ILNAS

TECHNICAL STANDARDIZATION

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CONFORMITY ASSESSMENT: OVERVIEW

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ANEC

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ILNAS
Institut Luxembourgeois de la Normalisation, de l'Accréditation, de la Sécurité et qualité des produits et services

ANEC
Agence pour la Normalisation et l'Economie de la Connaissance

Foreword

The "Institut Luxembourgeois de la Normalisation, de l'Accréditation, de la Sécurité et qualité des produits et services" (ILNAS), has developed the "Stratégie normative luxembourgeoise 2020-2030", signed by the Minister of the Economy, where standardization is presented as a tool of performance and excellence at the service of the economy of Luxembourg.

Among others, the strategy identifies the ISO committee for conformity assessment (ISO/CASCO), which develops policy guidelines and publishes standards on conformity assessment, as being of significant interest to support the national economy. To further develop this point, the "Politique normative nationale "ISO CASCO" 2022-2030" has been defined to foster national involvement in technical standardization activities related to conformity assessment, all in line with market needs. To this end, it aims for the progressive implementation of three lead projects:

- Strengthen national involvement in the ISO/CASCO committee,
- Promote ISO/CASCO developments at the national level,
- Develop the fields of research and education related to ISO/CASCO.

By demonstrating compliance to requirements, conformity assessment – and all underlying activities including standardization – is of special importance for the national economy as it highly contributes to building trust. Hence, it is essential for national stakeholders that this domain is introduced to them, clearly and in depth.

Thus, within this overall framework, this report outlines the conformity assessment process and explains the links with the work of ISO/CASCO and its European counterpart, CEN-CLC/JTC 1 (a CEN/CENELEC Joint Technical Committee). It also introduces the National Standardization Commission 02 (ILNAS/NSC 02) that allows national stakeholders to access information and participate in both the European and international standards development processes related to conformity assessment.

Following in the footsteps of ILNAS' 2022 report on Management System Standards, the current document raises awareness on the importance of technical standardization for the domain of conformity assessment and simultaneously constitutes a basis for the future development of research and education activities related to it.

Convinced of the importance of the whole conformity assessment process as a key element of the economy of trust, ILNAS, with the support of the "Agence pour la Normalisation et l'Economie de la Connaissance" (ANEC GIE), delivers this report with a view towards encouraging the national market's future use of related standards and its involvement in the related standards development process, for the benefit of Luxembourg's economy and its stakeholders.

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Abstract

This report provides an overview of the conformity assessment process, related European legislation, and associated standards. It highlights the importance of conformity assessment for the economy of trust and raises awareness on the technical standards that act as widely recognized good practices for the domain.

Section 1 presents the general context of conformity assessment, summarizing its role in building trust between organizations and their customers. This section also outlines the legal framework that shapes the conformity assessment activities in Europe and explains how these different elements contribute to the economy of trust.

Section 2 dives more deeply in the process of conformity assessment. It details the definitions, describes various activities that fall under the umbrella of conformity assessment, and pays particular attention to accreditation.

Section 3 presents technical standardization. It starts with a general overview of standardization processes, principles, and standards development organizations, then describes the specific rules for the development of standards related to conformity assessment in Europe and internationally, and concludes with concrete examples of standards.

Finally, Section 4 explains to all interested readers how they can access standards and contribute to their development.

Abbreviations

AB	Accreditation Body
CAB	Conformity Assessment Body
CASCO	Committee on Conformity Assessment
CEN	*Comité Européen de Normalisation* (European Committee for Standardization)
CENELEC or CLC	*Comité Européen de Normalisation Électrotechnique* (European Committee for Electrotechnical Standardization)
ETSI	European Telecommunications Standards Institute
EN	European Standard
EU	European Union
EA	European cooperation for Accreditation
IAF	International Accreditation Forum
ILAC	International Laboratory Accreditation Cooperation
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
ITU-T	International Telecommunication Union -Telecommunication Standardization Sector
JTC	Joint Technical Committee
NSC	National Standardization Commission

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1 Introduction to conformity assessment

1 Introduction to conformity assessment

1.1 Context

The acceptance and appropriation of products and services by customers – be it individual consumers or organizations – depends on whether their expectations, such as safety, performance and quality, have been met. Moreover, in some cases, when a producer wants to place goods on national or regional markets, it also needs to respect legal requirements aiming to protect interests such as consumers' security or the environment. To align with both scenarios, a product or service has to fulfill the requirements but also to show its compliance in order to be accepted by stakeholders, and consequently, be sold or used appropriately.

The collection of activities allowing to demonstrate compliance is called conformity assessment. It *"provides the means for checking the conformity of [...] products and services against [...] expectations, in accordance with relevant standards, regulations and other specifications. It helps to ensure that products, processes and services deliver on their promises. In other words, conformity assessment builds trust"* [1]. From this definition, conformity assessment can be understood from a narrow perspective as a set of activities for the evaluation of conformity of products and services with respect to specific requirements. From a broader perspective, conformity assessment can be seen as a complete ecosystem involving different parties such as the producers (manufacturers, service providers, etc.) and their customers, regulators, organizations that shape the requirements (such as standards development organizations), as well as the organizations that evaluate the conformity (conformity assessment bodies) and the organizations that verify if the latter are competent to perform their activities (accreditation bodies). In this sense, the main components of the ecosystem involve technical standardization, conformity assessment and accreditation. This report explores conformity assessment from this broader perspective.

The role of conformity assessment is crucial for the economy. Although its global goal is to increase the customers' trust, conformity assessment also contributes in turn to important objectives [2] [3]:

- to protect public interests such as health and safety, in general and at the workplace, welfare and environment, and guarantee security (for example, by avoiding that harmful products enter the market),
- to support end users/consumers and regulators (for example, through the detection and minimization of unfair trading practices),
- to facilitate national and cross-border trade by reducing technical barriers,
- to ensure compatibility and interoperability of components in products and systems.

1.2 Building trust

To build trust, merely demonstrating the outcomes of conformity assessment activities may not be sufficient. Indeed, how can we ensure that the technical requirements against which the evaluation was performed, reflect the user expectations? Is it certain that the organization carrying out the conformity assessment has the right experience and competencies for these activities? Trust is gained through several principles and key-concepts upon which the ecosystem is built.

1.2.1 Open and transparent

The whole ecosystem is intended to be transparent. Conformity assessment and the associated requirements are based on widely accepted best practices which are proposed by a variety of stakeholders and undergo an open and well-established validation process.

1.2.2 Inclusive and consensus-based

Conformity assessment best practices and requirements are intended to be inclusive of various human needs. A multitude of stakeholders is involved in formulating them, making sure that different possible risks and needs are considered and addressed. Then, they are finalized through a consensus-based validation process. The consensus reached guarantees the harmonization of various possible approaches. The good practices are regularly reviewed in order to preserve their relevance and currentness [3] [4]. Such good practices can be gathered by independent organizations or described in technical standards (see Section 3 for more information on the latter).

1.2.3 Independence and impartiality

The different parties involved in the process of conformity assessment accomplish a specific role with assigned responsibilities. For example, an entity (or part of an entity) that evaluates the conformity of a product cannot be involved in the process of product fabrication (be it in the design, manufacturing or other phase). These entities are completely independent one from each other, which helps to avoid any conflict of interests, ensure the impartiality of results and render their judgement trustworthy [2] [3] [4]. Another example of differentiation of roles and responsibilities in the process of conformity assessment is related to the object of conformity. For instance, the entities that evaluate products do not necessarily have the skill to assess persons, and so on. More information about the types of conformity assessment are found in Section 2.

1.2.4 Reinforcement by legal framework

Furthermore, in Europe the evaluation of conformity of products can be a legal obligation. There exist a number of product-specific directives and regulations that set the requirements for the security and safety of those products entering the European single market. However, in many cases the conformity assessment remains voluntary.

The general European legal framework for conformity assessment is presented in the next section.

1.3 European legal framework

The European legal framework for conformity assessment falls within the new approach to technical harmonization and standards (Council Resolution 85/C 136/01). The new approach aims at introducing essential legal requirements for the products entering the EU market and demanding a proof or a demonstration from the manufacturers that the products fulfill those requirements, through conformity assessment procedures defined in Decision No 768/2008/EC.

Decision No 768/2008/EC introduces the common framework for the marketing of products, that is the *"general obligations for economic operators and a range of conformity assessment procedures"* defining the rules for the CE marking for different categories of products. The conformity assessment procedures described in this Decision are used by [5]:

- Conformity assessment bodies: to perform their activities of conformity assessment,
- Accreditation bodies: to verify the competences of the conformity assessment bodies,
- Manufacturers: to be aware of the necessary legal requirements for their products to enter the market.

Decision No 768/2008/EC also outlines the reference provisions for harmonization legislation for products aiming to separate the essential requirements from technical specifications. These technical specifications are expected to be provided either in the form of standards, the so-called harmonized standards, or technical specifications in the absence of such. Compliance with the harmonized standards then grants a presumption of conformity with the legislation. European harmonized standards may rely on adopted international standards or can be developed directly by recognized European standardization organizations. The manufacturers have a choice of following harmonized standards (or in the absence of these, the established technical specifications) in order to fulfill the legal requirements but are not obliged to do so. More details about the standardization framework are presented in Section 3 of this document [5].

In addition, Regulation (EC) No 765/2008 sets out the requirements for accreditation relating to the marketing of products[1]. Accreditation facilitates the free circulation of products entering the European market thanks to the recognition of the competences of conformity assessment bodies in charge of the verification of security and safety of products. The principles of operation and the requirements for the accreditation bodies are detailed in Section 2.4.

1 It should be mentioned that any conformity assessment body can be granted an accreditation, independently of whether it is required by legislation or not. This is the case of voluntary accreditation, obtained in the spirit of building trust.

2

Conformity assessment concepts

2 Conformity assessment concepts

2.1 Definitions and ecosystem

Having set the context, this section formalizes the definition of conformity assessment.

In a narrow sense, **conformity assessment** can be defined as *"the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled"* [2].

In this one-layer process, only a **conformity assessment body** and the **object** of assessment (that is product, process, service, system, person, or body) are involved. The **conformity assessment bodies (CABs)** are bodies that perform the conformity assessment activities. They undertake different activities depending on what kind of objects they evaluate and what requirements they need to verify. A few examples of CABs are testing laboratories, inspection bodies, medical laboratories, bodies that certify management systems, etc. [1]

An entity that follows the rules and requirements and is being evaluated is called an **object** of assessment. Among the objects of conformity assessment, one can list products, processes, services, systems, installations, projects, data, designs, material, claims, persons, bodies or organizations, or any combination thereof [1] [6].

Conformity assessment requirements and activities can vary depending on the object of evaluation. The main activities are introduced in Section 2.2.1 below, and examples of standards containing the requirements are provided in Section 3.4.

Conformity assessment can also be considered as an ecosystem, as mentioned in Section 1.1. In this ecosystem, in addition to the CABs and the objects of conformity, other entities are involved, such as organizations providing the object of assessment, their clients and customers, regulators as well as the organizations that verify if the conformity assessment bodies are competent to perform their activities or standardization organizations which define the technical requirements. All of these entities contribute to the process to ensure its trustworthiness.

Indeed, in order to guarantee that in the process of conformity assessment various requirements (including public interests, industrial good practices or customer needs) are taken into account, the CAB has to demonstrate its competencies, impartiality and independence with respect to the object of assessment. This is done in the process of **accreditation**, that is *"an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonized standards and, where applicable, any additional requirements including those set out in relevant sectorial schemes, to carry out a specific conformity assessment activity"* [2]. In the European context, accreditation is performed by national **accreditation bodies (ABs)**, entities formally recognized by each member state. In order to assure a proper functioning of the system, the accreditation bodies are signatories of mutual recognition agreements at the European (through **European cooperation for Accreditation (EA)**) and international (through **International Accreditation Forum (IAF)** and **International Laboratory Accreditation Cooperation (ILAC)**) levels.

Figure 1 shows an example of how the different entities defined above interplay in the process of conformity assessment.

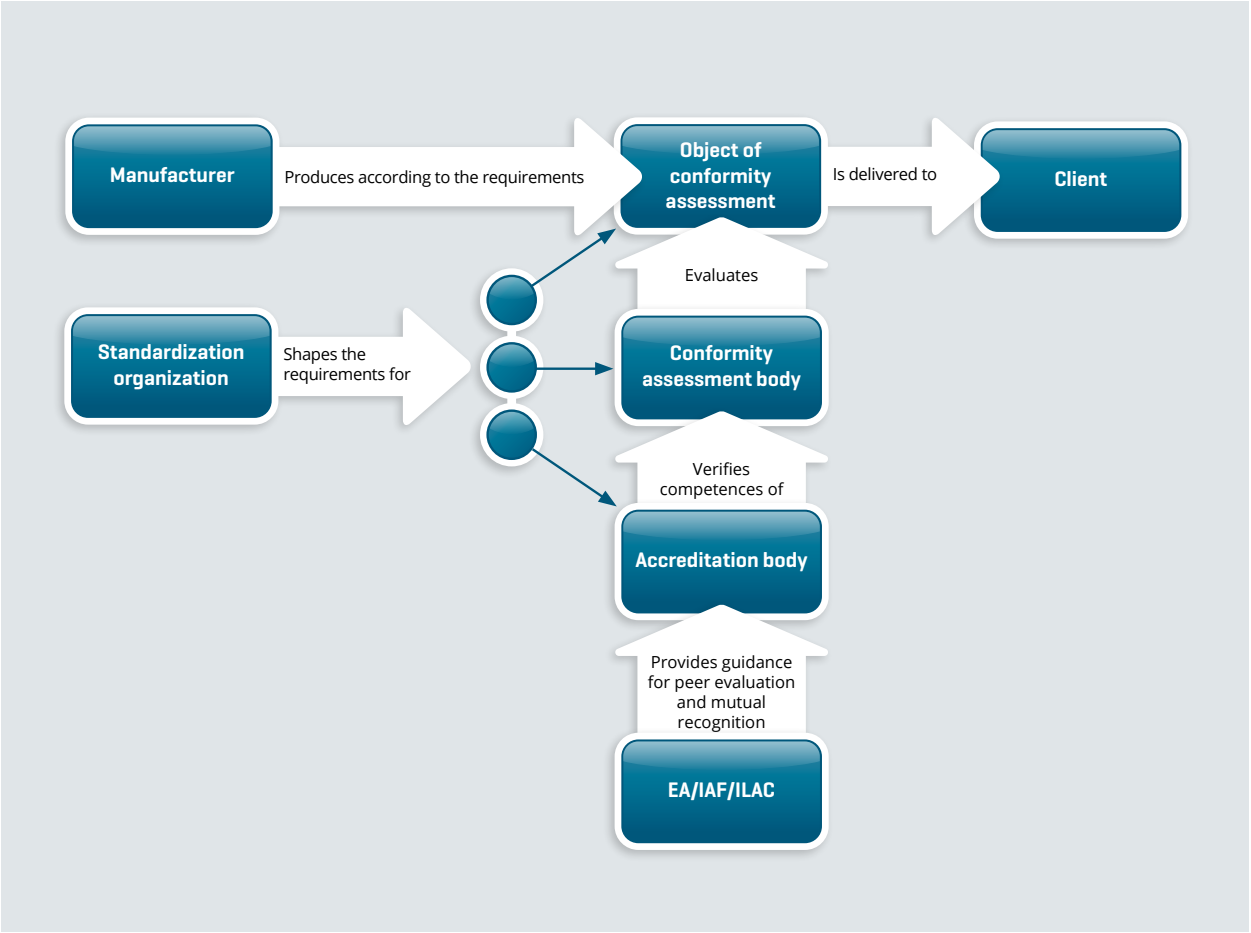

Figure 1: Example of authorities involved in conformity assessment and verification of products circulating on the EU market.

2.2 Conformity assessment activities

Depending on the object of conformity and the required outcome, there exist different conformity assessment activities that are described below.

2.2.1 Types of activities

Testing

Testing is a *"determination of one or more characteristics of an object of conformity assessment, according to a procedure"* [6]. It can be done on elements, materials or products, such as for example water, food, protective clothing, electrical appliances, medical equipment, etc. Testing may provide necessary information to reach the conclusion on whether a product complies with the requirements and thus can be a pre-requisite for product certification. It can also be part of the production controls in the production value chain or concern data collection for scientific purposes, medical prognosis, or law enforcement [7]. Testing is usually performed in a laboratory using specific equipment. To ensure their results are trustworthy, the laboratories can rely on standards specifying test procedures, test methods, equipment calibration, competencies, etc. [1] [8].

Inspection

Inspection is an *"examination of an object of conformity assessment and determination of its conformity with detailed requirements or, on the basis of professional judgement, with general requirements"* [6]. Such an examination can include observation (for example, visual examination of physical items or conditions), information gathering (for example, measurement or testing of physical items), examination of specification documents (for example, design drawings), comparison of findings with generally accepted good practices in the field [1] [7]. Inspection can apply to processes, products (for example, motor vehicles, lifting gears, lifts, electrical installations) and other activities, such as design confirmation. Inspection can be used in commercial supervision by third parties, including both for export and import, in in-house production control by manufacturers or in regulatory controls, mostly for safety purposes but also to ensure quality and enter new markets. Inspection can be a stand-alone activity or be combined with others [7].

Certification audit

A certification audit is an *"audit carried out by an auditing organization independent of the client and the parties that rely on certification"*, typically for the purpose of certifying the client's management system [9]. Certification audits can also apply to processes, products and services. Audit criteria can come from the policies, procedures, standards, and so on. When the audit findings confirm the audit requirements have been met, and the audit was carried out by a third party, a documented statement of conformity, called a certificate, is delivered to the object [6]. Certification can be required for the product to enter the market, for the organization to ensure the quality of its work and gain advantage over competitors, etc. [1] [6] [7].

> **NOTE:** Auditing can be combined with other activities of conformity assessment, as a *"process for obtaining relevant information about an object of conformity assessment and evaluating it objectively to determine the extent to which specified requirements are fulfilled"* [6]. In the audit process, the evidence established from the appropriate information coming from relevant identified sources, is evaluated against audit criteria to identify audit findings, review them and draw a conclusion [1] [6].

Verification and validation

Both verification and validation are used to confirm through the provision of objective evidence that specified requirements have been fulfilled. In the case of validation, it is a *"confirmation of plausibility for a specific intended use or application"* [6]. Thus, the process of evaluation determines whether the assumptions, limitations and methods to support claims about future activities are reasonable. Verification consists in the *"confirmation of truthfulness"* [6]. It is applied to claims based on historical data, regarding events that already took place or results that have already been obtained, to confirm their truthfulness [6] [10].

Peer evaluation

In addition to typical conformity assessment activities, it is worth mentioning peer evaluation, which is an *"assessment of a body against specified requirements by representatives of other bodies in, or candidates for, an agreement group"* [6] and which is currently not being accredited. It implies that a body that successfully accomplishes a peer evaluation can join that same group by which it has been evaluated in order to benefit from mutual recognition of the activities performed by the members of the group [1]. In the European context, peer evaluation is reserved for accreditation bodies, according to the Regulation (EC) No 765/2008, and is used to verify their good functioning and reliability.

2.2.2 Functional approach

Conformity assessment activities fall within the following functions [1] [6]:

- **Selection:** planning and preparation activities to collect or produce the necessary evidence for the subsequent determination function. Selection can involve the specification of standards against which conformity is assessed and/or a representative sample to be verified, where the object cannot be considered in its entirety (for example, in the case of a production line).
- **Determination:** activities necessary to determine whether the object of conformity, or its sample, fulfills the specified requirements. Principle determination activities involve testing, inspection, audit, validation and verification, and/or peer evaluation.
- **Review, decision and attestation:** reviewing is the final stage of checking before taking the decision on whether the object of conformity fulfills the specified requirements or not. Attestation results in a statement of conformity, that is a report communicating in the most accessible way the fact that the fulfillment of requirements has been demonstrated.
- **Surveillance** (if required): when the object of conformity changes over time, regular iteration of the above functions can be required to maintain the validity of conformity statements resulting from attestation.

Figure 2 shows the process of conformity assessment based on the functions involved.

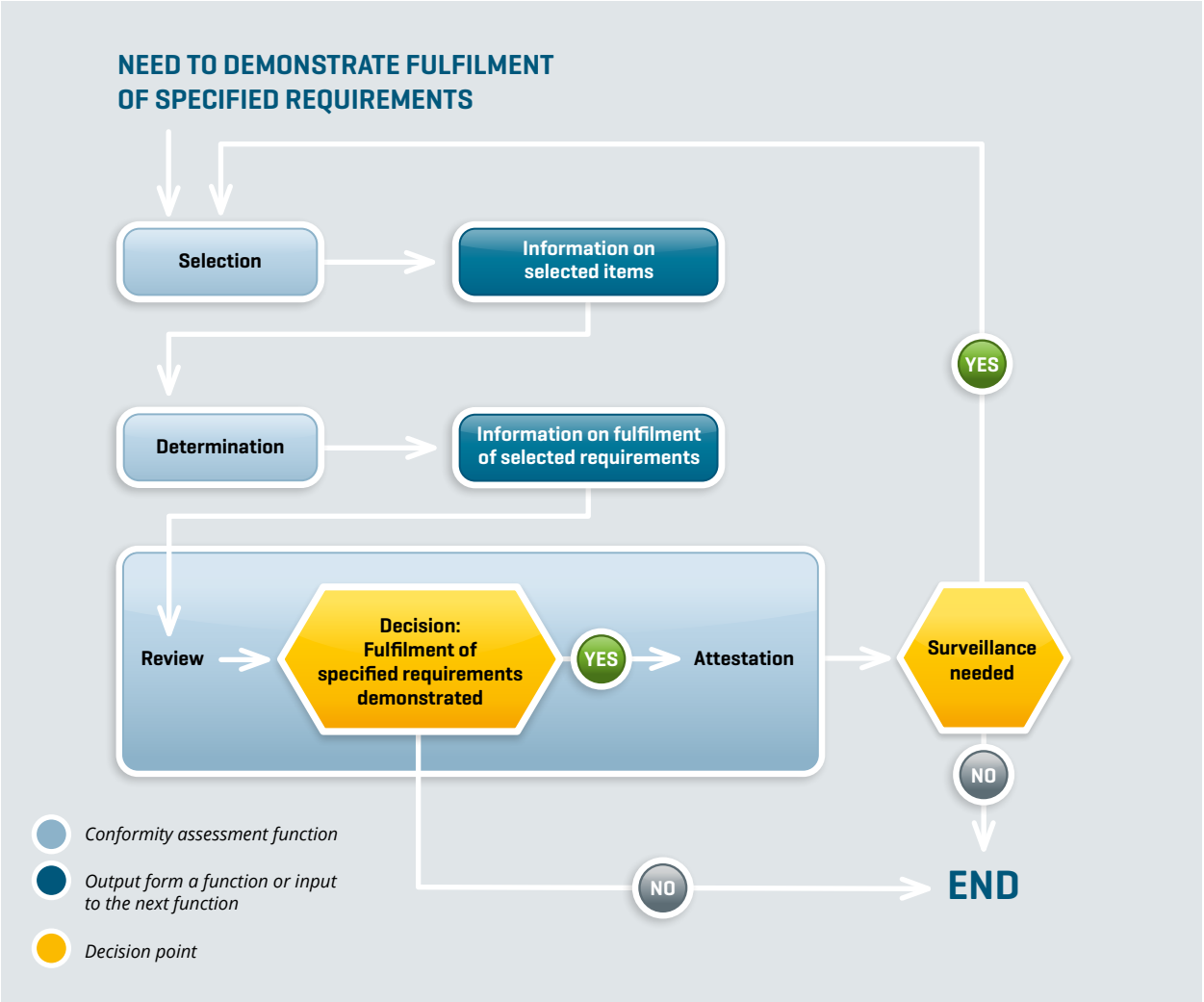

Figure 2: Functional approach to conformity assessment [1] [6]

2.2.3 Conformity assessment scheme

A systematic approach to conformity assessment can be achieved through conformity assessment schemes and systems. More concretely, a conformity assessment scheme is a *"set of rules and procedures that describes the object of conformity assessment, identifies the specified requirements and provides the methodology for performing conformity assessment"* [6]. A conformity assessment system is a way to manage several conformity assessment schemes. A scheme typically relates to a specific group of objects having similar characteristics so that same rules and procedures could be applied to them. There exist product, process, service, and person certification schemes [1].

A certification scheme is elaborated by a so-called scheme owner. It can be a manufacturer that sets up a scheme for its products for a follow-up declaration of conformity, or it can be a regulatory body, a standards body or a trade association that proposes a scheme and invites multiple certification bodies to operate it through a contract or other formal agreement [1].

The scheme is supposed to contain the necessary elements describing, where applicable, sampling process, requirements, rules for the acceptance of the conformity assessment results, outsourcing of conformity assessment activities to ensure impartiality, means to file complaints and appeals, rules for licensing and control of the mark, surveillance practices, ways to deal with non-conforming products and fraudulent certification, reporting rules, rules for the placement of the product on the market and eventually subcontracting of the operation of the scheme [11].

2.3 Who can perform the conformity assessment activities?

Conformity assessment is performed by bodies specialized with respect to the activities defined in Section 2.2.1. Moreover, conformity assessment can be realized at different levels, implying different degrees of independence and impartiality [1] [6]:

- **First-party:** the person or organization that provides or is the object of conformity assessment. For example, if a manufacturer provides a product, it is their primary responsibility to ensure that the product is conform with technical specifications and legal requirements. Thus, they will perform their own assessment first. A successful first-party conformity assessment results in a declaration.
- **Second-party:** a person or organization that is tied with the first party by a professional relation, such as client, customer, supplier, etc. For example, a consumer protection organization can specify its own requirements on a product and be responsible for assuring that the product conforms to them.
- **Third-party:** a person or organization that is not the provider of the object of conformity and has no user or other commercial interest in the object. Due to the absence of ties, a third party is considered an independent evaluator that could provide a reliable and impartial statement of conformity (or nonconformity), called certification[2].

In some cases, first-party assessment could be sufficient. It is, for example, the case (i) where the products are of low risk and complexity or (ii) of new innovative complex products for which the manufacturer is acknowledged to have higher skills and be better equipped to carry out the assessment than external bodies. The latter requires an accredited in-house department, that is independent from those involved in commercial, design and production activities [12]. Nevertheless, a third-party conformity assessment is preferable. Indeed, due to its impartiality and reliability, it inspires more trust from the market. In addition, in some cases when the conformity assessment activities are related to some legal requirements, third-party execution may be compulsory.

2 In this case the certification is the final statement delivered at the end of conformity assessment process, as opposed to the certification audit which refers to the whole activity.

Finally, in case where a third-party assessment is performed by a CAB that was accredited by a member of the IAF or ILAC, the subsequent statement of conformity is recognized and accepted throughout the world [13] and consequently facilitating the international trade between countries.

2.4 Accreditation

Accreditation is an additional step in building trust in products and services that are placed on the market, and the ABs are the highest entity in the chain of confidence. While CABs verify the conformity of goods, services, people and processes against the requirements of standards, specifications and other regulations, accreditation is used to check the competency and impartiality of CABs to do that work properly [1]. In Europe, the accreditation system is defined in Regulation (EC) No 765/2008.

The regulation outlines the general principles for accreditation and specifies the operation mode and the requirements for the ABs. It demands an appointment of a single accreditation body in each member state that operates on a non-for-profit basis and is deemed to exercise public authority. The ABs do not compete with CABs and other ABs, and cross-border accreditation is only allowed in specific cases.

The regulation also defines the European accreditation infrastructure called European co-operation for Accreditation (EA) and the principle of mutual recognition among ABs. When an AB is a member of the EA and is successfully peer evaluated (see Peer evaluation) it becomes a signatory of the EA mutual recognition agreement. Thus, the activities of CABs accredited by this AB are recognized across the EA region. Similarly, there is a mutual recognition among different regions in the world, including the EA region. Through this international recognition, the activities of accredited CABs are recognized across the world.

Accreditation can be voluntary. In this case it is used to get a competitive advantage over other players on the market. But in some cases it is required by legislation. For example, accreditation is mandatory in the frame of Regulation (EU) 2017/745 on Medical devices.

Accreditation Body in Luxembourg

OFFICE LUXEMBOURGEOIS D'ACCREDITATION ET DE SURVEILLANCE

In Luxembourg, the national accreditation body is the ***Office Luxembourgeois d'Accréditation et de Surveillance*** (**OLAS**), established in 2000. Since 2011, OLAS is part of the European and International accreditation network, and as such undergoes peer evaluation based on international standards and additional IAF and ILAC guidance, and benefits from mutual recognition among ABs. In this frame, the CABs accredited by OLAS deliver certificates that are valid across Europe and internationally. The organizations that receive such certificates gain simplified access to the European and international markets.

OLAS conducts the accreditation process and maintains a publicly-available list of accredited national organizations.

3

Standardization for conformity assessment

3 Standardization for conformity assessment

3.1 Standardization ecosystem

Conformity assessment activities are based on good practices and specified requirements. Such good practices and requirements can be found in standards. The European Regulation (EU) 1025/2012, recently amended by the Regulation (EU) 2022/2480, defines a standard as being a *"technical specification, adopted by a recognized standardization body, for repeated or continuous application, with which compliance is not compulsory"*.

Six main standards development organizations are officially recognized by the European Commission:

- European organizations:
  - European Committee for Standardization (CEN),
  - European Committee for Electrotechnical Standardization (CENELEC),
  - European Telecommunications Standards Institute (ETSI).
- International organizations:
  - International Organization for Standardization (ISO),
  - International Electrotechnical Commission (IEC),
  - International Telecommunication Union Telecommunication Standardization Sector (ITU-T).

At national level, one or several national standards bodies protect the interests of the country within each of the European and international standardization organizations (for example, in Germany, on the one hand DIN is the member of ISO and CEN, and on the other hand DKE is member of IEC, CENELEC and ETSI). In Luxembourg, ILNAS – the only national standards body – is a member of the European and international standardization organizations CEN, CENELEC, ETSI, ISO, IEC and ITU-T. Figure 3 shows the interactions between various standards development organizations at national, European and international levels.

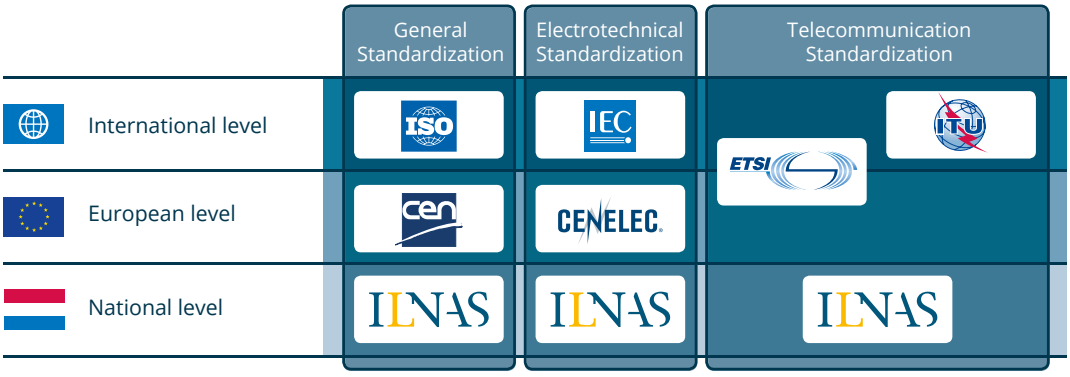

Figure 3: Interactions between the standards development organizations [14]

Several bridges exist between the national, European and international standardization organizations in order to facilitate the collaboration and coordination of standardization work in the different fields.

Why are standards helpful in general, and for conformity assessment in particular? Standards can be considered as recognized good practices, namely because in the process of writing standards the following principles are respected [15]:

- **Transparency**: any interested party can have access to all essential information regarding current work programs, as well as on proposals for standards, guides and recommendations under consideration and on the results.
- **Openness**: membership of an international/European standards body should be open on a non-discriminatory basis to relevant bodies.
- **Impartiality and Consensus**: all relevant bodies should be provided with the opportunities to contribute to the elaboration of an international/European standard so that the standard development process will not give privilege to, or favor the interests of, a particular supplier, country or region. Consensus procedures should be established that seek to take into account the views of all parties concerned and to reconcile any conflicting arguments.
- **Effectiveness and Relevance**: international/European standards need to be relevant and to effectively respond to regulatory and market needs, as well as scientific and technological developments in various countries.
- **Coherence**: in order to avoid the development of conflicting international/European standards, it is important that international/European standards bodies avoid duplication of, or overlap with, the work of other international/European standards bodies.

In some cases, such as for example with ISO 9001, the use of standards is voluntary by organizations to demonstrate their good functioning and gain customers' trust. In other cases, the use of standards falls within a legal framework. The standards can be either explicitly referenced in the legislation, or referred to as a possible means to achieve compliance, providing a presumption of conformity. The latter is the case of the harmonized standards. Harmonized standards are European standards developed upon a request issued by the European Commission to support the market with the application of Union harmonization legislation. Once developed, verified by an independent expert committee and published in the Official Journal of the European Union, harmonized standards can be used to demonstrate compliance with the legislation for which they were requested. If an organization is compliant with recognized harmonized standards, it is compliant with the legislation.

Standards development is carried out by technical committees, sub-committees and working groups within each standardization organization. Individual experts contribute to the standards working drafts, that are then reviewed by the committee members where the standard is elaborated to go through public enquiry, and publication. Figure 4 presents a simplified view of a standard's editing process.

Figure 4: Simplified view of the standards editing process

In the frame of conformity assessment, the main reference committees are ISO/CASCO, *Committee on conformity assessment* and CEN/CLC/JTC 1, *Criteria for conformity assessment bodies*, at international and European levels, respectively. More information about these committees and their standards are provided in Section 3.5.

European standard adoption and legal support

In Europe, standards which support legislation have to be issued or adopted by a recognized European standardization organization (CEN, CENELEC or ETSI). In the context of adoption of an international as a European standard, the prefix **EN** is placed in front of the standard reference (for example, EN ISO 21789:2022) and a foreword is given at the beginning of the document, providing the adoption conditions (with or without modification). Also, according to CEN-CENELEC internal regulations, all member countries have to transpose European standards at national level. Consequently, the reference of the above-mentioned standard becomes ILNAS-EN ISO 21789:2022 in Luxembourg, and the document receives the status of national standard.

3.2 ISO and CEN directives related to conformity assessment

In order to harmonize and support the activities related to the evaluation of conformity, international and European organizations put in place rules to be followed by their committees and working groups when developing standards. These rules can be summarized as follows [16] [17]:

- A neutrality principle shall be respected when drafting requirements for products, processes, services, persons, systems and bodies, so that they can be assessed and applied by first, second and third parties.
- The standards shall contain only the requirements necessary to provide repeatable and reproducible conformity assessment results.
- Any additional conformity assessment requirements can be specified in a separate document, so that they can be applied independently. ISO/CASCO or IEC Standardization Management Board, or both shall approve the development of such additional documents. In case of purely European deliverables, CEN/CLC/JTC 1 shall be consulted instead.
- The development of documents providing general requirements for conformity assessment schemes and systems is the responsibility of ISO/CASCO in liaison with IEC Conformity Assessment Board. For European purposes, such documents are developed by CEN/CLC/JTC 1, based on international documents as far as possible.
- Committees can develop documents relating to conformity assessment systems or schemes (for example, sector-specific schemes or procedures) but those shall (i) be in line with the conformity assessment policies and rules approved by ISO/CASCO and IEC Conformity Assessment Board and (ii) make normative reference to the relevant published ISO/IEC documents for conformity assessment procedures (such as ISO/IEC 17000 or ISO/IEC 17025), or CEN/CLC/JTC 1 documents for purely European developments.

These rules imply that general requirements for accreditation and conformity assessment are provided by ISO/CASCO, while sector-specific or object-specific requirements are developed by sectorial committees and/or working groups.

3.3 Classification of conformity assessment standards

Conformity assessment system, as defined by EA, distinguishes between five different levels depicted in Figure 5.

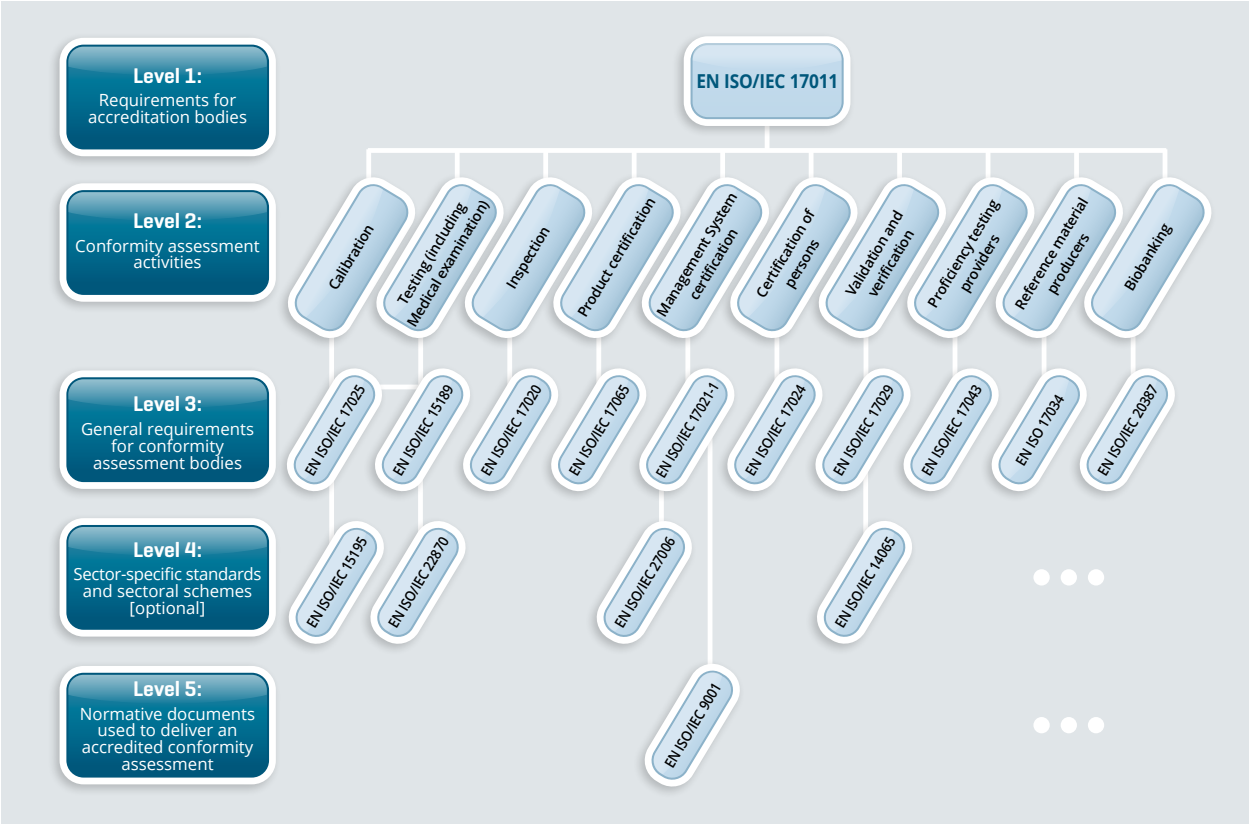

Figure 5: Conformity Assessment system: Classification of evaluation methods in level structure [18] [19]

Level 1: defines the requirements for the ABs. These are laid down in the standard ISO/IEC 17011:2017 *Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies*, and its European adoption EN ISO/IEC 17011:2017 and IAF and EA guidelines. Based on these requirements the ABs carry out peer evaluation to recognize each other's competencies. To perform peer evaluation, the ABs can use EN ISO/IEC 17040:2005 *Conformity assessment – General requirements for peer assessment of conformity assessment bodies and accreditation bodies* [18] [19].

Level 2: defines the activities of conformity assessment. In order to perform these activities and provide the attestation of conformity that is recognized internationally, the CABs need to go through accreditation and demonstrate their competences [18] [19].

Level 3: defines the requirements for the CABs, depending on the object of conformity and the activities they need to carry out. The requirements can be found in dedicated standards [18] [19]. A few examples of such standards are:

- EN ISO/IEC 17021-1:2015 — *Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements*
- EN ISO/IEC 17025:2017 — *General requirements for the competence of testing and calibration laboratories*
- EN ISO/IEC 17065:2012 — *Conformity assessment – Requirements for bodies certifying products, processes and services*

Level 4: defines sector-specific requirements that complement level 3 general requirements as well as sectoral conformity assessment schemes based on guidance from, for example, EN ISO/IEC 17067:2013 *Conformity assessment – Fundamentals of product certification and guidelines for product certification schemes* [18] [19]. The requirements from this level do not apply to all sectors, thus the requirements from level 5 can directly exploit the requirements from level 5.

Level 5: defines requirements for the object of conformity assessment (products, processes, services, persons, organizations, etc.). In some cases, for some sectors and requirements introduced in recognized harmonized standards, the compliance with these standards means compliance with the legislation [18] [19]. Some examples of the standards containing level 5 requirements are:

- EN ISO 9001:2015 *Quality management systems – Requirements*
- EN ISO 13485:2016 *Medical devices – Quality management systems – Requirements for regulatory purposes*

3.4 Standards for the object of conformity assessment

As explained in Section 2, the chain of conformity assessment starts with the requirements for the object of conformity that can be introduced in standards or other relevant documents. There exist standards for all kinds of products, services, processes, etc. This section provides a few examples for different categories of objects of conformity.

Management System Standards

- EN ISO 9001:2015 *Quality management systems – Requirements*
- EN ISO 14001:2015 *Environmental management systems – Requirements with guidance for use*
- EN ISO 45001:2023 *Occupational health and safety management systems – Requirements with guidance for use*

Products standards

- EN 71 family of standards *Safety of toys*
- EN 50121 family of standards *Railway applications – Electromagnetic compatibility*
- EN 1130 family of standards *Furniture – Cribs and cradles for domestic use*
- EN ISO 9994:2019 *Lighters – Safety specification*

Installation

- EN 81-70:2021 *Safety rules for the construction and installation of lifts – Particular applications for passenger and goods passenger lift*
- EN 50085 family of standards *Cable trunking systems and cable ducting systems for electrical installations*
- EN 17879:2023 *Fairground and amusement park machinery and structures – Safety*

Data and data exchange

- EN ISO 19115 family of standards *Geographic information – Metadata*
- EN ISO 14021:2016 *Environmental labels and declarations – Self-declared environmental claims*
- EN 14822 family of standards *Health informatics – General purpose information components*

3.5 Standards for accreditation

3.5.1 ISO/CASCO and CEN/CLC/JTC 1

Standards for the conformity assessment are produced by ISO/CASCO *Committee on conformity assessment*. Its primary role is to study the means of assessing the conformity of products, processes, services and management systems. CASCO also prepares international guides and standards relating to the practices of conformity assessment and promotes their appropriate use. ISO/CASCO is meant to support and improve national and regional conformity assessment systems and thus facilitate their mutual recognition. In this frame, ISO/CASCO collaborates with other technical committees to ensure a consistent and harmonized approach to the development of standards that are subject to conformity assessment.

The equivalent European committee is CEN/CLC/JTC 1 *Criteria for conformity assessment bodies*. The scope of this committee consists in the *"preparation of standards on criteria for bodies involved in testing calibration, certification, inspection, accreditation, their operation and assessment, and other related standards"*. Aside from a few exceptions, CEN/CLC/JTC 1 mostly adopts international standards from ISO/CASCO as European standards. As a reminder, only European standards, either adopted from international ones or developed from scratch, can be harmonized and used for the presumption of conformity with European regulation.

In Luxembourg, national market players can follow the activities of both ISO/CASCO and CEN/CLC/JTC 1 by registering in the National Standardization Commission 02 *Conformity*.

3.5.2 ISO 17000 family and other relevant documents

As discussed in Section 3.3, there are standards for ABs and CABs that allow to verify their competencies and that vary depending on the activities they perform. These standards form a family of standards EN ISO/IEC 17000.

Testing

- EN ISO/IEC 17025:2017 — *General requirements for the competence of testing and calibration laboratories*
- EN ISO 15189:2022 — *Medical laboratories – Requirements for quality and competence*

Proficiency testing providers

- EN ISO/IEC 17043:2023 — *Conformity assessment – General requirements for the competence of proficiency testing providers*

Reference materials producers

- EN ISO 17034:2016 — *General requirements for the competence of reference material producers*

Calibration

- EN ISO/IEC 17025:2017 — *General requirements for the competence of testing and calibration laboratories*

Inspection

- EN ISO/IEC 17020:2012 — *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*

Certification

- EN ISO/IEC 17021-1:2015 — *Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements*
- EN ISO 19011:2018 — *Guidelines for auditing management systems*
- EN ISO/IEC 17024:2012 — *Conformity assessment – General requirements for bodies operating certification of persons*
- EN ISO/IEC 17065:2012 — *Conformity assessment – Requirements for bodies certifying products, processes and services*

Verification and validation

- EN ISO/IEC 17029:2019 — *Conformity assessment – General principles and requirements for validation and verification bodies*

Standard to be used for peer evaluation of accreditation bodies

- EN ISO/IEC 17011:2017 — *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*
- Additional guidance provided in the publications from IAF, ILAC and EA is used

4

How to use and to contribute to conformity assessment standards

4 How to use and to contribute to conformity assessment standards

This report explains the principles of conformity assessment, and the role of technical standards in the process is discussed in Section 3. Applying standards is beneficial at all levels of conformity assessment even if it is not mandatory. To support national stakeholders and facilitate their access to standards, ILNAS has put in place several products and services.

4.1 How to access standards?

In Luxembourg, multiple options are available to get to know the content of published standards:

- **ILNAS e-Shop**: when an organization wants to implement standards, it can buy them from ILNAS e-shop. Also, the standard projects which are in the public enquiry stage are accessible free of charge during a specific period of time for public consultation.

- **Reading stations**: multiple reading stations are set across the country, through which any interested party can search for and read the published European and international standards. This is a useful option when an organization is looking for appropriate standards and is interested in getting a first appreciation of their contents.

4.2 Who can participate in standards development in Luxembourg?

In order to be aware of any new developments or revisions of existing standards, organizations in Luxembourg can register experts in the technical committees where the relevant standards are developed. Not only will the experts be able to keep themselves up to date, but they will also be able to contribute to the content of future standards, defending their organization's interests. It can be particularly helpful when defining standards requirements for future products and services to be put on the market.

Any interested stakeholder can get involved in the development of standards through ILNAS by becoming an active national delegate free-of-charge. Interested experts can easily request to ILNAS their registration using a dedicated form.

National Standardization Commission 02 – Conformity

Experts from Luxembourg can participate in ISO/CASCO or CEN/CLC/JTC 1, or follow the developments of both committees through the National Standardization Commission 02 (NSC 02). Through ILNAS/NSC 02 the delegates can access international and European documentation related to the standardization in the area of conformity assessment and contribute to the definition of national position for the topics under consideration.

4.3 Contact details

For any additional information the organizations in Luxembourg can address different departments of ILNAS and ANEC GIE.

- National Accreditation Body – OLAS: contact@olas.public.lu
- National Standards Body – OLN: normalisation@ilnas.etat.lu
- Agency for standardization and knowledge-based economy – ANEC GIE: anec@ilnas.etat.lu

We regularly publish news, propose information sessions, provide trainings, and so on. The information about our activities could be found on our website: portail-qualite.lu

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Conclusion

This technical report aims to familiarize the national stakeholders with the concept of conformity assessment and its role in building the economy of trust. The report presents different facets of conformity assessment and explains how they all fit together. Particular attention is given to technical standardization as a means to collect the good practices to support the evaluation of conformity, but also in some cases as a way to achieve compliance with legislation.

The current document can also be considered as an educational element as it starts from the definition of concepts and progressively builds on them to present the whole ecosystem.

The report is fully aligned with and supports the "Politique normative nationale "ISO CASCO" 2022-2030". It promotes the developments of the international committee ISO/CASCO and its European counterpart CEN/CLC/JTC 1 and could be used as support for further education programs or as a state of the art for research projects.

With respect to technical standardization in general, and ISO/CASCO developments in particular, one of ILNAS' missions, as stated in the "Stratégie normative luxembourgeoise 2020-2030", is to promote the use of standards and encourage the market players to contribute to their development. This report provides guidance on how to do both and presents relevant standardization activities for conformity assessment. More sector or topic specific information can be found in other reports and white papers, or in our national standards analyses (such as the Standards Analysis of the ICT sector), developed with the support of ANEC GIE. Additional information as well as thematic news are available on Portail-Qualite.lu.

ILNAS supports all national market players who are already involved in the process or would like to contribute to technical standardization and thus to the economy of trust. Free of charge registration is proposed for active experts as well as necessary assistance and guidance via our delegates' trainings.

Join ILNAS' network of experts and build an economy of trust together with other national stakeholders!

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