



**SLOVENSKA  
AKREDITACIJA**

# *Accreditation brings added value. Are you convinced?*

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# Accreditation

***Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks***

Key words: **competence**  
**specific tasks**

*(item 3.1 standard ISO/IEC 17011:2004 –  
'Conformity assessment – General requirements for  
accreditation bodies accrediting conformity assessment bodies)*

# Quality

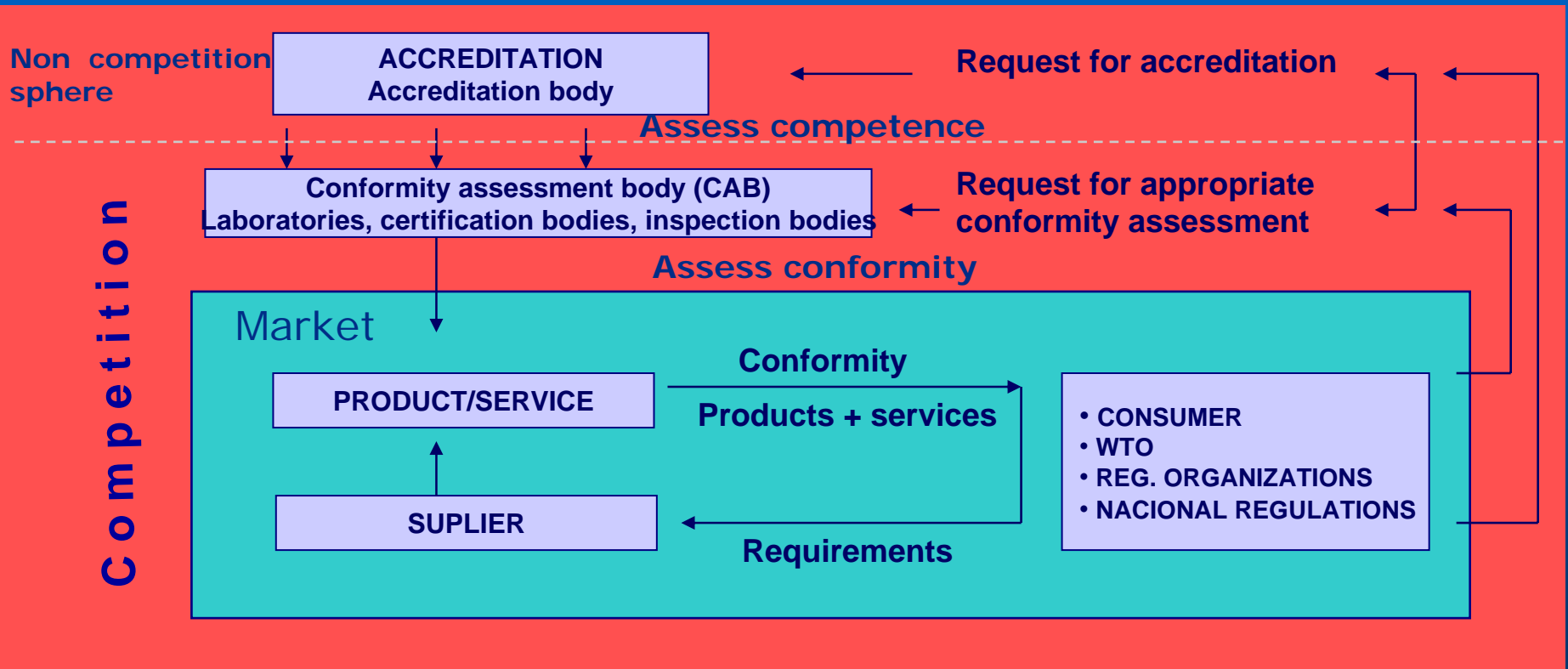
*Quality is a “ degree to which a set of inherent characteristics fulfils requirements”.*

ISO 9000:2000

customer – producer (**Commercial quality**)  
citizens – authorities (**Quality of governance**)  
organizations – their environment (**Organizational quality**)

Quality describes the relationship between expectations and outcomes.

# Overall Quality Picture



# *Accreditation model assures:*

- Harmonized approach
- Conformance with international agreed criteria
- International acceptance (MRA/MLA)
- Independent decision-making

and as a basic purpose:

**IDENTIFICATION OF TECHNICAL  
COMPETENCES**

# ***Accreditation – the essence:***

## **Objectivity:**

Accreditation body supplies value on basis of their authority and place in the quality chain

## **Security:**

Accreditation gives guarantee that work is done according to known and published rules

## **Quality:**

Accreditation promotes quality

# *Requirements for laboratory competence*

*(ISO/IEC 17025)*

## **Management requirements**

- Control of documents
- Suited premises
- Complaint handling
- Control improvement
- Corrective action
- Internal audits
- Management reviews
- Legal identity
- Impartiality
- Confidentiality
- Subcontracting

## **Technical requirements**

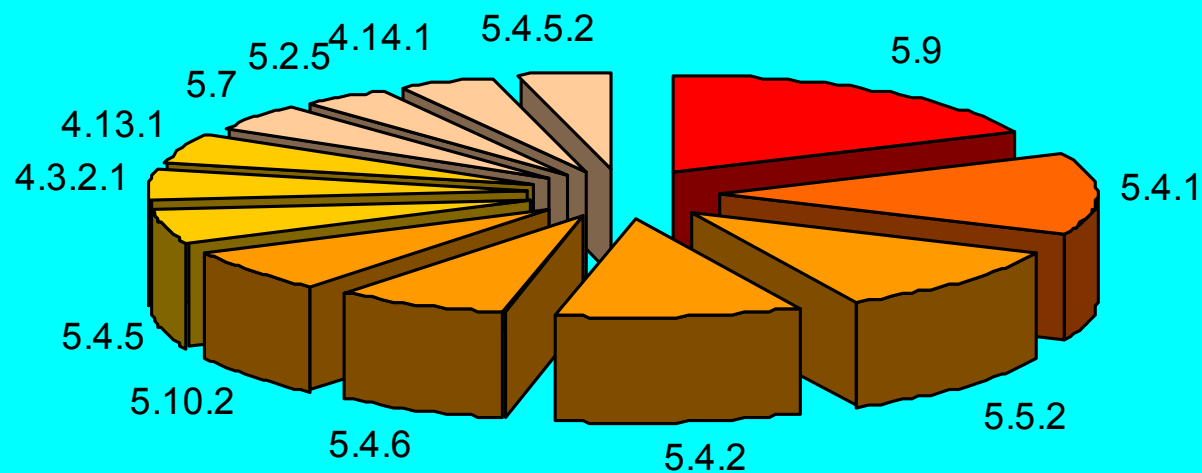
- Suited equipment and location
- Competent staff
- Traceability/calibration RMs & PTs
- Comprehensive reports
- Estimation of uncertainty
- Data verification

## **Management system**

The laboratories have to establish a QMS in order to facilitate the compliance with the requirements.

# Findings - testing labs (SA)

Testing laboratories



# *Critical issues for laboratory competence*

## ***Technical requirements***

- Use of PTs and RMs
- Appropriate methods and procedures
- Equipment
- Selection of methods
- Measurement uncertainty
- Test reports and calibration certificates
- Validation of methods
- Sampling
- Competence of personnel

## ***Management requirements***

- Control of documents
- Control of records
- Internal audits
- Management reviews

# *Main criticism of accreditation*

- Too much focus on bureaucratic details
- Process often takes too long
- Over-regulation by multitude of guidance documents which add requirements to the standards
- Added costs but not appropriate corresponding benefit

**Is this true?**

# *Added value of accreditation*

- Improve quality system and technical competence of CABs
- Reduction of trade barriers – “one stop” testing, inspecting, certifying
- Third party recognition competence
- Government requirements and acceptance
- Improve quality of products and services

# *EU legislation*

## *“GOODS PACKAGE”, Revision of New Approach*

### Regulation

Requirements for accreditation and market surveillance relating to the marketing of products

### Regulation

Procedures relating to the application of certain national rules to products lawfully marketed in another Member State and repealing Decisions 3052/95/EC

### Decision

Common framework for the marketing of products

# *Key issues of the EU Regulation on Accreditation*

## Basic principles:

- Public authority activity
- 1 national accreditation body (NAB) per member State
- Prevention of competition between NABs and between NABs and accredited CABs
- Set of requirements for NABs
- Peer evaluation
- Cooperation between national accreditation bodies → EA (European co-operation for accreditation)
- Rules applicable to mandatory & voluntary area

# *Regulation on Accreditation*

## Main changes

### a) **Strengthening of the requirements for notified bodies**

In practice accreditation is precondition for notification

### b) **Cross border accreditation**

CAB may ask foreign AB only in one of the following situations: no AB, AB not cover technical field, no MLA signatory

### c) **Greater involvement of all interested parties** in work of EA

### d) **Harmonization of ABs outcome** (strengthen peer evaluation, EA committee for harmonization)

# Conclusion

*Accreditation shall be as much as possible “output focussed”, namely at assuring the **quality** of the final output of the conformity assessment chain.*