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MANAGEMENT OF IMPARTIALITY - A KEY REQUEST OF NEW VERSION OF INTERNATIONAL STANDARDS FOR CERTIFICATION AND INSPECTION OF PRODUCTS AND SERVICES

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Abstract:
This paper presents analysis of the requests of new versions of international standards for certification and Inspection of products and services. Considering all standard modifications and primarily the new request for Management of Impartiality, it is obvious that complete documentation re-engineering of Certification and Inspection Body is necessary. The procedure for Management of Impartiality is presented, as well as the request for appropriate records.

Key words:
accreditation,
standards,
certification,
inspection,
management of impartiality.

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INTRODUCTION

Conformity assessment involves testing, inspection and certification of products, processes and services. The basic task of conformity assessment is creating confidence with all stakeholders that the product/process/service fulfills the established/prescribed requirements. Conformity assessment is performed by Accreditation Body.

Accreditation is an official acknowledgment by which the National Accreditation Body confirms that an organization fulfills the established requirements, stating that it is competent to perform the tasks of conformity assessment.

The criteria for acquiring and maintaining accreditation by the Accreditation Body of the Republic of Serbia (ATS) [1] have been established in the following documents:

- Law on Accreditation (Official Gazette RS No. 73/2010);
- Serbian standards, i.e. European and international standards, and the instructions containing general criteria, i.e. requirements to be fulfilled by applicants applying for specific kinds of accreditations;
- The documents with compulsory application, such as guidelines for implementing European and international standards and instructions in the field of conformity assessment, issued by the international accreditation bodies (EA, IAF i ILAC);
- ATS Rules of Accreditation.

The organizations performing conformity assessments should fulfill requirements and be accredited in compliance with the following Serbian, i.e. with taken over European and international standards:

- Certification of products is made by Certification Bodies which meet requirements of the standard *SRPS ISO/IEC 17065:2013 Conformity assessment – Requirements for bodies certifying products, processes and services* [2].
- Inspecting of products is done by Inspection Bodies meeting the requirements of standard *SRPS ISO/IEC 17020:2012 Conformity assessment – Requirements for operation of various types of bodies performing inspection* [3].
- Testing of products is performed by Testing Laboratories which meet the requirements of standard *SRPS ISO/IEC 17025:2006 – General requirements for the competence of testing and calibration laboratories* [7].

New versions of standards for certification and inspection bodies have appeared relatively recently, and ATS has just started accreditation in compliance with the requirements of recent standards versions.

The paper provides a general review of accreditation as an effective and efficient means for provision of competence, impartiality, independence and integrity of conformity assessing organizations, which creates confidence of all interested parties into the results of testing, inspection and certification of products processes and services [4]. New requirements are presented brought about by the new standards of *SRPS ISO/IEC 17065:2013* and *SRPS ISO/IEC 17020:2012*, as well as the differences with respect to previous versions of the standards. Special emphasis has been given to the new standard for Management of Impartiality. A proposal for adequate procedure is given, as well as requirements for the accompanying records with the VINČA Institute's Certification Body.

SIGNIFICANCE OF ASSESSING CONFORMITY OF PRODUCTS AND SERVICES

Development of the accreditation process has been accelerated by establishing of the European Union's single market and by development of the general approach to inspection through a "third party", in which all conformity assessment proceedings are conducted by competent organizations which are independent from both the manufacturer and buyer [5].

Implementation of international standards, as the accreditation proceedings brought into accord, provides similar levels of competence of conformity assessing bodies in all states and obtaining comparable results, thus contributing, within different international and regional agreements, to the possibility of creating mutual recognition of conformity documents – i.e. reports and certificates.

Certification of products or services is the way to acquire safety, i.e. to obtain a guarantee that a product/service is in conformity with the established standards or other normative documents.

In the field of mandatory certification, state authorities apply laws which cover approvals of products and services regarding safety, health, environment protection, preventing fraud or forbidden market behavior. In the domain of voluntary certification, many industrial branches have, both within one economy and globally, established conformity assessment systems and approvals, aimed at accomplishing one minimum technical level, as well as at enabling comparability and providing competition under the same conditions.

Certification of products or services should raise confidence of all stakeholders and provide proof on conformity, so that manufacturers or services providers can market their products/services. The basic purpose of products/services certification is:

- to meet the needs of consumers, clients, i.e. all stakeholders, raising confidence in fulfilling their requirements,
- to enable proofs for suppliers of products/services on conformity for the market, provided by a "third", independent party.

The international standard SRPS ISO/IEC 17065:2013 [2] for certification bodies, specifies requirements the application of which enables management of certification systems through "third parties", in consistent and reliable way, also alleviating acceptance of certification results at national and international levels [4].

The result of the products and services certification process is the report on conformity of products and services to adequate standards or to other normative documents, provided in the form of certificates or conformity signs. According to [2], the client is an organization or person responsible to the certification body to ensure that certification requirements have been fulfilled, including requirements for the product. In addition to this, the standard implies that the client is also the applicant.

Inspection of products is realized by Inspection Bodies which perform conformity assessment for products, processes and services for clients, for their own organizations and/or official administration bodies, so as to provide information to stakeholders in connection with conformity to regulations, standards or specifications. The inspection parameters can cover: quantity, quality, safety, usability and maintenance of continual safety of functioning of facilities or systems in operation.

The international standard SRPS ISO/IEC 17020:2012 [3], for the bodies performing inspection, is based on the experiences of European inspection bodies also covering the activities of testing of materials, products, installations, facilities, processes, work proceedings or services, as well as establishing their conformance with the requirements and, then issuing of reports/certificates on conformance to users and to the state administration supervisory authorities, if so required [4].

Controlling of a product, an installation or facility can cover all the phases of their life, including also the phase of designing. Such an activity usually requires expert estimation in rendering the service, especially in the case of conformity assessment. It is envisaged for this international standard to be used as the support for introducing the conformity assessment procedure, related to modules of various phases of conformity assessment proceedings in the directives based on the EU New and Global Approach.

REQUIREMENTS OF NEW INTERNATIONAL STANDARDS FOR CERTIFICATION AND CONTROL BODIES

The new issue of the international standard for certification bodies for certification of products was published by the Institute for Standardization of Serbia on March 20th, 2013. It is the standard *SRPS ISO/IEC 17065:2013 Conformity assessment - Requirements for bodies certifying products, processes and services*. By this standard, the Instruction 65:1999 (SRPS EN 45011:2004) is withdrawn and replaced. Subsequent to 15.09.2015, all accreditations awarded according to standard SRPS EN 45011:2004 will cease to be valid.

The new issue of the international standard for inspection bodies for products was published by the Institute for Standardization of Serbia on May 23rd, 2012. It is the standard *SRPS ISO/IEC 17020:2012 Conformity assessment - Requirements for the operation of various types of bodies*

performing inspection. By this standard, the standard ISO/IEC 17020:2002 is withdrawn and replaced. Subsequent to 01.03.2015., all accreditations awarded according to SRPS ISO/IEC 17020:2002 will cease to be valid.

Accreditation will be suspended and/or annulled to those accredited certification and inspection bodies which do not manage to conform themselves to the new issue of adequate standard.

With the aim of fulfilling the new standard versions' requirements, in the Certification and Inspection Body of VINČA Institute for Nuclear Sciences, these were first analyzed with respect to previous versions, then changes which should be realized were identified and plan was made for implementation of transition to the new standard issue with performing complete re-engineering of the documentation.

In connection with **products certification**, as compared to Instruction SRPS ISO/IEC Guide 65:1996, i.e. with standard SRPS EN 45011, the following significant changes were made in SRPS ISO/IEC 17065:2013 [1]:

- Restructuring the standard was based on the common structure accepted by ISO (the International Standardization Organization)/CASCO (Council Committee on Conformity Assessment);
- Modifications based on standards ISO/PAS 17001 (Impartiality), ISO/PAS 17002 (Confidentiality), ISO/PAS 17003 (Complaints and Appeals), ISO/PAS 17004 (Disclosure of Information) and ISO/PAS 17005 (Use of Management Systems);
- Introducing functional approach from ISO/IEC 17000 into the item 7 process requirements;
- information on implementing the standard for processes and services into Annex B,
- revision of terms and definitions, item 3;
- improving of impartiality requirements (mechanism),
- consolidation of the system management requirements, item 8;
- inclusion into Annex A of principles for certification bodies for products and their certification activities;
- improvements by taking into consideration of the IAF GD 5 document;
- inclusion of certification scheme references, where certification scheme implies certification system referring to specified products to which the same specified requests are applied, as well as specific rules and procedures, with the general instruction for scheme development given in ISO/IEC 17067.

Certification body is the body for conformity assessment which carries out certification scheme as the third party.

In connection with **products control,** the new version of the standard SRPS ISO/IEC 17020:2012 covers modifications/changes contained in the following requirements [1]:

- identification of risks to impartiality of inspection body and removing impartiality risk or reducing it to the lowest possible extent;
- legal takeover of obligations for information management in the inspection body; informing client in advance on information that will be publicly available;
- adequate insurance or reserves;
- having one or more persons in the role of technical executive;
- documented procedures for selection, training, official authorization and following of inspectors and other staff involved in the inspection activities;
- following of performances of all inspectors and other staff; results of following the work are taken into consideration in planning the trainings,
- informing clients if the method proposed by the client is not adequate;
- internal traceability of inspection reports/certificates to the inspectors who performed the inspection;
- mandatory elements presented in the inspection report/certificate; conformity statement is the mandatory element only when applicable;
- the process with complaints and applications (the prescribed minimum process elements and methods, requirements for reporting on progress and results,
- options A and B for the management system arrangement.

It should be pointed out that new versions of both international standards have got a completely changed structure with respect to previous standard versions. They also contain completely new requirements while the existing requirements were largely revised and appended. Bearing all this in mind, it was determined that it was necessary to perform complete re-engineering of the documentation of the Certification and Inspection Body for the Vinča Institute's products [6]. This primarily refers to developing of a new procedure regarding impartiality and independence, as well as to creating of the new version of Quality Manual.

For the purpose of full implementation of new versions of standards in the Certification and Inspection Bodies for products, changes and improvements must be carried out in the following documents:

- Quality policy statement
- Quality Manual
- Procedure regarding impartiality, independence and confidentiality
- Records in compliance with the procedure regarding impartiality, independence and confidentiality
- All existing procedures, instructions and records have been revised for the purpose of their adjustment to the new/amended standard requirements.

MANAGEMENT OF IMPARTIALITY

The greatest attention in the new standard versions for certification and inspection bodies has been paid to the provision of impartiality, from the point of view of:

- Identification of risks to impartiality.
- Impartiality with respect to other sections of the same legal person and person under the organizational command.
- Impartiality with respect to separate legal persons.
- Precluding the influence of organizations or personnel rendering consulting services.

Impartiality implies the presence of objectivity, i.e. that there is no conflict of interest or that it has been resolved to such extent that it has no adverse effects on the certification/inspection body's activities. The terms that are useful in conveying the element of impartiality are: freedom from favoring, independence, neutrality, fairness, even-handedness, detachment and similar.

Certification body for products has to be responsible for impartiality of its certification activities, and it cannot allow commercial, financial, political, or other pressures to exert compromising effect on impartiality, while the very mechanism for providing impartiality has to be officially documented.

The main purpose of the new documents of: quality manual, procedures, instructions and records, is to identify risks to impartiality of the certification/inspection body and to eliminate or minimize the risk to the least possible extent.

Bearing in mind the entire requirement regarding impartiality, the Certification Body for products (the Vinca Institute Certification Bureau) has defined a special procedure for management of impartiality, which encompasses several activities such as:

A. Mechanisms for safeguarding impartiality
B. Identification of threats/risks to impartiality
C. Aspects of the risk to impartiality
D. Analysis of the risk to impartiality
E. Contract with certification personnel
F. Analysis of quality policy with respect to impartiality

Mechanism for safeguarding impartiality

By setting up the Committee for safeguarding impartiality (KON), the Certification Body for products establishes and maintains the mechanism for safeguarding its impartiality. The Committee for safeguarding impartiality has got the following tasks:

- Assists in creating elements of the Certification Body's quality policy, relating to impartiality.
- Indicates the tendencies which could enable commercial and other reasons to affect the certification process objectivity.
- Opening the issues affecting impartiality and confidence in certification process.

The executive manager of the Certification Body is responsible to:

- present to the Committee for Safeguarding Impartiality the *List of risks related to impartiality* (for the previous and following years), as well as the *Contracts with certification personnel.*
- enable that the Committee for Safeguarding Impartiality provides balanced representation of all stakeholders, without domination of internal or external staff of the Certification Body. The Committee for Safeguarding Impartiality comprises:
  - members of the Certification Body for products and
  - representatives of stakeholders, who can be:
    - certification clients,
    - users of products/services of the certification clients,
    - manufacturers,
    - suppliers,
    - product users,
    - experts in the field of conformity assessment,
    - representatives of industrial associations,
    - representatives of legislative state bodies and state authorities or non-governmental organizations or consumers.

It is clearly impossible to present all the interests, but the Certification Body has to identify, call and attract significant stakeholders for its field of certification.

The tasks of the Committee for Safeguarding Impartiality are defined through the *Rule Book on Operation of the Committee for Safeguarding Impartiality* which is submitted to all the members. The KON's Rule Book envisages that in case of disrespect of the Rule Book/procedure, the members have got the right to take independent measures and to inform the Accreditation Body of Serbia about that. In that way, the standard's requirement is fulfilled that in case top management of the Certification Body does not adhere to the input elements of mechanism for safeguarding impartiality, then the mechanism itself has to envisage the right for taking independent measures (informing of competent authorities, accreditation bodies, etc.)

The Committee for Safeguarding Impartiality meets at least once a year and keeps *Minutes on Operation of the Committee for Safeguarding Impartiality*, which is considered in the course of annual review according to adequate procedure.

Identification of risk to impartiality

Certification Body has to identify, in the course of its work, the risks to its impartiality. These risks have to include those risks arising from its activities, from its relations or from the relations of its personnel. It should be noted that such relations may not necessarily represent a risk for the Certification Body's impartiality.

The risks to impartiality are identified within the *List of risks related to impartiality* which contains:

- risk description,
- assessment of risk existence/occurrence,
- proposed measures for risks elimination or keeping under control,
- assessment of undertaken measures success.

The *List of risks related to impartiality* is kept for each year. The list for the following year is defined at the end

of current year, while assessment of success of undertaken measures is done at the end of the year.

Members of the Certification Body analyze possible risks and define proposals of necessary measures for their prevention, while the Certification Body executive manager approves the *List of risks related to impartiality.* The *List of risks related to impartiality* is presented at the meeting of the Committee for Safeguarding Impartiality and all aspects of impartiality are considered, where assessment is made of the undertaken measures' success for the previous year and adopted at the end of the meeting.

Aspects of risk to impartiality

In analyzing risk to impartiality, a set of elements has to be covered, such as potential possibilities to favor, dependence, conflict of interest, presence of bias, as well as the issue of whether neutrality, fairness, openness and even-handedness are jeopardized.

The *List of risks related to impartiality* covers the risks based on:

- ownership,
- governance,
- management,
- personnel,
- shared resources,
- finances,
- contracts,
- marketing,
- sales commission.

The stated risks are considered from three aspects, depending on whether they ensue from:

- activities of Certification Body,
- relations established by the Certification Body with associated bodies/persons, where the associated body/person has evident interest regarding bringing of certification decisions or influences the process,
- relations established by the Certification Body personnel.

Certification Body may not:

- be the designer, manufacturer, installer, distributer of certified products, or maintainer of the certified product/process/service.
- offer or render consulting services to its clients.

Analysis of risks to impartiality

The *List of risks related to impartiality* is analyzed within the annual management reviewing, or at the executive management's request**.** The review covers all threats/risks and their elements (estimations) to performing objective product certification process. During the analysis, measures are defined for eliminating or for keeping under control of new risks, as well as possible additional measures, bearing in mind assessment of the implemented measures for the already determined risks.

If a risk to impartiality has been identified, the Certification Body has to be capable of showing how such a risk will be removed or reduced to minimum possible extent.

Contract with personnel

Certification Body has to request from the personnel involved in the certification process to sign contracts or other document, by which they undertake the obligations:

- to get adjusted to the rules defined by the Certification Body, including those related to confidentiality and freedom from commercial and other interests;
- to report any previous and/or existing connections, both one's own or those of one's employer with:
  - product supplier or designer, or
  - the one rendering or developing services,
  - those carrying out or developing processes for evaluation or certification to which they have been appointed,
- to reveal each situation known to them which can represent conflict of interest for them or for the Certification Body.

The *Contract with Certification Personnel* is a document which is filled in each year by all associates – personnel of the Certification Bureau. By this Contract, the personnel:

- undertakes the obligation to become adjusted to the rules defined by Certification Bureau, including those related to confidentiality and freedom from commercial and other interests,
- state/report their previous and /or existing connection which can affect independence.

The person participating in the certification process may not be involved in design, manufacture, supply, installation, buying, ownership, use or maintenance of the products being certified.

Quality manager of the Certification Body is responsible for filing the *Contract with Certification Personnel.*

The personnel of the Certification Body for products are responsible for the correctness of data in their *Contract with Certification Personnel.* The filled in *Contracts with Certification Personnel* are verified by the manager of the laboratory for the corresponding field, and approved by the executive manager.

In case that changes occur in the personnel status in the course of the year, with respect to the data stated in the *Contract with Certification Personnel*, the personnel is obligated to report the changes to the Quality Manager and to sign a new Contract.

Analysis of the *Contract with Certification Personnel* is done by the Executive Manager in cooperation with the Certification Body members. If it is determined that conflict of interest exists, decision is brought on partial or full exclusion of that person from the product certification process, which is recorded in the Contract. All *Contracts with Certification Personnel* are presented to the Committee on Safeguarding Impartiality, within the impartiality analysis.

Quality policy analysis with respect to impartiality

The Certification Body for products has to have its top management devoted to impartiality. It states its dedication to impartiality through the quality policy as well, which is reviewed within the annual management review. If it is determined that it is necessary to point out some new aspects related to impartiality and independence, proposal is given for the quality policy change/appending.

CONCLUSION

Assessment of accredited certified and inspection bodies by the Accreditation Body of Serbia, in the sense of making transition/adjustment/conformity to new versions of standards for the certification and inspection bodies for products and services, is to be conducted during regular surveillance assessments or reassessments, and at the latest until the end of 2015.

In accordance with the ATS recommendation regarding transition to new standards versions, the Inspection Body and Certification Body for products of the Vinča Institute first of all made detailed analysis of the standard's requirements, then identified the changes to be realized, made the implementation plan for transition to new standard issue, and made complete re-engineering of the accompanying documentation of the Certification and Inspection Bodies for products. The design documentation has been fully changed of both Certification and Inspection Bodies in the VINCA Institute for Nuclear Sciences, involving the following: Quality Manual, generating of a new procedure for safeguarding impartiality and independence, and of accompanying records, as well as adjusting existing procedures, instructions and records to the changed/appended standard's requirements.

Re-accreditation of the Inspection Body for products according to the new standard requirements was successfully performed at the beginning of this year, by the Accreditation Body of Serbia's assessment team. The design documentation conforming to the new standard requirements for re-accreditation of the Certification Body for products is in the final phase of its forming and submitting to the ATS, for the purpose of conducting the assessment process in the course of this year.

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MENADŽMENT NEPRISTRANOŠĆU - KLJUČNI ZAHTEV NOVIH VERZIJA MEĐUNARODNIH STANDARDA ZA SERTIFIKACIJU I KONTROLISANJE PROIZVODA I USLUGA

Abstract:
U radu je prikazana analiza zahteva novih verzija standarda koji se odnose na sertifikaciju i kontrolisanje proizvoda i usluga. Imajući u vidu sve izmene, a pre svega novi zahtev koji se odnosi na menadžent nepristrasnošću, utvrđeno je da je neophodno sprovesti kompletan reinžinjering prateće dokumentacije sertifikacionog i kontrolnog tela. Dat je predlog procedure za menadžment nepristrasnošću, kao i zahtevi za prateće zapise.

Key words:
akreditacija,
standardi,
sertifikacija,
kontrolisanje,
menadžment nepristrasnošću.