

ISO 20607: 2019

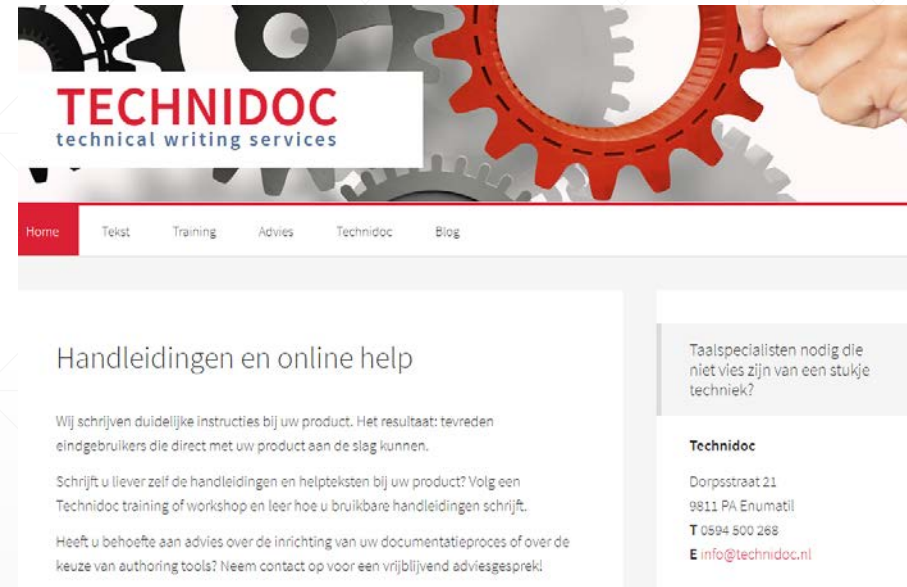
Just another standard that tells you how to do your job?

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- Technidoc, since 1991
- Training 'How to write a CE-compliant user manual'
- Workshops 'Tech writing for engineers'
- MadCap Flare addict
- I hate standards. Usually.

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Session overview

- Recap machinery directive
 - CE and the machinery directive
 - Requirements for instructions for use
- Introduction ISO 20607:2019
 - New terminology
 - Structure
 - What's new
- How to use the new standard

CE and the Machinery Directive

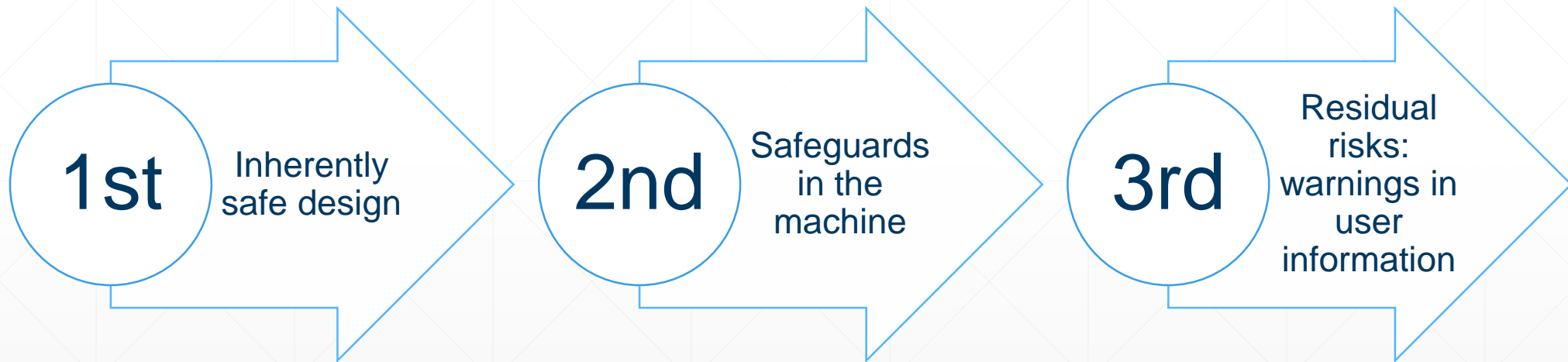
- Free movement of machinery within the single market
- High level of protection for EU workers and citizens.

Overall objectives of the Machinery Directive

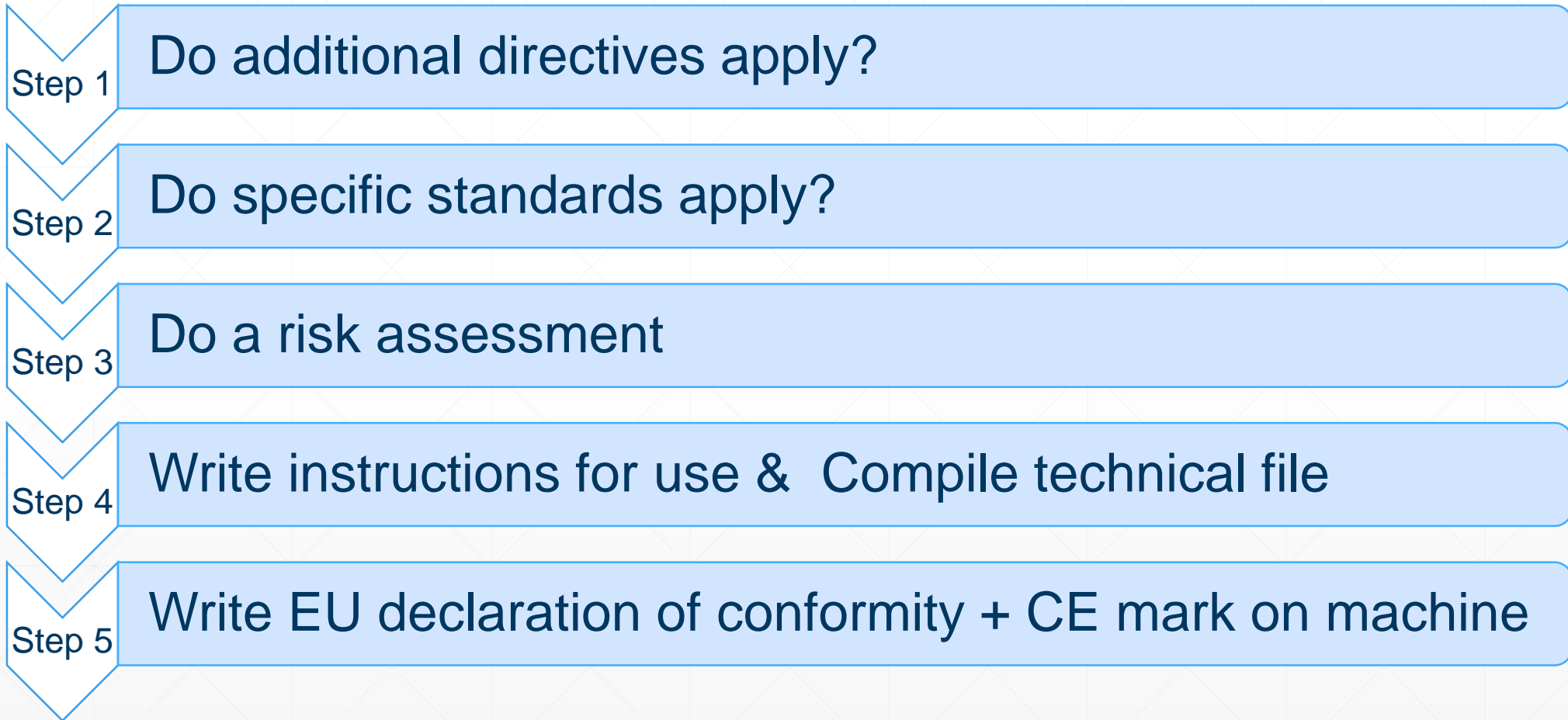
2006/42/EC

The MD is in need of revision

3 Phases in product safety



Steps in CE – product within the scope of MD



Requirements – Instructions for use (1)

- ‘Instruction for use’ = essential health and safety requirement
- Manufacturer/authorized representative is responsible for supplying the instructions for use
- 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
- Information on **residual risks**
- Instructions must cover not only the **intended use** of the machinery but also any **reasonably foreseeable misuse**.

Requirements – Instructions for use (2)

- Instructions must be in a form that is **unambiguous and easily understood**. It must not be excessive to the extent of overloading the operator.
- Instructions must be available in one or more official Community **languages**. The words ‘Original instructions’ must appear on the language version(s) verified by the manufacturer/his authorized representative
 - Exception: instructions for specialized personnel (e.g. maintenance instructions) may be supplied in one Community language that specialized personnel understand
- Instructions should contain all information that is required for **safe use** of machinery

Contents of the instructions

Each instruction manual must contain, where applicable, at least the following information:

- (a) the business name and full address of the manufacturer and of his authorised representative;
- (b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3);
- (c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature;
- (d) a general description of the machinery;
- (e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;
- (f) a description of the workstation(s) likely to be occupied by operators;
- (g) a description of the intended use of the machinery;
- (h) warnings concerning ways in which the machinery must not be used that experience has shown might occur;

ISO 20607:2019

Safety of machinery – Instruction handbook – General drafting principles

Why created / purpose

- To provide guidance to machine manufacturers on how to provide an instruction handbook
- To improve the safety specifications and readability / ease of use of the instruction handbook of the machine
- To specify requirements for the machine manufacturer for preparation of the safety relevant parts of an instruction handbook (more specific than IEC/IEEE 82079-1).

ISO 20607 is a Type-B standard

- Generic safety
- The requirements of ISO 20607 can be supplemented or modified by a type-C standard

Reference: ISO 12100:2010 “Safety of machinery – General principles for design – Risk assessment and risk reduction”

Relationship with Directive 2006/42/EC

Compliance with the normative clauses of ISO 20607 confers a **presumption of conformity** with the corresponding essential requirements of Directive 2006/42/EC

- Stick to what the standard tells you to do on the subject of instructions for use/ instruction handbook
- Check the official list regularly (<https://eur-lex.europa.eu/oj/direct-access.html>; accessed September 2019)
- ISO 20607 is not on the list yet

Commission Implementing Decision (EU) 2019/436 of 18 March 2019 on the harmonised standards for machinery drafted in support of Directive 2006/42/EC of the European Parliament and of the Council
C/2019/1932

OJ L 75, 19.3.2019, p. 108–119 (BG, ES, CS, DA, DE, ET, EL, EN, FR, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)

● In force

CELEX number: 32019D0436

Date of document: 18/03/2019; Date of adoption

Form: Implementing decision



New terminology

Instruction handbook Part of the information for use provided by a machine manufacturer to the machine user that contains instructions and advice concerning the use of the machinery during all phases of its life cycle.

Purpose of the instruction handbook is to provide the user with information that enables him/her to effectively and safely use the machine during the life cycle of the machine, also considering reasonably foreseeable misuse.

Vulnerable user User at greater risk of harm from products or systems, due to age, level of literacy, physical or mental condition or limitations, or inability to access product safety information

What is in the standard

- Scope, normative reference, terms and definitions (the usual content)
- Principles and general information
- Content and structure of the instruction handbook (example)
- Language and formulation/style guide
- Forms of publication
- Annexes
 - Correspondence between ISO 12100:2010, 6.4, and ISO 20607
 - Presentation and formatting
 - Recommendations for writing instructions
- Bibliography

Section 4 Principles and general information

- Identify target groups/persons who interact directly with the machine
- Identify tasks that target groups shall perform / Information needs per target group
 - Use comprehensible and consistent language (short and simple sentences, chronological, logical and sequential writing, active voice, ...)
 - Write easily translatable text
- Create a single document or multiple documents
- Warnings, hazards etc must stand out
- Describe residual risks
- Create a clear structure
- Provide info concerning IT security vulnerabilities

Target groups

- Target group = any group that interacts with the machine
- Describe/specify the target group in the instruction handbook

Take into account:

- specific needs
- knowledge
- technical vocabulary

Target groups - examples

- Installers (e.g. system integrators)
- Operators
- Maintenance personnel or technicians
- Cleaning personnel
- Dismantling personnel

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Section 5 Content and structure of the instruction handbook

- Title page, TOC, Introduction / purpose of this instruction handbook
- Safety
- Machine overview
- Transportation, handling and storage
- Assembly, installation and commissioning
- Original equipment manufacturer settings
- Operation
- Product or capacity changeover
- Inspection, testing and maintenance
- Cleaning and sanitizing
- Fault finding / troubleshooting and repair
- Dismantling, disabling and scrapping
- Index, glossary, annex(es)

What does it look like?

5.2.8 Product or capacity changeover

The instruction handbook shall include instructions and safety requirements on foreseeable product or capacity changeover, if applicable:

- product or workpiece size changes;
- tool changes;
- material changes;
- energy changes;
- equipment changes;
- data changes;
- process changeover; and
- procedures to restore operation.

The instruction handbook shall include product-specific set-up information.

5.2.9 Inspection, testing and maintenance

The instruction handbook shall include general maintenance instructions and safety-relevant information, such as:

- intended lifetime for the machine and its components;
- nature, frequency and criteria for inspections;

Section 6 ...more advice

- Language and formulation / style guide
 - Provide the instruction handbook in the language(s) agreed with the customer
 - Again: Formulation guidance for instructions
 - How to ...Simple wording for instructions
 - How to ... for Warnings

Warning:

- A signal word
- Describe the nature or type of hazard
- Identify possible injury or damage
- How such injury or damage can be avoided

Section 7

Forms of publication

- Provide in the form(s) agreed with the customer.
- Provide in the language(s) agreed with the customer.
- Manufacturer must be aware of applicable legal requirements of the country in which the machine is placed on the market and/or put into service the first time.

Provide in one or more of the following ways:

- paper publication
- electronic storage medium made available with the machine
- external server, website or storage location with info how to access, available with the machine
- internal server or storage location
- visual and/or auditory forms (HMI, video, internet-based, audio recording ...).

Annexes

- Annex A Correspondence between ISO 12100:2010 (section 6.4) and this document
- Annex B Presentation and formatting (cf. IEC/IEEE 82079-1:2019)
- Annex C Recommendations for writing instructions - again, with lots of examples (cf. NEN 5509)

What's new

- Emphasizes the complete life cycle of a machine
- Statement on IT security vulnerabilities*
- Enormous list of aspects you should consider, with many examples
- Suggests that it is good practice to create **a different instruction handbook for each target group**
- Explains how to handle info from component or subsystem suppliers
- The standard helps you/ manufacturers decide what type of information should go where
- Digital is allowed 😊 - just not by the MD (yet)

*ISO/TR 22100-4:2018, 10.4

ISO 20607 workflow

Workflow based on checklist

Is it time to update your workflow?

Use section 5 of ISO 20607,
or use the checklist.

CHECKLIST ISO 20607:2019

Checklist ISO 20607:2019 – What to include in an instruction handbook (interpretation of ISO 20607:2019)

Please note:

- The writer/manufacturer determines which topics must be included (refer to ISO 20607, section 5.1) in the instruction handbook(s).
- The writer/manufacturer determines which target group(s) to address in an instruction handbook.
- This checklist follows the order of topics given in the standard. You do not have to follow to this order in your instruction handbook(s).
- Use this checklist as an aid in determining the content of the instruction handbook(s).

Use this checklist as follows:

1. Determine the **purpose** of the instruction handbook.
2. Determine the **target group(s)** for the instruction handbook.
3. Do a **task analysis** for each target group.
4. Copy this checklist for each target group.
5. Use the checklist to indicate for each item whether it is relevant for the target group and/or the machine.
6. Save the checklist.
7. Use the results of the task analysis and the selected items in the checklist to determine the structure of the instruction handbook.

Feel free to use the checklist in a different way. Please send any suggestions for improvement to info@technidoc.nl

Use this checklist at your own risk. No rights can be derived from the content of this checklist in its current form.

For more in-depth information, please refer to the original text of the standard; this can be purchased via www.iso.org

Suggested workflow

1. Define purpose(s)
2. Define target group(s) / user analysis
3. Do a task analysis per target group
4. Use the checklist to help determine content
5. Design a logical structure for your content
6. Apply navigational aids

-
- Create an instruction handbook for each target group
 - Give each instruction handbook an appropriate title

References

CE

- <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006L0042-20091215>
- https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en
- <https://ec.europa.eu/docsroom/documents/24722> (Guide to application of the Machinery Directive 2006/42/EC)

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- <https://www.iso.org/standard/68519.html>
- <https://www.evs.ee/products/evs-en-iso-20607-2019>



- Checklist
- ISO 20607
- IEC 82079-1

Would you like to receive a copy
of the checklist?

info@technidoc.nl