

Module 1: Legal requirements and international standards for technical documentation

- Submodules:
- 1.1 Basic legal requirements technical communication
 - 1.2 National and international standards
 - 1.3 Principles for the management of legal requirements
 - 1.4 Risk analysis and internal technical documents for manufacturers

About the topic

Technical communication is subject to certain legal requirements because the information given, such as instructions for use, is essential for the safe and satisfactory use of the given product. The user has the right, based on legal regulations, to receive all information necessary to enable him or her to use the product properly and to avoid any kind of damage that might result from improper use. Persons in charge of technical communication in a company, such as technical communicators, managers, and vendors offering technical writing services, are all obliged to comply with regulatory law related to technical writing.

Compliance with these regulations requires that those in charge must be knowledgeable on the governing law. A lack of knowledge will not be accepted as an excuse if a manufacturer or any other organization is found liable for not providing sufficient information for the proper use of a product.

Any technical communication that does not comply with the applicable law could cause legal consequences for the manufacturer or any other organization dealing with the product. One possible consequence is that a customer can claim their rights under the warranty or terminate the purchase contract. In the case of damages or of personal injury or fatalities resulting from the improper use of a product the customer can make a claim for compensation. As an additional consequence, market surveillance authorities may prohibit the further distribution or sale of the relevant product. In cases involving personal injury or fatality, authorities may also initiate a criminal investigation.

The obligation to comply with legal requirements goes beyond the laws and other regulations of a company's domestic market. In the age of globalization manufacturers have to comply with the applicable laws and regulations in each market they target. The principles of Contract Law and Product Liability Law are more or less similar in most countries. In contrast, Health and Safety Regulations differ significantly (except under the multinational legal framework of the European Community – "New Approach Framework").

Unfortunately, the legal requirements regarding the content, structure, and design of technical documentation are usually not explicitly defined. More detailed requirements may be found in national or international standards, which describe the state of the art regarding product design including the technical documentation.

In some case the legal requirements refer directly to industry standards. This method of additionally referring to technical standards is often used in the EU-Health and Safety

Regulations. For example, the requirements for the documentation of machines as defined in the EU-Machine Directive 2006/42 is set forth in the European standard EN 12100:2.

Despite the key role played by such international standards, it is important to know that they are not equal to statutory law. Unlike laws or other regulations, standards are not legally binding. Their legal implications and effects, however, must be carefully examined and analyzed, and technical communicators need to be aware of this issue.

In the light of the complex system employed in this area of law, it is necessary for manufacturers as well as service vendors to implement a proper management structure for compliance with both applicable laws and the corresponding standards. Compliance management should comprise proper up-to-date research and the interpretation of the retrieved requirements. Furthermore, the role of technical communicators should be clearly defined. It is important for them to know their responsibilities with regard to legal regulation.

For compliance with legal requirements dealing with product safety, it is mandatory to conduct a risk analysis for each individual product as a first step. This in turn may result in the implementation of changes within the manufacturing or design process. Technical communicators should be involved in this process because they must be able to draft any safety related information like warning messages or safety signs for product users.

The general learning target of Module 1 is to enable technical communicators and their employers (manufacturers and service vendors) to minimize the risk of claims based on technical documentation that does not comply with the applicable legal requirements and international standards. In addition, the acquired background knowledge about prevailing legal requirements and applicable standards will support the production of high quality technical documentation, including user friendly instructions for use.

Submodule 1.1: Basic legal requirements regarding technical communication

Background

Contract law

According to the general principles of contract law, the customer (buyer) has to be provided with all information necessary for the proper use of the purchased product. "Proper use" has to be understood on one hand as the use intended by the customer and on the other hand as use without any risk of personal injuries, fatalities or damage of property.

The technical documents accompanying a purchased product must first of all fulfill the requirements as stipulated within the underlying contract. Sellers and buyers are free to agree on specific requirements with regards to the deliverable technical documentation.

In addition, contract law as stipulated in the applicable statutory law sets forth requirements that are applicable in the event that the contract parties do not explicitly agree on specific requirements, or in the event that the stipulations within the contract are incomplete. These requirements include the requirement that the goods to be delivered must fit the purpose of use intended by the buyer.

To avoid claims it is crucial that technical communicators understand these legal requirements.

Product liability law

Product liability law deals with the general requirements with which manufacturers must comply in order to design and manufacture safe products. This in turn means that the manufacturer is obliged to exclude any risk that may result in personal injury, fatalities or property damage resulting from the use of the product. In the event that a risk cannot be eliminated by means of design and manufacturing, this risk must be minimized by providing appropriate safety related information (safety notes and warning messages).

In order to provide the users with the information they need, it is crucial to identify the potential user group(s) and their technical background and corresponding capabilities very carefully. Furthermore, the intended use of the product and the potential misuse of the product have to be considered. Lastly, the formal aspects of how to provide the necessary information are important for compliance with the requirements that arise from product liability laws of the respective countries.

To avoid claims and prosecution it is crucial that technical communicators understand all the legal requirements arising from product liability laws.

Health and safety law

Health and safety law also focuses on the minimization of risk by means of technical documentation. Generally, health and safety regulations empower the relevant authorities to take appropriate action against manufacturers or distributors of potentially dangerous products in order to avoid any personal injuries, fatalities or property damage resulting from their use.

Nearly all countries have a system of market surveillance through which the respective authorities evaluate products, checking for risks relating to potential personal injury, fatalities or significant property damage.

An essential criterion for risk evaluation is the information provided to the user of the product. If the relevant authorities determine that the provided information is incomplete or inappropriate with respect to the actual use of the product and the risks resulting from that use, the product will be deemed to be a dangerous product.

A consequence of such categorization of a product is that further distribution may be prohibited. In case of significant danger of personal injury, the product can be recalled from the market. Detailed criteria for the evaluation of information provided to users are given in the applicable health and safety regulations of each country. These regulations may in turn refer to subsidiary legislation or other standards.

It is crucial for technical communicators to have full knowledge of the applicable health and safety regulations of the target markets in order to enable them to draft complying technical documentation and to avoid any issues.

Technical communicators should be aware of the fact that jurisdiction may differ significantly in different countries. Furthermore, it is useful to have basic knowledge about the key differences between common law and principles contained in civil code. This knowledge provides a good basis for the assessment of legal requirements in cross-border transactions, and for communication with the management of the company they work for.

Learning contents

- Requirements arising from contract law
- Requirements arising from product liability law
- Requirements arising from health and safety regulations
- Legal aspects of cross-border selling
- Analyzing of special local legal requirements
- Consequences of non-compliance with legal requirements, including
 - liability of manufacturers
 - warranty claims
 - prohibition of product distribution by statutory authorities in the course of market surveillance

The most important learning objectives

The test candidates ...

- ◆ can give a general overview about the legal requirements regarding technical communication
- ◆ can describe the general principles of contract law with regard to technical documentation
- ◆ can give an overview about the technical writing requirements resulting from product liability law
- ◆ can demonstrate their knowledge in the relationship between health and safety regulations and technical documentation
- ◆ can describe the legal impacts of cross-border selling, in particular the impacts resulting from different health and safety regulations
- ◆ can present an overview about the consequences of non-compliance with legal requirements

Submodule 1.2: National and international standards

Background

Standards define specifications for the whole range of technical products. These standards have been agreed upon between manufacturers, customers, and users to establish minimum requirements for product quality, e.g., product safety. Many product related standards include stipulations regarding technical documentation. These stipulations may be specific, for example in chapter 6.0 of EN12100:2 (Safety of Machines), or they may contain more general statements, such as requirements to provide “useful information” regarding specific products.

Standards are often believed to be legally binding. But they usually are not. It is important to understand that national or international standards can neither replace nor modify nor overrule any statutory regulations such as laws.

In many cases the legal status of a particular technical standard is difficult to define. The status varies and depends on the specific circumstances under which the particular standard is applied.

Standards may become legally binding if they are referred to in a contract. Alternatively, national or international standards may become automatically applicable because of general obligations owed by the seller to the buyer of a product, for example the obligation to deliver goods that are fit for their intended use.

Product liability law requires manufacturers to comply with the relevant standards that reflect the current “state of the art” in the fields of technology and science. In other words, individual manufacturers are obliged to inform themselves about the latest scientific research and the extent of tests conducted in such research, as well as the extent to which technical knowledge and scientific theories are generally applied in their distinctive field of economic activities. Notwithstanding, standards only reflect the average technical level adopted, proven, and generally accepted by the majority of manufacturers in the process of standardization.

It may therefore be true that a piece of technical documentation does not comply with general product liability law, but it complies with the applicable national or international standards. On the other hand, a technical document that does not fulfill the applicable national or international standards would not comply with general product liability law.

Health and safety regulations may also refer explicitly to standards. In many countries, for instance within the European community, such references to technical standards are intended to substantiate and bolster the abstract and general rules contained in health and safety directives or respective laws.

It is useful for technical communicators to be familiar with the organizations/bodies drafting and editing national or international standards. Technical communicators should keep in mind that standards are just a basis for technical writing. The actual scope of the technical documentation that has to be delivered still depends on the specific use of a product.

Organizations/bodies in charge of issuing standards are usually private or private-public organizations that are independent from any state authorities. Any company or person is free to submit their proposals/feedback to the standardization work of these organizations. Manufacturing companies play a significant role in the drafting process of standards. Within the standardization organizations, technical committees are formed to draft and issue standards. In these times of globalization, standardization on an international level under the umbrella of ISO, IEC, and ITU plays the most important role.

Technical communicators should know the standardization process well enough to understand that the resulting approved and published standards are often a compromise agreed to by various and often competing interests. This is increasingly the case as more standards are approved on an international level, and as a result, many standards are of a very general character.

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Due to the challenges of globalization, technical communicators should share basic understanding of the technical standards applicable in the main international markets.

In the EU, technical communicators need to be familiar with the European standards connected with the “new approach framework.”

In the United States the situation is unfortunately much more complex. A variety of different national standards dealing with different technical aspects of specific products may apply. It is therefore important to first identify and subsequently understand these standards. It is also important to know that the American National Standards Institute (ANSI) has issued two standards - ANSI 564:4 and 564:6 - that deal with the form and content of warning messages, warning signs and labelling, user manuals, and instructions for use.

The People’s Republic of China also has national standards regarding technical products. These national standards are applicable in the developing process of technical documentation. It is also important to know that there are Chinese national standards that require technical documentation to be written with the Chinese character sets defined in these standards.

In addition, it would be useful to be familiar with Russian national standards (CHOST-Standards) as well as national standards applicable in India and Japan.

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In addition to the most relevant national standards concerning technical documentation, technical communicators should also know the most important international standards. The most important of these for technical communication is ISO/IEC 82079-1 – Preparation of Instructions for Use. This standard deals with the structuring, content, and presentation of technical documents as well as the drafting process of such documents. ISO/IEC 82079-1 includes general principles of technical writing for all kinds of products, software, and services. It also reflects the basic requirements for safety related information and it defines a substantial and essential basis for the drafting of technical documentation at a high level of quality. For these reasons technical communicators must be familiar with the requirements and principles of ISO/IEC 82079-1.

Learning contents

- Standardization and legal requirements
- The role of standardization organizations
- Important national standards
- The European “new approach”-framework and technical standards
 - TC-related national standards in the United States
 - TC-related national standards in the People’s Republic of China
 - TC-related national standards in Russia
 - TC-related national standards in India
 - TC-related national standards in Japan
- Important TC-related international standards, in particular ISO/IEC 82079-1

The most important learning objectives

The test candidates ...

- ◆ can demonstrate a general understanding of the interdependence between standards and legal requirements
- ◆ know the different branches of law that relate to technical communication and the typical forms of legislation
- ◆ can present a general overview on the role of standards organizations and the drafting of technical standards
- ◆ can demonstrate knowledge of the European standards for the new approach framework.
- ◆ can present an overview about the relevant standards in the U.S., the People’s Republic of China, Russia, India, and Japan.
- ◆ can apply in detail the safety related requirements of ISO/IEC 82079-1
- ◆ can apply in detail the user experience related requirements of ISO/IEC 82079-1

Submodule 1.3: Principles for the management of legal requirements

Background

For every manufacturer or distributor, the complex nature of legal requirements relating to technical communication makes it a critical management task to integrate compliance with rules and regulations into all operations as a part of strategic organization. This management task is usually not the responsibility of technical communicators. But very often the members of management are unfamiliar with the legal requirements regarding technical communication. In such cases, technical communicators should be able to offer their specific knowledge to the management team; they may even act as a kind of internal consultant regarding the legal aspects of technical documentation including applicable standards.

Such extensive and complex research can only be done effectively if technical communicators know how to retrieve the relevant information from information databases available for this purpose. Most of the legal requirements can be researched via the Internet.

Having identified the legal requirements and/or applicable standards, technical communicators must interpret the stipulated requirements. To fulfill this task in an appropriate manner, it is necessary that they know about the corresponding statutory requirements and keep themselves updated about any updates, amendments or revisions.

Learning contents

- Research on legal requirements
- Information retrieval of relevant technical standards
- Analysis of legal requirements
- Integration of legal requirements in the information creation process
- Evaluation of legal requirements
- The role of technical communicators regarding legal requirements

The most important learning objectives

The test candidates ...

- ◆ can demonstrate their abilities in information retrieval on legal requirements and technical standards
- ◆ can demonstrate basic knowledge about research via the Internet
- ◆ know how to implement legal requirements in the content creation process
- ◆ know in principle the importance of the evaluation of legal requirements
- ◆ know the role of technical communicator

Submodule 1.4: Risk analysis and international technical documents of manufacturers

Background

Manufacturers have the legal obligation to minimize any risks that may result from the use of their products. To fulfill this obligation, manufacturers must analyze the specific risks that arise from the use of their products, and initiate risk minimizing measures. Risk analysis therefore automatically becomes an essential part of the product development process and a prerequisite for giving correct safety related information.

Although risk analysis is a part of product development processes, its role is not limited to the same. Instead, its role extends to the actual creation of technical documentation.

Manufacturers are not allowed to minimize any risk by instruction or warning if the risk could also be minimized by better design of the product or – if this is not possible – by protective measures. A proper and risk minimized design overrules any intentions to minimize the risk with the assistance of instructions and warnings.

In addition, in order to fulfill the applicable legal requirements, instructions and warnings have to be efficient. Instructions and warnings must reflect the concrete risks that may occur from the use of the product. Technical documentation may not be based on a mere theoretical evaluation of risks; it must be based on real-life risk analysis.

According to the usual regulations of product liability laws, a manufacturer is obliged to observe the product in real operation and to analyze any critical situation that may occur during the life cycle of a product. Manufacturers are obliged to observe products continuously. If any problems occur, another risk analysis must be performed. Such an additional risk analysis may result in a modification of the instructions for use.

Technical communicators are not responsible for performing risk analysis themselves. As a thorough knowledge of all technical aspects of the product is necessary for proper risk analysis, this task should be undertaken by the product developers.

Technical communicators should, however, request that risk analysis be performed and if necessary, they should ask for a second analysis to be performed in case the first results suggest any defects in the product.

Risk analysis forms an essential part of “internal technical documentation” for many kinds of products. Usually, internal technical documentation will not be disclosed to any other persons other than manufacturers’ staff.

Pursuant to health and safety regulations in many countries, market surveillance authorities are entitled to require the delivery of internal documentation if they want to evaluate the compliance of the product with the applicable legal requirements. This right is explicitly provided for in the health and safety directives of the European community.

Learning contents

- Risk analysis as an important basis for the creation of safety related information
- Risk analysis as a permanent process
- Risk analysis and the design process
- Risk analysis and the responsibilities of technical communicators
- Principles of internal technical documentation according to EC Health and Safety regulations DIN-Mitteilungen mit DIN-Anzeiger für technische Regeln

The most important learning objectives

The test candidates ...

- ◆ can explain the role of risk analysis, in particular for technical writing
- ◆ know the basic requirements of risk analysis
- ◆ know the importance of risk analysis as a part of the permanent quality process
- ◆ know the international standard ISO 12100:2

