TOC

Getting Started

Thanks to this knowledge base:

- You will know how to find out which directives are related to which types of products regulated in the EU.

- You know how to identify the EU requirements for user manuals.

- You will know which standards to use for creating user instructions.

- You will know how to write warnings, precautions for use and safety information

- You will identify legislation (laws/directives) and standards,

- You will identify requirements of the legislation and standards that apply to your product;

- You will add legal content to the instruction manual.

  The Manual is part of the product. It therefore requires the same attention and quality criteria as the product itself thus it is a particularly important tool for fulfilling the instruction responsibility. Only a contextually correct and complete Manual permits exculpatory evidence.

Overview

The goal of Knowledge Base is to help assure that all users and customers of your products have readable and understandable instructions in order to operate devices safely and effectively.

This Knowledge Base contains law regulations, EU directives to help technical writers to develop high quality Manuals. .

In preparing Manuals, in addition to focusing on the needs of the user, you must comply with all applicable regulations, requirements. The following guidance provides a basic framework for compliance and the obligations of the customer / user.

"As per ISO's definition, the term "documented information" refers to information that must be controlled and maintained." Therefore, it expects that you also maintain and control the medium as well as the information. Documented information is used as evidence of conformance.

Remember:

The Manuals provide directions to help users operate devices safely and effectively only when are compliance with applicable requirements. By complying with the legal requirements and applying standards, you create a user guide that is legally compliant.

Understanding
ISO 9001:2015:
Document
control

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Legally Required Content

According to the law regulations the manufacturer must inform the user comprehensively concerning all risks and hazards related to the product. The manufacturer must provide for a complete and comprehensive guide for the user to enable the user to properly and safely install, use and handling of the products. Likewise, any applicable product safety laws are to be observed in the Manual draft process. User Manuals should meet at least the following minimum requirements:

a) Clear, understandable and complete statement concerning:

• intended and approved use;

• limits to such use; and

• concerning other additional limits and conditions, such as limits of technical application, user qualification, user habits and language.

b) Notes and warnings concerning:

• misuse; or

• use which could be dangerous; and

• foreseeable misuse

• with understandable explanation and pointing out of risks for users or third parties

c) Notes and Instructions for:

• installation

• maintenance, preventive maintenance and service

• inspection, repair and general overhaul

• disposal and recycling

This means as a consequence: Technically unsustainable, exaggerated claims of performance or the concealment of foreseeable hazards or dangers or foreseeable uses may give raise to liability.

Terminology

IATE ('Interactive Terminology for Europe') is the EU's inter-institutional terminology database for all EU terminology resources and enhancing the availability and standardisation of the information. The entire IATE glossary database can be downloaded for free in a zipped format, then multilanguage glossaries can be generated using a free tool.

The IATE contains specialised words and expressions specific to a particular subject field and support technical writers in using correct and consistent terminology

https://iate.europa.eu/home

This database assists translators with their day-to-day work, to facilitate terminology research and terminology management

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Product Safety Instructions and Warnings

Safety instructions are of particular importance for the drawing of Manuals. They should warn the product user of danger and risks.

Product sellers must provide "reasonable warnings and instructions" about their product's risks. The law differentiates between warnings and instructions as follows: "Warnings alert users and consumers to the existence and nature of product risks so that they can prevent harm either by appropriate conduct during use or consumption or by choosing not to use or consume." Instructions "inform persons how to use and consume products safely." 1

When the law talks about the "duty to warn," it includes warning labels on products, safety information in instruction manuals, and safety information in other communications such as company websites, social media, advertising, and catalogs.

Product specific standards promulgated by ISO 3864,ANSI, ASTM, UL, CSA, etc., generally talk about what warnings have to be attached to the product and what information, including warnings, have to go in the manual.

	ISO 3864-2	ANSI Z535.6
DANGER	Signal word used to indicate an imminently hazardous situation which, if not avoided, will result in death or serious injury	Indicates a hazardous situation that, if not avoided, will result in death or serious injury.
WARNING	Signal word used to indicate a potentially hazardous situation which, if not avoided, could result in death or serious injury	Indicates a hazardous situation that, if not avoided, could result in death or serious injury.
CAUTION	Signal word used to indicate a potentially hazardous situation which, if not avoided, could result in minor or moderate injury	Indicates a hazardous situation that, if not avoided, could result in minor or mod-

	ISO 3864-2	ANSI Z535.6
		erate injury.
NOTICE	N/A	Indicates information considered important, but not hazard-related

A good warning consists of three parts:

- The type and source of hazard;

- The consequences in the event of non-compliance;

- Measures to avoid the hazard.

- A warning is preceded by the signal word danger, warning, caution or notice.

Compare a hazard safety panel according to ISO 3864 and ANSI :

ISO 3864-2

ANSI Z535.6

⚠ CAUTION

⚠ WARNING

⚠ DANGER

⚠ DANGER

⚠ WARNING

⚠ CAUTION

NOTICE

SAFETY INSTRUCTIONS

Safety Sign Standard Updated to ANSI Z535 Format:

If the device is a restricted device, tell the user to use it only for the person for whom it was ordered and only for the use for which it was intended. A common general warning would alert the user to stop using the device if certain symptoms or operating problems occur. An important general warning for users may be information about the need for a back-up device in case significant problems occur. In the case when a backup is not possible, your warning could contain emergency instructions.

https://ansi.org/news/standards-news/all-news/2011/09/silently-guiding-safety-american-national-standards-for-safety-signs-and-colors-22

https://instrktiv.com/en/how-to-write-a-manual/

Protection Notices for Restricting the Use of Technical Documentation (ISO16016)

The current wording on the protection of technical data in Terms and Conditions of Purchase is as follows:

Technical Data and Confidentiality. All information, data, specifications and drawings provided by company to Supplier for the purpose of providing the relevant goods prior to or subsequent to the formation of the contract, shall not be used for any other purpose, nor copied, disclosed or made available to third parties. . . Supplier shall consider the purchase order itself, as well as any related work and deliveries, as trade secrets and shall therefore treat them confidentially.

This wording adequately protects company documentation is in line with the recommendations of ISO16016. It is not necessary to include a specific reference to ISO16016 to ensure adequate protection.

Legal Requirements

In many countries at least safety manuals are a basic requirement for selling a product: they legally must be included with the product at the time of sale. Often there are linguistic requirements as well — usually that the safety manual must be available in the country's official language(s).

Products in Canada, for example, must have safety manuals translated into both English and French. Countries in the European Union also have strict requirements regarding safety manuals and their translation into different languages. Certain countries require user manuals in specific languages. Also Further country-specific metrology and currency settings may be required in particular for industrial scales and retail scales.

Feature 3

Here is some general text for a topic. Replace this with your own content.

Create Compliant Manuals for the EU

In the European Union there are several EC Directives and Regulations which affect products.

In short: Under certain European Directives, the respective local implementation of such and local law, there is an obligation to provide user manuals in the official languages of the respective Member State as it regards relevant instructions to the user

Rules for EU product safety standards, health and environmental standards, sector-specific standards, standards in international trade.

http://eur-lex.europa.eu

The technical documentation provides information on the design, manufacture, and operation of a product and must contain all the details necessary to demonstrate the product conforms to the applicable requirements.

If you are the manufacturer, there are certain rules that must be followed when placing a product on the market; you must:

prepare the technical documentation before placing a product on the market

ensure the technical documentation is made available to the market surveillance authorities (should they request to see it) as soon as the product is placed on the market

keep the technical documentation for 10 years from the date the product is placed on the market (unless explicitly specified otherwise)

The technical documentation is necessary to prove the product meets the essential requirements and therefore justify and support an EU declaration of conformity. You need this documentation in order to affix the CE marking to the product.

The compliant EN technical documentation should include at least

- name and address of authorised representatives
- a brief description of the product

- identification of the product, for example, the product's serial number

- the name(s) and address(es) of the facilities involved in the design and manufacture of the product

- the name and address of any notified body involved in assessing the conformity of the product

- a statement of the conformity assessment procedure that has been followed

- the EU declaration of conformity

- label and instructions of use

- a statement of relevant regulations to which the product complies

- identification of technical standards with which compliance is claimed

- list of parts

- **test results**

As a manufacturer, you should be able to demonstrate where and how the various parts of the document are held and maintained.

You can usually choose in which language you want to prepare the technical documentation. However, the market surveillance authorities Open as an external link may ask you to translate the technical documentation depending on the EU country where the product has been placed on the market. If requested, you can also provide it in electronic format.

EU legal documents

- **Legislative Framework (NLF)**

Under the New Legislative Framework (NLF), it has become a requirement to provide instructions and information to the user in all the 25 European official languages.Directive 2014/30/EU relating to electromagnetic compatibility, and/or

- **Directive 2014/53/EU on radio equipment,**

- **Directive 2014/35/EU relating to electrical equipment designed for use within certain voltage limits,**

- **Directive 2011/65/EU relating to restrictions on hazardous substances.**

Create Compliant Manuals for the US

By following the steps you should be able to create compliant documentation (Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials) with **ANSI Z535.6** for the US market

A specific standard has been developed dealing with the content, location and the ways warnings are presented in user manuals.

According to US law, a manufacturer has a duty to warn where:

- **the product is dangerous;**
- **the danger is or should be known by the manufacturer;**
- **the danger is present when the product is used in the usual and expected manner; and**
- **the danger is not obvious or well-known to the user.**

Steps for drawing up compliant US user manuals:

Step 1:Identify the applicable acts, laws, and regulations for your product.

- Go to www.usa.gov/laws-and-regulations

Step 2: Identify the competent federal agencies for your produc

- Go to www.cpsc.gov/en/Regulations-Laws--Standards/Regulations-Mandatory-Standards-Banst.

Step 3:Identify which standards are mandatory for your product.

Section 102 of the CPSIA requires every manufacturer or importer of consumer products that must comply with the rules set forth by CPSC to create certificates stating the product is in compliance with each regulation, standard, or ban.

Product specific standards may include requirements regarding the instructions for use.

To identify which standards are mandatory for your product:

- Navigate to the page with the overview of mandatory Standards (for example, www.cpsc.gov-/en/Regulations-Laws--Standards/Regulations-Mandatory-Standards-Bans)

- Click on the link to more information about your product (for example, for Toys, find Toys, mandatory standard in the left column. Click on the hyperlink in the right column. The following page opens: www.cpsc.gov/en/Business--Manufacturing/Business-Education/Toy-Safety)

- See which standard is mandatory (for example, the toy safety standard, ASTM F963-11).

Step 4:Identify the minimum specific requirements for adequate instructions.

Apart from product specific mandatory and voluntary standards, there are some commonly used inter-national standards that set out requirements for just the instructions for use. Some of these commonly used standards for user's instructions are:

- IEC/IEEE 82079-1 Information for Use

- ISO/IEC Guide 37:2012 - Instructions for use of products by consumers

Step 5:Implement ANSI Z535.6

As an example, the ASTM F963-11 standard gives the requirement

5.11.2 For toys and games intended for children at least 3 years old but less than 6 years of age, and which contain as-received small part(s), the labeling shall read:

⚠ WARNING:
CHOKING HAZARD—Small parts.
Not for children under 3 yrs.

Figure 1: Requirement from the F963-11 standard.

Step 6:Write the instructions (and other technical documentation) according to the requirements.

The use of words may, shall and should is regulated in the ANSI Z636.6:

may: This word is understood to be permissive (use may instead of can or could).

shall: This word is understood to be mandatory (use shall instead of must).

should: This word is understood to be advisory.

Legal Requirements

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Machinery

Machinery and Installations (MD)

EU Machinery Directive 2006/42/EC

CE certification in accordance with the Machinery Directive 2006/42/EC.

.Most of our products are machinery in terms of the Directive (band conveyers, price labeling machinery, cargo scan etc.). Please verify by yourself whether the products in question can be subsumed under the definition in Article 1 and 2 (a) of the Directive.

According to Annex I Section 1.7.4:

Information and Warnings

Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.

Information to Control the Machinery

The information needed to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator. Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.

Instructions

All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service. The instructions accompanying the machinery must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.

Maintenance Instructions Intended for Use by Specialized Personnel

By way of exception, the maintenance instructions exclusively intended for use by specialised personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand. This exception does not apply to instructions for maintenance operations that can be carried out both by the user itself or by maintenance personnel mandated by the user. The exception applies only if the manufacturer's instructions to the user specify clearly which maintenance operations are only to be carried out by specialized personnel mandated by the manufacturer.

General principles for the drafting of instructions

• The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative.

• Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words 'Translation of the original instructions'.

• The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.

• In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.

Further Definitions

Communication of "original" instructions

The "original" instructions are the instructions on which the manufacturer decides to accept liability. These instructions are definitive. The "original" instructions must come and go with the machine. The manufacturer must draw up these "original" instructions in an official language of the European Union. The "original" instructions are not therefore necessarily written in the language of the manufacturer. The manufacturer may draw up "original" instructions in several languages. It is recommended that the manufacturer indicates "original" instructions on the versions for which he accepts liability in order to distinguish them from translations which are not definitive.

Instructions have to be translated when put in service

In practice, the translation will be done by the person who introduces the machine into the linguistic area (manufacturer, distributor, importer, user where he is an importer, etc.). Manufacturers are advised to settle this question explicitly in their sales contracts and/or in their offers.

Responsibility for translation in this area is usually the manufacturer's, the distributor's or the importer's, but not the end-user's.

A user who imports a machine directly performs an act of marketing and may be likened to the manufacturer. He introduces a machine into his linguistic area and must therefore attend to translation of the instructions if the original manufacturer did not do so.

Measuring instruments

Directive 2004/22/EC

This Directive is especially for getting certificates of the authorities of each Member State and is relevant for automatic weighing machinery (cargo scanner, price labeling machinery etc.). Member States may require, if it needed for correct use of the instrument, the information referred to in Annex I or in the relevant instrument specific annexes to be provided in the official language(s) of the Member State in which the instrument is placed on the market. The conformity of a measuring instrument with the essential requirements shall be assessed in accordance with Article 9.

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Electronic Equipment

Electrical Equipment

(LVD)

CE certification in accordance with the Low Voltage Directive 2014/35/EU

Electronic Equipment (EMC)

CE certification in accordance with the EMC Directive 2014/30/EU.

Medical Devices

Medical Devices (MDD/MDR)

CE certification in accordance with the Medical Devices Directive 93/42/EEC.

Toys

CE certification in accordance with the Toys Safety Directive 2009/48/EC.

Checklist

Use this checklist to make sure that you have considered all the recommendations in this entry when developing your Manual:

The Manual:

- complies with all labeling regulations.

- is written for the type of people who use the device.

- tells the user how to get help from you.

- includes a table of contents.

- has general warnings and precautions at the beginning.

- describes the purpose of the device.

- gives a physical description of the device with a graphic.

- explains conditions under which the device should and should not be used.

- gives clear setup instructions.

- gives clear check-out procedures.

- gives clear and easy to follow operating instructions.

- provides cleaning instructions.

- describes maintenance that the lay user must do.

- explains storage.

- has a clear, easy to use and find troubleshooting section.

- explains disposal and recycling processes and obligations.

- has a summary page with all the critical information on it.

- has an alphabetized index.

- has an easy to find date of printing.

- includes instructions on any accessories.

- has the necessary disclaimers and copyright notices.

- has a durable distinctive cover.

- will stand up to the conditions in which it will be used.

- is constructed of non-shiny durable paper.

- is laid out to make sections easy to find and update (tabs, binding, page numbering).

- uses white space and other highlighting techniques to focus user attention on important information.

- is printed in at least 12 point type.

- has clear, well-labeled graphics in key places to help user understand text.

- is printed in proper contrast.

You have:

- done a task analysis for the procedures in our Manual.

- selected a suitable format (text, flowchart, list).

- written and formatted procedures correctly.

- used appropriate sentence construction and word choice.

- tested our Manual to assure sixth to seventh grade reading level.

- properly written and placed specific warnings and cautions.

- tested the Manual to make sure that our users can read, understand and follow it.

- have taken steps to make sure that our Manual gets to our users.

Content of a Manual

In addition to the instructions for the intended and approved use of our product, the Manual shall at least comprise of the following:

• Clear, understandable and complete description of the boundaries of technical applications for different uses of the products.

• Clear and complete description of the necessary qualifications of the user.

• Evaluable statements about the limits of the intended and approved use (e.g. as it regards food production or pharmacy faicilities; or use outside in windy or cold or hot areas; etc.).

• Description of the foreseeable hazards and risks, triggered by improper use and the possible consequences for users and third parties.

• Product-specific and application-specific information concerning the installation, maintenance and disposal.

• Warning of any other use or dangerous misuse stating the process, means and tools that allows to prevent the misuse or to prevent the hazards and risks caused by misuse.

From a legal point of in particular the following content should be covered within the contractual process and not only in the Manual:

• Scope and content of warranties,

• Purchase obligation of certain spare parts,

• Exclusion of responsibility for damages resulting from an improper use,

• Technical changes shall be possible without notice,

• Product descriptions, contracts, or other information which were not submitted to the user before order confirmation.

• Reservations of technical changes by company.

• Restrictions on use.

• Exclusion of certain generally common applications.

• Unusually short maintenance or overhaul periods.

• Disposal and recycling obligations and options.

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Sample Structure

The Manual can be structured as follows (example):

Specifications:

- What does the product (performance)?
- Which requirements does it fulfill?
- What can the user do with the product and what can he not do?

Product Description

- How is the product interface designed?
- Which actions lead to which reactions?
- What are the names of the parts of the product and what are they good for?

Job Description for the User

- What shall the user do when?
- How shall he do it?
- The desription could be structured in: Objective of the action - summary of actions - description of the action (step by step) - result of action.

Decription of the functioning of the Product

- How do individual processes of the product work?
- What technologies are included in the product?

Design of the Manual as it regards risks and hazards, Risk analysis of the product

- Which residual risks are based on the product?

- Are hazardous materials used? Do they require special disposal and recycling treatment?

- Are misuses obvious or are those known?

- Conditions under which a safe use is possible?

- What accident prevention regulations and other company requirements shall be observed by the user?

- Can information from accident prevention regulations or professional standards be adopted, e.g. safety signs or security text?

- What warnings can prevent dangers and misuse?

- Important! Manuals cannot make up for a structural defect

Checklist for Safety Instructions and Warnings in the Manual

- Front of Manual should have a summarized list of Safety Instructions or a copy of the warnings within the Manual.

- The first warning should be to "Read and Understand All the Following Safety Precautions before Operating or Repairing the Equipment"

- If graphics are used solely for safety alert to paragraphs or sections of a Manual, there should be a summary of their meanings in the front of the Manual

- If safety labels (Caution, Warning, and Danger) are used on the product, a copy of these labels should be also used in the Manual. Additional warnings may be required in the Manual that may not be used on the product.

- Special safety instructions or warnings should be used for Installation, Operation, Cleaning, Maintenance, Repair, Retrofit or Replacement of the product.

- For critical environments such as Hazardous Locations, more detailed instructions or warnings should be provided in a separate section of the Manual or within as a separate Installation Manual.

- If CD's are used instead of a hard copy of the Manual, there should be at least one printed page covering the safety warnings along with a warning to read and understand the operation Manual included with the product on CD.

- Special safety instructions should be included if equipment is rated for protection from water or dust ingress.

- If replaceable batteries are included, special instruction should be added to replace with correct type and in proper orientation.

- If rechargeable batteries included, special instructions may be required when charging those batteries.

- Special instructions should be added, for equipment to be hard wired, to follow national and local regulations.

- Consideration should be given to a special warning "Repair of Equipment by Authorized Mettler Toledo Personnel Only or "Repair of Equipment only by Properly Trained personnel".

- Special warnings may be required when equipment is controlling other equipment remotely. For example if controlling a conveyor motor not within operator range the may be a need for a warning to install Emergency Stop Switches within operator reach of each moving piece of equipment.

- Installation Safety Considerations

- Proper mounting instructions to ensure equipment does not fall

- Wiring instructions (if appropriate)

- Note to wire according to National and local electrical codes

- Note special training if required for installation

- Warning to remove from power before cleaning or repairing equipment

- Special warnings if in Hazardous Locations as required. These include making location safe before working on equipment, special cleaning needs and matching entity parameters when required.

- Warning about making in-authorized modifications of equipment

- Operation Safety Considerations

- Caution about proper powering up of equipment

- Caution about proper precautions of removing power before cleaning or proper cleaning methods when necessary

- Caution about leaving equipment un-attended if that is an issue

- Caution or Warning about proper battery replacement if equipment has operator replaceable batteries

- Proper charging of re-chargeable batteries. If hazardous location, Warn about not charging in the hazardous location

- Caution or Warning to not put hands and feet in pinch point areas if this hazard exists.

- Warning to check equipment on regular interval for improper operation or any safety concerns and report it to supervision immediately

- Maintenance and Cleaning Safety Considerations

- Caution or Warning about proper lubrication if equipment requires it. This includes suggested types of cleaners or oils if that is critical

- Caution about minimum quality of air if equipment is air driven

- Warning to check equipment on regular interval for improper operation or any safety concerns and report it to supervision immediately

- Many of the same items listed under Installation Safety Considerations may apply

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FAQs

What does the directive do?

It establishes the principle of liability without fault applicable to European producers. Where a defective product* causes damage to a consumer, the producer may be liable even without negligence or fault on their part.The aim of the Directive is to facilitate the free movement of goods whilst maintaining a fair balance between the interest of consumers and producers.

What is difference between Regulations and Directives?

Regulations

A "regulation" is a binding legislative act. It must be applied in its entirety across the EU. For example, when the EU wanted to make sure that there are common safeguards on goods imported from outside the EU, the Council adopted a regulation.

Directives

A "directive" is a legislative act that sets out a goal that all EU countries must achieve. However, it is up to the individual countries to devise their own laws on how to reach these goals. One example is the EU consumer rights directive, which strengthens rights for consumers across the EU, for example by eliminating hidden charges and costs on the internet, and extending the period under which consumers can withdraw from a sales contract.Do you always need to state the hazard, consequences and avoidance procedures even if they are obvious?

The ANSI Z535.4 standard says in Annex B:

"The word message on a hazard alerting sign typically communicates information to a viewer on the type of hazard, the consequence of not avoiding the hazard, and how to avoid the hazard. Many factors must be considered when determining whether to omit consequence, avoidance, or type of hazard information in the word message. Factors to consider include whether the message can be inferred from a symbol, other text messages, user training, or the context in which the safety sign is used."

When can safety messages be in the manual and not on the label? When on the label and not in the manual?

Steve Hall from Applied Safety and Ergonomics said on this question:

"There is no hard and fast rule, but generally you want to try to provide messages in a way that gives people a reasonable chance to read them at an appropriate time. So, for tasks that are expected to involve referring to the manual (e.g., assembly, troubleshooting, maintenance, etc.), it is generally reasonable to provide safety messages in the relevant part of the manual, and not on a label. Conversely, for scenarios where the target audience is not reasonably expected to have access to a manual, a label may be more appropriate."

In addition, a product liability law professor said:

"Whether adequacy requires in any given case that warnings be placed directly on the product involves a balance of the significance of the hazard, the user's need for the information, the availability of a feasible means to place the warnings on the product, and other factors in the calculus of risk. If feasible, reason normally suggests that important warnings be placed on the product itself rather than in a pamphlet, booklet, or information sheet that can be damaged, lost, destroyed or stuffed in an office drawer… Depending on the circumstances, however, a warning may still be adequate even if it is provided off the product in a manual or other writing."[1]

Do I always need to provide a hard copy of the manual, or can I put the manual on a CD that's included with the product, or have a reference (website link or QR code) to the manual on the label to the company's website?

The standards don't discuss whether a hard copy is required or whether the information can be provided in another way. The reason is probably that most manufacturers provide their instructions in a hard copy. However, there have been manufacturers of certain products that have recently asked about not providing a hard copy, but instead including the instructions as an electronic file in the product or in a CD or just provide on a label a link to the manual on a website. Examples of such products would be cell phones, computers, TVs, and certain machinery or equipment run by computers.

I have seen no law that discusses this issue and, as a result, a manufacturer could omit the hard copy and argue that what they provided was adequate under the circumstances.

At a minimum, if there is room, the on-product warnings should tell the user to read the manual before using the product and tell them how to obtain a replacement manual if one is missing. This can be done by providing an 800-number to call or website link to download a replacement manual.[2]

Is it mandatory to have a manual for every product category?

No. For example, a teddy bear does not need a manual. Although a teddy bear does not need a user manual, the manufacturers have to keep a technical file in which they state that the product is safe to use, including the reasons why.

When a user manual is required?

One of the requirements in any EU Directive is that a user should clearly understand how to use a product and, as a consequence, use it safely.

If it is not immediately obvious how to use the product, a user manual is required.

For which product categories is it mandatory to include a manual?

if you would like to have an indication which products probably need a user manual, you can find the relevant product categories on a specific EU website: .

Here, you'll find all the information on all 25 product categories that the EU distinguishes – among them boilers, lifts, machinery, medical devices and toys.

Endnotes

[1]Product Liability Law, 2d Edition, page 601 (Thomson West 2008).

[2]htttps://incompliancemag.com/article/product-safety-instructions-and-warnings/

PDF Downloads

Below is a list of documents required for legally compiled product documentation:.

ISO/IEC/ IEEE 26513	Systems and software engineering — Requirements for testers and reviewers of information for users	
ISO 29845:2011	Technical product documentation — Document types	establishes and defines the types of documents required to be in the documentation for the specification of products, equipment and plants at all levels of complexity. It deals with the range of document types used from the conceptual phase to finished product, in all engineering fields
ISO 10209:2012	Technical product documentation — Vocabulary	Terms relating to technical drawings, product definition and related documentation
IEC/IEEE 82079-1:2019	Preparation of information for use (instructions for use) of products	Principles and general requirements
ISO 21600:2019	Technical product documentation (TPD)	General requirements of mechanical product digital manuals;specifies the com-

		position, basic principles, preparation process, general requirements, detailed requirements, publication and application requirements, and management requirements of mechanical product digital manuals.

ISO 9001:2008	Guidance on the Documentation Requirements of ISO 9001:2008	

ISO 9001:2015	Guidance on the requirements for Documented Information	modern forms of communication such as video, audio, and other electronic records, but to allow an organization the flexibility to reuse appropriate information, maintain current versions easier, provide broader access/distribution and reduce costs associated with documentation.
IEC 82079-1	Preparation Of Instructions For Use	standard specifically covers product documentation.
Directive 2011/95/EC (GPSD)	General Product Safety Directive 2011/95/EC (GPSD)	
IATE		

	ISO 3864-2	ANSI Z535.6
	Location of Warnings: On Product or in the Manual?	
	Design standards for safety warning messages in manuals	
	Writing Safety Instructions for Consumer Products	

Glossary

B

Batch target

A special target that lets you build and/or publish multiple other targets in a single group (or "batch"). You can schedule batches to run at any time.

Block snippet

A snippet that is created out of one or more paragraphs.

C

Condition tag

A marker that you can apply to different areas of your content so that some sections show up in some of your outputs but not in others.

Cross-reference

A navigation link that lets you connect text in one topic to another topic (or a bookmark within a topic). Cross-references let you create "automated" links that are based on commands you provide. This allows you to keep links consistent and change them in just one place by using the "xref" style.

D

Drop-down text

A feature that lets you collapse content in your topic. The content is expanded (and therefore displayed) when the end user clicks a link.

F

Footnote

A comment that is used to explain a specific area of the text. Both the area in the text and the comment contain a number or symbol that ties the two together. A footnote (or endnote) comment can be placed at the end of a page, document, chapter, section, or book.

S

Single-Sourcing

Reusing content and producing multiple outputs from the same set of source files. Flare lets you single-source your projects in many ways, using various features. This includes features such as topic-based authoring, conditions, snippets, variables, multiple tables of contents, and more.

Snippet

A pre-set chunk of content that you can use in your project over and over. Snippets are similar to variables, but snippets are used for longer chunks of content that you can format just as you would any other content in your topic. In snippets, you can also insert tables, pictures, and whatever else can be included in a normal topic.

Span

A tag that is used to group inline elements to format them with styles. A span tag doesn't perform any specific action; it simply holds the attributes (e.g., font size, color, font family) that you apply to inline content.

Style

An element to which you assign a certain look and/or behavior. You can then apply that style to your content. Different kinds of styles are available in a stylesheet, to be used for various purposes in your content.

T

Table

A group of intersecting columns and rows that you can add to a topic for various purposes, such as comparing one thing with another or giving field descriptions for a software dialog.

Target

One "instance" of an output type. When you build your final output, you are essentially building one or more of the targets in your project.

Text snippet

A snippet that is created out of a portion of one paragraph.

Topic

A chunk of information about a particular subject. Topics are the most important part of a project. Everything else is contained within topics (e.g., hyperlinks, text, pictures) or points toward topics (e.g., table of contents, index, browse sequences). The very reason end users open a Help system is to find information, a little direction. They find that help within individual topics.

V

Variable

A pre-set term or content that you can use in your project over and over. Variables are similar to snippets, but variables are used for brief, non-formatted pieces of content (such as the name of your company's product or your company's phone number).

X

XML Editor

The window in the Flare interface where you can add content and formatting to elements such as topics and snippets.