NAVIGATING THE WORLD OF STANDARDS AND REGULATIONS:

How to create legally compliant technical documentation (EU)

Jessica Block

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THE CHALLENGES FACING TECHNICAL COMMUNICATORS

UNDERSTANDING REGULATIONS, DIRECTIVES, LAWS, AND STANDARDS

Regulations

> A regulation is a binding legislative act, which must be applied in its entirety across all member states. Regulations become binding automatically throughout the EU on the date they enter into force.

UNDERSTANDING REGULATIONS, DIRECTIVES, LAWS, AND STANDARDS

Directives

> A directive is a legislative act that sets goals that all member states must achieve, yet individual countries may decide how those goals will be reached. Directives must be incorporated by member states into their national legislation, pursuant to a deadline by which the provisions must be incorporated.

UNDERSTANDING REGULATIONS, DIRECTIVES, LAWS, AND STANDARDS

Laws and standards

> Directives are implemented on a national level through national laws, while provisions in laws and directives are further elaborated and clarified in harmonized standards. Standards are technical specifications, which are not legally binding.

Harmonized standards represent the state of the art and might be part of the contract

STANDARDS: THE LONG AND THE SHORT OF IT

The importance of standardization

Establishing the European single market

Improving quality assurance and the efficiency of European legislation

Reduce costs, improve safety, and enhance competition, as well as serve to safeguard people and goods, which improves quality in all areas of life

Help encourage exports and the free movement of goods

STANDARDS: THE LONG AND THE SHORT OF IT

Harmonized standards

Developed by one or more of the European standards organizations

- European Committee for Standardization (CEN)
- European Committee for Electrotechnical Standardization (CENELEC)
- European Telecommunications Standards Institute (ETSI)

In response to a mandate issued by the European Commission (EC).

Developed to facilitate compliance with the essential health and safety requirements of one or more EU directives.

Published in the official journal of the EU.

STANDARDS: THE LONG AND THE SHORT OF IT

Harmonized standards

Machinery Directive 2006/42/EC, developed under the New Approach framework

Low Voltage Directive 2014/35/EU and **Radio Equipment Directive 2014/53/EU**, updated based on the New Legislative Framework

THE STEPS TO DEVELOPING A EUROPEAN STANDARD (EN)

1. **Proposal**
2. **Draft**
3. **Enquiry**
4. **Publication**
5. **Review**

THE CATEGORIZATION OF STANDARDS

Fundamental standards
terminology, conventions, signs, and symbols

Test methods and analysis standards
measure characteristics (e.g., temperature, chemical composition)

Specification standards
define characteristics of a product, or a service and their performance thresholds

Organization standards
describe the functions and relationships of a company and elements (e.g., quality management and assurance, maintenance, logistics)

THE FRAMEWORK FOR INTERNATIONAL MACHINE SAFETY STANDARDS

Machinery Directive 2006/42/EC
Based on EN ISO 12100, standards related to machinery safety are structured as type A-B-C.

THE FRAMEWORK FOR INTERNATIONAL MACHINE SAFETY STANDARDS

Type A

Type A standards are basic safety standards covering basic concepts, design principles, and general aspects that can be applied to all machinery.

Type B (B1 and B2)

Type B standards are generic safety standards covering safety aspects or one type of safeguard that can be used across a wide range of machinery; however, there are two types of B standards: Type B1 standards for particular safety aspects and Type B2 standards for safeguards.

Type C

Type C standards are machine safety standards dealing with the details of safety requirements for a particular machine or group of machines.

THE ORGANIZATIONAL STRUCTURE OF STANDARDS

Horizontal or general standards:
apply to any industry
e.g., IEC 82079-1

Vertical or particular standards: relevant
only to a particular industry
e.g., EN 60335-1

UNDERSTANDING THE NAMING CONVENTION

Number of the standard

Date of issue (preceded by a colon)

BS EN 60335-1:2012+A11:2014

Standards body

Number of the part of the standard

Amendment

UNDERSTANDING THE NAMING CONVENTION

Example 1: BS EN 603351:2012+A11:2014

European standard (EN) that has been implemented, unaltered, on a national level in the United Kingdom as the British standard (BS) by the British Standards Institution (BSI). The standard is part 1 of the 60335 series, which came into effect in 2012, plus the 11th amendment, which came into effect in 2014.

UNDERSTANDING THE NAMING CONVENTION

Example 2: DIN EN 82079-1:2013-06

European standard (EN) that has been implemented, unaltered, on a national level as a German standard by the German Institute of Standardization (DIN). The standard is part 1 of the 82079 series, which came into effect in June 2013.

UNDERSTANDING THE NAMING CONVENTION

Example 3: DIN EN ISO 9001:2015-11

Standard published by the International Organization of Standardization (ISO) and the European Committee for Standardization (CEN) then adopted, unaltered, on a national level as a German standard by the German Institute of Standardization (DIN). The standard with the standard number 9001 came into effect in November 2015.

THE STRUCTURE OF STANDARDS AND HOW TO READ THEM

Foreword: mandatory and is a fixed, generic text

Introduction: optional but inclusion is encouraged

Scope: mandatory and describes what the document does

Normative References: mandatory, even if there are no normative references in the document

Terms and Definitions: mandatory clause clarifying the meaning of certain words in the context of the document

Technical content: define requirements and provide additional information

Annexes: provide additional information

TERMINOLOGY: SHALL, SHOULD, AND MAY

SHALL

“is used to express mandatory requirements or provisions that have to be followed: the negative form is shall not.”

SHOULD

“is used to express recommendations or provisions that an implementation is expected to follow unless there is a strong reason for not doing so: the negative form is should not.”

MAY

“is used to express permissible actions or provisions that an implementation is able to follow or not follow: the negative form is need not.”

THE PRACTICAL DETAILS: LEGAL OBLIGATION

In case of damage, faulty technical documentation may lead to liability by the manufacturer; although, standards are considered state of the art at the time of publication and can when being applied, limit liability.

The use of standards, including harmonized standards, is voluntary which means that there is no automatic legal obligation to apply them.

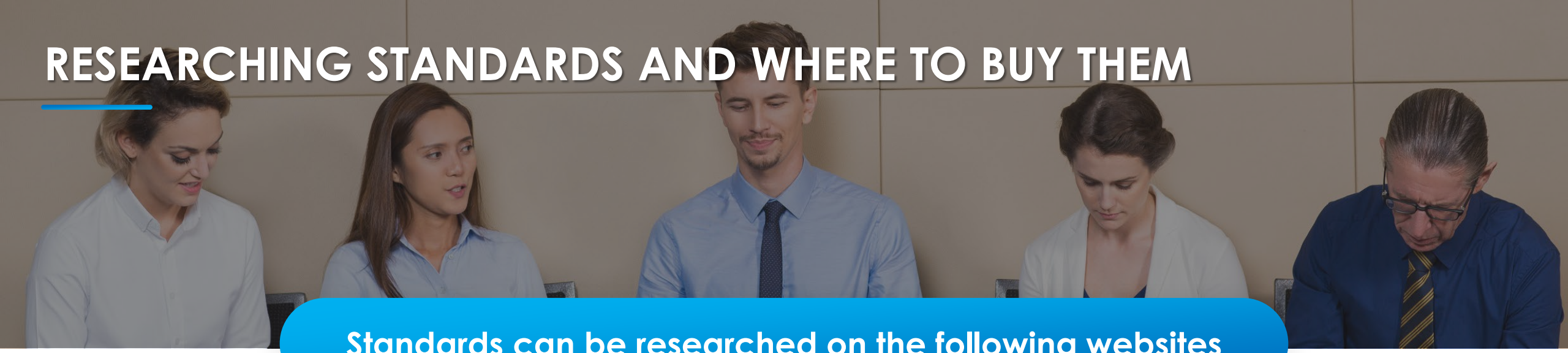
The EU applies the freedom of contract, which allows nonviolent contractual agreements to be drafted between parties or corporations without, or with limited, government interference.

RESEARCHING STANDARDS AND WHERE TO BUY THEM

Starting the research by answering questions such as:

1. "What should be documented?"
2. "Who is the audience?"
3. "What activities may the audience perform or not perform?"
4. "Does the contract specify any details?"
5. "Are test reports/certificates available?"
6. "Do I have access to a technical expert?"

RESEARCHING STANDARDS AND WHERE TO BUY THEM



Standards can be researched on the following websites

International standards: ISO-Online Browsing Platform

Harmonized European standards: published in the Official Journal of the European Union published on the EUR-Lex website

- Research by directive on the European commission web site

European standards: websites of the European Standards Organizations, CEN, CENELEC, and ETSI

The national standards bodies of the member states can help find the right standard according to the activities and needs

IEC 82079-1: THE STANDARD FOR TECHNICAL DOCUMENTATION

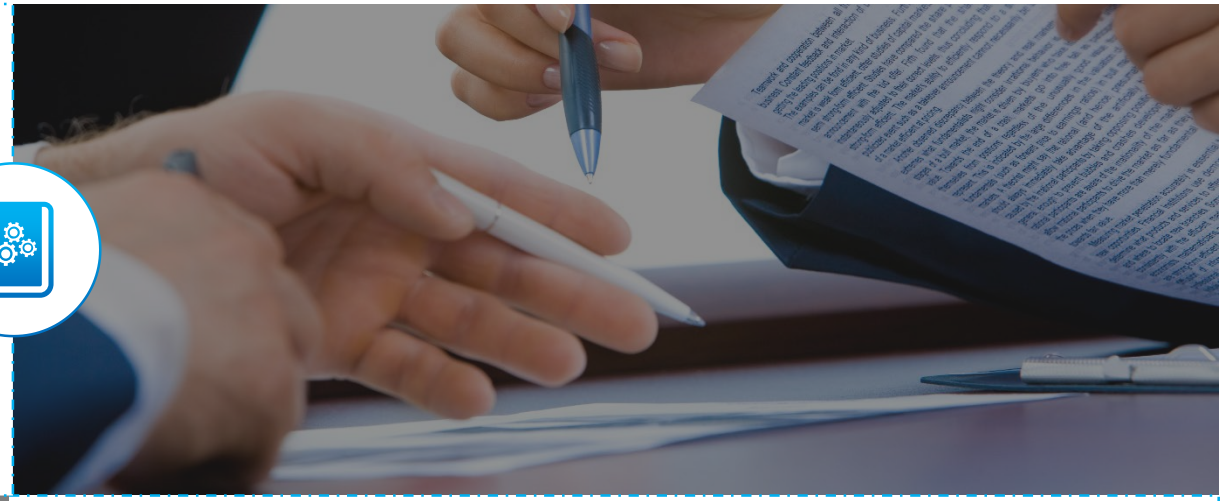
No harmonized European standard specifically for the creation of technical documentation

IEC 82079-1 is the most important standard for technical communicators

The international standard published by IEC and ISO has been adopted at the European and national levels

IEC 82079-1: THE STANDARD FOR TECHNICAL DOCUMENTATION

The standard is applicable to all types of instructions for use and all kinds of products, therefore, not all parts are applicable to all products.



Not a harmonized standard, thus has no legal obligation. The standard describes the state of the art in technical documentation and might be part of a contract.

EDITION 1: IEC 82079-1:2012

Preparation of instructions for use – Structuring, content and presentation

Part 1: General principles and detailed requirements

Outlines general principles and detailed requirements, as well as, provides risk mitigation approaches to all parties involved in creating technical documentation.

Delves into detail with requirements on content, the quality, and efficiency of the documentation as well as possibilities of presentation.

EDITION 2: IEC/IEEE 82079-1 (estimated publication Q2/Q3-19)

Preparation of information for use (instructions for use) of products

Part 1: Principles and general requirements

Has a large number of new features in the normatively regulated part, not only structurally, but also in terms of content and terminology.

Will follow a new structure, including a more detailed scope, details on skills, and a new clause on professional competencies, and safety-related information is addressed in an exhaustive sub-clause

IN A NUTSHELL

Directives are implemented on a national level through national laws

Provisions in laws and directives are further elaborated and clarified in harmonized standards (state of the art)

Manufacturers benefit from a presumption of conformity when meeting harmonized standards

> “Technical documentation cannot entirely ensure legal compliance; however, by complying with the requirements of laws, regulations, directives, and standards it can significantly reduce the risk for the manufacturer and limit liability.”