SLOVENSKA AKREDITACIJA

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GUIDE TO CORRECT USE OF ACCREDITATION IN REGULATORY TEXTS AND COOPERATION WITH SLOVENIAN ACCREDITATION

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1 INTRODUCTION

Slovenian Accreditation (hereinafter called "SA", website http://www.slo-akreditacija.si) is the national accreditation body responsible for establishing, developing and maintaining a professional, independent and impartial accreditation system in Slovenia, and for performing the related assignments.

SA was established by the Republic of Slovenia on the basis of the Accreditation Act (RS OG No. 59/99) and the Decision on the establishment of Slovenian Accreditation (RS OG, Nos. 36/00, 23/01, 121/04, 22/08). It operates as a public institute, which by authorisation of the state, as the only independent and non-profit institution performs the assignments of a public service in the regulated and non-regulated areas.

The basic activity of SA is accreditation of conformity assessment bodies (CABs). The accreditation system in Slovenia is in line with the requirements of the Regulation (EC) No 765/2008 on accreditation and market surveillance. SA is organised and performs in line with the standard SIST EN ISO/IEC 17011:2004, and it complies with the rules of the international associations for accreditation (EA, ILAC and IAF). This enables it to implement the accreditation system in Slovenia in a transparent, credible and internationally comparable way.

SA is also involved in accreditation activities at the international level. It concludes MLA/MRA agreements; therefore, the documents it issues are also internationally recognised. SA participates in European and international associations for accreditation and represents in them the interests of the Republic of Slovenia.

2 WHAT IS ACCREDITATION?

Accreditation means the attestation of competence of a conformity assessment body, and it is the last level of public control in the European conformity assessment system. Accreditation is designed to ensure and attest that conformity assessment bodies (e.g. laboratories, inspection and certification bodies or verifiers) are competent to perform their duties adequately.

Accreditation thus reinforces the mutual recognition of products, processes, services, systems, persons and bodies at the international level and across the EU. It is based on a peer evaluation system that ensures the proper functioning of accreditation across the EU. The relevant rules are set out in Regulation (EC) No 765/2008.

3 WHO BENEFITS FROM ACCREDITATION?

Accreditation affects many areas of public interest such as health and safety, environment, competitiveness of industry, and other. It contributes to safety in the market, thus building up the users' confidence in the European market, which is of key importance for proper functioning of the market. Accreditation is used as a tool for recognizing technical competence in different areas, such as environmental management systems, environmental management and audit systems (EMAS), and food safety management systems.

Accurate calibration, inspection, certification and testing performed in accordance with best practice, can provide the essential competitive advantage for a company, and also contribute to limiting errors, lowering production costs and creating an innovative environment. Accreditation can also be an important tool in decision making, risk management and selecting suppliers. It can ensure competitive advantage in domestic markets through access to public sector contracts, as well as in foreign markets through higher acceptability in export markets.

For the regulator, accreditation is the priority mechanism to determine the competence of the relevant bodies implementing governmental policy and regulations in fields such as: protection of health, environment, consumers' interests, and safety of products and services. It can be the key tool in support of legislation. In notification procedure for conformity assessment bodies within the framework of the New Approach Directives, accreditation enables all notified bodies to operate in compliance with the requirements.

For consumers, accreditation means contribution to reliability, quality and safety of products and services.

4 ACCREDITATION AND LEGISLATION

Cooperation between ministries as the regulators and the national accreditation body is particularly important when legislation including requirements for certain services to be provided by accredited conformity assessment bodies only is in preparation. In this case accreditation represents the pre-condition for performance of specific tasks.

According to Article 4 of the Technical Requirements for Products and Conformity Assessment Act (ZTZPUS-1, RS OG No. 17/2011) and Article 2 of Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products:

"Accreditation shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity".

Thus accreditation attests the competence of conformity assessment bodies. It represents an official and independent statement of their technical competence. It is used as a mechanism to ensure public trust in relation with activities which primarily affect health, safety or the environment.

Accreditation system operates according to binding rules that are equal for all. Among the EU Member States it contributes to the enhancement of mutual trust in the competence of conformity assessment bodies, and consequently, in the test reports and certificates issued by these bodies.

Accreditation infrastructure provides the "passport to international trade", thus encouraging the competitiveness of the national economy.

4.1 Why and how to use accreditation in drafting regulations

Originally, accreditation was meant to be a voluntary step of companies who used accreditation upon their own initiative with the aim of enhancing customers' trust in their proficiency, and as a competitive advantage.

Today, accreditation is above all a tool that enables government agencies to create efficient systems of regulation and verification, and to avoid unnecessary limitations on the economy.

Regulators can decide for accreditation to be mandatory in certain sectors, in order to prove, recognize and monitor the competence of conformity assessment bodies for a longer period of time. Accreditation provides the infrastructure for verifying competence, so that ministries and other administrative authorities need not set up their own systems. This reduces their need for additional recruitment or outsourcing of professional staff.

When a regulator plans to impose mandatory accreditation on a certain field, it is recommended to contact SA before the inter-ministerial coordination of the text of the legal act takes place. In this way it will be possible, at the preliminary level, to align the needs of the legislative draftsman with the capabilities of accreditation procedure. When a state authority wishes to use accreditation as infrastructure for verifying the competence of conformity assessment bodies, it may also address its questions to the Ministry of Economic Development and Technology, Internal Market Directorate, Supply and Commodity Reserves Sector, which is responsible for the operation of SA, and has experience in providing support to the ministries.

On the other hand, SA shall, prior to starting the procedure of assessing certain conformity assessment body, become familiar with the legislation actually in force, also by contacting the regulator or the authority responsible for conformity assessment bodies, when necessary.

This communication between the regulator and SA is also helpful for SA to be informed in a timely manner of changes in the legislation concerning the object of assessment procedure of a certain conformity assessment body.

The necessary specific requirements concerning the sector in question may be provided in the legislative text; however, most of the requirements for competence of CABs are already defined in international standards that support accreditation (http://www.mgrt.gov.si/si/zakonodaja_in_dokumenti/notranji_trg/seznami_harmoniziranih_standardov/ under indent Uredba 765/2008). With regard to the needs of the regulator SA will identify the most appropriate standard for accreditation.

When the basic analysis of needs for implementation of the provided legislation has been done, a consultation is recommended also with all other interested parties (CABs, industry, chamber of commerce, representatives of consumer organisations …), in order to verify the analysis of the effect of the proposed measure of introducing accreditation.

In identifying the needs and expectations the regulator may use the following questions.

Why is conformity assessment by accredited bodies necessary at all? How and how much an accredited body can contribute in terms of assuring safety, reducing risk, increasing certainty and, last but not least, reducing costs and time, as compared to a system where conformity assessment is performed by non-accredited bodies or the state itself?

What is the object of testing, inspection, certification or verification? Does conformity assessment involve products, services, persons, production processes, or maybe a combination thereof?

In what way should accredited bodies perform conformity assessment? Should tests be carried out by a testing laboratory, should inspection body give expert opinions, or is this a combination of several ways of conformity assessment?

Who is already capable of performing the proposed activities? Which conformity assessment bodies may already hold accreditation for the field in question? Have they also been accredited in other fields?

How much do such activities cost? Does the financial burden justify the introduction of accredited conformity assessment, and what will be the financial impact on conformity assessment bodies and economic entities?

4.2 Parameters to be considered when enforcing accreditation requirement through legislation

Costs of accreditation

The costs of obtaining accreditation are fully borne by the conformity assessment body. They are laid down in the Rules on Price Formation for the Services Provided by Slovenian Accreditation (http://www.slo-akreditacija.si/media/s10.pdf). In addition to this, indirect costs related to any purchase of additional equipment, employment or education should be taken into account. It should be kept in mind that the costs incurred by accreditation will eventually be borne by the users of CAB's services, indirectly through higher rates.

According to Article 4 (9) of Regulation 765/2008, each Member State shall ensure that its national accreditation body has the appropriate financial and personnel resources for the proper performance of its tasks. Any regulator intending to lay down accreditation in a new field, or changes of requirements concerning accreditation, shall first check the availability of resources with SA.

SA formulates the costs of its services in accordance with its public mission, i.e., without creating profit, therefore it does not have any own funds for developing new activities. Introduction of accreditation into fields in which it has not yet been used requires, among other, selecting and training new assessors.

Timeframe for implementing legislation

It must be taken into consideration when introducing mandatory accreditation that a certain transitional period should be provided by law for SA to be able to set up all the necessary mechanisms and CABs to adapt to new requirements. The transitional period shall depend on the complexity of the new field and on the number of CABs applying for accreditation procedure. In most cases this would mean at least a two-year transitional period.

Conformity assessment bodies will also need certain time to adapt their internal procedures to new requirements. Practice shows that in most cases at least one year will be needed from the moment of filing application for accreditation till obtaining it.

For more complex fields, the transitional period can be even longer.

Monitoring of scopes of accreditation and the consequences of not meeting the requirements for accredited bodies

SA publishes the scopes of accreditation for all accredited bodies on its website (http://www.slo-akreditacija.si/katalog/).

Any additional information on changes in scopes of accreditation will be specially defined by SA and the relevant ministry.

It is the responsibility of the relevant ministry to take proper action in case of change in scope of accreditation (e.g. cancel or extend authorization).

5 LEGEND OF ABBREVIATIONS

CAB – conformity assessment body (laboratories, inspection bodies and certification bodies)

EA – European co-operation for Accreditation

ILAC – International Laboratory Accreditation Cooperation

IAF – International Accreditation Forum

EC – European Commission

MLA/MRA – Multilateral Arrangement/Mutual Recognition Agreement, which can only be signed by an accreditation body after it has proved, through a peer evaluation procedure, to meet all the requirements applicable to accreditation bodies.

6 CONTROL OF THE DOCUMENT

The original document is available on SA's portal. A valid copy is published on SA's website. Other electronic copies and printouts shall have informative nature and shall not be considered as controlled copies.

This document is accessible to all SA employees on the portal, and to others on SA's website and at the SA Head Office.

7 REFERENCE DOCUMENTS

More information at:

http://www.slo-akreditacija.si/

http://www.european-accreditation.org/

https://www.ilac.org/

http://www.iaf.nu

http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/new-legislative-framework/index_en.htm

http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/accreditation/index_en.htm

Sources:

- General guidelines for the cooperation between EA and EC, EFTA and the competent national authorities (OJ EU, 2009/C 116/04),
- Guide to correct use of accreditation in regulatory text (Ministry of Economy, Finance and Industry, French Republic)
- How does using an Accredited Laboratory benefit Government and Regulators? (ILAC)
- Accreditation Body Communication with National Regulators, Best Practice Guide, EA-INF/07:2011

This Guide has been drawn up by the Ministry of Economic Development and Technology in collaboration with Slovenian Accreditation.