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The Commonwealth Standards Network

Department for International Development

UKaid from the British people

Standards: A tool to support regulatory policy

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Standards are simply an agreed way of doing something; they capture current good practice through trusted processes involving all relevant stakeholders.

Standards: A tool to support regulatory policy

- **Terminology** has potential for confusion:
  - 'Standards' don't always mean agreed National/Regional/International standards;
  - 'Regulations' don't always mean to legal Technical Regulations.

……but in International Standardization and WTO they have specific meaning.

- **Legislation:** Laws, directives;
- **Regulations:** Details for application of legislation;
- **Regulators:** Industry regulators and ombudsmen for specific industries;
- **Enforcement:** Courts, trading standards, police;
- **Standards:** 'How to', minimum requirements, guidance for good practice;
- **Trade Associations:** Industry codes of practice;
- **Charities/consumer groups** – campaigning, information, advice, advocacy.

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Standards: A tool to support regulatory policy

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- **Standards:**
  - Voluntary, market-led;
  - Sharing knowledge;
  - Written by experts;
  - Consensus based;
  - Public consultation;
- **Regulations:**
  - Minimum legal requirements;
  - Technical regulations are mandatory (and WTO should be notified);
  - Written by lawyers for governments.

STATUTORY INSTRUMENTS

2011 No. 1881

CONSUMER PROTECTION

The Toys (Safety) Regulations 2011

Made - - - - 24th July 2011

Standards and regulations

How can standards work alongside policies and regulations?

- **Technical regulations:**
  - Government documents that lay down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory.
  - They may also include or deal exclusively with terminology, symbols, and packaging, marking or labelling requirements as they apply to a product, process or production method.
  - No consensus is necessary for establishment of the regulation.
  - The difference between a standard and a technical regulation lies in compliance. While conformity with standards is generally voluntary, technical regulations are by nature mandatory.

- **Regulation** may be an appropriate solution when bringing about change, e.g. to address market failures and to set minimum requirements. It can, however:
  - Be expensive to develop and enforce;
  - Fail to deliver the intended result;
  - Be intrusive to business and restrict innovation and international competitiveness;
  - Be costly to achieve desired benefits.

- **International standards:**
  - Developed in a multi-stakeholder environment and reflect a double layer of **consensus** (between the technical experts and also between countries);
  - Allow products to be supplied and used across different markets, reducing market inefficiencies and **facilitating regulator compliance**;
  - Can be used **for conformity assessment** to enhance confidence in products, systems , processes, services or personnel;
  - Offer the same level of **consumer protection** whether applied in a mature or evolving economy
  - Are **globally applicable.**

- **Conformity assessment** processes test the compliance of products and services with relevant standards, regulations and other specifications;
  - This helps ensure products and services deliver on their promises and builds consumer trust.
  - Governments and buyers often only invite bids for procurement contracts from manufacturers and service providers that meet conformity assessment requirements.
- Standards that form the basis of industry self-regulation, combined with **accredited conformity assessment** to give the highest degree of confidence in compliance where required, can produce benefits for all parties, with a cheaper and more effective basis for the adoption of best practice.

- **Standards and accredited conformity assessment** offer a business and consumer friendly alternative to regulation, or can support regulation and enable its simplification.
  - Market-based tools that can support risk-based regulation by providing information to help target Government intervention where it is most needed- to deliver outcome-focused regulation;
  - Can ease pressure on the legislative process and reduce implementation costs for Government;
  - Have the necessary legitimacy and market acceptance to be used as tools to support policy delivery due to their openness, independence and stakeholder involvement.

- **CASCO** members develop ISO policy on issues such as mutual recognition and acceptance of national and regional conformity assessment systems.
  - They also develops conformity assessment standards and guides for certification bodies (that certify products, processes, services and management systems), testing laboratories, inspection bodies and accreditation bodies.
  - https://www.iso.org/casco.html (includes 5 minute video)

- **CASCO** online platform:
  - Interactive online tool to promote a harmonized approach to conformity assessment (CA) and support national regulators when they deal with CA matters.
  - Based on the CASCO toolbox; combines concepts and practical examples of the role/use of conformity assessment in regulations;
  - Intended for use by members together with national regulators;
  - www.iso.org/cascoregulators

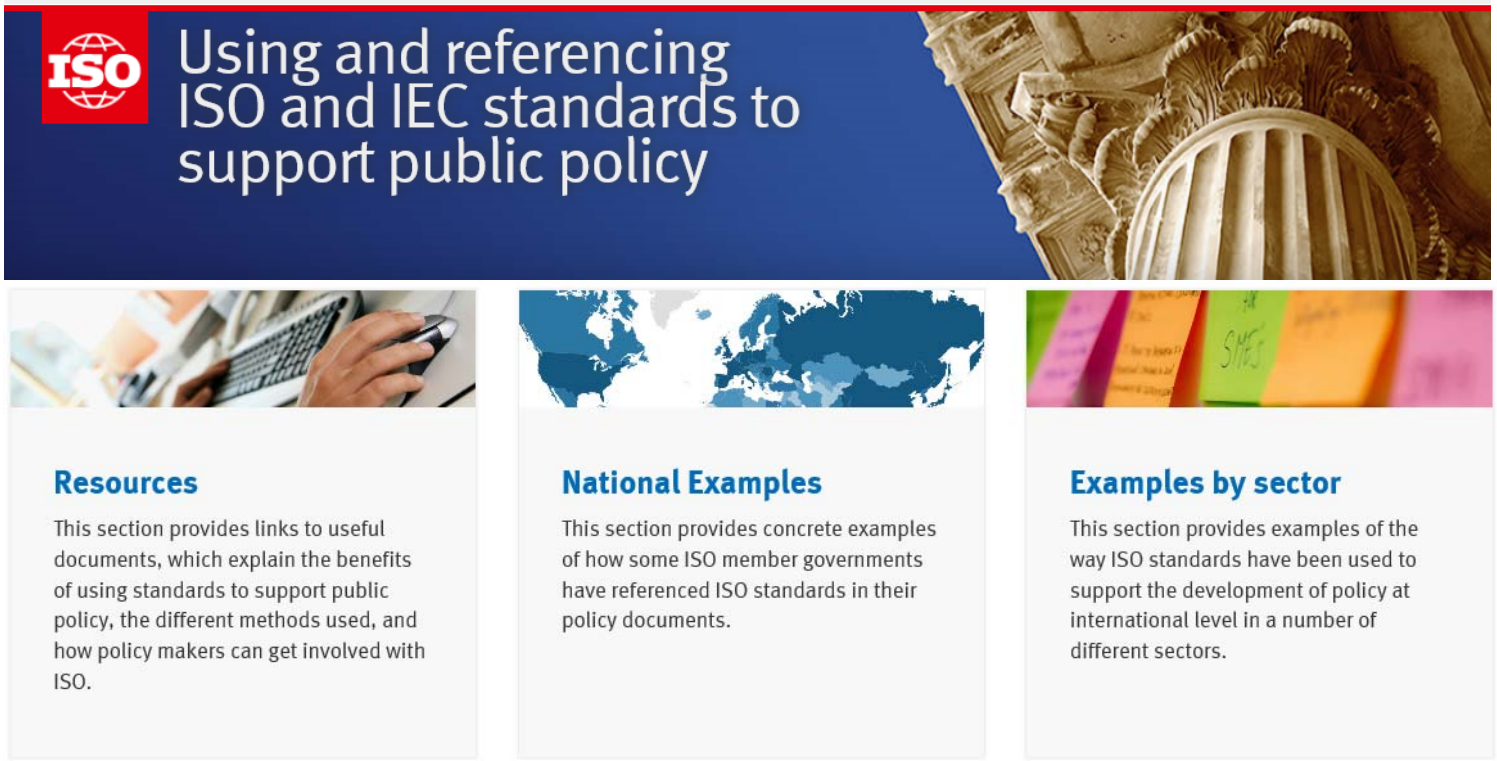
Standards: A tool to support regulatory policy

- **ISO/IEC standards** do not seek to establish, drive or motivate public policy or regulations, social or political agendas. And do not set performance thresholds (these are set by policy makers/regulators according to their requirements).
  - They can provide valuable support to the implementation of public policy.

- **ISO and IEC standards to support public policy** https://www.iso.org/sites/policy/

  - On-line help for public policy-makers, regulators and standards developers to understand how International Standards can be used to support policy initiatives;
  - Includes referencing International Standards in legislation or regulation, as well as using them to support other kinds of public policy decisions or actions (such as in public procurement, incentive systems, or awareness campaigns);
  - ISO's International Standards are voluntary. They do not seek to establish, drive or motivate public policy, regulations, or social or political agendas, but they can provide valuable support to the implementation of public policy – The resources and examples brought together on the website to show you how.

- **ISO and IEC standards to support public policy** https://www.iso.org/sites/policy/



- **ISO and IEC standards to support public policy:**

Legislative actions

- Laws (or Acts of Parliament)
- Technical regulations (which support the requirements of laws)
- Other actions include rules, notices, orders, determinations, and warrants.

Non-legislative actions

- Funding priorities
- Incentive systems
- Awareness campaigns
- Public procurement
- Codes of conduct

- **BSI/ISO workshop 'how can standards work alongside policies and regulations?'**
  - Confusion over what is a standard and what is a regulation is a common theme in many countries, boundaries between standards and regulations are blurred;
  - Value in re-stating the potential of true consensus based voluntary standards to achieve regulators' aims whilst achieving industry buy-in;
  - A widespread view of standards as quasi-regulation was prevalent in much of the business community, which then obscured the value of standards as a positive choice for businesses of all sizes.

- **BSI/ISO workshop 'how can standards work alongside policies and regulations?'**
  - Need to distinguish clearly between voluntary and mandatory standards;
  - Help regulators to understand that standards are their 'workhorse' – a tool for them to use (one tool among many);
  - Encourage early engagement of public authorities by standards-writing committees;
  - Ensure that, when policy makers have an objective, they reach out for standards automatically;
  - Produce guidance materials and case studies.

- **Policy professionals** have to assess which option will provide the best value for money and outcome, or whether Government intervention is required at all.

- Considerations when **referencing standards in regulations**:
  - Should the use of the standard by mandatory (providing the only solution) or voluntary (providing one possible solution)?
  - What level of checks should be put in place to ensure the standard is suitable for the intended use and addresses all needs?
  - Will the reference be to the whole standard or selected parts (only to certain clauses and sub-clauses)?
  - How will the regulation be kept up-to-date if the standard is revised?

- The **WTO's Agreement on Technical Barriers to Trade** (TBT) exists to ensure that national regulations, standards, and procedures for assessment of conformity do not create unnecessary obstacles to international trade;
  - The TBT Agreement recognizes the contribution international standards can make toward improving the efficiency of production and international trade.
  - 6 core principles of international standards development agreed by the TBT committee:
    1. Transparency
    2. Openness
    3. Impartiality and consensus
    4. Effectiveness and relevance
    5. Coherence
    6. Addressing the concerns of developing countries

- **Government's role in standardisation (UK)**
  - Most standardization activity takes place without the UK government getting involved at all;
  - Organizations use standards simply because they help them perform better;
  - It's precisely because standards work so well that the UK government wants to encourage new standards – to help the economy grow and to help meet its policy goals.

- **Government's role in standardisation (UK)**
  - In the UK, The Department for Business, Energy and Industrial Strategy (BEIS) is responsible for government policy on standards;
  - BEIS/BSI aims include:
    - Encouraging innovation among UK businesses;
    - Helping UK businesses participate in new markets;
    - Reducing businesses' exposure to risks of different kinds;
    - Helping particular sectors of the economy work more efficiently;
    - Keeping the UK at the forefront of international standardization.

- **Government's role in standardisation (UK)**
  - BEIS offers BSI support for:
    - BSI projects, to create new standards, codes of practice and guides, write case studies and research reports, and organise an array of events. (e.g. innovative areas anticipating industry needs- such as standards for smart cities);
    - Helps fund the UK's participation in international standards by contributing to the travel costs of UK experts;
    - Consumer representation in standards-making activities; influencing the standards to reflect the needs and expectations of the general public;
    - BEIS gives government departments discounted access to standards so they, too, benefit from them.

- **Self-regulation;**
  - Under this approach businesses voluntarily agrees to meet certain standards. It is used where there is a need to reassure markets on the conduct of business but where there is no desire by government for regulatory intervention, for example where products are deemed low risk.
- **Earned recognition;**
  - Companies which demonstrate compliance with standards may earn recognition from regulators, who trust them to comply with their legal obligations. In this way, the cost of regulation is reduced for both the state and the regulated business. The state can focus resources on the worst performing organisations.
- **Co-regulation;**
  - Government sets the top level regulatory requirements and agrees with industry how these general principles should be met in terms of technical solutions. In some cases, the use of standards is referenced or cited in regulation. In others, the market itself may decide to develop standards for their own guidance on the technical state of the art and thus assist with compliance.

Self-regulation:

- Undertaken by those businesses that voluntarily agree to meet certain standards.
- Can be used where there is a need to reassure markets on the conduct of business but where there is no desire by Government for regulatory intervention.
  - e.g. an industry might choose to develop and adopt its own code of practice promoting ethical conduct.
- Government can encourage the use of standards to deliver policy, or may wish to sponsor the creation of a standard for a particular purpose, such as a Publicly Available Specification (PAS), or a means of determining compliance that involves other parties in setting standards and authorising the activity. Examples include:
  - customer charters;
  - codes of conduct;
  - voluntary agreements.
- Standards developed in support of self-regulation can be supported by accredited conformity assessment if greater assurance of compliance is required e.g. if there are serious health and safety implications.

Self-regulation: Case study 'Combating Legionella'

- The UK Health and Safety Executive approved code of practice on the control of Legionella requires employers and landlords to carry out a risk assessment, undertaken by a 'competent person';
- BSI developed a standard for Legionella risk assessment (BS 8580: 2010);
- Businesses use BS 8580 to ensure that they comply with the HSE code of practice;
- UKAS accredits inspection organisations to assess against BS 8580;
- Businesses and HSE can have confidence in the risk assessments carried out by accredited inspectors.

BS 8580:2010

Water quality – Risk assessments for *Legionella* control – Code of practice

Earned recognition:

- Companies that demonstrate compliance with standards may 'earn recognition' from regulators, who trust them to comply with their legal obligations. This enables regulators to reduce oversight and inspection visits;
- 'Earned recognition' can achieve the same or better outcomes as regulation, but on a voluntary basis. In this way, the cost of regulation is reduced for both the state and the regulated business.

Earned recognition: Case study 'Environmental management'

- BSI developed the Environmental Management System standard ISO 14001 as a business management tool;
- Accredited certification bodies certify those businesses that comply with the standard;
- The UK Environment Agency recognises the value of accredited certification to ISO 14001 and gives credit under the Integrated Pollution Prevention and Control legislation resulting in:
  - Reduced environmental levies for businesses;
  - Reduced inspection requirements.

Environment Agency

Co-regulation:

- When a co-regulatory approach is used, Government sets the top level regulatory requirements in broad terms of performance and leaves the market to define how these general principles should be met in terms of technical solutions;
- In some cases, the use of standards is referenced in regulation as a way of achieving compliance. In others, the market itself may decide to develop standards for their own guidance on the technical state of the art and thus assist with compliance;
- The co-regulatory approach has been used both in Europe, most notably for product regulation "New Legislative Framework", (previously known as the New Approach) where over 4,000 standards are used to support performance based regulation. Accreditation is used to ensure the competence of those organisations that deliver conformity assessment services for businesses under this legislation ('Notified Bodies');
- In line with the World Trade Organization's Technical Barriers to Trade Agreement (WTO TBT Agreement), compliance with the regulation is mandatory, but compliance with standards remains voluntary.

Co-regulation: Case study 'Electronic Identification and trust services for electronic signatures'

- The eiDAS Regulation (Regulation (EU) 910/2014) requires auditing of Trust Service Providers (TSPs – bodies providing digital certificates creating and validating electronic signatures) by a certification body accredited by UKAS to the requirements of ISO/IEC 17065 – the international standard for organisations certifying products, services or processes;
- BSI brought together key stakeholders to represent the UK's interest in developing the standard;
- UKAS worked with the Information Commissioner's Office to produce guidance for the implementation of eiDAS in the UK;
- UKAS accredits certification bodies to certify TSPs;
- Government and consumers can have confidence in TSPs without direct Government intervention.

Case study: Canada, ISO 5001

- The Canadian government offers grants for industrial organizations that adopt systems and processes to improve energy performance. One of the criteria for eligibility to receive a grant is that companies must implement the CAN/CSA ISO 50001 Energy Management Systems Standard.

ISO 50001
ENERGY MANAGEMENT

Case study: Japan, 'Eco-friendly goods and services'

- The Japanese government's 'Basic Policy for the Promotion of Procurement of Eco-Friendly Goods and Services' defines 267 items as eco-friendly goods and, as of 2014, it references 72 JIS standards (including IEC and ISO standards that have been nationally adopted as JIS standards) as test and product standards.

Case study: USA, IEC 60079-11

A direct reference to an IEC International Standard in a US regulation:

46 CFR (U.S. Code of Federal Regulations) 111.105-11 Title 46 — Shipping Chapter I — Coast Guard, Department Of Homeland Security, Part 111_Electric Systems — General Requirements, Subpart 111.105_Hazardous Locations, Sec. 111.105-11 Intrinsically safe systems. Sec. 111.105-11 Intrinsically safe systems.

Extract from the regulation: "(a) Each system required by this subpart to be intrinsically safe must use approved components meeting UL 913 or IEC 60079-11 (both incorporated by reference; see 46 CFR 110.10-1)."

Case study: EU, ISO 22716

An indirect reference to an ISO International Standard in EU regulation:

Regulation (EC) 1223/2009 *Cosmetics*. Article 8, clause 2 of this regulations states that "Compliance with good manufacturing practice shall be presumed where the manufacturer is in accordance with the relevant harmonised standards, the references of which have been published in the *Official Journal of the European Union*."

The reference to EN ISO 22716:*2007 Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices* (ISO 22716:2007) can be found in the Harmonised standards (HAS) database, http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/cosmetic-products/index_en.htm

Case study: European 'New Legislative Framework'

- EU legislation (Directives) define essential requirements - in relation to safety and other aspects of public interest - which should be satisfied by products and services being sold in the Single Market.
- The EC issues standardization requests (Mandates) to the European Standardization Organizations (CEN, CENELEC and ETSI), which are responsible for preparing technical 'Harmonized' standards and specifications that facilitate compliance with these essential requirements.

Case study: European 'New Legislative Framework'

- Around 25% of European Standards published by CEN have been developed in response to standardization requests issued by the EC;
- To facilitate the functioning of a harmonised common market, new ENs must be adopted as national standards by all their national members;
- Public authorities must recognize that all products manufactured (and services provided) in accordance with harmonized standards are presumed to conform to the essential requirements;
- European Standards (ENs) are voluntary, there is no legal obligation to apply them. Any producer (or service provider) who chooses not to follow a harmonized standard is obliged to prove that their products (or services) conform to the essential requirements.

cen CENELEC ETSI

EUROPEAN STANDARDS ORGANIZATIONS

Case study: European 'New Legislative Framework'

- The foreword of all standards intended to be cited in the Official Journal (OJ) of the European Union under (a) New Approach Directive(s) shall include the following sentence:

  "This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s). For relationship with EU Directive(s), see informative Annex Z..., which is an integral part of this document."

Official Journal **L 27**

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Contents | *II Non-legislative acts* | page

INTERNATIONAL AGREEMENTS

Case study: European 'New Legislative Framework'

- When businesses make use of harmonized European standards, they benefit from a 'presumption of conformity' with the requirements set out in the relevant European legislation. This means that they can sell their products or services throughout the Single Market – reaching a potential 600 million consumers in at least 34 countries;
- Consumers benefit from safe and environmentally-friendly products and services.

Case study: European 'CE Marking'

- CE marking allows you to legally market products within the European Economic Area (EEA);
- CE marking is required for many products, it:
  - declares that products comply with all applicable European Directives and Regulations (safety, health or environmental requirements);
  - is a manufacturer declaration (unless high-risk e.g. medical devices- which require pre-market verification and certification from independent notified bodies);
  - allows the free movement of products within the European market.

Engagement with Policy makers:

- Objective – to better inform Government policy makers about the value that standards can play to support the delivery of policy.
  - Outreach programme to relevant Government Ministries and Regulators.
  - Increase visibility of the role that standards play to support Government policy.
  - Discuss potential areas of new standards development that would support Government outcomes (e.g. BIM in the UK).
  - Align standards development with strategically important sectors.
  - Encourage Government representatives to participate in standards development.
  - Potential funding opportunities.
  - Provision of standards to Government.

Engagement with Policy makers:

- Policy makers should be encouraged to:
  - Include education on the use and benefits of standards in programmes designed to support new exporters.
  - Note how standards can assist:
    - economic growth;
    - innovation;
    - meeting policy goals;
    - international trade;
    - meeting SDGs;
    - achieving the same or better outcomes as regulation with reduced costs.
  - Consider working with stakeholders to promote the increased use of international standards in priority export markets, as countries that increase the use of international standards provide fertile new export markets.

Sustainable Development Goals:

- In 2015, the UN set an ambitious 15-year plan to address some of the most pressing issues faced by the world.

Sustainable Development Goals:

- For each Goal, ISO has identified the standards that make the most significant contribution.
- Engage Policy makers: Standards can assist them reaching SDGs.

SUSTAINABLE DEVELOPMENT GOALS

This standard contributes to the following Sustainable Development Goals:

1 2 3 4 5 6 7 8 9 12 13 14 15

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