



HSbooster.eu
TRAINING ACADEMY

Conformity Assessment Schemes & Systems

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Biljana Tošić

University of Belgrade,
Faculty of organizational sciences



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QUALITY INFRASTRUCTURE (QI)

The members of the International Network on Quality Infrastructure (INetQI) have recently agreed upon the definition of **Quality Infrastructure (QI)** as "the system comprising the organisations (public and private), together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services, and processes".

QI relies on:

- › metrology,
- › standardisation,
- › accreditation,
- › conformity assessment, and
- › market surveillance.

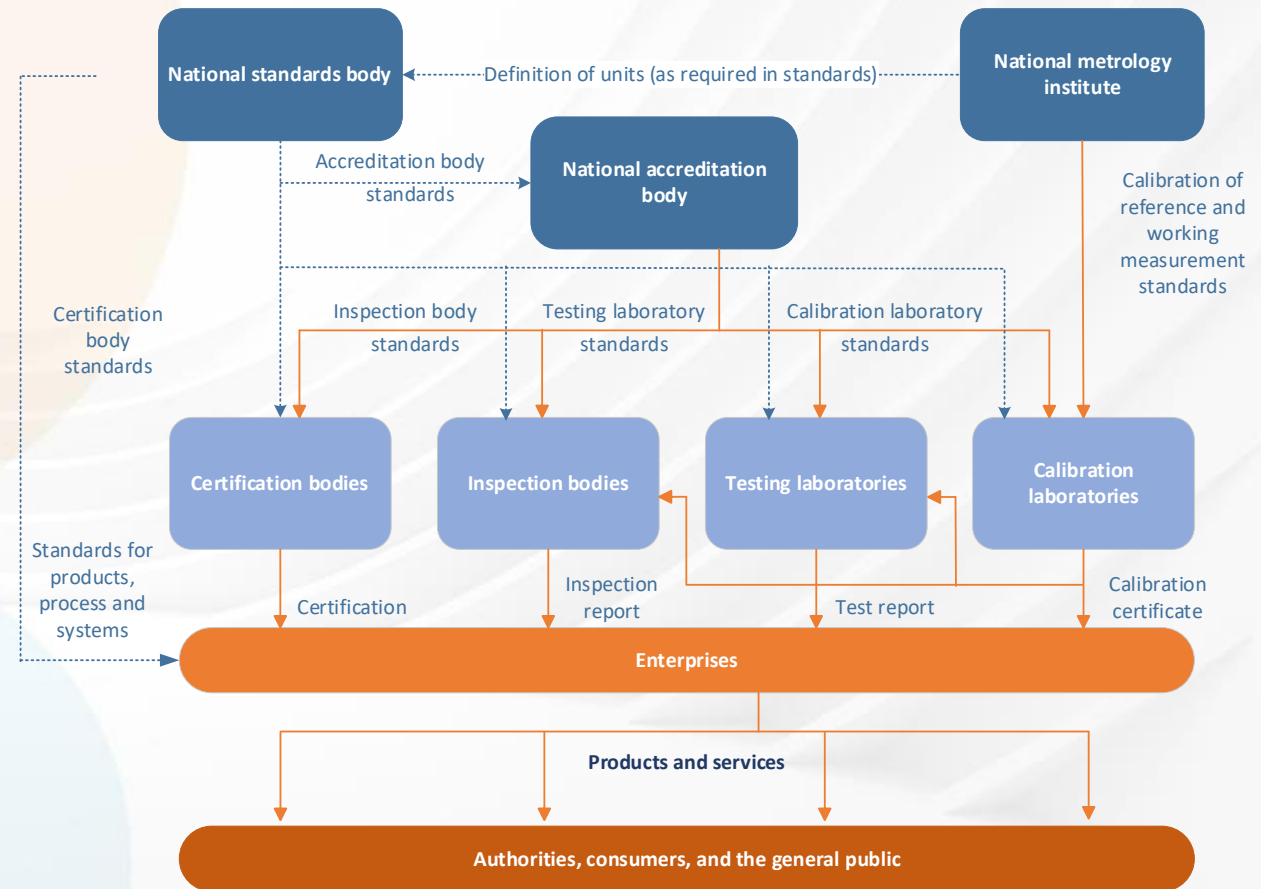


International Network on
Quality Infrastructure

- › Over the years, many countries have established national policies to develop efficient and effective QI.

QUALITY INFRASTRUCTURE (QI)

- › **National Quality Infrastructure (NQI)** is a system which consists of three core components without which its other parts cannot operate optimally:
 - › metrology,
 - › standardisation, and
 - › accreditation, and
- services based on these components consist of
 - › calibration,
 - › testing,
 - › inspection, and
 - › certification
- (collectively called conformity assessment), that are also enhanced by market surveillance.



CONFORMITY ASSESSMENT (CA)

According to **ISO 17000:2020, Conformity Assessment: Vocabulary and General Principles**, **conformity assessment** is defined as "a demonstration that specified requirements are fulfilled".

Accordingly, conformity assessment can also have a negative outcome, thereby demonstrating that the specified requirements are not fulfilled.

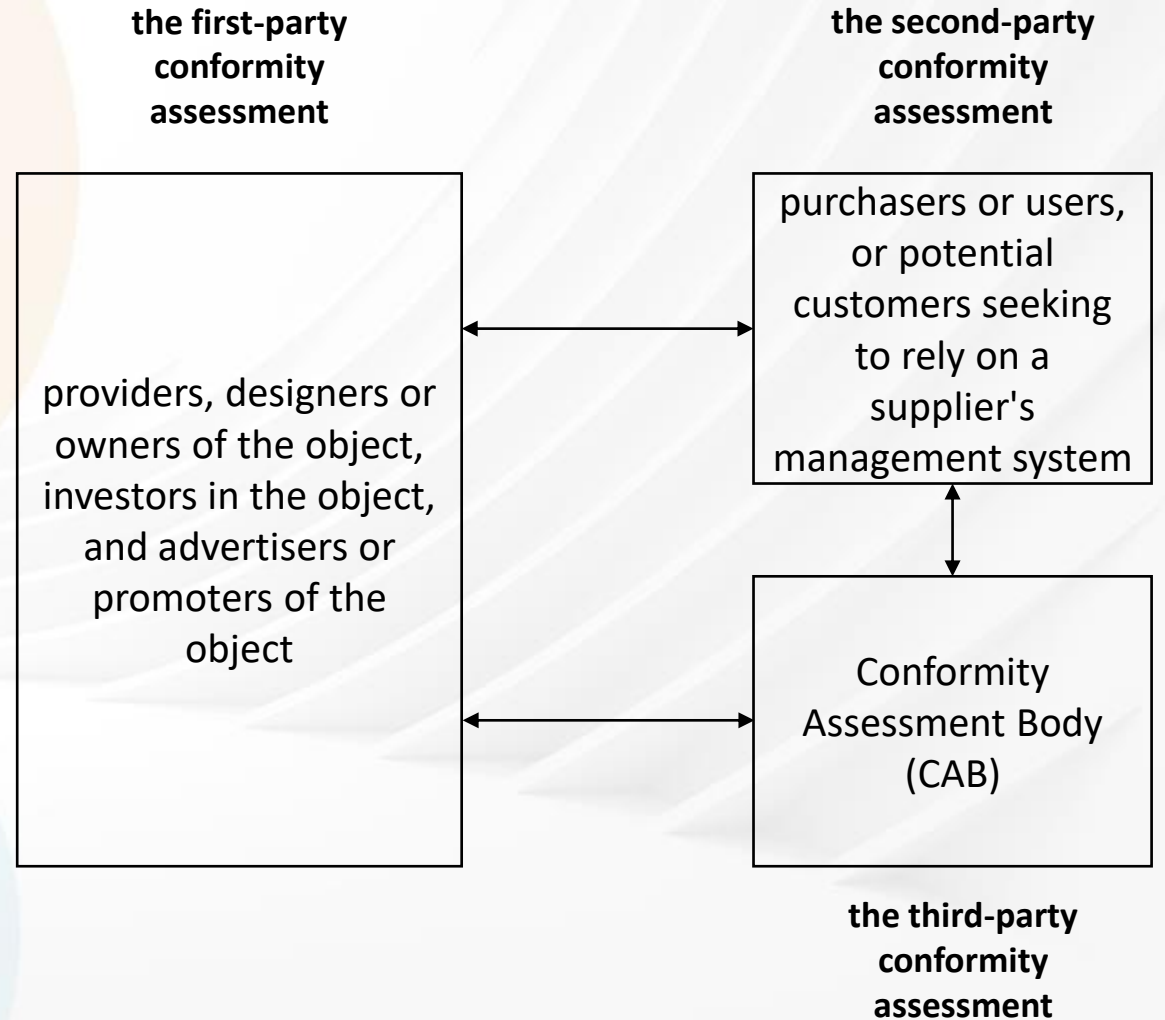
These specified requirements may be detailed or general and may be stated in normative documents, such as regulations, standards, and technical specifications.

Accordingly, **the object of conformity assessment** is defined as "an entity to which these specified requirements apply (e.g., product, process, service, system, installation, project, data, design, material, claim, person, body or organisation, or any combination thereof)".

CONFORMITY ASSESSMENT (CA)

Additionally,

- › **the first-party conformity assessment activity** is performed by the person or organisation that provides the object of conformity assessment or that is the object of conformity assessment,
- › **the second-party conformity assessment activity** is performed by a person or organisation that has a user interest in the object of conformity assessment
- › **the third-party conformity assessment activity** is performed by a person or organisation that is independent of the provider of the object of conformity assessment and has no user interest in the object of conformity assessment.



CONFORMITY ASSESSMENT SCHEMES AND SYSTEMS 01/02

While each conformity assessment activity should be treated differently, there are several proven advantages of using a systemic approach and the concepts of conformity assessment schemes and systems.

According to **ISO 17000:2020, Conformity Assessment: Vocabulary and General Principles** –

- › **a conformity assessment scheme** (which is sometimes referred to as a conformity assessment programme) is defined as "a set of rules and procedures that describes the objects of conformity assessment, identifies the specified requirements and provides the methodology for performing conformity assessment" whereas
- › **a conformity assessment system** is defined as "a set of rules and procedures for the management of similar or related conformity assessment schemes".

Although rules and procedures may need to be detailed in different ways for different schemes, there are several proven advantages (in terms of efficiency and consistency) to working within a common framework.

CONFORMITY ASSESSMENT SCHEMES AND SYSTEMS 02/02

Several types of conformity assessment schemes currently exist:

- › certification schemes,
- › testing schemes,
- › inspection schemes,
- › verification schemes,
- › validation schemes,
- › accreditation schemes, etc.

Schemes can be set up for:

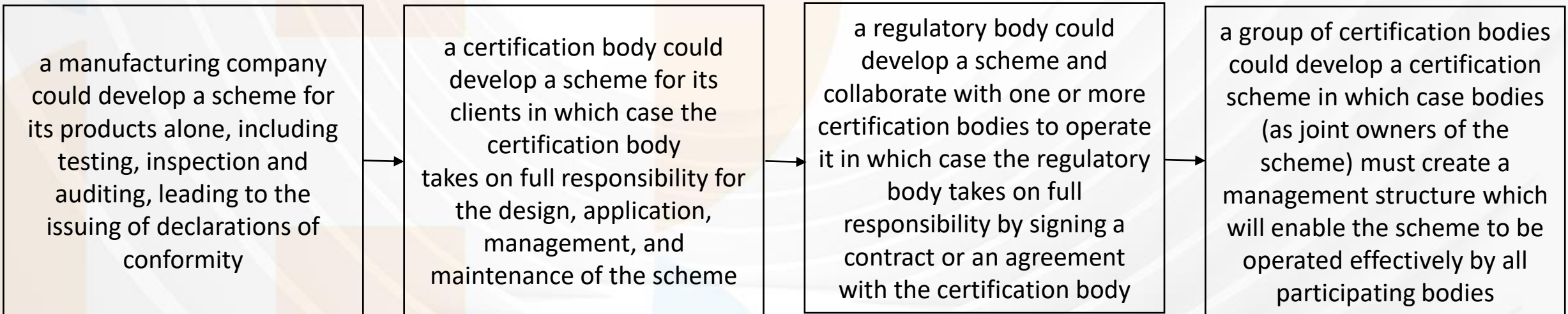
- › voluntary (self-regulation) or commercial (marketing) purposes or
- › regulatory purposes (to ensure compliance with legal requirements).

Conformity assessment schemes can be developed by:

- › professional and industry associations,
- › purchasers,
- › regulators,
- › non-governmental groups,
- › Conformity Assessment Bodies (CABs),
- › National Standardisation Bodies (NSBs), etc.

WHAT IS A SCHEME OWNER?

Each conformity assessment scheme has an owner which means that:

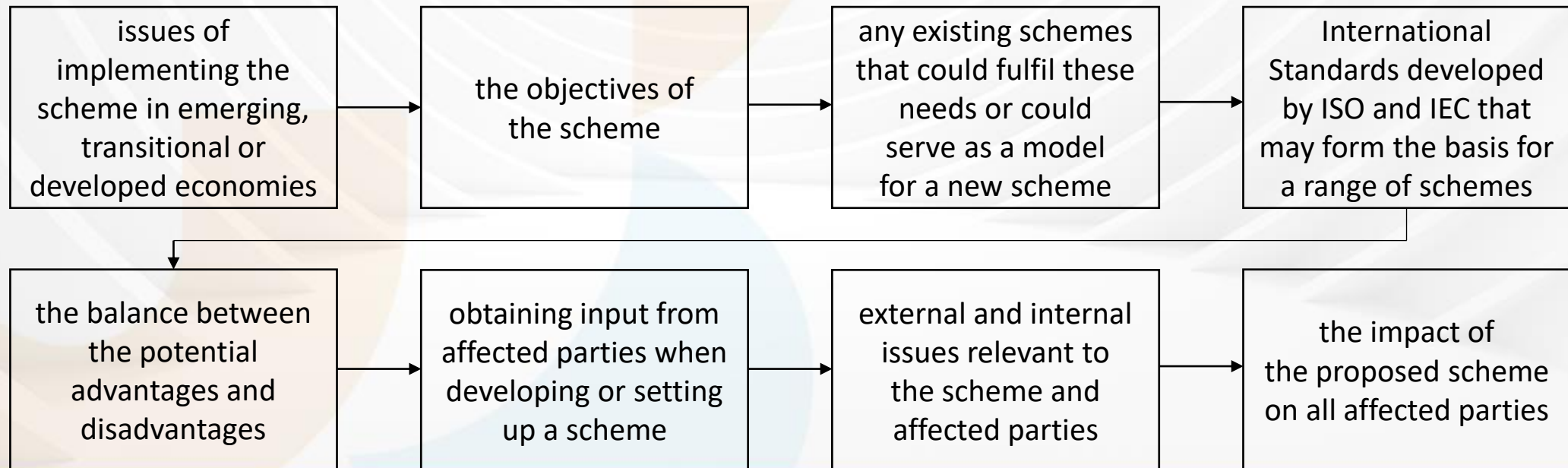


- › If several schemes are using the same rules and procedures, the scheme owner(s) should set up a system under which all the schemes will effectively operate.
- › In this case, the scheme owner will become the system owner and will become responsible for the management of the whole system (and the schemes operating within it).

THE NEED FOR A SCHEME

A key step when setting up a conformity assessment scheme is determining the need(s) for such a scheme (and conformity assessment in accordance with such a scheme). This means addressing different demands and/or requirements to demonstrate that an object of conformity assessment fulfils specified requirements.

If the need exists, several additional issues must be considered:



THE SCHEME DESIGN BASED ON THE RISK OF NON-CONFORMITY

- › **A key decision when setting up a conformity assessment scheme is deciding who should carry out the conformity assessment.**
- › This decision should be based on **the risk assessment** and the analysis of not only **the likelihood** of non-conformity but also **the consequences** which can arise from the non-conformity of products/services.
- › Sometimes, the consequences could be of a commercial nature (e.g., market reputation and sales volume) and sometimes, the consequences could be hazards to health and safety or damage to the environment.
- › Consequently, the amount of time and money being spent must be balanced against these consequences.
- › As the risks (and related consequences) become higher, conformity assessment activities become more extensive (involving expensive test equipment/procedures), so it may be reasonable to contract out conformity assessment activities to a third party.



CREATING A SCHEME

- › When creating a scheme, scheme developers should consider **ISO/IEC 17007, Conformity Assessment – Guidance for drafting normative documents.**
- › While International Standards are incorporated into many conformity assessment schemes around the world, such schemes cannot replace International Standards.
- › Rather, schemes may list additional requirements, besides those already given in International Standards.

- › Additionally, scheme developers may also find useful the good standardisation practices given in –
 - › the ISO/IEC Directives (which specify the requirements for ISO and IEC normative documents),
 - › the World Trade Organisation’s Agreement on Technical Barriers to Trade (WTO TBT Agreement), Annex 3, Code of Good Practice for the Preparation, Adoption and Application of Standards, and
 - › the ISO/IEC Directives, Part 2, 2004, 6.7, also covers aspects relevant when creating schemes & systems.

PRODUCT CERTIFICATION SCHEMES

- › **Product certification** is the mechanism whereby a certification body attests that products (either a batch or the continuous production thereof) have been inspected and tested by it and that the products collectively comply with specified requirements, usually contained in a standard.
- › The attestation by the certification body is issued in the form of a **certificate** which is supported by a **product certification mark** that the manufacturer is entitled to affix on a product after showing compliance with specified requirements.

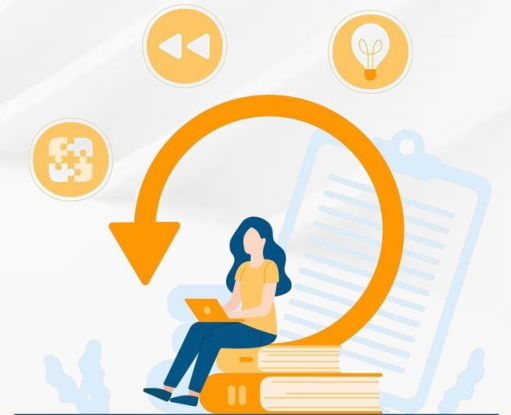


PRODUCT CERTIFICATION SCHEMES

- › **Product certification schemes** are developed by certification bodies in both the public and private sectors, at both national and international levels, offering services in both the regulated and non-regulated domains.
- › Within emerging economies, the NSB is usually the only organisation which offers product certification at the national level, while within more developed economies, product certification is offered by private sector certification bodies (eventually leading to the total withdrawal of the NSB and the state in many instances).
- › **ISO/IEC 17067, Conformity Assessment — Fundamentals of product certification and guidelines for product certification schemes** describes seven types of product certification schemes thereby suggesting that the elements in these seven existing schemes can be combined in other ways to create additional scheme types.

MANAGEMENT SYSTEM CERTIFICATION SCHEMES

- › While product certification is all about the supplier-consumer relationship (as it determines product quality), **management system certification** is all about building confidence in the supplier's ability to continuously provide the products and services that fulfil specified requirements.
- › The attestation by the certification body is issued in the form of a **certificate** which is supported by a **wide range of materials and documents** that the organisation being certified can use for marketing and public relations.



MANAGEMENT SYSTEM CERTIFICATION SCHEMES

- › Compared to product certification which is usually supported with a product certification mark that the manufacturer is entitled to affix on a product after demonstrating compliance with specified requirements – the management system certification **does not actually assess or make any claims about the product quality (per se)**.
- › Rather, the management system certification denotes only **the capability of the supplier to continuously provide products and services complying with contractual obligations** which is why the management system certification emblem **should not be affixed to the product – because it does not denote product compliance**.



PERSON CERTIFICATION SCHEMES

- › **Person certification schemes** set out "the competence and other requirements related to specific occupational or skilled categories of persons".
- › People who fulfil these requirements might end up being recognised as Certified Auditors, Certified Welders, and Certified IT Security Specialists.
- › **ISO/IEC 17024, Conformity assessment, General requirements for bodies operating certification of persons** contains principles and requirements for a body certifying persons against specific requirements and includes the development and maintenance of a certification scheme for persons.
- › **ISO/IEC TS 17027, Conformity assessment — Vocabulary related to competence of persons used for certification of persons** specifies terms and definitions related to the competence of persons used in the field of certification of persons, in order to establish a common vocabulary.

CERTIFICATION SCHEME SELECTION

Several questions must be considered when choosing the type of certification scheme:

- › should it be a product certification scheme or a management system certification scheme?
- › if the choice is a product certification scheme, is one already developed by a certification body or would a national one be more appropriate to serve the purpose in the short and long terms?
- › is a more general certification scheme required or would a sector-specific scheme be more appropriate?
- › if the choice is a general management system certification scheme, would it be focusing on quality, the environment, information security, food security, energy efficiency, etc., or their combination?
- › if the choice is a sector-specific scheme, would it be focusing on automotive parts or medical devices?
- › is the cost of developing a certification scheme worthwhile (compared to the potential benefits)?

CERTIFICATION SCHEME SELECTION

Several questions must be considered when choosing the certification body:

- › is the certification body accredited for a standard to which certification is required?
- › is the accreditation body (by which the certification body is accredited) a signatory to a multilateral recognition agreement (MRA) covering the scope you are interested in, such as those operated by the IAF for public standards or (in the case of private standards), the relevant multinational one?
- › does the accreditation of the certification body cover the scope of the certification scheme?

Another criterion is whether the certification body is recognised in the marketplace, e.g., Does it have a list of well-known names among its certified clients and is this list of clients publicly available on the website? A recognised certification body will not object to providing evidence and feedback from its certified clients.

THANKS!

biljana.tosic@fon.bg.ac.rs

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