Getting involved in Healthcare Standards

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About NSAI

Standards

Certification

Legal Metrology

National Metrology Laboratory

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What is a Standard ?

"A technical specification adopted by a recognized standardization body for repeated or continuous application with which compliance is not compulsory"

European regulation on standardization 1025/2012

Benefits of Standards

- Assist trade by eliminating technical barriers

- Promote interoperability of products and services

- Promote new technologies and good practices

- Increase safety of products and protect consumer, environment, health and safety etc

- Assist with compliance with legal obligations

Standards supporting regulations

<u>Harmonised Standards</u>

"A harmonised standard is a European standard developed by a recognised European Standards Organization (CEN, CENELEC, ETSI). It is created following a request from the European Commission to one of these organizations. Manufacturers, other economic operators or conformity assessment bodies can use harmonised standards to demonstrate that products, services or processes comply with relevant EU legislation"

Harmonised standards & Regulations

Manufacturers responsible for product safety
& "placing on the market"

Harmonised Standards support:
- European single market
- CE Marking of products
- Different product sectors – Healthcare engineering

  - MDR (18 Harmonised to date)

  - IVDR (11 Harmonised to date)

Health data - EHDS regulation - new
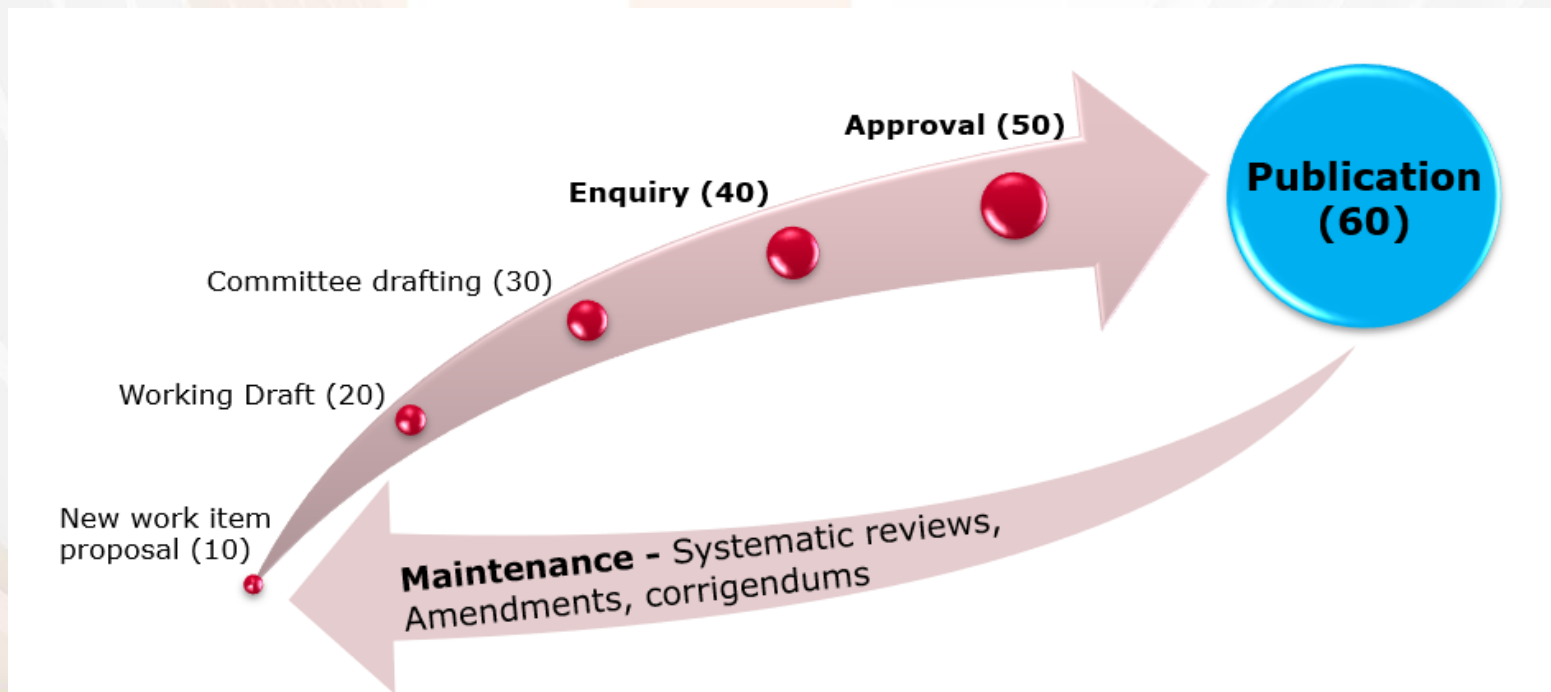
Types of Standard Deliverables

Type of Deliverable	CEN/CENELEC	ISO/IEC
Standard – EN/ISO	**EN** – Normative, adopted by CEN-CENELEC, obligation of national implementation & withdrawal of conflicting national standards – consensus achieved	**ISO/IEC** – Normative, approved by members, consensus on rules, characteristics or results for optimum order in a given context – consensus achieved
Technical Specification - TS	**CEN TS** – Normative, Topic still developing, future possibility of agreement on a European Standard- not full consensus	**ISO TS** – Normative, topic under technical development – possibility of a future International standard – not full consensus
Technical Report - TR	**CEN TR** – Informative material not suitable to be published as an **EN** or a **TS** e.g. data on the "state-of-the art", data obtained from a survey etc	**ISO TR** - Informative - data or information on perceived "state of the art" e.g. informative report or survey results.

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Standard Development Process - ISO

Standard Development Organisations (SDO) - Member Bodies (MB)

CEN Members	CENELEC Members	ISO Members	IEC Members
34 Member Bodies CEN Community - List of members (cencenelec.eu)	34 Member Bodies CENELEC Community - List of members (cencenelec.eu)	Over 160 Member Bodies ISO – Members	Over 80 Member Bodies National Committees | IEC
Technical committees CEN - List of CEN Technical Bodies (cencenelec.eu)	Technical committees CENELEC - List of CENELEC Technical Bodies (cencenelec.eu)	Technical Committees ISO - Technical Committees	Technical committees Technical committees and subcommittees | IEC

Health sector – NSAI National committees

Health Sector topic	International Technical Committees	NSAI National Committees
Medical devices/ IVD	**ISO/TC 210, CEN/CLC JTC 3, -** Quality and risk management, labelling – **ISO/TC 150 -** Implants for surgery **ISO TC 194 & CEN/TC 206 -** Clinical evaluation & biocompatibility **ISO/TC 198 & CEN/TC 204 -** Sterilisation & packaging **ISO/TC 212 & CEN/TC 140 -** In-vitro diagnostics **IEC/TC 62 -** Medical equipment, software and systems	**NSAI TC 5 –** Healthcare Standard Committees **NSAI ETC/TC 10 – Electrical equipment in medical practice**
Health Informatics	**ISO/TC 215 & CEN/TC 215**	**NSAI/TC 21 –** Health Informatics
Healthcare	**ISO/TC 304 -** Healthcare Organization management, **CEN/TC 403 –** Aesthetic surgery services **CEN/TC 470 –** Quality along the patient pathway in medical imaging	**NSAI/TC 152 -** Healthcare services
Biotechnology	**ISO/TC 276 -** Biotechnology	**NSAI/TC 62 -** Biotechnology

New standard developments topics

- Additive manufacture – implants
- Artificial intelligence – risk management
- Machine learning enabled medical devices- performance evaluation
- Health devices and health apps
- Personalised digital health & digital therapeutics health software
- Organ on chip – CEN Focus group

Take away message

Contact Member Body (MB) in your country to:

- research what exists - *Published standards*
- check what is being worked on - *Work programme of international TC's*
- review new areas of standard development – *pre standard work, NWI, CWA's etc*
- find out about National committee membership – *national mirror committees & contributing at national level*
- engage in TC's at ISO/IEC & CEN/CENELEC - *International committee participation*
- identify possible New Work Items (NWI) for standard development – *Research outputs as Standard deliverable.*

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