The process of standardisation

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32nd Cold Spray Club
27 June

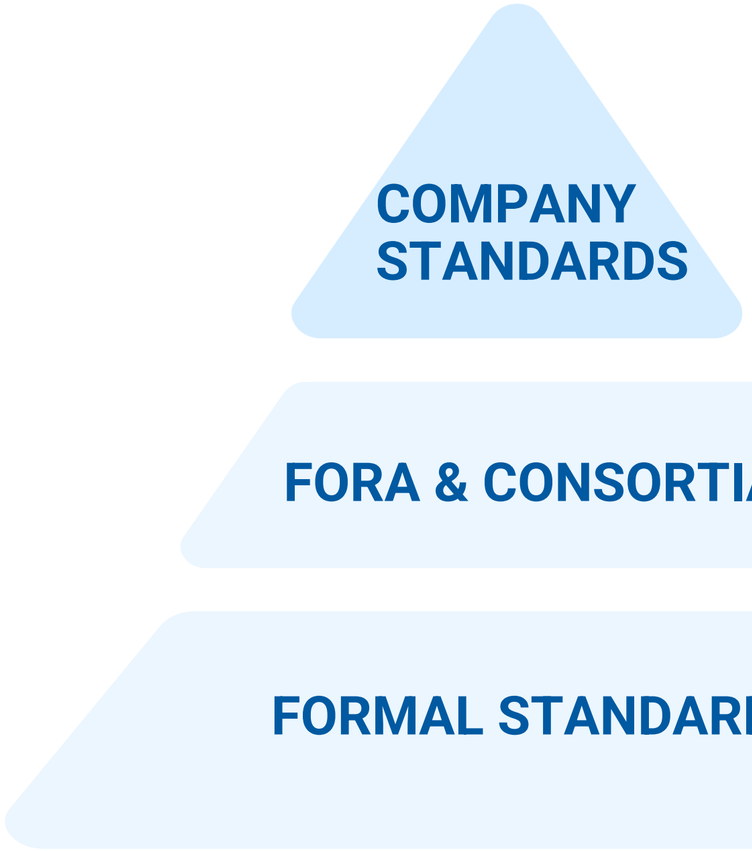
Small Business Standards

WHO I AM

Maitane OLABARRIA

- Secretary General, Small Business Standards (SBS) since January 2020 focusing on the representation of European SMEs in (European+international)standardisation
- Previously worked 11 years at CEN (European Committee for Standardisation) and 3 years at CECIMO (European Machine tool industry association)
- 20+ years experience in European policy & standardisation

TYPES OF STANDARDS



Internal specifications (e.g. for quality control or in-house processes)

Developed by industry groups often used in fast-moving tech sectors

Adopted by recognised standards bodies reflecting wide consensus

IMPORTANCE OF MOVING FROM PROPIETARY PRACTICES TO BROADLY ACCEPTED FORMAL STANDARDS FOR SCALABILITY & TRUST

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WHAT IS A STANDARD?

- A voluntary technical document designed to be used as a rule, guideline or definition.
- An agreed repeatable way of doing something.
- They can define common terminology, requirements for products and services related to safety, performance, quality, test & measurement methods, define processes to reach specific goals….
- Created by bringing together all interested parties such as manufacturers, users, users and regulators of a particular material, product, process or service.

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STANDARDS & CONFORMITY ASSESSMENT

- Standards define the technical and quality requirements a product, process or service should meet.

- Conformity Assessment is how we check whether those requirements are met — through testing, inspection, certification, etc.

- **CONFORMITY ASSESSMENT CAN BE**:
    - **FIRST PARTY:** self-declaration made by manufacturer or service provider
    - **SECOND PARTY:** declaration made, for example, by the client of the supplier
    - **THIRD PARTY (e.g. certification):** declaration made by independent organisation

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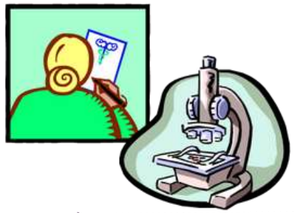
CLAIMS OF CONFORMITY ASSESSMENT

+

Object

Requirements

Test done by:	Attestation type
 1st party (the manufacturer, service provider)	Self-declaration of Conformity)
 2nd party (the purchaser, the client)	Contract
 3rd party - independent (certification body, laboratory, inspection body...	Certificate

3rd party bodies can be accredited

WHO DEVELOPS STANDARDS?

International

ISO

IEC

ITU

Regional (European)

CEN

CENELEC

ETSI

National

Austria
Austrian Standards
OVE

Belgium
NBN
CEB BEC

Bulgaria
BDS

Croatia
HZN

Cyprus

Czech Republic
ÚNMZ

Denmark
DS

Estonia
EVS

Finland
SESKO

France
afnor

Germany
DIN DKE

Greece
EAOT

Hungary
MSZT

Iceland
IST

Ireland
NSAI

Italy
UNI

Latvia
LVS

Lithuania

Luxembourg
ILNAS

Malta
MCCAA

Netherlands
NEN NEC

Norway
standard norge NEK

Poland
PKN

Portugal
IPQ

Republic of North Macedonia

Romania
asro

Serbia
DIS

Slovakia
SLOVAK OFFICE OF STANDARDS, METROLOGY AND TESTING

Slovenia
SIST

Spain
UNE

Sweden
SIS SVENSK ELSTANDARD

Switzerland
electro suisse

Turkey
TSE

United Kingdom
bsi.

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COOPERATION BETWEEN STANDARDS BODIES

ISO & CEN also cooperate with other standards developing organisations in some specific areas (e.g. ISO cooperation with ASTM in relation to additive manufacturing)

ALLOWS FOR THE DEVELOPMENT OF COMMON EUROPEAN AND INTERNATIONAL STANDARDS

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HOW TO PARTICIPATE IN CEN/ISO?

Manufacturers, users, public authorities, consumers, researchers, NGOs…

NATIONAL MIRROR COMMITTEE

Agrees on common national position

TECHNICAL COMMITTEE

PLENARY
NATIONAL DELEGATIONS
(Voting rights)
Takes decisions

WORKING GROUPS

EXPERTS
(drafting work)

LIAISON ORGANISATIONS
- Without voting rights in Plenary
- Can nominate experts in WG

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STAGES IN STANDARDS DEVELOPMENT

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PROPOSAL

- **Anyone can submit a proposal** to develop a standard (or revise an existing one). Normally through National Standards Body or liaison organisations, also legislators at European level (Standardisation request)
- New work should be proposed to:
  - **Relevant Technical Committee** (TC) dealing with the subject (if it exists)
  - To the **relevant Standards organisation** (if a TC does not exist)

- **Proposals are assessed and submitted to consultation among the national standards bodies** (who consult national stakeholders) to assess:
  - Market relevance, need of proposed standard and stakeholder support
  - Availability of resources to be able to develop the standard

- **Forms** to submit a proposal:CEN/CENELEC and ISO (Form 4) NWI Proposal Forms, CEN/CENELEC and ISO (Form 1) new field of activity forms

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ENQUIRY

- Open consultation of draft standard via National Standards Bodies

- Anyone should be able to provide feedback on adraft standard –In Europe often through **national online portals** where comments can also be submitted (these are normally validated by the National mirror committee before submitting it to the relevant CENor ISO Committee)

- **They are then sent to the relevant Technical Committee** that will **review them and modify the draft standard** if needed

- **Enquiry is accompanied by a vote (qualified majority)** to check possible acceptance of the draft --- If no technical comments are received and necessary majority achieved, the standard may then be adopted

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APPROVAL AND PUBLICATION

- **If the Technical Committee introduces technical changes** into the draft standard then a Formal vote (qualified majority) on the final draft will take place
- In the case of **European Standards** National Standards Bodies will have to **adopt the European Standard as national standard and withdraw conflicting ones;**
- International Standards developed **DO NOT carry out an obligation** for National Standards Bodies to **implement them as national standards**

EUROPEAN STANDARDS ARE ADOPTED IN 34 COUNTRIES AS IDENTICAL NATIONAL STANDARD

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REVIEW

- Standards are reviewed regularly – at least every 5 years (but it can also be done earlier)
- Outcome of the review can be:
  - Confirmation of the standard
  - Need for modification or revision
  - Withdrawal of the standard
- If a need for revision is identified the process starts from the beginning

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OTHER DELIVERABLES

- But Technical Committees can also **deliver other documents than European/international Standards**
  - **Technical Specifications (TS),** used in areas under technical development or where consensus cannot be achieved yet
  - **Technical reports (TR),** informative nature

- These documents have a lower level of consensus than European/international Standards:
  - No need for public enquiry
  - In Europe NO adoption at national level
  - Adopted by lower qualified majority (TS) or simple majority (TR)

HARMONISED STANDARDS

- A subset of European standards
- Harmonised standards are voluntary
- Developed following a request from the European Commission
- Support implementation of European Directives and Regulations (Machinery Regulation, Pressure Equipment Directive, ATEX…)
- References of harmonised standards are published in the EU Official Journal

IF YOU FOLLOW HARMONISE STANDARDS, IT IS ASSUMED YOU MEET THE REQUIREMEN OF THE RELATED EU LAW

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POSSIBLE RELEVANT TCs

- **ISO/TC 261 – Additive Manufacturing (works in close cooperation with ASTM F42 and CEN/TC 438)**
  The main TC responsible for standardisation in additive manufacturing including terminology, processes, test methods, quality parameters,data formats…

- **ISO/TC 107 – Metallic and other inorganic coatings (works in close cooperation with CEN/TC 262 "Metallic and other inorganic coatings, including for corrosion protection and corrosion testing of metals and alloys" & CEN/TC 240 "Thermal spraying and thermally sprayed coatings)**
  Standardises the characteristics of protective and decorative metallic and non-metallic inorganic coatings applied to metal surfaces by electrolysis, fusion, vacuum, chemical, or mechanical means. It also develops standards for testing and inspection methods for these coatings, as well as for substrate preparation prior to deposition.

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THANK YOU!

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Financed by the European Union and EFTA