Figure 1**).

This confidence should be ensured in obligatory and in non-obligatory areas with harmonized standards, with the application of quality assurance methods, with the testing, inspection and certification of products as well as with the introduction of a modern and independent

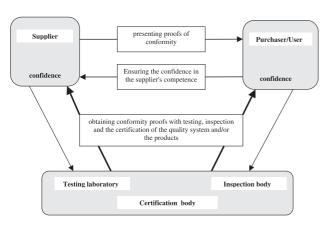


Figure 1: Procedure for ensuring confidence in supplier's competence Slika 1: Procedura za zagotovitev zaupanja v kompetenco dobavitelja

organization for cooperation in testing, certification and accreditation at the European level.

The basic task is to support the establishment of agreements on the mutual recognition of tests in the non-obligatory area.

If accreditation bodies certify and announce that services from bodies they have accredited are based on the same rules and, for this reason, to be trusted and accepted, then all services will be acceptable in all countries that have signed the document of agreement. In this way, it is possible to build up the "pyramid of confidence", an example of which is shown for the EU in **Figure 2**.

Accreditation is, indeed, the basis for establishing the mutual confidence between the conformity-assessment bodies. It ensures the transparency of the activity of accreditation bodies at national and regional levels.

4 ACCREDITED LABORATORIES OF THE METALLURGICAL INSTITUTE

"Kemal Kapetanović", d.o.o., ZENICA

The metallurgical Institute "Kemal Kapetanović", d.o.o., Zenica (formerly "Hasan Brkić") has been active in Bosnia and Herzegovina for almost 45 years, and it is, for this field of activity, the only organization in the country.

Several institute laboratories served initially as a testing and analytical base for scientific investigations; later they also provided services to outside customers, sometimes with a smaller participation in the scientific analysis of the experimental data. During more than 40 years a great deal of experience in laboratory work was gained and many testing methods have been developed, e.g., mechanical testing of different materials (metallic and non-metallic), metallography, chemical, ceramic and mineralogical analysis, calibration methods for force, hardness, torque, temperature and pressure. In the time of war, the market required laboratory services, and priority was given to this activity and to continuous

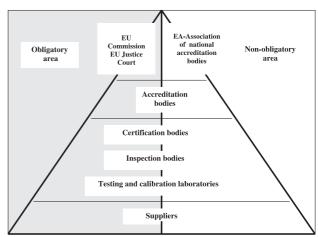


Figure 2: Example of the pyramid of confidence for the EU **Slika 2:** Primer piramide zaupanja za EU

efforts to work in accordance with European and international standards.

In accordance with the available recourses, it was decided to further improve the quality system. This began with the laboratories and inspection bodies, and to ensure an efficient and transparent operation at all levels of the institute, taking care that the interest of the customers is considered.

The laboratories were the first accredited laboratories in Bosnia and Herzegovina in 1998. The accreditation was carried out by the National Department for Standardization, Metrology and Patents BiH (now the Institute for Accreditation BiH) in accordance with the EN 45001 standard. Later, the laboratories were reaccredited according to the ISO/IEC 17025 standard, and the institute has the following accreditations:

- LK 02-01 (calibration scope: calibration of equipment for force, torque and hardness);
- LI 02-02 (testing scope: mechanical testing of metallic materials);
- LI 02-03 (testing scope: metallographic testing of metallic materials);
- LI 02-04 (testing scope: chemical analysis of metallic materials and petroleum products, physical and mechanical testing of construction materials, including refractories);
- LK 02-05 (calibration scope: calibration of measuring instruments for temperature and pressure).

5 CONCLUSION

From the experience of countries in transition, it is known that a very important part of the agreement for all the candidate countries for inclusion in the EU is the chapter related to the free exchange of products. This requires the conforming of the technical legislature, the reciprocal recognition of results of assessment of conformity and the establishment of mechanisms for the

removal of trade barriers. For this reason, the competence of laboratories for testing materials and products is very important, since it determines which test results will be the basis for the assessment of the conformity of products to standards. The mutual confidence in the competence is the condition for the acceptance of the global principle: "once tested and once certificated", based on accreditations that are themselves based on multi-national agreements of recognition of the equality of results of national conformity assessments.

The Metallurgical Institute "Kemal Kapetanović" Zenica has the possibility to perform, together with the accredited laboratories, an important role in this area in Bosnia and Herzegovina, having already gained sufficient experience, satisfactory resources and the confidence of customers/users of services resulting from many years of cooperation. In recent years, the laboratories were certified by the Croatian Register of

Shipping and Metallurgical Institute "Kemal Kapetanović" Zenica has got opportunity to be in the list of approval service suppliers in the important areas for conformity assessment.

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