CENELEC

EUROPEAN COMMITTEE
FOR ELECTROTECHNICAL STANDARDIZATION

Drafting for compliance: best practices in standards in support of the Low Voltage Directive (LVD)

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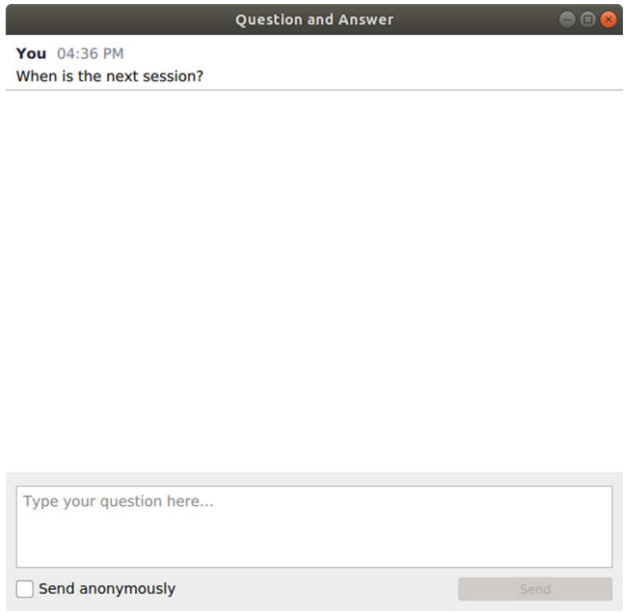


- Talk about us on X, Bluesky or LinkedIn #training4standards

Agenda

10:00	Welcome
10:05	Opening remarks by the European Commission
10:10	Key development processes and drafting reminders (CCMC)
10:20	HAS process overview & sector update (EY)
10:35	Best practices and recurring issues (HAS Consultants)
11:20	Q&A
12:00	End of the webinar

Opening remarks by the European Commission

Anastasios HERACLEOUS (DG GROW – Desk Officer for Low Voltage Directive)

The Low Voltage Directive 2014/35/EU

Drafting for compliance: best practices in standards in support of the Low Voltage Directive – 18 November 2025

DG GROW.H2

Tasos Heracleous

Scope of the Low Voltage Directive (LVD)

- **LVD covers Health and Safety risks:** ensures that a compliant product placed on the EU market is safe
- **Scope:** electrical equipment between 50-1000 V (AC) and 75-1500 V (DC)
- **Exemptions:** lifts; electricity meters; explosive atmospheres; equipment for use on ships, aircraft or railways; domestic plugs and sockets, as well as equipment excluded due to exemptions in other EU legislation (e.g. Machinery, Radio Equipment)

General principles of the LVD

- LVD is a total harmonisation Directive
- Manufacturers shall ensure that products are fully compliant (Technical documentation, Declaration of Conformity, CE Marking)
- Manufacturers are not obliged to be established in the EU
- LVD does not require obligatory testing in recognised laboratories (Notified bodies do not exist under LVD)
- Harmonised standards are voluntary, if applied they provide a presumption of conformity
- Public authorities monitor the compliance

Points of attention as regards LVD

- Use of the CLC Guide 32 ➔ Risk assessment
- References in Annex ZA ➔ complete and dated
- Granularity of Annex ZZ ➔ Only ref to relevant clauses/sub-clauses (safety objectives)
- Multipart standards ➔ ensure that all parts are compliant
- Standards that apply to other/several Directives simultaneously
- Measurement uncertainties ➔ No clause required (if needed - normative)
- Routine tests ➔ They shall never be informative

Thank you

Key development processes and drafting reminders

Frédéric Mlanao, Account Manager at CEN and CENELEC

Innovative Process – homegrown hEN

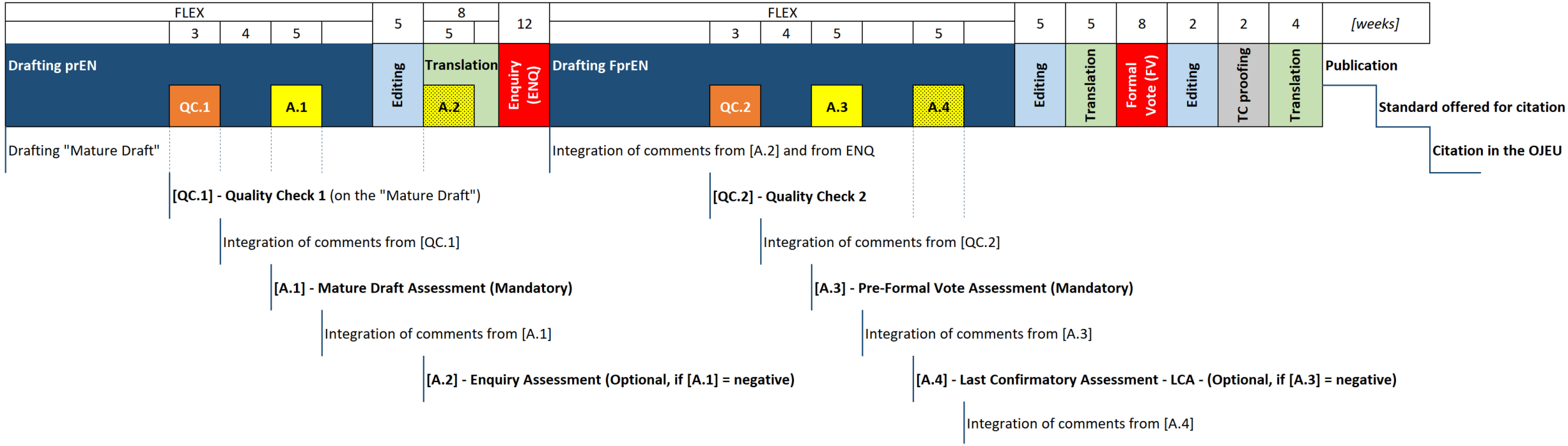
Target: To increase the number of "compliant" assessments and, in fine, the number of standards cited in the OJEU.

Innovative process based on 2 main pillars:

- Mature draft concept
  - Draft ready for ENQ
  - Mature draft assessment **mandatory**
- CCMC Quality Check
  - help Technical Bodies identify elements in the draft, or the related Annexes, that could potentially lead to a lack of compliance assessment
  - Uses Common checklist as support document

Innovative Process – homegrown hEN

Workflow

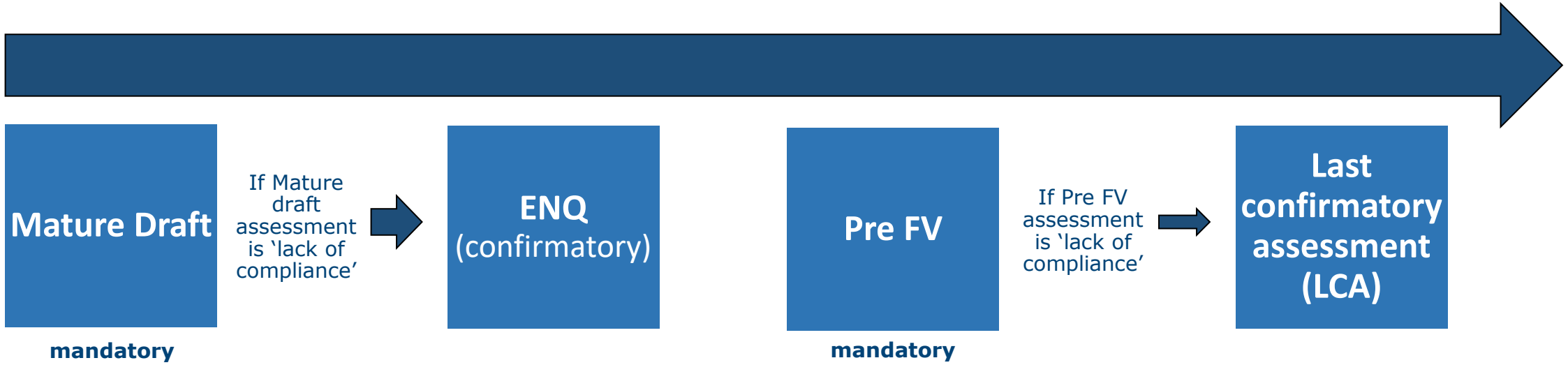


Innovative Process – homegrown hEN

Operational instruction for TC

- Step 1: WG Convenor considers the draft being a “Mature draft” and WG Secretariat sends it to TC Secretary
  - Mature Draft = Draft of an EN, before the stage of submission for the preparation of the enquiry, considered by the TC to be mature on both following dimensions:
    - Reflection of the consensus reached by the working group on the technical content;
    - Compliance to the EC requirements related to harmonized standards (criteria subject to QC and HAS assessment).
  - Attention: Mature Draft is not necessarily the first Working Draft (FWD)
- Step 2: TC Secretary fills in the “Checklist for hEN”
- Step 3: TC Secretary sends the draft and the Checklist **by email** to CCMC HSC (Harmonize Standards Compliance Team, hsc@cencenelec.eu)
- Step 4: CCMC executes the Quality Check [QC.1]
  - Duration = max. 15 working days
- Step 5: HSC sends the Quality Check results to the TC Secretary
- Step 6: TC reviews the draft based on the elements flagged during the Quality Check and submits the updated draft **by email** to CCMC HSC (Harmonize Standards Compliance Team, hsc@cencenelec.eu)
  - Duration = max. 4 weeks
- Step 6: CCMC HSC requests the Mature Draft Assessment [A.1]

When to request an assessment



- Maximum 4 assessments per WI
- LCA: full assessment, should become exceptional
- Not possible to request assessments of published standards

Parallel Projects Process

Key factors for the International Standardization process:

- **Consensus-Building** at European and International level
- **Strong Communication and Coordination** between the European TC and the International TC (specific role for secretaries, convenors and TPM)

For Harmonized ENs

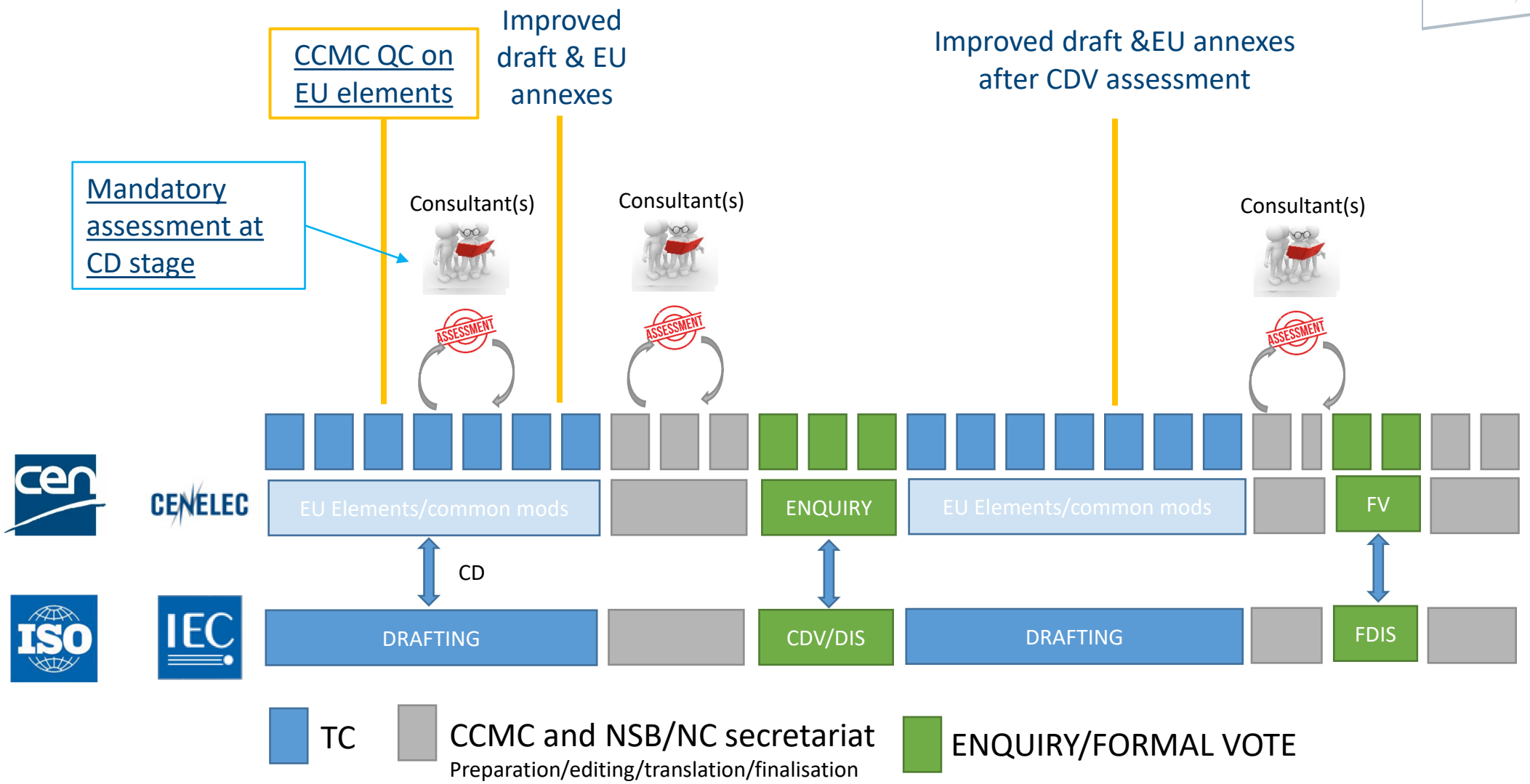
The same Standard applies Worldwide and provides presumption of conformity to the European Legislation

‘New’ Process for Parallel Projects (hENs)

Process intended to:

- Improve timely delivery for parallel ISO/IEC Harmonized Standards
- Avoid blocked draft Standards before Publication
- Minimize interference with International Projects timeframe

‘New’ Process for Parallel Projects (hENs)



Key points for // development

- Start the process as early as possible
  - European TC invited to closely follow work at international level and to develop Annex Z in parallel with CD draft
- 'New' Process will only apply if:
  - CD available
  - European Elements available
- Communication is key
  - Ensure communication flows between CEN-CLC/TC (interaction with the HAS consultants) and ISO-IEC/TC (writing the standard)
- Common checklist not mandatory, but highly recommended when drafting European Annexes

Key drafting reminders

- Perform self assessment using Common checklist
- Draft **clear** and **verifiable provisions**

- Normative References :
  - should be **dated**, **active**, **published** when hEN is made available
  - Recommended to **refer to a specific clause** within the NR (to avoid issues with chains of NRs)

- Use CCMC guidance documents: do your homework ☺

Useful Links

- CEN webinar ‘Drafting harmonized standards - IR3 rules, requirements and normative references’
- Webpage: Drafting European standards for citation in the OJEU
- Guidance document: Guidance on normative references in harmonized standards
- Webinar 'New process for harmonized standards under parallel development’
- Webinar 'Presentation of the new EC/HAS ESOs Common checklist’
- Webinar 'Innovative process for homegrown harmonised standards (hENs)’

HAS process overview & sector update

EY – HAS Support

The better the question. The better the answer. The better the world works.

Shape the future with confidence

Roles & responsibilities, processes and key tasks

Building a better working world

HAS Support Team

Joke Wiercx

Project Manager

Daan Bijwaard

Core Team Leader

Emilia Pauwels

HAS Operations Coordinator

Milko Goossens

Operational Support

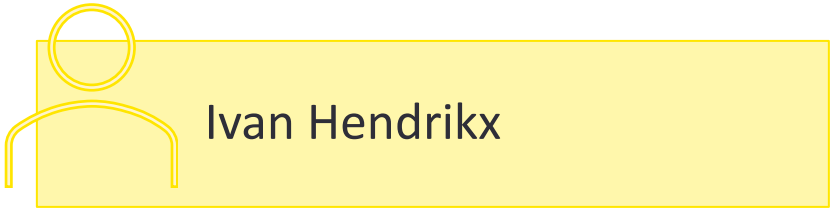
Maciej Korochoda

HAS Operations Executor

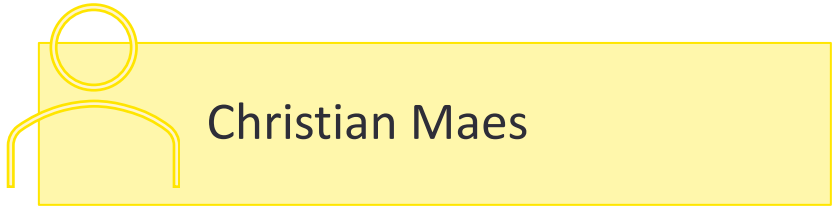
Hanna Falkiewicz

Invoicing Coordinator

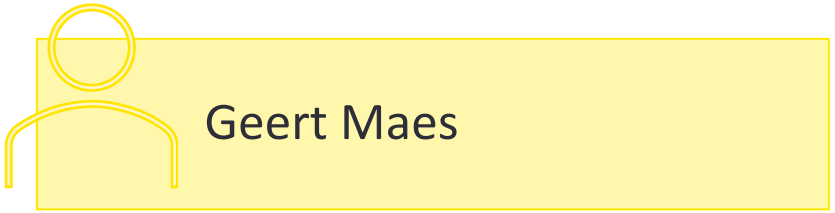
HAS Consultants (LVD Sector)



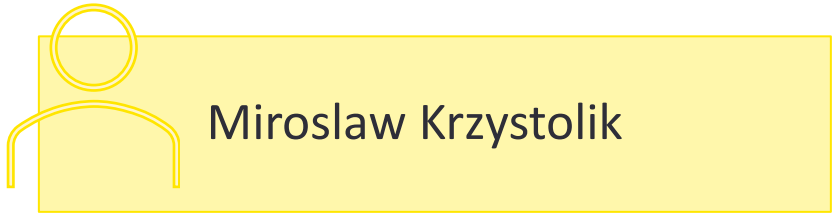
Ivan Hendrikx



Christian Maes

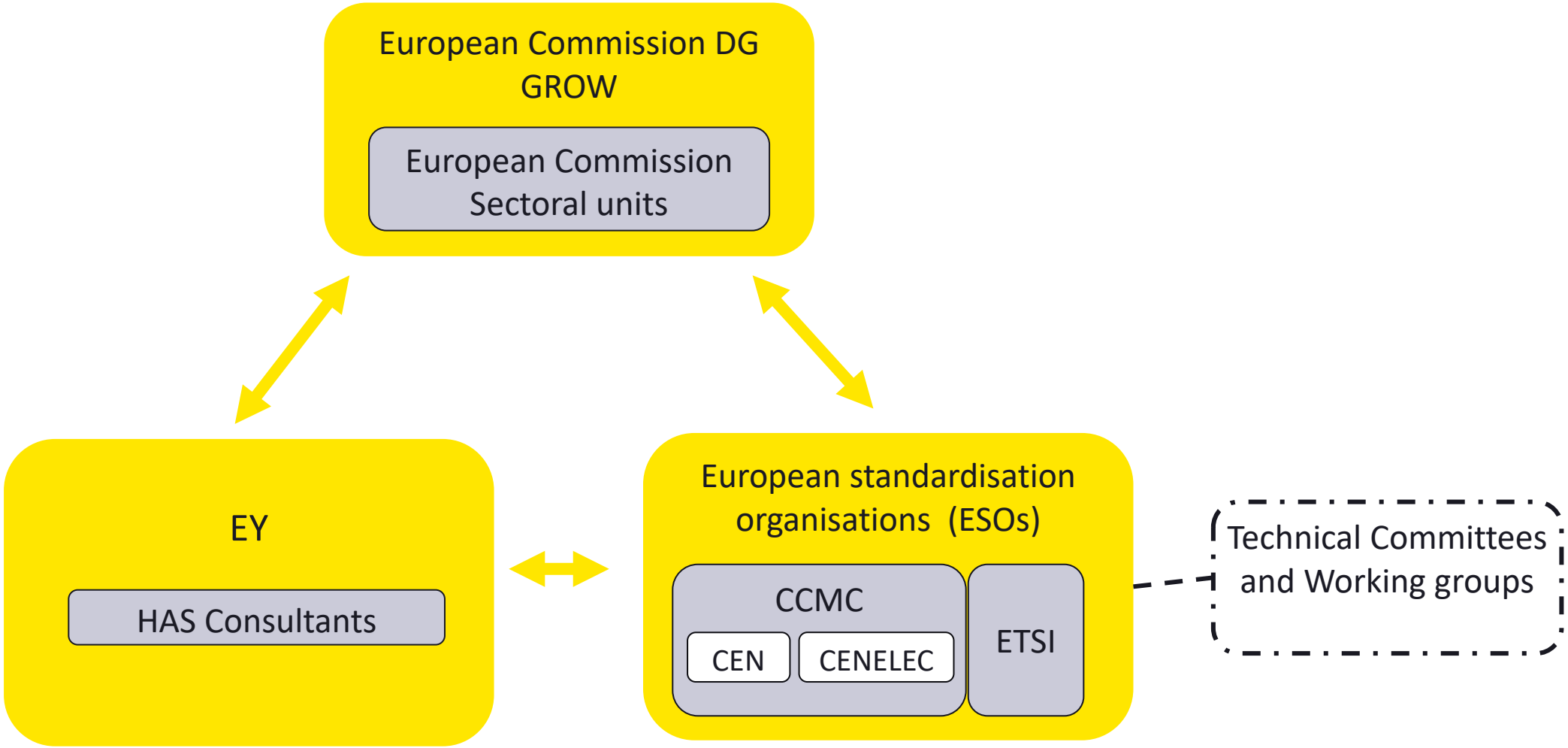


Geert Maes



Miroslaw Krzystolik

Key stakeholders



DGs involved and sectors covered

DG GROW

Unit H.2 Machinery & Equipment

- Equipment for potentially Explosive Atmospheres (ATEX)
- Machinery (MD)
- Measuring Intruments (MID&NAWI)
- Gas Appliances (GAR)
- Lifts (LD)
- Electro-magnetic Compatibility (EMC)
- Radio Equipment (RED)
- Pressure equipment and Simple Pressure Vessels (PED&SPVD)
- Recreational Craft (RCD)
- Protective Equipment (PPE)
- Cableway installations (CWR)
- Low Voltage Equipment (LVD)

Unit F.2 Bioeconomy, Chemicals & Cosmetics

- Explosives for Civil Use (Expl)
- Pyrotechnic Articles (Pyro)
- Toys
- Fertilisers (Fert)

Unit D.3 Market Surveillance

- New Legislative Framework (NLF)

Unit H.1 Construction

- Construction Products (CPR)

Unit I.3 Green and Circular Economy

- Eco Design (ED)

DG SANTE

Unit B.6 -Medical devices, Health Technology Assessment

- Medical Devices (HE)

DG DEFIS

Unit A.1- Defence Industry and Market Policy

- Unmanned Aircraft Systems (UAS)

DG JUST

Unit E.4- Product safety and Rapid Alert System

- General Product Safety (GPSD)

DG MOVE

Unit C.4- Rail Safety and Interoperability

- Interoperability of Rail Systems (IRS)

The HAS project as a Service

Service to the:

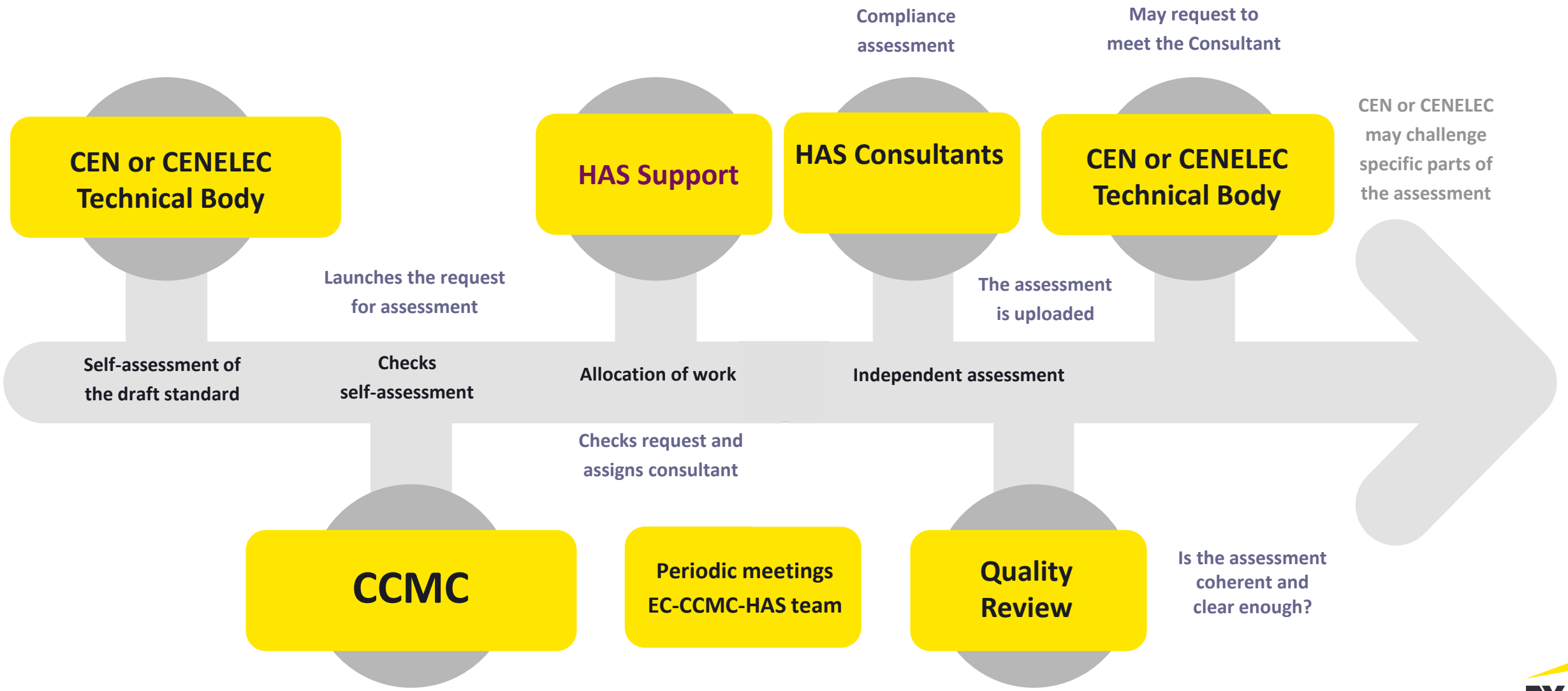
- European Commission
- Technical bodies of the European Standardisation Organisations

Aims to **increase confidence and compliance** of harmonised standards and hence an **increased publication rate of references** in the OJEU

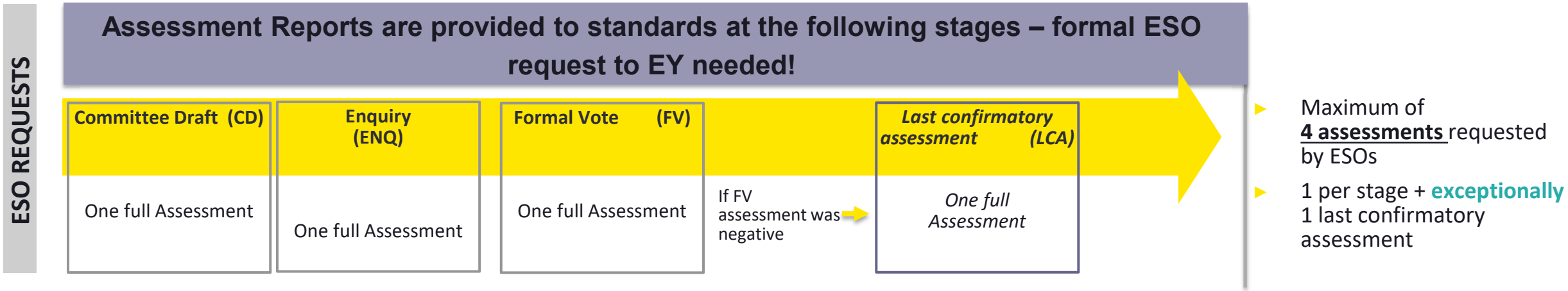
Main features:

- Ensure **typical compliance concerns** are **identified to reduce noncompliance**
- Provide targeted training /support to HAS consultants, ESOs and internal EC services
- Support the EC in its efforts to **reduce the number of non-cited hENs**
- Ensure HAS Consultants tasks and resources are focused and limited to the **assessments of compliance of candidate hENs**

HAS system process overview



When to request and assessment and what to expect?



Recap on role of HAS Consultants:

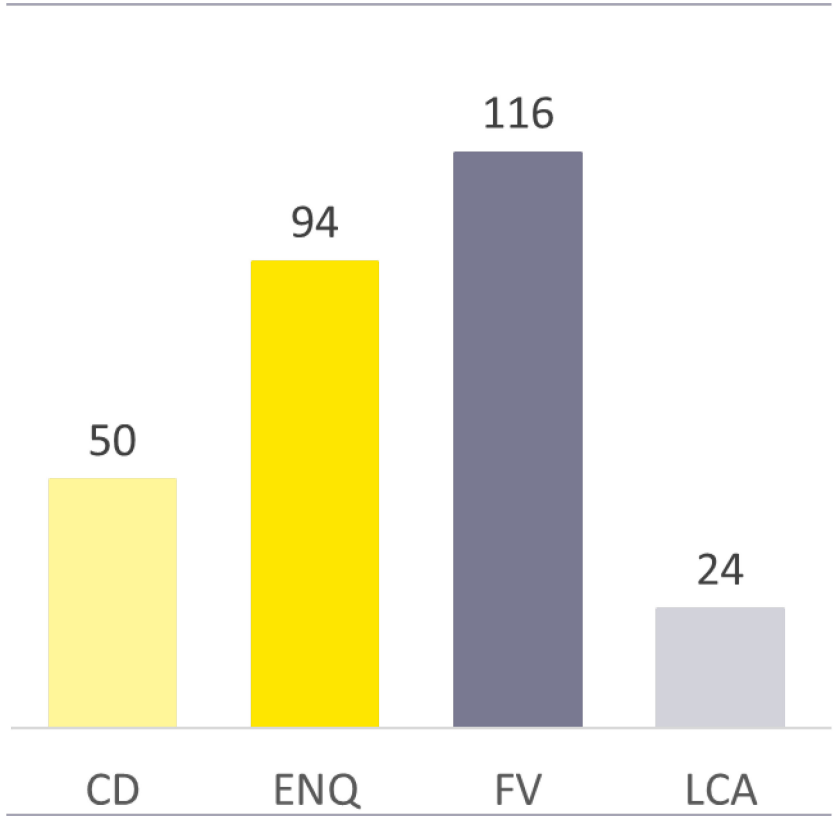
- Perform verification and assessment tasks
- Work in support of but do not represent the Commission
- Convey the Commission's positions to the ESOs or their technical bodies
- Are not allowed to modify their report(s) or assess revised documents during meetings with TCs
- Do not contribute to the standards development process

The EC considers but is not bound by the results of the assessments performed by the HAS Consultants

Update on the progress in the assessment work

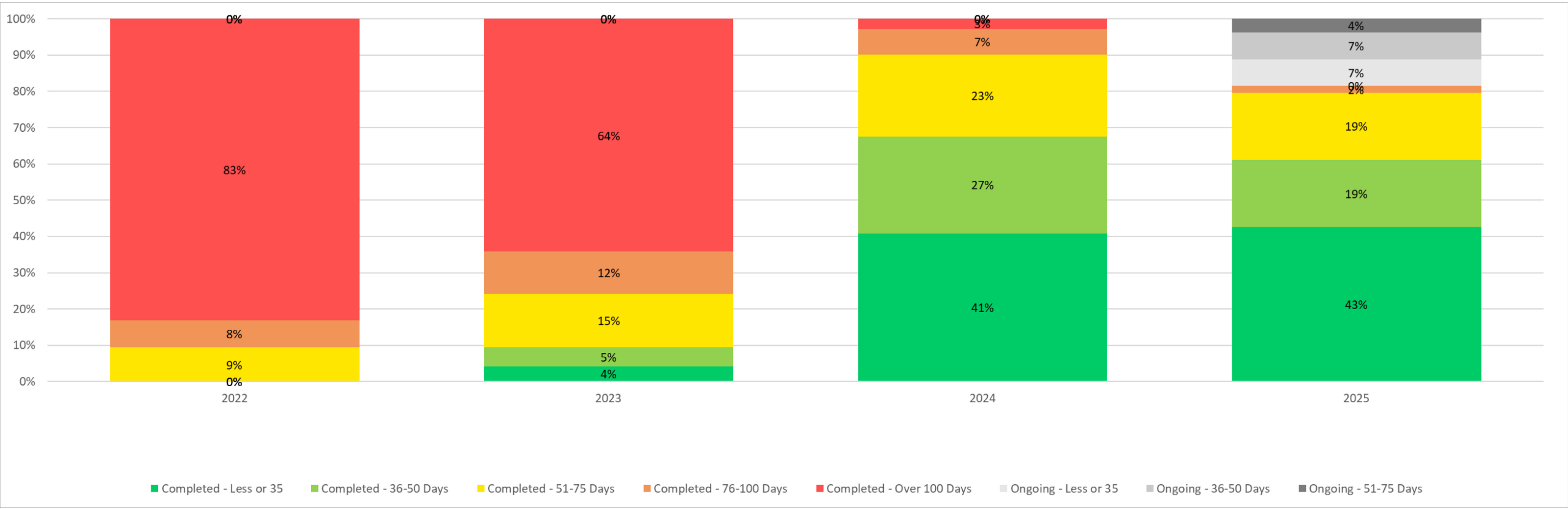
Building a better working world

Stages of assessment requests

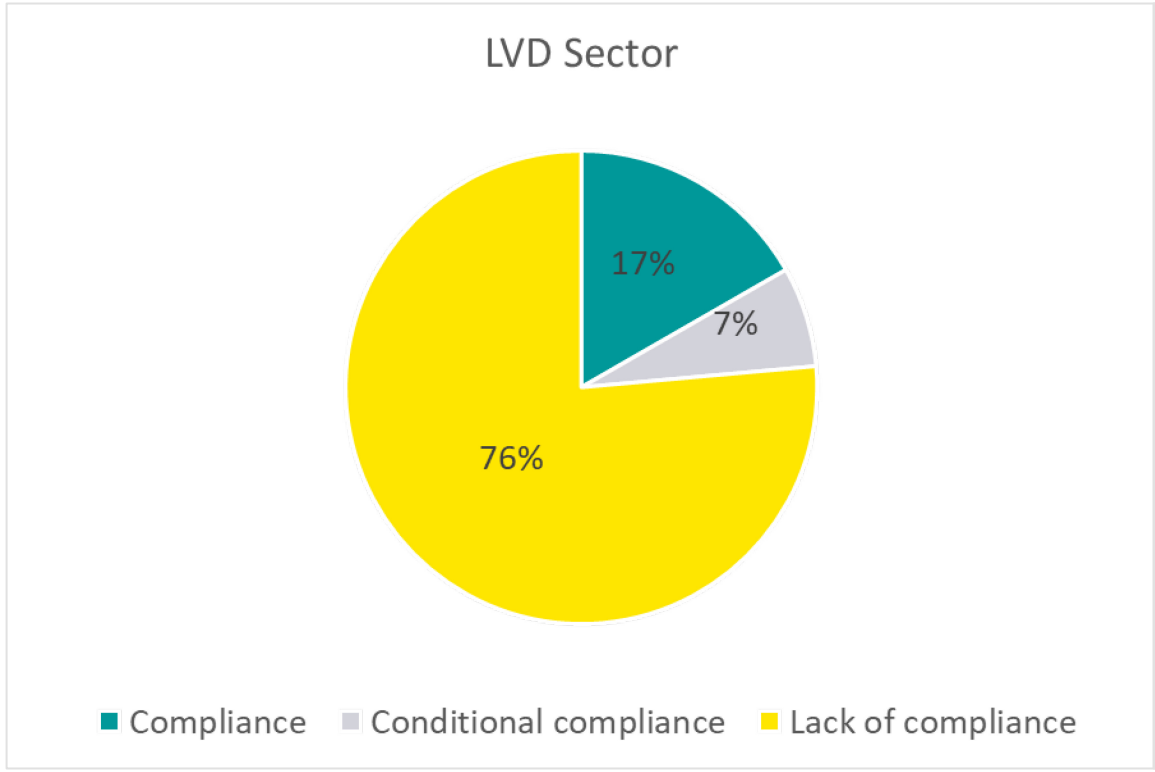


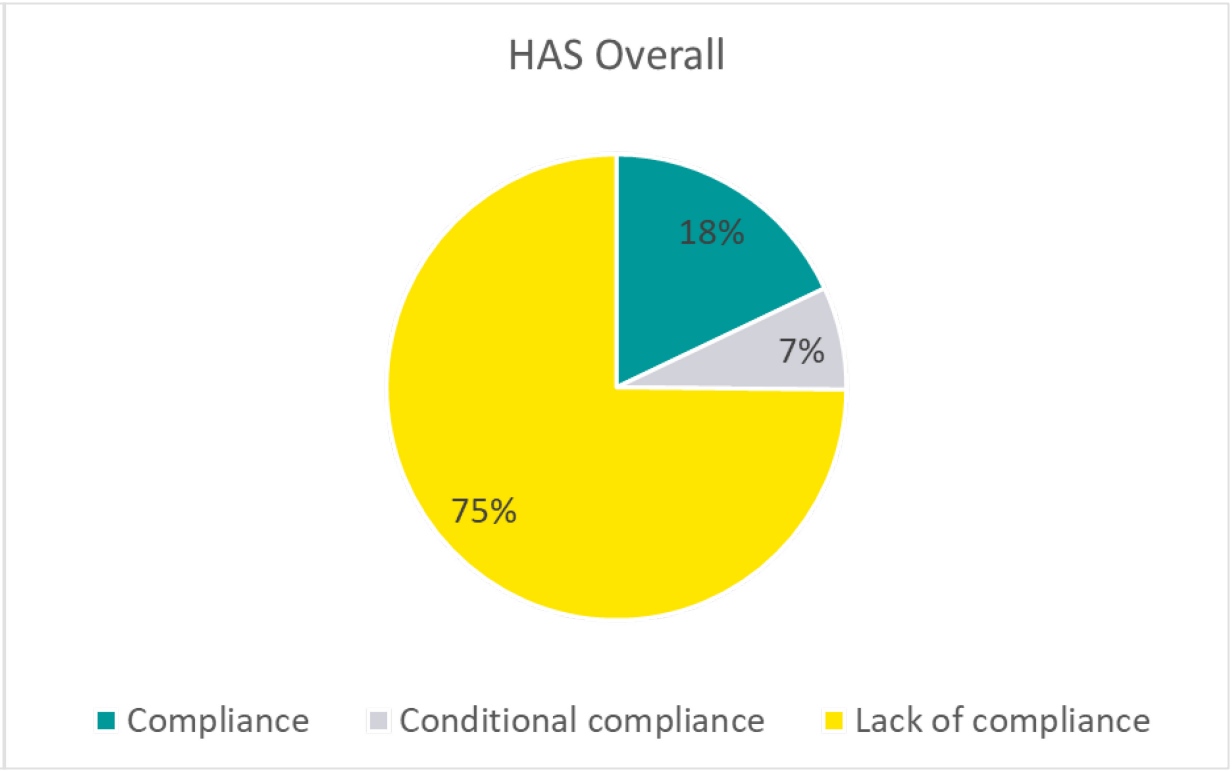
- TCs are **encouraged** to requests an assessment at the **early stages** of drafting (CD and ENQ) to increase the compliance rate at later assessment stages
- In case of lack of compliance, TCs must wait until the **next stage** to submit a new request
- In between two assessments, TCs are encouraged to **request a meeting** with HAS Consultants (to receive clarification on comments received)
- HAS Consultants are **not allowed to modify their report(s)** or assess revised documents during meetings with TCs

Timeliness of assessments (LVD Sector)



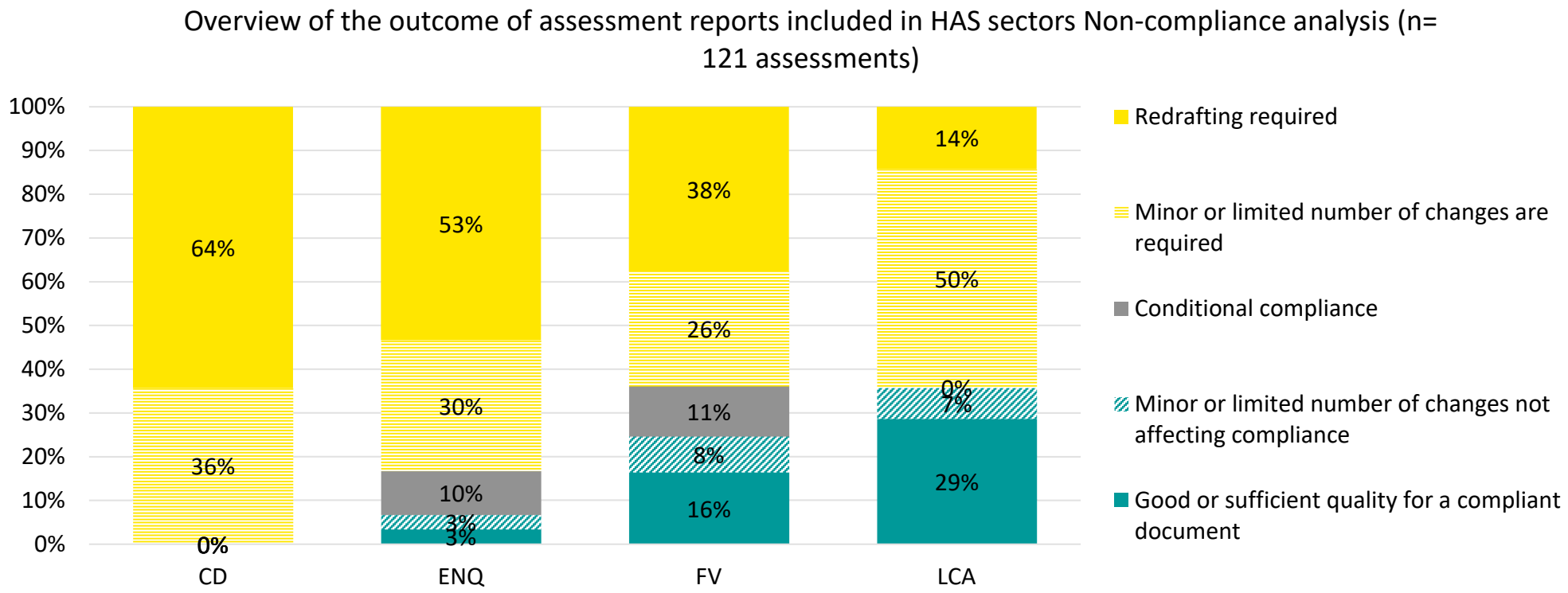
Assessment compliance outcomes*





*Based on 263 LVD assessments completed since October 2023 (using new assessment template).

Share of outcomes by stage of assessment requests in LVD sector



*Based on 14 assessments at LCA, 61 at FV, 30 at ENQ, 14 at CD, and 2 at PUB stages completed since October 2023 (using new assessment template)

Continuous improvement of the HAS system

We learn everyday and have taken a range of steps to further improve the HAS system

AVOID CHANGING CONSULTANTS BETWEEN DIFFERENT ASSESSMENTS AS MUCH AS POSSIBLE

IMPROVED SPEED OF RESOLUTION WHEN DISCREPANCIES IN ASSESSMENTS

IMPROVED COORDINATION BETWEEN CONSULTANTS

INCREASED CONSISTENCY THROUGH GUIDANCE AND TRAINING

STREAMLINED THE PROCESS TO REQUEST MEETINGS WITH CONSULTANTS

INCREASING COMMUNICATION AND MUTUAL LEARNING WITH TECHNICAL COMMITTEES

Meeting requests – best practices

- Meetings adhering the below criteria are encouraged
- Meeting requests should be submitted minimum 4 weeks prior to the meeting date
- A full agenda of the meeting should be provided to allow the HAS consultants to prepare
- Only meetings linked to a previous assessment are allowed under the HAS project
- Physical meetings are possible but subject to approval by HAS Consultants
- Link to meeting tool: **Link**

Reminder on the role of HAS consultants during meetings with TCs

What a HAS Consultant can do

- Convey the Commission's positions to the ESOs or their technical bodies
- Participate in meetings to offer clarifications on their previously completed assessments* (but max. 25% of time is spent on meetings)

*Consultants should check if the harmonised standards are compliant with the legislation. Technical comments on elements not linked through Annex Z are considered as recommendations.

What a HAS Consultant cannot do

- Contribute to standard development process
- Offer guidance to the TCs on how their standards can become compliant
- Perform Assessments on documents received from the TCs/ESOs directly
- Modify completed Assessment Reports
- Participate in meetings without EY approval

Thank you!

If you have any queries or comments, please reach out to:

has.support@be.ey.com

Best Practices and recurring issues

Ivan Hendrikx (HAS Consultant)

18 November, 2025

Agenda

- ✓ LVD Non-Compliance: Top 5 Critical Findings ⚠️
- ✓ Specific technical non-conformities found in candidate harmonised standards under the Low Voltage Directive

LVD Non-Compliance: Top 5 Critical Findings

- Based on **121 non-compliant LVD assessments** since 2023, the following are the top five critical findings:

  - ***B- 1.2.22*** *The Annex ZZ* ***properly relates*** *the relevant legal requirements of EU legislation to the clauses or sub-clauses of the document.*
  - ***B- 1.2.11*** *All the* ***normative references reflect the state of the art*** *(e.g. not withdrawn standards) and have a relevance for the compliance with EU legislation.*
  - ***B- 1.2.17*** *The tests and/or assessment methods* ***are reproducible and appropriate****, and they can be applied to demonstrate compliance with the legal requirements in an objectively verifiable manner the technical specifications in support of the legal requirement, as indicated in Annex ZZ.*
  - ***B- 1.2.20 Risk assessment*** *or identification of relevant risks is* ***available or complete*** *and/or there is evidence that all relevant risks were considered. The document clearly specifies in the Annex ZZ the* ***relevant risks that it does not cover.***
  - ***B- 1.2.9*** *The document contains exclusively* ***dated normative references*** *or, if it does not, there is an accompanying acceptable justification for the use of specific undated normative references.*

1. Annex ZZ and Legal Requirements (41%)

- The most critical finding relates to the **proper linkage between the standard's content and the EU's legal requirements.**

Finding Code	Description	LVD % of non-comp. assessments
B- 1.2.22	The **Annex ZZ properly relates the relevant legal requirements of EU legislation to the clauses or sub-clauses** of the document.	41%

- **Practical Examples of Non-Conformity:**
  - **Missing or Vague Links:** A safety objective from the LVD (e.g., protection against electric shock) is either **not listed in Annex ZZ** or it may not be covered (then this should be clear from the scope and mentioned in the annex ZZ), or is linked generally to an entire section of the standard, not to the **specific**, supporting technical clause **containing a requirement.**
  - **A test method only is not a requirement**. Sometimes **requirement and test are mixed up**. E.g. Clause 4.2 sets as requirement: pass the test in clause 10.3, clause 10.3 then reads 'test as follows…, acceptance when…'. Tests and requirements should be separated if possible, to make clear what is a requirement and therefore shall be referenced in Annex Z.

1. Annex ZZ and Legal Requirements (41%)

- **Practical Examples of Non-Conformity: (continued)**

  - **Incorrect Mapping:** Annex ZZ incorrectly maps an LVD safety objective to a clause in the standard that addresses only a **minor or peripheral aspect** of that requirement, instead of the core technical solution.

2. Normative References and State of the Art (36%)

- Issues with the quality and relevance of standards referenced within the document are a frequent cause of non-compliance.

Finding Code	Description	LVD % of non-comp. assessments
B- 1.2.11	All the **normative references reflect the state of the art** (e.g., not withdrawn standards) and have a **relevance for the compliance with EU legislation**.	36%

- **Practical Examples of Non-Conformity:**
  - **Use of Withdrawn Standards:** The standard references an older, **withdrawn, or superseded** international standard (e.g., an IEC standard), meaning the document's requirements do not reflect the current *state of the art*.
  - The reference **needs to be specific**, i.e. points to a specific clause (or clauses) of the NR to be applied, rather than making the whole NR applicable.
  - To avoid **misuse of Annex ZA**. Annex ZA is not intended to add new references introduced in e.g. an amendment. New NRs shall be included in clause 2 of the amendment.
  - **Irrelevant References:** The document includes a normative reference to a standard that is **not actually required** to prove compliance with the LVD essential requirements, adding complexity without supporting the legal basis. References for information should go in bibliography.

3. Test/Assessment Reproducibility (33%)

- Non-compliance is often rooted in **inadequate or unverifiable methods** for demonstrating product compliance.

Finding Code	Description	LVD % of non-comp. assessments
B- 1.2.17	The **tests and/or assessment methods are reproducible and appropriate,** and they can be applied to **demonstrate compliance with the legal requirements in an objectively verifiable manner** the technical specifications in support of the legal requirement, as indicated in Annex ZZ.	33%

- **Practical Examples of Non-Conformity:**
  - **Ambiguous Test Criteria:** A test method specifies equipment or procedure parameters using **vague language** (e.g., "apply adequate pressure," or "test until failure is observed") without defining measurable, objective criteria, making the test results impossible to reproduce reliably.
  - **Missing Acceptance Criteria:** A requirement is set, but the corresponding clause fails to define the **clear pass/fail criteria** (e.g., maximum permissible temperature rise or minimum dielectric strength value) necessary for an objective assessment.
  - Selection of **alternative test method**s to be avoided. There should be only **one single reference test method** identified. Often this is associated to the manufacturer, where it is overlooked that other actors such as MSAs or testing houses will use the standard too.

4. Dated Normative References (31%)

- The use of **undated references** presents a moving target for compliance and must be strictly justified.

Finding Code	Description	LVD % of non-comp. assessments
B- 1.2.9	The document contains **exclusively dated normative references** or, if it does not, there is an accompanying **acceptable justification** for the use of specific undated normative references.	31%

- **Practical Examples of Non-Conformity:**
  - **Undated Reference without Justification:** The standard uses an **undated reference** (e.g., "IEC 60384-14") which implies the use of the latest edition. Without specific justification (e.g., that only the latest edition is relevant), this prevents legal certainty, as a manufacturer may comply with one edition while a subsequent one is legally required.
  - **Lack of Justification:** The document uses an undated reference, and the justification provided (e.g., in the Foreword or Introduction) is **not deemed acceptable** or does not exist, leaving users unclear on the exact version to use for compliance.
  - As a reminder, IR3, clause 10.4 states that undated references are **only allowed if 3 conditions are simultaneously met**. An undated reference creates a "dynamic" link, meaning a new, unassessed edition of the referenced document could change the requirements and break the legal presumption of conformity.

5. Risk Assessment Completeness (31%)

- A full and documented consideration of **all relevant risks** is mandatory for harmonized standards.

Finding Code	Description	LVD % of non-comp. assessments
B- 1.2.20	**Risk assessment or identification of relevant risks is available or complete** and/or there is evidence that all relevant risks were considered. The document clearly specifies in the **Annex ZZ the relevant risks that it does not cover**.	31%

- **Practical Exa**
  - **Unaddressed Foreseeable Risks:** The standard focuses only on basic electrical risks but **fails to address reasonably foreseeable risks** for the product, such as the risk of fire from an internal component fault or risks associated with predictable user misuse, as required by the LVD. It can be that the safety objective or risk is not addressed, then this should be clear from the scope and Annex ZZ.
  - **Annex ZZ Omission:** in case the standard is intentionally limited in scope (e.g., only covering a power supply for building in, not the final equipment). However, **Annex ZZ does not clearly state which specific risks** related to the LVD (e.g., accessibility of hazardous parts in the final assembly) **it does *not* cover**.

Specific technical non-conformities found in candidate harmonised standards under LVD

1. Leakage current versus touching current and PE current

- **Current Measurement Terminology and Scope**

  - Standards still refer to the ambiguous term **"leakage current"** instead of the precise terms defined in IEC 60990: **"touch current"** and **"protective conductor current"**.
  - Furthermore, some product safety standards fail to consider measurement methods for **non-sinusoidal** currents (d.c. and a.c.) which are relevant when using controls with switching devices.

2. Inadequate test specifications

- **Transient Voltage Testing:**
  - Standards often do not provide the **internal impedance** for a 1.2/50 microsecond transient generator, which compromises the reproducibility of the test results.

- **Measurement Uncertainty (MU):**
  - Standards generally fail to define the necessary pass/fail criteria, limits, and tolerances for the covered appliances, incorrectly assuming that IEC Guide 115 is sufficient

3. Functional safety and electromagnetic disturbances

- **Neglect of Functional Safety and Environmental Factors**:
  - Technical Committees (TCs) often assume that electromagnetic disturbances are covered by the EMC product standard, overlooking the need for requirements in their HSs to ensure **safe functioning** of equipment is **not compromised** by electromagnetic interference (EMI)—known as **Functional Safety**.
    - A practical case is a toaster with a built-in electronic timing circuit, which if not well designed, the timing cycle may be extended by transients on the mains and **cause the bread in the toaster to ignite**. Testing has shown that it takes about **5-7 minutes to ignite the bread**, which could lead to a **risk of fire**. This potential hazard has been dealt with in the **Opinion of EC dated 4/12/2002**.

4. Unrealistic temperature and user requirements

- **Touch Temperature**:
  - Standards often define temperature hazards as **rise values** against a 25 degrees C ambient but burns happen at absolute temperatures. TCs must demonstrate compliance with guides that consider burn thresholds and contact periods.

- **Consumer Issues:**
  - Instructional requirements are frequently too **technical** or contain **unrealistic requirements** (e.g., constant supervision of children) that consumers cannot practically follow, potentially leading to foreseeable risk.

Thank you!

Questions?