A World Built on Standards

A Textbook for Higher Education

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Foreword

Standards are used every day by businesses, manufacturers, public bodies and other organisations as a tool for managing vital issues such as trade, regulation, quality, health and safety, new technologies energy efficiency, environmental impact, connectivity and interoperability.

Understanding standards and standardization is essential for students as this knowledge can be an important asset during their studies but more importantly in their future careers as managers, engineers, scientists or any other profession they choose.

This publication is the result of work carried out by the British Standards Institute, Danish Standards, the National Standards Authority of Ireland, the Finnish Standards Association and the University of Zagreb under the auspices of the CEN and CENELEC Joint Working Group for Education about Standardization in order to support education about standards and standardization in Europe.

A World Built on Standards is supported by multiple choice questions, Power Point presentations and Case Studies about how others have taught standards and standardization. After each chapter in the textbook, questions that can be used as discussion points on matters related to the chapter are provided.

This publication and all supporting material can be found online and free of charge on www.ds.dk/education. This publication and all supporting material can be distributed, but is not intended for commercial use.

If you have any questions, comments or suggestions for this material, do not hesitate to contact us at uni@ds.dk

– The project team

Introduction

Education about standards and standardization plays a key role in an increasingly international world. Students with knowledge on this topic are in a strong position to deal with a wide range of situations they might encounter in their professional lives.

For a global company such as BBOXX, standards are vital to the success of our business; working across multiple countries, with design teams in the UK, manufacturing teams in China and installers and operators spread across multiple countries in Africa and Asia. This means that we are often working across multiple languages, cultures and ways of operating. Although this could be a potentially dangerous recipe for mistakes and delays when it comes to the development and production of new products, standards help our different business units communicate better and reduce the potential for confusion throughout our supply chain and in our sector. Working to standards that are approved by the industry helps raise the confidence for investors, customers and partners.

As a student or in the early stages of your career, learning about standards and standardization will help you get ahead; it will not only teach you crucial engineering/science processes and techniques that are widely accepted, but it will also demonstrate that you have knowledge of CE-marking and market access, can plan projects, reduce costs, improve quality for you and your business and demonstrate that products meet test criteria in regard to e.g. safety.

BBOXX designs, manufactures, distributes and finances innovative plug & play solar systems to improve access to energy across Africa and the developing world. More than 41 000 BBOXX products have been sold in more than 35 countries, improving the lives of more than 205 000 people. BBOXX leads and manages all aspects of its business operations – engineered from its lab in London, manufactured in its factory in China, followed by distribution to partners in 35 countries and more than 30 local shops in Kenya, Rwanda and Uganda.

Christopher Baker-Brian

Entrepreneur, co-founder
and Chief Technology Officer, BBOXX

BBOXX

Content

Chapter 1

What is a standard?

Jørgen Hagelund
Standardization manager ISO/CEN
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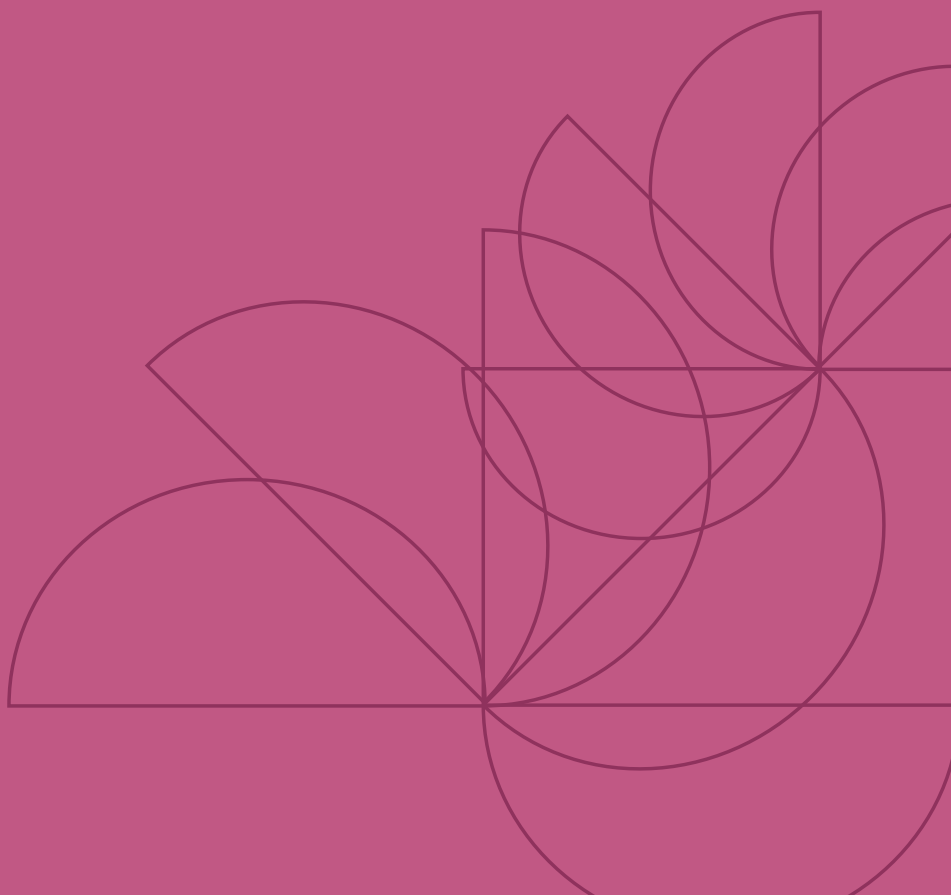

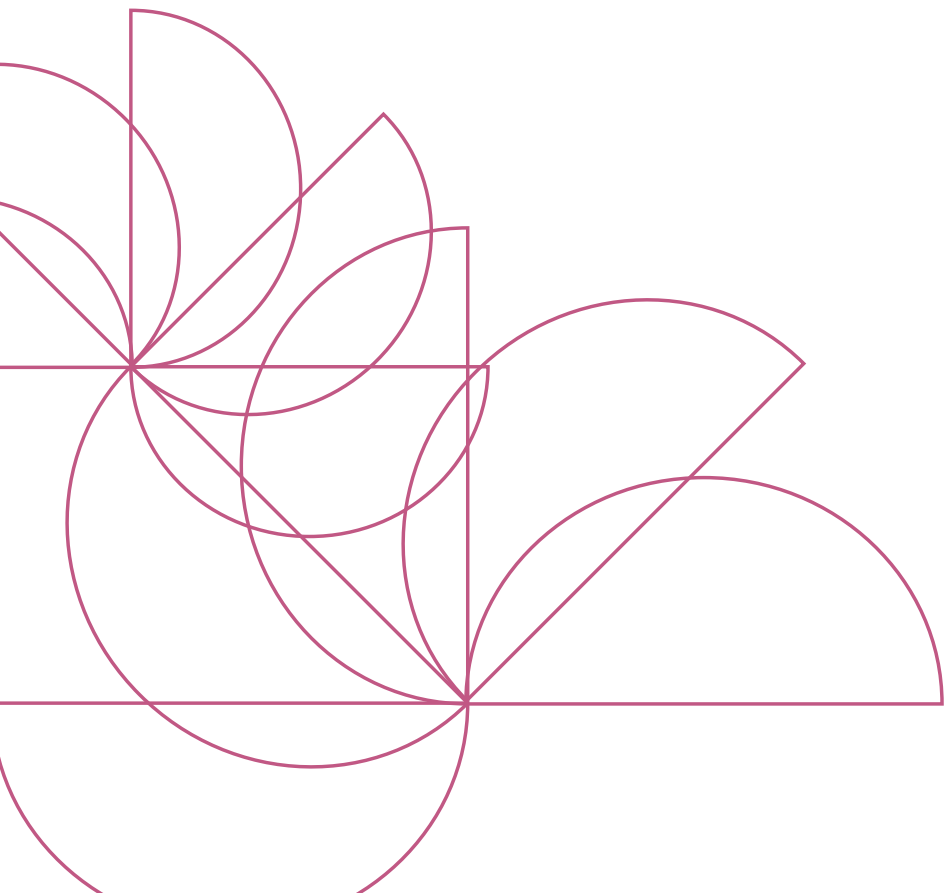

Introduction

Standards influence the daily life of every citizen as standards exist in a wide range of areas (such as construction, food, toys, buildings, machinery, healthcare, environment, services, etc.) and cover many layers (e.g. safety, management, testing, compatibility, etc.). Different types of standards fulfil different needs.

In this chapter, you will be introduced to what a standard is and the different types of standards. Moreover, the distinction between de jure standards and de facto standards and the relation between standards and patents will be covered.

This knowledge will give you a basic understanding of standardization in general and provide you with the background information needed for the rest of this book.

Standards in everyday life

Imagine a world without standards... even a day without standards. It would be quite difficult if not impossible! Life would be unsafe and nothing would fit together. To get an idea of how many standards we meet during the day, one would only have to try to count the amount of standards that we meet from the moment we step out of bed in the morning until we go to bed at night. It would be a considerable amount. If you take the first 30 seconds after you wake up you would already have met several standards such as the dimensions for a bed, standards for alarm clocks, lamps, bed lined, etc. Luckily, one of the features of standards is that we coexist with standards without even noticing the existence of them. Who thinks of furniture standards when sitting around the table having breakfast?

Standards are in fact very common in every-day life – even though most of us are not aware of this. Recall for example when you walk up and down a flight of stairs, in most cases it will feel natural and familiar. The reason is that the height of stairs have been standardized through gen-

erations[1]. However, we sometimes experience that walking on a set of stairs feels unnatural and unfamiliar. The cause of this will most likely be that those stairs were built using a different standard than the one you are used to. Also, take for instance the clothes you wear, the home you live in, the way you transport yourself around during the day, the electrical equipment you use – the list of standards is endless. You cannot go through a day without being in contact with standards, and to illustrate this take a look at the figure below:

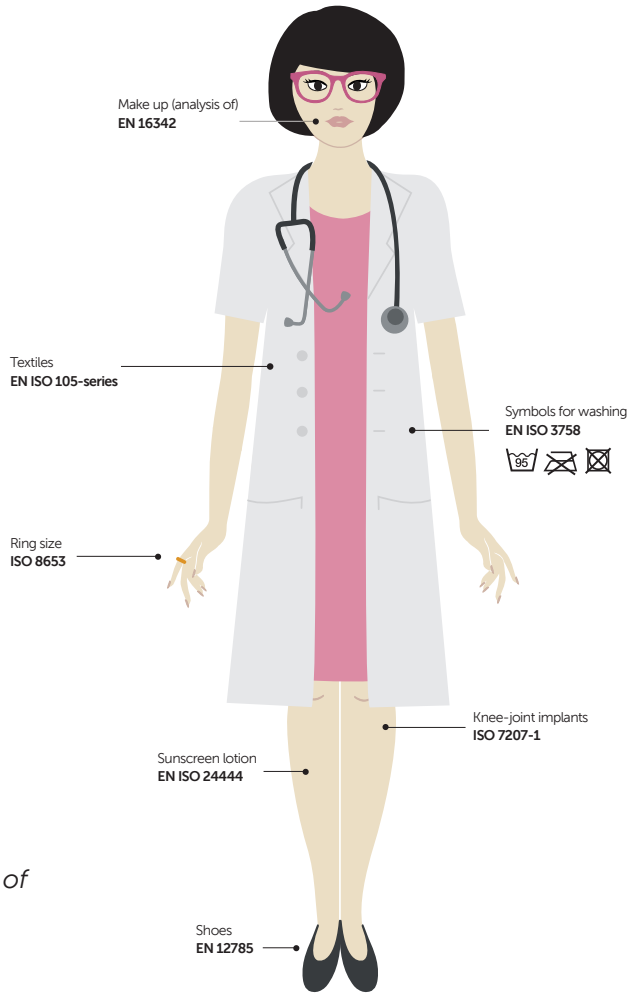

Figure 1: Examples of standards in life.

1 The standard may vary from country to country.

The definition of a standard

Standards are a way of communicating – a kind of common language – in the form of a technical specification. Often it is an ability to communicate across languages to avoid misunderstandings. Standards only exist because we use them, and because we benefit from using them. If they did not bring value, their justification for existing would no longer apply.

Standards have always existed in one form or another. The first standards were made to enable trade. It was important to have standards defining the product and how to test them e.g. by measurement. Standards for safety are also some of the oldest standards.

Today there are more standards than ever, and they are common in most areas and in a wide range of fields. Some standards reflect common practice and are taken over from one generation to another; other standards are developed by consortia or by formal standardization organizations. There are a tremendous number of standards in the world and standards developed in the formal standardization system (e.g. CEN, CENELEC, ETSI, ISO, IEC, ITU) are only the tip of the iceberg. However, it is these formal standards that often have the highest impact and the widest recognition in the global society and on which we will mainly focus in this chapter and in this book in general. The other standards belonging to "the iceberg" vary considerably from company specific standards to systems describing methodology like the Gregorian calendar, music notes and rules for sports (e.g. soccer game rules).

There is not just one definition of a standard – there are several. In the Oxford Dictionary[2], six different meanings of a *standard* are listed. The most relevant definition in this perspective is: *Something used as a measure, norm, or model in comparative evaluations*[3]. That is a very broad definition! The different organizations using or producing standards have made their own definitions. The main definitions are given in the table below.

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2 http://www.oxforddictionaries.com/ (2014-12-15).

3 http://www.oxforddictionaries.com/ (2014-12-15).

Table 1: Definitions of a standard.

CEN CENELEC[4]	Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. **NOTE** Standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.
ISO IEC[5]	Document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.
European Commission[6]	Means a technical specification, adopted by a recognised standardization body, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following: (a) 'international standard' means a standard adopted by an international standardization body; (b) 'European standard' means a standard adopted by a European standardization organization; (c) 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation; (d) 'national standard' means a standard adopted by a national standardization body;

WTO[7]	Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method. **EXPLANATORY NOTE** The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods. Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents. Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus.
De facto	There are many definitions of de facto standards. One definition is *"Standards that emerge as a result of market-mediated processes … are referred to as de facto standards… de facto standards [are based] on a high level of competition."* (Oshri & Weeber 2006).

4 EN 45020 – *Standardization and related activities – General vocabulary.*

5 ISO/IEC Guide 2 – *Standardization and related activities – General vocabulary.*

6 Regulation (EU) No 1025/2012.

7 WTO: Agreement on Technical Barriers to Trade (Uruguay Round Agreement), Annex 1: Terms and their Definitions for the Purpose of this Agreement.

The definitions have many similarities but are also distinct. In this chapter, we will not go into detail with an academic analysis of the different definitions. When we use the word standard in this book, we refer to the definition from CEN, CENELEC, ISO and IEC – unless something else is explicitly mentioned. Those are the kind of standards also referred to as *de jure* standards.

In brief, standardization can be described as the "activity of establishing a standard" (Choi et al). Standardization in CEN, CENELEC, ISO and IEC standards is subject to specific rules, which are described in chapter 3: *How are standards developed and structured?*

The characteristics of a standard

The characteristics of a standard can give a good understanding of the nature of a standard. The characteristics that give standards value is the fact that they are:

- **Voluntary and market driven** – which means that every interested party can participate in the making of a standard and provide comments when a standard is submitted to public consultation. The decision to develop new standards is driven by market needs/requests.
- **Consensus based** – which means that *all standards are subject to dialogue in order to establish general agreement characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments* (definition of *consensus* from EN 45020). Afterward the standard goes through a formal vote procedure to get it approved.
- **Approved by a recognized body** – which means that a recognized standards body such as CEN, CENELEC, ISO, IEC or a national standards body has approved the document and that the document has gone through the necessary procedures, public consultations, etc.

How to influence the content of a standard

Many people have the impression that standards are written by the standardization organizations themselves. This is a significant misunderstanding of the core values of the standardization system; i.e. the involvement, consensus and influence of all interested parties. Standards are the distilled wisdom of people with expertise in their subject matter who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, researchers, trade associations, users, regulators, etc. The role of the standardization organizations is to ensure that the standardization system works and that all relevant stakeholders come to a common agreement on what is the best standard for a particular need.

Standardization organizations is open for participation for all interested parties. Participation typically takes place through the network that the national standardization organizations constitute under the European or international organization (e.g. CEN or ISO). If you wish to influence a standard, you should join the national standardization organization[8]. In fact, standardization organizations strive to have as broad a representation in the standardization committees as possible. Joining your national standardization organization may even allow you to become part of the European or international standardization activities. (The standardization process is described in chapter 3: *How are standards developed and structured?*).

The figure below gives an impression of the benefits of standards – for society, business and participants in the standardization activities. (The benefits will be described in chapter 2: *Why do standards exist?*).

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8 In some countries a fee is charged for participation

SOCIETY	BUSINESS	PARTICIPANTS
• Reduced technical barriers to trade • Trust in products and services • Increased quality and safety • Dissemination of best practices • Economic growth	• Market penetration • Global availability • Increased sales • Knowledge and sharing best practice • Increased productivity • Frame innovation and reduce development cost • Improved quality/cost balance	• Influence on standards – being the standard setter • Up front knowledge on coming standards • Deeper understanding of standards • The networking effect – creating and maintaining contacts

Figure 2: Illustration of the common benefits of a standard and standardization in general.

Different types of standards

At the moment of the publishing this book, there are more than 35 000 different CEN, CENELEC, ISO and IEC standards. Additionally, there are tens of thousands of national standards published by national standards bodies throughout the world.

Standards cover a wide range of subjects. There are different types of standards for different types of tasks. One way of categorising them is by requirements:

- **Dimension systems** – e.g. paper formats, threads, classification systems
- **Performance** – e.g. breaking strength, energy performance, safety, ergonomics, noise
- **Methods/testing** – e.g. test schemes, chemical analysis, documentation of performance

- **Management systems** – e.g. quality, risk, energy or environmental management
- **Symbols** – e.g. pictograms, symbols for machines
- **Terminology** – e.g. definitions of main terms within different fields
- **Products** – e.g. toys, electrical equipment, construction products
- **"Basic" standards** – e.g. SI[9] units.

For an elaboration of the different types of standards – see chapter 2: *Why do standards exist?*

As the general rule, standards are voluntary to use, however, standards are sometimes referred to by national or regional (European) legislation, which in practice makes them mandatory. Standards can also become mandatory if they form part of a contract between parties or if a company announce that their product fulfils the requirements of a voluntary standard. (Standards in relation to legislation are described in chapter 4: *Standards and Regulations – how are they related and how do they interact?*

De jure vs de facto

De jure and de facto standards are distinct and subject to different requirements in terms of preparation, process, revision, etc.

De jure standards are formal standards – standards developed by official standardization organizations. These organizations can be international (like ISO and IEC), regional (like the European CEN, CENELEC, ETSI) or national (like NF, DIN, DS, etc.) and have been given formal recognition to produce formal standards. De jure standards are developed under the requirements of the formal standardization system which implies consensus, voluntarism and the fact that they are market-driven. One important

9 International System of Units. Originally French *Le Système International d'Unités*.

characteristic to stress is the fact that de jure standards can be purchased by any interested party.

De facto standards are, so to speak, the remaining group of standards, i.e. standards that are not developed by one of the above-mentioned recognized bodies. These are standards that have gained currency over time e.g. music notes. Other de facto standards could be a result of one or more companies' products where the products become a 'standard' itself. Due to the different kinds of de facto standards, they are developed in different ways. De facto standards can be developed by consortia or fora, where the development process has great similarities with the formal standardization process by e.g. being consensus based and including public consultations. These types of de facto standards are often developed by standards developing organizations (SDOs). In other cases, de facto standards are developed by one organization or a closed circle of organizations, where the development process is often unknown to other parties. In the latter case, the developer(s) may own the utilization of the standardized technology. De facto standards developed in this way sometimes result in different standards describing the functionality of the same type of product. Here several standards emerge and compete for the market. An example of this was the battle between VHS and Betamax for the home videocassette recorder market. Needless to say, VHS won the battle and got to set the standard on the market – but ultimately the DVD took the prize.

There are different strengths and weaknesses in the different approaches and sometimes a standard can start as a de facto standard and end up being approved as a de jure standard. One example of this is the pdf document. This started as a de facto standard but was eventually approved by ISO and is today described in ISO 32000. Many people throughout the world use the pdf every day, as it is one of the most widespread and compatible file formats that exists[10].

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10 Choi et al.

Standards can also grow old

Standards may become obsolete for many reasons, mostly due to technological advancement. Often new technologies and research have led to the development of new standards to replace old standards. Just think of VHS and the use of DVD's and now today's streaming. Another example is the multitude of standards for flexible disk cartridges (e.g. floppy disks) – today we use the USB stick or the cloud for storage.

In the article *The Paradox of Standardization and Innovation* Henk J. de Vries, associate professor of standardization at Rotterdam School of Management, Erasmus University Rotterdam, explains how standards may become outdated but still are used extensively in society and business.

"A classic example of this is the QWERTY keyboard. QWERTY was developed in the 1870s to slow down the speed of typists in order to reduce the incidence of jamming. This would improve the reliability of the machine. The design was based on the frequency of use of the letters of the alphabet in the English language. Since electrotechnical and electronic machines have replaced mechanical constructions, the reasons for the QWERTY design no longer make sense. Better keyboards have been invented with improved ergonomics that allow for more speed. However, QWERTY is the common solution implemented everywhere, so the costs of conversion are too high. More than the costs of replacing the hardware are the education costs of learning to work with the new standard. Moreover, there is a 'prisoner's dilemma.' The new standard would be attractive only if others would use it – typists as well as keyboard manufacturers – but this applies to everyone; so everyone waits for everybody else and, in the end, no one starts. Thus, everyone is ' locked-in ' in the old technology." [11]

Take a look at your keyboard. Are the top letters QWERTY? If not then you belong to the minority who use a different keyboard layout.

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11 De Vries, Henk J. 2006.

Figure 3: QWERTY Keyboard.

Even if the QWERTY standard has grown old, it still exists in its own right. For example, it enables economies of scale for producers and ensures that new companies can enter a market without having to convince consumers that their keyboard has the same or better functionalities than the ones developed by established producers.

Standards and patents

An important aspect of standardization is the relation to patents and the role patents play in standards.

A standard is normally intended to be used by all interested parties, whereas a patent is only used by the patent holder and by third parties who have been granted a license[12]. Even though standards and patents may seem opposites, then when handled correctly the interplay between standards and patents can be beneficial both for the patent holder and for society as a whole. An example of this is the smartphone industry where patents promote innovation of R&D results and standards maximize dif-

12 Hesser et al 2010.

fusion, and inter-operability. This industry could not function without the interplay of standards and patents as smartphones require inter-operability, and the latest patented technology.

The European standardization organizations CEN and CENELEC have an intellectual property rights policy for many years under the provision of the CEN-CENELEC Guide 8 "Standardization and intellectual property rights (IPR)". The purpose of these common guidelines is to provide practical and easy-to-understand guidance to the participants in their technical bodies in case patent or other intellectual property rights matters arise.

All participants in the work of CEN and CENELEC are requested to declare any known patent or any known pending application for a patent that may be considered relevant for the standard. This concerns both their own patents and patents in any other organization they might know. In doing so, potential patent rights problems can be avoided.

For a patent to be included in a standard, it must be considered as *essential* for the future use of the standard. CEN and CENELEC are not involved in evaluating patent relevance or essentiality, nor do they interfere with licensing negotiations, or engage in settling disputes on patents. This is left to the parties concerned.

For a patent to be included in a standard, the patent holder must fill in the Declaration Form[13], where the submitting party declares its willingness/unwillingness to license the patent(s) on fair, reasonable and non-discriminatory conditions (also known as FRAN).

In the Declaration Form three choices are given to the patent holder:

1. The Patent or other IPR Holder is prepared to grant an **irrevocable free of charge licence to an unrestricted number** of applicants on a worldwide, non-discriminatory basis and under other reasonable terms and conditions to make, use, and sell implementations of the above document [CEN-CENELEC Guide 8][14].

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13 The Declaration form can be found in CEN-CENELEC Guide 8.

14 CEN-CENELEC Guide 8.

2. The Patent or other IPR Holder is prepared to grant **an irrevocable licence to an unrestricted number** of applicants on a worldwide, non-discriminatory basis and on fair, reasonable terms and conditions to make, use and sell implementations of the above document [CEN-CENELEC Guide 8][15].

3. The Patent or other IPR Holder is **unwilling to grant licences** in accordance with provisions of either 1 or 2 above.

The international standardization organizations ISO, IEC and ITU also have a similar IPR policy, which can be found online in the document *ISO/IEC/ITU Common patent policy.*

Whereas de jure standards are subject to the above mentioned patent policy, ensuring that they can be used by every interested party, de facto standards can be protected by patents. However, the role patents play in de facto standards differs greatly depending on the standard and method used to develop it. Consortium and forum standards will often be subject to a patent policy, which in most cases strives to ensure that the content of standards and recommendations is, as far as possible, royalty-free. In other cases, where a de facto standard is made by one organization or a group of organizations, the standard may include or refer to patents belonging to the developing organization or a third party. In these cases, the developing organization can license the patents included in the standard without considering fair, reasonable and non-discriminatory conditions.

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15 CEN-CENELEC Guide 8.

Rounding off the chapter

The modern and globalized world cannot exist without standards supporting cooperation, trade, health, safety, economic growth etc. Standards have a huge influence on everyday life and it is therefore crucial that they are developed in a context where anybody has the possibility of participating and where a standardization process governed by consensus allows all views to be heard and discussed in an open and transparent way. Openness and transparency are fundamental aspects of the work of standardization organizations.

The importance of standards makes it vital that we all have some knowledge of standards and standardization. Some need only a general insight into the nature of standards whereas others need in-depth knowledge of the dynamics of standardization and standards – the influence standards have on the market – how to implement standards in a business or how to get most out of standards. The importance of standards gives **you** a responsibility to define your involvement in standardization. Which knowledge is relevant to you? How can you use standards? And how can you contribute to the development of standards?

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WTO: Agreement on Technical Barriers to Trade (Uruguay Round Agreement).

Discussion points

Below are some suggestions for further discussion or study. These can be discussed during class, in groups or be used as ideas for further study.

1. What are the definitions of a standard. What are the differences between these? And what do these differences mean for society, businesses, consumers, etc.?
2. Do you think that there will be more or less standards in the future? And will they primarily be national, regional or international?

Chapter 2

Why do standards exist?

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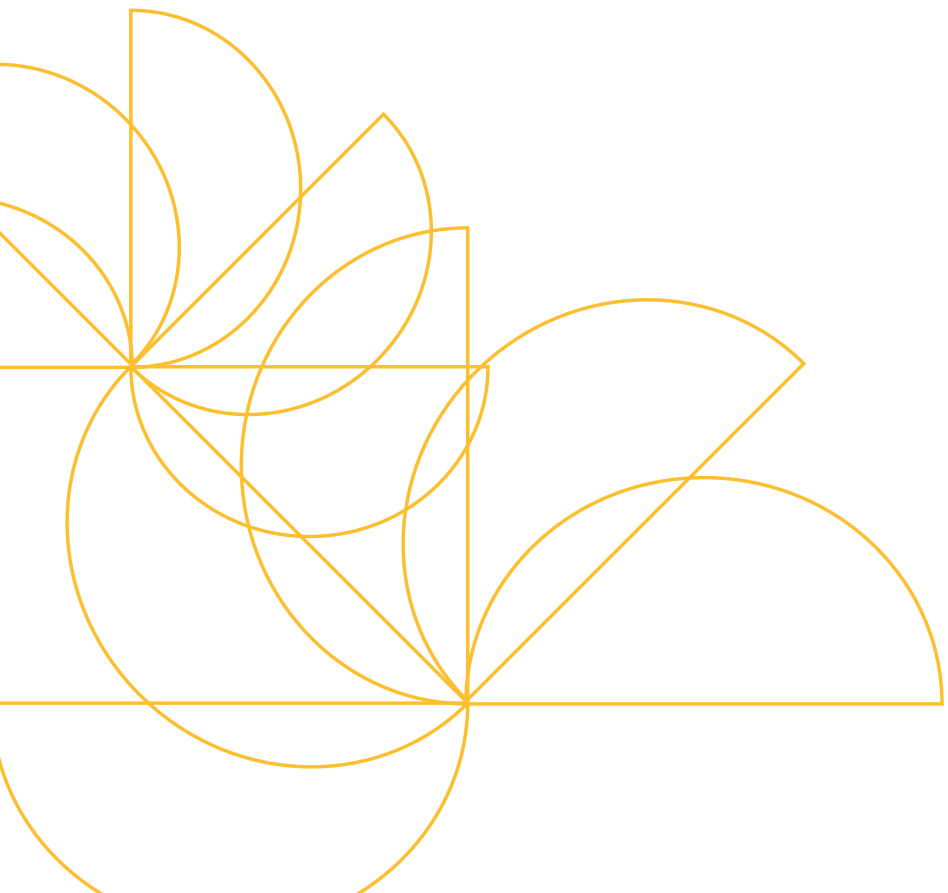

The evolution of standards

Since ancient history, standards have proven to be a valuable tool. In classical Greece, the first written standard (chiselled in stone) was made to ensure the quality of the pins used for holding columns together. The Greeks and Romans used standards for making bridges and aqueducts safe structures.

In early days, standards were used in connection with trading. Pots for example, although handmade, were produced in fairly uniform sizes, hence ensuring comparable cubic measures. Coins were introduced in an attempt to have more standardised units of payment. Likewise, scales were standardised to avoid cheating in trade.

Introduction of the metric system is thought to be among the first international standards, facilitating the comparison of distances across country borders and the preparation of more accurate maps.

The industrialisation and increasing cross-border trade augmented the need for standards as a common platform for agreement. In 1865, the first international standardization organization, International Telegraph Union, ITU, was founded in Paris in connection with the extended use of telegraphy. In 1906, the International Electrotechnical Committee was founded, and in 1920 the forerunner of ISO, International Organization for Standardization, was set up. Since then tens of thousands of standards have been made that benefit society, business and consumers in various ways.

Case 1:
An indispensable tool – the screwdriver

The screwdriver has been selected as the best tool invented for the past 1000 years by a New York Times article. However, without standardization, the screwdriver would never have been a success.

Until the 1800s screws were custom-made for each machine. In 1841, an apprentice tool and die maker named Joseph Whitworth collected screws from companies across Britain and reported his findings to the Institute of Civil Engineering. His idea was to standardize the screw threads determined by the average of the existing screws.

This resulted in a screw with a thread angle of 55° which became the standard for 20 years. However, as machinists had difficulty producing this particular angle, American engineer William Seller proposed a 60° angle instead. This type of screw would later become known worldwide as the Unified Thread Standard and it has since been recognized internationally as the ISO screw thread standard[16].

Figure 4: Screwdriver – an indispensable tool.

16 Choi et al.

What are the benefits of using standards?

Organizations use standards for a number of purposes and different types of standards meet different needs. Standards are about creating a *lingua franca* and agreeing which requirements a product, service or process must fulfil. Standards are a business tool for communication between supplier and provider and are indispensable in the global value chains of modern times. Standards also help to ensure that products, materials and constructions are safe so that we, as users, can be sure that houses, bridges, machinery, electrical appliances etc. are safe to use.

There are a number of different types of de jure standards, which serve different purposes.

Terminology standards are used to create a common language and are especially utilised in new innovative areas, where the need to establish clarity about terms and definitions is profound. **Standards for symbols** are a variety which defines the meaning of a number of symbols used e.g. in technical drawings, diagrams or signposting.

Compatibility standards are used to ensure that different parts or products fit together e.g. a plug fitting into a socket, nuts and bolts matching the thread etc. These are typically standards specifying requirements for size and design. An example from everyday life is the A4 paper size that makes it possible to develop a variety of products such as ring binders, folders, printers and so on without having to make an endless number of sizes. Consequently, variation is reduced by this type of standards. This means that consumers can be more confident that things fit together despite the fact that they are produced by different organizations, and for organizations it means that they can limit the number of models and thereby reduce their costs.

Performance standards specify requirements for operation, quality, safety or other parameters such as the environment, health etc. This means that the standards secure a minimum level of e.g. performance or safety. They contribute to building confidence because users can rest assured that a product conforms to the required safety or quality level. As consumers, we like to assume that the products we buy are safe without having to investigate the risks presented by a particular product. Buyers

of e.g. medical devices must be able to assume that the devices they purchase do not harm patients. The standards contribute to ensuring the necessary safety level.

Producers benefit from the fact that development can be based on known requirements and that it is possible to qualify for market access by conforming to well-defined standards. Standards thus create a level playing field, which makes it easier also for small enterprises to gain a market foothold. As the standards do not only describe performance requirements but include guidance on how to achieve performance, they serve as a tool for sharing best practices and provide a shortcut for product development.

Performance standards ensure that organizations that supply safe products operate under reasonable competitive conditions and that competition is not based on lowest price at the expense of safety and performance. The level playing field defined by standards ensures that competition takes place at an adequately safety level. Conversely, there is a risk that one or a group of predominant organizations will stipulate requirements that are so strict that they in fact limit the market access of other organizations and thereby impede competition.

Measurement and test standards make it possible to test products in a uniform manner and to establish confidence in the product. Measurement and test standards allow producers to demonstrate and document the quality of a product or a service and they can help provide the sufficient level of information for the purchasers. In this way measurement and test standards may be used to reduce risks and transaction costs in trade. Furthermore, measurement standards allow comparison of measurements. Different measuring methods, e.g. for measuring harmful substances in flue gases from power plants, may yield very different results. Standardised measuring methods ensure that politically determined limit values and the control measurements made are consistent.

Management standards constitute a tool for organizations to effectively manage their efforts for improvement with respect to diverse parameters such as quality, environmental aspects, energy consumption, working environment, information security, food safety, etc. Management standards provide a means to systematic planning and follow-up action

and may consequently serve to improve efficiency and quality, reduce costs etc. Organizations may use certification[17] for marketing purposes to boost their business profiles. A number of major organizations have adopted this approach to quality management throughout their entire value chain by systematically requiring that all subcontractors implement quality management standards. The result is input of a much more uniform quality and a potential for considerable cost reductions.

A summary of some of the effects of standards is given in Table 2 on next page.

17 Conformity assessment of products or systems by an independent third party often against a standard.

Table 2: Effect and value in relation to types of standards.

Type of standard	Technical effect and value	Economic effect and value
Terminology and symbols	• Clarity of concepts, definitions and symbols • Common language	• Reduced transaction costs • Networking benefits
Compatibility	• Coherent systems • Reduced number of variants • Interoperability	• Networking benefits • Scaling opportunity • Reduced costs • Innovation
Performance	• Safe products • Reduced risk • Known requirements • Confidence • Level playing field • Sharing of best practices	• Open markets • Fewer market penetration barriers • Reduced transaction costs • Competence accumulation and dissemination of knowledge • Potential to deny market access if requirements are too strict
Measurement and test	• Demonstration and documentation of product properties • Higher precision • Comparable measurements	• Open markets • Fewer market penetration barriers • Reduced transaction costs • Competence accumulation and dissemination of knowledge
Management	• Management and quality improvement • Optimisation of processes • Reduced risk • Marketing opportunity	• Reduced costs • Innovation • Economic and business growth

The value of standards for a company

A Danish survey revealed that a majority of organizations primarily use standards because they are required to do so, either by the market or their customers or by legislation[18]. However, the same group of organizations also replied that the use of standards offered a number of advantages: acquiring knowledge and best practices, easier communication with customers as well as suppliers, higher quality, increased efficiency and fewer defects and complaints (DAMVAD 2013).

Standards give organizations the possibility of focusing on and unambiguously identifying the requirements set by customers for products and services. Standards ensure that you do not have to start from scratch every time and that you have a platform to build on (also see chapter 5: Standards supporting innovation). Standards thus constitute an important tool for product development and hence for innovation. In addition to this, most new products are to be used in connection with existing products and compatibility therefore becomes an essential aspect. One example is the charging plugs of electric cars that should match the outlets of charging stations.

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18 Standards are in general voluntary, but can be closely linked to legislation (see chapter 4).

Case 2:
Company survival 1.0 – How to ensure that your business is not stifled by a standard

DAKA Biodiesel has developed and refined the conversion of waste to 2nd generation biofuel, which can be used to power cars, busses etc. The company by incident learned that the European standard for biodiesel, EN 14214, was about to be revised in a way that would make DAKAs product more expensive and reduce its marked value. This could mean the end for the company, but DAKA Biodiesel became a member of the CEN-committee through Danish Standards as the Danish expert. Here DAKA Biodiesel representative Mr. Kjær Andreasen got the opportunity to prevent the development of a standard that would have made it much harder to use residual products to make biodiesel. "We knew that we had a good product, but still it was a long tough battle to formally be able to sell the product directly to the market," explains Kjær Andreasen technical director in DAKA. He continues: "When you have an innovative product, you have to relate to the existing market. Even though you have a brilliant product, you have a problem if it does not correspond to the standards. It can be an advantage to make products to a market regulated by standards – then you know exactly which requirements your product must meet." (Danish Standards. *Vækst + Kvalitet*. 2012.)

As standards provide knowledge and best practices, organizations will experience that standards often result in improved products and services and in enhanced and more efficient and effective processes. Standards thereby have a positive impact on the organizations' productivity. This is also seen from surveys of the connection between the use of standards and the development and growth of organizations. A Danish survey made in 2007 shows that organizations using standards experience an increase of their productivity by 10 % to 15 % compared to organizations which do not use standards and that their added value is 20 % to 25 % higher (CEBR 2007). It may be a two-way interaction: Organizations that use standards increase their productivity and/or the most productive organizations use standards. A British study shows standards supported 37.4 % of labour productivity growth and 28.4 % of GDP growth in the UK economy between 1921 and 2013 (CEBR 2015), and a similar Canadian study shows that from 1981 to 2004 standards accounted for approx. 17 % of the growth of work productivity in Canada (Standards Council of Canada. 2007). Australian and French studies have calculated that a 1 % increase of the number of standards results in a productivity growth of 0,12 % to 0,17 % (AFNOR 2009, Standards Australia 2007 and Standards Council of Canada 2007).

Participation in the standardization work can also benefit the companies by ensuring that their product fit the current and future standards. The companies can for instance achieve this by participating in the standards development process and through that obtain influence when a standard is revised or the company can take the initiative to the creation of a new standard. Research and innovation consortia, where research institutions and companies work together, can – depending on the kind of research they are doing – benefit from fostering the making of a pre-standard to promote their results or methods to the standardization community and all the standard users. The benefits are exemplified in the following case:

Case 3:
How to gain market access with standards

The architect company 3XN and its innovation unit GXN, are working on the development of new bio based composite material for the building industry. They are working together with 12 other European companies and organizations in a European Innovation project. One of the organizations is the Portuguese National Laboratory for Civil Engineering, who make sure that the development will both take existing standards for building materials into account and can initiate the development of new standards to secure that the new bio based composite materials can get fast market access. Often 3XN and GXN experiences that the lack of standards for CE-marking (also see the paragraph on Conformity Assessment) of building materials can hinder the innovation in the building industry: "When the regulation is missing for new materials and alternative use of existing materials, both our work and the engineers' work of proving compliance gets slow." If a new product does not fit existing standards, the consequence can be that you are forced to choose a more expensive, less resource effective, or environmentally stressing solution instead of cheaper and more sustainable components, because the documentation process for the innovative component becomes insuperable without standards. Standardization takes time and therefore the standards should be taken into account from the beginning of R&D-projects to minimize the risk of slowing down the dissemination of new methods and technologies because of outdated standards or no standards at all. (Morten Norman Lund, engineer GXN).

The value of standards for society

As described above, standards have a number of positive effects in terms of quality, interoperability, safety, the environment etc. Solely by contributing to safer products, standards play a role in preventing a substantial number of accidents and thereby save the society a considerable sum of money.

Many countries have implemented standards as a supplement to their legislation. This is typically done by laying down in legislation the overall requirements for e.g. safety and referencing to one or more standards for the specific technical requirements, which a product must fulfil in order to conform to legislation. By using standards as a basis, legislators reap several benefits: Firstly, they gain access to the expertise of experts from business, organizations, universities and NGOs, secondly they have access to the resources provided by these experts, and thirdly they benefit from the fact that standards are more frequently updated than legislation. By choosing to refer to international or regional (European) rather than national standards, authorities at the same time open markets and increase competition, resulting in better and less expensive products.

The most extensive use of standards in legislation takes place in the EU where regulation of the Single Market is primarily based on the "New Approach" principle. Here legislators define the essential requirements in regulations and directives while European standards specify the technical specifications required. The European Commission identifies the need for standards for the purpose of a specific directive, and the European standardization organizations, CEN, CENELEC and ETSI are entrusted with a standardization request to develop the relevant standards. These standards, which are termed harmonised standards, provide a presumption of conformity with the directive or regulation. (see chapter 4: *Standards and Regulations - how are they related and how do they interact?*).

To this must be added the impact of standards on the economic development. The increasing number of international and regional (European) standards secure a level playing field for the corporate sector and remove the technical barriers to trade often constituted by national standards and regulations. This means that standards play a key role in international trade.

Case 4:
Containerisation – the value of being inside the box

Up until the 1950s goods were transported in crates, plastic or bags that were customized to fit that particular batch in size. This made placing cargo into the hulls of transport ships difficult and time consuming and the goods took up more room in the hull than necessary.

In 1968 ISO published a revolutionary standard, ISO 668, that unitised shipping containers. Simply put, the standard set the dimensions of a standard container in addition to some features that made transporting the containers easier.

By standardising container sizes across country borders, substantial efficiency improvements have been obtained. ISO-containers are "intermodal" meaning that the container can be moved from one mode of transport to another (from ship to rail etc.) without reloading the contents of the container. In addition to this, ISO-containers are reusable and have castings with openings for twist lock fasteners at each of the eight corners, making the container easy to load on trucks and stack on ships. Similarly, identical equipment can be used in all ports worldwide, and containers can be stacked regardless of their country of origin.

The ISO-container has had a great impact on the world, now setting the dimensions for a multitude of logistic aspects such as the height of tunnels, the width of vehicles, the design of ships and handling equipment for loading and unloading the containers etc. And pallets and boxes have been be standardised to fit into containers. (Choi et al).

Figure 5: Standardized contained.

By stimulating productivity and innovation as described above, standards becomes an essential driver for economic growth; a driver similar to patents, in fact. A number of studies carried out in Denmark, Germany, United Kingdom, France, and Canada have investigated the connection between standards and economic growth and they show that standards account for 1 % to 4 % of the growth of the Gross National Product (GNP) (Swann 2010).

The value of standards for consumers

Standards also have a direct value for the consumer, although few consumers are aware of the extent that standards affect their daily lives. Standards are all over – furniture, textiles, coffee machine, bicycle helmets, emission of hazardous substances from, for example, child care products etc. Standards ensure safety, security, and affordable, compatible products in the everyday lives of consumers.

In a purchasing situation, checking if a product or a service complies with certain standards may help consumers choose the right product or service depending on what is important to them (e.g. environment, safety,

size etc.). Checking compliance to standards will also ensure compatibility between products, which can be crucial to functionality in for example IT equipment. Standardization also enables mass-customization, providing consumers with the opportunity to customize their product without raising costs significantly (Choi et al).

Throughout a day consumers run into thousands of standards for anything from bed-sheets to energy efficiency. Although it is impossible for the consumer to have knowledge of all these standards, consumers should be aware of the existence of standards as the "invisible" structure that helps them to be able to rely on products without actually having to read the standards themselves.

Conformity assessment

More and more organizations operate on the world market instead of only nationally. This means that it is crucial that their products and services can be sold in several countries and that they can easily import parts for their production. In the 1980s this need gave rise to a great increase in European[19] and international standards that provide requirements which span beyond national borders. To make a strong European market (The

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19 The increase of standards in Europe from 1985 and forth mainly has to do with the implementation of "The New Approach" in the European Union. The New Approach is to make framework directives instead of directives with very specific requirements to safety etc. This was mainly done in areas regarding product requirements e.g. machine safety where you need to CE-mark the product to show compliance with the directive. To support the framework directives with some more detailed information on testing etc. the European Commission harmonized a number of standards to each framework directive. If you follow the harmonized standard – you follow the requirements in the directive and can CE-mark your product.

The reason for making framework directives and harmonized standards instead of directives with more specific requirements was to make the system smoother. The framework directives can function longer, because you only need to make changes in the harmonized standards when a new type of product is invented or when you wish to change the requirements. This created a demand for many more European standards.

(For more information, see e.g. Growth – *Internal Market, Industry, Entrepreneurship and SMEs.* http://ec.europa.eu/growth/index_en.htm.).

Single Market) all standardization organizations in Europe are obliged to withdraw national standards if a European standard is being developed, and if they wish to make a national standard they must first ask the other European standardization organizations it they are interested in making a European standard before they start the work at national level. This means that it is only necessary for a company to demonstrate conformity against one standard in all of Europe.

Conformity assessment involves a set of processes that show that a product, service or a system meets the requirements of a standard. Undergoing conformity assessment has a number of benefits:

- It provides consumers and other stakeholders with added confidence
- It gives a company a competitive edge by documenting that it meets the requirements of a standard
- It ensures that health, safety, and environmental conditions are met.

The main forms of conformity assessment are testing, certification, and inspection[20].

Conforming to standards reduces technical barriers to trade and opens markets by making it easier to export and import products. This means that e.g. sub-components for a product can be produced in several countries and assembled in another. The car industry is an example where this has been done for many years, giving them the advantage of mass-customization.

In many areas, it is possible for a company to declare that they meet the requirements of a standard by self-declaration of conformity. However, in some areas it is required that a third party (a neutral and independent certification organization) tests and verifies that a product, component, service etc. follows the criteria in a standard in order to be able use a mark of con-

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20 What is conformity assessment: http://www.iso.org/iso/home/about/conformity-assessment.htm

formity. Certification organizations must be given formal recognition by an authoritative party (accreditation body) that they are competent to carry out certain certification tasks in order to be allowed to certify. In both cases the company is liable for the claim that they meet certain requirements and are therefore subject to liability legislation (Hesser et Al 2010).

Examples of marks of conformity are:

- UL-mark
- CEN keymark
- CE-mark.

The CE-mark is in a sense unique, as products covered by certain European Union directives (e.g. Safety of Toys) have to bear the CE-mark to be sold in Europe, other marks are voluntary.

In 1985, the European Commission recognized the need for conformity throughout Europe and the so-called New Approach was developed. The European Union directives, known as the "New Approach Directives", define "essential requirements" related to health, safety and environmental issues. Products must meet these requirements in order to be placed on the European market[21]. A way to demonstrate the fulfillment of these requirements is by using standards. The standards related to the New Approach are called harmonized standards, meaning that they are recognized, approved and accepted throughout the EU. The New Approach and European standardization have contributed significantly to the development of the Single Market.[22] (See Chapter 4: *Standards and Regulations – how are they related and how do they interact?*).

The need for conformity has also led to so called Mutual Recognition Agreements where one party (often a country) agrees to recognize the results of conformity assessment procedures produced by the other party's conformity assessment bodies (Hesser et Al 2010).

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21 http://www.cenelec.eu/aboutcenelec/whatwestandfor/supportlegislation/newapproachdirectives.html

22 *New Approach Standardisation in the Internal Market.* http://www.newapproach.org/

An example of this is the European Community-Australia Mutual Recognition Agreement (EC-MRA). In the case of Australian exporters, this means that compliance with the relevant EC Directives can be established in Australia. In this way, products can be placed on the EC market without further intervention by EC authorities.[23]

Standardization creates value at many levels

As described in this chapter, standards influence society and business in numerous ways and have been creating a common language for producers and consumers for hundreds of years. Standards can define many aspects ranging from terminology, symbols, compatibility, performance, measurement, test methods, and management systems. Standards are the backbone of the European Single Market and are key components in creating safety, interoperability, efficiency etc. to the benefit of both business and consumers.

Consumers are also highly effected by standards. Each day consumers run into thousands of standards – often without even noticing the great impact they have on our daily lives.

However, whether standards are used deliberately as part of product development, business strategy or in a purchasing situation, or go unnoticed by the masses, one thing is certain; throughout the world, standards play an enormous role in society and for companies and consumers.

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23 *European Community-Australia Mutual Recognition Agreement.* http://www.industry.gov.au/industry/IndustryInitiatives/TradePolicies/TechnicalBarrierstoTrade/Pages/ECAustMRA.aspx

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Discussion points

Below are some suggestions for further discussion or study. These can be discussed during class, in group discussions or be used as ideas for further study by the students.

1. How are the benefits of standards for the different target groups taken into account in the standardization process? And how can these benefits be maximized (e.g. involvement, dissemination, etc.)?
   (Target group in this case is: society, business and consumers.)
2. Choose a standard and discuss the societal, business and consumer benefits and impact of that specific standard. Are the benefits and impact different for society, business or consumers? Why or why not?
3. Why would you, as a company, get your product certified against a standard? What are the benefits of a third-party certification contra a self-declaration?

Chapter 3

How are standards developed and structured?

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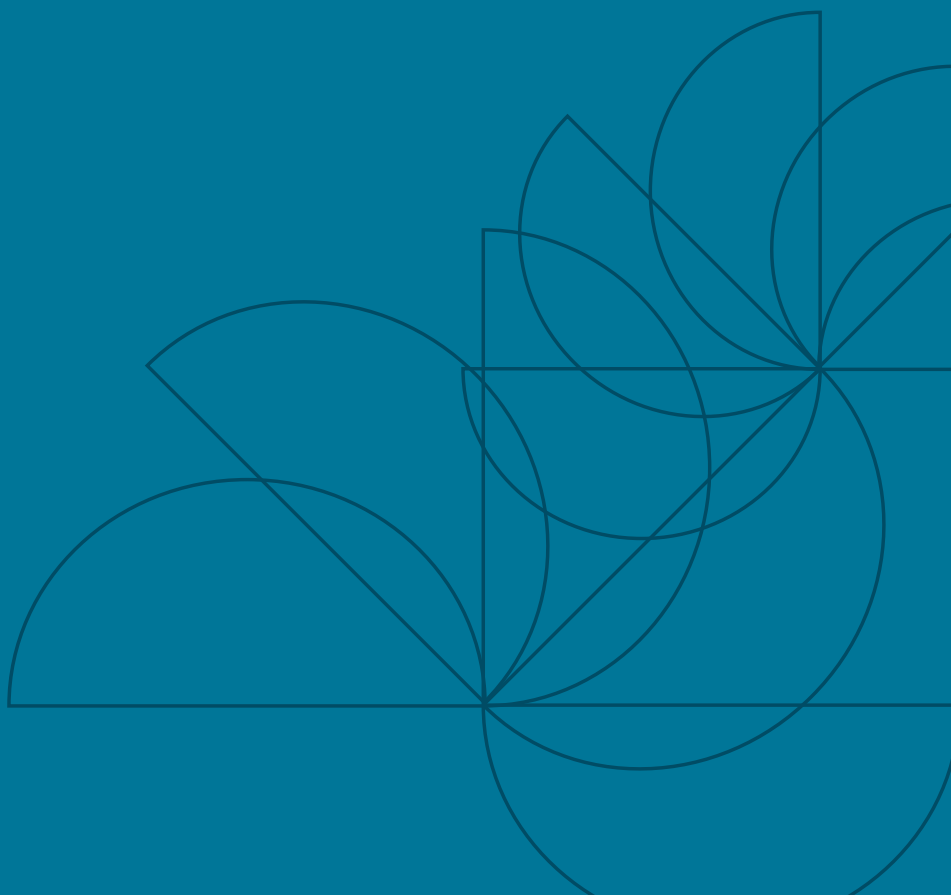
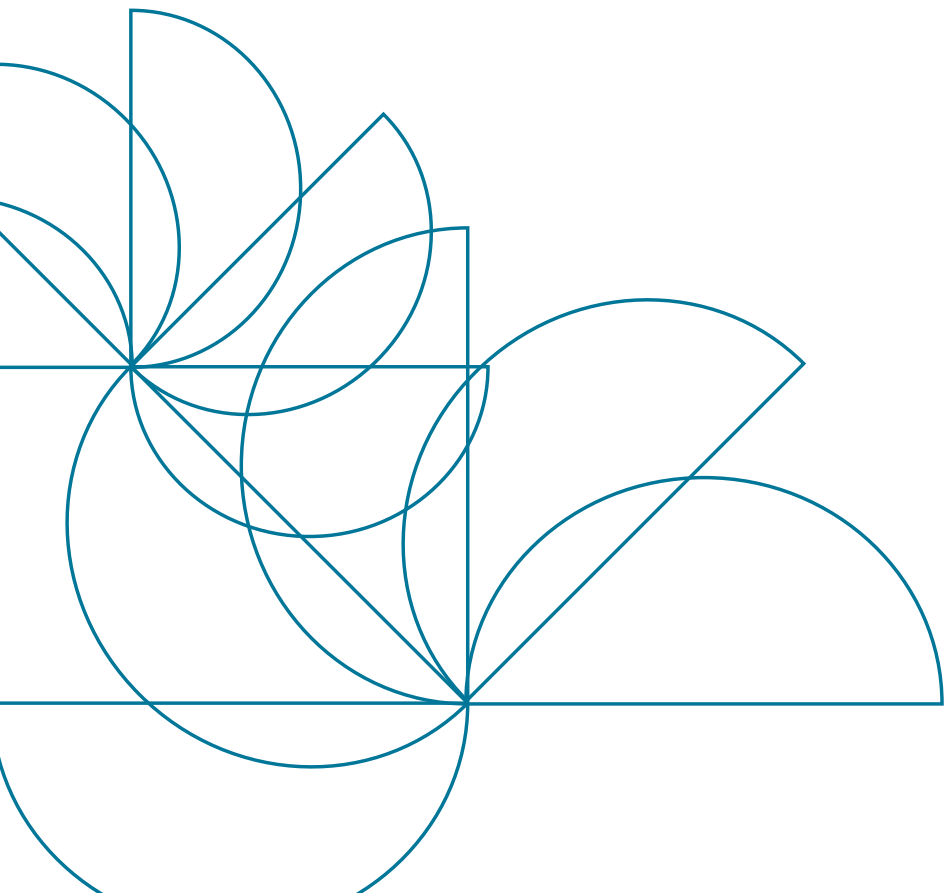
Finnish Standards Association, Finland





Why is knowledge of the standardization process relevant?

In this chapter, you will be introduced to the standardization process, the development of standards, participation in the development of de jure standards, how standards are structured, and the most common types of standards documents. This will give you knowledge about the structures behind the standard to help you better understand and read them. All national, European and international de jure standards are structured the same way so if you are familiar with this structure you will be able to get an overview of a new standard very fast. You will also gain knowledge on how to participate in the development of standards if one day you should wish to do so e.g. to ensure that your company is familiar with any upcoming standards, which may be used in your marketplace or by your competitors.

A Map of the Standardization world

Standards are prepared at various levels: some standards are developed for national purposes; others are developed and published for the European region. Furthermore, there are standards, which are used globally. National standardization organizations are responsible for preparing national standards and participating in European and international standardization. Each European country has its own National Standardization Organization, which is responsible for developing national standards and participates in the European as well as international standardization.

De jure standardization

De jure European standards[24] are developed and published by CEN (the European Committee for Standardization), CENELEC (European Committee for Electrotechnical Standardization and ETSI, the European Telecom-

[24] See chapter one *What is a standard?* for at definition of de jure standards.

munications Standards Institute). They act as a cooperation organization for the national standards bodies of all the EU and EFTA countries. CEN has over 30 member countries. CEN and CENELEC are international non-profit associations that are officially recognized as European Standardization Organizations alongside ETSI, the European Telecommunications Standards Institute.

CEN and CENELEC member countries are obliged to adopt each European standard as a national standard. They also have to withdraw any existing national standard that conflicts with a new European standard. All of the European standards that have been approved and adopted by CEN or CENELEC are therefore automatically accepted and recognized in all of the member countries of CEN and CENELEC. The aim of the procedure is to guarantee a common collection of standards for the European region. Standards published by CEN and CENELEC are identified by a unique numeric identifier with the prefix "EN" on the front page of the standard.

De jure international standards are developed and published by ISO (International Organization for Standardization), established in 1947. The national standards bodies from over 160 countries are members of ISO. The standards for electrical, electronic and related technologies are developed and published by IEC (International Electrotechnical Commission), who have more than 80 member countries. At the international level, ITU develops standards for the telecommunication field.

The member countries can adopt international standards as national standards, although this is voluntary. CEN and CENELEC cooperate with ISO and IEC according to mutual agreements[25] so that international standards (ISO or IEC) are often adopted as European (EN) standards, in which case they are also nationally adopted as e.g. EN ISO or EN ISO/IEC standards in the member countries. In addition to working toward a coherent standards collection at both European and international level, standardization bodies of different regions cooperate to ensure standards complement rather than conflict with each other. For instance, around 30 % of the CEN standards are based on the work made carried

25 Defined in the Vienna and Dresden agreements.

out by ISO. Around 75 % of the European electro-technical standards of CENELEC are based on the international standards prepared by IEC. This means that through national implementation, many national standards are based on or identical to international standards.

Table 3: The relation between standardization organizations at national, European and international level.

International	IEC	ISO	ITU
European	CENELEC	CEN	ETSI
National	National Standardization Organization		

Other standard developing organizations

There are organizations specializing in developing standards other than the formal standardization organizations described above (also see chapter 1: *What is a Standard?*). This means that their core business is standardization, but they do not have government-related accreditation or a formal relationship with a government as the formal standardization organizations do.

These organizations structure their standardization process in a way that is often similar to that of the formal standardization organizations, as consensual documents developed by committees that are open to all interested parties (Hesser et Al 2010). Examples of organizations specialized in standardization are: the Institute of Electrical and Electronics Engineers (IEEE), American Society for Testing and Materials (ASTM) etc.

Consortia and market dominance

Standards can also be developed by consortia or come into being as an effect of market dominance (de facto standards). The process being open only for those invited to join characterizes this ways of developing standards. Consortia are often formed with the purpose of advancing a particular technology and standards are developed to promote practices set by a single company (Hesser et Al 2010).

By developing a standard in this way, companies or consortia can acquire a large market share by dominating the market. However, this is also a risky strategy, as it can result in standard wars where more than one company or consortia try to set the standard for a market.

How does the standardization process work?

Standards are developed in technical committees and their sub-committees as well as in working groups. There are several hundred technical committees in the system of CEN, CENELEC, ISO and IEC. The member organizations contribute to and assist in the standardization work where they represent the interests of their stakeholders. All member organizations have the right to participate in the work of all the committees and can nominate experts to the working groups. In the course of international committee work, member bodies can be designated 'P' (participating) members or 'O' (observing) members.

Participation in standards development in the formal system is open to everybody. It is voluntary work based on consensus. The standardization committees should preferably consist of experts from each relevant sector of society, e.g. industry and commerce, consulting agencies, academia and research bodies, consumers and labour, public authorities as well as government. Participation from a wide field of experts leads to creation of agreed practice within the field.

The lifecycle of a de jure standard

Drafting a standard goes through a certain path from a draft standard to the phase of a public consultation, balloting, publishing, and finally, the implementation of a standard.

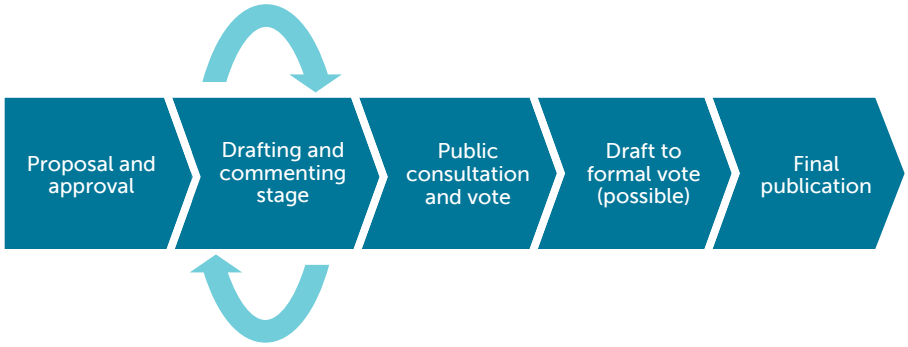


Figure 6: Stages for developing a formal standard. Minor differences can appear form organization to organization.

A public consultation means that each member body releases the draft standard for public comments in their own country. The opinion of each member country is developed by consensus in a national mirror committee or on the basis of public consultation. If the text of the standard is approved in the consultation stage there is no need to have a further vote.

Revision is also a stage of the lifecycle of a standard. A technical committee makes sure that a standard is up-to-date, and whether a standard needs to be revised or not is checked regularly. The first review is required to take place within five years after a standard has been implemented.

For a more detailed chart about developing standards, see the Annex A: *Detailed Description of the Standardization Process in CEN.*

How to get involved?

Standardization is open to everybody[26]. The easiest way to find out about ongoing standardization activities and to get involved in standardization is to contact your National Standardization Body. (A list of member countries with contact information can be found e.g. on the European and international organization's webpages[27]). The member bodies create mirror committees for the committees and areas of national interest.

A mirror committee is a standardization group that gives the national stakeholders an opportunity to gain insight and participate in European and/or international standardization from a national level with a national perspective and in the national language.

Different ways to be involved in standardization

Following standardization in your field of interest helps you to anticipate any forthcoming changes.

See below the details of the different levels of involvement in the standards development process;

- Becoming a member of a national mirror committee
  - Membership of a national mirror committee offers the possibility of following standardization work from the very beginning and gives a chance to have a say in the national comments. It is possible to get involved with the work of mirror committees through national standardization bodies.
- Becoming a delegate in a technical committee
  - As a delegate, you represent your national mirror committee and thus your country in the European or international technical committee.

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26 In some countries a fee is charged for participation.

27 www.cencenelec.eu, www.iso.org, www.iec.ch.

- Membership of working groups
  - As a member of a working group, you can take part in the development of the contents of a standard. Members of the working groups also deal with the comments gathered from each participating country during public consultations, and decide on eventual changes. The working groups can be joined through national standardization bodies.
- Submitting comments at the public consultation stage
  - All draft standards must go through a public consultation, during which anyone interested in the matter can approve/disapprove the draft standard content with technical and/or editorial comments.

One can have different roles in committees and working groups. Here are some examples of key roles:

Expert

An expert is a person nominated as a member of a working group or a technical committee by the national standardization organization. An expert participates in the technical writing of standards.

WG Convenor

Person responsible for the administration of a working group, meeting arrangements, acting as a chair of the meetings and delivering documents. His/her task is to help the experts find a sufficiently wide consensus on subjects. He/she also reports on the achieved work to the technical committee.

Delegate

A delegate is nominated by a national standardization organization, which he/she represents in the meetings of the technical committee. A delegate participates in creating a multinational consensus and decision making as a representative of his/her own country. Unlike in the role of an expert, a delegate comments on the issues according to the prevailing view of his/her own country.

TC chair

The chair of a technical committee has the overall responsibility for the management of a committee. He/she must take all the members' views equally into account by then leading the work towards the consensus of all the stakeholders. The TC chair will be a person nominated by a committee secretariat, often originating from the country holding the secretariat[28].

TC secretary

The TC secretary is the person who takes care of the administrative work of a technical committee. Together with the TC chair he/she takes care that the committee work is carried out according to the current rules. In questions of substance, the TC secretary has to act in a neutral way with no connections to national views.

How are standards structured?

One important feature of de jure standards is that they are all structured in the same way. This makes it much easier to get an overview of, and to find specific information in a standard (e.g. the normative references, a list of other standards to refer to while using the standard). If you are familiar with this structure, you will be able to quickly understand and use a standard – and avoid spending time reading standards that are not relevant to you.

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28 Secretariate: Each technical committee has a secretariate responsible for the administrative work and the general progress of the standards."

Table 4: A typical arrangement of a standard document [29]

Type of element	Arrangement of elements[a] in document
Preliminary informative	*Title page*
	Table of contents
	Foreword
	Introduction
General normative	**Title**
	Scope
	Normative references
Technical normative	Terms and definitions Symbols and abbreviated terms ... Normative annex
Supplementary informative	*Informative annex*
Technical normative	Normative annex
Supplementary informative	*Bibliography*
	Indexes

[a] **Bold type** = mandatory element; upright type = normative element; *italic type* = informative element.

29 CEN-CENELEC Internal regulations, part 3, pg. 17.

Table 5: Elements in a de jure standard.

Title page	The title page contains the title and number of the document. If CEN or CENELEC adopts an ISO or IEC standard, there is an additional EN title page with that information. The same applies to the national title page. Similarly, if the standard is a national implementation of a European and/or international standard, the information is stated on the national title page. If the European Standard is identical with the international standard, the title is the same. In the national standards, a translation of the title in the national language may appear in the national title page.
Table of contents	The table of contents is entitled "Contents" and lists clauses and annexes (together with their status in parentheses), the bibliography, indexes, figures and tables.
Foreword	The foreword gives the following information: • the designation and name of the committee that prepared the document; • information regarding the approval of the document; • the latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement and the latest date by which the national standards conflicting with the EN have to be withdrawn. It includes, when appropriate • a statement of significant technical changes from any previous edition of the document • an indication of any other international organization that has contributed to the preparation of the document; • a statement that the document cancels and replaces other documents in whole or in part; • the relationship of the document to other documents; • the relationship of the standard to European legislative documents. The foreword may not contain requirements, recommendations, figures or tables.

Introduction	The introduction gives specific information about the technical content of the document and the reasons for its preparation as well as some background information to help in understanding the content of the standard. The introduction may not contain requirements.
Scope	The scope defines the subject of the document and the aspects covered. It indicates the limits of applicability of the document. It may not contain requirements. The scope shall be sufficient enough so that it can be used as a summary for bibliographic purposes.
Normative references	Normative references gives a list of the referenced documents cited in the document that are indispensable for the application of the document.
Terms and definitions	This element gives the definitions that are necessary for the understanding of certain terms used in the document.
Symbols and abbreviated terms	This element gives a list of the symbols and abbreviated terms necessary for the understanding of the document.
Main body of the document	This element contains the requirements, statements and/or recommendations presented in the standard, including a) all characteristics relevant to the products, processes or services covered by the document, b) the required limiting values of quantifiable characteristics c) for each requirement, either a reference to the test method for determining or verifying the values of the characteristic, or the test method itself. Additionally, technical elements include, as appropriate, specifications for sampling; test methods; classification, designation and coding; and marking, labelling and packaging. A clear distinction is made between requirements, statements and recommendations.

Normative annexes	Normative annexes give provisions additional to those in the body of the document. An annex's normative status is made clear in the table of contents and under the annex's heading.
Informative annexes	Informative annexes give additional information intended to assist the understanding or use of the document. They may not contain requirements. An annex's informative status is made clear in the table of contents and under the annex's heading.

For more detailed information, see CEN-CENELEC Internal Regulations Part 3: Rules for the structure and drafting of CEN-CENELEC Publications.

Standards and other deliverables

Standards are the best known deliverables, but there are others as well. Different documents have different statuses and development processes.

Here are some of the most common deliverables and their abbreviations. For a more detailed list, see the Annex A: *Detailed Description of the Standardization Process in CEN.*

European standard

EN

A standard developed or adopted by CEN, CENELEC and ETSI carrying an obligation of implementation as an identical national standard and withdrawal of conflicting national standards.

International standard

ISO

An international standard developed or adopted by ISO.

IEC

An international standard developed or adopted by IEC.

EN ISO

An international standard that has been adopted by CEN or CENELEC, carrying an obligation of implementation in European member states as an identical national standard and withdrawal of conflicting national standards.

Technical specification

TS

A document developed or adopted by CEN, CENELEC, ETSI, ISO or IEC for which there is the future possibility of agreement on a European standard, but for which at present:

- the required support for approval as a European standard cannot be obtained,

- there is doubt on whether consensus has been achieved,
- the subject is still under technical development, or
- there is another reason precluding immediate publication as a European standard.

Technical report

TR

A document developed or adopted by CEN, CENELEC, ISO or IEC containing informative material not suitable to be published as a European standard or a technical specification.

Guide

A document published by CEN,CENELEC, ISO or IEC giving rules, orientation, advice or recommendations relating to European standardization.

CEN-CENELEC Workshop Agreement

CWA

CEN-CENELEC agreement, developed by an "open workshop" outside the normal committee system, which reflects the consensus of identified individuals and organizations responsible for its contents.

Amendments and corrigenda

Standards can also have amendments and corrigenda that amend or correct it before a full revision is carried out.

How are standards numbered?

Each standard is given an identification number by the secretariat of the European or international standardization organizations. The letters of identification tell what or which standardization organizations have developed the standard.

The identification number can refer to different parts of a standard, e.g. standards EN 71-1, 71-2, 71-3 etc. are all parts of the standard EN 71 Safety of toys. Standard series are often given consecutive numbers, e.g. the EN ISO 14000 series on environmental management. However, not all consecutives numbers are related to each other. Always check the title of a standard to make sure you have the right one.

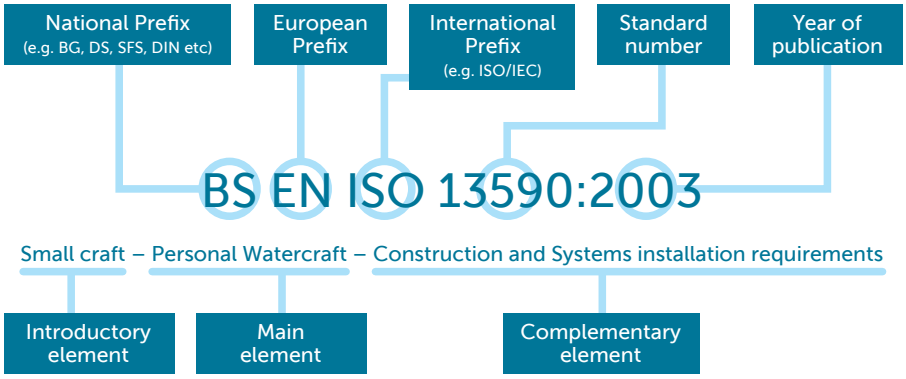
The EN stands for a European standard published by CEN, CENELEC or ETSI. The standards published by ISO have the prefix ISO. The reference code EN ISO again implies that the standard has been implemented by both CEN and ISO. The standards published by IEC have the prefix IEC.

Apart from the EN or EN ISO prefix each European standard will be given a national prefix once the National Standardization Organization implements it. Here are some examples: DIN, BS, DS. A standard beginning with "DIN EN ISO" refers to an EN ISO standard, which has been implemented in Germany by Deutsches Institut für Normung, DIN.

How are standards titled?

The title of the standard indicates the subject of the document without unnecessary details. Any additional particulars shall be given in the scope. The title normally contains a main element, which covers the subject treated in the document. If the standard covers only one or a few aspects of the subject in question, a complementary element can distinguish the subject more. The title elements can appear as a single title, or the complementary element can identify a part in a standard series.

Figure 7: How standards are titled.



Annex A: Detailed Description of the Standardization Process in CEN

CEN	
Preliminary stage **PWI** **Preliminary Work Item**	A committee can accept any work Item as a Preliminary Work Item, if the work area is not sufficiently ready for the standardization work or the subject will be given to a working group for preparation before processing to further stages.
Proposal stage **NWIP** **New Work Item Proposal**	All members can propose a New Work Item. Also the technical committees of CEN and CENELEC, CEN Technical Board (BT), The European Commission, EFTA Secretariat and a few other organizations can make proposals for a new standard. The Technical Committee makes the decision whether the proposal can be accepted and carried out. A proposal can be approved after weighted formal voting, and at least five member bodies have to be committed to undertake the work needed for the drafting of a standard. The technical committee determines the working group of the standard. The maximum time for the standard writing is three (3) years.
Drafting **WD** **Working draft**	The members of the Working Group are experts nominated by National Standardization Bodies. A draft standard has one or several draft versions before it reaches the technical contents outlined in the proposal phase. When the working group has reached a consensus on the contents of the draft standard it is sent for the attention of the Technical Committee and to CEN-CENELEC Management Centre, which finalizes the draft standard as a working draft.

Public Consultation **prEN** **Draft European Standard**	Each member body releases the draft standard for public comments in their own country in a so-called Public Consultation. The aim is to get as much feedback as possible. The opinion of each member country is developed by consensus in a national mirror committee or on the basis of public enquiries. Consultation stage is a weighed vote where the members vote for "yes", "no" or "abstain". Approval of the Consultation requires 71 % positive weighted vote and simple majority. A technical committee or a working group deals with the comments and draws up a final Draft Standard.
Formal Vote (optional) **FprEN** **Final Draft European Standard**	If the conditions of acceptance are met in the Public Consultation, the Techical Committee can decide to proceed to publication without a Formal Vote. Formal Vote is a weighed vote where the members vote for "yes", "no" or "abstain".
Publication **EN** **European Standard**	CEN-CENELEC Management Centre prepares the final contents of an EN-Standard in English. A standard is adopted in the member countries as an identical national standard, and eventual conflicting standards are withdrawn. Member bodies decide whether a standard is translated into its own language.
Review of a standard	The Standard is valid for five years. During this period it is reviewed, which means that it is evaluated whether a standard is still up-to-date and necessary. If there is no need for revision, another five years' period is confirmed. A standard can also be withdrawn without replacing it with a new one. Furthermore, a standard can be modified by technical corrigenda or amendments.

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CEN-CENELEC Internal Regulation Part 3: Rules for the structure and drafting of CEN-CENELEC Publications (ISO/IEC Directives – Part 2, modified). [Accessed 2014-12-17]. Available from http://boss.cen.eu/ref/IR3_E.pdf

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EN 45020 Standardization and related activities. General vocabulary. CEN European Committee for Standardization: 2007.

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Discussion points

Below are some suggestions for further discussion or study. These can be discussed during class, in group discussions or be used as ideas for further study by the students.

1. What are the positive sides of the standards development process being open to everyone? Are there any negative sides?
2. How can it be ensured that participation in standardization is equal?
3. The standardization process is open to all[30], but how open is it in reality? What about the ethical aspects of involving all interested parties in the process and of the public consultation, which has been created to ensure openness and dialogue on standards. Is the process open and inclusive enough from an ethical point of view?

30 Sometimes a participation fee is charged depending on business model of the national standardization organization.

Chapter 4

Standards and Regulations – how are they related and how do they interact?

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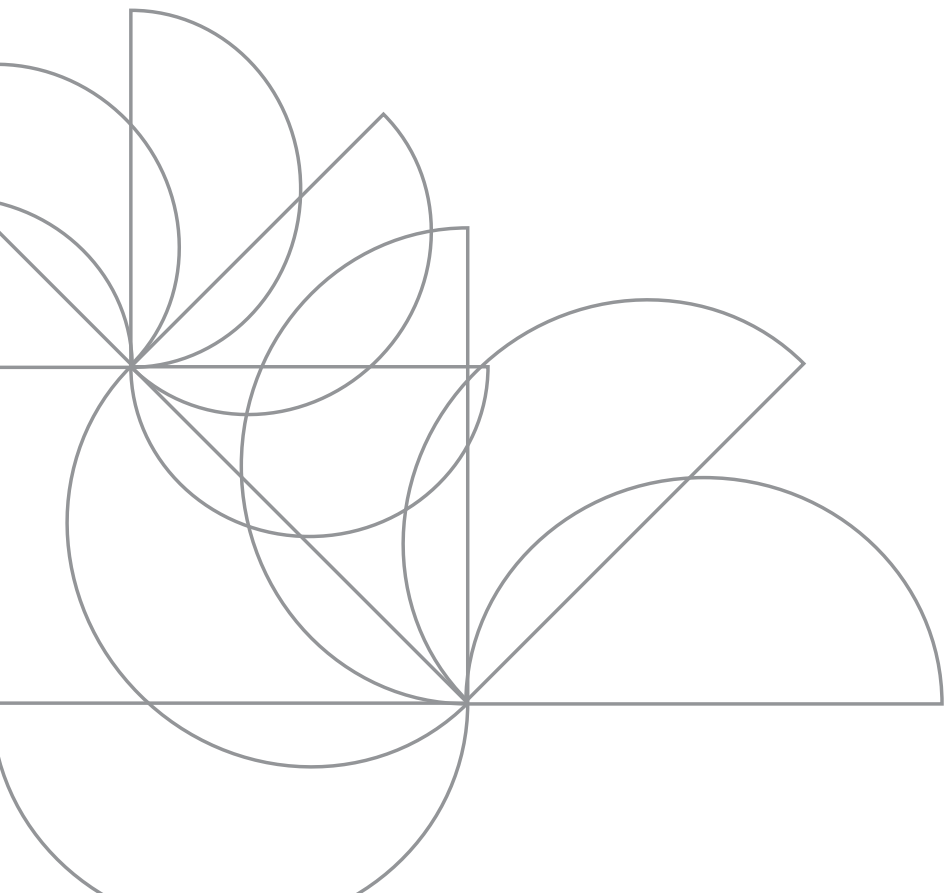

This chapter introduces the relationship between regulations and standards. It sets out basic definitions and outlines the interaction between them. The chapter focuses on regulations and standards in the European Union.

Definitions

ISO/IEC Guide 2:2004 "Standardization and related activities – General vocabulary", defines a regulation as a document providing binding legislative rules. Regulations[31] are adopted by an authority, and as such are mandatory. This means that a regulation defines what must be done and not done in order to comply. Furthermore, this means that there is, usually, a mechanism, which provides sanctions for those who do not comply.

Standards are voluntary documents based on the consolidated results of science, technology and experience; there is no obligation to apply them or comply with them and there are no sanctions for non-compliance. The only exception appears for standards that are called in and required by regulations. Standards can fall in to one of two categories. A de jure standard is a document, established by consensus and approved by a recognized body. A de facto standard is not approved by a recognized body, but is an agreement within an organization or between two or more organization. (See chapter 1: *What is a standard?*, for an elaboration of this definition.) This chapter will focus on de jure standards; they are the most common standards used in relation to regulation.

Interaction between regulations and standards

Regulations are mandatory instruments set either by national governments, or by the European Parliament/Council, in order to define legal minimum context for the smooth functioning of society. Standards are voluntary instruments for business facilitation and they are developed by the standardization organizations, which can have a national, regional (European) or international character. One of the strengths of standards is that all the relevant market stakeholders can be involved in the stand-

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[31] For the purposes of this chapter, a 'regulation' is considered to mean any legal act, such as the EU Regulation and Directive.

ards development. This means that standards are much easier to adapt to technological trends and to all the necessary modifications and updates than national regulations or EU directives or regulations.

The WTO Agreement

The World Trade Organization (WTO) is a global international organization that deals with the rules of trade between nations, in order to achieve a more prosperous economic world. WTO functions as multilateral trading system with WTO's agreements. The WTO's actions are based on consensus among all member countries and ratified by members' parliaments. WTO's agreements are contracts that define international commerce with guarantees of important trade rights to member countries and to the benefits of everybody involved.

The WTO Agreement on Technical Barriers to Trade (TBT Agreement)[32] promotes free trade and avoidance of any kind of technical barriers, through clearly defining voluntary standards and mandatory regulations that define technical requirements (referred to as technical regulations). Annex 1.1 to the TBT Agreement defines "technical regulation" as a "document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process, or production method." A measure is a technical regulation if: (1) it applies to an "identifiable product or group of products"; (2) it lays down product characteristics or their related processes or production methods, including the applicable administrative provisions; and (3) it is mandatory. According to the WTO TBT Agreement, technical regulations should be based on international standards. Countries have the right to establish protection at levels they consider appropriate and should not be prevented from taking measures. Governments are recommended to regulate only when necessary.

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[32] WTO TBT Agreement, Uruguay Round, 1995. https://www.wto.org/english/docs_e/legal_e/legal_e.htm

Standards play an important role and are needed as market-based instruments. They are also important in providing support to public policies and mandatory legislation in:

- Self-regulation, where there is no regulatory intervention by government, so businesses apply this approach to voluntarily agree to meet certain standards.
- Earned recognition, where regulators trust companies on the basis of compliance demonstration with standards.
- Co-regulation, where governments set the top level legal requirements and leave the market to deliver technical solutions in standards.

The New Approach and CE-marking

The European New Approach to technical harmonization was introduced in 1985 (Council Resolution 85C 136/01[33]) to enable the creation of the Single Market within the EU. The change was based on the joint contribution of legislative and standardization measures; this is a co-regulatory initiative, meaning that the European Commission issues standardization requests to the European standardization organizations (CEN, CENELEC and ETSI). The core of the New Approach is to use so-called framework directives that do not regulate at a technical level of detail, but describes the essential requirements such as safety, health or environmental protection. The essential requirements are described relatively general in the directives and are then detailed in so-called harmonized standards. Adherence to these harmonized standards is a way to comply with the directives and thus have access to the Single Market. European standards have significantly contributed to the success of the EU to ensure free movement between Member States and to remove technical barriers to trade.

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33 EUR-Lex – Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31985Y0604(01).

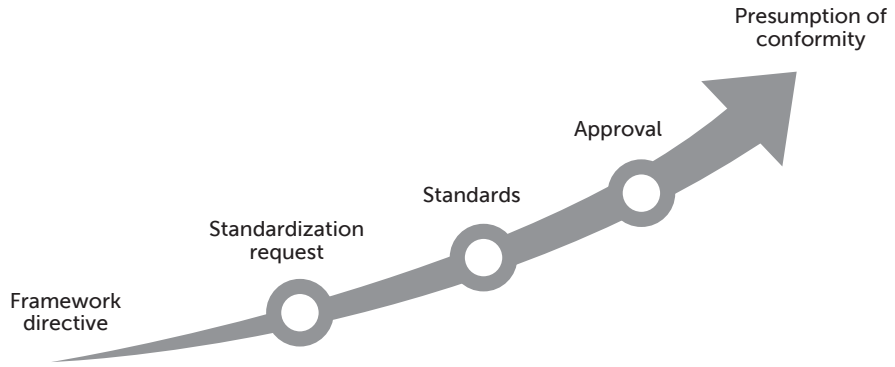

Figure 8: The New Approach.

As mentioned before, the first step in the New Approach is the framework directive. The first directive, which formed the school of the New Approach, was the Low Voltage Directive of 1973 (Directive 73/23 EEC). The purpose of the Low Voltage Directive is that all low voltage devices (between 50 and 1000 volts AC) must be safe to use. As the directive covers a very broad group of devices and products, it was obvious that one could not regulate this directly in legislation. Therefore, the directive describes only the broad, essential requirements for safety.

The next step in this co-regulatory initiative is the preparation of standardization requests (also known as mandates) by the European Commission to the European Standardization Organizations to develop and adopt European standards in support of European policies and legislation. A standardization request is a "job description" that stipulates how the standardization organization should implement the essential requirements from the directive in a number of standards for the different types of products. The standardization request is part of the political process, but also the transition to a market-driven, technical process. To come into force, the standardization request is accepted by the relevant standardization organization, which undertakes the development of the standards in a given timeframe. European Standardization Organizations are independent organizations and, therefore, have the right to refuse any standardization request if they do not think that standards can be produced. In the case of the Low Voltage Directive, CENELEC accepted the standardization request and issued the relevant standards.

After acceptance of the standardization request, a standardization program is established and the harmonized standards are developed, submitted for public consultation followed by a final ballot by the National Standardization Organizations (see chapter 3: *How are standards developed and structured,* for an explanation of the process).

A harmonized standard is a European standard developed by a recognized European Standardization Organization: CEN, CENELEC, or ETSI and is created following a request from the European Commission to one of these organizations.

Currently CEN and CENELEC have over 4000 harmonized standards, which support European regulation. This accounts for app. 19 % of the total number of CEN and CENELEC European standards[34].

All New Approach harmonized standards need to clearly indicate how they interact with the relevant directive(s) by means of an informative annex (typically named "Annex ZA" or "Annex ZZ"), which describes the relationship between the content of the standard and the requirements of the relevant directive(s).

For all standardization requests, the European Commission appoints one or more consultants who assess if the standards meet the description in the standardization request and thus details the requirements of the directive.

Lists of all harmonized standards are published in EU's Official Journal, and both the New Approach directives and the lists of harmonized standards can be found on the European Commission's website for the New Approach[35]. Once the reference of a harmonized standard is announced in the Official Journal of the European Union, compliance with the standard can bring a presumption of conformity with any relevant legal requirement. In the Official Journal, the date of cessation of presumption of conformity of a superseded standard is also published. This date marks the end of the period during which both the old and the new version of

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34 CEN CENELEC Statistical Pack 2015 Q1.

35 *New Approach Standardisation in the Internal Market.* http://www.newapproach.org/

the standard can be used to claim presumption of conformity. After that date, presumption of conformity can no longer be claimed for a product manufactured according to the old version of the standard. European standards, even developed under a standardization request and for European legislation, remain voluntary in their use[36].

One of the measures related to the application of the Single Market is the introduction of CE marking. The letters "CE" are the abbreviation of the French wording "Conformité Européenne" which means "European Conformity". "CE Marking" was introduced by Directive 93/68/EEC[37] in 1993 and since then it has been the official term for a mandatory conformity marking. It consists of the CE logo and the four-digit identification number of the notified body involved in the conformity assessment procedure. The manufacturer affixes the CE mark, after carrying out a conformity assessment, setting up a technical file and signing an EC declaration of conformity. This documentation has to be available to authorities on request. The CE mark is the declaration that the product is assessed before being placed on the market and meets the essential requirements of the relevant European health, safety and environmental protection legislation, known in practice as "Product Directives".

CE marking a product indicates to governmental officials that the product may be legally placed on the market in their country, and permits the withdrawal of any non-conforming products by customs and enforcement/vigilance authorities. It is also a passport of a product, because it ensures the free movement of the product within the EFTA and European Union (EU) single market.

The last link in the chain is market control of compliance with the harmonized standards. This task is carried out by national authorities and consists in sampling the products that come on the market and checking them for conformity. However, in practice, the extent of market control varies greatly depending on the member states and region.

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36 For further knowledge on the new Approach please see the Blue Guide: http://ec.europa.eu/enterprise/newsroom/cf/itemdetail.cfm?item_id=7326

37 *EUR-Lex – Council Directive 93/68/EEC of 22 July 1993* http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:31993L0068

Standards supporting regulation

Using standards as a tool for supporting regulation has both strengths and weaknesses. However, it can generally be considered to be a reliable and effective system that has managed to ensure the implementation of a number of important directives in Europe. Without a system like the New Approach, it is highly doubtful that the Single Market would be able to function as it does today.

Among the strengths of the New Approach is the separation of the political and technical levels of regulation, enabling the technical experts from companies and organizations to specify the details of the standards. This separation allows for a much broader base of expertise, which increases the level of competence.

Although standardization may be considered to be a not very fast process, its speed is actually a strength compared to the more traditional legislation, which has previously been shown to be highly tedious. An example can be found in machine safety, where standardization organizations managed to revise more than 700 harmonized standards that support the Machinery Directive in less than two years.

A third key strength is the cooperation between the European and the international standardization system. CEN and CENELEC have cooperation agreements with the international standardization organizations ISO and IEC, which allows for standards that support European legislation to gain global recognition. This can be seen especially in the field of electrotechnology, where approximately 77 % of CENELEC standards are identical to or (slightly) modified versions of the international IEC standards[38].

The standardization request process can be seen as a weakness of the system as it is still not optimized in terms of speed, quality and participation. In addition to typically being quite lengthy, it remains a challenge to make sufficiently precise standardization requests, which has meant that parts of the political process has been carried over into the technical

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38 CEN CENELEC Statistical Pack 2015 Q1.

work. However, this challenge has been greatly reduced since the first generations of New Approach Directives.

Another weakness may be found from the above mentioned market surveillance, which in a number of EU member states is far from effective enough. Where standards may form the basis for CE marking, the market surveillance instrument has been created to ensure that only those products that meet standards are CE marked. In European directives, standardization requests and standards, market surveillance is incumbent on the authorities of the member states. Due to the different levels of market surveillance in the member states, the confidence in the CE mark could ultimately be undermined.

However, despite these weaknesses, the overall conclusion is that the European standardization system and the New Approach is a very effective tool to ensure dissemination of common requirements for quality, safety, health and environment in the European Single Market. Therefore, standards continue to be a key element in European regulation.

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WTO TBT Agreement, Uruguay Round, 1995. WTO [Accessed March 2015]. https://www.wto.org/english/docs_e/legal_e/legal_e.htm

Discussion points

Below are some suggestions for further discussion or study. These can be discussed during class, in group discussions or be used as ideas for further study by the students.

1. What are the advantages and disadvantages of the New Approach? Could it be done in a different way?
2. How do standards support the WTO Agreement on Technical Barriers to Trade (TBT Agreement)?

Chapter 5

Standards Supporting Innovation

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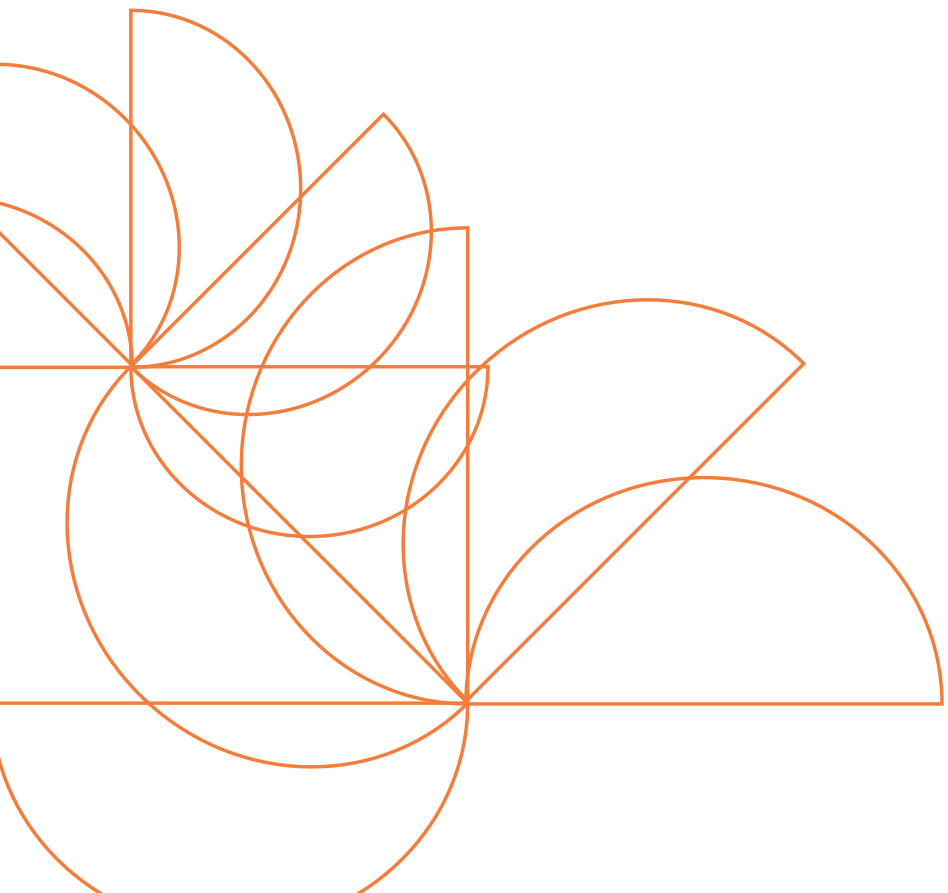

Introduction

Knowledge can come from many different sources. From Twitter to tabloids to text books, trust is an important factor to consider when allowing yourself to be influenced by what you have read. As detailed earlier in this book, standards are written by industry experts and practitioners combining and transferring their valuable knowledge to create agreed practice within their industry. This process of knowledge transfer leads many to consider standards a trusted and valuable source. This chapter will go further and propose that standards can take a supporting role in the drive for innovation.

Standards help innovation in a number of ways. In the area of new technologies in particular, standards are an essential tool to enable new ideas to take root and progress.

The most basic contribution standards make in a new market is establishing common vocabularies upon which that market will be based. This enables innovators working on the same technology in different organizations and locations to communicate confidently, especially about common subject matter, without being hampered by the need to spend time and effort establishing what it is they are talking about. The collaborative nature of the standards framework levels the playing field which, in turn, frees innovators to concentrate on finding ways to differentiate their products and services.

The commercial exploitation of innovative ideas is also facilitated by standards, which provide a basis for dissemination of information and an accepted framework within which patents can be drawn up. This removes undue proprietary interests and barriers to trade, whilst ensuring a platform of interoperability upon which emerging technologies can be built. The use of a standards framework enables innovative companies to increase the speed with which they can bring their products to market.

Getting market acceptance for an emerging technology can be a difficult process. The use of standards makes a significant impact in easing this by allowing investors to understand what their potential investment involves and enabling companies and developers to describe their prod-

ucts and services in marketable terms. Furthermore, the independence of a National Standardization Organization and its standards development process – and, by implication, the freedom from particular commercial bias – can be critical in gaining public acceptance of new technologies.

Finally, standards can increase quality and provide assurance of health, safety and other aspects crucial to the development of viable markets in new technologies. This can be vital to encourage government to promote and use innovative products and services in its procurement process. Standards allow government, industry, and the public to know clearly what those products and services are, and how they can be tested and measured against each other and existing products for quality and safety.

Standards are supporting innovative research

Standards can seamlessly integrate into research processes to assist the work and strengthen its reliability. Blind and Gauch (2007) explored how standards can integrate into the research process and mapped where certain standards could make a positive difference at relevant stages in the process, as the diagram below shows.

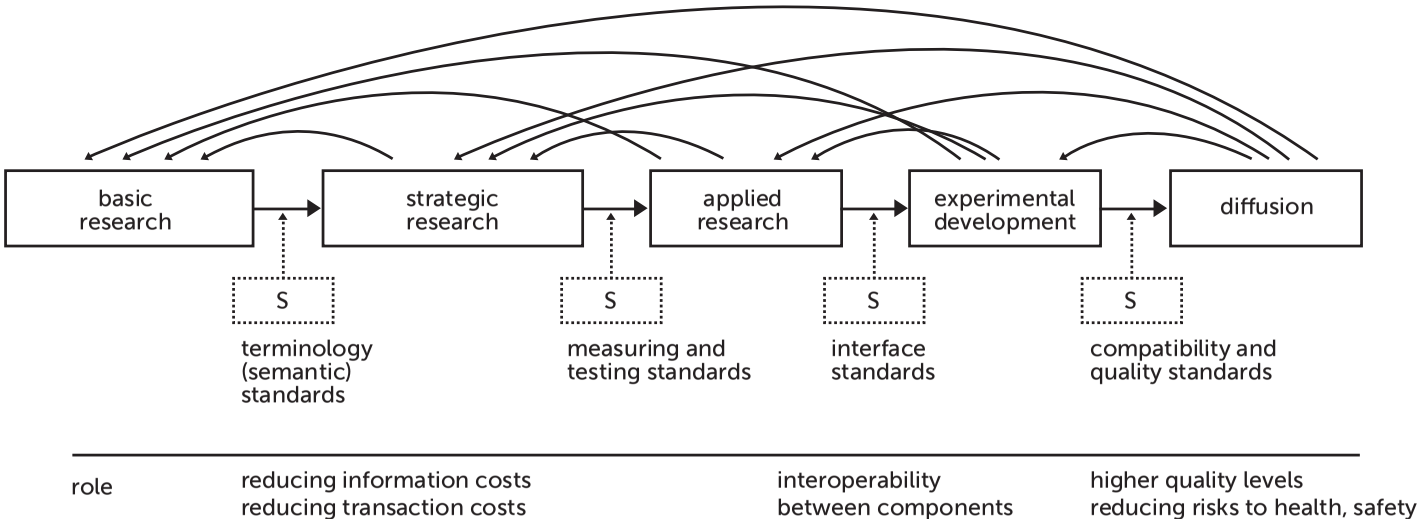

Figure 9: Standards in the research and innovation process (Blind & Gauch 2007).

Blind and Gauch found different standard types perform different roles, bringing different benefits to the process. As figure 8 above shows, different types of standards can intersect at any point of the research process. Where a standard can intersect, the diagram above shows a boxed 's'. Before basic research can progress to more strategic research, terminology standards can ensure ideas are communicated correctly with industry recognised terms and definitions. Measuring and testing standards need to be referred to before any research is applied to reinforce the legitimacy of any results found as well as ensure the correct tests are done to ascertain the most accurate results. Once applied research is complete and prototype models or other experimental items are created, interface standards increase the chances of success when user tested. Finally, reference to compatibility and quality standards before the final product is completed and sent out to market, can improve the chances of an innovation working with any complementary products or tools that would enhance it, widen accessibility to more specialist areas of the market and ensure reliability of producing a consistent final product to be diffused into the market.

Standards are supporting innovative products

In a 2011 article for RTC Magazine, IBM's Martin Bakal discussed how *IEC 62304 medical device software – software life cycle processes* has affected IBM's work in the medical devices industry. Bakal stresses the importance of standards, stating:

> "By applying best practices guidance and process automation, companies have a new opportunity to improve on their fundamental business goals, while getting through regulatory approvals faster." *(Bakal 2011).*

Bakal used "the standard V diagram", seen below, to show the hardware and software device life cycles in the industry, looking at the typical stages for analysis, design, implementation, and testing.

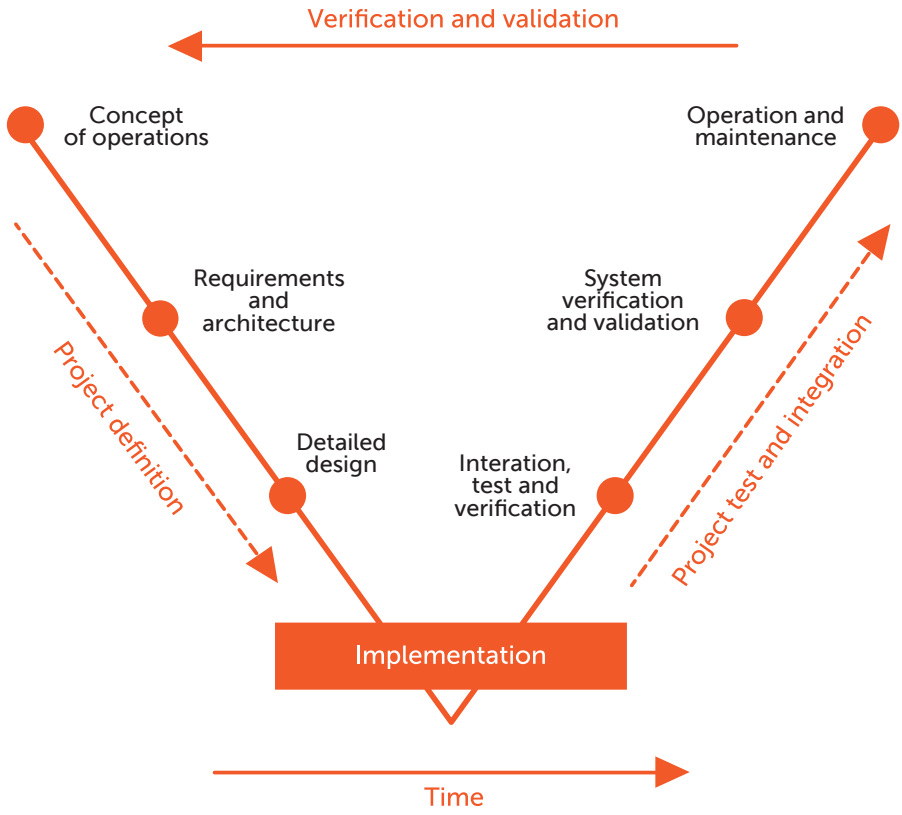

Figure 10: Bakal's typical stages both software and hardware teams use for analysis, design, implementation, and testing (Bakal 2011).

This particular diagram, like Blind & Gauch's research model, was created for a specific criteria, however is open to being adapted in a way that can help show how standards can fit into the design and engineering of any innovation. Combining the two creates the Innovation/Standardization Cycle, below, which outlines the relationship between standards and the innovation process, showing how standards can be a catalyst, rather than an inhibitor for innovation.

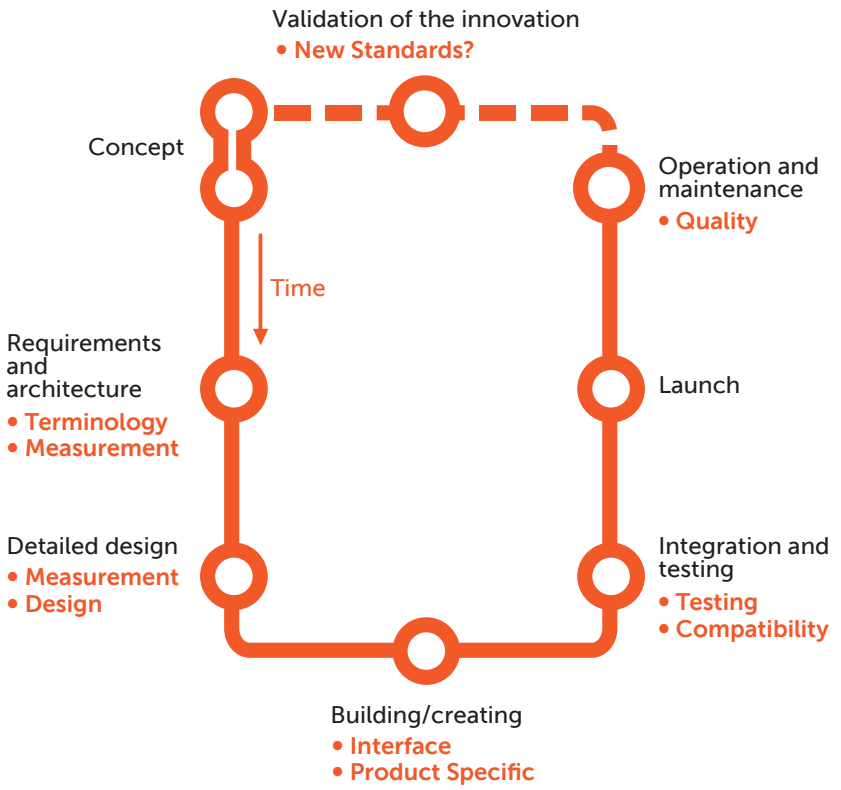

Figure 11: The Innovation/Standardization cycle, (Hampson-Jones 2011).

The concept stage is purely borne by the inception of an innovative idea. Once the concept is formed, the requirements & architecture need to be detailed so that others can share the broader vision. Firstly, terminology standards will need to be used in order to communicate the vision effectively and-once the first rough design drafts are written-measurement standards will need to come in to play at the detailed design stage. On any project, a mistake in measurement could be disastrous-especially on larger projects, like bridges or public buildings. Design standards for engineering projects would be vital at this stage as well.

Once the project has reached the building or physical creation stage, interface standards are important for the same reason they are for research, but – more importantly – standards, which are specific to the

industry, will also be vital. Standards can be found for a range of specific areas, like civil engineering, agriculture and food, and information technology. Discovering which standards will specifically affect the design and building of a project, and deciding which are non-pertinent could be just as important as the innovation itself. A mistake here could slow the creation process, reduce the possible market for the innovation or see it fail altogether.

As seen in Figure 10, testing of the product requires the relevant standards be followed to ensure success and using compatibility standards to integrate the innovation with pre-existing technology makes the product easier to use for a wider audience. Once the product is launched, quality standards can ensure there are systems in place to maintain the quality and continuity of products produced. These standards can mitigate the risk of failures, which could harm users or restrict the long-term success of your innovation.

In some cases an innovative project or product could inspire a new standard as others in the industry realize the advantages of following suit. Therefore, as the innovation becomes imbedded in the industry and validated as successful, a new standard may be written. This could, in turn, be a catalyst to inspire new ideas and concepts, beginning the innovation process once more.

The way a standard is written has great impact on the interplay between the standard and innovation. Some standards are descriptive and others performance-based.

A performance-based standard sets out the performance required or the objective to be achieved without prescribing how it is to be achieved. A prescriptive provision sets out a rigid specification for compliance.

Performance-based standards are often associated with innovation, since they set up objectives for the outcome of a process or of using a certain product instead of providing strict rules for the process or product itself. Thereby it is up to the producer to decide how to achieve the objectives in the standard. Objectives in a performance-based standard could for example be achieving a certain level of cleanness in a hospital or the quality of a product as perceived by a certain market.

However, prescriptive standards also have an important role to play in innovation as they provide a framework for innovation. An example of a prescriptive standard that has resulted in a vast amount of innovations is the USB-stick. The size of the USB-stick is defined in a standard, but whatever is on the other end is up to the producer. Here compatibility is crucial for a producer to enter a market, therefore they have to build their innovations on the USB-stick standard.

Table 6: The relation between innovation and prescriptive and performance standards.

	Prescriptive	Performance
Opportunity	• Provides a platform for measuring and encouraging innovation by providing scales, measurement methods, variety reduction and compatibility	• Allows alternative ways to achieve same result
Challenge	• Inflexible • No room for different context	• Can give uncertainty

As prescriptive and performance-based standards influence innovation in different ways, it is important to keep in mind the reasons for developing the standard, when drafting a standard, to make sure that it is written in the correct and most beneficial way.

The European context

Standards bodies around the world are looking at how they engage with their innovation communities to address innovation. In the European Union, standards have been identified as key enablers for technologies in the Horizon 2020[39] communications issued by the European Commission's Directorate General for Research and Innovation, and their importance for international collaboration and involvement of smaller businesses is also recognized. (Technopolis 2012).

A recent study commissioned by the European Standardization Organizations CEN and CENELEC has demonstrated how standardization contributes to innovation in European-funded research projects. The study, led by the Technopolis Group research consultancy, analysed how different research projects included standardization and the benefits brought by such inclusion of standards.

Furthermore, six case studies were identified as 'Success Stories' (Advanced manufacturing, Energy, Environment, ICT, Security and Transport) where standardization had played a key role in overcoming any obstacles encountered in European research projects.

European standardization organizations CEN and CENELEC have recently been shaping how the European standardization system as a whole responds to the imperative to support innovation through standards. This has involved developing an 'integrated approach' to standards and innovation (i.e. a holistic view of how standards work with research and innovation) and the establishment of a network of national contact points for standards and innovation within each national member of CEN and CENELEC[40].

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39 Horizon 2020 is the biggest EU Research and Innovation programme ever with nearly €80 billion of funding available over 7 years (2014 to 2020).

40 http://www.cencenelec.eu/research

A national context

National standardization organizations will engage with their local government, industries and stakeholders to ensure standards support innovation. One example is in the UK, where there has been a lot of thought about the role of standards in the economy. In his 2012 report *'No Stone Unturned: In Pursuit of Growth',* former UK Deputy Prime Minister Lord Heseltine made 89 recommendations to the Government. Number 44 was:

> "The British Standards Institution, Technology Strategy Board and Research Councils UK should work together to ensure that new standards are set earlier in the development of new technologies" *(Heseltine 2012).*

The report went further, highlighting the importance of standards in supporting innovation:

> "Standards play a vital role in bringing new ideas to market faster. They are the priceless ingredients that underpin the dissemination of all emerging technologies. They are a form of knowledge – setting out a way forward for new technologies as they are being developed." *(Heseltine, 2012).*

This is the latest in a number of government reports that have identified the potential for standards to support innovation, including the Innovation Review published by the (then) Department for Trade and Industry (DTI) in December 2003, and the subsequent review published by the DTI's successor organization, the Department for Business, Innovation and Skills (BIS) in December 2010.

Standards play a key role in driving innovation and creating wealth. Their timely, consensus-based use ensures that pioneering knowledge can be brought to market. As Lord Heseltine's recommendation acknowledges, this is aided by the early use or creation of standards, which benefits UK businesses and the national economy.

An opposing viewpoint

Some feel the role of standards in innovation has its drawbacks. Some criticism focuses on who is able to sit on the committees that write the standards; is the process accessible enough to work? In maintaining a diverse stakeholder base, Orviska, Nemec and Hudson, note there are difficulties, which can be hard to manage in practice and influence the direction of work:

> "There are, however, problems as to how one effectively represents such disparate groups as 'consumers' or 'SMEs' (Hudson & Orviska, 2011). Rural consumers, for example, have different concerns and attitudes to urban ones, young from old, and educated from the less well educated." *(Orviska, Nemec and Hudson 2013).*

There has been much of work at national, regional (European) and international level to address these concerns and great strides have been made to make the process more accessible. Alternatively, critics have noted the speed at which standards can take to develop, can place it behind the innovation it is meant to support and be outdated by the time it is published. Again, this is an area of priority for standardization organizations at all levels, however Orviska, Nemec and Hudson point out the difficulty in effectively resolving these two criticisms:

> "The two aims, 'speed' and 'increasing stakeholder involvement', are not only extensive but also conflicting. One can implement some changes, which help attain one objective without adversely impacting on the other. But the fundamental point is that given the framework, increasing the number of participants in standard development will almost inevitably slow the process down, particularly if new participants have substantially different preferences to existing ones." *(Orviska, Nemec and Hudson 2013).*

There are no easy answers to perfecting the standardization process and the standards system it sits in. The strength of standardization is also one of its biggest weaknesses: a standard is only as strong as the committee that wrote it and its members. With all that in mind, as the case studies[41] related to this chapter show, it is still clear that standardization plays an important, even vital, role in supporting and safeguarding innovation at an international, national and even an individual level.

41 The case studies are found in Annex B: *Standards Supporting Innovation, Cases.*

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Discussion Points

Below are some suggestions for further discussion or study. These can be discussed during class, in group discussions or be used as ideas for further study by the students.

1. A standard consist of several elements (e.g. tables with tolerances or values to be put into mathematical formulas). Discuss or consider how these elements can influence innovation – both in a positive and a negative manner.

2. The content of standards can be formulated in different ways. How should they be formulated to best stimulate innovation? (Hint: e.g. prescriptive and performance).

   - What is the advantage of formulating the content as performance requirements?

   - Does it sometimes make sense to have prescriptive requirements? When?

3. Using the Innovation/Standards Cycle Figure 10, come up with your own innovative product idea. With that idea, think which standards may directly, or indirectly, affect the development of your product at the following product stages: Concept, design, building, testing, launch and maintenance.

Annex B – Standards supporting innovation, cases

There are many practical examples of how standardization has aided the innovation process. Below are three cases where standards and strategic standards making have proven to be catalysts to the success of new technologies.

Case study – Biometrics

Biometrics

A biometric system enables automated recognition of people based on their biological characteristics (e.g. fingerprints, face geometry, iris patterns) as well as their behavioural characteristics (e.g. how someone writes their signature rather than what it looks like).

The iris-related part of the biometric data interchange standard, ISO/IEC 19794-6, was revised in 2011 to provide a clearer explanation of how to produce images in more formats, including a new heavily compressed format.

World's largest biometric project

Recently, the revised standard has helped to make the world's largest biometric project possible.

Since 2011 it has helped the Unique Identification Authority of India (UIDAI) to begin the process of scanning the iris patterns, finger prints and facial images of all 1.24bn residents of India as part of a national identification number scheme called Aadhaar, which (according to UIDAI) seeks to "give the poor an identity" so that they can claim their rightful benefits and enjoy greater social inclusion.

So far, more than 400m citizens in India have had their iris patterns stored in formats specified by the standard. Every day another million are added at some 36 000 enrolment stations nationwide, which are managed by 83 agencies.

Bandwidth limitation

As part of the national identification number scheme, iris images are sent for authentication from a variety of locations (including remote rural areas) to a central database over channels with very limited bandwidth, which meant having to transmit digital images in small payloads, which requires significantly more time to process.

However, research carried out at Cambridge University showed that with suitable pre-processing, iris images could be compressed to less than 1 % of the original size, remaining usable at a data size of just 2000 bytes.

Immediate authentication

In May 2013, UIDAI confirmed successful use of the revised standard's heavily compressed image format in large-scale field trials, which yielded an impressive 99.13 % successful online authentication (compared to 99.30 % for uncompressed images).

This had an unexpected additional benefit, in that it enables rural shopkeepers to use their cash tills as a remote ATM service that offers immediate authentication and online counter-transfer into the shopkeeper's bank account, which means local people no longer have to make lengthy journeys into a city to visit a bank.

Case study – Biological Manufacturing

Biological Manufacturing

Synthetic biology and cell therapies/regenerative medicine were both identified by former UK Universities and Science Minister David Willetts as one of the "Eight Great Technologies" the UK needs to prioritize and in which the government is to invest more than £600m. Part of that investment has been utilising the expertise of the UK's National Standards Body to set the standards that can create new, innovative industries.

Synthetic biology

Synthetic biology refers to the design and construction of biological parts, devices and systems. Cell therapies/regenerative medicine means replacing or regenerating human cells, tissues or organs to restore or establish normal function. A key challenge is to establish how standards can encourage innovation and advancement in both.

Based at Imperial College London and funded by UK organizations the Engineering and Physical Sciences Research Council, Biotechnology and Biological Sciences Research, and InnovateUK, SynBiCite is a new Innovation and Knowledge Centre created to improve the UK's ability to translate the emerging field of synthetic biology into application and provide a bridge between academia and industry.

In partnership with Innovate UK, the UK's National Standards Body, BSI, has been working with SynBiCite to develop a strategy for standards to help accelerate synthetic biology technological development and increase its chances of success, seeking input from UK stakeholders to achieve consensus on the right way forward for cell therapy standardization.

The centre will become a national resource and involve researchers from 17 other UK universities and academic institutions, as well as 13 industrial partners, including the research arms of Microsoft, Shell and GlaxoSmithKline.

Standards developed in this area could play a key role in enabling various organizations to work in partnership, as well as ensure interoperability between synthetic biology technologies developed.

Cell therapies

In recent years BSI has been working with the UK research base, academia, regulatory bodies and other public and private sector organizations to better understand the challenges faced by those involved in cell therapies/regenerative medicine.

The standards body has provided guidance documents, codes of best practice and, ultimately, formal standards in response to stakeholders' needs. Examples include *PAS[42] 84:2012 Cell therapy and regenerative medicine.* Glossary, developed to encourage use of common terms and definitions within regenerative medicine.

Since 2013, BSI has worked with the Cell Therapy Catapult, a London-based centre of excellence for regenerative medicine that was established by InnovateUK in 2012. It was created to be a catalyst for the development, delivery and commercialization of cell therapy.

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42 PAS – Public Available Specification.

Case study – Smart Cities

Smart Cities

The smart cities of the future will make use of data capture and communication management technologies to deliver high quality services to citizens. Smart approaches to transport, utilities and waste management could transform the efficiency and sustainability of urban communities, leading to significant reductions in service provision costs and carbon emissions.

In reality, though, what will be so different about the smart cities of the future, how will pioneering technologies improve people's lives and what role will standards play?

Roads

Smart traffic systems will better regulate traffic flow. Less congestion and real-time traffic jam warnings will enable drivers to take alternative routes.

Vehicles

Hydrogen powered buses and electric cars (supported by on street recharging points). Self-driving cars will be able to locate available parking spaces.

Buildings

Built to rigorous environmental standards and super energy efficient. Carbon dioxide emissions minimized.

Street lights

Dynamically operated city lights will reduce energy consumption.

Homes

Air-conditioning, heating, lighting, appliances operable by mobile phone. Green meters enable tracking of daily energy consumption. Solid waste removed by pipe network.

Transport

Soft transport options such as walking and cycling are favoured. Better integrated, ultra-efficient and sustainable public transport. Payment by smartphone.

Rubbish

Smart bins will automatically notify waste removal service providers when they need to be emptied.

Water

Significantly more efficient water consumption. Grey water (ie waste from wash basins, showers and baths) recycled for reuse. Easier for municipal authorities to detect water leaks and optimize irrigation of parks.

Electricity

Smart grid uses information and communications technology to gather information about consumer behaviour to improve efficiency, reliability and sustainability of electricity production and distribution.

Shopping

NFC technology enables payment by smartphone at shops, restaurants, cafes, museums, galleries, etc. Information about special offers revealed by pointing your phone at shop as you walk by.

Health

Delivery of health-related services and information via telecommunications technologies. Data about patients generated by wireless sensors in their home.

WiFi

High-speed internet available in public places throughout the Smart City. Displays will also communicate information about weather, traffic, transport, health, tourism, entertainment, etc.

What role will standards play?

Smart City technologies, based on digital infrastructure and digital services, potentially offer a better and more efficient way to monitor and manage resources in cities.

Smart approaches to transport, utilities and waste management could transform the efficiency and sustainability of urban communities, significantly reducing costs and carbon emissions. The Smart Cities of the future will also be more attractive to citizens and businesses, and they will help to drive economic growth and prosperity.

But Smart Cities are only possible if technologies can function in harmony (i.e. 'interoperate') and data can flow successfully between infrastructure, systems and services. Not only must it be possible to capture information, but also to ensure that it can be shared. This is where standards can make a huge contribution.

The complexity of a Smart City will also require guidelines, metrics and technical specifications to support collaboration between municipal authorities, the private sector and citizens. Standards can accelerate the implementation of Smart City solutions, while providing assurance to citizens that risks relating to information security, data protection and privacy are being managed properly.

Every waken moment of your life you are surrounded by standards. Even while you sleep, you are in contact with a vast amount of standards for bed size, bed linen, lamps, smoke detectors, curtains, etc. In fact, standards influence the daily life of every citizen as standards exist in a wide range of areas (such as construction, food, toys, buildings, machinery, healthcare, environment, services, etc.) and cover many layers (e.g. safety, management, testing, compatibility, etc.).

The importance of standards makes it vital that we all have some knowledge of standards and standardization. Some need only a general insight into the nature of standards whereas others need in-depth knowledge of the dynamics of standardization and standards, the influence standards have on the market, how to implement standards in a business or how to get most out of standards. The importance of standards gives you a responsibility to define your involvement in standardization. Which knowledge is relevant to you?

This textbook guides you through the world built on standards. You will be introduced to topics such as; what is a standard, what are the benefits, who makes a standard, how do I read a standard, what is CE-marking, how do standards relate to regulation and can standards support innovation?

In addition to this textbook, you may find supporting material such as Power Point slides and multiple choice questions at www.ds.dk/education.