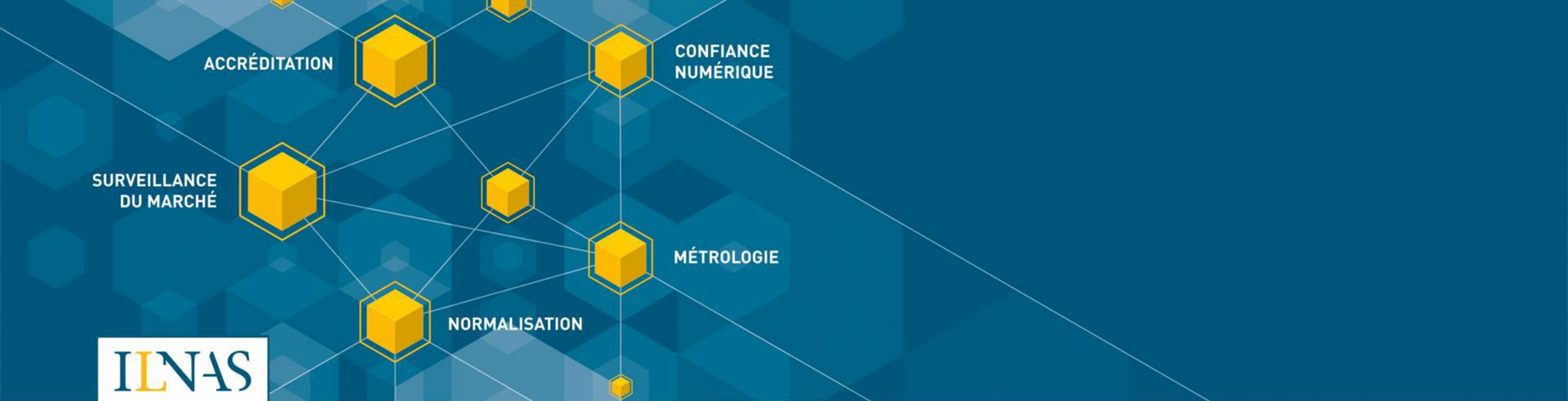# Presentation Breakfast of Technical Report « Conformity Assessment: Overview »

12/06/2024

Introduction

Jérôme Hoerold, ILNAS/OLN, Head of department
12/06/2024

o Public administration under the authority of the Minister of the Economy, SME, Energy and Tourism

o Interesection of several technical and administrative attributions

o 65 collaborators (June 2024)

o ISO 9001:2015 certified

ORGANISME LUXEMBOURGEOIS DE NORMALISATION

- National standardization body

- Close collaboration with GIE ANEC-N (4 persons)

- Main goals:

  o Set-up a national normative culture

  o Create national standards

  o Manage the contribution of national experts to the drafting of European and international standards

  o Representation of Luxembourg at European and international level

Technical standardization
"Inclusive tool for performance and excellence to serve the economy"

STRATÉGIE
NORMATIVE
LUXEMBOURGEOISE
2020-2030

NORMALISATION TECHNIQUE
« Outil inclusif de performance et
d'excellence au service de l'économie »

ILNAS

→ Strategy signed by the
Minister of the Economy of
Luxembourg

PERFORMANCE

- Pillar 1 – Use of relevant technical standards

- Pillar 2 – Involvement in the standardization process

EXCELLENCE

- Pillar 3 – Active participation of the NSB in the European and international standardization organizations

- Pillar 4 – Development of research and education about standardization

Technical standardization
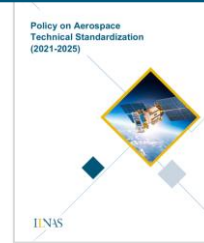**"Inclusive tool for performance and excellence to serve the economy"**

3 growth sectors identified

ICT

Policy on ICT Technical
Standardization (2022-2025)

CONSTRUCTION

Politique pour la normalisation
technique du secteur de la
construction (2020-2025)

AEROSPACE

Policy on Aerospace
Technical Standardization
(2021-2025)

CASCO

Politique normative nationale
« ISO CASCO » 2022-2030

"Foster and strengthen the national economic sectors involvement in standardization work"

Politique normative nationale
« ISO CASCO » 2022-2030

ILNAS

1 Promoting technical standardization to the market

2 Reinforcing the valorization and the involvement regarding technical standardization

3 Supporting and strengthening the Education about Standardization and the related research activities

ILNAS, in collaboration with ANEC GIE, offers the following products and services to national socio-economic actors:

- **Dissemination of normative information**

  - Sectoral Standards Analyses ("Fundamental" Sectors, e.g. Aerospace, 2023)

  - White papers (Trustworthiness in ICT, Aerospace, and Construction applications - Scientific Research and Technical Standardization, 2023)

  - Technical reports (Quantum technologies, 2023)

  - Newsletters

  - Etc.

- **Informative sessions**

- **Continuous training in standardization**

- **Targeted standards watch**

https://portail-qualite.public.lu/fr/normes-normalisation/produits-et-services.html

➢ Published technical standards (ILNAS, ETSI, CEN, CENELEC, ISO and IEC) can be freely consulted on the ILNAS reading stations

     Locations:

- University of Luxembourg (Campus Kirchberg)

- Luxembourg House of Cybersecurity (**with an appointment**)

- Chambre des métiers

- Lifelong Learning Center

- ILNAS (**with an appointment**)

- LIST (Belvaux)

- Administration communale de la Ville d'Echternach

- Atert-Lycée Redange

- Lycée des Arts et Métiers
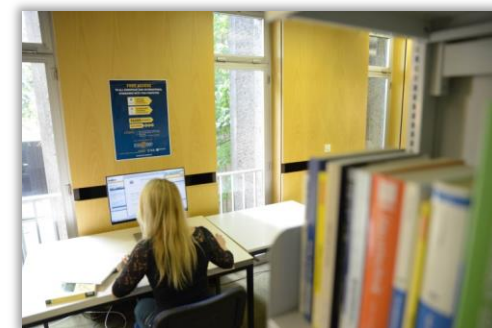
➢ These standards can also be purchased through the ILNAS e-shop at competitive prices

     Over 200,000 normative documents available

     Format: electronic

     Language: English, French and German

Informative session following the revision decision of the standard ISO/IEC 17020

25th January 2023

2 LU delegates registered

Consultative meeting for the revision of ISO/IEC 17025:2017

15th February 2023

Luxembourg position: confirmation of the standard

Consultative meeting for the revision of ISO/IEC 17011:2017

2nd March 2023

Luxembourg position: confirmation of the standard

Breakfast
**« Introduction to the conformity assessment »**
25th May 2023

Presentation of the different activities and stakeholders involved in the chain of trust-building related to the conformity assessment domain

1 LU delegate registered

- **Conformity assessment** is "The process of conformity assessment demonstrates whether a product, service, process, claim, system or person meets the relevant requirements"[1]

Chain of trust-building
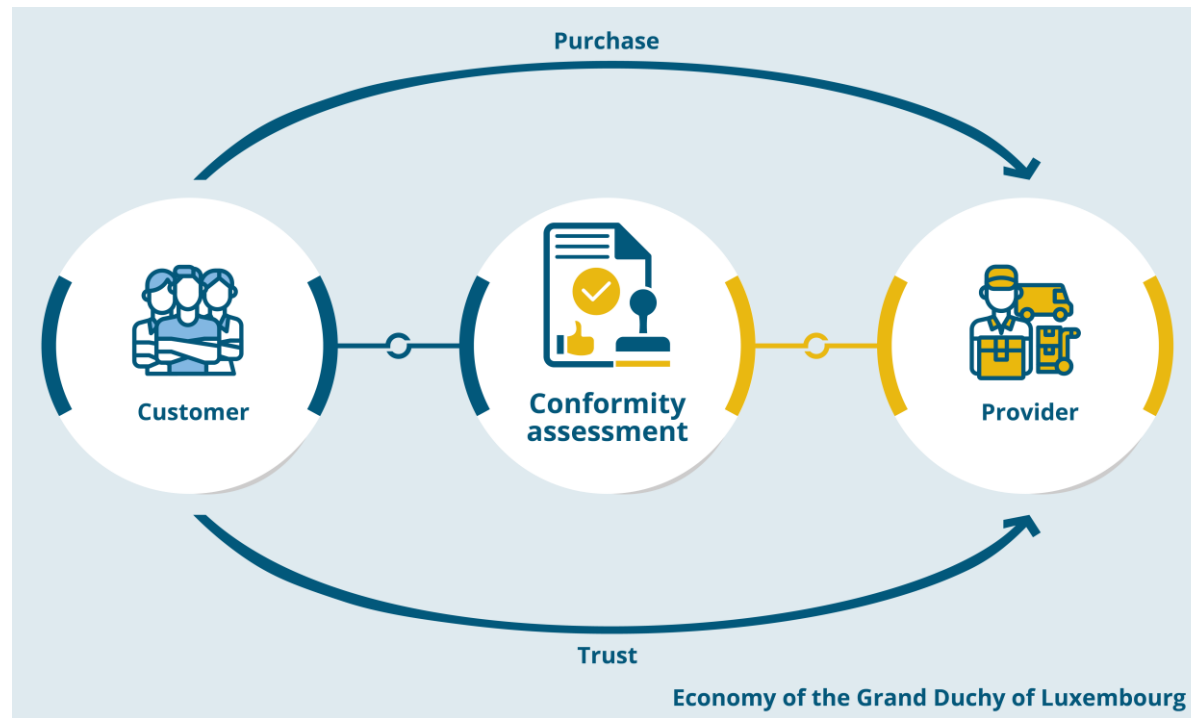
Conformity assessment is a great tool to reach high economical confidence

[1]https://www.iso.org/conformity-assessment.html

- **What are the characteristics to be followed in order to build trust through conformity assessment ?**

Coherence	Transparency	Openness	Quality
Consensus	Independence	Impartiality	Objectivity

Thank you for your attention

Questions ?

ILNAS

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Accreditation as keystone for Trust

Dominique Ferrand

Head of OLAS Department

12th of June 2024

Welcome · Bienvenue · Willkommen

Source : ISO/IEC 17000:2020 – Conformity assessment – Vocabulary and general principles

➢ Conformity assessment : demonstration that specified **requirements** are fulfilled

➢ Conformity assessment activities : Activities covering testing, calibration, inspection, certification of products, management systems, personnel, validation, verification

➢ conformity assessment scheme or conformity assessment program : **set of rules and procedures** that describes the objects of conformity assessment, identifies the specified requirements and provides the methodology for performing conformity assessment

➢ Conformity assessment body (CAB) : **Body** that performs conformity assessment activities, excluding accreditation

Source : ISO/IEC 17011:2017 - Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies

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

Source : Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products

➢ Accreditation : Attestation by a national accreditation body (NAB) that a conformity assessment body meets the requirements set by **harmonized standards** and, where applicable, any **additional requirements** including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity

Conformity assessment bodies:

Conformity assessment bodies can be public or private bodies **evaluating the conformity** of products, services, systems, persons… according to recognized standards or regulations.

Conformity assessment can be performed by manufacturers, distributors or third party bodies.

Accreditation bodies:

Accreditation bodies are public or private third party bodies **attesting the technical competence** of conformity assessment bodies to perform certain conformity assessment activities. Accreditation is only delivered to **organizations** (not to persons).

Conformity assessment and Accreditation are **complementary activities**. From the product, service, system, persons… to the consumer, these two activities constitute the **chain of trust** supported, for example, by the European regulations.

OFFICE LUXEMBOURGEOIS D'ACCREDITATION ET DE SURVEILLANCE

European Accreditation

Peer-evaluation system

Trusted
NAB

Accreditation activities

Trusted
CAB

Conformity assessment activities
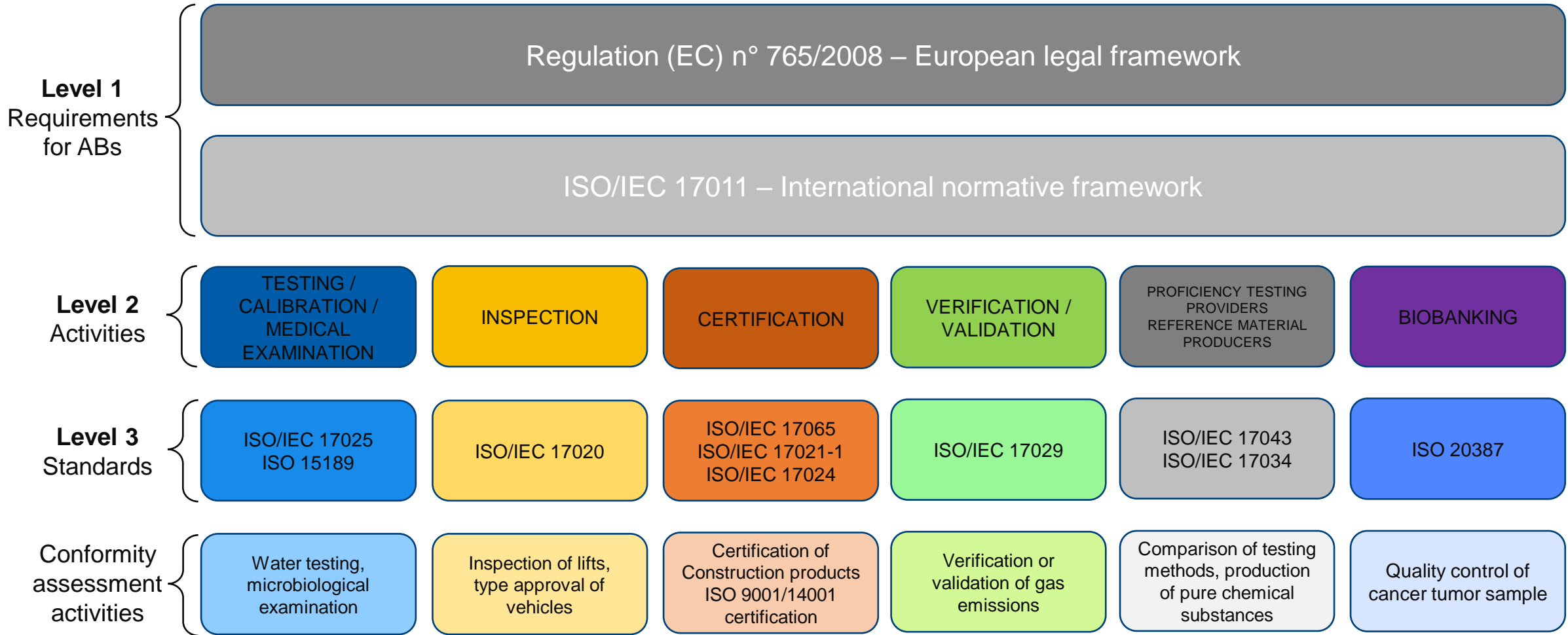
Trusted
Product

Standard for NABs organization

Accreditation standard for laboratories

Technical standards for water testing

OFFICE LUXEMBOURGEOIS D'ACCREDITATION ET DE SURVEILLANCE

Level 1 Requirements for ABs	Regulation (EC) n° 765/2008 – European legal framework
	ISO/IEC 17011 – International normative framework

Level 2 Activities	TESTING / CALIBRATION / MEDICAL EXAMINATION	INSPECTION	CERTIFICATION	VERIFICATION / VALIDATION	PROFICIENCY TESTING PROVIDERS REFERENCE MATERIAL PRODUCERS	BIOBANKING
Level 3 Standards	ISO/IEC 17025 ISO 15189	ISO/IEC 17020	ISO/IEC 17065 ISO/IEC 17021-1 ISO/IEC 17024	ISO/IEC 17029	ISO/IEC 17043 ISO/IEC 17034	ISO 20387
Conformity assessment activities	Water testing, microbiological examination	Inspection of lifts, type approval of vehicles	Certification of Construction products ISO 9001/14001 certification	Verification or validation of gas emissions	Comparison of testing methods, production of pure chemical substances	Quality control of cancer tumor sample

Domains of legislations	Number of EU legislations
Union harmonization for products to guarantee EU free movement	32
Food and Feed	17
Climate / Environment	38
Vehicles	7
Railway	6
Transport	7
Aviation	1
Forensic	1
Data protection	2
Cybersecurity / IT security	3
Medical	1
Sustainability / Eco design / Green transition	4
Total	**119**

Coherence	Transparency	*Openness*	*Quality*
Consensus	Independence	Impartiality	Objectivity

Coherence and objectivity in accreditation

European and national legal framework

➢ Regulation (EC) n° 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products – *Accreditation definition*

➢ Loi du 4 juillet 2014 portant réorganisation de l'ILNAS – *Definition of OLAS missions (accreditation and notification of CABs)*

➢ RGD du 12 avril 2016 pour la mise en application des articles 5 et 7 de la loi ILNAS – *Details of the definition of OLAS missions (accreditation and notification of CABs)*

International normative framework

➢ Standard ISO/IEC 17011 – Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

Independence and impartiality in accreditation

Regulation (EC) n° 765/2008 – Definition of <u>European principles</u>

➢ **One NAB** by Member State

➢ NAB acts as a **public authority**

➢ **Not-for-profit** activity

➢ Accreditation – **last level of control** in the conformity assessment chain

➢ **Non-competition** between NABs

Independence and impartiality in accreditation

Regulation (EC) n° 765/2008 – Definition of <u>European principles</u>

➤ Access to **competence** to perform accreditation of CABs

➤ **Independence** form the CABs and **impartiality** of decision making process (third-party)

➤ Cross-border accreditation

➤ European accreditation infrastructure

➤ **Peer evaluation system** managed by EA – tool for **Mutual recognition agreement**

Application of these principles guarantee <u>trust in the accreditation system</u>

Impartiality, coherence and transparency of accreditation

Regulation (EC) n° 765/2008 : Article 10 – Peer evaluation

➤NABs shall participate to the peer evaluation organized by EA

➤Peer evaluation is operated based on a coherent and transparent evaluation system

➤The results of the peer evaluation is published by EA, via its website, to all the Member States and to the European Commission

➤European Commission, in cooperation with the Member States, is supervising the rules and the proper implementation of the peer evaluation system

Guarantee of the <u>harmonization</u> in accreditation system performed by NABs

Coherence and objectivity in accreditation through mutual recognition agreement

Mutual recognition agreement main objectives:

➢ Recognition of the competences of CABs by the NABs signatories of the mutual recognition agreements

➢ Acceptance of products, services, certificates, reports… delivered by accredited CABs, across national borders,

➢ Removal of barriers to global trade

"Accredited once, accepted everywhere"

Coherence and objectivity in accreditation through mutual recognition agreement

Benefits of mutual recognition agreement:

➢ For government: government to government bilateral and multilateral international **trade agreements**

➢ For regulators: internationally recognized 'stamp of approval' to demonstrate compliance against agreed **standards and requirements**

➢ For industry users: ensures that businesses depending on conformity assessment activities are **performed in a competent way**

➢ For manufacturers: **reduce the costs of internal assessments** to confirm the quality of products by using the services of recognized accredited CABs.

➢ For consumers: **provide confidence** to consumers by using conformity assessment services delivered by accredited CABs.

European co-operation for Accreditation (EA)

Regional Association of NABs (Regulation (EC) No 765/2008)

Defining, harmonizing and building consistent accreditation services in Europe.

Maintaining a **Multilateral Agreement (MLA)** between accreditation activities and reciprocal acceptance of accredited conformity assessment services and results.

EA MLA incorporates EU & EFTA NABs, Council of Europe and EU neighborhood policy NABs (49 NABs).

EA MLA means for the signatories:

> ➢ The **equivalence** of the accreditation systems operated by the signatories (peer-evaluation system);

> ➢ The **reliability** of the results provided by CABs accredited by the signatories for the relevant scope.

EA MLA provides trust on conformity assessment results to all interested parties (e.g. reports and certificates) provided by CABs accredited by EA MLA signatories.

International Laboratory Accreditation Cooperation (ILAC)

International association of NABs (6 regions + 110 members)

Defining, harmonizing and building consistent international accreditation services.

Maintaining a **Mutual Recognition Agreement (MRA)** between accreditation activities (Testing, Calibration, Medical laboratories, Inspection bodies) and reciprocal acceptance of accredited conformity assessment services and results.

International
Laboratory
Accreditation
Cooperation

International Accreditation Forum (IAF)

International association of NABs (6 regions + 95 members + 27 associations)

Defining, harmonizing and building consistent international accreditation services.

International
Accreditation Forum

Maintaining a **Multilateral recognition Agreement (MLA)** between accreditation activities (Products and Management System Certification bodies) and reciprocal acceptance of accredited conformity assessment services and results.

ILAC MRA and IAF MLA provide trust on conformity assessment results to all interested parties (e.g. reports and certificates) provided by CABs accredited by signatories.

Accreditation is providing the following **benefits** to accredited CABs:

➢ Verification of conformity with standards and regulations,

➢ Demonstration of competence,

➢ Assessment of management system and risk,

➢ Guarantee of independence and impartiality,

➢ Facilitates cross border trade (trade agreements),

➢ Minimize product failure and recalls,

➢ Delivers public confidence.
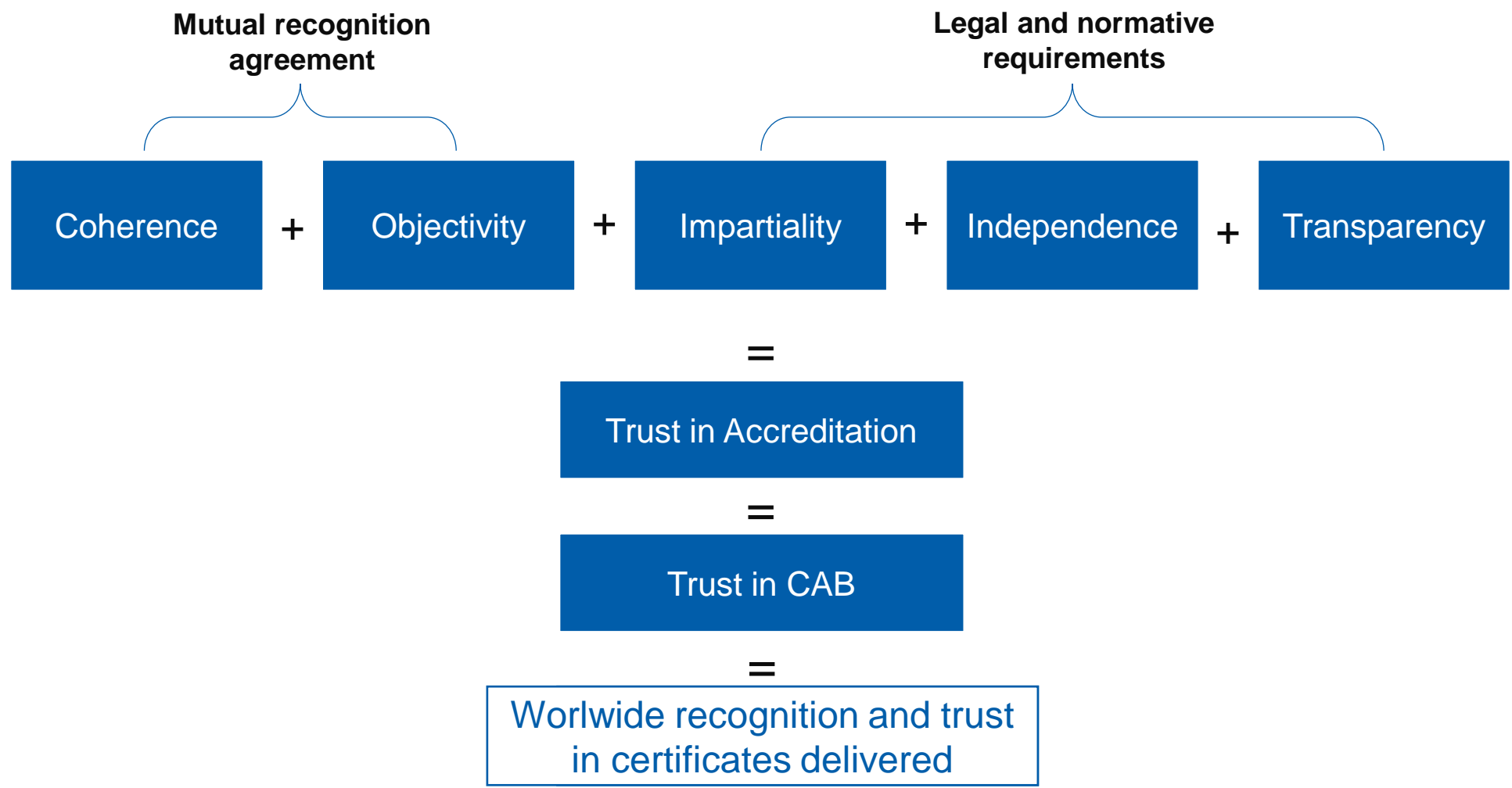
Mutual recognition agreement

Legal and normative requirements

Coherence + Objectivity + Impartiality + Independence + Transparency

=

Trust in Accreditation

=

Trust in CAB

=

Worlwide recognition and trust in certificates delivered

Office Luxembourgeois d'Accréditation et de Surveillance (OLAS):

- Created in 2001

- 6 internal staffs

- 16 members in the accreditation committee part of the decision making process

- 140 experts (QMS and technical) to cover all the domains accredited by OLAS

- 60 accredited CABs

- Signatory of EA, ILAC and IAF multilateral recognition agreements

Questions ?

OFFICE LUXEMBOURGEOIS D'ACCRÉDITATION ET DE SURVEILLANCE (OLAS)

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Thank you · Merci · Danke

Standardization and conformity assessment

Lucas Cicero, ILNAS/OLN, Project officer

12/06/2024

a) Standard definition

Defined in Regulation (EU) No 1025/2012 on European standardization

" 'standard' means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory"

(1) technical specification: document that prescribes requirements to be fulfilled by products, services, processus, competencies, etc.

(2) recognised standardisation body: standard publication is limited to
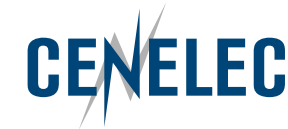
(3) repeated or continuous application: aims to cover well established activities

(4) compliance is not compulsory: up to you to follow them… or not !

b) Standards in conformity assessment activities

Role of standard in the conformity assessment landscape

Object of conformity (*e.g product, organization, service, person, etc.*)	← certifies	Conformity assessment body	← accredites	National accreditation body

Ex. EN ISO 9001:2015
Quality management systems —
Requirements

Ex. EN ISO 17021-1:2015
and certification of management systems

Ex. EN ISO 17011:2017
Requirements for accreditation bodies
accrediting conformity assessment bodies

How can we trust these standards ?

Developed in domain dedicated Technical Committees

Developed in specific Technical Committees

How can we trust standards content ?

- **Standardization has legal framework in Europe**

The « REGULATION (EU) No 1025/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2012 REGULATION (EU) on European standardisation » L 316/12 is currently the legal act in-force for the European standardization. It aims to define….

> « […] *rules with regard to the cooperation between European standardisation organisations, national standardisation bodies, Member States and the Commission, the establishment of European standards and European standardisation deliverables for products and for services in support of Union legislation and policies, the identification of ICT technical specifications eligible for referencing, the financing of European standardisation and stakeholder participation in European standardisation* »

Content

- o Clear **definition** of standard
- o **Founding principles** of standardization
- o **Who are able to create standard in EU**
- o Principles of **European standard creation**
- o **Standards « harmonization »** inside EU
- o The **Annual Work Programme on Standardization**
- o The specific role of ICT
- o Standardization funding

…but… → Practical rules are defined by recognized European standardization organizations

How can we trust standards content ?

- **Standardization activities meet several attributes of trust**

Coherence	Transparency	Openness	Quality
Consensus	Independence	*Impartiality*	*Objectivity*

Coherence… between international, European and national standardizations

- **European standardization rules are similar to international ones**

  - *CEN/CENELEC Internal Regulations = ISO/IEC Directives – Part 2*

- **Agreements between European standardization organizations and international ones**

  -

    Vienna agreement

  -
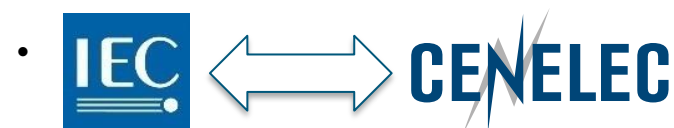
    Frankfurt agreement

- **Notification of standard projects between national standardization organizations, but also to European organizations**

  - *Defined in Regulation (EU) No 1025/2012*

- **Yearly publication of work programmes**

  → **Standards applicability is worlwide and duplication of work is avoided**
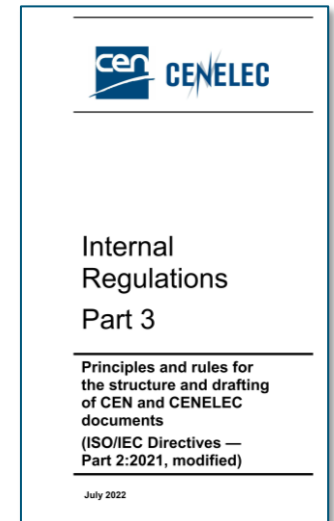
Transparency... during the process of creation of standards
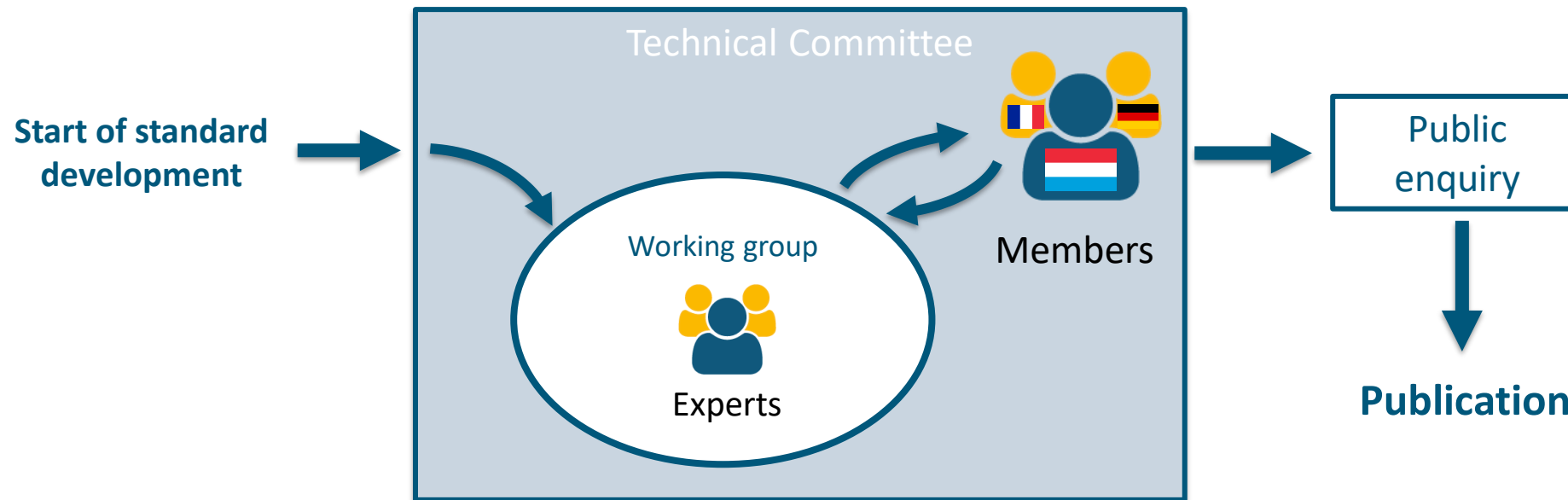
→ Rules and roles are **described** within the *Internal Regulations* of recognized standardization organizations and disclosed

→ **All standards are issued in a common way and more easily accepted**

Transparency and consensus... of the decisions
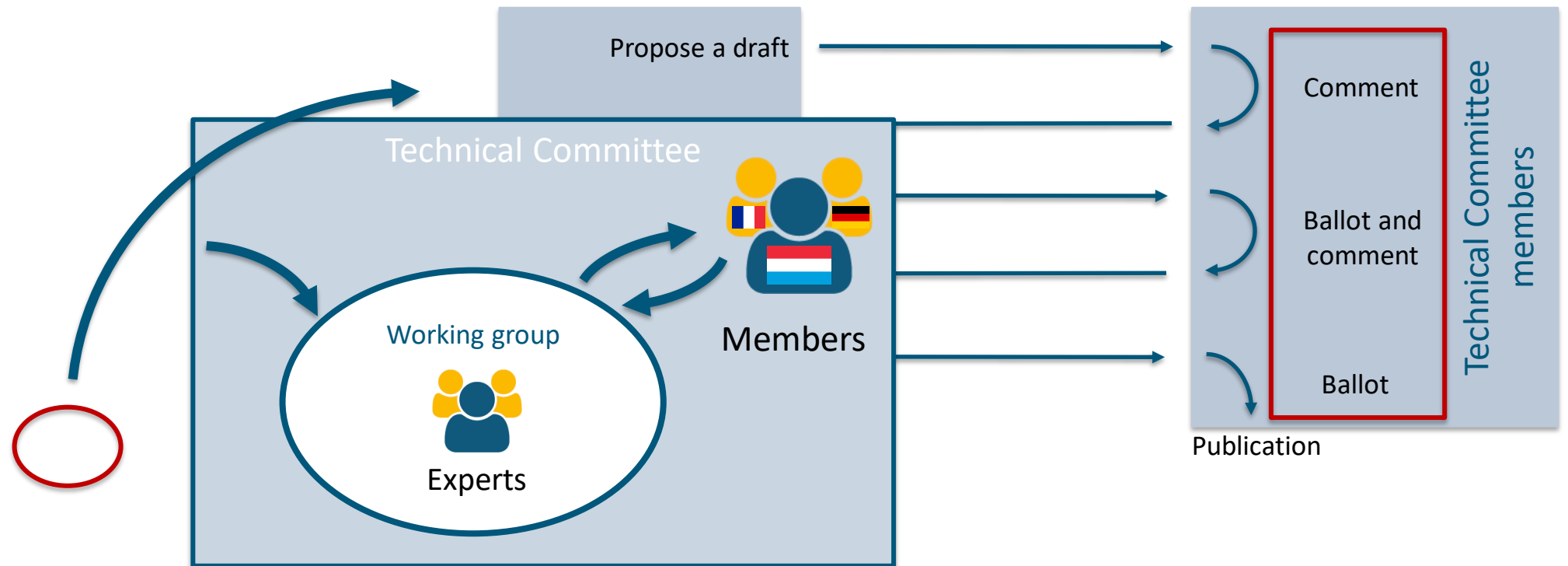
→   For each standard development, results and comments are recorded, and final decision is based on known criteria

→ **Standards content is accepted by all stakeholders contributing to standard development**

Quality… inside the standard content
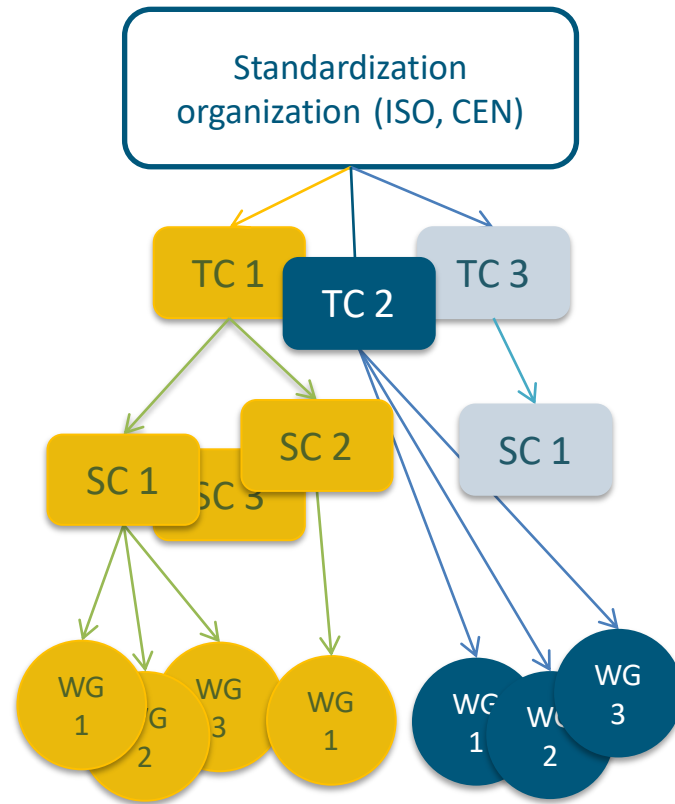
Standardization organization structure

- **Presence of several Technical Committees and Subcommittees, covering specific domains**
  - *e.g. ISO/TC 207/SC 1 - Environmental management systems*

- **Presence of Joint Technical Committee**
  - *e.g. ISO/IEC JTC 1 - Information technology*

- **Tackling very specific topic**

→ **Standards are drafted in a domain specific ecosystem which act as a catalyst**

41

Quality… inside the standard

PROPOSAL

Following the identification of a need, an economic actor proposes a new work item

STUDY & PREPARATION

A technical committee prepares the normative document

**REVISION
Stage 90**
A standard shall be revised every 5 years (Confirmation, Revision, Withdrawal)

PUBLIC ENQUIRY & APPROVAL
The standard draft is submitted first to public enquiry, and then for validation by the TC in charge

PUBLICATION

Publication of the approved standard

Standardization process

- As final step, **the public** is consulted to **approve and comment** the draft standard

- Standards are submitted to **revision vote every 5 years**

  - Decision can go to the direction of **revision**, **confirmation** or **withdrawal**

- Revision can be triggered by members if judged necessary

→ Standards content is always relevant and up to date

Quality, openness and independence... via the participation

Standardization organization (ISO, CEN)

TC 1 TC 2 TC 3

SC 1 SC 2 SC 3 SC 1

WG 1 WG 2 WG 3 WG 1 WG 1 WG 2 WG 3

NMC
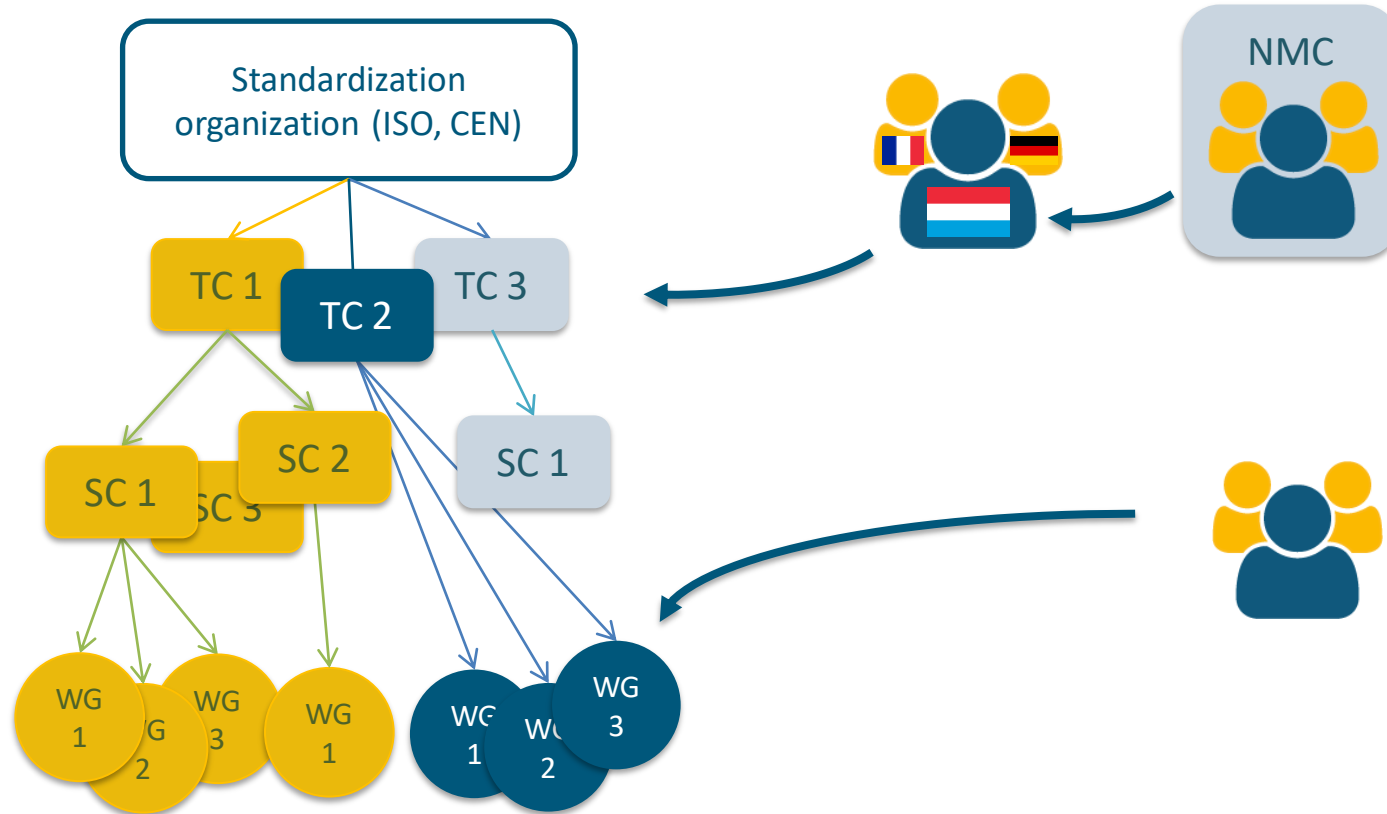
National delegates

- Participation of organizations through the **National Mirror Committee**
- National interests are **defended** at this step
  - **Goal :** review and comment the drafted documents, and set the position of Luxembourg
- **Participation promoted** by NSO and has to **include** all stakeholders (industrials, SMEs and governmental institutions)

Experts

- No national interests **defended** at this step
  - **Goal :** best translation of the state-of-the-art inside a standard
- **Open to everyone** who has expertise
- **Participation promoted** by NSO and has to **include** all stakeholders (industrials, SMEs and governmental institutions)

➔ **Expertise and inclusiveness of participating members allow to translate every standpoint within standard**

Quality, openness and independence… via the participation
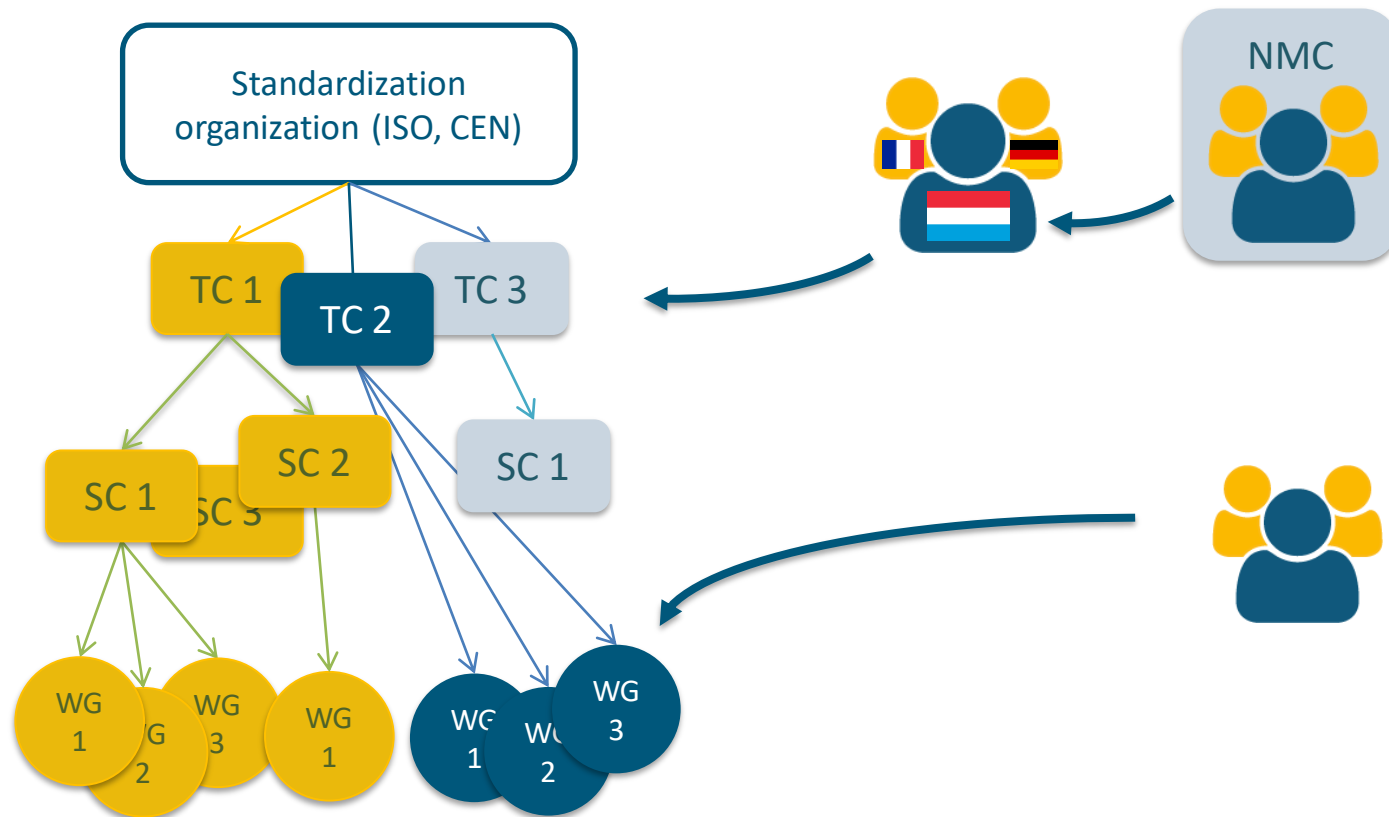
In Luxembourg

- Participation is **open to everyone**

- **Registration process is disclosed** on portail-qualite.lu

- To maintain openness and independence, **a decision board** takes place constantly in order to review the applications

- By participating to standardization, **national delegates has dues and rights**, available in ILNAS' policy related to participation to standardization

- **Participation register** is available on portail-qualite.lu website

Quality, openness and independence... via the participation
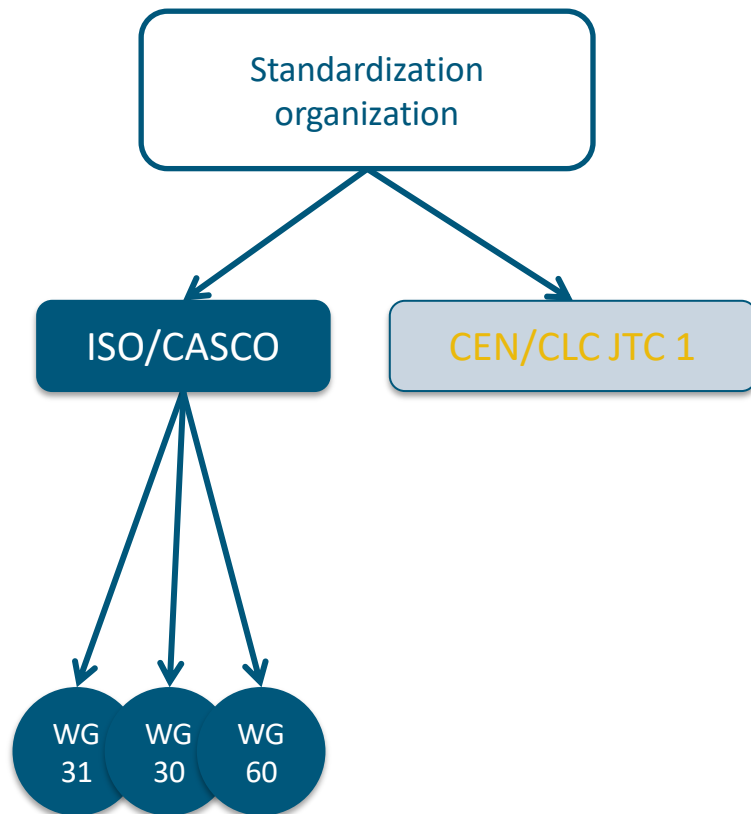
ISO/CASCO

International technical committee in charge of the development of CASCO Toolbox (family of standards ISO 17000) supporting mostly accreditation activities

CEN/CLC JTC 1

European joint technical committee, supporting the transposition of ISO/CASCO standards to European standards
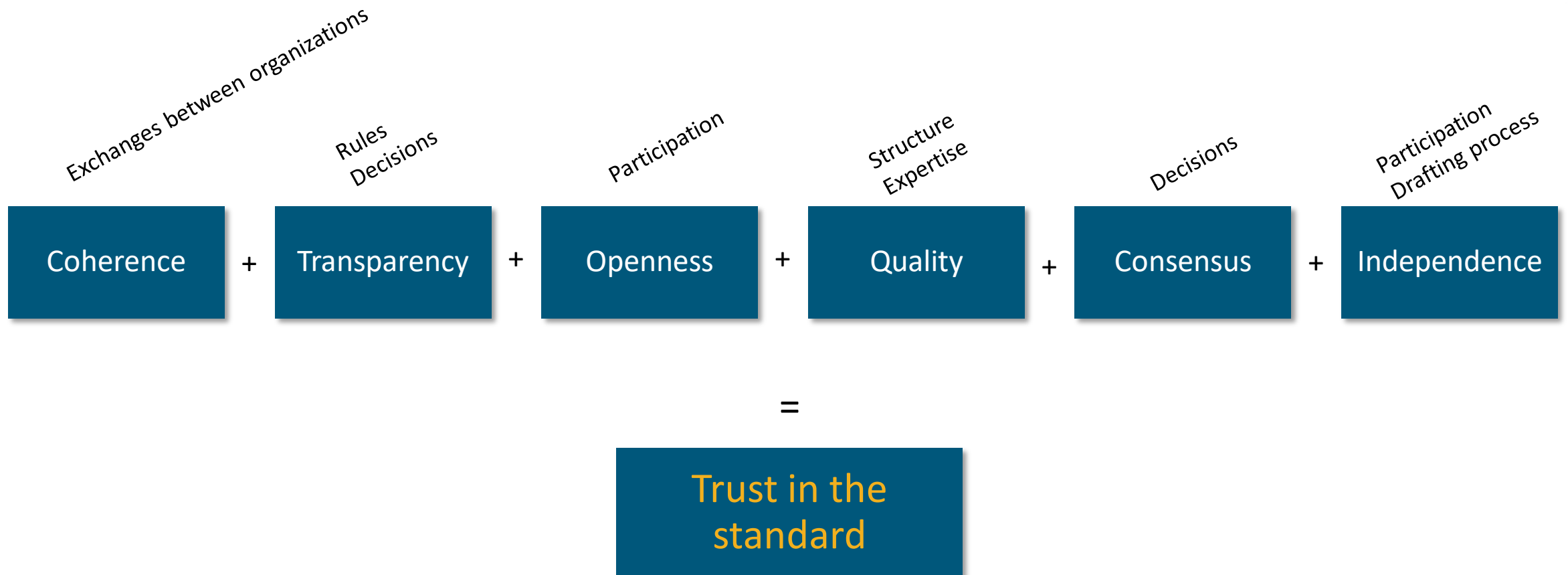
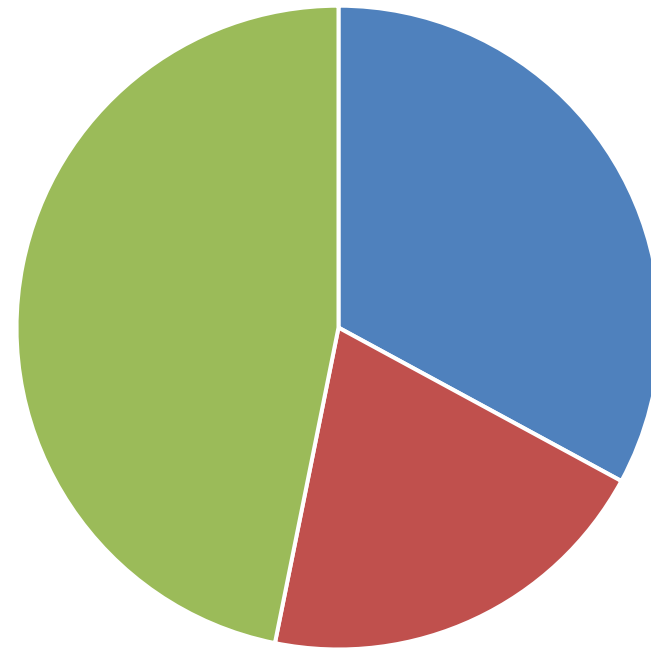**Quality, openness and independence… via the participation**

Standardization organization

ISO/CASCO

CEN/CLC JTC 1

WG 31

WG 30

WG 60

ILNAS

ILNAS/NSC 02 « Conformity »
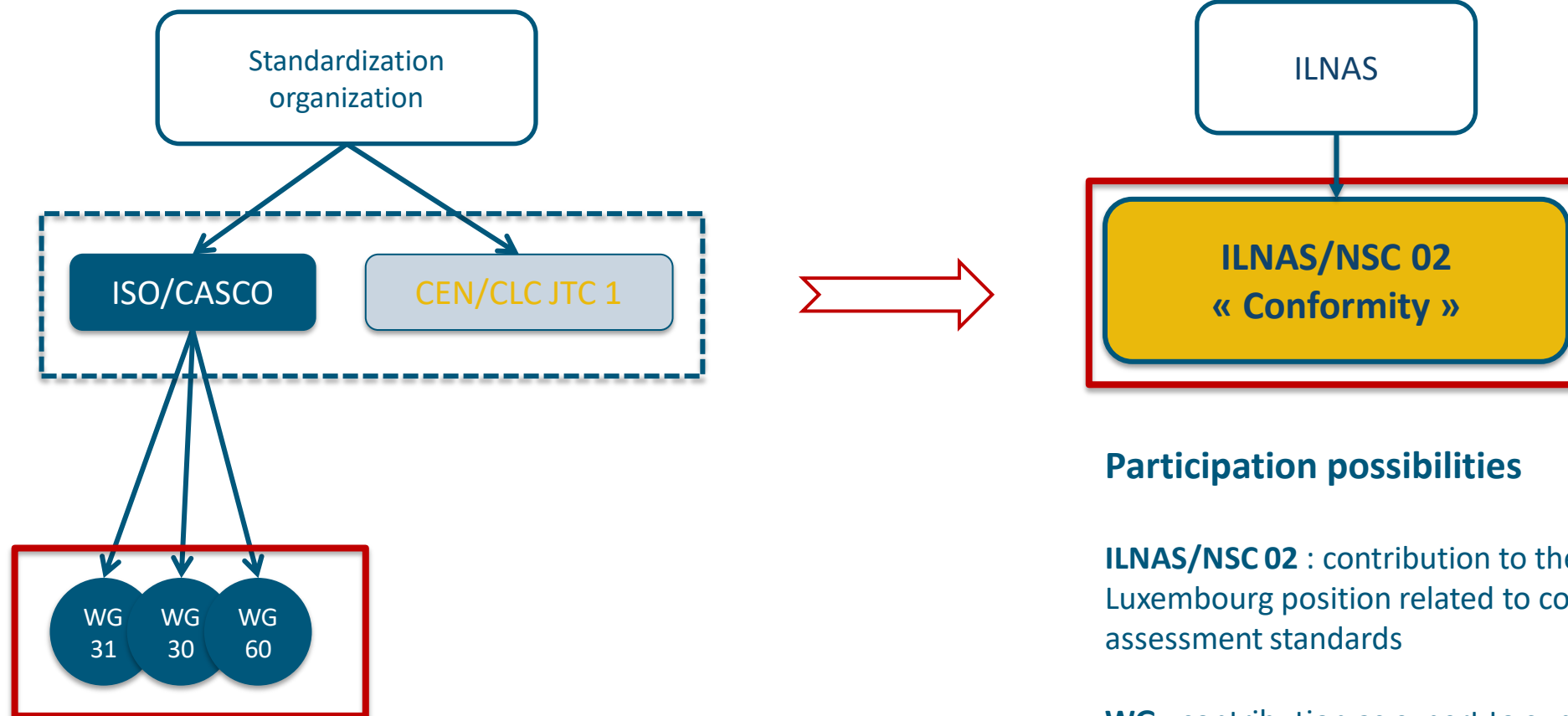
Participation possibilities

ILNAS/NSC 02 : contribution to the definition of Luxembourg position related to conformity assessment standards

WG : contribution as expert to support drafting activities of international standard

Exchanges between organizations

Rules
Decisions

Participation

Structure
Expertise

Decisions

Participation
Drafting process

| Coherence | + | Transparency | + | Openness | + | Quality | + | Consensus | + | Independence |

=

Trust in the standard

Trust in economy

■ Accreditation ■ Standardization ■ ?

Thank you for your attention

Question ?

ILNAS

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Technical Report
Conformity Assessment: Overview

12/06/2024, Natalia Vinogradova, ANEC GIE

Main information

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.
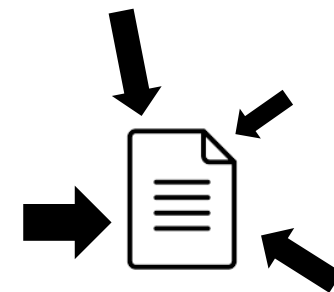
Purpose
- Evangelization of the concept of conformity assessment
- Explaining how conformity assessment helps building trust
- Pointing to relevant technical committees and standards
- Encouraging to join the standardization efforts

What aims?
- Point out various elements in the ecosystem of conformity assessment
- Identify legal framework
- Explain principles underlying the conformity assessment and standardization process
- Fit all the element together

Part 1

Introduction to conformity assessment
- Introduction to conformity assessment
- Conformity assessment and trust
- European legal framework

Part 2

Conformity assessment concepts
- Conformity assessment ecosystem
- Conformity assessment activities
- Who performs conformity assessment?
- Accreditation
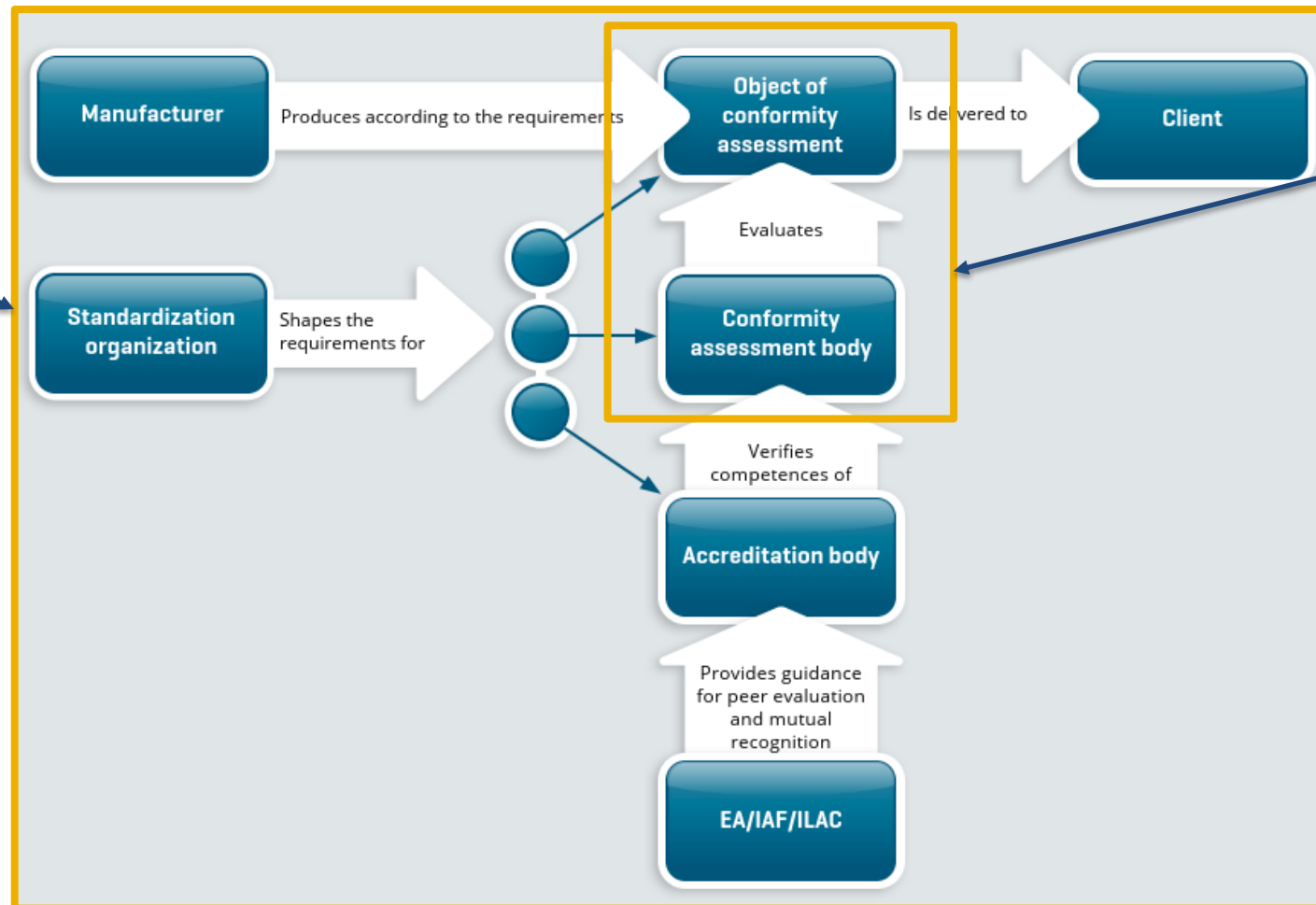
Part 3

Standardization for conformity assessment
- Standardization ecosystem
- Principles related to writing conformity assessment standards
- Classification of conformity assessment standards
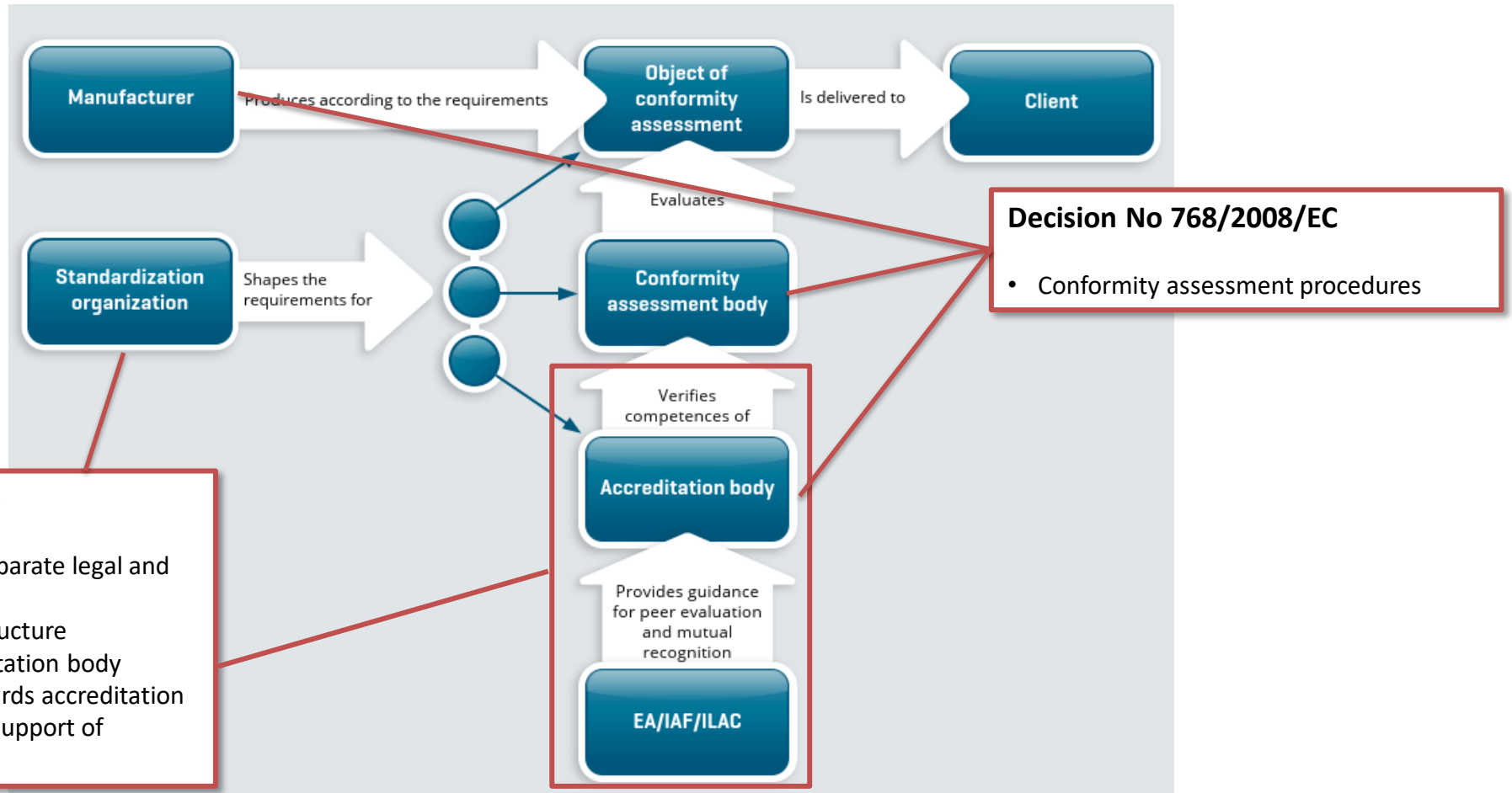- Examples of standards for conformity assessment, including accreditation

Part 4

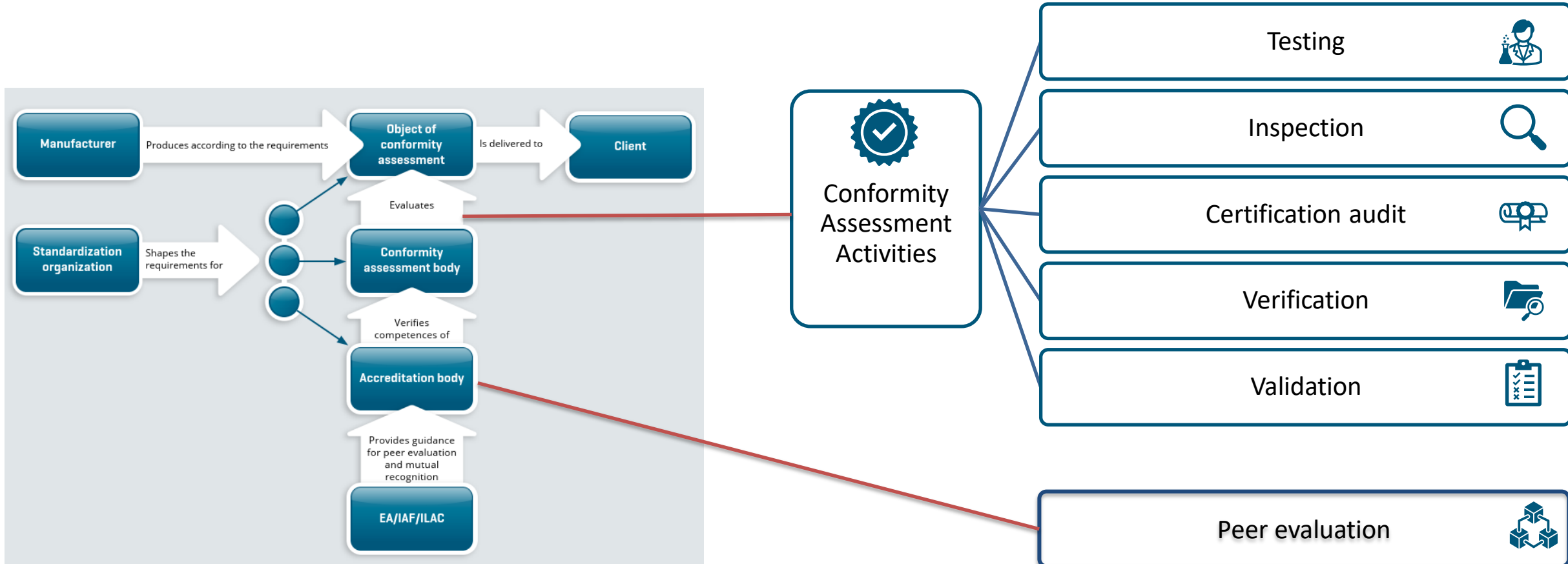**Standardization opportunities in Luxembourg**
- How to access the standards
- How to get involved in standards development
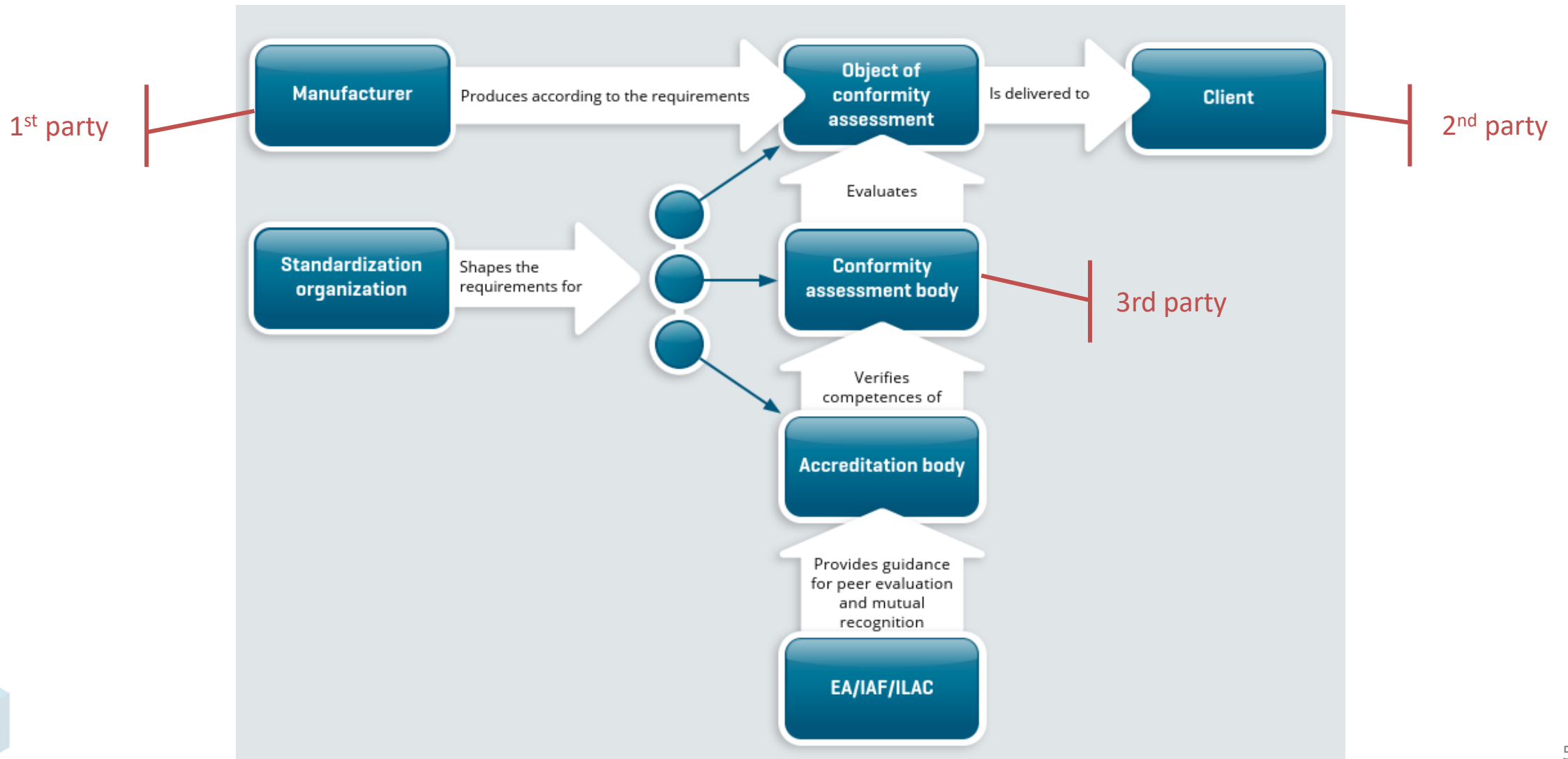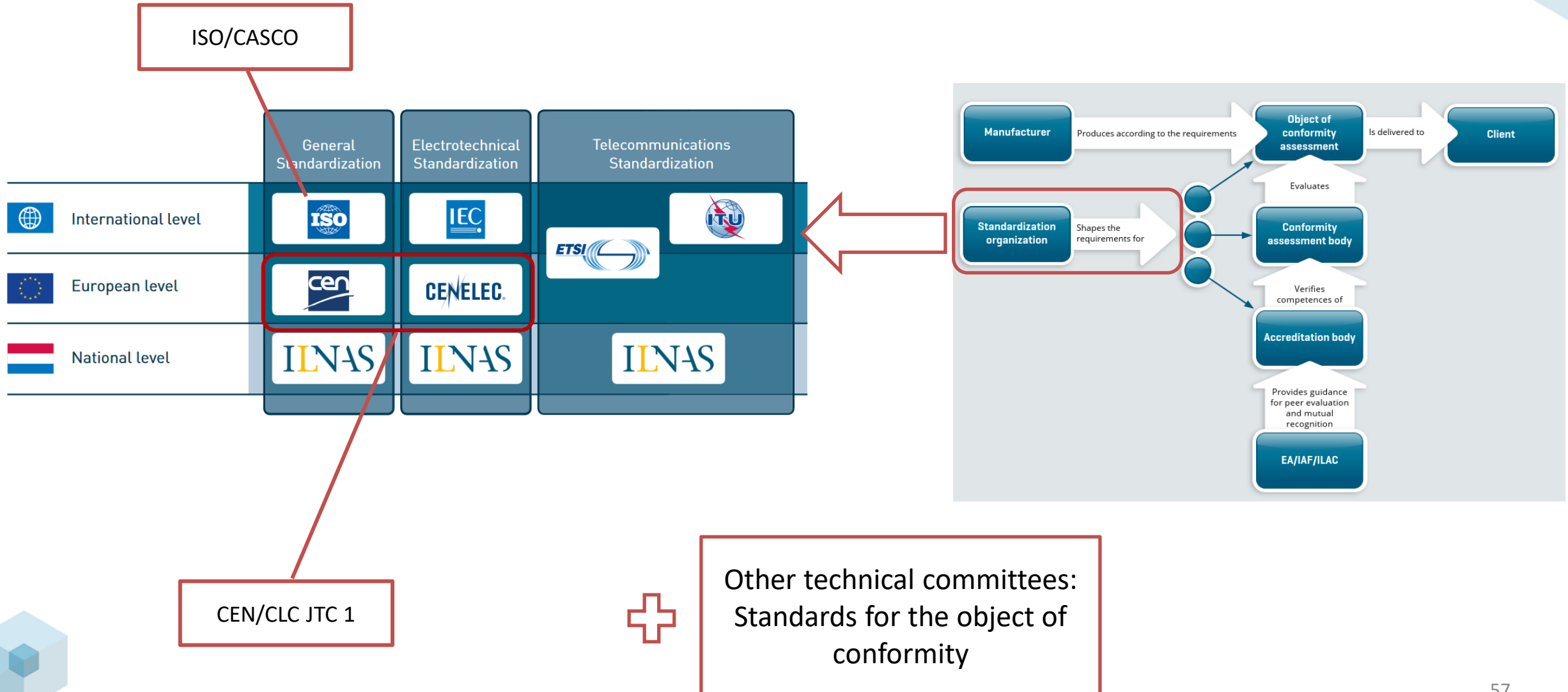
Broad perspective

Narrow perspective

Decision No 768/2008/EC

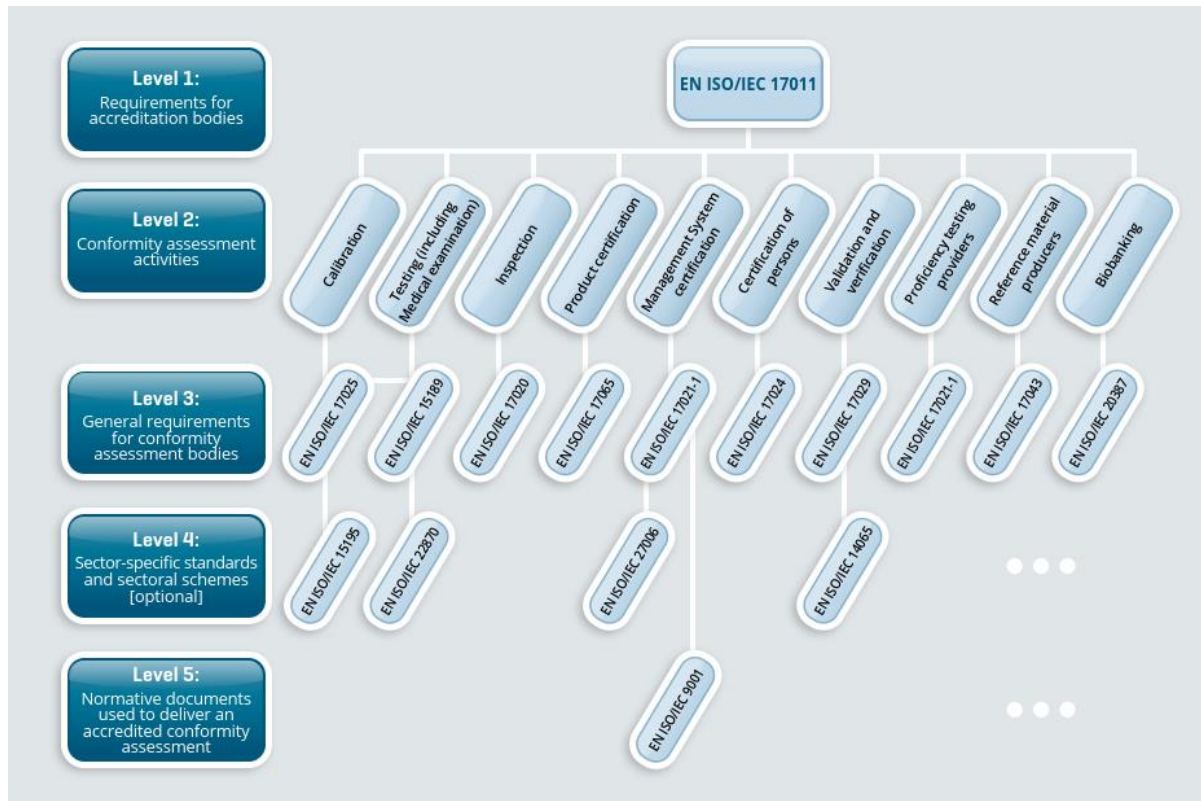- Conformity assessment procedures

Regulation (EC) No 765/2008

- New Legislative Framework: separate legal and technical requirements
- European accreditation infrastructure
    - OLAS – national accreditation body
- Standardization request as regards accreditation and conformity assessment in support of Regulation (EC) No 765/2008

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1st party · 2nd party · 3rd party

ISO/CASCO

CEN/CLC JTC 1
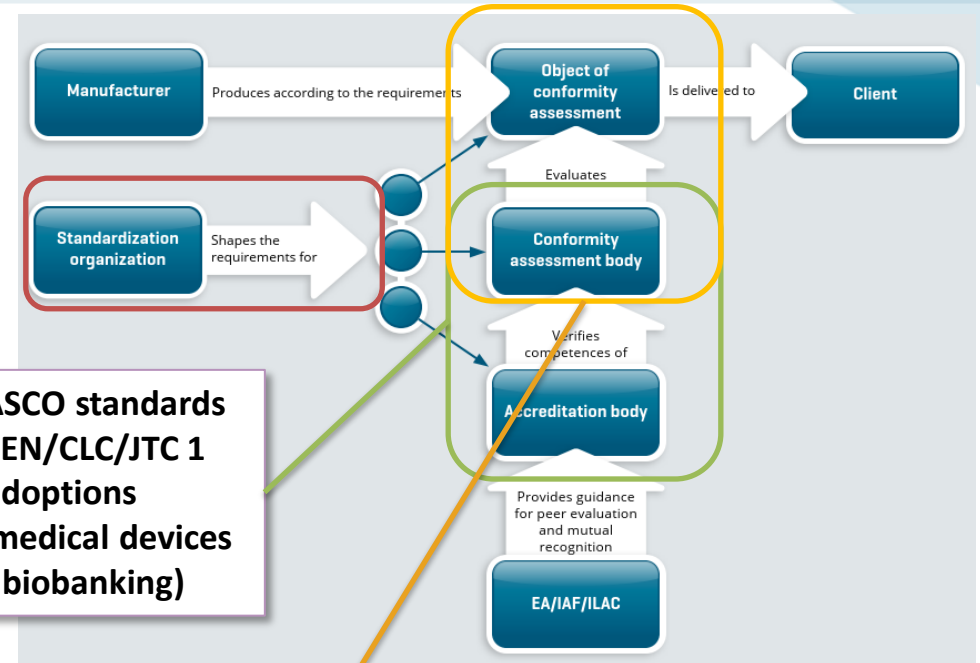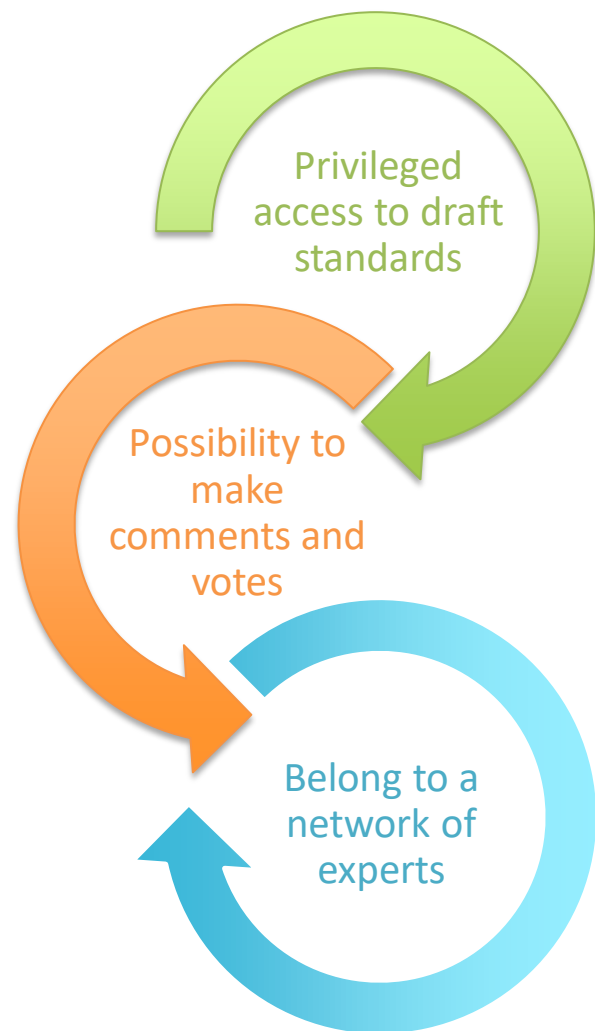
Other technical committees: Standards for the object of conformity

ISO/CASCO standards and CEN/CLC/JTC 1 adoptions (aside medical devices and biobanking)

Other sector-specific technical committees

Privileged access to draft standards

Possibility to make comments and votes

Belong to a network of experts

Consulting and purchasing standards

- Reading stations
- e-Shop

Who can participate?

Open to all socio-economic actors in Luxembourg

Costs of participation?

Registration is free-of-charge

How to register?

Registration is done using ILNAS/OLN/F001a form (Initial registration) or ILNAS/OLN/F001b form (Additional registration).

NSC 02 Conformity
- ISO/CASCO
- CEN/CLC/JTC 1

To conclude

Main takeaways of the conformity assessment report

- **Know the importance of conformity assessment and related technical standards**
  - Understand the ecosystem of conformity assessment
  - Know how conformity assessment benefits from standardization
  - Know who is developing standards related to conformity assessment and accreditation
  - Follow their work, their evolution
  - Join them as delegate to
    - Rework published standards that are under revision
    - Propose new standards and lead projects
    - Shape new standards that are in project form

- **Know what services ILNAS and ANEC GIE can offer to support you**
  - Coach you as a delegate
  - Serve as an interface to submit comments

DON'T HESITATE TO:

- **DIVE INTO THE DOCUMENT!**

- **CONTACT ILNAS or ANEC GIE PROJECT OFFICERS!**

ACCRÉDITATION

CONFIANCE NUMÉRIQUE

SURVEILLANCE DU MARCHÉ

MÉTROLOGIE

NORMALISATION

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