

Learning unit 4 Standards and characterization of functional and smart textiles
Lesson 4.1

Standards and regulations for smart textiles



Innovative smart textiles & entrepreneurship

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Content

Content	1
Introduction	2
1. The need for standardization in the field of smart textiles	2
1.1. Standards – definition, types of technical standards, life cycle of a technical standard	2
Classification of technical standards	2
Structure of a technical standard	3
Life-cycle of a technical standard	3
1.2. The need for standardization in the field of smart textiles	4
2. Organizations involved in developing standards and regulations for smart textiles	6
3. Correlation between the end-use requirements and standards for smart textiles	10
Summary	13
References	14

Introduction

Due to the diversity of materials, processes, products, applications and requirements that characterise the domain of smart textiles, this lesson is intended only to be an introduction in the subject of standardization and regulations for smart textiles, emphasising the importance of this topic in the development of smart textiles.

The objective of the lesson is to present basic information regarding standards in general, the state of current standards developed and used for the design, manufacturing and evaluation of smart textiles. The connection with standards from other fields, like electrical measurements, electronics, chemistry, etc., that is specific to the multidisciplinary nature of this domain, will be mentioned and discussed, but not in particular details, leaving such information to be looked for by the ones interested in a certain type of application for smart textiles.

1. The need for standardization in the field of smart textiles

1.1. Standards – definition, types of technical standards, life cycle of a technical standard

Standardization is a major part of all engineering activities, from R&D to manufacturing, services and commercialization, as well as research. Its significance comes from the set of rules and compliance criteria that are defined by the standards, that organize and secure the results of these engineering activities. The International Standard Organization ISO defines a standard as “a document, established by a consensus of subject matter experts and approved by a recognized body that provides guidance on the design, use or performance of materials, products, processes, services, systems or persons” (ISO, ISO's committee on consumer policy (COPOLCO), n.d.).

Classification of technical standards

The classification of technical standards and regulations, including those for smart and functional textiles, has to be multicriterial.

Based on what level of acceptance they have, standards can be:

- Voluntary consensus standards, which are standards developed or adopted by standardization organizations, as those presented in this lesson.
- Industry standards, also referred to as private standards, developed in the private sector but not through a full consensus process
- Government standards, regulations, directives - refer to the rules that must be respected at national, regional or international level. Conformity with such regulations is essential for any company, any type of activity and all markets.

Technical standards can be normative or informative, as described by the European Committee for Standardization CEN (CEN/CENELEC, n.d.). There are different types of materials published by such organizations, reflecting their content and level of acceptance.

- Normative
 - Standard, that “provides rules, guidelines or characteristics for activities or their results, for common and repeated use”. Technical standards relate to products, services or systems.
 - Technical Specification (TS), that precedes a standard, being not yet approved by all members of the issuing organization.
- Informative
 - Technical Report (TR) provides information on measurement techniques, test approaches, case studies, methodologies, etc. that are useful for standard development, but can also be of significance for R&D (<https://www.iec.ch/publications/technical-reports>).

Structure of a technical standard

All standards have a typical denomination which contains :

- Initials of the organizations adopting the standard – the standard can be adopted by several organizations, all initials will be present
- Number of the standard, followed by the year when the standard was adopted
- Title of the standard
- Any modifications, amendments

Apart from its name, describing clearly and succinctly the topic, a standard has a code that indicates the organization that created the standard, the domain the standards addresses and the identification number, including the year in which it was issued. Any modification of the standard will be mentioned in the latest variant. For example,

- EN 16812: 2016 Textiles and textile products - Electrically conductive textiles - Determination of the linear electrical resistance of conductive tracks is a standard issued by CEN, adopted in 2016 and the original version is not yet modified or amended.
- ISO 6330: 2021 Textiles — Domestic washing and drying procedures for textile testing is a standard that has its fourth edition, the last one in 2021. The content of the previous editions was modified.
- IEC 62899-201:2016+AMD1:2018 (Consolidated version) Printed electronics - Part 201: Materials – Substrates is a standard issued in 2016 and amended in 2018. The consolidated version refers to the fact that both the original and amended content is included.

Regardless of their domain and the issuing organization, all technical standards are organized in a similar manner. As defined by ISO, standards are organized in the following manner.

- Scope of the standard;

- Normative references that are referred in the standard (other standards and norms, required to be considered when applying the standard);
- Terms and definitions of the technical words used in the standard;
- Specifications - presenting the general characteristics and specific characteristics;
- Sampling - defines how the samples should be obtained; what restrictions should be followed when taking the samples;
- Annexes are used to define more clearly and in-depth information and clarifications, examples related to the content of the standard;
- Bibliography – all standards indicate the materials used.

Life-cycle of a technical standard

The main stages in the life cycle of a standard are illustrated in Figure 1 below.

Technical standards are initiated through a proposal that is approved by the technical body/committee of the standardization organization. The content is drafted and then subjected to the approval of those interested in the topic – manufacturers, researchers, etc. If the draft is not approved, then it is reformulated and again subjected to the enquiry process. Once approved, a standard is published. After publication, it is revised periodically. The revision can lead to the standard being reconfirmed, replaced by another version, amended or withdrawn. It is therefore important to check to see the status of the respective standard and to use an approved and up-to-date version.

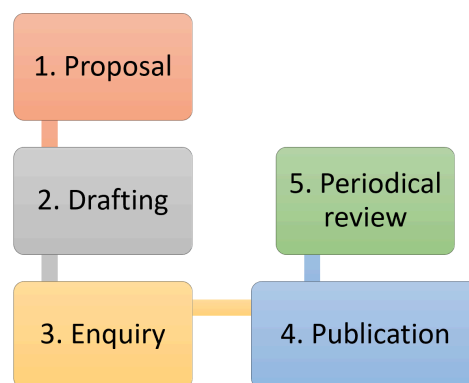


Figure 1. Life cycle of a technical standard

1.2. The need for standardization in the field of smart textiles

For a developing sector such as smart textiles, that have not reached its market maturity yet, standardization is an important issue, complicated by the fact that it involves not only textile knowledge, but also knowledge related to the domains of application, for example medicine, protective equipment, sports and leisure, military, etc. This means that standards referring to smart textiles must consider all domains, each with different characteristics/properties, design, approaches to manufacturing, modus operandi, etc.

The use of standards and regulations in the field of smart textiles presents significant advantages:

- 1) In terms of R&D of smart textiles
 - a) unity in reporting research results – a common ground and adoption of the same working protocols give results credibility and avoid repetition of particular research subjects
 - b) consistent design procedures for smart textile products – create quality and guarantee that the smart textile product satisfy all requirements imposed by the application
 - c) recognised and consistent testing procedures for the characterization of materials/products for the evaluation of their behaviour allow the comparison of research results and avoid confusions
 - d) design in conformity with the regulations regarding product sustainability – the development of new materials and technologies, of new smart products have to consider the rules for sustainable design, making sure that the regulations can be respected
- 2) In terms of manufacturing smart textiles
 - a) Accurate and repeatable smart products, as well as their conformity to requirements established through different official documents (like EU directives) and/or agreed upon between business partners facilitate the manufacturing process throughout its entire value chain
 - b) Efficient organization and control of the production systems is guided by environmental standards that are mandatory to respect for products that need to be certified in the EU
 - c) Procedures for quality assurance in the case of the manufacturing process or commercialised smart textile products – quality standards allow producers to organize a manufacturing system that creates quality products and to present proof of this quality, as mentioned by the regulations
- 3) In terms of trade
 - a) Clear understanding and communication between business partners will facilitate trade and eliminate possible misunderstandings
 - b) Adherence to EU regulations for import/export products is mandatory and standards express these regulations as accepted procedures to evaluate product conformity
 - c) Insurance of proprietary information and knowledge – standards help define new and innovative products, processes, testing methods that become the subject of patents
 - d) Providing reference data in commercial disputes
- 4) in terms of product life-cycle, environmental issues, sustainability
 - a) adherence to EU regulations on environment, climate change, sustainability is an extremely important issue. The regulations regarding the life cycle of products will affect the R&D of smart textiles, that will have to focus on ways to ensure that materials, components of products have the smallest carbon footprint possible and can be recycled easily. This itself is a challenge, as smart textiles are made of materials of different natures. EU manufacturers are bound to respect these regulations.

- b) identification of the impact on the environment and development of new, innovative solutions to mitigate it. Regulations and standards represent the framework for the measurement of environmental impact of smart textiles.
- c) Transition to eco, cradle-to-cradle design of smart textiles.

Want to learn more about this topic?

On the sites https://en.wikipedia.org/wiki/Technical_standard and <https://www.etsi.org/standards/types-of-standards> and <https://www.iso.org/deliverables-all.html> you will find more about standards.

On the site <https://forcetechnology.com/en/articles/the-life-cycle-of-standards> you will find more about the life cycle of a standard.

2. Organizations involved in developing standards and regulations for smart textiles

Standards, including those related to engineering, are developed by national, regional and international organisations. A standard can be developed at any level but nowadays standards are mostly developed by regional and international organizations and adopted by national organizations. International standards are recognised and valid worldwide, while regional standards, as is the case with the EU, are valid at European level. National standards are adopted only by the respective country and are in the respective national language.

Knowing what organizations create standards for textiles in general and smart and functional textiles in particular is of utmost importance in finding out what are the newest standards to be used, what was modified or what standards are withdrawn and/or no longer apply.

Each country has a national organization that develops and manages standards, that is connected to organizations that are at regional and international level. Some examples of European national organizations include:

- SIS Swedish Institute for Standards (Sweden)
- ELOT Hellenic Organization for Standardization (Greece)
- ASRO Organismul National de Standardizare (Romania)
- UNI Ente Italiano di Normazione (Italy)
- UNE Asociación Española de Normalización (Spain)
- SIST Slovenian Institute for Standardization (Slovenia)
- DIN Deutsches Institut für Normung e. V. (Germany)
- AFNOR Association française de normalisation (France)
- BSI British Standards Institution (UK)

The national standards are denominated starting with initials signifying they belong to the respective national system. If the standard was issued by a regional or an international organization, the denomination contains the initials of that organization. For example, standard EN 16812:2016 adopted by the Slovenian standardisation body is registered as SIST EN 16812:2016.

National organizations can also create and adopt their own standards, and if a national standard is deemed significant, it can be adopted by the regional organizations.

Apart from the national organizations for standardization, in Europe there are 3 standardization bodies involved in this process that are of interest:

- the European Committee for Standardization CEN (<https://www.cencenelec.eu/>),
- the European Committee for Electrotechnical Standardization CENELEC (<https://www.cencenelec.eu/>),
- the European Telecommunications Standards Institute ETSI (<https://www.etsi.org/>)

These organizations are mandated by the EU Commission to develop standards for certain domains that use smart textiles. Approximately 20% of the European standards are created

following a request (mandate) from the EC. For example, for protective equipment there are mandates regulating the type of standards to be developed:

- Mandate M/509 Programming mandate to CEN, CENELEC and ETSI on protective textiles and personal protective clothing and equipment (European Commission, 2012).
- Mandate M/553 COMMISSION IMPLEMENTING DECISION on a standardisation request to the European standardisation organisations as regards advanced garments and ensembles of garments that provide protection against heat and flame, with integrated smart textiles and non-textile elements for enhanced health, safety and survival capabilities, in support of Regulations (EU) No 1007/2011 and (EU) 2016/425 of the European Parliament and of the Council (eNorm platform - European Commission standardisation requests, 2017).

These organizations develop standards through technical committees and groups. All European standards are identified with the denomination EN. Standards for smart textiles are developed by the technical committee CEN/TC248 Textiles and textile products, working group WG31 Smart textiles and electronic textiles.

Other working groups that develop standards that could be of interest for smart textiles, as they address controlled functionalities of textiles and other aspects important for the sector, such as sustainability, are:

- CEN/TC 248/WG 4 Coated fabrics
- CEN/TC 248/WG 14 UV protective properties
- CEN/TC 248/WG 24 Test methods for the flammability of textiles
- CEN/TC 248/WG 28 Thermoregulatory properties of textiles and textile products
- CEN/TC 248/WG 39 Circular Economy for textile products and the textile chain

Standards are also developed at international level, many organizations collaborating with specialists from universities, research institutes and companies throughout the world. Two organizations are of interest:

- International Standard Office ISO (<https://www.iso.org/home.html>)
- International Electrotechnical Commission IEC (<https://iec.ch/>)

For ISO, standards regarding smart textiles are developed by technical committee TC38, working group WG32 Smart textiles. The IEC also has a technical committee involved in standards for e-textiles, TC 124 Wearable electronic devices and technologies.

In USA, there are two organizations developing standards relevant to the field of textiles in general and smart textiles in particular that have an international reach:

- ASTM International (former American Society for Testing and Materials), Smart textiles subcommittee (known as D13.50) and

- AATCC – Association of American Textile Chemists and Colorists, technical committee RA111, Electronically-Integrated Textiles.

IPC is an American non-profit organization for the electronics sector that is developing standards at a global level. They have the E-textiles initiative, that brings together specialists from the textiles and electronics industries and intends to develop a series of standards concerning e-textiles (IPC E-Textiles Initiative - Get Involved Today, n.d.). The IPC D-70 committee is organised in several groups, as follows:

- D-71 E-textiles joining and interconnection techniques
- D-72 Textile materials
- D-73a e-textiles printed electronics design
- D-74 E-textiles test methods development and validation
- D-75a -EU E-textiles wearables (standard task group in Europe)

Use of common standards is extremely important for ensuring products/results are what they are intended to be for everybody involved in the value chain, as well as customers. For this reason, the European standardization organizations and by consequence the national bodies in the European network propose their own standards or adopt standards proposed by international organizations like ISO and IEC. This process, in which standards are aligned and the redundant ones are eliminated is called standard harmonization. Harmonized standards have the indicatives of all agencies that adopted them.

Another aspect of standard harmonization refers to the domain of use, for which EU directives are adopted. Such directives regulate the development, manufacturing and trade of technical products, including applications for which smart textiles can be used. For example, medical applications are an important end-use for smart textiles, therefore the *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC* (REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 2017) is definitory and mandatory in terms of requirements for medical smart textiles. The same goes for PPE, for which the *Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC* is mandatory (REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 2016).

Harmonization gives to everyone the presumption of conformity with the essential requirements of that directive. This harmonization is mandatory and the harmonized standards and regulations imposed for a certain domain have to be understood and followed.

An important aspect of regulations concerning certain applications is the need to certify such products. Certification is attested by “the CE marking that indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. It is required for products manufactured anywhere in the world that are then marketed in the EU.” (Internal Market, Industry, Entrepreneurship and SMEs , n.d.).

The steps needed by a manufacturer to receive the CE certification (CE marking, 2019) are presented in Figure 2.

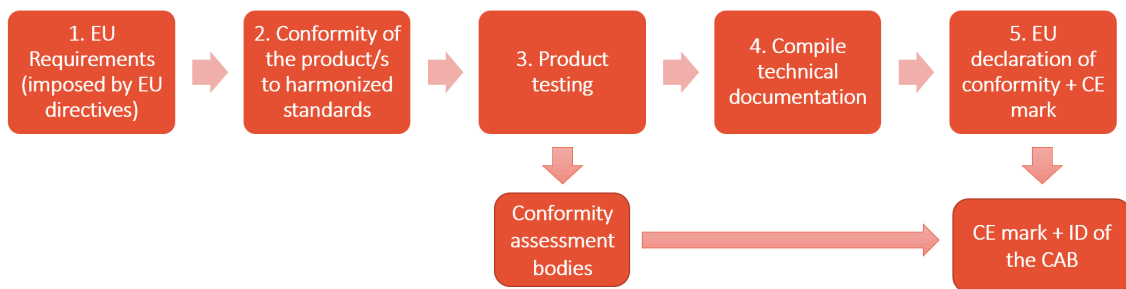


Figure 2. Steps for the CE certification

Certain applications of smart textile products, like PPE and medical products, can require certification: any company that wants to produce (or import/export) products within the EU must follow the regulations stipulated in the Directives and may have to use a certified conformity assessment body (from an official list provided on the EU sites) to verify if the product and/or the manufacturing process is in agreement with EU mandatory requirements.

The certification process is important for company management, that will have to ensure the resources so that the proper documentation is registered for the CE marking.

Want to learn more about this topic?

In https://single-market-economy.ec.europa.eu/single-market/european-standards_en you will find information regarding the EU policy on standardization, harmonized standards and standardization organizations.

3. Correlation between the end-use requirements and standards for smart textiles

Smart textiles require the use of standards and implementation of regulations in different stages of their life-cycle, from design to manufacturing to use and end-of-life. The multidisciplinary essence of the domain imposes the use of standards from different sectors, some addressing specific issues for textiles, some from the other fields involved in a particular type of smart product (like electronics or chemistry) and some deal with the manufacturing and performance of the entire product (Shuvo, 2021).

Figure 3 presents a schematic view of the standards that are currently used or are needed to be adopted for smart textiles.

Each smart textile product has a specific application, most known being health, PPE, sports, automotives, fashion, military. The intended application defines the functions of the product and therefore the requirements imposed on the product design. For the design stage, there are standards establishing guidelines on product specifics and characteristics according to the domain of use.

Performance (behaviour) is evaluated at each stage of the product throughout its value chain. For textile materials, these stages are fibres, yarns, materials (fabrics) and the final product. As mentioned, smart textiles have textile and non-textile components. Textile characteristics should be evaluated both for the textile materials and for the materials/products that have integrated non-textile components. Textiles are evaluated using testing methods defined by standards – ISO, European and national standards, ASTM, etc. Their behaviour is expressed in terms of comfort properties, mechanical properties, chemical properties, maintenance, etc. Durability and reliability represent a significant problem for smart textiles and are expressed in terms of how mechanical, chemical and thermal stresses affect the functionality of the materials or products. Washing/dry cleaning is another issue for durability as most of the smart textile products are garments and therefore require cleaning. Smart textiles should also be evaluated for the level of safety they exhibit during use, especially for e-textiles, for which the use of electrical current can become a hazard. Another aspect of smart product performance is the efficiency, showing how efficient is the response under a stimulus, the response uniformity, etc.

All these characteristics are very important for the textile materials, but also for the smart textiles, as many non-textile components (especially electronics) affect the way the textile behave and interact with us. Non-textile components are evaluated using specific standards (for example, for the electronic parts introduced in the textile materials, in the case of e-textiles or for the paraffins in the microcapsule for PCMs).

Another domain subjected to regulations is referring to data privacy and processing, applicable to e-textiles. When discussing the data obtained from monitoring people for medical purposes or for sport using a smart textile product, one must consider how to develop data storage and processing that respect regulations like GDPR.

Apart from the performance of smart textile materials/products, manufacturing also has to be regulated and controlled. For products that are subjected to EU directives, the manufacturer must ensure that the production processes respect all technical and quality requirements (according to ISO 9000 series for quality management and quality assurance). Depending on what is stipulated, conformity to all requirements is either provided by the manufacturer or by a specialised body, enabled to make the documentation for the CE marking.

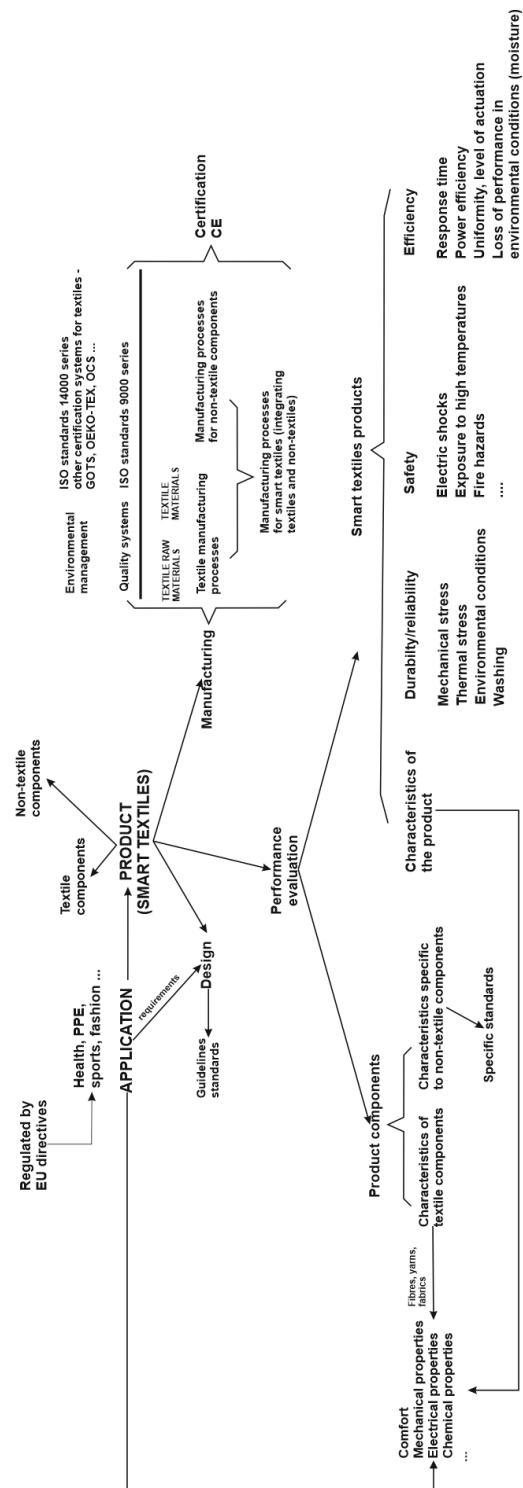


Figure 3. Use of standards for smart textiles

Another aspect that is more and more regulated is production and product sustainability. The ISO 14000 series of environmental management standards, guides, and technical reports that

specify requirements for establishing an environmental management policy, determining environmental impacts of products or services, planning environmental objectives, implementing programs to meet objectives, and conducting corrective action and management review (ISO, ISO 14001 and related standards, n.d.). There also quality evaluation systems used to evaluate the sustainability of textile materials/products like OEKO-TEX, GOTS, OCS, etc. The specificities related to these standards will be discussed in Unit 5.

Want to learn more about this topic?

In <https://www.iso.org/iso-9001-quality-management.html> and <https://asq.org/quality-resources/learn-about-standards> you will find more about quality standards that are used in manufacturing to ensure the conformity and quality of products, including smart textiles.

Summary

Standards and regulations are essential for developing smart textile products, as they impose the norms for the entire value chain, from design to manufacturing to use and to end-of-life. They represent sets of rules accepted by everybody in the sector. Standardization presents advantages in terms of products (R&D), manufacturing, trade, sustainability. Standards can be normative (standards and technical specifications) and informative (technical reports).

The organizations involved in developing standards for smart textiles are national, regional (at EU level -CEN/CENELEC and ETSI) and international (ISO, ASTM, AATCC, IPC). The EU Commission is involved in the standardization of the sector through directives and mandates. The process in which standards are aligned and the redundant ones are eliminated is called standard harmonization.

An important aspect of regulations concerning certain applications is the need to certify such products. Certification is attested by the CE marking that indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements.

All activities related to smart textiles are regulated by standards. Standards concerning the design of smart textiles depend on the regulations imposed to the domain of application, especially PPE and medical textiles. Such standards contain guidelines and indications regarding the type of product and their performance level. Standards evaluating the performance of products/materials (textile components – fibres, yarns, fabrics and non-textile components) contain test methods and processing of results. Manufacturing is subjected to standards related to quality management and assurance (ISO 9000 series) and environment and sustainability (ISO 14000 series).

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