IMDRF International Medical Device Regulators Forum

Ensuring patient safety: Development & application of medical devices standards

Lena Cordie-Bancroft
Sector Lead – Medical Devices
BSI

What is a Standards Development Organisation (SDO)?

An organization responsible for **developing, publishing, and maintaining** technical standards for specific industries, technologies, or sectors.

Some SDOs operate independently, while others are linked to – or designated as – a national standards body or government agency.

Examples of SDOs:

- ISO – international standards across multiple industries
- IEC – electrical and electric technologies
- ASTM – materials, products, and services
- AAMI – medical instrumentation, healthcare, and MedTech (US)
- CEN – European standards for multiple industries

Functions of a Standards Development Organization

Standards development

- Create and maintain technical guidelines, specifications, and best practices

Consensus-based approach

- Engage stakeholders to achieve broad acceptance of standards

Collaborate with national and international bodies

- Work with national standards bodies and global organizations

Industry-specific focus

- For example, healthcare, manufacturing, pharmaceuticals

bsi.

ISO
164 National Members

IEC
80 National Members,
80 Affiliates

CEN
33 National Members

CENELEC
24 common members with CEN

What is a National Standards Body (NSB)?

An SDO designated in a country that is responsible for developing, maintaining, and promoting **national standards** to ensure that products, services, and systems meet quality, safety, and efficiency requirements.

Each country typically has one main NSB responsible for coordinating standardization efforts.

Examples of NSBs:

- ANSI (USA) – American National Standards Institute
- BIS (India) – Bureau of Indian Standards
- BSI (UK) – British Standards Institution
- DIN (Germany) – Deutsches Institut für Normung
- JISC (Japan) - Japanese Industrial Standards Committee

What was the world's first NSB?

Functions of a National Standards Body

Standards development

- Create and maintain national standards for different industries

International alignment

- Adopt and harmonise global standards to facilitate trade

Certification and accreditation

- Provide certifications for compliance to national or international standards

Consumer protection

- Ensure products and services meet quality and safety standards

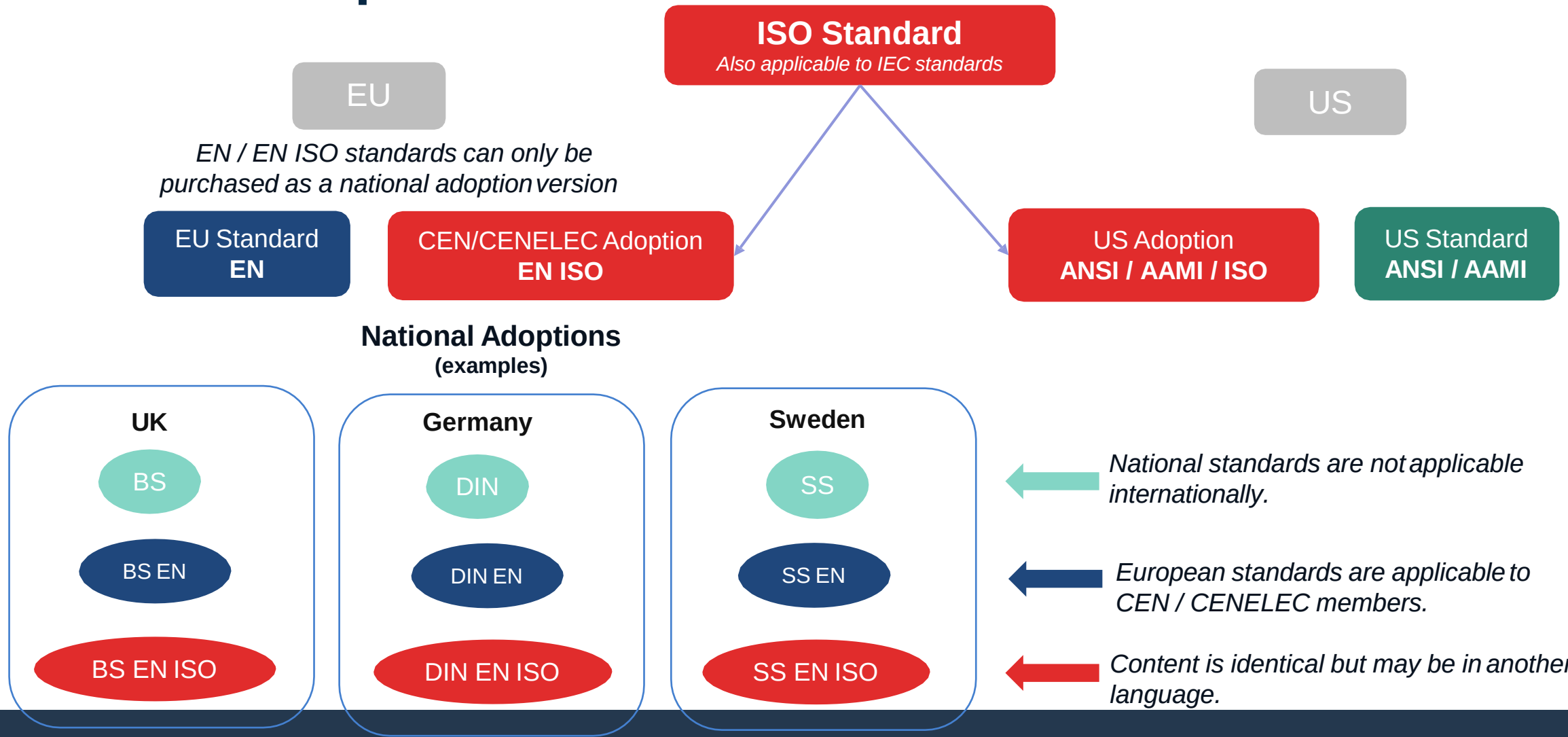
Regulatory support

- Assists governments by providing standards to support policy and regulations

Support industry and innovation

- Help improve quality and competitiveness through standardization

Relationship between international & national standards



Types of standards

- Quality assurance
- Safety & compliance
- Interoperability
- Trade & market access
- Efficiency & Innovation

Standards deliverables

Specification

- Most common
- Highly prescriptive with detailed absolute requirements
- Used for product safety or where high degree of certainty & assurance are required

Code of Practice

- Good practice recommendations
- Degree of flexibility in application
- Include reliable indicative benchmarks
- Commonly used in construction & civil engineering

Methods

- Highly prescriptive
- Agreed way of measuring, testing or specifying reliable repeatability

Guides

- Provide less prescriptive advice
- Reflects current thinking and practice among experts

Horizontal vs Vertical Standards

BS EN ISO 13485:2016+A11:2021
Incorporating corrigenda March 2016 and December 2016

Medical devices — Quality management systems — Requirements for regulatory purposes

BS EN ISO 15223-1:2021

Medical devices — Symbols to be used with information to be supplied by the manufacturer

Part 1: General requirements

BS ISO 8549-1:2020

Prosthetics and orthotics — Vocabulary

Part 1: General terms for external limb prostheses and external orthoses

Process

Product

Why should standards be used?

Benefits of Using Standards

- Alignment with regulatory & customer expectations
- Need to provide less data and technical documentation
- Facilitates procurement & tendering processes
- Tried & tested best practices help ensure compliance

Implications of Not Using Standards

- Delays in device approval due to missing features or requirements
- Competitive disadvantage
- Restricts access to markets
- More cost, time and resource heavy
- Decreased user confidence

How do manufacturers use standards?

Design & Development	Quality Management	Testing & Validation	Regulatory Compliance
• Guidance on best practice to inform design decisions	• Framework for establishing & maintaining a QMS	• Guidance on testing & validation procedures for safety, performance & usability	• Presumption of conformity to requirements
• Requirements for performance, safety & usability	• Ensure QMS meets relevant regulatory requirements	• Develop test protocols	• Access to international markets
• Ensure product meets relevant technical & safety requirements	• Products consistently produced to required quality standards	• Ensure products are validated to required standards	• Common language of understanding with regulatory bodies

Relationship between Regulations and Standards

Official rules controlling products & services that need to be conformed to

CE UKCA

Regulations

Mandatory

Provide requirements to protect the public interest

Created by legislators

Decided upon and revised by Government Bodies

Standards

Voluntary

Defined best practices, agreed by consensus

Created by experts & organisations

Facilitated by standards development organisations

Standards can be written as requirements, test methods, codes of practice, guidance

Co-regulation: Legislation and Best Practices working together

89% of companies say that **standards contribute** to the optimisation of compliance with regulations such as health and safety legislation

Requirements hierarchy

UK	• Medical Device Regulation 2002	EU	• Medical Device/ IVD Regulations	USA	• US Code of Federal Regulations (CFR)
UK	• Designated standards	EU	• Harmonised standards	USA	• Recognised standards
UK	• National standards	EU	• National standards	USA	• National standards
UK	• Guidance documents	EU	• Guidance documents	USA	• Guidance documents
UK	• Local procedures	EU	• Local procedures	USA	• Local procedures

Harmonized vs Designated vs Recognized

Harmonized

- EU process to support CE marking
- Harmonised to MDR and/or IVDR
- 250 standards requested for harmonisation by 2028
- Annex ZA/ZB identified as A+11:2021
- Maps the GSPRs to clauses and subclauses of the standard

Designated

- UK process to support UKCA marking
- Process still being developed
- Currently designated to Medical Device Regulations 2002
  - 276 MD standards
  - 44 IVD standards

Recognized

- US process for declaring conformity to regulations*
- Supplemental Information Sheet (SIS) – recognition number, extent of recognition, transition period for standard, rational for recognition
- No alignment/ relationship to regulation provided other than ‘Extent of Recognition’ in SIS

Regulator Involvement

Approved Body

Designated & regulated by the MHRA

Responsible for conducting conformity assessments to UK regulations

Issue UKCA marking for medical devices placed on the UK market

Notified Body

Designated & regulated by the EU Commission

Responsible for conducting conformity assessments to EU regulations

Issue CE marking for medical devices placed on the EU market

Certification Body

Private organizations accredited by national or international bodies

Issue certification for compliance with specific standards (i.e., ISO 13485, ISO 9001)

nvolvement in regulatory approval process dependent on device classification

Conformity Assessment

- Process of evaluating whether a medical device meets the regulatory requirements for safety, performance, and effectiveness, and is therefore suitable for marketing and distribution
- Range of activities including review of technical documentation, safety & performance testing, inspection/audits, and certification
- Requirements for conformity assessment depend on the regulatory framework in the relevant jurisdiction, as well as the classification of the device and its intended use

UK:
conducted by Approved Bodies to assess conformity with UK regulatory requirements

EU:
conducted by a Notified Body to ensure that the device meets the requirements of the MDR/IVDR

US:
pre-market review by the FDA to evaluate safety and effectiveness and other requirements

Key Standards Applicable to all/most Devices

ISO 13485:2016

Medical devices. Quality management systems. Requirements for regulatory purposes

Provides QMS requirements for an organization that needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements

ISO 14971:2019

Medical devices. Application of risk management to medical devices

Specifies terminology, principles and a process for risk management of medical devices to assist manufacturers with identifying hazards associated with the medical device, estimate and evaluate the associated risks, control these risks, and monitor the effectiveness of the controls

ISO 15223-1:2021

Medical devices. Symbols to be used with information to be supplied by the manufacturer — General requirements

Specifies symbols used to express information supplied for a medical device

Applicable to symbols used in a broad spectrum of medical devices, that are available globally and need to meet different regulatory requirements

Key Standards Applicable to all/most Devices

ISO 20417:2021

Medical devices. Information to be supplied by the manufacturer

Specifies requirements for information supplied by the manufacturer for a medical device or accessory. Includes generally applicable requirements for identification and labels on the device, packaging, and accompanying information.

ISO 17664-1:2021

Processing of health care products. Information to be provided by the ¥medical device manufacturer for the processing of medical devices — Critical and semi-critical medical devices

Provides requirements for information to be provided by the MD manufacturer for processing of critical or semi-critical medical devices or medical devices that are intended to be sterilized.

ISO 17664-2:2021

Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices — Non-critical medical devices

Provides requirements for the information to be provided by the MD manufacturer for processing of non-critical medical devices not intended to be sterilized.

Key Standards Applicable to Software & AIaMD

BS EN 62304:2006+A1:2015 *Medical device software. Software life-cycle processes*

Defines the life cycle requirements for medical device software

The set of processes, activities, and tasks described in this standard establishes a common framework for medical device software life cycle processes

BS ISO/IEC 22989:2022 *Information technology. Artificial intelligence. Artificial intelligence concepts and terminology*

Establishes terminology for AI and describes concepts in the field of AI and can be used in the development of other standards and in support of communications among diverse, interested parties or stakeholders

AAMI CR34971:2022 *Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning*

Provides guidance for applying an ISO 14971 risk management process when evaluating medical technology utilizing machine learning (ML)

Intended to apply to ML-enabled medical devices throughout all phases of the product lifecycle

Key Standards Applicable to Circular Economy

AAMI CR34971:2022 *Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning*

Provides guidance for applying an ISO 14971 risk management process when evaluating medical technology utilizing machine learning (ML)

Intended to apply to ML-enabled medical devices throughout all phases of the product lifecycle

BS ISO 8887-1:2017 *Technical product documentation. Design for manufacturing, assembling, disassembling and end-of-life processing - General concepts and requirements*

Specifies requirements for the preparation, content & structure of technical product documentation of design output for the cycles of manufacturing, assembling, disasse mbling and end-of-life processing of products

BS 8001:2017
Framework for implementing the principles of the circular economy in organizations

Provides guidance and recommendations to help an organization turn the circular economy concept and theory into practical action

Provides environmental benefits through improved resource use in addition to delivering financial and social benefits, through economic, employment, and innovation opportunities.

V

IMDRF International Medical Device Regulators Forum

Thank you/Questions