CEN GUIDE 17

Safety of pressure equipment - Rules and recommendations for the drafting and presentation of safety standards

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European Committee for Standardization

Avenue Marnix, 17

B – 1000 Brussels

Tel: +32 2 550 08 11

Fax: +32 2 550 08 19

www.cen.eu

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European foreword

This document (CEN Guide 17:2019) has been prepared by CEN Pressure Equipment Advisory Nucleus (CEN/PE/AN) and endorsed by CEN BT.

This document is intended for the use of Technical Committees writing product and/or supporting standards in the field of safety of pressure equipment.

It gives the rules for the development of standards requested by CEN/BT in the programme mandated by the European Commission to support the essential safety requirements of the Pressure Equipment Directive 2014/68/EU.

This CEN Guide follows the CEN/CENELEC Internal Regulations, resolutions and guidance of CEN/BT, and the CEN Business Operations Support System.

Introduction

As a response to the increased global trade in pressure equipment, the relevant CEN/CENELEC Technical Committees have undertaken publication of a series of related pressure equipment safety standards. It has thus been necessary to develop rules and recommendations for the preparation, drafting and presentation of such safety standards, supplementing the CEN/CENELEC Internal Regulations, Part 3, which sets out general principles and requirements for all European Standards.

This document provides those rules and recommendations. Every standard developed under mandate from the European Commission to support the essential safety requirements of the Pressure Equipment Directive 2014/68/EU is, ipso facto, a safety standard. The hazards and risk factors on account of pressure are addressed by the Essential Safety requirements of the Pressure Equipment Directive 2014/68/EU. The goal of the risk assessment is the appropriate consideration of the relevant essential safety requirements of Annex I of the Pressure Equipment Directive 2014/68/EU and the implementation of associated measures in order to avoid failure of the pressure equipment and / or assembly.

1 Scope

This document presents rules and recommendations for the drafting and presentation of European Standards dealing with pressure equipment safety, primarily to achieve consistency and acceptable quality of the various standards to be prepared.

It also gives recommendations on the criteria for the selection of new work items and for procedures to prepare, produce or revise standards in an efficient and effective way.

This document gives recommendations that are additional to the CEN/CENELEC Internal Regulations, Part 3, when this is necessary owing to the special requirements of pressure equipment safety standards.

This document is intended for the drafting of product standards, as well as of material standards and qualification and testing standards.

This document deals only with safety aspects of pressure equipment. Other aspects are already covered by other CEN publications.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CEN/CENELEC Internal Regulations, Part 3, *Rules for the structure and drafting of CEN-CENELEC Documents: 2017* (ISO/IEC Directives – Part 2, modified)

EN 764 (series), *Pressure equipment*

EN 13445 (series), *Unfired pressure vessels*

EN 13480 (series), *Metallic industrial piping*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in the CEN/CENELEC Internal Regulations, Part 3 apply and EN 764-1.

4 General principles

The CEN/CENELEC Internal Regulations, Part 3 should be used in conjunction with this document when preparing a new standard dealing with pressure equipment or revising an existing one.

When drafting or revising a pressure equipment standard, the latest version of EN 764 series has to be considered and be compliant with the Pressure Equipment Directive 2014/68/EU (PED).

In general, the standards should not repeat or paraphrase the text of other reference standards; however, for better understanding of safety standards, it is acceptable to repeat a basic definition, concept or the scope of the standard.

5 Principles to be considered before and during drafting process

5.1 General

The main target of the safety standard is the appropriate consideration of the relevant essential safety

requirements of Annex I of the Pressure Equipment Directive and the implementation of associated measures in order to avoid failure of the pressure equipment and / or assembly.

Before a standard is drafted, the need for it should have been established, using the criteria given in 5.2.

NOTE The result of the procedure can provide information which can be used in the scope (see 5.3).

During the drafting process and the revision of a standard, the procedure given in 5.3 to 5.4 should be carried out in the order indicated, in order to provide information that allows an appropriate standard to be drafted.

5.2 Determination of necessity for standardization and/or revision

The need for standardization and/or for the revision of an existing standard and the respective priorities should be determined from the answers to the questions in 5.2 a) to 5.2 k), as applicable.

a) Is there a demand for European Standards arising from interested bodies (relevant market players such as regulatory bodies, manufacturers' associations, employees' or employers' associations, trade unions, accident prevention organizations or consumer organizations)?

b) Can the national implementation of a European Standard be facilitated in the framework of existing agreements between CEN/CENELEC and regional standards development organizations (SDO)?

c) Is there a need for a standard (for example, terminology) to support other safety standards?

d) Are there significant hazards generating risk related to pressure already addressed by existing standards?

e) If a new technology is to be standardized, is it sufficiently stable and established in the market and can it be therefore considered as state-of-the-art?

f) Are there national standards/specifications giving specific requirements, either directly or by reference to another document, which can be barriers to international trade?

g) Are there proven professional, national or international documents or other documents available to give a reasonable expectation of positive and rapid results?

h) Is there sufficient expertise, collective knowledge and experience for standardization?

i) Is there sufficient availability of experts (in principle from at least five members), project leader and support (secretariat, financial resources)?

j) Is there sufficient feedback on the use of the existing pressure equipment standard?

k) Has the state of the art changed such that the existing safety standard has become at least partly obsolete?

5.3 Definition of scope

The precise limits of the product/material/ qualification and testing to be standardized should be established and should include the following:

a) definition of the product/material/ qualification and testing;

b) determination of the intended use of the product/material/ qualification and testing;

c) determination of the foreseeable "life limit", when applicable;

d) definition of the field of application;

e) state explicitly items or conditions which are excluded from the standard;

f) any risk intentionaly not covered by the standard should be clearly stated in the scope;

g) the various phases in the life of the equipment to be dealt with in the standard should be established.

5.4 Essential Safety Requirements / Hazards and risks identification and analysis – for the product standards particularly

5.4.1 The safety standards shall clearly specify that the Essential Safety Requirements laid down in the Pressure Equipment Directive are compulsory and the legal obligations derived from the Essential Safety Requirements apply only if the corresponding hazards exist for the relevant pressure equipment when it is used under reasonably foreseeable conditions. When appropriate and clearly foreseen, the risk of misuse and its consequences shall also be considered.

5.4.2 The standard should instruct the manufacturer to analyse the hazards and risks applicable to the equipment in question on account of pressure and consequently design, manufacture and test the equipment taking into account his analysis. All hazards directly related to the pressure shall be assessed for the intended use and fluids and including internal/external leakage and the functional requirements related to the pressure hazards.

See PED - Guidelines E-03 and A-15.

5.4.3 The pressure equipment shall be designed, manufactured and checked and if necessary equipped and installed in such a way as to ensure its safety when put into service in accordance with the manufacturer's instructions and in reasonably foreseeable conditions.

5.4.4 The safety standard shall specify the principles to be applied for the hazards and risks analysis, choosing the most appropriate solutions:

— eliminate or reduce identified hazards as reasonably practicable;

— apply protection measures against hazards which cannot be eliminated.

When relevant, inform the users of residual hazards and require to take special measures to reduce the risks at the time of installation and/or use.

Where the potential for misuse is known, the pressure equipment shall be designed to prevent the risks from such misuse or, if not possible, adequate warning to be provided to avoid the use of the relevant pressure equipment in the dangerous way.

For a consistent view on the terms, definitions and the inclusion of the safety aspects (hazard and risk analysis included) in the standards, the ISO/IEC GUIDE 51:2014 may be useful. See also the PED Guidelines H-04 and H-20.

5.4.5 The Essential Safety Requirements are to be applied in such a way as to take into account the state of the art and current practice, as well as the technical and economic considerations which ensure a high degree of safety.

5.4.6 The obligations arising from the Essential Safety Requirements for the pressure equipment also apply to assemblies if the corresponding hazards exist.

5.4.7 Obviously, not all functional features of a pressure equipment product are covered by the Essential Safety Requirements of Pressure Equipment Directive. Specific clauses should / could be inserted in the safety standard to respond to those functions. Some of them may be covered by other directives, like Measuring Instruments Directive, Machinery Directive, Gas Appliances Directive, etc.

6 Format of a safety pressure equipment standard

6.1 General

The format of a safety standard should comply with the CEN/CENELEC Internal Regulations, Part 3 (see model format given in Annex A of this document) and the specific requirements for safety pressure equipment standards given in 6.2 to 6.10.

The model format given in Annex A is intended to help standards developers and to provide a consistent presentation for all safety related standards according to Clause 6.

6.2 Foreword

The Foreword is an unnumbered mandatory element. It shall be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 12.

If relevant, the significant technical changes in relation to the previous edition should be stated.

As a minimum requirement, the following statement[1] should be inserted in each mandated standard:

"This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex Z [appropriate letter(s)], which is (are) an integral part of this document."

In case of revision or amendment of a standard, the standard makers should consider the transition period of application of the previous and the revised standard or amendment. The transition period should be defined in the enquiry document (prEN – stage 40.20).

See Annex B for additional guidance on consideration of the transition period.

6.3 Introduction

6.3.1 Although the Introduction is a conditional element according to the CEN/CENELEC Internal Regulations, Part 3, it is an unnumbered mandatory element in pressure equipment safety standards. It should be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 13.

6.3.2 At least the following statement should be inserted in each safety related standard.

"*This document is a product/ material or qualification and testing standard" [to be chosen, non-exclusive possible] standard.*

This document is of relevance, in particular, to the following stakeholder groups representing the market players with regard to pressure equipment safety:

— pressure equipment manufacturers (small, medium and large enterprises);

[1] These sentences are taken from CEN BOSS. In case of modification of the guidance given by CEN BOSS the current version of that guidance should take precedence over this document.

— health and safety bodies (regulators, accident prevention organizations, market surveillance, etc.) Others can be affected by the level of pressure equipment safety achieved with the means of the document by the above-mentioned stakeholder groups:

— pressure equipment users/employers (small, medium and large enterprises);

— pressure equipment users/employees (e.g. trade unions, organizations for people with special needs);

— service providers, e.g. for maintenance (small, medium and large enterprises);

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.

The pressure equipment concerned and the extent to which hazards, hazardous situations or hazardous events are covered are indicated in the Scope of this document.

6.4 Scope

6.4.1 The Scope is a mandatory element. It should be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 14, and should be drafted using the result of the procedure according to 5.3 of this document. It should be numbered as Clause 1.

6.4.2 In addition to the requirements detailed in the 5.3 above, the following shall be specified in the scope of a Pressure Equipment Directive related safety standard.

a) For product standards:

— The range extent of the relevant products (pressure equipments) by volume V or by the nominal size DN;

— The maximum allowable pressure PS (related to the PN or Class designations when appropriate);

— The materials envisaged or specified;

— The function (if relevant) of the pressure equipment;

— Items or conditions which are excluded from the standard.

b) For material standards:

— Specification for a material or a group of materials (including process requirements, delivery conditions, mechanical properties, chemical composition, etc.);

— Specification for a type of product – flat products, tubes, rods, etc.

In all cases, the “Scope” of a material standard has to include the following note:

NOTE Once this standard is published in the EU Official Journal (OJEU) under Directive 2014/68/EC, presumption of conformity to the Essential Safety Requirements (ESRs) of Directive 2014/68/EC is limited to technical data of materials in this standard and does not presume adequacy of the material to a specific item of equipment. Consequently, the assessment of the technical data stated in this material standard against the design requirements of this specific item of equipment to verify that the ESRs of Directive 2014/68/EC are satisfied, needs to be done. See guideline G – 01.

c) For qualification and testing standards:

— The various requirements, specifications and conditions necessary for the relevant process.

The scope has to indicate what similar products/materials/ qualifications and testing are not covered by the relevant standard and for what reasons. It may also specify which standards address those similar issues.

The scope should also indicate that the standard is not applicable to pressure equipments which are manufactured before the date of publication of the standard. As a minimum requirement, the following statement should be inserted in scope:

"*This document is not applicable to [*<precisely state the pressure equipmentpressure equipmentpressure equipment here*>] manufactured before the date of its publication*."

6.5 Normative references

This clause is a mandatory element. It should be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 15, and should be numbered as Clause 2.

a) Only documents (standards) to which normative reference is made in the text of the safety standard should be listed in this clause.

Normative references in the text of a standard need to be made using the verbal form "shall", signifying a requirement.

EXAMPLE "This shall be in accordance with EN 12345:201x, Clause 6."

When a reference is made only for information, it should be introduced by the phrase "see EN ..." and the standard referenced should be listed, not in this clause, but in a Bibliography (see 6.10).

This document, even though applicable to the drafting and presentation of the safety standard, should not be given as a normative reference.

b) Reference to standardization documents should be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 15 and should be dated in accordance with 10.5 of those Internal Regulations.

When a normative reference, e.g. to an ISO/IEC International Standard, is required, the safety standard should:

— either reproduce the text of the normatively referenced document, in the main body of the safety standard or in a normative annex, clearly indicating its origin by "(extract from ISO/IEC ...)", or

— make dated reference to a specific clause(s) or subclause(s) of the referenced document (without reproducing it), or

— make dated (preferably) or undated reference to the whole of the normatively referenced document, if applicable — for example, in cases where the subject of the normatively referenced document is an applicable test method.

c) For the harmonized standards candidates to be referenced in the Official Journal of the European Union, the normative references shall be dated – at least those which are specified in the clauses/subclauses addressed in the Table ZX.1. This is due to the fact that once published in the

Official Journal of the European Union, the harmonized standard provides presumption of conformity with the Essential Safety Requirements of the Pressure Equipment Directive.

In principle, the referenced documents should be documents published either by CEN, CENELEC, ISO or IEC. Documents published by other bodies may be referred to in a normative manner provided that the criteria listed in the CEN/CENELEC Internal Regulations, Part 3:2017, 10.2 are met.

d) Particular attention should be paid to the normative references chain to ensure that all normative references used, whatever position in the chain, satisfy the following requirements:

— Represent the state of the art;

— Are not outdated, withdrawn or superseded;

— Are not in contradiction;

— Clearly set the relevant specification;

— Are not so numerous that it would be impossible for a SME to acquire and apply them all;

— Have not been object of a formal objection and removed from the OJEU;

— Do not include legal acts.

6.6 Terms and definitions [symbols and abbreviated terms]

6.6.1 This clause is a mandatory element. It should be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 16 and should be numbered as Clause 3.

6.6.2 The terms and definitions given in relevant pressure equipment safety standards should be used as far as applicable. For new terms and definitions, the association of the word “safety” with the name of a component or a device should be avoided. A recommended approach is to replace, where possible, the word “safety” by an indication of the objective or characteristic.

6.6.3 When there is a need to define symbols or abbreviations (especially for test methods), this conditional element should be included in line with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 16.

6.7 Pressure equipment safety requirements and/or protective/risk reduction measures

6.7.1 General

As a minimum requirement, the following statement should appear in this clause:

“Pressure equipment should comply with the essential safety requirements and/or risk reduction measures of this clause.

The standard safety requirements subclauses correspond to the main clauses of the Essential Safety Requirements of the Annex I of the Pressure Equipment Directive. When drafting those subclauses it is highly recommended to use the relevant parts of the EN standards series:

— EN 13445 for the unfired pressure vessels;

— EN 13480 for the metallic industrial piping;

— EN 764 for pressure equipment, including definitions, symbols and units, technical delivery conditions for metallic materials, inspection documentation, operating instructions, safety systems.

6.7.2 Design

6.7.2.1 General

The safety standard shall underline the fact that the pressure equipment shall be designed taking all relevant factors into account such as to ensure the equipment will be safe throughout its entire intended life.

6.7.2.2 Design for adequate strength

6.7.2.2.1 Factors

Even though the hazard and risk assessment has been carried out concerning the main risk - pressure, the actual design (when relevant) will need to reflect other loadings that could impact the design for pressure. For example, the following factors should be considered; it should also be considered that the loadings could occur together:

— internal and external pressure;

— ambient and operational temperatures;

— static pressure and mass of contents in both the operating and test conditions;

— traffic, wind, earthquake loading (when appropriate);

— reaction forces and moments which result from the supports, attachments, piping;

— corrosion and erosion, fatigue, etc.;

— decomposition of unstable fluids (which may generate undesirable overpressures);

To ensure adequate strength, the Essential Safety Requirements specify a number of design methods which shall be selected by the standard:

— Calculation method which may be supplemented by an experimental design method;

— Experimental design method without calculation; however there is a limit on the volume or pressure and diameter – PS x V lower than 6000 bar. L or PSxDN lower than 3000 bar. See PED Guideline E–01; PED Guideline E–07 and PED Annex I section 2.2.4.

6.7.2.2.2 Calculation method

The calculation method, when selected by the relevant safety standard, shall consider three aspects:

a) Pressure containment and other loadings: This method applies safety factors which eliminates any uncertainty arising out of manufacture, operational conditions, stresses, calculation models and the properties and behaviour of the material. Subclause 7.1 of Annex I Pressure Equipment Directive shall be followed for the allowable stresses such as to provide sufficient safety margins for the calculation and Subclause 7.2 of Pressure Equipment Directive Annex I to be considered for the welds joint coefficients mandatory values. There are a number of different methods that can be applied either individually or in combination, design by formula, analysis, or fracture mechanics.

b) Resistance: The calculation pressure should not be less than the maximum allowable pressures allowing for static head and dynamic fluid pressures and the decomposition of unstable fluids.

Where a vessel comprises different compartments the partition wall shall be designed on the basis of the highest possible chamber pressure relative to the lowest pressure possible in the adjacent chamber. The following also needs to be considered:

— calculation temperatures;

— all possible combinations of temperature and pressure;

— maximum and peak stress;

— calculation for pressure should use appropriate material properties;

— joint factors based on non-destructive testing, the materials joined and the operating conditions envisaged;

— potential degradation mechanisms (e.g. corrosion, creep, fatigue).

c) Stability aspects: If the calculated thickness does not allow for adequate structural stability, e.g. during transport or handling, then the thickness may need to be amended accordingly.

6.7.2.2.3 Experimental design method

If this method has been chosen by the safety standard drafters, the design of the equipment may be validated by a test programme carried out on a sample representative of the equipment.

This programme should consider a pressure strength test to check the sample resistance. Where the risk of creep or fatigue exists, appropriate tests based on the service conditions and the consideration of other factors such as corrosion or external damage should be undertaken. The test programme details which shall be either specified by the standard or left to the standard user decision, have to consider and follow the requirements of Subclause 2.2.4 of the Annex I of Pressure Equipment Directive and be accepted by the notified body responsible for the conformity assessment module, where it exists.

6.7.2.3 Provisions to ensure safe handling and operation

The safety standard shall take into account the equipment method of operation such as to preclude any reasonable foreseeable risk in operation. Where necessary, it may also be required to consider the closures and openings, the dangerous discharge of pressure relief blow-off, the devices to prevent physical access whilst pressure or a vacuum exists, the surface temperature and the decomposition of unstable fluids.

Where the pressure equipment is fitted with an access door, it shall not present any risk. If the opening can be operated quickly, the pressure equipment shall be fitted with a device to prevent it being opened whenever the pressure or temperature of the fluid presents a risk.

6.7.2.4 Means of examination

The product safety standard shall ensure the pressure equipment is designed and constructed so that all necessary examinations can be carried out with means of determining the internal condition of the equipment, such as access openings allowing physical access to the inside.

Other means of ensuring the safe condition of the pressure equipment may be required if it is too small for physical internal access, where opening the pressure equipment would adversely affect the inside, where the substance contained has been shown not to be harmful to the material from which the pressure equipment is made and no other internal degradation mechanisms are reasonably foreseeable.

6.7.2.5 Means of draining and venting

When relevant, means shall be provided for the draining and venting of pressure equipment, to avoid harmful effects such as water hammer, vacuum collapse, corrosion and uncontrolled chemical reactions and to permit cleaning, inspection and maintenance.

6.7.2.6 Corrosion or other chemical attack

Where necessary, there should be allowance or protection against corrosion or other chemical attack. See also PED Guideline E-05 in connection to the experimental design method.

6.7.2.7 Wear

In case severe conditions of erosion or abrasion occur, they can be reduced by the use of additional material or by the use of liners or cladding materials, by the replacement of parts or by drawing attention, by the use of instructions, to provide measures for continued safe use.

6.7.2.8 Assemblies

The standard, when relevant, has to draw attention on the components which need to be designed so that they can be assembled together are suitable and reliable for their duty, and are integrated and assembled in an appropriate manner.

6.7.2.9 Provisions for filling and discharge

The design may need to consider safe filling and discharge in particular with respect to risks such as:

— On filling: overfilling or over pressurization having regard to the filling ratio and to vapour pressure at the reference temperature, and the instability of the pressure equipment;

— On discharge: the uncontrolled release of the pressurized fluid;

— On filling or discharge: unsafe connection and disconnection.

6.7.2.10 Protection against exceeding the allowable limits of pressure equipment

Where the allowable limits could be exceeded, the equipment be suitably protected. The device or combination of such devices shall be determined on the basis of the particular characteristics of the equipment or assembly.

6.7.2.11 Safety accessories

6.7.2.11.1 General

The safety standard shall point out that the safety accessories shall:

— be designed and constructed as to be reliable and suitable for their intended duty and take into account the maintenance and testing requirements of the devices;

— be independent of other functions;

— comply with appropriate design principles in order to obtain suitable and reliable protection. These principles include, in particular, fail-safe modes, redundancy, diversity and self-diagnosis. See PED Guideline E–08.

6.7.2.11.2 Pressure limiting devices

These devices shall be designed so that the pressure will not permanently exceed the maximum allowable pressure PS. Reference to be considered to the Subclause 7.3 of Annex I of the Pressure

Equipment Directive. However, a short duration pressure surge is allowable, where appropriate. See PED Guideline E–09.

6.7.2.11.3 Temperature monitoring devices

These devices shall have an adequate response time on safety grounds, consistent with the measurement function.

6.7.2.12 External fire

Considering the intended use, pressure equipment shall be adequately designed and/or fitted with suitable accessories or provision made for their fitting, to meet damage-limitation requirements in the event of external fire. Standards specifying fire resistance capability testing and/or certification method for designated pressure equipment are of highest importance for the industry/market.

6.7.3 Manufacturing

6.7.3.1 General

The safety standards have to address, when relevant, at least the below requirements whose task is to eliminate or significantly reduce the risks generated by the manufacturing process.

6.7.3.2 Manufacturing procedures

6.7.3.2.1 General

The manufacturer should ensure the execution of the provisions set out by the design by applying appropriate techniques and procedures and should consider the following items.

6.7.3.2.2 Preparation of the component parts

It is useful for the safety standard to specify that the preparation of the component parts (e.g. forming and chamfering) shall not give rise to any defects, cracks or produce changes in the mechanical properties of the material. See PED Guideline F-03.

6.7.3.2.3 Permanent joining

This is a critical manufacturing issue which deserves particular attention in a pressure equipment safety standard, whether of product or supporting standard type. The following need to be addressed for all pressure bearing components in order to eliminate/reduce the risks of the inherent welding process pressure hazard.

— Permanent joints and adjacent zones shall be free of any surface or internal defects which could be detrimental to the safety of the equipment.

— The properties of permanent joints need to meet the minimum properties specified for the materials unless other relevant properties have been taken into account by the design.

— Permanent joining shall be carried out by suitably qualified personnel using suitable procedures.

For pressure equipment in categories II, III and IV, operating procedures and personnel need to be approved by a competent third party which, at the manufacturer's discretion, may be:

— a notified body;

— a third-party organization recognized by a Member State.

The above applies also to other types of permanent joints like those obtained by braze welding, expansion, frettage, riveting. See PED Guideline F-05.

To carry out these approvals the third party must perform examinations and tests as specified in the harmonized standards or perform equivalent examinations and tests or have them performed. For the appropriate harmonized standards, see PED Guideline F–08.

6.7.3.2.4 Non-destructive tests

Non-destructive tests of permanent joints shall be carried out by suitable qualified personnel. For pressure equipment in categories III and IV, the personnel shall be approved by a recognized third-party organization. Note: not applicable to the personnel in charge of visual examination.

6.7.3.2.5 Heat treatment

Where there is a risk that the manufacturing process envisaged and/or specified by the standard will change the material properties to an extent which would impair the safety of the pressure equipment, suitable heat treatment needs to be applied. It is recommended the standard addresses this issue in detail.

6.7.3.2.6 Traceability

Suitable procedures need to be established and maintained for identifying the material from receipt, through production, up to the final test of the pressure equipment. See Guideline G–04.

6.7.3.3 Final assessment

6.7.3.3.1 General

Pressure equipment shall be subjected to a final assessment.

6.7.3.3.2 Final inspection

Pressure equipment shall undergo a final inspection to assess visually and by examination of the accompanying documents compliance with the Essential Safety Requirements of the Directive.

Any tests carried out during manufacture may be taken into account.

When applicable the final inspection shall be carried out internally and externally on every part of the equipment, and where appropriate during the course of manufacture e.g. where examination during the final inspection may no longer be possible.

For the list of the documents required for the final inspection, in addition to those requested by the relevant conformity assessment module, see PED Guideline F–02.

6.7.3.3.3 Proof test

A safety pressure equipment product or assembly standard shall, in all cases, specify a proof test. A product standard where the proof test is missing is not acceptable.

The final assessment of pressure equipment shall include a test for the pressure containment aspect, which will normally take the form of a hydrostatic pressure test. For category I series-produced pressure equipment, this test may be performed on a statistical basis.

Where the hydrostatic pressure test is harmful or impractical, other tests of a recognized value may be carried out, where these are used additional measures, such as non-destructive tests or other methods, shall be applied before those tests are carried out.

6.7.3.3.4 Inspection of safety devices

When the safety pressure equipment standard addresses assemblies, the final assessment shall also include a check of the safety devices which need to satisfy the Pressure Equipment Directive, Annex I Subclause 2.10 requirements.

6.7.3.4 Marking and labelling

In addition to the CE marking and the information to be provided in accordance with Article 6(6) (for the manufacturers) and Article 8(3) (for the importers) of the Directive, the safety standard shall provide the following information

— For all pressure equipment:

— The year of manufacture,

— Identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number,

— Essential maximum/minimum allowable limits.

— Depending on the type of pressure equipment, further information necessary for **safe installation, operation or use and, where applicable, maintenance and periodic inspection** such as:

— The volume V of the pressure equipment in L,

— The nominal size for piping DN,

— The test pressure PT applied in bar and date,

— Safety device set pressure in bar,

— Output of the pressure equipment in kW,

— Supply voltage in V (volts),

— Intended use,

— Filling ratio kg/L,

— Maximum filling mass in kg,

— Tare mass in kg,

— The fluid group.

— Where necessary, warnings can be fixed to the pressure equipment drawing attention to misuse which experience has shown might occur.

The information referred to the three points above shall be given on the pressure equipment or on a data plate firmly attached to it.

There are exceptions: appropriate documentation may be used to avoid repetitive marking of individual parts such as piping components, intended for the same assembly, or where the pressure equipment is too small, e.g. accessories, this information may be given on a label attached to it, labelling or other adequate means may be used for the mass to be filled and the warnings provided it remains legible for the appropriate period of time.

6.7.3.5 Operating instructions

When pressure equipment is made available on the market it shall be accompanied, with instructions for the user, containing all the necessary safety information relating to:

— mounting including assembling of different pieces of pressure equipment,

— putting into service,

— use,

— maintenance including checks by the user.

Instructions shall cover information affixed to the pressure equipment in accordance with the above "Marking and labelling" with the exception of serial identification, and shall be accompanied, by the technical documents, drawings and diagrams necessary for a full understanding of these instructions.

If appropriate, other instructions which should be included in a safety pressure equipment standard are those referring to:

— risks arising from misuse;

— particular features of the design.

Those instructions, partially or in full, should be included in the pressure equipment safety standard if appropriate. Particularly the risks of and from misuse and the measures to eliminate or reduce them.

6.7.4 Materials

6.7.4.1 General

Materials used for the manufacture of pressure equipment (particularly for the main pressure bearing parts (see guideline G-06) shall be suitable for the use over the entire scheduled lifetime of the equipment under the designed and/or foreseeable working conditions.

6.7.4.2 Materials for pressurized parts

The safety standards shall specify the appropriate materials to be safely employed in order to satisfy the following requirements.

1) Feature the adequate properties for all operating and test conditions. Particularly the materials shall be sufficiently ductile and tough. This is a major safety issue.

2) Materials shall be selected such as to avoid/limit the brittle–type fracture risk where relevant.

   In case for specific reasons, brittle materials need to be used, adequate protective measures have to be taken.

3) Where appropriate, the characteristics of the steels shall comply with the requirements of the Subclause 7.5 of Annex I of the PED. To be also considered the following PED guidelines: G-17, G-22, G-28, H-06.

4) Be sufficiently chemically resistant to the fluid contained in the PE, but also to the potentially corrosive environment.

5) Not be affected by ageing.

6) Be suitable for the intended processing procedures.

7) Avoid significant unwanted effects when various materials are put together.

6.7.4.3 Manufacturer's responsibility for the materials specification and selection

1) The standard shall confirm the PE manufacturer responsibility in defining the values necessary for the design calculations (see section DESIGN) and the essential characteristics and treatment of the materials to be employed.

2) A specific clause of the standard should address the selection of the appropriate materials for the pressurized parts in order to ensure compliance with the materials specifications of the PED, by using one of the following options:

   — Materials which comply with **harmonized standards**. This is the preferred option as long as the relevant required materials standards have been harmonized and listed in the OJEU. It is recommended to check the latest available list of harmonized standards published regularly In the Official Journal of the European Union, a copy is available on the on the PED website of the European Commission.

   — Materials covered by a **European Approval of Materials** (EAM) (list available on the EC site and published in the OJEU). For details, see PED Guideline G–26.

   — Materials covered by a **Particular Material Appraisal** (PMA). This is the only way to comply with the PED materials requirements when neither harmonized standards, nor EAMs are available. For a better understanding of this PMA process, it would be useful to refer to EN 764-4 and the document PE-03-28 rev 5 published by the WGP in 2006 – Guiding Principles for the contents of PMA and available on the EC PED website. It would also be profitable to have the standard reminding that for the higher categories III and IV, a specific assessment of the PMA shall be performed by the Notified Body in charge of the conformity assessment procedure for the relevant pressure equipment.

3) The standard may specify what is understood by "certificate of specific product control" required to claim compliance with the materials specifications for the main pressure bearing parts in categories II, III and IV, as well as the advantage of working with a material manufacturer whose appropriate quality- assurance system has been certified by a competent body established within the European Union. Refer to PED guidelines G-05, G-07, G-16 and G-27.

4) In addition to the numerous harmonized supporting standards for materials, the drafters of unfired pressure equipment products and metallic industrial piping, would have great advantage by considering, respectively, the EN 13445-2 and EN 13480-2 standards addressing the materials issues.

6.7.5 Specific pressure equipment requirements

6.7.5.1 Fired or otherwise heated pressure equipment with a risk of overheating as referred to in the PED art. 4(1)

For the pressure equipment covered by the Clause 5 of Annex I PED (steam and hot-water –acc. to PED art. 4.1b and process-heating equipment falling under PED art. 4.1.a), the relevant safety product standard shall require (in addition to the applicable requirements of 6.7.2 to 6.7.4) the equipment to be calculated, designed and manufactured such as to avoid or minimize the risks of a significant loss of containment from overheating, by ensuring:

a) Appropriate means of protection are provided to restrict operating parameters such as heat input, heat take-off, fluid level, in order to avoid any risk of local and general overheating.

b) Sampling points are provided to allow evaluation of the fluid properties such as to avoid risks related to deposits and/or corrosion.

c) Adequate provisions are provided to eliminate risks of deposit from deposits.

d) Means of safe removal of residual heat after shutdown are provided.

Steps are taken to avoid a dangerous accumulation of ignitable mixtures of combustible substances and air or flame blowback.

6.7.5.2 Piping as referred to in Article 4(1) (c)

For the piping covered by PED, the relevant safety standard shall require, in addition to the requirements specified in 6.7.2 to 6.7.4, the design and the construction to ensure:

a) the risk of overstressing from inadmissible free movement or excessive forces is adequately controlled by various means (support, constraint, anchoring, alignment, pre-tension);

b) where there is a possibility of inside pipes condensation for gaseous fluids, means are provided for drainage and removal of deposits from low areas to avoid damage from water hammer or corrosion;

c) due consideration is given to the potential damage from turbulence and formation of vortices; the relevant parts of PED Annex I, 2.7 are applicable;

d) due consideration is given to the risk of fatigue due to vibrations in the pipes;

e) where fluids of Group 1 are contained in the piping, appropriate means are provided to isolate take-off pipes the size of which represents a significant risk;

f) the risk of inadvertent discharge is minimized; the take-off points shall be clearly marked on the permanent side, indicating the fluid contained;

g) the position and route of underground piping is at least recorded in the technical documentation to facilitate safe maintenance, inspection or repair.

Developers of piping safety standards should refer to EN 13480-1 to -8

6.7.6 Safety requirements and/or protective/risk reduction measures

The safety requirements and/or protective/risk reduction measures specified should be expressed in terms of verifiable performance with regard to safety, using performance characteristics (parameters), together with their values, rather than merely descriptive characteristics.

To minimize restraint on design, safety standards should specify requirements in terms of the objective to be met and then define the means for achieving it, such as by giving examples or defining test specifications. The safety requirements and/or protective/risk reduction measures should be sufficiently precise to allow verifications.

More than one solution for reducing the risk may be given if allowing the same objective of risk reduction to be reached.

Measures in terms of objectives, and measures defined by data, limits, results and requirements giving the practical means for achieving the objectives, may be given together or in separate subclauses.

Protective/risk reduction measures should be laid down in precise and clearly understandable terms such that they:

a) ensure that the objective is met;

b) are technically correct and precise;

c) are unequivocal as to whether a measure is optional or mandatory, using verbal forms.

6.8 Information for the users

6.8.1 General

This clause is a mandatory element and should be numbered. The safety standard shall address the requirements of the 6.7.3.5 “Operating instructions”, and should contain, when relevant, additional information for the use of the pressure equipment in particular environments and specific working conditions.

The *Instructions for the users* clause is the only one in which the standards developers can provide instructions on installation and use of the pressure equipment in relation to the above mentioned particular hazards and related risks.

6.8.2 Signals and warning devices

Where safety signals or pictograms are fitted to the pressure equipment, they should be described in this clause.

6.8.3 Instruction handbook

The pressure equipment safety standard should contain a requirement for the manufacturer to provide an instruction handbook. The standard should make reference to the above 6.7.2 to 6.7.5 and should give specific information (e.g. intended use, reasonably foreseeable misuse, training, systems of work and personal protective equipment (when appropriate), preventive and corrective maintenance) to be included in the handbook. This Installation and Operating Manual is additional to and completes the Operating and Safety Instructions required under 6.7.3.5.

6.8.4 Marking

All safety standards should require at least the marking as specified in EN 13445-2, 4.4; EN 13445-4, 4.2.2, 4.2.4, 4.2.5, 9.8; EN 13445-5, 6.3, 11; EN 13445-6, 9.1; EN 13480-2, 4.4; EN 13480-4, 11, as appropriate.

6.9 Annexes

6.9.1 Normative annexes

When it is foreseeable that certain parts of the safety standard could be applicable to other documents (e.g. test methods), these parts should be included as normative annexes.

A normative annex should be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 20.

6.9.2 Informative annexes

6.9.2.1 General

Informative annexes should be in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 20.

6.9.2.2 Significant technical changes between this standard and the previous edition

This annex should be drafted only in cases where the significant technical changes from one edition to the next are not stated in the Foreword of the revised standard. See 6.2.

6.9.2.3 Annex Z [appropriate letter]

Each mandated standard should contain for each EU New Approach Directive an Annex Z [followed by a

letter to be precised] (informative) about the relationship between the standard clauses and the Essential Requirements of the relevant EU Directive. Without an Annex ZX, a standard, even developed as a request of the relevant EC mandate, has no chance to be cited in the OJEU.

NOTE This annex being always located as last annex of the standard, it will normally be called "ZA". However, if one or more European annexes exist after an adopted International standard, the letter A will be replaced by the letter following the previous European annex (e.g. if there is an Annex ZD, the annex about the relationship to an EU Directive becomes Annex ZE).

The latest EC template should be specified for the Annex ZA indicating which ESR of PED ANNEX I are covered by the standard. The ZA format could be found on CEN BOSS. See template below

If other directives essential requirements cover the pressure equipment in question, other ZX annexes shall be added following the same format as the ZA annex. They will be numbered ZB, ZC, etc.

A few rules / recommendations for the content of the ZA.1 table:

— It is not allowed to specify legal acts in this table

— Do not cite PED guidelines; if necessary, this may be done in the standard body

— Only normative clauses of the standard shall be cited in the ZA Annex

— Do not add "notes" in the ZA.1 table

— Try to be as accurate as possible when identifying the relevant ESR of the Annex I

— Avoid too heavy ZA.1 tables – try to group the clauses when acceptable.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of Directive 2014/68/EU aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/071 to provide one voluntary means of conforming to Essential Requirements of Directive 2014/68/EU.

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of Directive 2014/68/EU, and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 2014/68/EU

Requirements of Directive 2014/68/EU	Clause(s)/subclause(s) of this EN	Remarks/Notes

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

6.10 Bibliography

Standards or documents that give only information, or which have served as references in the preparation of the standard, should appear in a Bibliography in accordance with the CEN/CENELEC Internal Regulations, Part 3:2017, Clause 21 and not in the Normative references clause.

Documents that are not publicly available should not be referenced.

Annex A
(informative)

Template structure of pressure equipment product and materials standards

A.1 Template structure of pressure equipment product standard

Foreword (European foreword)

Introduction

1. Scope

2. Normative references

3. Terms and definitions

4. General principles – safety requirements and protection/risk reduction measures

5. Design

6. Manufacturing

7. Materials

8. Specific PE requirements (if relevant)

9. Instructions for the user

Annexes (normative and informative)

Annex ZA (for the HS candidates to citation in the OJEU)

Bibliography

A.2 Template structure of pressure equipment materials standard

1. Scope

2. Normative references

3. Terms and definitions

4. Classification, definitions

5. Informations for the purchaser

6. Manufacturing process

7. Delivery conditions, requirements (chemical composition, mechanical properties, corrosion resistance, weldability, etc.)

8. Inspection, testing

9. Marking

Annexes (normative and informative)

Annex ZA (for the HS candidates to citation in the OJEU)

Bibliography

Annex B
(informative)

Guidance on extension of transition period

B.1 General

When a European Standard (EN) is approved, implementation is compulsory for all CEN National Members from EEA countries.

European Standards will be implemented by the CEN National Members within a period expressed in months from the date of availability (dav) of the EN. This is normally three months for the date of announcement (doa), six months for the date of publication (dop) and six months for the date of withdrawal (dow).

The date of withdrawal (dow) is by definition the latest date by which any national standard conflicting with an EN should be withdrawn. It is a date common to all CEN National Members.

B.2 Exceptional extension of the date of withdrawal

To allow the industry (manufacturers) to make an ordered conversion to the new EN it should be considered by the responsible TC if an extension of the transition period *(dow later than dav + 6 months)*, is justified and should be therefore requested.

As a first step a transition period, if necessary, should be proposed by the standardization body (e.g. WG) in charge of elaborating the draft standard and be included in the document intended for CEN Enquiry using the following wording:

"A transition period of *X* months *(dav + 6 months + **X extra months**)* is proposed."

After the CEN Enquiry the responsible TC should decide on an extended transition period *(dow later than dav + 6 months up to maximum of dav +36 months)* in accordance with the CEN BOSS Guidance document "Date of withdrawal.

B.3 Consequences for European Standards to be cited in the Official Journal of the European Union

European Standards can be listed in the 'Official Journal of the European Union' (OJEU) under one or more New Approach directives. In practice, this means that a product manufactured according to a European Standard, the reference of which is cited in the Official Journal of the European Union under a New Approach directive, is presumed to comply with the essential requirements of that directive (this is called 'presumption of conformity').

When a European Standard that is cited in the OJEU is replaced by a new version (also to be cited in the OJEU under the same directive), the European Commission (EC) will generally use the dow of that new version as the 'Date of cessation of presumption of conformity of the superseded standard'. This date marks the end of the period during which both the old and the new version of the standard can be used to claim 'presumption of conformity' to the essential requirements of the relevant directive. After that date, 'presumption of conformity' can no longer be claimed for a product manufactured according to the old version of the standard.

It should be noted that extending the dow does not lead to an automatic extension of the 'Date of cessation of presumption of conformity of the superseded standard', for standards that have already been sent to the EC for citation in the OJEU. When it is deemed necessary to extend the 'Date of

cessation of presumption of conformity of the superseded standard' for such standards, CCMC should be contacted for guidance[2]

For the process for requesting and deciding on a dow later than dav + 6 months see CEN BOSS.

[2] This Annex is based on the guidance document "Date of withdrawal" from CEN BOSS. In case of modification of the guidance given by CEN BOSS the current version of that guidance takes precedence over this Annex.

Bibliography

[1] CEN BOSS. *Date of withdrawal*, Guidance document https://boss.cen.eu/reference%20material/Guidancedoc/Pages/Dow.aspx

[2] International Organization for Standardization (ISO) European Committee for Standardization (CEN), *Agreement on technical co-operation between ISO and CEN (Vienna Agreement)*

[3] International Organization for Standardization (ISO) European Committee for Standardization (CEN), *Agreement on technical co-operation between ISO and CEN (Vienna Agreement) — Guidelines for the implementation of the agreement on technical co-operation between ISO and CEN (Vienna Agreement)*

[4] United Nations, Economic and Social Council, Economic Commission for Europe (UN/ECE), UNECE Recommendation "L", *An international model for technical harmonisation based on good regulatory practice for the preparation, adoption and application of technical regulations via the use of international standards*

[5] PED Guidelines: E-05, E-07, E-08, E-09, F-02, F-03, F-05, F-08, G-04, G-05, G-06, G-07, G-16, G-17, G-22, G-27, G-27, G-28, H-04, H-06, H-20 available on: https://ec.europa.eu/docsroom/documents/33402