

Guidelines related to the Pressure Equipment Directive 97/23/EC (PED)

In order to ensure a coherent application of the Pressure Equipment Directive 97/23/EC (PED), Guidelines are developed and agreed by the Commission's Working Group "Pressure" (WGP). This working group, created as a result of Article 17 of the PED, which requests the Member States to cooperate in order to assist the functioning of this Directive, is composed of representatives of Member States, European federations, the Notified Bodies Forum and CEN and chaired by a representative of the Commission services.

Remarks or questions concerning this document should be addressed via the email to the unit in the European Commission dealing with the Pressure Equipment Directive:

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Status of the guidelines

The PED Guidelines are not a legally binding interpretation of the Directive. The legally binding text remains that of the Directive. However, the PED Guidelines represent a reference for ensuring consistent application of the Directive. They represent, unless indicated differently in the respective guideline text, the unanimous opinion of the Member States.

Classification of the guidelines

The guidelines carry a x/y type numbering. The first number (x) relates to the subject, the second (y) is a sequential numbering. The numbers x relate to the following subjects:

1. **SCOPE AND EXCLUSIONS OF THE DIRECTIVE**
2. **CLASSIFICATION AND CATEGORIES**
3. **ASSEMBLIES**
4. **EVALUATION ASSESSMENT PROCEDURES**
5. **INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON DESIGN**
6. **INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MANUFACTURING**
7. **INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MATERIALS**
8. **INTERPRETATION OF OTHER ESSENTIAL SAFETY REQUIREMENTS**
9. **MISCELLANEOUS**
10. **GENERAL-HORIZONTAL QUESTIONS**

Document history		
Version	Date	Comment
1.0	1/12/2010	Includes PED Guidelines up to WGP meeting of 24/11/2010
1.1	19/7/2011	Quality check, correction of links, introduction
1.2	30/8/2011	Quality check
1.3	20/03/2012	Includes PED Guidelines up to WGP meeting of 06/03/2012
1.4	26/03/2013	Includes PED Guidelines up to WGP meeting of 07/03/2013
1.5	4/4/2014	Includes PED Guidelines up to WGP meeting of 22/03/2014
1.6	31/3/2015	Includes PED Guidelines up to WGP meeting of 11/03/2015

1. SCOPE AND EXCLUSIONS OF THE DIRECTIVE

1	SCOPE AND EXCLUSIONS OF THE DIRECTIVE
2	CLASSIFICATION AND CATEGORIES
3	ASSEMBLIES
4	EVALUATION ASSESSMENT PROCEDURES
5	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON DESIGN
6	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MANUFACTURING
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8	INTERPRETATION OF OTHER ESSENTIAL SAFETY REQUIREMENTS
9	MISCELLANEOUS
10	GENERAL-HORIZONTAL QUESTIONS

1.1. Guideline 1/1

Guideline related to: Article 3 paragraph 1.1; Article 1 paragraph 3.19; Annex II, Table 2

Question: Are portable extinguishers within the scope of the Pressure Equipment Directive or are they covered by the exclusion in Article 1.3.19 for equipment covered by the ADR?

Answer: They are covered by the Pressure Equipment Directive.

Reason: Portable extinguishers are specifically mentioned in Article 3 paragraph 1.1.a) second indent and Annex II, Table 2 of the Pressure Equipment Directive.

Furthermore, fire extinguishers are specifically mentioned in special provision 594 of ADR as an exclusion when appropriately packed for transport.

Thus, these extinguishers are not covered by the exclusion in Article 1 paragraph 3.19 of the PED.

Accepted by WPG on:	2010-09-21
Accepted by Working Group "pressure" on:	2010-11-24

1.2. Guideline 1/2

Guideline related to: Article 1 paragraph 2.1

Question: Are tanks intended for the transport of non-dangerous goods (as defined by ADR), which are not pressurised during carriage but are pressurised during other foreseeable operations, e.g. filling, emptying or cleaning, within the scope of PED?

Answer: Yes. If the PS of the tank is more than 0,5 bar.

Reason: Such tanks are not excluded by Article 1 paragraph 3.19.

Note: Refer also to guidelines [1/14](#), [1/34](#) and [8/7](#).

Accepted by WPG on:	2009-10-01
Accepted by Working Group "pressure" on:	2009-10-26

1.3. Guideline 1/3

Guideline related to: Article 1, Annex I section 3.4

Question: Are replacements, repairs or modifications of pressure equipment in use covered by the Pressure Equipment Directive (PED) ?

Answer: 1) Entire change: the complete replacement of an item of pressure equipment by a new one is covered by the PED.

2) Repairs are not covered by the PED but are covered by national regulations (if any).

3) Pressure equipment which has been subject to *important* modifications that *change* its original characteristics, purpose and/or type after it has been put into service has to be considered as a new product covered by the directive. *This has to be assessed on a case by case basis.*

Note 1: Operating instructions in the sense of the PED (see guideline 8/3) cover documentation concerning safe operation including maintenance, but not necessarily detailed information concerning repair or modification of the equipment (e.g. material certificates or qualification of welding procedures). Such information may be provided by a specific contractual agreement between manufacturer and user.

Note 2: The directive applies only to the first placing on the market and putting into service.

See "blue guide" chapter 2.1

Accepted by WPG on:	2004-02-24
Accepted by Working Group "pressure" on:	2004-03-17

1.4. Guideline 1/4

Guideline related to: Article 1 paragraph 2.1.2

Question: When is a modification of a piping system not covered by the PED?

Answer: When the content, main purpose and safety systems remain essentially the same, it may be regarded as a non important modification of an existing piping system and is therefore not covered by the PED.

Reason: See Guideline 1/3

Accepted by WPG on:	1998-10-13
Accepted by Working Group "pressure" on:	1999-01-29

1.5. Guideline 1/5

Guideline related to: Article 3; Annex II

Question: Which conformity assessment category applies to vessel with a volume less than or equal to 0.1 litre?

Answer:

Vessels referred to in Article 3 (volume less than or equal to 0,1 litre)	Table in Annex II	Category (Volume less than or equal to 0,1 litre)
1.1(a) first indent	1	If PS \leq 200 bar, then Article 3.3 applies otherwise see point 3 below
1.1(a) second indent	2	If PS \leq 1000 bar, then Article 3.3 applies otherwise see point 3 below
1.1(b) first indent	3	If PS \leq 500 bar, then Article 3.3 applies otherwise see point 3 below
1.1(b) second indent	4	If PS \leq 1000 bar, then Article 3.3 applies otherwise see point 3 below

Reason: 1. The conformity assessment categories for vessels with a volume less than or equal to 0,1 litre cannot be determined from Tables 1, 2, 3 and 4 because the Tables are not specified for volumes less than 0,1 litre. However, Article 3 paragraph 1 together with Article 3 paragraph 3 can be used to determine which vessels must satisfy the essential safety requirements and those that must be designed and manufactured according to the Sound Engineering Practice (SEP) of a Member State.

2. If a vessel has a volume less than or equal to 0,1 litre, and a value of PS above the limits defined in Article 3 paragraph 1, then the vessels must satisfy the essential safety requirements of Annex I.

3. In the absence of specific information in the Tables of Annex II for the conformity assessment of vessels described in point 2 above, the manufacturer may choose any module, or single combination of modules, set out in section 1 of Annex II.

Accepted by WPG on: 1999-04-21, editorially corrected on 2002-06-18

Accepted by Working Group "pressure" on: 1999-11-08, confirmed by WGP on 2002-10-03

1.6. Guideline 1/6

Guideline related to: Article 1 paragraph 2.1.3; Annex I point 2.10

Question: How will pressure gauges be classified?

Answer: A pressure gauge may possibly be regarded as a protective device within the meaning of Annex I, point 2.10 b.

The Directive does take account of these items of equipment but they are not safety accessories within the meaning of Article 1, paragraph 2.1.3.

They are pressure accessories within the meaning of Article 1, paragraph 2.1.4, which may be covered by CE marking for high pressure (cf WPG 1/5 on Article 3 on low volume-high pressure equipment).

Accepted by WPG on:	1998-10-13
Accepted by Working Group "pressure" on:	1999-01-28

1.7. Guideline 1/7

Guideline 1/7 has been withdrawn.

1.8. Guideline 1/8

Guideline related to: Article 1 paragraph 2.1.4

Question: What is a pressure accessory?

Answer: According to the definition (see Article 1 Paragraph 2.1.4) pressure accessory means a device with an operational function and having an identifiable pressure-bearing housing - i.e. the device has a function additional to that of containing pressure.

The pressure accessory can be attached to other pressure equipment for example by bolting, brazing, soldering or welding. A pressure accessory has a specific operational function (or functions), which could be for example: measurement, change the mechanical characteristics of the fluid flow, taking a sample, removal of sediment or gas. A pressure accessory does not necessarily have moving parts.

Typical examples of pressure accessories are: valves, pressure regulators, measurement chambers, pressure gauges, water gauge glasses, filters, expansion joints and manifolds.

The following examples are not pressure accessories:

- safety valve (a safety accessory)
- cover, collar, gasket, flange, bolt (components of a pressure equipment)
- sight glass with its frames (components of a pressure equipment)
- Y-shape or similar fittings (piping components)

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1.9. Guideline 1/9

Guideline related to: Article 1 paragraph 2.1.2

Question: Are piping components, such as a pipe or system of pipes, tubing, fittings, expansion joints, hoses, or other pressure bearing components, considered to be piping when they are placed on the market as individual components?

Answer: Individual piping components, such as a pipe or system of pipes, tubing, fittings, expansion bellows, hoses, or other pressure bearing components are not “piping”.

However, a single pipe, or a system of pipes, for specific application, may be classed as “piping”, provided all appropriate manufacturing operations such as bending, forming, flanging and heat treatment, have been completed. Some piping components (e.g. expansion joints) may be considered to be pressure accessories (see Guideline 1/8).

Remark: Please note the definitions related to expansion joints and to expansion bellows.

Expansion joints are devices containing one or more bellows used to absorb dimensional changes such as those caused by thermal expansion or contraction of a pipeline, duct or vessel.

Expansion bellows are flexible elements of an expansion joint consisting of one or more convolutions and the end tangents.

Accepted by WPG on:	1998-11-27
Accepted by Working Group “pressure” on:	1999-01-28

1.10. Guideline 1/10

Guideline related to: Articles 1 paragraph 3.19, Article 3 paragraph 1.1 second indent

Question: Are the bottles for breathing equipment covered by the Pressure Equipment Directive?

Answer: Bottles/gas cylinders for breathing apparatus are covered by the Pressure Equipment Directive, for example:

- bottles/gas cylinders for compressed air, oxygen or other breathable mixtures, such as portable cylinders for divers, fire fighters and asbestos workers

The following bottles for breathing equipment are not in the scope of the Pressure Equipment Directive:

- gas cylinders to be installed in oxygen/air centres of hospitals
- cryogenic receptacles

According to the circumstances of the transport, the requirements of ADR/RID/IMDG/ICAO may also be applicable.

If the manufacturer intends bottles to be used both for breathing equipment and also for transport of dangerous goods, they shall meet the requirements of both directives and bear both the CE-mark and the π -mark (see guideline 1/30).

Reason: The specific reference to bottles for breathing apparatus in Article 3 limits the general exclusion in Article 1, section 3.19.

Furthermore the Transportable Pressure Equipment Directive (TPED) specifically excludes gas cylinders for breathing appliances (Recital 9 and Article 2, section 1).

Note: A breathing apparatus is a personal protective equipment and therefore designed to be worn or held by an individual.

Accepted by WPG on:	2002-12-04
Accepted by Working Group "pressure" on:	2003-01-27

1.11. Guideline 1/11

Guideline related to: Article 1 paragraph 3.10

Question: How can article 1.3.10 more specifically be understood, especially the wording “for which pressure is not a significant design factor”?

Answer: 1. Article 1.3.10 excludes pressurized equipment comprising casings or machinery from the scope of the PED

a) if this equipment is primarily dimensioned for loads other than pressure, i.e. for which pressure is not the significant design factor

and

b) if it is primarily designed to move or rotate or fulfil other functions than pressure containment.

2. Such equipment may include

- engines including turbines and internal combustion engines;

- steam engines, gas/steam turbines, turbo-generators, compressors, pumps, actuating devices and curing moulds for tyres.

3. For such equipment, pressure can be considered as not being a significant factor, if other factors alone or together are more significant than pressure. Other factors are, e.g.:

- dynamic loads with vibrations or very high number of cycles;

- thermal loads together with a complicated form of structure;

- stiffness of the structure because of external mechanical loads or requirements related to high weight;

- requirements related to low elongation, low change of diameter or low other deformation because of functional requirements to rigidity.

This shall be decided on a case by case basis, taking into account established safe industrial practice.

4. An over-dimensioning as such shall not result in exclusion from the PED with regard to article 1.3.10.

Accepted by WPG on:	1999-06-10
Accepted by Working Group “pressure” on: 1999-11-08, editorially amended on 2003-05-15 and confirmed on 2003-11-03	

EXPLANATORY NOTES

(1) No factor is included in the requirements of the PED. Any factor given in a guideline would therefore go beyond the PED and should be avoided.

- (2) If a factor were used to decide whether the requirements of the PED are applicable or not, overdimensioning could result in a case where pressure equipment need not fulfil the requirements of the PED. This is not acceptable.
- (3) To decide on the exception with a factor of overdimensioning would consequently result in the necessity of a detailed stress analysis, especially if this factor would have been connected to the primary membrane stress. This is far beyond the present established industrial practice.
- (4) Furthermore, there is a danger that the more important influences explained in paragraphs 1 to 3 could be overlooked if the decision whether the pressure is a significant design factor were based on a factor of overdimensioning only.

1.12. Guideline 1/12

Guideline related to: Article 1 paragraphs 3.6 and 3.10

Question: Are hermetically sealed and semi-hermetic compressors in the scope of the directive?

Answer: 1) Equipment classified as no higher than category I as defined by PED and falling in the scope of one of the directives as listed in article 1, paragraph 3.6, e.g. for low voltage or machinery, is excluded from the scope of PED. This applies to hermetic and semi-hermetic compressors no higher than category I.

2) The exclusion in article 1, paragraph 3.10 is not applicable to hermetic compressors because pressure is a significant design factor since their external envelope has as its principal function to ensure that the refrigerant is confined.

3) For semi-hermetic compressors which include moving parts and for which the external envelope is primarily designed for mechanical loads (speed and vibration), thermal load (to limit the possible deformation due to temperature), stiffness of the structure (external mechanical loads and weight of the equipment), an exclusion based on article 1 paragraph 3.10 is to be assessed on a case by case basis (see guideline [1/11](#)).

Note: In application of the definition of “volume” given in article 1, paragraph 2.5, the volume of the mechanical parts is to be excluded from the volume to be taken into account but not the volume of the oil contained.

Accepted by WPG on:	2004-04-15
Accepted by Working Group “pressure” on:	2004-09-07

1.13. Guideline 1/13

Guideline related to: Article 1

Question: Is the pressure equipment directive applicable to vacuum insulation of pressure vessels?

Answer: Yes.

Reason: Vacuum casings which do not have a maximum allowable pressure greater than 0.5 bar are therefore not pressure equipment in their own right. However as structural elements attached to pressurized parts, they are part of pressure equipment and any negative effects of the vacuum casing and insulation on the pressurized parts must be taken into account and avoided.

Accepted by WPG on:	1999-01-27
Accepted by Working Group "pressure":	1999-01-28

1.14. Guideline 1/14

Guideline related to: Article 1 paragraph 2.1

Question: If transport tanks for use in any mode of transport have been designed, manufactured and approved for the carriage of dangerous goods under the ADR, RID, IMDG code or the ICAO convention, will it also be necessary for them to comply with the PED when they are placed on the market?

Answer: No. Article 1.3.19 of the PED excludes transport tanks covered by ADR, RID, IMDG code or the ICAO convention.

If a manufacturer declares that transport tanks designed, manufactured and approved for the carriage of dangerous goods under the ADR, RID, IMDG code or the ICAO convention, are intended to be used for both dangerous and non-dangerous goods then the exclusion in Article 1.3.19 may still apply (see guideline [1/30](#)).

On the other hand, if a transport tank is not designed, manufactured and approved under the ADR, RID, IMDG code or the ICAO convention, then it will be limited to the transport of non-dangerous liquids and solids. These transport tanks will not be excluded from the PED and will be covered if they are in the scope.

All transport tanks covered by the agreements and conventions in Article 1.3.19 must be designed and built to a maximum allowable working pressure, satisfy the requirements for initial pressure testing and undergo periodical examination throughout their service life.

These requirements deal with safe containment and hazards due to pressure, but primarily only for the safety of transport. With regard to the use of a transport tank, for example as a storage tank, or being emptied outside the scope of the transport codes, consideration should be given to applicable national legislation. For example, the question of safety valves in the tank itself or in the emptying station should then be considered. This paragraph does not apply to tanks bearing both CE-mark and π -mark (see guideline [1/30](#)).

Note: Refer also to guideline [1/2](#)

Accepted by WPG on:	2002-12-04
Accepted by Working Group "pressure" on:	2003-01-27

1.15. Guideline 1/15

Guideline related to: Article 1 paragraph 2.1.4

Question: Is the operational function of a pressure accessory, as described in article 1 section 2.1.4 covered by the directive?

Answer: Yes, if a pressure related hazard is identified in relation with the operational function of the pressure accessory (see also guideline 1/8).

Examples for valves:

- Where a valve is intended to be used as the sole mean of isolation of the content of an item of pressure equipment from the atmosphere, or from downstream equipment which is not designed to withstand the upstream pressure, the internal parts of the valve which contribute to the isolation must satisfy the relevant essential safety requirements in Annex 1;
- Where a valve is intended to be fitted between a pressure vessel and pressure piping and both are designed to contain pressure, no pressure related hazard exist in relation to the operational function of the valve, therefore internal parts of the valve do not have to satisfy the relevant essential safety requirements in Annex 1.

The intended use of the valve shall be described in the operating instructions, and where it is to be used as a sole mean of isolation, it shall meet the essential safety requirements of the directive.

Accepted by WPG on:	1999-07-15
Accepted by Working Group “pressure” on:	1999-11-08

1.16. Guideline 1/16

Guideline related to: Article 1 paragraph 3.2

Question: Article 1, paragraph 3.2 excludes from the directive “networks for the supply, distribution and discharge of water and associated equipment”. Clarification is required in respect of water, networks and associated equipment in this context?

Answer: ‘Water’ means: potable water, waste water and effluent, and sewage.

‘Networks and associated equipment’ means: complete systems for the supply distribution and discharge of water. They extend up to the point of use in buildings, industrial sites and plants, and include equipment closely related to these networks such as water meter and line valves. Pressure vessels, such as expansion vessels, however are not considered to be part of such ‘networks and associated equipment’ and are therefore not excluded.

NOTE For district heating water, refer to guideline **1/18**

Reason It was clearly the intention of the Council. It should be noted that some linguistic versions are unclear on this point.

Accepted by WPG on:	2000-05-03
Accepted by Working Group “pressure” on:	2000-06-29

1.17. Guideline 1/17

Guideline related to: Article 1 paragraph 3.1

Question: What is the meaning of the expression "standard pressure equipment" in article 1 § 3.1 on pipelines

Answer : A standard pressure equipment is not specially designed and manufactured for a specific conveyance pipeline, but is intended for use in a number of applications, including other conveyance pipelines or, for example, industrial piping.

Typical examples of standard pressure equipment annexed with pipelines, pressure reduction stations or compression stations may include: measuring devices, valves, pressure regulators, safety valves, filters, heat exchangers, vessels.

Such equipment is covered by the directive.

Accepted by WPG on:	1999-09-03
Accepted by Working Group "pressure" on:	1999-11-08

1.18. Guideline 1/18

Guideline related to: Article 1 paragraph 3.1

Question: Are pipelines for conveyance of district heating water covered by the directive?

Answer: No. According to article 1 point 3.1 "...a system of piping designed for the conveyance of any fluid ...to or from an installation (onshore or offshore)" is excluded from the directive. This covers pipelines for district heating, whereas standard pressure equipment in e.g. boiler houses and pumping stations are included (refer to guideline [1/17](#)).

Reason: It has from the beginning been the intention that these pipelines should be excluded from the directive. This is obvious from the original Commission proposal from 1993-07-14, where, in the definitions (article 1 point 2.1.2), it is stated that "Piping" does not include pipelines and their accessories specifically designed for the conveyance of district heating fluids. This was later moved to the generalised exclusion in article 1 point 3.1.

Accepted by WPG on:	1999-10-25
Accepted by Working Group "pressure" on: confirmed on 2000-06-29	2000-03-23,

1.19. Guideline 1/19

Guideline related to: Articles 1 paragraph 3.6, Article 1 paragraph 3.10

Question: Are fluid power components and systems using liquids or gases of group 2 covered by PED ?

Answer : For fluid power components and systems using liquids or gases of group 2 according to Article 9.2.2, the following applies :

(1) Excluded from PED

(1.1) due to exclusion 3.6 of Article 1 (e.g. machinery directive)

- piping and connecting devices for liquids of group 2 when $DN \leq 200$ whatever the pressure is, and when $DN > 200$ and $PS \leq 500$ bar

- piping and connecting devices for gases of group 2 when $DN \leq 100$ or $PS \leq 3500$ bar

- pressure accessories (e.g. filter housing) no higher than category I

- fluid power actuators, pumps and control valves no higher than category I.

(1.2) due to exclusion 3.10 of Article 1 (refer to guideline **1/11**)

- fluid power actuators (e.g. motors, cylinders, ...)

- fluid power pumps

- fluid power control valves (distributors).

(2) Included in the PED

- all accumulators (bladder, piston and diaphragm types)

- pressure equipment not excluded by (1) above.

Accepted by WPG on:	1999-10-25
Accepted by Working Group "pressure" on:	2000-03-24

1.20. Guideline 1/20

Guideline related to: Article 1 paragraph 2.1.3; Annex I sections 2.10 and 2.11

Question: When is a measuring or control system considered as a safety accessory under the PED?

Answer: A measuring system alone cannot be considered as a safety accessory, as a safety accessory as defined in PED necessarily requires :

- a measuring or detection function and
- an activation function for correction, or shutdown, or shutdown and lockout.

In order for a control system to be classified as a safety accessory, it shall be designed and placed on the market as an ultimate means of protecting pressure equipment from exceeding allowable limits, and therefore it shall meet the corresponding essential requirements of Annex I, section 2.11.

Note: It is foreseeable that some measuring or control devices could be inadvertently used as safety accessories. Where this is possible manufacturers should include an appropriate warning in their instructions for use.

See also Guidelines: [1/25](#) and [2/16](#)

Accepted by WPG on:	2002-06-19
Accepted by Working Group "pressure" on:	2002-10-03

1.21. Guideline 1/21

Under development

1.22. Guideline 1/22

Guideline related to: Article 1 paragraph 2.1

Question: What guidance can be given regarding the application of the Directive to component parts of pressure equipment such as flanges, dished ends and nozzles?

Answer: If these component parts are incorporated to an item of pressure equipment, the relevant requirements of the directive will apply.

However, these component parts do not meet the definition of pressure equipment in Article 1.2.1, therefore they shall not bear the CE mark.

It is the responsibility of the pressure equipment manufacturer to ensure that the component parts enable the pressure equipment to meet the essential safety requirements of the directive.

(See also guideline 1/8)

Note: Another example of a component part is a split tee.

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Accepted by Working Group “pressure” on:	2000-06-29

1.23. Guideline 1/23

Guideline related to: Article 3 paragraph 1.1a

Question: Is the operational function of portable extinguishers covered by PED?

Answer: No, only the aspects of pressure-related hazards are covered.

(see also guideline 1/1)

Accepted by WPG on:	1999-12-14
Accepted by Working Group "pressure" on:	2000-03-24

1.24. Guideline 1/24

Guideline related to: Article 1 paragraph 2.7

Question: According to the definition of Article 1 paragraph 2.7 fluids may contain a suspension of solids. Is a system of solid pieces or liquid drops distributed in a gas still a fluid in the sense of the PED?

Answer: Yes

Note Despite the use of the term suspension in Article 1 paragraph 2.7, which in some languages only refers to a liquid containing solids, it is obvious from the context of this definition that a gas containing pieces of solids or drops of liquid is also to be considered a fluid.

Accepted by WPG on:	2002-06-19
Accepted by Working Group "pressure" on:	2002-10-03

1.25. Guideline 1/25

Guideline related to: Articles 1 paragraph 2.1.3 and Article 1 paragraph 2.1.4

Question: Are the sensors which are used as part of a safety system to protect pressure equipment covered by the PED ?

Answer : A sensor alone does not meet the definition of a pressure accessory, as per Article 1.2.1.4 (see guideline 1/8), nor the definition of a safety accessory, as per Article 1.2.1.3. Consequently, no CE marking (due to the PED) is to be put on the individual sensor.

The conformity assessment procedure and essential safety requirements of the directive relate to the complete safety system. The requirements to the sensor may be different depending upon the safety concept employed (for example redundancy or fail safe, see Annex I point 2.11.1).

NOTE For the purpose of this guideline, sensor means “element of a measuring instrument or measuring chain that is directly affected by the measurand” as defined in the International Vocabulary of Basic and General Terms in Metrology, prepared by BIPM, OIML, ISO, IEC.

Accepted by WPG on:	2000-05-05
Accepted by Working Group “pressure” on:	2000-06-29

1.26. Guideline 1/26

Guideline related to: Article 1 paragraph 3.6 first indent

Question: Which rules apply for pressure equipment which also meets the definition of machinery in the machinery directive or which is intended to be installed in machinery?

Answer: The Pressure Equipment Directive (PED) applies to pressure equipment in the sense of Article 1 paragraph 2 of the PED in general, but also the exclusions of Article 1, paragraph 3 have to be considered.

Article 1, paragraph 3.6 first indent states that:

"equipment classified as no higher than category I under Article 9 of this Directive and covered by one of the following Directives: [among others the machinery directive] are excluded from the scope of this Directive".

That means, when a product which is placed on the market is covered by the machinery directive, the exclusion of Article 1 paragraph 3.6 first indent applies to any item of pressure equipment not higher than category I which is a part of that machine (i.e. the pressure equipment directive does not apply).

The exclusion also applies to items of pressure equipment not higher than category I separately placed on the market, if their intended use is to be part of machinery which must be laid down in the operating instructions.

In those cases, the essential safety requirements of PED are an appropriate way to obtain the required safety level regarding the pressure hazard.

Pressure equipment of higher categories than category I is within the scope of the PED even when it is machinery in the sense of the machinery directive or intended to become part of machinery. See therefore article 3 of the machinery directive 2006/42/EC:

"Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives."

The PED is such a *"Community Directive"* in the sense of Article 3 of the machinery directive 2006/42/EC.

Note: (1) This does not prohibit the inclusion of CE-marked items of pressure equipment in machinery.

(2) See also guideline [1/11](#) for exclusion 3.10 of Article 1

REASON FOR THE REVISION OF THE GUIDELINE:

The new machinery Directive 2006/42/EC no longer excludes boilers and pressure vessels from its scope

Accepted by WPG on:	2010-09-21
Accepted by Working Group "pressure" on:	2010-11-24

1.27. Guideline 1/27

Guideline related to: Article 1 paragraph 3.14

Question: What is meant by the term mobile offshore unit?

Answer: A mobile offshore unit is an offshore unit that is not intended to be placed permanently or long term on the field, but is designed to be moved from location to location whether or not it has a means of propulsion or of lowering legs to the seafloor (e.g. a unit used solely for exploration).

For example, floating units intended for production, such as FPSO's (Floating Production, Storage and Offloading installations usually based on tanker designs) and FPP's (Floating Production Platforms based on semi-submersible vessels), are not considered to be mobile.

Note Items of pressure equipment specifically intended for mobile offshore units are excluded from the PED. However, items of pressure equipment intended to be installed on both FPSO's/FPP's and mobile offshore units are not excluded from the PED.

Accepted by WPG on:	2002-03-13
Accepted by Working Group "pressure" on:	2002-05-23

1.28. Guideline 1/28

Guideline related to: Article 1 paragraph 3.1

Question: Are conveyance pipeline stations such as compressor, reduction, metering stations covered by PED?

Answer: These stations contain pressurised systems which may include compressors, heat exchangers, valves, filters, piping, etc. When they are specifically designed for pipelines, they are considered as annexed equipment, and as such are excluded from PED, according to Article1, paragraph 3.1.

However, this exclusion does not apply to standard pressure equipment which may be found in these stations, see guideline 1/17.

Accepted by WPG on: 2001-02-21 (editorially amended by WPG of 2012-04-25 + WGP 2013-03-07)
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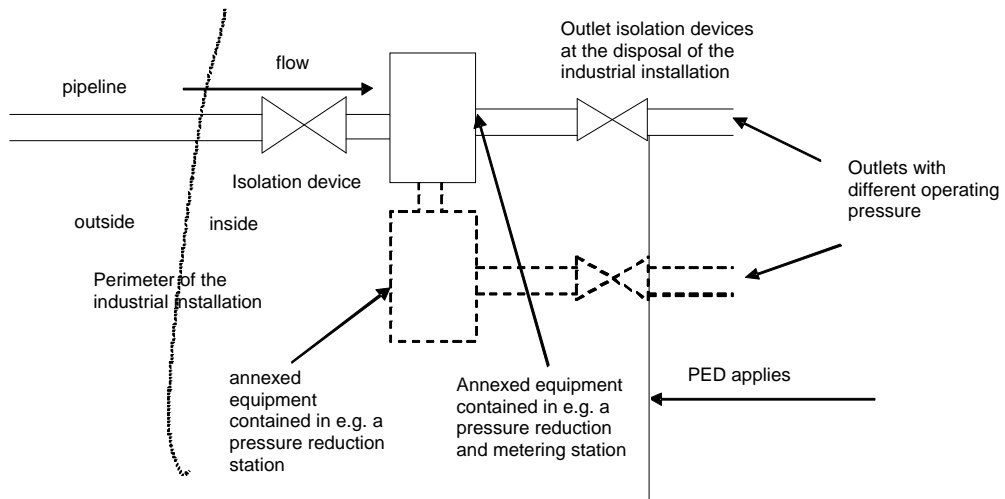
Accepted by Working Group "pressure" on: 2001.04.03

1.29. Guideline 1/29

Guideline related to: Article 1, paragraph 3.1

Question: Where does the exclusion under Article 1, paragraph 3.1 end when a pipeline crosses the perimeter of an industrial installation ?

Answer: The exclusion of Article 1 paragraph 3.1 ends at the outlet isolation device of the annexed equipment contained in stations supplying the fluid to the industrial installation.



See also Guidelines [1/28](#) and [1/17](#).

Note: The installation beyond the outlet isolation devices detailed in the above diagram, is covered by the PED; this includes any pressure equipment, any piping between individual operating units or plants, or storage facilities.

Accepted by WPG on: 2013-01-17

Accepted by WGP on: 2013-03-07

1.30. Guideline 1/30

Guideline related to: Article 1 paragraph 3.19

Question: Is it permissible to affix both the CE marking for the PED and the π mark for the TPED on an item of pressure equipment?

Answer: Yes.

This double marking proves that the item of pressure equipment complies with both directives, and can be used in both contexts without further assessment.

A similar item bearing only the π mark could also be used for pressure purposes outside the scope of ADR/RID but consideration would need to be given to possible national regulations, or to PED if included in a PED assembly.

Hence, if a manufacturer intends a product to be used in both contexts and designs and manufactures it accordingly so that it complies with both applicable Directives, it shall bear both markings, to the extent foreseen by each Directive (e.g. no CE marking for SEP equipment (Article 3 paragraph 3), and no π -marking for certain accessories).

If the manufacturer of the product only foresees it to be used in the scope of one of the Directives, only one Directive applies and one marking (as far as applicable) shall be affixed (see also guideline 1/33).

See also guidelines 1/14 and 1/33.

Reason: While in principle, Article 1.3.19 of the PED excludes equipment covered by ADR/RID, it is not always possible for the manufacturer to know whether or not a particular item of equipment he manufactures will during its use come into the scope of these International Transport Agreements. This is in particular true for accessories, which may well be used for both purposes with no technical alterations. In such a case, it would only be possible after the user has taken the product into service, to know, which of the two Directives does not apply to the product. Until then, both Directives shall be considered to be applicable. Such double marking would not violate the provisions of Article 16 of the PED, as, up to the moment the product was placed on the market, it was not excluded from the scope of the PED. When at a later point in time the product is de facto used in the context of a transportation of dangerous goods, the fact that it bears the CE marking is insignificant.

Accepted by WPG on:	2002-11-06
Accepted by Working Group "pressure" on:	2003-01-27

1.31. Guideline 1/31

Guideline related to: Articles 1, paragraph 3.1, 1, paragraph 3.10

Question: Are NGV (Natural Gas Vehicles) filling stations covered by the PED?

Answer: NGV filling stations are covered by PED. They are not excluded by Article. 1 § 3.1as annexed equipment designed specifically for pipelines.

However, compressors are considered machinery as specified under Article. 1 § 3.10 and thus may be excluded from PED (see guideline [1/11](#)).

Accepted by WPG on:	2000-11-28
Accepted by Working Group "pressure" on:	2001-04-03

1.32. Guideline 1/32

Guideline related to: Article 1 paragraphs 3.1 and 3.20

Question: Are substations for district heating pipelines to be considered as “assemblies” in the Pressure Equipment Directive (PED) ?

Answer: Yes.

These substations are located after the last isolation device, normally within the confines of the building or industrial installation, and thus are not covered by exclusion 3.1 of Article 1.

Note: See also guideline 3/2 when the items of the substation are joined under the responsibility of the user.

See also guideline 3/8 for the definition of an assembly.

Accepted by WPG on:	2002-11-05
Accepted by Working Group “ pressure ” on:	2003-01-27

1.33. Guideline 1/33

Guideline related to: Article 1 paragraph 3.19

Question: Can receptacles (in the meaning of Article 2 of Transportable Pressure Equipment Directive) that are « pi » marked be used as static pressure equipment without being CE marked?

Answer: Yes, provided the « pi » marked receptacle has been placed on the market and used as transportable pressure equipment, it can then be used permanently as static pressure equipment without being CE marked.

Note 1: For static use the receptacle may be subject to national regulation dealing with conditions of use, installation and periodic inspection. (see also Article 3 of TPED 2010/35/EU- On-site requirements)

Note 2: The term “static pressure equipment” has to be understood as “pressure equipment under the scope of Pressure Equipment Directive”, even though these receptacles fall under exclusion 3.19 of Article 1 of PED.

Note 2: See guideline [1/30](#) for receptacles with double CE-mark and π -mark.

Accepted by WPG on:	2002-12-04, editorially revised 2014-07-01
Accepted by Working Group "pressure" on:	2003-01-27

1.34. Guideline 1/34

Guideline related to: Article 1 paragraph 3.19; Article 3 paragraph 1.1 and Annex II

Question: Is a slurry tanker that is emptied by compressed air within the scope of the Pressure Equipment Directive?

Answer: Yes, if the PS of the compressed air is greater than 0,5 bar. The PS of compressed air and internal volume of the tank determine the category according to the table 2 of Annex II.

Reason : Slurry tankers are not excluded from the scope of the PED due to Article 1 section 3.19. They are not tanks intended for carriage of dangerous goods.

NOTE “Slurry tanker” is used in farms to fertilize the fields with liquid manure. It is a tank on wheels usually pulled by a tractor in the fields and from one field to another. Compressed air facilitates the emptying of the tank.

See also guideline [1/2](#).

Accepted by WPG on:	2001-02-21
Accepted by Working Group “pressure” on:	2001-04-04

1.35. Guideline 1/35

Guideline related to: Article 1 paragraph 3.19 and Article 3 paragraph 1.1(a)

Question: Are propellant gas cartridges *) for portable extinguishers in the scope of the Pressure Equipment Directive?

Answer: No, those cartridges are covered by ADR and consequently excluded from PED due to Article 1, paragraph 3.19.

Note: See guidelines [1/1](#) and [2/14](#).

*) the term used in the context of the ADR is different: non refillable and refillable propellant gas cartridges are called cylinders in the ADR. Gas cartridges defined by ADR are limited to a pressure of 13,2 bar which is exceeded by the receptacles concerned by this guideline.

Accepted by WPG on:	2002.01.15
Accepted by Working Group "pressure" on: 2002.02.27, editorially reviewed on 2002.03.14	

1.36. Guideline 1/36

Guideline related to: Article 1 paragraph 3.19, Article 3 paragraph 1.1 second indent, Annex II, table 2

Question: Are gas cylinders, which are placed on the market to be used for fixed fire extinguishing installations, covered by the Pressure Equipment Directive (PED) or by the Transportable Pressure Equipment Directive (TPED)?

Answer: If they are transported in a pressurized condition (e.g. to or from the filling station) they are covered by the ADR convention. Such gas cylinders are therefore excluded from the PED by virtue of Article 1 paragraph 3.19. Such cylinders are covered by the TPED.

Note 1: They do not fall under the case of Article 3 paragraph 1.1 second indent, which only refers to portable extinguishers.

Note 2: If they are not transported in pressurised condition but filled/refilled at the installation site they are covered by the PED.

Accepted by WPG on:	2012-01-12
Accepted by Working Group "pressure" on:	2012-03-06

1.37. Guideline 1/37

Guideline related to: Article 1 paragraph 3.9

Question: Are items of pressure equipment such as manifolds, valves and piping used as well-control equipment and placed between a subsea well template and the processing platform for the oil and gas extraction and processing industry covered by the Pressure Equipment Directive (PED) ?

Answer: No

Reason: The exclusion of Article 1 paragraph 3.9 applies to all the well-control equipment listed therein, plus all equipment UPSTREAM in relation to that well-control equipment.

Note 1: In some cases, processing equipment is interposed on the seabed (e.g. separators) between the equipment listed in Article 1 paragraph 3.9 and the pipeline(s). In such cases, the processing equipment is covered by the PED.

Note 2: The PED in general, and Article 1 paragraph 3.9 in particular, does not distinguish between subsea and surface equipment.

Note 3: Specific solutions to essential safety requirements shall take account of the subsea use of this equipment, as a result of the hazard analysis.

Accepted by WPG on:	2003-06-24
Accepted by Working Group "pressure" on:	2003-11-03

1.38. Guideline 1/38

Guideline related to: Article 1 paragraph 2.1.2, Article 1 paragraph 3.2, Annex II Table 7 and Table 9

Question: Is piping in fire extinguishing systems in the scope of the Pressure Equipment Directive (PED)?

Answer: Yes.

Reasons: 1) Even though extinguishing gas (such as CO₂ or inert gas) piping will be only momentarily pressurised during activation of the extinguishing system and such piping is open at the discharge end, it will be exposed to a pressure PS above 0,5 bar.

2) The piping of a sprinkler system is not considered to be covered by exclusion 3.2 of Article 1, as it is not a network for the supply, distribution and discharge of water.

Note 1: The location where the pressure PS is specified shall be such to be representative of the maximum pressure to which the piping will be exposed.

Note 2: Table 7 of Annex II is to be used for classification if content is CO₂, or inert gas. For sprinkler systems, table 7 is to be used for "dry piping installation", and table 9 for water.

Note 3: The PED is limited only to pressure-related hazards. Function and performance of fire extinguishing systems are not covered by the PED.

See also guidelines [1/9](#) and [9/8](#).

Accepted by WPG on:	2002-04-09
Accepted by Working Group "pressure" on:	2002-05-23

1.39. Guideline 1/39

Guideline related to: Article 1 paragraph 3.6

Question: Article 1, section 3.6 states that all "equipment classified as no higher than category I under Article 9 of this Directive and covered by one of the following Directives: [...] are excluded from the scope of this Directive:". Does this exclusion also cover assemblies?

Answer: Yes.

Reason: While the categories are defined in Article 9 for items of pressure equipment, the same categories are applied to and used in the context of Assemblies in Article 10. The Directive clearly defines a category for each assembly in Art. 10.2.b and requires that the applicable conformity assessment modules are used as per 10.1.3.

Consequently there is no problem to determine, which assemblies are excluded from the pressure equipment directive by article 1, section 3.6.

Note: There is ambiguity in some language versions of the directive regarding Article 10 paragraph 2.b.

Accepted by WPG on:	2002-03-14
Accepted by Working Group "pressure" on:	2002-05-23

1.40. Guideline 1/40

Guideline related to: Article 1 paragraph 2.1.4

Question: What does pressure bearing housing mean in the definition of pressure accessory in Article 1 paragraph 2.1.4?

Answer: The term pressure bearing housing refers to an envelope in which fluid under pressure ($PS > 0,5$) is contained or transported (volume $V > 0$).

Therefore, a product whose only pressure-bearing surface is a flange or screwed fitting is not a pressure accessory but is a component of an item of pressure equipment under the Pressure Equipment Directive (PED) when used on such equipment.

Typical examples of components which are not pressure accessories: Level Switch, Flush Mounted Pressure Transmitter and Thermowell.

Note: This does not apply to such devices when employed in a safety function.

See also guidelines [1/8](#), [1/22](#), [1/25](#) and [7/19](#).

Accepted by WPG on: 2002-04-10, editorially amended by WPG on 2006-10-18
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Accepted by Working Group "pressure" on: 2002-05-23, with editorial amendment on 2004-03-17, and 2006-11-21

1.41. Guideline 1/41

Guideline related to: Article 1 paragraph 3.5, Article 1 paragraph 3.19

Question: Is a liquefied petroleum gas (LPG) or compressed natural gas (CNG) vessel (tank) permanently installed in an engine powered fork lift truck in the scope of the PED?

Answer: Yes, such an LPG or CNG vessel is in the scope of the PED and must be assessed according to its maximum allowable pressure and volume.

Reason: An engine powered fork lift truck is not a motor vehicle in the sense of Council Directive 70/156/CEE, so the exclusion of the Article 1 paragraph 3.5 does not apply.

Note 1: Transportable gas cylinders which can also be used for fork lift trucks are in the scope of ADR and as such are excluded from the PED, due to Article 1 paragraph 3.19.

Note 2: The same applies to similar machinery not covered by Directive 70/156/CEE.

Accepted by WPG on:	2002-11-06
Accepted by Working Group "pressure" on: 2003-01-27, editorially amended by WPG on 2007-01-30, confirmed by WGP on 2007-04-18	

1.42. Guideline 1/42

Guideline related to: Article 1 paragraph 2.1.2 and Annex I section 2.2.1

Question: Is the discharge piping from a pressure safety accessory, which will be exposed to a pressure PS above 0,5 bar, in the scope of the Pressure Equipment Directive (PED) when exhausting to ambient atmosphere?

Answer: Yes.

Reason: Even though discharge piping will be only momentarily pressurised, and such piping is open at the discharge end, it fulfils the definition of piping in paragraph 2.1.2 of Article 1.

Note 1: A silencer installed in the discharge piping is excluded according to Article 1 paragraph 3.16.

Note 2: The location where the pressure PS is specified shall be such to be representative of the maximum pressure to which the piping will be exposed.

Accepted by WPG on:	2002-11-05
Accepted by Working Group "pressure" on:	2003-01-27

1.43. Guideline 1/43

Guideline related to: Article 1 paragraph 2.1.3, Annex I section 2.10a and 2.11

Question: Are safety accessories as defined by the PED limited to equipment which prevents hazards due to overpressure?

Answer: No.

Safety accessories are devices designed to protect pressure equipment against exceeding the allowable limits (pressure, temperature, water level, ...). The suitability of the device or combination of devices is determined on the basis of the particular characteristics of the equipment or assembly.

For example:

- a) A combination of a level gauge and a pressure relief system
- b) A combination of a low level water gauge and the burner shutdown device installed on a steam boiler, including all elements of the safety logic
- c) A safety-related system detecting the rate of a chemical reaction to avoid a run away reaction and initiating corrective action.

See also guidelines [1/20](#)

Accepted by WPG on:	2003-03-05
Accepted by Working Group "pressure" on:	2003-04-28

1.44. Guideline 1/44

Guideline related to: Article 3 paragraph 1.1

Question: Is breathing apparatus, such as SCBA (self-contained breathing apparatus, generally composed of a bottle, a regulator, a flexible hose and mouth or face piece) in the scope of the PED?

Answer: Yes, breathing apparatus shall be considered as an assembly in the sense of the PED, the items of which have to be conformity assessed according to their individual design pressure and other characteristics, and the assembly shall be subjected to a global conformity assessment.

Reason: Breathing apparatus is personal protective equipment and, as such, covered by the PPE directive 89/686/EEC. This does however not exclude it from the scope of the PED dealing with the associated pressure risk.

See also guidelines [1/10](#), [2/16](#) and [3/8](#).

Note: The same reasoning applies for diving breathing apparatus.

Accepted by WPG on:	2003-03-05
Accepted by Working Group "pressure" on:	2003-04-28

1.45. Guideline 1/45

Guideline related to: Article 1 paragraph 3.5

Question: When does the exclusion of Article 1, paragraph 3.5 apply?

Answer: Where the pressure equipment is directly contributing to the functioning of the vehicle (see guideline 1/46) and the vehicle is defined in one of the directives 70/156/EEC, 74/150/EEC and 92/61/EEC and the item of pressure equipment is assessed by type approval under one of these directives or by single approval of the vehicle under national regulations, it is excluded from the PED.

If not, the PED applies.

WPG: directly discussed in Working Group "Pressure Equipment" on:	2007-12-07
Accepted by Working Group "pressure" on:	2007-12-07

1.46. Guideline 1/46

Guideline related to: Article 1 paragraph 3.5

Question: Are items of pressure equipment installed on vehicles covered by the PED?

Answer: Article 1 paragraph 3.5 excludes from the scope of the directive "equipment intended for the functioning of vehicles defined by the following Directives and their annexes:

- Council directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member states relating to the type-approval of motor vehicles and their trailers;

- Council directive 74/150/EEC of 4 March 1974 on the approximation of the laws of the Member states relating to the type-approval of wheeled agricultural or forestry tractors;

- Council directive 92/61/CEE of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles"

For example, the following items directly contributing to the functioning of the vehicles are within this exclusion: tanks such as the auxiliary tanks for braking energy systems (which may be covered by the directive 87/404/EEC on simple pressure vessels that does not contain an exclusion for equipment installed in vehicles), LPG, CNG or hydrogen tanks, those hydraulic systems contributing to the functioning of the vehicle such as shock absorbers.

An item of pressure equipment not contributing directly to the functioning of the vehicles is covered by the PED (e.g. air conditioning system, fire extinguisher, fixed LPG tanks in camping-cars for heating or cooking purposes only). For hydraulic systems see also guideline 3/13.

Note: Article 1 paragraph 3.15 excludes pressure equipment consisting of a flexible casing. Tyres and airbags (air cushions) are within this exclusion.

See also guideline [1/45](#).

Accepted by WPG on:	2003-05-15
Accepted by Working Group "pressure" on:	2003-11-03

1.47. Guideline 1/47

Guideline related to: Article 1 paragraph 2.1.1, Article 9 paragraph 3, Article 15 paragraph 2

Question: Is it correct to have a spare bundle of a shell & tube heat exchanger CE marked separately from the CE-marking of the heat exchanger ?

Answer: No.

Reason: A shell & tube heat exchanger is one vessel with two chambers (guideline 2/19); it is not permissible to have one chamber of a vessel separately CE-marked. A bundle is a component of a heat exchanger, it is not an item of pressure equipment

See also guidelines **1/3**, **1/22**, **4/9** and **7/19**

Accepted by WPG on:	2003-09-03
Accepted by Working Group "pressure" on:	2003-11-03

1.48. Guideline 1/48

Guideline related to: Article 1 paragraph 2.1.4, 2.3 and 3.6, Annex I section 2.2.1

Question: Are Flame Arresters and flash back arresters covered by the Pressure Equipment Directive (PED)?

Answer: Yes, when the maximum allowable pressure PS they can be exposed to is above 0,5 bar, flame arresters and flash back arresters are covered by the PED and, in general, should be considered as pressure accessories.

Such flame arresters are generally also covered by ATEX directive ; in that case, they are excluded from PED if they do not exceed Category I (Article 1 paragraph 3.6).

Specific solutions to essential safety requirements shall take account of the potential explosion, as a result of the hazard analysis; the essential safety requirements from ATEX directive need also to be taken into account.

Note 1: In accordance with Article 1 paragraph 2.3, PS would be the maximum pressure for which the flame arrester housing is designed. PS is not necessarily the explosion pressure; in any case the explosion pressure shall be taken into account and may be considered as a load case following the hazard analysis (see Annex I section 2.2.1).

Note 2: In general, the flame arresters will be classified using Annex II table 6.

Note 3: For the definition of flame arresters, see EN 12874:2001.

Accepted by WPG on:	2004-01-20
Accepted by Working Group "pressure" on:	2004-03-17

1.49. Guideline 1/49

Guideline related to: Article 1 paragraph 3.12

Question: Are fluid power accumulators intended for the operation of high-voltage electrical equipment covered by exclusion 3.12 of article 1?

Answer: No, these accumulators are covered by the Pressure Equipment Directive.

Reason: The exclusion of article 1 paragraph 3.12 covers only the enclosures of the high-voltage electrical equipment and not the items of pressure equipment supplied with these high voltage electrical products.

See also Guideline [1/19](#).

Accepted by WPG on:	2003-12-17
Accepted by the Working Group "pressure" on:	2004-03-17

1.50. Guideline 1/50

Guideline related to: Article 1 paragraph 3.10

Question: Is the flare tip at the end of piping in the scope of the Pressure Equipment Directive (PED)?

Answer: The flare tip is covered by the PED, when the internal pressure exceeds 0,5 bar, in which case it is a pressure accessory.

Note 1: A flare (or flare system) can be considered as two parts: the lower part, which essentially comprises discharge piping and the upper part, at the extremity of the piping (usually joined by a flanged connection), which is the flare tip, where the flame is ignited. In some designs a device is installed as part of the flare tip to regulate flow.

Note 2: The discharge piping is covered by the PED (see guideline [1/42](#)).

Accepted by WPG on:	2004-02-24
Accepted by Working Group "pressure" on:	2004-03-17

1.51. Guideline 1/51

Guideline related to: Article 1 paragraph 3.12

Question: What is meant by high-voltage in the context of Article 1 paragraph 3.12 ?

Answer: High voltage means that the highest voltage in normal conditions, either between the two connectors or between one connector and the ground, exceeds the following values:

- for alternating current : 1000 V;
- for direct current : 1500 V.

Reason: The Low voltage directive 73/23/EEC and its amendment 93/68/EEC say:
"Article 1 For the purposes of this Directive "electrical equipment" means any equipment designed for use with a voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current."

Accepted by WPG on:	2004-04-16
Accepted by Working Group "pressure" on:	2004-09-07

1.52. Guideline 1/52

Guideline related to: Article 1 paragraph 3.6, Article 3 paragraph 1.2, Annex II, Table 5

Question: Article 3 paragraph 1.2 states that all pressure cookers shall satisfy essential requirements set out in Annex I ; Article 1 paragraph 3.6 excludes from the scope of the Directive equipment classified as no higher than category I and covered by Directive 73/23/EEC (as replaced by Directive 2006/95/EC). How to apply these two Articles to electrical pressure cookers?

Answer: All electrical pressure cookers with a maximum allowable pressure above 0,5 bar are also in the scope of the Directive 97/23/EC, irrespective of their product pressure-volume.

Reason: The pressure hazard of pressure cookers could be high if the design is not adequate. It is the reason why their design must be subject to a conformity assessment of at least one of the category III modules. This applies to electrical pressure cookers as well as externally fired pressure cookers. The sixth recital of the Directive explains that the exclusion laid down in Article 1 paragraph 3.6 is intended for equipment where the hazard due to pressure remains small.

Accepted by WPG on:	2006-11-22
Accepted by Working Group "pressure" on:	2007-04-18

1.53. Guideline 1/53

Guideline related to: Article 1 paragraph 3.10

Question: Are dryer rolls for the paper industry covered by the PED ?

Answer: Yes

Reason: Even if thermal, dynamic and other non-pressure loads are important for the design of dryer rolls, for most pressure is a significant design factor when dimensioning the equipment.

Note 1: However some dryer rolls with a specific design such as the incorporation of many small holes may be excluded from the PED on the basis of Article 1 paragraph 3.10 because pressure is not a significant design factor.

Note 2: Some dryer rolls are regularly ground to meet the process requirements. This loss of thickness can eventually oblige the user to reduce pressure loads according to a curve called "derating curve" provided by the manufacturer.

See also Guideline [1/11](#).

Accepted by WPG on:	2011-10-06
Accepted by Working Group "pressure" on:	2012-03-06

1.54. Guideline 1/54

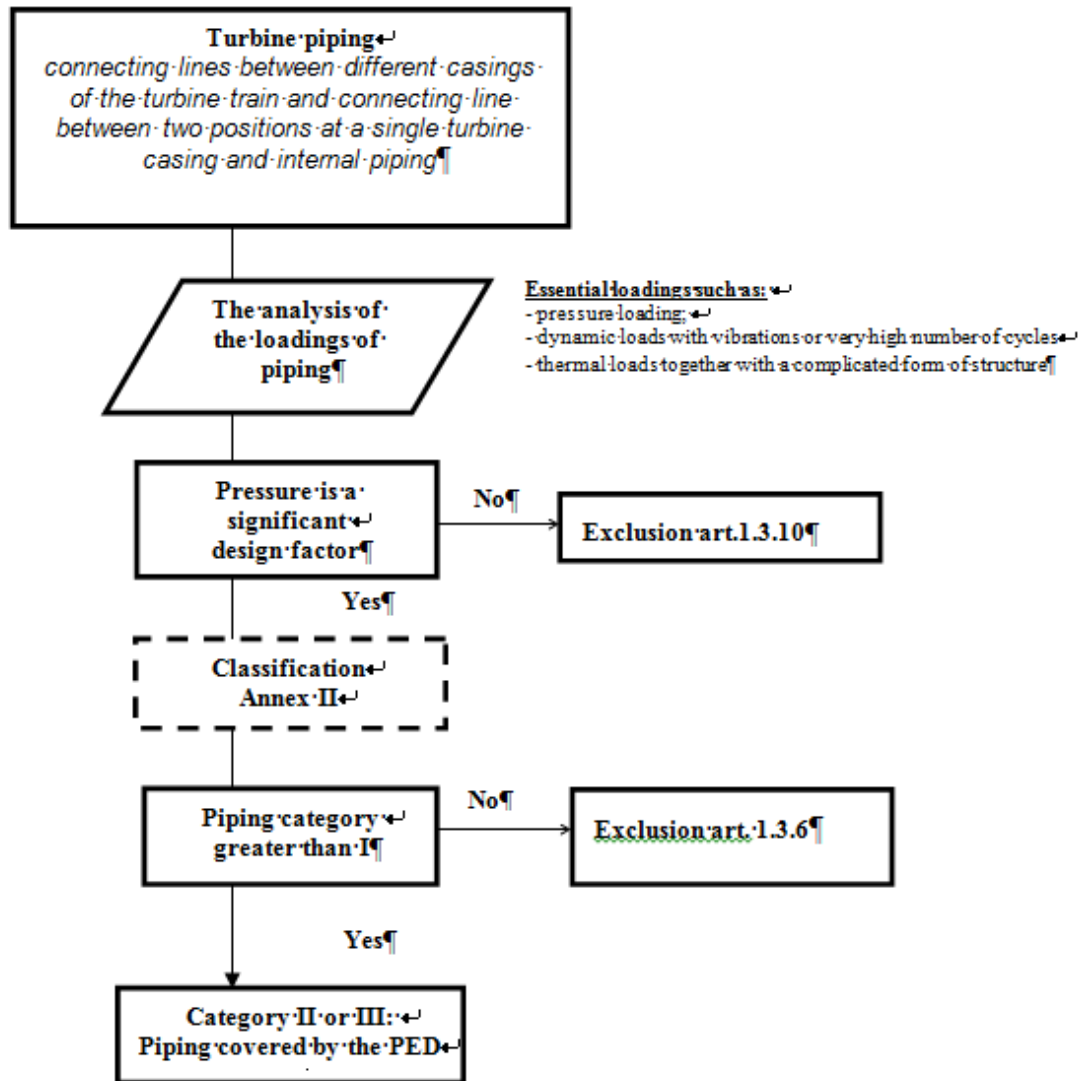
Not yet adopted

1.55. Guideline 1/55

Guideline related to: Article 1, paragraphs 2.1.2, 3.6 and 3.10

Question: Is turbine piping covered by the Pressure Equipment Directive (PED)?

Answer: Turbine piping defined as “connecting lines between different casings of the turbine train and connecting line between two positions at a single turbine casing and internal piping” is evaluated as follows:



Note 1: The manufacturer has the ultimate responsibility to perform a hazard analysis and to determine the Directives applicable to the equipment.

Note 2: Inlet and outlet piping is not part of the turbine, so it shall be evaluated separately against PED.

Note 3: See also guidelines 1/11, 1/26 and 8/4.

Accepted by WPG on:	2013-01-17
Accepted by Working Group “pressure” on:	2013-03-07

1.56. Guideline 1/56

Guideline related to: Annex I Section 2.2.1

Question: Is equipment with a maximum allowable pressure $PS \leq 0,5$ bar in the scope of the PED if it is also designed to take account of an explosion pressure in an abnormal condition?

Answer: No

Reason: The classification under the PED is based on PS in normal or foreseeable operating conditions.

When the manufacturer classes an explosion as an incident, rather than as operation as intended, the explosion pressure shall not determine the classification according to the PED.

When an explosion is considered included as part of the intended operation of the equipment, if the resultant pressure PS is greater than 0,5 bar then the equipment is covered by the PED.

See also Guideline 8/7.

Examples of such equipment could be e.g. grain silos.

Accepted by WPG on:	2012-09-12
Accepted by Working Group "pressure" on:	2013-03-07

1.57. Guideline 1/57

Guideline related to: Article 1 paragraph 2.2

Question: Are vessels designed to operate under vacuum conditions in the scope of the PED?

Answer: No.

However if there are other foreseeable conditions such as cleaning, transport, maintenance etc. where the vessel is subject to a pressure greater than 0,5 bar, the PED does apply.

See also Guideline [1/2](#), [1/13](#) and [8/7](#)

Reason: According to Article 1 the PED directive applies to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS **greater than** 0,5 bar.

Further, section 2.2 defines pressure relative to atmospheric pressure, i.e. gauge pressure. As a consequence, vacuum is designated by a negative value.

Accepted by WPG on: 2013-04-25
Accepted by Working Group "pressure" on: 2014-03-20

2. CLASSIFICATION AND CATEGORIES

1	SCOPE AND EXCLUSIONS OF THE DIRECTIVE
2	CLASSIFICATION AND CATEGORIES
3	ASSEMBLIES
4	EVALUATION ASSESSMENT PROCEDURES
5	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON DESIGN
6	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MANUFACTURING
7	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MATERIALS
8	INTERPRETATION OF OTHER ESSENTIAL SAFETY REQUIREMENTS
9	MISCELLANEOUS
10	GENERAL-HORIZONTAL QUESTIONS

2.1. Guideline 2/1

Guideline related to: Article 3 paragraph 1.4 and Annex II point 3

Question: There is a contradiction between the requirements in article 3 paragraph 1.4 and those in annex II point 3.

Can pressure accessories be classified as “article 3.3” as indicated in the tables in annex II or must all of them satisfy the essential requirements as indicated in article 3 paragraph 1.4 ?

Answer: In accordance with annex II point 3, pressure accessories have to be classified using the appropriate table(s) of annex II on the basis of their PS, their V and/or DN, and the group of fluids for which they are intended. Pressure accessories with low PS, volume and/or DN will therefore fall under the requirements of article 3.3. Such pressure accessories do not have to satisfy the essential requirements but only sound engineering practice.

Reason: Requirements in annex II are more precise and should prevail. When the directive was developed, it was clearly not the intention to require that all pressure accessories intended for equipment which have to satisfy the essential requirements also have to satisfy those requirements.

Accepted by WPG on:	1998-10-13
Accepted by Working Group “pressure” on:	1999-01-28 (re-edited 01-2001)

Reservation from Sweden and Denmark

2.2. Guideline 2/2

Guideline related to: Article 1, paragraph 2.6; Article 3, paragraph 1.3

Question: The Directive uses the notion of DN (defined in Article 1, paragraph 2.6) for the classification of piping or piping accessories (cf. Article 3, paragraph 1.3). How to apply the Directive for classifying the tubular products or accessories for which the notion of DN does not exist (copper tubes, plastic valves, pressure regulators, hollow sections...)?

Answer: In the absence of DN in the standards, it shall be assumed that DN corresponds to the internal diameter in millimetres for circular products or the diameter in millimetres of the equivalent flow section for non-circular products.

In case of pressure accessories this assumption is made regardless of the diameter of the connection (which is usually expressed by DN).

For non-circular piping a comparative diameter must be determined from the existing cross-section. This comparative diameter must be used as the basis for classification.

Accepted by WPG on:	2013-01-17
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Accepted by Working Group “pressure” on:	2013-03-07
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2.3. Guideline 2/3

Guideline related to: Article 3 paragraph 1; Annex II

Question: How should vessels and piping for superheated water be classified?

Answer: Vessels for super-heated water are covered by article 3, paragraph 1.1 a), second indent and table 2 applies.

Piping for super-heated water is covered by article 3, paragraph 1.3 a), second indent and table 7 applies.

These replies are applicable to unheated vessels or pipes with temperatures $> 110^{\circ}$ C.

Fired or otherwise heated vessels or piping with the risk of overheating that are intended for generation of steam or super-heated water at maximum allowable temperatures $> 110^{\circ}$ C are covered by article 3, paragraph 1.2 and table 5 applies.

See also guidelines [2/13](#) and [2/22](#).

Accepted by WPG on: editorially corrected on 2002-04-10	1998-11-27,
Accepted by Working Group "pressure" on:	1999-01-28

2.4. Guideline 2/4

Guideline related to: Article 1 paragraphs 2.1.1 and 2.1.2

Question: Which type of pressure equipment is a heat exchanger?

Answer: Heat exchangers are considered to be vessels.

As an exception, heat exchangers which consist of straight or bent pipes which may be connected by common circular header(s) made also from pipe are classified according to Article 1 paragraph 2.1.2 last sentence as piping if, and only if, the 3 following conditions are met:

- air is the secondary fluid,
- they are used in refrigeration systems, in air conditioning systems or in heat pumps,
- the piping aspects are predominant.

For such heat exchangers with headers, the piping aspects are predominant if $Cat_p \geq Cat_v$ where:

Cat_p = Abstract category that would be applicable according to 97/23/EC if the heat exchanger were classified as piping using DN of the biggest header.

Cat_v = Abstract category that would be applicable according to 97/23/EC if the biggest header, without the connecting piping, were classified as a vessel (i.e. for determining Cat_v , not the total volume V of the heat exchanger is taken into account, but only the volume V_H of the biggest header).

When the result is $Cat_v > Cat_p$, the appropriate vessel classification shall be determined by using the volume of the entire heat exchanger (headers plus connecting tubes).

The abstract category approach for determining the predominant aspect is limited to this specific application dealt with in Article 1 paragraph 2.1.2. The use of this concept outside this context is not supported by the directive and thus is not permissible.

Note: Piping heat exchangers which do not meet the requirements of the exception are not to be classified according to the last sentence of Article 1 paragraph 2.1.2 as piping; they are to be classified as vessels. For example:

- Heat exchangers which are not used in refrigeration systems, in air conditioning systems or in heat pumps, and for which the main purpose is to heat or cool the contained fluid by using the surrounding air;
- Half-pipe coil or a similar « jacket » construction that heat or cool a vessel;
- Pipe coil that is inside a vessel to heat or cool its content.

Accepted by WPG on:	2003-05-14
Accepted by Working Group "pressure" on: 2004-09-07, Swedish reservation updated on 2005-03-16	2003-11-03, editorially amended by

***Swedish reservation** on the determination of Cat_v based only on the biggest header and not on the sum of the header volumes, and on the inclusion "refrigeration systems" and condensers in the second indent of the answer.*

2.5. Guideline 2/5

Guideline related to: Article 1 paragraph 2.4, Article 3 paragraph 1.2, Annex II table 5

Question: Some warm water generators having a volume greater than 2 L are intended to generate water at a temperature less than 110 °C, but are fitted with a safety temperature limiter which is set to a temperature of 120 °C.

What value of maximum allowable temperature, TS, shall be declared by the manufacturer?

Answer: If the equipment is designed to operate at a temperature up to, but not exceeding 110 °C, then 110 °C shall be the value of TS, as defined in Article 1.2.4, specified by the manufacturer. In this case, the temperature limiter shall be set to ensure that the water temperature will not exceed 110 °C.

In the example given in the question, TS is 120 °C.

See also guideline [2/12](#).

Accepted by WPG on :	2000-02-08
Accepted by Working Group “ pressure ” on : amended on 2006-11-22, confirmed by WGP on 2007-04-18	2000-03-24, editorially

2.6. Guideline 2/6

Guideline related to: Articles 3. paragraphs 1.1, 2.1, 2.2

Question: How should a fired or otherwise heated equipment be classified if a fluid other than water is being heated ?

Answer: This equipment shall be considered as vessel in accordance with article 3.1.1 of the directive. It may also be considered as assembly in accordance with article 3.2.2.

The definition of assemblies in article 3.2.1 concerns only the assemblies intended for generating steam or superheated water and does not concern equipment where a fluid other than water is heated.

As a consequence, the classification shall not be made using table 5.

Examples of such equipment are oil heating furnaces, heat exchangers (refer also to guideline 2/4), and induction heaters.

Note: The essential requirements of annex I section 5 are applicable to such pressure equipment, if it presents a risk of overheating, unless the equipment is covered by Article 3.3.

Accepted by WPG on :	2000-02-17
Accepted by Working Group “ pressure ” on :	2000-03-24

2.7. Guideline 2/7

Guideline related to: Articles 9 paragraphs 2.1 and 2.2

Question: Article 9 classifies fluids with reference to Article 2 (2) of Directive 67/548/EEC. Does this mean that all fluids classified as dangerous are group 1?

Answer: NO, only those fluids the properties of which are cited in Article 9 paragraph 2 of the Pressure Equipment Directive (PED) are to be classified as group 1. According to the classification of Annex VI of the latest amendment of Directive 67/548/EEC they have one or more of the following risk phrases.

(This list relates to the version dated November 2005)

- R2, R3 for explosive
- R12 for extremely flammable
- R11, R15, R17 for highly flammable
- R26, R27, R28, R39 for very toxic
- R23, R24, R25, R39, R48 for toxic
- R7, R8, R9 for oxidising.

For flammable fluids, see guideline 2/20.

Note 1: The reference to the directive 67/548/EEC is used for the definitions of the risks of the substances. Annex I of this directive is not exhaustive whatever the version is. The fact that a substance is not listed in Annex I of this directive does not imply its classification in Group 1 or 2. It is advisable then to refer to the safety data sheet supplied with the product in accordance with the directive 91/155/EEC to identify whether the risks of Group 1 are included or not. The classification of substances according to directive 67/548/EEC may also be checked on the website of the European Chemical Bureau <http://ecb.jrc.it>

Note 2: Fluids which have the symbol T or T+ are not necessarily group 1. As an example, fluids that are classified carcinogenic may have the symbol T. However, they don't belong to Group 1 fluids of the PED because they are not classified toxic (e.g. 2-naphtylamine salts, index no. 612-071-00-0). In directive 67/548/EEC, the symbols and classification are not the same. The symbols are defined in article 6 of Directive 67/548/EEC (article 16 of amendment 79/831/EEC) and this article is not mentioned in Article 9 of the PED. Classification and symbols are listed separately in the lists of fluids, Directive 93/21/EEC, and amendments.

Accepted by WPG on:	2004-12-16,
editorially amended on	2005-11-28

Accepted by Working Group "pressure" on:	2005-01-19
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agreed 2006-03-31

2.8. Guideline 2/8

Guideline related to: Article 9 paragraph 3

Question: How should a vessel which is intended to contain water below 100 °C be classified when there is a marginal gas cover?

Answer: This type of vessel is classified according to Table 4, provided the gas is being continuously removed.

Examples of such vessels are domestic warm water vessels, where entering air is accumulated on the top, and is normally being removed by operation.

Accepted by WPG on:	1999-12-14
Accepted by Working Group "pressure" on:	2000-03-24

2.9. Guideline 2/9

Guideline related to: Article 3 paragraph 1.1 and Article 9 paragraph 3

Question: Which pressure and volume values must be used to determine the category of vessels used as gas-loaded accumulators, or other vessels with a flexible or non fixed membrane, given that these are made up of two chambers with different fluids?

Answer: The maximum allowable pressure (PS) of the vessel and the total volume of the vessel shall be used according to Article 9.3.

Accepted by WPG on:	1999-12-14
Accepted by Working Group "pressure" on:	2000-03-24

2.10. Guideline 2/10

Guideline related to: Article 3 paragraph 1.1 and Article 9 paragraph 3

Question: If a vessel contains a fluid which meets the conditions of the introductory paragraph to Article 3, paragraph 1.1(a) (e.g. air) and a liquid which meets the conditions of the introductory paragraph to Article 3, paragraph 1.1(b) (e.g. water) - how shall the vessel be classified?

Answer: Article 9, paragraph 3 states that the classification shall be on the basis of the fluid which requires the higher category. The total volume (V) of the vessel, as defined in Article 1, paragraph 2.5, shall be used to determine the conformity assessment category, not the actual volume occupied by the individual fluids at any particular time.

See also guidelines 2/8 and 2/9.

Accepted by WPG on :	2001-02-20
Accepted by Working Group “ pressure ” on :	2001-06-26

2.11. Guideline 2/11

Guideline related to: Article 10, section 1.4, Annex II, Annex III

Question: When is it possible for a manufacturer to apply a module from a higher category and what are the consequences ?

Answer: Article 10.1.4 states that manufacturers can choose to apply one of the procedures which apply to a higher category if available. The words ‘if available’ make it clear that if an item of pressure equipment was classified as category IV, then a module from a higher category is not available. Even for those tables in Annex II where categories III and/or IV are not listed, such procedures can be chosen.

The procedures available are the modules or module combinations described under Article 10.1.3.

If a module (or a module combination) from a higher category is chosen, all the requirements of that module must be met, including the marking of the identification number of the Notified body.

However, the use of a module (or a module combination) from a higher category does not change the actual classification of the equipment. The requirements of Annex I are those resulting from the actual classification unless the module itself gives specific requirements.

See also guideline [2/18](#).

Note: When particular modules are explicitly referenced in the text of the directive, they cannot be substituted, as for example in Table 4 of Annex II.

Accepted by WPG on:	2000-08-25
Accepted by Working Group “ pressure ” on:	2000-11-07

2.12. Guideline 2/12

Guideline related to: Article 1 paragraph 2.4

Question: For warm water boilers which are controlled by a temperature thermostat and protected by a safety temperature limiter, does the maximum allowable temperature (TS) mean:

(a) the maximum intended operating temperature under normal conditions as controlled by the thermostat; or;

(b) the temperature setting of the ultimate over-temperature safety device i.e. the limiter?

Answer: (b) is correct.

Note: manufacturers must ensure that the equipment is sufficiently robust to deal with any residual heat after activation of the limiter.

See also WPG 2/5

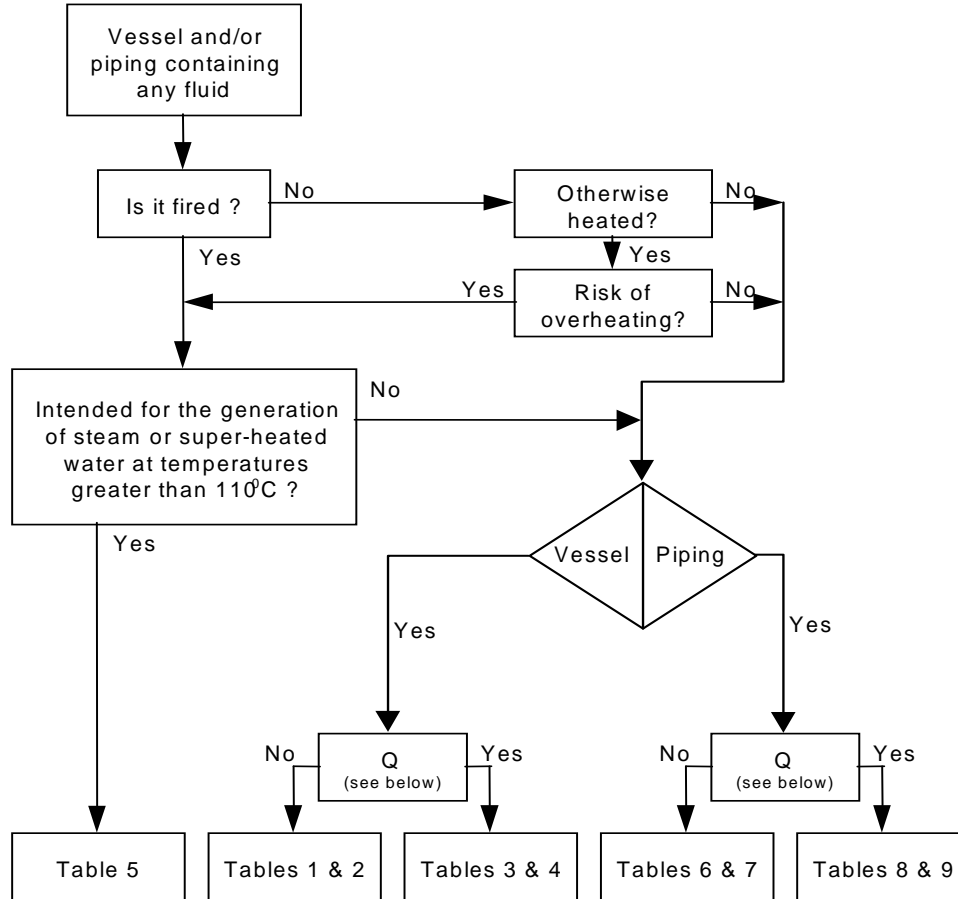
Accepted by WPG on :	2000-02-18
Accepted by Working Group "pressure" on :	2000-03-24

2.13. Guideline 2/13

Guideline related to: Article 3 paragraphs 1.1, 1.2, 1.3 and Annex II

Question: How can manufacturers use Article 3.1 to determine the appropriate conformity assessment Tables in Annex II?

Answer:



Q. Does the vessel or piping contain liquid whose vapour pressure at the maximum allowable temperature is not more than 0,5 bar above normal atmospheric pressure?

Accepted by WPG on:	2000-05-05
Accepted by Working Group "pressure" on:	2000-06-29

2.14. Guideline 2/14

Guideline related to: Article 3, paragraph 1.1(a) and Annex II, Table 2

Question: Article 3, section 1.1(a) second indent, states that all portable extinguishers must comply with the essential safety requirements (ESRs) and be assessed according to Annex II, Table 2. In addition, Table 2 states that portable extinguishers must exceptionally be classified at least in category III. To what parts of a portable extinguisher do these requirements apply?

Answer: Article 3, section 1.1(a) and Annex II, Table 2 are applied to vessels and therefore the requirements are relevant to the cylinder (bottle) of the portable extinguisher. The other parts of the portable extinguisher which are pressure equipment are classified according to Article 3 and assessed according to the appropriate Tables.

Note: A portable extinguisher is an assembly referred to in Article 1, section 2.1.5 and Article 3, section 2.2. It shall be subjected to a global conformity assessment procedure of Article 10, section 2 and it shall bear the CE marking as an assembly.

The global conformity assessment procedure of Article 10, sections 2 (b) and 2 (c) is determined by the highest category applicable to the equipment concerned other than that applicable to any safety accessories. Because the cylinder (bottle) of a portable extinguisher is classified at least in category III the global conformity assessment procedure to be applied must be chosen among those laid down at least for category III.

Accepted by WPG on :	2000-10-02
Accepted by Working Group “ pressure ” on :	2000-11-07

2.15. Guideline 2/15

Guideline related to: Article 3 paragraph 1.2, Annex II table 5

Question: Does the classification of the pressure cookers in category III for the assessment of the design mean that also the essential safety requirements are linked to category III?

Answer: No

In accordance with Article 3 paragraph 1.2, all the pressure cookers shall satisfy the essential safety requirements of the directive and shall bear the CE marking.

The determination of the category of the pressure cookers regarding essential safety requirements following Article 9 paragraph 1 is made in accordance with table 5 of Annex II, i.e. :

- Category I for the pressure cookers for which the product PS.V is not greater than 50 bar.L

- Category II for the pressure cookers for which the pressure is not greater than 32 bar and the product PS.V is over 50 bar.L and not greater than 200 bar.L

The only differences in essential safety requirements with regard to category are stated in Annex I sections 3.1.2, 3.1.3, 3.2.2, 4.2c and 4.3 (see also guideline [2/11](#)).

The design assessment shall be made in accordance with a module of Category III or IV, i.e. modules B, B1, G, H or H1.

Note: When module B or B1 is used and no notified body is involved at the production phase, there shall be no marking of the identification number of the notified body.

Accepted by WPG on:	2001-12-19
Accepted by Working Group "pressure" on:	2002-02-02

2.16. Guideline 2/16

Guideline related to: Article 1, paragraph 2.1.3, Annex I, section 2.11

Question: Are pressure regulators safety accessories in the sense of PED?

Answer: In general pressure regulators are pressure accessories.

Only in the case where they fulfil the definition of safety accessory and consequently have a specified safety function, they are to be considered safety accessories and they shall meet requirements of Annex I, section 2.11.

When a pressure regulator is installed in an assembly where the design pressure of the system downstream of the device is lower than the pressure which can occur upstream of the device, and the system downstream is not protected by a safety accessory, the manufacturer of the assembly must ensure that this pressure regulator fulfils the requirements of a safety accessory.

Note: It is foreseeable that some pressure regulators without specific safety function could be inadvertently used as safety accessories. The manufacturer of the pressure regulator must include an appropriate warning in their instructions for use.

Acceptedby WPG on:	2001-01-10
Accepted by Working Group "pressure" on: 2001-06-26, editorially amended by WPG on 2007-03-27, confirmed by WGP on 2007-04-18	

2.17. Guideline 2/17

Guideline related to: Article 9 and annex II point 3

Question: How are pressure accessories classified?

Answer: The guiding factor should be based on the characteristic of the pressure accessory.

In some cases both volume and DN are considered appropriate. In such cases, the pressure accessory must be classified in the highest category.

In the case of valves, DN is normally the more appropriate.

Reason: It should be noted that some linguistic versions are unclear on this point.

See also guideline [2/1](#).

Acceptedby WPG on:	2000-11-29
Acceptedby Working Group "pressure" on:	2001-06-26

2.18. Guideline 2/18

Guideline related to: Article 3 paragraph 3 and Article 10 paragraph 1.4

Question: Article 10, section 1.4 states that a manufacturer may choose to apply one of the conformity assessment procedures which apply to a higher (conformity assessment) category if available. Does this mean that a manufacturer of pressure equipment covered by Article 3, section 3, referred to as Sound Engineering Practice (SEP), can choose to apply Module A for example and hence apply a CE Marking?

Answer: No.

Article 9, section 1 deals with the classification of pressure equipment referred to in Article 3, section 1 (not section 3) and Article 10 sets out how the conformity assessment procedures should be determined for such equipment. Therefore Article 10, section 1.4 does not apply to SEP pressure equipment and it does not provide any derogation to the provision in Article 3, section 3 that specifically prohibits CE Marking of SEP pressure equipment.

Accepted by WPG on:	2000-08-25
Accepted by Working Group "pressure" on:	2000-11-07

2.19. Guideline 2/19

Guideline related to: Article 1 paragraph 2.1.1; Article 3 paragraph 1.1; Article 9 paragraphs 1 and 3, Annex I section 2.2.3b first indent, Annex I section 3.3(a)

Question: Do two housings, designed to contain fluids under pressure and which have a common boundary (e.g. separating wall), constitute two vessels, or two chambers of the same vessel and what requirements apply to such an item of pressure equipment?

Answer: They constitute two chambers of the same vessel.

Technical requirements and conformity assessment procedure to be applied are determined as follows:

- each chamber will be classified according to Article 3, paragraph 1.1 and Article 9, paragraph 1. This establishes the technical requirements for each chamber.
- the conformity assessment procedure to be applied to the whole vessel is based on the highest category of the chambers.

The technical requirements to be applied to the common boundary are those of the highest category of the two chambers.

Hazard analysis of individual chambers must take account of the effect of any perceived hazard on the vessel as a whole.

The marking shall include the limits of the two chambers even if the limits of one chamber do not exceed the limits of Article 3 paragraph 1.1.

Reason: If a vessel is composed of a number of chambers each individual chamber must be first classified. The classification and the technical requirements of each individual chamber are based to Article 3, paragraph 1.1 and Article 9, paragraph 1. The conformity assessment procedure to be applied to the whole vessel is determined by the highest category.

Examples:

- A refrigerant heat exchanger that has water in tube or shell side,
- A valve body or a pipe with heating or cooling jacket that has a small volume.

Note 1: Sound engineering practice can be applied as technical requirement for a chamber that does not exceed relevant limit of Article 3, paragraph 1.1.

Note 2: Refer to guideline [1/13](#) for those cases where maximum allowable pressure of a chamber does not exceed 0,5 bar.

Accepted by WPG on:	2005-07-05
Accepted by Working Group "pressure" on:	2006-03-31

Reservation from Denmark and Sweden.

2.20. Guideline 2/20

Guideline related to: Article 9, paragraph 2.1, 4th indent

Question: What is meant by “flammable” in article 9 paragraph 2.1, 4th indent of the PED?

Answer: Flammable means any fluid which is intended to be used at a maximum allowable temperature TS above its flashpoint.

Reason: Although this is not fully in line with the definition of Directive 67/548/EEC, this answer was clearly the intention of the Council and Parliament, as shown by the sentence between brackets in the text of the PED.

Note 1: A fluid defined as flammable according to Directive 67/548/EEC does not belong to group 1 in the case the maximum allowable temperature (TS) is below its flashpoint.

Note 2: Heat transfer oils are not defined as ‘flammable’ according to the Directive 67/548/EEC (and its amendments) because their flashpoint is above 55 °C. However, if the maximum allowable temperature (TS) is above flashpoint the hazard of heat transfer oil corresponds with the definition of Article 9, section 2.1, of flammable group 1 fluid.

Accepted by WPG on:	2004-12-15
Accepted by Working Group “pressure” on:	2005-01-19

2.21. Guideline 2/21

Guideline related to: Annex I sections 2.2.1 and 2.3, Annex II Table 1 Annex II Table 6

Question: Tables 1 & 6 of annex II of PED include a reference to unstable gas (this implies that we should classify the equipment in categories III or IV). How does one define an unstable gas?

Answer: An unstable gas in this context is a gas or a vapour liable to transform itself spontaneously, producing a sudden pressure increase.

Such transformation as an example can result from a relatively small variation of an operating parameter (e.g. pressure, temperature) in a confined volume.

These substances are generally put on the market in a stabilised form. ADR:2001, chapter 2.2.2.1 contains the general criteria for the classification of gases. An indication is given with the notion "stabilised" in tables A and B in chapter 3.2 of ADR:2001.

Typical examples of unstable gases: acetylene (UN 1001), methyl acetylene (UN 1060), vinylfluoride (UN 1860).

Note: Directive 67/548/EEC on classification, packaging and labelling of dangerous substances does not deal with this point.

Acceptedby WPG on:	2002-03-13
Acceptedby Working Group "pressure" on:	2002-05-23

2.22. Guideline 2/22

Guideline related to: Article 3 paragraph 1.2, Annex I section 5

Question: What does overheating mean in Article 3 paragraph 1.2?

Answer: Overheating in the sense of Article 3 paragraph 1.2 means exceeding the design temperature, for instance in the case of a failure of a safety system, or through operator error.

Overheating is a hazard which cannot be eliminated through a safety system, but the risk can be minimized.

However if the design temperature is chosen to take into consideration the highest temperature in all foreseeable conditions, the hazard of overheating does not exist.

Note: Design temperature will have to take account of the highest temperature of the material, and not only of the fluid content.

Accepted by WPG on:	2002-04-10
Accepted by Working Group "pressure" on:	2002-05-23

2.23. Guideline 2/23

Guideline related to: Article 3 paragraph 1 and 3, Annex II

Question: How should a solar panel be classified?

Answer: This pressure equipment shall be considered as a heat exchanger containing super-heated or hot water (with or without additives)

Only when a solar panel in its entirety is designed to withstand the highest possible temperatures (stagnation conditions are within the normal operation range), a risk of overheating does not occur (see guideline 2/22). As a consequence the classification shall be made using table 2, Annex II (see guideline 2/13).

See also guideline 2/4.

Note: A typical solar panel would be classified as Article 3, paragraph 3 equipment, due to the maximum allowable pressure and volume.

Accepted by WPG on:	2002-04-10, editorial change on 2005-11-28
Accepted by Working Group "pressure" on:	2002-05-23, accepted on 2006-03-31

2.24. Guideline 2/24

Guideline related to: Article 1 paragraph 2.7, Article 9 paragraph 3

Question: Article 9, paragraph 3 states that where a chamber contains several fluids, classification shall be on the basis of the fluid which requires the highest category. Can some guidance be provided on how to proceed with the fluid mixture classification?

Answer: When a mixture of fluids contains at least one fluid classified to group 1, the mixture shall be classified to group 1 unless the safety data sheet of the mixture allows its classification to group 2.

A "safety data sheet" is a document established according to Directive 91/155/EC, in application of Directives 67/548/EEC and 99/45/EC (*). It gives all necessary safety information, in particular classification of the hazard properties referred to in Article 9 paragraph 2.1 of PED.

Note: When an equipment is manufactured for a specific application defined by the user, it is normally the user who specifies the fluid to be contained or transported in the pressure equipment. Hence, the user should tell the pressure equipment manufacturer the fluid classification or give necessary details so that the pressure equipment manufacturer can classify the fluid.

(*) - **Council Directive 67/548/EEC of 27 June 1967** on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of *dangerous substances*.

- **Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999** concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of *dangerous preparations*.

- **Commission Directive 91/155/EEC of 5 March 1991** defining and laying down the detailed arrangements for the system of specific information relating to *dangerous preparations* in implementation of Article 10 of Directive 88/379/EEC.

Accepted by WPG on:	2002-06-18
Accepted by Working Group "pressure" on:	2002-10-03

2.25. Guideline 2/25

Guideline related to: Annex II

Question: Is it possible to classify pressure equipment in a Category higher than the category resulting from the application of tables in Annex II ?

Answer: No

The classification of a pressure equipment is based on the following factors:

- Type of equipment (vessel, piping, or pressure accessory),
- Type of fluid: gas or liquid,
- Group of fluid: group 1 or 2.

These factors determine the table of Annex II to be used. In the appropriate table, the maximum allowable pressure and the volume for vessels or the maximum allowable pressure and the nominal size DN for piping determines the Category of the equipment.

For example a valve classified as DN 25 can only be Sound Engineering Practice according to Article 3 paragraph 3 and must never be CE-marked (see also guideline [2/17](#)).

Note 1: The directive exceptionally requires use of a higher Category (for instance vessels for unstable gas, or portable extinguishers), but even then there is no choice of category for the manufacturer.

Note 2: The classification of safety accessories is not covered by the tables of Annex II (see section 2 of Annex II)

Note 3: The PED gives flexibility for a manufacturer to apply a conformity assessment procedure from a higher category, if available (see guideline [2/11](#)). For Sound Engineering Practice equipment see guideline [2/18](#).

Accepted by WPG on:	2002-09-19
Accepted by Working Group "pressure" on:	2002-10-04

Swedish reservation on the example due to guideline 2/1.

2.26. Guideline 2/26

Guideline related to: Article 1

Question: How to classify a vessel which contains a "non-suspended dangerous" solid blanketed by a group 2 gas?

Answer: It will be classified according to table 2.

Reason: Article 1 paragraph 2.7 defines fluids as gases, liquids and vapours and covers fluids containing a suspension of solids (see guideline 1/24). Article 9 in connection with Article 3 only mentions gases, liquids and vapours for classification purposes.

Note: The characteristics of the solid should be considered as part of the hazard analysis and do not influence the classification of the vessel.

Accepted by WPG on:	2003-03-05
Accepted by Working Group "pressure" on:	2003-04-28

2.27. Guideline 2/27

Guideline related to: Article 9 paragraph 2.1, 2.2 and 3

Question: How to classify pressure equipment containing one or more fluids when a chemical or physical reaction takes place therein?

Answer: The classification shall be determined by the fluid which gives the highest category taking into account the starting, intermediate and final fluids, which could arise from all reasonably foreseeable conditions.

See also guidelines [2/21](#) and [2/24](#).

Accepted by WPG on:	2003-03-24
Accepted by Working Group "pressure" on:	2003-04-28

2.28. Guideline 2/28

Guideline related to: Article 1 paragraph 2.1.2, Article 3 paragraph 1.3 and Annex II

Question: How shall a "piping" (as defined in Article 1 paragraph 2.1.2), comprising pipes with different DN's, be classified?

Answer: For such a piping the maximum DN used shall be the basis for the classification.

Note: The term a "piping" as used above means an item of pressure equipment, and not an "assembly" as defined in Article 1 paragraph 2.1.5.

Accepted by WPG on:	2003-03-24
Accepted by Working Group "pressure" on:	2003-04-28

2.29. Guideline 2/29

Guideline related to: Annex I, section 2.10

Question: A pressure vessel (PS > 0,5 bar) has a vacuum relief valve mounted to protect against collapsing (external pressure) when drained.

Is this valve a safety accessory?

Answer: Yes, if a vacuum relief valve is designed to be fitted to pressure equipment (PS > 0,5 bar) where collapse due to vacuum is possible under reasonably foreseeable conditions. The valve is a safety accessory as defined by Article 1, paragraph 2.1.3 and must be assessed as such.

See also guideline [1/43](#).

Note 1: Only those valves with a direct safety function shall be classified as a safety accessory.

Accepted by WPG on:	2004-12-15
Accepted by Working Group "pressure" on:	2005-01-19

2.30. Guideline 2/30

Guideline related to: Article 1 paragraph 2.7, Article 9 paragraph 2.1, 2.2

Question: How should a fluid containing a suspension of a solid be classified?

Answer: This classification shall take account of the group of the fluid and of the group of the solid and of the group of the mixture if available.

When the group of the mixture is known according to directive 99/45/EC "Dangerous preparation directive", this group is used for the classification.

If not, the classification is based on the higher group of the fluid and the solid.

See also guidelines [1/24](#), [2/24](#), [2/26](#), [2/27](#).

Reason: Article 1.2.7 of the PED stipulates that a fluid may contain a suspension of solids. The directive 67/548/EEC referenced in article 9 of the PED addresses "substances", defined as "chemical elements and their compounds as they occur in the natural state or as produced by industry" and "preparations", defined as "mixtures or solutions composed of two or more substances", i.e. its scope is not limited to "pure fluids". Article 3 of the directive 67/548/EEC provides the classification to be performed according to the greatest degree of hazard.

Note: When a solid is suspended in a fluid the risk of the release of solid particles by a pressure accident is substantially higher than in case of a solid block blanketed by a fluid (case of guideline [2/26](#)). This supports the different conclusions of this guideline and guideline [2/26](#).

When the solid particles are big enough that the release of solid particles cannot be expected in case of a pressure accident, then guideline [2/26](#) applies.

Accepted by WPG on:	2003-05-15
Accepted by Working Group "pressure" on:	2003-11-03

2.31. Guideline 2/31

Guideline related to: Article 1 paragraph 2.1.2, Article 1 paragraph 2.1.4

Question: How to consider, in application of the Pressure Equipment Directive (PED), piping components connected together and connected also to valves, and which are the provisions for the placing on the market?

Answer: The PED makes the distinction in article 1 paragraph 2 between pressure equipment (vessel, piping, safety accessory and pressure accessory) and assemblies.

Connecting together piping components (flanges, pipes, fittings, reducers for example) constitutes an "*item of piping*" (see also guideline 1/9). The valves are pressure accessories, and not components of piping.

An item of piping, of category I and above, shall be placed on the market with the CE marking. The same applies to each valve individually.

To determine whether the joining of valves and piping constitutes an assembly to be CE-marked or not, see guidelines 3/9, 3/10 and 3/17.

Note 1: An item of piping can integrate a valve along its route. However, the valve is not considered as a piece of this item of piping. The same applies to any pressure accessory joined with a piping, for example a filter or a meter.

Note 2: The joining of valves and piping could then be integrated, by an assembly manufacturer or a user, with other items of pressure equipment to constitute a PED assembly or an installation submitted to national regulations (Guideline 3/2). In this case, it may be useful that a contractual document specifies all the elements that the manufacturer of that joining will communicate to his purchaser to allow him to check the compliance to the essential safety requirements of the final assembly or installation.

Note 3: Some linguistic versions are unclear on the terminology used for the components making up an item of piping.

Accepted by on: WPG:	2003-12-17
Accepted by the Working Group "pressure" on:	2004-03-17

2.32. Guideline 2/32

Guideline related to: Article 1 paragraph 2.1.3, Annex I section 2.3

Question: A quick opening closure on a pressure vessel is “fitted with a device to prevent it being opened whenever the pressure or temperature of the fluid presents a hazard” in accordance with annex I section 2.3.

Is such a preventive device to be considered as a safety accessory according to the Pressure Equipment Directive (PED)?

Answer: No, according to the definition in Article 1 paragraph 2.1.3, a safety accessory is designed to protect pressure equipment against exceeding the allowable limits.

Note 1: However, there are important safety implications for these devices which are covered by the essential safety requirement 2.3 of the PED. The manufacturer shall address this as part of the hazard analysis.

Note 2: This control equipment could be of a simple self-acting type or of a more complicated type, e.g. with a pressure transmitter and an actuator.

Accepted by WPG on:	2004-01-20
Accepted by Working Group "pressure" on:	2004-03-17

2.33. Guideline 2/33

Guideline related to: Article 1 paragraph 2.1.3, Annex II

Question: When a safety accessory consists of a safety chain which itself includes “items of pressure equipment” (for example a valve or a cylinder), in which category shall this “equipment” be classified?

Answer: When items of pressure equipment are integrated in a safety chain, they are considered as parts of the safety chain and therefore fall under the hazard analysis of the safety chain, which include the pressure containment aspect of this item. When the hazard analysis of the safety chain shows that the failure of an individual item of pressure equipment within the chain would have no detrimental effect on the safety function to be ensured (i.e. fail-safe), the requirements of a category lower than category IV for the said "item of pressure equipment" can satisfy the requirement resulting from the hazard analysis of the safety chain.

Its integration in the safety chain is achieved by using the category IV or the category of the equipment for which the chain is specifically designed.

Note 1: This does not preclude the use of standard CE-marked items of pressure equipment as parts of a safety chain.

Note 2: A safety accessory, even when it is a safety chain, cannot be classified as an assembly.

Accepted by WPG on:	2004-02-25
Accepted by Working Group “ pressure ” on:	2004-03-17

2.34. Guideline 2/34

Guideline related to: Article 1 paragraph 2.1.1, Article 1 paragraph 2.5, Article 9 paragraph 3

Question: How to determine the category of a hermetically sealed refrigeration compressor?

Answer: Hermetically sealed refrigeration compressors are pressure vessels.

Usually, a compressor is composed of two chambers: the low pressure side PS1, the volume of which is V1, and the high pressure side PS2, the volume of which is V2. The equalizing pressure during standstill is PS3 (always higher than PS1).

The category is the higher of the low pressure side (based on PS3 and V1) and of the high pressure side (based on PS2 and V2).

See guideline [1/12](#).

Note 1: The highest pressure cannot occur simultaneously on both sides; during standstill there is no direct communication between the 2 chambers, due to the presence of the valves; if a valve fails, the movement of the piston cannot create pressure.

Note 2: When a compressor has more than 2 chambers (i.e. several chambers constitute the low pressure side and several chambers constitute the high pressure side) the above volumes V1 and V2 are the sums of the low pressure and the high pressure chambers respectively.

Accepted by WPG on:	2004-04-15
Accepted by Working Group "pressure" on:	2004-09-07

2.35. Guideline 2/35

Guideline related to: Article 1 paragraph 2.1.2

Question: Some piping is provided with a double envelope. How do these double envelopes have to be considered?

Answer: These double envelopes are to be considered as part of piping if the function of these double envelopes cannot be disassociated from the internal piping intended for the transport of the fluids.

Reason: The technical rules for the design and the manufacture of these double envelopes are usually the same as those for piping.

Note 1: The double envelopes of piping covered by this guideline are of two types:

- those intended to insulate products transported by the internal piping by circulation of a fluid (vapor, coolant, glycol water, etc);

- or those intended to ensure the containment of the product transported in the event of loss of tightness of the internal piping (double envelope for the transport of very toxic fluids for example).

Note 2: This guideline does not address heat exchangers (see guideline 2/4), or reactor loops.

Accepted by WPG on:	2004-12-16
Accepted by Working Group "pressure" on:	2005-01-19

2.36. Guideline 2/36

Guideline related to: Article 1 paragraph 3.11

Question: Are hot blast stoves, which heat incoming cold air to a blast furnace by a regenerative process, covered by the exclusion in Article 1 paragraph 3.11?

Answer: Yes, they are excluded.

Reason: While recuperators and hot blast stoves operate in different ways, the first heating incoming cold air by heat exchange with another hot gas and the second by the firing of an alternative heat source, they can be considered similar for the purposes of exclusion under this article. Those hot blast stoves should be included under Article 1 paragraph 3.11.

Accepted by WPG on:	2004-12-16
Accepted by the Working Group "pressure" on:	2005-01-19

2.37. Guideline 2/37

Guideline related to: Article 1, paragraph 2.1.2 and 2.1.4

Question: How to consider, for the application of PED, a condensate trap installed on piping?

Answer: A condensate trap is intended to play an operational role which is the collection of condensates. Therefore it is generally considered as a pressure accessory, placed on the market with CE marking where appropriate.

However, a condensate trap specifically designed and manufactured as a part of a given item of piping may be assessed as part of the whole piping and, in that case, is not subject to individual CE marking.

Accepted by WPG on:	2004-12-16
Accepted by the Working Group "pressure" on:	2005-01-19

2.38. Guideline 2/38

Guideline related to: Article 1 paragraph 3.16

Question: What kind of silencers is covered by the exclusion of Article 1 paragraph 3.16?

Answer: This exclusion concerns only exhaust and inlet silencers that are subjected to a back-pressure lower or equal to 0,5 bar.

Generally these devices are directly in contact with atmosphere.

Silencers subjected to a back-pressure higher than 0,5 bar (for example outlet silencer of a booster) are submitted to the directive as pressure accessories.

Accepted by WPG on:	2004-12-16
Accepted by the Working Group "pressure" on:	2005-01-19

2.39. Guideline 2/39

Guideline related to: Article 9, paragraphs 2.1 and 2.2

Question: Article 9 classifies fluids with reference to Article 2 (2) of Directive 67/548/EEC. This directive will be repealed by the Regulation No 1272/2008 (“CLP Regulation”). In this regulation the classification of some substances has changed. Which document shall be used for the determination of the fluid group and then the applicable category of pressure equipment?

Answer: The classification according to Directive 67/548/EEC shall be used provided the PED is not amended or revised on this issue but not after 1 June 2015 when the Directive 67/548/EEC is repealed.

Reason: The Classification in the PED refers to a restricted range of risks related to substances to categorize items of pressure equipment for their pressure hazard.

The impact of the CLP Regulation on the classification of items of pressure equipment will be assessed, and an appropriate update of Directive 97/23/EC will be proposed before 1 June 2015.

Acceptedby WPG on:	2009-10-01
Acceptedby Working Group "pressure" on:	2009-10-26

2.40. Guideline 2/40

Guideline related to: Article 1 paragraph 2.1.3, 2.1.4 and 2.1.5

Question: How to apply the Pressure Equipment Directive (PED) to a pressure accessory equipped with a safety accessory?

Answer: The pressure accessory does not become a safety accessory by putting both accessories together. The combination does not expand the different functions of the individual items.

Both accessories shall be subjected to appropriate conformity assessment and marking.

Note 1: A pressure accessory equipped with a safety accessory is not an assembly because it does not constitute a functional whole as per Article 1 paragraph 2.1.5. See also Guideline 3/8.

Note 2: The global conformity assessment is conducted on the assembly, the functional whole, placed on the market.

Accepted by WPG on:	2012-01-12
Accepted by Working Group "pressure" on:	2012-03-06

3. ASSEMBLIES

1	SCOPE AND EXCLUSIONS OF THE DIRECTIVE
2	CLASSIFICATION AND CATEGORIES
3	ASSEMBLIES
4	EVALUATION ASSESSMENT PROCEDURES
5	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON DESIGN
6	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MANUFACTURING
7	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MATERIALS
8	INTERPRETATION OF OTHER ESSENTIAL SAFETY REQUIREMENTS
9	MISCELLANEOUS
10	GENERAL-HORIZONTAL QUESTIONS

3.1. Guideline 3/1

Guideline related to: Articles 10.2 and 3.2.1

Question: Must the global conformity assessment procedure be applied to assemblies covered by article 3.2.1, e.g. to boilers, even if the assembling is done under the responsibility of the user?

Answer: No.

Reasons: PED Article 1.2.1.5 states that “assembly” in the sense of the directive must be assembled by a manufacturer, otherwise it is not in the scope of the directive. This is further supported by recital 5 last sentence. An installation performed by or under the responsibility of the user would normally not be under the scope of the Directive. It would be under the applicable national legislation. See guideline [3/2](#).

Accepted by WPG on:	2000-08-24
Accepted by Working Group "pressure" on:	2000-11-08

3.2. Guideline 3/2

Guideline related to: Article 1.2 and 3.2

Question: Are joining operations on site covered by the PED?

Answer: For the joining on site of components or equipment, two cases have to be considered:

1) Joining of component parts: joining of component parts to comprise an item of pressure equipment is subject to the requirements of the Directive. The manufacturer –even if he is the user- has the responsibility that the resulting item of pressure equipment is in compliance with the Directive.

2) Joining of items of pressure equipment.

The joining is not covered by the PED if it is carried out to constitute an installation ⁽¹⁾ under the responsibility of the user but remains covered by national rules.

If the joining is carried out under the responsibility of a manufacturer to constitute an assembly covered by the definition given in Article 1.2.1.5, this assembly must fulfil the requirements of the Directive.

Reason: The fifth recital of the Directive says: « This Directive does not cover the assembly of pressure equipment on the site and under the responsibility of the user, as in the case of industrial installations ».

Notes: (1) The definition of assembly in Article 1.2.1.5 is limited to those assemblies assembled by a manufacturer. When items of pressure equipment or assemblies are being put together by a user, to avoid confusion, the term “installation” is used.

(2) See also guideline [3/8](#)

Accepted by WPG on:	2000-10-03
Accepted by Working Group « pressure » on:	2000-11-08

3.3. Guideline 3/3

Guideline related to: Article 3 paragraph 2.3

Question: The effect of the derogation in Article 3.2.3 from the introductory paragraph in Article 3.2 is not clear. In the circumstances, how should Article 3.2.3 be applied?

Answer: The assemblies set out in Article 3.2.3 must comply with the essential requirements referred to in 2.10, 2.11, 3.4, 5(a) and 5(d) of Annex I of the Directive, even if all the items of pressure equipment comprising the assembly fall under Article 3.3.

Reason: This was the intention of the Member States which proposed the text and the intention of the Council when approving the text.

Accepted by WPG on:	1999-02-25
Accepted by Working Group "pressure" on:	1999-11-08

3.4. Guideline 3/4

Guideline related to: Article 3 section 2.1 and Annex I section 5

Question: What shall be the minimum extent of the assembly "boiler" which shall be subjected to a global conformity assessment procedure in accordance with article 3 section 2.1?

Answer: The assembly shall comprise, as a minimum, the boiler including all the pressure parts from the feedwater inlet (including the inlet valve) up to and including the steam and/or hot water outlet (including the outlet valve or, if there is no valve, the first circumferential weld or flange downstream of the outlet header). This includes all economisers, superheaters and inter-connecting tubing which may be exposed to a risk of overheating and are not capable of isolation from the main system by interposing shut-off-valves. Additionally included are the associated safety accessories and the tubing connected to the boiler involved in services such as draining, venting desuperheating, etc., up to and including the first isolating valve in the tubing line downstream of the boiler.

Note 1: This definition is based on draft standard prEN 12952-1:1997 and is in conformity with annex 1 section 5 of the directive.

Note 2: This is a MINIMUM definition of the assembly.

Note 3: The ISOLATABLE superheaters, reheaters, economisers and related interconnecting tubing are not part of this minimum assembly. They can bear a CE marking separately or be integrated in the assembly if the manufacturer wishes so;

Note 4: The means of providing the boiler with feedwater and the means of preparing and feeding the fuel to the boiler are not part of this minimum assembly. They can bear a CE marking separately or be integrated in the assembly if the manufacturer wishes so.

Accepted by WPG on:	1999-07-15
Accepted by Working Group "pressure" on: on 2001-02-20)	1999-11-08 (editorial change by WPG

3.5. Guideline 3/5

Guideline related to: Article 3 paragraph 2.3, Article 15 paragraph 2, Annex II table 4

Question: Shall the assemblies defined in the Article 3 paragraph 2.3 carry the CE-marking?

Answer: Yes, in accordance with Article 15 paragraph 2, but the identification mark of the notified body is left out if the manufacturer has selected the use of module B1.

Reasons: The applied conformity assessment procedure is defined in table 4 of the Annex II, where the modules B1 and H are given as alternatives. In the case of module B1 there is no notified body involved at the production control phase, and according to article 15 paragraph 1 no identification mark is accompanied.

Note: Article 3 paragraph 2.3 assemblies to be CE-marked shall comprise, as a minimum, the boiler with its protection devices.

Accepted by WPG on:	2001-01-10
Accepted by Working Group "pressure" on:	2001-06-26

3.6. Guideline 3/6

Guideline related to: Annex I, sections 3.2.2 and 7.4

Question: **Must a hydrostatic pressure test be carried out on an assembly and should the value laid down in section 7.4 then be followed?**

Answer: Using the global conformity assessment of Article 10.2, each item of pressure equipment and the integration of the items of pressure equipment (Annex I, section 2.8) should be assessed.

Annex I, first preliminary observation determines that the requirements of Annex I also apply to assemblies, if corresponding hazard exists.

Each item of pressure equipment making up the assembly and referred to in Article 3.1 shall meet Annex I, section 3.2.2, and the pressure containment aspects for the connections/joinings should be assessed by appropriate methods, for example pressure test, NDT.

Accepted by WPG on:	1999-12-14
Accepted by Working Group "pressure" on:	2000-03-24

3.7. Guideline 3/7

Guideline related to: Article 10.2 (a)

Question: Which conditions shall be used in the assessment of an item of pressure equipment referred to in Article 3.1 without a separate CE-marking in an assembly being subject to the global conformity assessment procedure?

Answer: The conditions to be used to determine the category of this item shall be:

- the volume or nominal size DN, as appropriate, of the item ;
- at least the conditions PS, TS or group of fluid, for which the assembly is designed, which can be lower than the intrinsic conditions of the item.

For safety accessories, article 2 of Annex II applies.

Reasons: According to article 10.2. (a) the global conformity assessment procedure shall comprise assessment of each item of pressure equipment making up the assembly and referred to in Article 3 (1) which has not been previously subjected to a conformity assessment procedure and to a separate CE marking. The assessment procedure shall be determined by the category of the item, which may be based on the conditions of the assembly.

Accepted by WPG on:	2000-08-25
Accepted by Working Group "pressure" on:	2000-11-07

3.8. Guideline 3/8

Guideline related to: Article 1 paragraph 2.1.5

Question: Can some guidance be provided on the terms used in the definition of an assembly?

Answer: Items of pressure equipment form an assembly if :

1. they are integrated, i.e. they are connected and designed to be compatible with each other and
2. they are functional, i.e. together, they achieve specific, overall objectives and could be put into operation, and
3. they form a whole, i.e. all the items which are necessary for the assembly to function and be safe are present and
4. they are assembled by one manufacturer who intends the resulting assembly to be placed on the market and who will subject the assembly to a global conformity assessment procedure.

It is irrelevant whether completion of the assembly takes place at the manufacturer workshop or by the manufacturer on site.

Other factors will need to be considered to determine whether the Directive applies to a particular assembly. (See guideline 3/2).

Some possible examples of assemblies are pressure cookers, portable extinguishers, breathing apparatus, skid mounted systems, autoclaves; air conditioner, compressed air supply in a factory, refrigerating system, shell boilers, water tube boilers, distillation, evaporation or filtering units in process plants, oil heating furnaces.

Accepted by WPG on:	2000-10-02
Accepted by Working Group "pressure" on:	2000-11-07

3.9. Guideline 3/9

Guideline related to: Article 1, section 2.1.5, Article 10, section 2

Question: Does the Pressure Equipment Directive put formal upper limits to the extent of an assembly?

Answer: The PED does not limit the extent of an assembly, which can range from simple standard products up to large complex industrial plants.

An assembly can itself be composed of other assemblies and further items of pressure equipment.

For such a final assembly, two cases are possible:

- 1) When a manufacturer places on the market a product as a final assembly, consisting of assemblies and items of pressure equipment, intended to be put into service as such, he has to perform the global conformity assessment resulting in the CE-marking of the final assembly. If some of the constituent assemblies are not CE-marked – see guideline **3/10** - the individual items of pressure equipment shall be included in the global conformity assessment.
- 2) When a user takes the responsibility for the final assembly, it constitutes an installation as explained in guideline **3/2**.

Note: The definition of an assembly is explained in guideline **3/8**.

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Acceptedby Working Group "pressure" on:	2001-10-18

3.10. Guideline 3/10

Guideline related to: Article 3 paragraph 2.2, Article 14 paragraph 3, Article 15 paragraph 2

Question: Is it possible to put assemblies on the market which are not CE-marked?

Answer: Yes, for assemblies referred to in Article 3, paragraph 2.2:

– If the intention of the manufacturer is to place on the market an assembly not to be put into service as such but to become part of a bigger assembly or installation (see guideline 3/2), the global conformity assessment according to PED does not need to be applied to this assembly, which in this case will not be CE-marked. In this case, conformity assessment according to PED shall have been conducted for each item of pressure equipment.

– However, if the intention of the manufacturer is to place on the market an assembly to be put into service as such, the global conformity assessment procedure described in the directive must be conducted, resulting in the CE-marking of the assembly.

For boilers (Article 3 paragraph 2.1) refer to guidelines 3/1, 3/4 and 3/5.

Note 1: Assemblies the conformity of which has been assessed by a user inspectorate shall not bear the CE-marking.

Note 2: Assemblies in accordance with Article 3 paragraph 3 shall not bear the CE-marking (see guideline 2/18).

Note 3: This does not restrict the integration of CE-marked assemblies into bigger assemblies.

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Accepted by Working Group "pressure" on:	2001-10-18

3.11. Guideline 3/11

Guideline related to: Article 20; Article 3, section 2, Article 10, section 2.a)

Question: If an item of pressure equipment complies with national pre-PED Regulations and is placed on the market on, or before, 29 May 2002, is it possible for it to be subsequently included in an assembly which is placed on the market after 29 May 2002?

Answer: Only if it is shown that such pre-PED item of pressure equipment also complies with the requirements of the directive.

If an assembly, as referred to in Article 3, section 2, is placed on the market after 29 May 2002 then it must comply with the Directive. This requirement can only be met if the individual items of pressure equipment which form the assembly also comply with the Directive. This is achieved by using the global conformity assessment procedure as per Article 10.2a, where required (see also guideline [3/7](#)).

Accepted by WPG on:	2000-10-02
Accepted by Working Group "pressure" on:	2000-11-07

3.12. Guideline 3/12

Guideline related to: Article 10 paragraph 2; Annex I

Question: Do only the essential requirements given in Article 10 paragraph 2 apply to assessment of the integration of assemblies?

Answer: No, according to Annex I, first preliminary observation, the requirements of Annex I also apply to assemblies, where the corresponding hazards exist.

Examples of other ESRs which may be relevant to assemblies: 3.1.2 Permanent joining, 3.2.2 Proof test (see guideline 3/6), 3.4 Operating instructions, 6 (a) and (d) Thermal expansion and vibration of piping, ...

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Accepted by Working Group "pressure" on:	2001-10-18

3.13. Guideline 3/13

Guideline related to: Article 1 paragraph 2.1.5, Article 3 paragraph 2.2, Article 10 paragraph 2

Question: When several items of pressure equipment are assembled by a manufacturer to constitute a functional whole, and when one or several of those items are excluded from the PED, is the resulting whole considered as an assembly covered by the PED ?

Answer: The definition 2.1.5 of Article 1 does not prohibit non PED pressure equipment (pressurised equipment excluded by Article 1 paragraph 3) to be included in an assembly covered by the PED.

In the case of a PED assembly, the global conformity assessment required by Article 10 paragraph 2 does not include the assessment of non-PED items of pressure equipment.

The assessment of

- the integration of the assembly
- the protection of the assembly against exceeding the permissible operating limits shall be conducted in the light by the highest category of PED items of pressure equipment included, but it shall also take account of the characteristics of the non-PED equipment.

See also guideline [3/12](#).

Note 1: A hydraulic system of an item of machinery can meet the definition of Article 1 paragraph 2.1.5, but as it is not intended to be put into service as such, it is not covered by Article 3 paragraph 2.2 (see guideline [3/10](#)). On the other hand, a refrigeration system is considered to be a PED assembly even if some of the pieces under pressure are excluded from PED.

Note 2: In the sense of PED, an assembly is a pressurised system; a machine-tool, an earthmoving machinery, an agricultural tractor, a mobile crane is not, as a whole, a PED assembly.

Accepted by WPG on:	2002-04-10
Accepted by Working Group "pressure" on:	2002-05-23

3.14. Guideline 3/14

Guideline related to: Article 1 paragraph 2.1.5, Article 3 paragraph 2.3, Annex II, table 4

Question: Article 3, paragraph 2.3 states that the manually fed assemblies must comply with certain essential requirements. Furthermore article 1, section 2.1.5 states that the assemblies shall be assembled by the manufacturer.

Assuming that the manufacturer wants to use EC design-examination (module B1) in accordance with annex II, table 4, is it then sufficient that the manufacturer of the boiler gets an EC design-examination certificate or shall it be the installer (plumber), who assembles the protective devices to the boiler on site that must obtain the EC design-examination certificate?

Answer: As stated in guideline 3/5, Article 3 paragraph 2.3 assemblies comprise, as a minimum, the boiler with its protective devices.

However, it is sufficient that the manufacturer of the boiler gets an EC design-examination certificate, provided that he clearly specifies in his installation instructions which protective device can be used in the assembly and how it shall be installed.

The installation instructions shall be part of the EC design-examination.

See also guidelines 3/3 and 3/5.

Note: The module B1 assessment shall comprise essential safety requirements from Article 3 paragraph 2.3 as well as the operating instructions.

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Accepted by Working Group "pressure" on:	2002-10-03

3.15. Guideline 3/15

Guideline related to: Article 10 paragraph 2, Annex I section 3.1.2

Question: How are the categories of permanent joints in an assembly to be determined?

Answer: The category of permanent joints between the items of pressure equipment of an assembly shall be determined individually, taking into account the effect of the joining on the integrity of each of the items to be joined.

For example, the connection of a pipe to a vessel through a nozzle (already connected to the vessel) will, in general, be made according to the category of the pipe, provided that it does not affect the integrity of the vessel.

Note 1: For assemblies, the directive defines a global conformity assessment procedure and determines the category to be followed for essential safety requirements related to design (as stated in Article 10 paragraph 2b), and for the assessment of the protection (as stated in Article 10 paragraph 2c). For the other essential safety requirements applicable to the assembly (see guideline 3/12), in the absence of specific information in the directive for the category, it should be based on the categories of the items concerned.

Note 2: This is consistent with guideline 2/15, which makes a distinction between the category used for the assessment of the design, and the determination of the category regarding essential safety requirements.

See also guideline 3/16 for the category of the global conformity assessment procedure.

Accepted by WPG on:	2004-06-15
Accepted by Working Group "pressure" on:	2004-09-07

3.16. Guideline 3/16

Guideline related to: Article 10 paragraph 2b

Question: In Article 10.2.b what does the “highest category applicable to the equipment concerned” mean?

Answer: The category of each item of equipment making up the assembly is based on the conditions which can occur in the assembly, taking into account:

- the volume or nominal size DN, as appropriate, of the item ;
- at least the conditions PS, TS, type or group of fluid, for which the assembly is designed, which can be lower than the intrinsic conditions of the item.

The highest category determined from these conditions will then determine the assessment of the integration of the items in the assembly.

See also guidelines [3/7](#) and [3/15](#).

Note: When determining the conformity assessment module(s) for an assembly, it is possible to assign to an item of pressure equipment a lower category than that to which it was originally assessed. As a consequence, an assembly which is covered by Article 3 paragraph 3 can include a CE-marked item of pressure equipment.

Accepted by WPG on:	2003-03-24
Accepted by Working Group "pressure" on:	2003-04-28

3.17. Guideline 3/17

Guideline related to: Article 1 paragraph 2.1.5; Article 10 paragraph 2, Annex I sections 2.10, and 3.2.3

Question: Is it permissible to place on the market a CE marked assembly not equipped with protective devices where there is a risk of exceeding the allowable limits?

Answer: No, see guidelines 3/8, 3/9, 3/10 and 5/6.

Note 1: As required in Annex I section 3.2.3, the final assessment of the assembly includes checking of the safety devices. In some cases, this can be done only after assembly at the user's premises.

Note 2: The Declaration of Conformity shall not be drawn up for the assembly until the checking of safety devices has been completed.

Accepted by WPG on :	2005-11-28
Accepted by Working Group "pressure" on:	2006-03-31

3.18. Guideline 3/18

Guideline related to: Article 10 paragraph 2, Article 15 paragraph 3, Annex I section 3.3

Question: When items of pressure equipment making up an assembly have not been previously subjected to an assessment and are therefore assessed at the same time as the assembly in accordance with the point a) of article 10 paragraph 2, shall they carry the information required in annex I section 3.3?

Answer: No.

In that case Annex I section 3.3 requires that an appropriate document (operating instructions for the assembly) includes the information specified in this section. It is reminded that the operating instructions shall clearly identify all items of pressure equipment making up the assembly.

Reason: As the product put on the market is an assembly, the requirements only apply to this assembly. This is confirmed by Article 15 paragraph 3.

Note 1: In conformity with Annex VII of PED, the declaration of conformity of the assembly must also contain the description of the items of pressure equipment constituting the assembly (See also guideline 10/8).

Note 2: This does not preclude the assembly manufacturer from marking appropriate characteristics on items of equipment which can be necessary for safe installation, operation or use and, where applicable, maintenance and periodic inspection.

Accepted by WPG on :	2011-01-27
Accepted by Working Group "pressure" on:	2012-03-06

3.19. Guideline 3/19

Guideline related to: Article 10 paragraph 2

Question: If, during functional testing of an assembly at the user's premises by the manufacturer before placing it on the market, modification of an item of pressure equipment is necessary, shall this modification be carried out in accordance with Directive 97/23/EC?

Answer: Yes.

It is necessary to assess any modification within the global conformity assessment of the assembly even if the declaration of conformity for the item was already issued. This implies checking the technical documentation of this item by the manufacturer and the notified body to verify whether the original design is impacted.

Note: See Guidelines [1/3](#) and [1/4](#) for modification of pressure equipment in use.

Accepted by WPG on :	2011-01-27
Accepted by Working Group "pressure" on:	2012-03-06

3.20. Guideline 3/20

Guideline related to: Article 1 paragraph 3.19, Article 1 paragraph 2.1.5, Article 10 paragraph 2

Question: How to consider a transportable (TPED) pressure receptacle incorporated in an assembly being placed on the market under PED?

Answer: Two different cases have to be considered:

- 1) The TPED pressure receptacle will remain transportable pressure equipment which will be used as gas storage system and further on will be transported under transport regulations and filled in filling stations.

It is not required to re-assess such TPED pressure receptacle against PED.

- 2) The TPED pressure receptacle will permanently become part of a PED assembly (which means it will only be filled on-site).

The change of status from transportable (TPED) to static (PED) pressure equipment requires the formerly TPED pressure receptacle to be categorized and re-assessed against PED.

However for either case the correct incorporation has to be assessed against PED, see guideline [3/13](#).

Note: See also guideline [1/33](#).

Accepted by WPG on:	2013-01-17
Accepted by Working Group «pressure» on:	2014-03-20

4. EVALUATION ASSESSMENT PROCEDURES

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4.1. Guideline 4/1

Guideline related to: Annex III, module G

Question: Is design approval by a notified body required under module G?

Answer: Module G does not explicitly require formal design approval by a notified body but it does require the manufacturer to submit to a notified body, technical documentation to enable the design, manufacture and operation of the pressure equipment to be understood. It also requires the notified body to examine the design and construction of the pressure equipment to ensure its conformity with the requirements of the Directive which apply to it. It is expected that the notified body will report the outcome of the examination of the design to the manufacturer and this will effectively constitute design approval.

Reason: As stated above, module G does not contain any explicit requirement for approval of the design by the notified body. However, it is understood that design approval is common practice for the types of pressure equipment to which module G would be applied. Module G does require that a notified body must examine the design of the pressure equipment and it is considered reasonable to expect the notified body to inform the manufacturer of the results of the examination.

Accepted by WPG on:	1998-09-18
Accepted by Working Group "pressure" on:	1999-01-28

4.2. Guideline 4/2

Guideline related to: Annex III

Question: Can a manufacturer's existing QA certification which is in accordance with the standards EN ISO 9000 be taken into account by the notified bodies when approving QA systems for modules D, D1, E, E1, H or H1 of the PED?

Answer: A notified body when approving QA systems according to the modules D, D1, E, E1, H or H1 should take into account that the manufacturer already has ISO 9000 certification particularly if it has been certified by an accredited certifying organisation. However, the notified body has overall responsibility for ensuring that the QA systems satisfy the pressure equipment directive in particular on aspects in pressure equipment technology.

Reason: Q.A. systems under the modules D, D1, E, E1, H or H1 must cover the technical aspects in relation to the pressure equipment.

Accepted by WPG on:	1998-10-12
Accepted by Working Group "pressure" on:	1999-01-28

4.3. Guideline 4/3

Guideline related to: Annex III

Question: How to apply conformity assessment modules when some parts of an item of pressure equipment or some operations are sub-contracted?

Answer: There is only one manufacturer taking responsibility for each item of pressure equipment, who chooses one module (or combination of modules).

The conformity assessment is related to an item of pressure equipment and not to the parts considered alone.

It is the responsibility of the pressure equipment manufacturer to obtain from his sub-contractor the information and documentation required for the application of the module chosen. Depending on the module, the notified body could be required to visit the sub-contractor site, and it is the responsibility of the pressure equipment manufacturer to ensure access. If relevant work has been performed by different notified bodies at the sub-contractor site, it should be taken into account.

See also the Blue Guide (Guide to the implementation of directives based on New approach and Global approach) 3.1.1

Accepted by WPG on:	2000-05-04
Accepted by Working Group "pressure" on:	2000-06-29

4.4. Guideline 4/4

Guideline related to: Annex III

Question: If a manufacturer chooses to apply module B or B1 for the design phase, in combination with another module for the production phase, does the manufacturer have to choose the same notified body for the design and production modules?

Answer: No.

As requested by modules B and B1 (Annex III, points 5 and 6 of the corresponding modules), the examination certificate shall annex a list of the relevant parts of the technical documentation and any other relevant information, which allow the requirements of the production modules to be applied.

The number to be affixed to the pressure equipment is the number of the body involved at the production control phase (Article 15).

Accepted by WPG on:	2000-05-04
Accepted by Working Group "pressure" on:	2000-06-29

4.5. Guideline 4/5

Guideline related to: Annex III, module B1

Question: Clauses 3 and 4 of module B1 in Annex III deal with information concerning qualifications or approvals of permanent joining that may not be available at the design stage. What are the minimum requirements in clause 3, last indent, and clause 4.1, 2nd and 3rd indents?

Answer: Approval of operating procedures for permanent joining shall be made at the design stage, if not previously approved.

For the personnel performing permanent joining and non-destructive tests, the requirement at the design stage may be limited to the verification of the criteria for qualifications or approvals.

The need to perform the personnel approval verification at a later date before start of production should be pointed out in the design examination certificate.

See also guideline 4/4.

Accepted by WPG on :	2001-04-23
Accepted by Working Group “ pressure ” on :	2001-06-26

4.6. Guideline 4/6

Guideline related to: Article 10.2, Annex III

Question: Can an assembly be composed of pressure equipment dealt with using different conformity assessment modules?

Answer: Yes, by application of Article 10.2a).

For example, the valves can have a module different from that applied to the vessel or the piping on which they are placed.

Accepted by WPG on:	2000-08-25
Accepted by Working Group "pressure" on:	2000-11-07

4.7. Guideline 4/7

Guideline related to: Annex I, sections 1.2, 3.2.1 and 3.4, Annex III

Question: Shall the manufacturer of pressure equipment submit operating instructions as part of the conformity assessment by a Notified Body, and shall the Notified Body verify the content?

Answer: Yes.

PED requires the manufacturer to prepare operating instructions (see guideline 8/3) and supply them together with the equipment.

Appropriate operating instructions are an essential safety requirement (ESR) and shall therefore be part of the conformity assessment procedure.

When the Notified Body's duty includes performing or monitoring final assessment, it shall verify the existence of operating instructions and check their compliance with the Directive.

When the Notified Body's duty includes design examination, it shall verify that the intended use and residual hazards are described, and are intended to be included in operating instructions.

For modules based on quality systems, the existence of proper procedures to establish the various elements of the operating instructions shall be verified as part of the assessment of the quality system.

Accepted by WPG on:	2002-04-10
Accepted by Working Group "pressure" on:	2002-05-23

4.8. Guideline 4/8

Guideline related to: Annex III, module B1, sections 4.2 and 4.3

Question: Are tests by the notified body required for module B1?

Answer: No.

In contrast to module B, module B1 consists solely of the examination of drawings, calculations and relevant information concerning manufacturing. The experimental design method may not be used in this module. There are no examinations or tests to be performed on a representative example of the production envisaged.

See also guideline 4/5.

Note: There is inconsistency in some language versions.

Accepted by WPG on:	2001-04-23
Accepted by Working Group “pressure” on:	2001-06-26

4.9. Guideline 4/9

Guideline related to: Annexes I and III

Question: Is a manufacturer of component required to include a design examination, proof test and final inspection by a Notified Body if the component is intended for later use in PED equipment?

Answer: No. Components are not items of pressure equipment, and therefore are not subject to individual conformity assessment procedures.

For requirements on components to be used in pressure equipment, see guidelines [1/22](#) and [7/19](#).

Note 1: The final inspection including the proof test applies to the complete item of pressure equipment and not to the component itself.

Note 2: If the component is not designed according to a harmonised standard, design information may also be requested by the equipment manufacturer.

Note 3: There is no legal basis in PED for a Notified Body to issue a certificate of conformity for components.

Accepted by WPG on:	2003-03-06
Accepted by Working Group “pressure” on:	2003-04-28

4.10. Guideline 4/10

Guideline related to: Article 10, Annex I preliminary observation 3, Annex III

Question: There are many organisations that design pressure equipment that is subsequently fabricated by another organisation. Is it permissible for the company responsible for the design to obtain an EC design examination certificate (B1) and the fabricator obtain an appropriate certificate for the manufacturing phase, e.g. Product Verification (F).

Answer: No.

Even if different organisations can be involved, the directive clearly indicates that there can be only one "manufacturer" who is responsible for design, manufacture and conformity assessment of the pressure equipment.

The "manufacturer" may subcontract tasks in relation to design and/or manufacture but must retain overall control and have the necessary competence to take the responsibility for the product.

See also guideline 4/3.

See also the Guide to the Implementation of Directives based on New Approach and Global Approach.

Accepted by WPG on	2003-03-25
Accepted by Working Group "pressure" on:	2003-04-28

4.11. Guideline 4/11

Guideline related to: Article 1 Paragraph 2.1.3, Article 3 Paragraph 1.4 and Article 15

Question: Should the holder and the bursting disc which combine to produce a bursting disc safety device for use above 0,5 bar carry separate CE marking?

Answer: No, only the complete safety device can be conformity assessed, and only one CE marking shall be affixed. The CE marking shall be on the holder which is less likely to be replaced.

The declaration of conformity and instructions for use shall describe in an appropriate manner the components of the bursting disc safety device, and instructions for use shall identify which safety discs can be used on a specific holder.

Reason: Bursting disc safety devices are usually supplied as a set containing one holder and several spare discs. While both are components of a safety device and therefore should not be CE marked until assembled, for practical purposes the holder carries CE marking.

See also guideline [1/22](#).

Accepted by WPG on:	2005-04-20
Accepted by the Working Group "pressure" on:	2005-06-28

4.12. Guideline 4/12

Guideline related to: Annex III Module D, Module D1, Module E, Module E1, Module H and Module H1

Question: What information shall be included in the quality system approval notification document issued by the notified body concerning the scope of products?

Answer: The document for all quality system modules shall contain sufficient information to clearly define the scope of products covered by the approval and where applicable, any limitations or restrictions.

The following list of examples is not exhaustive:

- Product description (e.g. pressure vessels, shell boilers, shut-off valves, safety valves, piping, assembly)
- Product design code(s) applied (e.g. EN 13445, EN 12952, EN 12953, EN ISO 4126, EN 13480)
- Materials (e.g. ferritic steels, austenitic steels, non-ferrous, metals, plastics)
- Limitations/Restrictions, if applicable (e.g. dimensions, weight, performance)

In the case of modules D and E the initial quality system approval document shall include a listing of the relevant EC-type examination or EC Design Examination certificates as relevant.

In the case of module H1, it is not required that the results of the EC design examinations are listed in the initial quality system approval document.

For module H1, in addition to the requirements of module H, the notified body must examine the application and, where the design meets the provisions of the Directive which apply to it, issue an EC design-examination certificate to the applicant.

The certificate must contain the conclusions of the examination, the conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the functioning of the pressure equipment or accessories. So the initial stage of H1 is an approval of the management system.

In all cases the system must require the assessment of whether new or modified products will necessitate changes to the quality system, and that these are submitted to the notified body. The Notified Body shall inform the manufacturer if a reassessment of the quality system is required or if the new or modified products are within the scope of the existing system. In cases where no changes are required, a new quality system approval document does not need to be issued.

Any re-issue of the document shall update the list of type approval certificates.

WPG: only written consultation	
Accepted by Working Group "pressure" on:	2007-12-07

4.13. Guideline 4/13

Guideline related to: Annex I sections 3.2.1 and 3.2.2, Annex III Module F section 4.1 and Module G section 4.

Question: Is it permissible for the Notified Body to delegate the witnessing of the final inspection and proof test under module F or the proof test under module G to the manufacturer?

Answer: No.

In modules F and G, means and resources for carrying out the final inspection and/or proof test can be provided by the manufacturer to the Notified Body inspector, but the Notified Body shall be present during the final inspection and proof test.

Accepted by WPG on:	2005-11-28
Accepted by the Working Group "pressure" on:	2006-03-31

4.14. Guideline 4/14 (pending)

4.15. Guideline 4/15

Guideline related to: Article 15 paragraph 1, Annex III Modules D/D1, E/E1, H/H1

Question: A manufacturer has equipment in stock manufactured under a QA module (D/D1, E/E1 or H/H1). After expiry of the QA system certification the manufacturer switches from Notified Body "X" to Notified Body "Y" for the new certification.

Can the manufacturer deliver equipment with Notified Body number "X" to his customers after the expiry date of the certificate?

Answer: Yes,
Provided that the final assessment has been performed under the QA system certified (and surveyed) by Notified Body "X" before the expiry date of the system certificate.

The manufacturer must keep records of which notified body approval his equipment was manufactured under. One solution is to include a date on the declaration of conformity.

Accepted by WPG on:	2010-11-25
Accepted by the Working Group "pressure" on:	2012-03-06

5. INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON DESIGN

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5.1. Guideline 5/1

Guideline related to: Annex I Paragraph 2.2.2; Annex I Point 2.2.4

Question: How should the condition related to the experimental design method without calculation in Annex I, Section 2.2.2 be interpreted stipulating that:

Experimental design may be carried out without any calculation in accordance with Section 2.2.4 if the product of the maximum permissible pressure PS and the volume V is less than 6000 bar.litre or the product PS.DN is less than 3000 bar?

Answer: It shall be understood that:

- the condition $PS.V < 6000 \text{ bar.L}$ is applicable to equipment for which the classification criterion in annex II is the volume (vessels, boilers and when applicable, accessories, etc.);
- the condition $PS.DN < 3000 \text{ bar}$ is applicable to equipment for which the classification criterion in annex II is the nominal size (piping and when applicable, accessories, etc.).

Note: Module B1 is not applicable to equipment validated by experimental design.

Accepted by WPG on:	1998-11-27
Accepted by Working Group "pressure" on:	1999-01-28

5.2. Guideline 5/2

Guideline related to: Annex I, sections 2.11.2, 2.12

Question: In respect of pressure limiting devices, does the PED require that the permitted short duration pressure surge of 1,1 PS be maintained when the equipment is exposed to external fire conditions ?

Answer: The 1,1 PS restriction does not apply to fire.

Reasons: The requirement in Annex I section 2.12 for external fire refers to damage limitation, and does not serve the purpose of pressure limiting device in normal operation.

Accepted by WPG on:	2000-05-05
Accepted by Working Group "pressure" on:	2000-06-29

5.3. Guideline 5/3

Guideline related to: Annex I point 3 of preliminary observations, sections 1.1, 2.1, 2.3 and 2.8

Question: Is leakage of pressure equipment covered by PED?

Answer: Yes, whenever internal or external leakage (i.e. leakage to atmosphere/environment) is a hazard due to pressure, it is covered by the essential safety requirements of PED.

All hazards arising from pressure shall be assessed for the intended use and the intended contained fluid(s), not only the requirement for sufficient strength but also internal/external leakage and all functional requirements related to pressure hazards (see also guideline [1/15](#)).

For pressure equipment where the detailed specific use is not known by the equipment manufacturer, the above consideration shall be addressed by the assembly manufacturer as per Annex I section 2.8.

Remark: The version of 26 June 2001 is revised to make clear that this guideline does not only apply to valves.

Accepted by WPG on:	2003-02-19
Accepted by Working Group "pressure" on:	2003-04-28

5.4. Guideline 5/4

Guideline related to: Article 10 paragraph 2(c) and Annex I, sections 1.3, 2.8, 2.9, 2.10, 2.11, 2.12 and 3.2.3

Question: Shall portable extinguishers be equipped with protective devices against over-pressure?

Answer: The prevention of danger due to overpressurization of fire extinguishers shall be achieved for all foreseeable circumstances either by eliminating the hazard by the design, or by providing a protective device.

The risk of external fire shall be adequately considered according to the type of fire extinguisher.

Due to the fact that portable extinguishers are very wide-spread and are also consumer products, their possible misuse (over-filling, use of incorrect cartridge ...) must be carefully assessed. Written instructions alone cannot be regarded as sufficient.

Examples: In general the risk of over-filling is significant for cartridge type fire extinguishers, which are manually (re-)filled.

External fire will cause high risks for CO₂ fire extinguishers (cylinders).

In such cases protective devices or similar methods shall be taken to meet damage limitation requirements.

Accepted by WPG on:	2002-04-09
Accepted by Working Group "pressure" on:	2002-05-23

5.5. Guideline 5/5

Guideline related to: Annex I section 2.1 and section 2.2.4

Question: Is it possible that the sample to be tested for the experimental design method be produced without its thicknesses reduced by the corrosion allowance?

Answer: Yes, but the corrosion allowance as well as other characteristics are to be used as corrective factors to determine the minimum value for the test pressure, as stated in 2.2.4 a) second paragraph.

Accepted by WPG on:	2002-09-19
Accepted by Working Group "pressure" on:	2003-01-27

5.6. Guideline 5/6

Guideline related to: Article I paragraph 2.1.3, Annex I section 2.10, Annex I section 2.11

Question: Does the essential safety requirement 2.10, which deals with protective devices, give the choice of the use of a safety accessory or of the use of a monitoring device?

Answer: No.

When, under reasonably foreseeable conditions, the allowable limits could be exceeded, a protective device in the form of a safety accessory must be provided, with the addition, where appropriate, of a monitoring device.

Note: Annex I section 2.11 sets out the essential safety requirements for the safety accessories that do not apply to monitoring devices. In particular, safety accessories shall comply with the essential safety requirements by appropriate design principles. This is in order to obtain suitable and reliable protection that does not rely on instructions for regular supervision during use.

Accepted by WPG on :	2006-11-22
Accepted by Working Group "pressure" on:	2007-04-18

5.7. Guideline 5/7

Guideline related to: Annex I section 2.2.2

Question: Are the limits in Annex I section 2.2.2 applicable to components of pressure equipment (like manhole covers, special flanges, etc)?

Answer: No. The limits specified in Annex I section 2.2.2 second indent concern the item of pressure equipment, not its components.

The results of the experimental method applied to components are taken into account in the design of the item of pressure equipment.

See also guideline 4/9.

Accepted by WPG on:	2005-04-20
Accepted by the Working Group "pressure" on:	2005-06-28

5.8. Guideline 5/8

Guideline related to: Annex I Section 2.11.1

Question: In the 3rd paragraph of the essential safety requirement 2.11.1, there is the sentence “These principles include, in particular, fail-safe modes, redundancy, diversity and self-diagnosis.”, therefore do all safety accessories require to be for example “self-diagnosis”?

Answer: No.

The sentence lists a number of separate possible design principles that could be used to obtain suitable and reliable protection; it is not an exhaustive list. “Self-diagnosis” is for example part of the list of separate possible design principles, not an additional requirement. The design principle to be used for any particular application should be based on the hazard analysis and could indicate that other methods are just as suitable or that more than one design principle should be used.

Accepted by WPG on:	2011-10-06
Accepted by the Working Group "pressure" on:	2012-03-06

5.9. Guideline 5/9

Guideline related to: Annex I section 2.11.2

Question: Is there a value defined for the acceptable limit of the short duration referred to in Annex I section 2.11.2?

Answer: No

The duration corresponds to the time needed to reduce the pressure below PS. It depends on the dynamics of transient pressure surges that can be highly variable from one equipment to another.

The pressure limiting device shall have appropriate characteristics (flow capacity, set pressure in relation to PS, etc) to relieve the pressure safely.

Accepted by WPG on	2013-04-25
Accepted by Working Group “pressure” on:	2014-03-20

6. INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MANUFACTURING

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6.1. Guideline 6/1

Guideline related to: Annex I, section 3.1.2

Question: According to section 3.1.2 (permanent joining) of Annex I, the third party must perform examinations and tests in order to carry out the approvals of operating procedures and personnel. Must the representative of the third party witness the whole permanent joining and testing process?

Answer: No, in accordance with and under the responsibility of the notified body or of a third party organisation recognised by a Member State, some practical tasks concerning the approval of joining operating procedures and personnel may be accomplished by a competent person of a manufacturer according to a quality system.

Note 1: The Notified Body or Recognised Third Party Organisation must attend part of the different steps in the process for each procedure and for each person.

Note 2: See also section 6.5 of the “Blue Guide”

Acceptedby WPG on:	2005-11-28
Acceptedby Working Group "pressure" on:	2006-03-31

6.2. Guideline 6/2

Guideline related to: Annex I, section 3.2.1

Question: Which documents have to be available for the final inspection specified in Annex I, section 3.2.1?

Answer: In general the following documents should be available as appropriate:

- evidence of qualification of NDT personnel relevant to the equipment category;
- evidence of qualification of permanent joining personnel relevant to the equipment category;
- data dealing with heat treatment (e.g. diagram of temperatures);
- inspection documents for base materials and consumables;
- procedures for assuring material traceability;
- NDT test reports, including radiographic films;
- test reports of destructive tests (e.g. test coupons);
- reports on defects or deviations arising during manufacture;
- data related to the preparation of component parts (e.g. forming chamfering);
- evidence of qualification of permanent joining procedures;

These documents shall be available for final inspection whether that inspection is carried out by the manufacturer, the user inspectorate or the notified body.

Accepted by WPG on:	1998-11-26
Accepted by Working Group “pressure” on:	1999-01-28

Outcome of WGP discussions on 28/1/1999: To indicate that the need for documents for final inspection can vary depending on the case, the first sentence of the answer has been changed to start with “in general”. An editorial amendment has been inserted in the last dash of the answer.

WGP agreed to the proposal. However, WPG was asked to include a requirement on the submission of some drawings.

6.3. Guideline 6/3

Guideline related to: Annex I, points 3.1.1 and 3.1.2

Question: How to interpret point 3.1.1 of Annex I as far as the forming procedures are concerned?

Does it impose for the manufacturer a qualification procedure for forming operations which will be validated by the Notified Body?

Answer: The Directive does not require for qualification of forming procedures in point 3.1.1 of Annex I, although it includes such a qualification for permanent joints in point 3.1.2 of Annex I.

But there is an essential requirement about the preparation of the component parts (cf Annex I, point 3.1.1) and the manufacturer shall demonstrate in the technical documentation of the equipment that this requirement has been satisfied.

Depending on the modules, the Notified Body may examine this technical documentation.

Accepted by WPG on:	1998-10-13
Accepted by Working Group "pressure" on:	1999-01-28

6.4. Guideline 6/4

Guideline related to: Annex I, point 3.1.2

Question: **Must a Notified Body take into account a procedure of permanent joints qualified by another Notified Body or a recognised third-party organisation?**

Answer: Yes, a Notified Body is not allowed to reject an approval of procedure of permanent joints made on the basis of a precise reference and applying competence in accordance with the PED.

Nevertheless, it is its responsibility to verify, if needed, that the joining process and the reference to the manufactured product are adequate.

Accepted by WPG on:	1998-11-26
Accepted by Working Group “pressure” on:	1999-01-29

6.5. Guideline 6/5

Guideline related to: Annex I, points 3.1.2 and 3.1.3

Question: Do the requirements related to permanent joints given in Annex I, sections 3.1.2 and 3.1.3 apply also to permanent joints other than welded joints?

Answer: Yes.

Reason: The definition in Article 1 paragraph 2.8 also covers other permanent joints such as e.g. those produced by brazing, braze welding, expansion, gluing, fretting and riveting.

For that reason, the requirements of 3.1.2 and 3.1.3 apply also for these types of joints.

Note: Removable expansion devices (e.g. expansion plug for sealing exchanger tubes) do not require destructive methods to be disconnected and therefore are not permanent joints.

Accepted by WPG on:	2012-01-12
Accepted by Working Group "pressure" on:	2012-03-06

6.6. Guideline 6/6

Guideline related to: Article 1 paragraph 2.8, Annex I section 3.1.2

Question: In the absence of harmonized standards, what approach is to be followed for the approval of personnel carrying out permanent joining?

Answer: In the absence of harmonized standards, the manufacturer shall refer to an existing document (draft standard candidate for harmonization, professional document, guide, recognised third party/notified body document, company document, etc.) or shall establish a specific document.

Such a document shall define at least:

- equipment to be used by the personnel;
- degree of automatization of the process and the operations to be carried out by the personnel;
- conditions to apply when making the test piece to be used for the test approval and results to be achieved;
- range of validity and conditions for the duration of the validity.

See also Guideline [6/1](#).

For welding, see Guideline [6/12](#).

Accepted by WPG on:	2002-03-13
Accepted by Working Group "pressure" on:	2002-05-23

6.7. Guideline 6/7

Guideline related to: Annex I, section 3.1.3

Question: Does the concept of non-destructive testing as mentioned in Annex I section 3.1.3 also cover visual examination?

Answer: No.

Consequently, section 3.1.3 in Annex I is not applicable to personnel undertaking "visual testing" as dealt with in EN 473:2000.

Accepted by WPG on:	2002-09-18
Accepted by Working Group "pressure" on:	2002-10-03

6.8. Guideline 6/8

Guideline related to: Annex I, section 3.1.2

Question: What are "the appropriate harmonized standards" in Annex I, section 3.1.2, last paragraph, which set out the examinations and tests for the approval of permanent joining procedures and personnel ?

Answer: The appropriate harmonized standards are

- the specific harmonized supporting standards, subject to verification of their suitability for the equipment being built.
- or
- the relevant harmonized product standards.

In both cases the relevant requirements of PED Annex I section 3.1.2 are to be covered by the standard and these provisions are to be referenced in Annex ZA.

Accepted by WPG on:	2001-02-21
Accepted by Working Group "pressure" on:	2001-06-26

6.9. Guideline 6/9

Guideline related to: Annex I sections 3.1.1, 3.1.2, 3.1.3 and 7.2

Question: Does the Pressure Equipment Directive require accreditation for the manufacturer's testing laboratory that carries out non-destructive tests (NDT) or destructive tests (DT) of pressure equipment or of parts intended as pressure bearing parts of pressure equipment?

Answer: No.

According to Annex I section 3.1.3 the PED requires qualification for NDT personnel that carry out NDT of permanent joints. No accreditation is required for the manufacturer's NDT or DT laboratory or for the testing laboratory that the manufacturer may subcontract for NDT or DT.

Accepted by WPG on:	2001-02-21
Accepted by Working Group " pressure " on:	2001-06-26

6.10. Guideline 6/10

Guideline related to: Annex I, section 3.1.2

Question: If a manufacturer has a procedure for permanent joining approved by a notified body or other recognized third-party organization at one site (location), may that manufacturer use the same procedure at other sites for similar applications?

Answer: Yes, provided the other sites are under the same technical and quality management.

Note: Standard EN 719 on welding co-ordination and standard EN 729-1 on quality requirements for welding define manufacturing organization as welding workshops or sites under the same technical and quality management. Standard EN 288-3 on welding procedure tests states that an approval of a welding procedure specification (WPS) obtained by a manufacturer is valid for welding in workshops or sites under the same technical and quality control of that manufacturer.

Accepted by WPG on:	2001-11-21
Accepted by Working Group "pressure" on:	2002-02-27

6.11. Guideline 6/11

Guideline related to: Article 1 paragraph 2.8, Annex I section 3.1.2

Question: In the absence of harmonized standards, what approach is to be followed for the approval of permanent joining procedures?

Answer: In the absence of harmonized standards, the manufacturer shall refer to an existing document (draft standard candidate for harmonization, professional document, guide, recognised third party/notified body document, company document) or shall establish a specific document.

Such a document shall define at least:

- essential variables for the procedure that may affect the properties of the permanent joining;
- inspection and testing to be carried out for the qualification of the procedure;
- acceptance criteria ;
- range of validity.

Note: The directive states that “the properties of permanent joints must meet the minimum properties specified for the materials to be joined unless other relevant property values are specifically taken into account in the design calculations”.

See also Guideline [6/1](#).

For welding, see Guideline [6/12](#).

Accepted by WPG on:	2002-03-13
Accepted by Working Group "pressure" on:	2002-05-23

6.12. Guideline 6/12

Guideline related to: Annex I section 3.1.2

Question: In the context of approval of welding procedures and personnel, what is meant by “the third party must perform examinations and tests as set out in the appropriate harmonized standards or equivalent examinations and tests”?

Answer: Where the directive refers to equivalent examinations and tests it is required that suitable and sufficient tests are conducted to determine the same range of technological properties as those in the harmonized welding standards. Where similar tests have already been conducted that establish a particular property but the precise testing conditions vary from those in the above standard, there is no requirement to repeat the test. However, those technological properties which are not the subject of these similar tests shall be added to the testing schedule. If for example the impact property in the weld has already been tested but not the heat affected zone (HAZ), this latter remains to be tested.

Note 1: The tests which are intended to determine the same range of technological properties are the non destructive and destructive tests required by the relevant harmonized welding standards.

Note 2: The additional tests shall be performed under the responsibility of a competent third party (see also Guideline [6/1](#)).

Note 3: The current version of ASME Boiler & Pressure Vessel code Section IX is an example of where properties are not sufficiently dealt with for some applications in order to comply by itself with the PED (for example: impact property in the HAZ; hardness test etc.). Furthermore, it does not require that the tests and examinations shall be performed under the responsibility of a third party (see also Guidelines [6/1](#) and [6/4](#)).

Accepted by WPG on:	2013-09-18
Accepted by Working Group "pressure" on:	2014-03-20

6.13. Guideline 6/13

Guideline related to: Annex I section 3.1.3.

Question: For pressure equipment in categories III and IV, can Non-Destructive Testing personnel holding qualifications other than those satisfying criteria of the harmonised standards (e.g. EN 473:2000 General principles for qualification and certification of NDT personnel) be approved by Recognised Third Party Organisations (RTPO) notified by a member state under Article 13 paragraph 1?

Answer: Yes.

NDT personnel certified under standards, other than the harmonised standards, may be approved by a RTPO provided it is satisfied that certification criteria equivalent to the harmonised standards have been met, and that the scope of certification is relevant to the testing of permanent joints in pressure equipment.

A RTPO may sub-contract part of its work, within the provisions of the New Approach guide, but shall keep the full responsibility and issue the approval. The approval of the personnel shall be done by a RTPO on an individual basis.

Note: Approval of an individual solely on the basis of a certificate issued by another body where no contractual arrangement exists with the RTPO does not fulfil the requirement of the Pressure Equipment Directive.

Accepted by WPG on:	2003-12-17
Accepted by the Working Group "pressure" on:	2004-03-17

6.14. Guideline 6/14

Guideline related to: Annex I sections 3.1.1 and 3.1.2

Question: Does any welding operation on a pressure bearing component have to require a qualification of the welding procedures and of the welders/welding operators?

Answer: Yes, when the weldment can create a pressure hazard on the pressure bearing component.

Examples of welding operation for which qualification is required according to Annex I section 3.1.2 include:

- 1) Welding of a lifting lug on a pressure bearing chamber;
- 2) Welding of an attachment to a valve body;
- 3) Welding of reinforcing pads for nozzles;
- 4) Repair by welding on a chamber before placing on the market;
- 5) Major welding on a casting during production.

Examples of welding operations for which qualification is required according to Annex I section 3.1.2, unless the hazard analysis demonstrates that there is no pressure hazard, include:

- 1) Minor welding on a casting during production;
- 2) Buttering of a tubesheet;
- 3) Overlay welding on a pressure chamber (anticorrosive, wear coating...).

Accepted by WPG on:	2004-12-16
Accepted by the Working Group "pressure" on:	2005-01-19

6.15. Guideline 6/15

Guideline related to: Annex I section 3.1.2

Question: Where approval of operating procedures for permanent joining is required by the PED and the approval is granted on the basis of a document other than a harmonized standard, should this approval explicitly mention the PED?

Answer: Yes.

The approval certificate should also indicate the tests performed in addition to those in the document used for approval.

If certificates do not include a reference to the PED, the application of the last paragraph of Annex I section 3.1.2 shall be checked through the detailed examination of the WPQR (Welding Procedure Qualification Record).

Accepted by WPG on:	2012-04-24
Accepted by Working Group "pressure" on:	2013-03-07

Remark: Reservation by Sweden

6.16. Guideline 6/16

Guideline related to: Annex I Section 3.1.2 and 3.2.2

Question: Do the essential safety requirements apply to temporary components used by the equipment manufacturer either during the manufacturing or for the proof test of a pressure equipment?

Answer: No, unless the joining of this temporary component, for example by welding, is likely to affect the safety of the equipment during its future operation.

However, the manufacturer is responsible for the application of these components, which must have an adequate level of safety and meet the national labour regulation. Examples of temporary components: temporary closure for proof testing, lifting lugs welded on an additional thickness to be removed later.

Accepted by WPG on:	2013-04-25
Accepted by Working Group "pressure" on:	2014-03-20

6.17. Guideline 6/17

Guideline related to: Annex I section 3.2.2

Question: Is the manufacturer allowed to replace non permanent joining components (bolts, studs, nuts, washers, gaskets) at the end of the proof test without carrying out a new proof test?

Answer: Yes

Note: The manufacturer should ensure that the replacement components are equivalent to those specified in the technical documentation.

Accepted by WPG on:	2013-04-25
Accepted by Working Group “pressure” on:	2014-03-20

6.18. Guideline 6/18

Pending

6.19. Guideline 6/19

Guideline related to: Annex I section 3.1.2

Question: The Essential Safety Requirements define in Annex I chapter 3.1.2 that the properties of welded joints shall meet the minimum properties specified for the materials to be joined unless other relevant property values are specifically taken into account by the design process.

Do these requirements apply also for impact property values?

Answer: Yes, in general also the impact property values shall meet the specified minimum properties of the materials joined.

Lower values are acceptable if specified by the product standard or justified by the design.

Annex I, 4.1(a) refers to 7.5 regarding specific requirements of materials. To reach sufficient ductility for steel the impact value shall be at least 27 J at lowest operating temperature.

Accepted by WPG on:	2014-07-01
Accepted by Working Group "pressure" on:	2015-03-11

7. INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MATERIALS

1	SCOPE AND EXCLUSIONS OF THE DIRECTIVE
2	CLASSIFICATION AND CATEGORIES
3	ASSEMBLIES
4	EVALUATION ASSESSMENT PROCEDURES
5	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON DESIGN
6	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MANUFACTURING
7	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MATERIALS
8	INTERPRETATION OF OTHER ESSENTIAL SAFETY REQUIREMENTS
9	MISCELLANEOUS
10	GENERAL-HORIZONTAL QUESTIONS

7.1. Guideline 7/1

Guideline related to: Annex I, section 4.2 b)

Question: What is to be understood by harmonised standard as referred to in Annex I, section 4.2 b)?

Answer: A harmonized standard in this context can be a harmonized product standard for an item of pressure equipment or an assembly which may be CE marked.

It could also be a harmonized supporting standard for materials, that contains technical data clearly indicating the field of application.

In the case of a harmonised supporting standard for materials, presumption of conformity to the ESRs is limited to technical data of materials in the standard and does not presume adequacy of the material to a specific item of equipment. Consequently the technical data stated in the material standard shall be assessed against the design requirements of this specific item of equipment to verify that the ESRs of the PED are satisfied.

Note: Subsequent manufacturing processes affecting properties of the base material shall be taken into account when assessing the conformity of the pressure equipment to the material requirements of the directive.

Acceptedby WPG on:	2001-02-21
Acceptedby Working Group "pressure" on:	2001-06-26

7.2. Guideline 7/2

Guideline related to: Annex I, section 4.3, third paragraph

Question: What is a ‘competent body’ for the certification of the quality (assurance) systems of material manufacturers?

Answer: A ‘competent body’ for certification of the quality systems of material manufacturers can be any third party body established as a legal entity within the Community which has recognized competence in the assessment of quality (assurance) systems for the manufacture of materials and in the technology of the materials concerned. Competence can be demonstrated, for example, by accreditation.

See also guideline 7/7.

Note 1: A body not established as a legal entity within the Community, even if it has a recognition agreement through the International Accreditation Forum, does not comply with the requirements of Annex I section 4.3.

Note 2: A notified body may perform this task only if it has a recognized competence in the field of quality assurance, materials and related process technology. For this certification, the possible use of the notification number for PED is irrelevant.

Note 3: The certificate of quality system shall make reference to the legal entity established in the Community and its address.

Acceptedby WPG on:	2005-11-28
Acceptedby Working Group "pressure" on:	2006-03-31

7.3. Guideline 7/3

Guideline related to: Article 11.2

Question: A notified body is in the process of giving a European approval for materials. In Article 11.2 an information process with delays is given. Having sent out the information the notified body must wait for comments. How long must the body wait?

Answer: The approval can be given three months after the mailing date of the information, with one exception: if a Member State or the Commission refers the matter to the Standing Committee set up by Article 5 of Directive 98/34/EC (ex 83/189/EEC), it must inform the notified body which must wait for a letter from the Commission giving the conclusions of the Committee.

Accepted by WPG on:	1998-11-26
Accepted by Working Group "pressure" on:	1999-01-29

7.4. Guideline 7/4

Guideline related to: Annex I, section 3.1.5

Question: What are the 'suitable means' for traceability referred to in annex I, section 3.1.5?

Answer: The objective of traceability is to avoid any doubt about the material specification used for a type of equipment. The suitable means shall be determined according to the type of equipment and its manufacturing conditions: for instance, complexity of the product, unitary or serial products, risk of mixing of material grades, etc.

These means range from physical marking of individual items by stamping or colour coding to procedural methods. It is not always necessary for the identification of material to be linked to a specific delivery.

The traceability system should be proportionate to the risk of mixing material grades during the manufacturing process. When there is no such a risk, the system may be limited to administrative means.

Note 1: The traceability system of the manufacturer shall allow him to provide to a market surveillance authority, upon request, the technical documentation related to a specific item of pressure equipment and the material certificate.

Note 2: When a national authority applies the safeguard clause for a particular product due to the material, the decision will relate to all products made from the same material grade specification, if the traceability system does not allow the identification to relate to (a) specific delivery(ies). The same will apply if a manufacturer withdraws non-compliant or defective products from the market.

Accepted by WPG on:	2002-04-09, proposed amendment on 2006-10-18
Accepted by Working Group "pressure" on:	2002-05-23, amended on 2006-11-21

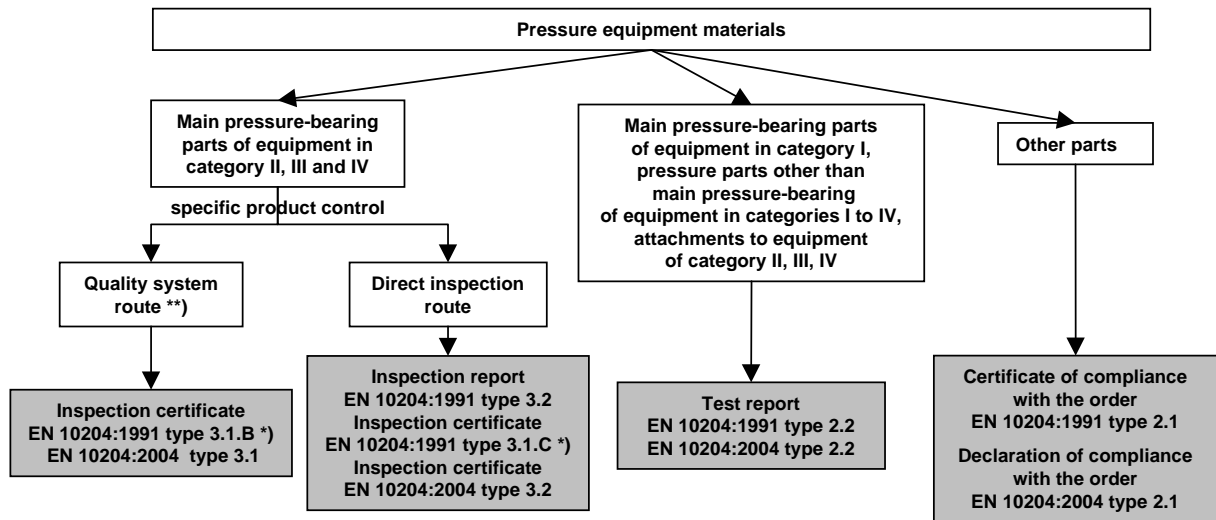
7.5. Guideline 7/5

Guideline related to: Annex I, section 4.3

Question: Annex I, section 4.3 of the PED requires that the equipment manufacturer must take appropriate measures to ensure that the material used conforms with the required specification. In particular, documentation prepared by the material manufacturer affirming compliance with a specification must be obtained for all materials.

How may these requirements be applied in terms of required inspection documents?

- Answer:**
1. According to the 1st paragraph of Annex I, section 4.3, the material manufacturer shall certify, that the delivery complies with the requirement of the specification and the order he has received. This affirmation of compliance shall be stated on or appended to the certificate, whichever type is issued.
 2. According to the 2nd paragraph of Annex I, section 4.3 a certificate of specific product control is required for the main pressure-bearing parts of pressure equipment in categories II, III and IV. Account shall be taken of the requirements in 4.1 and 4.2 (a) of Annex I.
 3. According to the 3rd paragraph of Annex I, section 4.3 a distinction is made for the material manufacturer's fabrication system: where he has an appropriate quality (assurance) system certified by a competent body established within the Community, and having undergone a specific assessment for materials, an inspection document from the manufacturer is appropriate (see also guidelines 7/7 and 7/16).
 4. The general requirements for all other cases are given in the first 2 paragraphs of Annex I, section 4.3.
 5. A scheme of the relevant inspection documents when following EN 10204:1991 or EN 10204:2004 is given in the following diagram:



*) see also item 1) of the answer

**) see also item 3) of the answer

- Notes:**
- 1) An inspection document of a higher level is always acceptable.
 - 2) Material from stockists shall be accompanied by inspection documents from the material manufacturer.
 - 3) For traceability and transfer of marking, see also guideline [7/4](#).
 - 4) For main pressure bearing parts, see also guideline [7/6](#), and for attachments see definition 2.1 of Article 1 of the Directive.
 - 5) For components, see guideline [7/19](#).
 - 6) As regards joining materials, see guideline [7/10](#)
 - 7) Previously, the affirmation of compliance was not included in the definition of certificate 3.1.B or 3.1.C according to EN 10204:1991, but is now included in the definition of certificate 3.1 of EN 10204:2004.

Accepted by WPG on:	2007-03-27
Accepted by Working Group "pressure" on: with integration of guideline 7/20	2007-04-18,

7.6. Guideline 7/6

Guideline related to: Annex I, section 4.3

Question: The 2nd paragraph of section 4.3 of Annex I gives requirements for the main pressure-bearing parts. How are they defined?

Answer: The main pressure-bearing parts are the parts, which constitute the envelope under pressure, and the parts which are essential for the integrity of the equipment.

Examples of main pressure-bearing parts are shells, ends, main body flanges, tube sheet of exchangers, tube bundles.

The materials for these main pressure-bearing parts of equipment of categories II to IV shall have a certificate of specific product control (see Guideline 7/5).

See also guideline 7/8 for bolting parts (fasteners).

Accepted by WPG on:	2000-11-29
Accepted by Working Group "pressure" on:	2001-06-26

7.7. Guideline 7/7

Guideline related to: Annex 1, paragraph 4.3

Question: To what apply the terms “having undergone a specific assessment for materials” of third § of 4.3 of annex I?

Answer: It is the quality (assurance) system of the material manufacturer which shall have undergone a specific assessment for materials (and not the competent body).

Note: See also guideline 7/2.

Accepted by WPG on:	1999-07-15
Accepted by Working Group “pressure” on:	1999-11-08

7.8. Guideline 7/8

Guideline related to: Annex 1, section 4

Question: What are the certificates required for bolting parts?

Answer: The bolting parts (screw, nut, stud, etc) are joining components.

When these components contribute to the pressure resistance, their materials shall fulfil the relevant requirements of annex I, section 4.

Regarding section 4.3 of Annex I, a bolt is not considered to be a main pressure bearing part unless its failure would result in a sudden discharge of pressure energy.

When bolts are used as

- main pressure bearing parts a certificate of specific product control is required (unless the item of pressure equipment itself is in Category I)
- pressure bearing parts a test report is sufficient,
- non pressure bearing part a certificate of compliance is sufficient.
(refer to guideline [7/5](#)).

Accepted by WPG:	2000-10-02
Accepted by Working Group “pressure” on:	2000-11-07

7.9. Guideline 7/9

Guideline related to: Annex I, section 4

Question: Can a material manufactured according to a standard or another publicly available specification for which a European Approval of Materials (EAM) is available, but for which the inspection document only refers to the standard or the specification on which the EAM has been based, be used for pressure equipment manufactured under the PED ?

Answer: Yes, if the EAM does not have any additional technical specification compared to the standard or the specification. The inspection document must satisfy the requirements of section 4.3 of Annex I (see also guidance 7/5).

Accepted by WPG on:	1999-10-26
Accepted by Working Group “pressure” on:	2000-03-24

7.10. Guideline 7/10

Guideline related to: Annex I, sections 3.1.2; 3.1.5; 4.1; 4.2(a) and 4.3 1st paragraph

Question: What are the requirements for the documentation and traceability of welding consumables:

- Inspection documents
- Suitable procedures for traceability?

Answer: Manufacturers of welding consumables shall provide inspection documents affirming compliance with the specification.

Based on section 4 of Annex I and guideline 7/5 manufacturers of welding consumables shall provide test report "2.2" as an inspection document in accordance with the standard EN 10204.

The traceability requirement of Annex I section 3.1.5 applies also for welding consumables. It can be maintained by procedural methods that cover receipt, identification, storage, transfer to production, temporary storage and use in production, availability of correct inspection documents at the final inspection (see also guideline 7/4).

Note: Welding consumables are defined by trade name, designation and relevant EN classification standard. Inspection documents of welding consumables should give test results, for technical characteristics according to designation and classification standard, such as:

- Chemical composition of welding filler metal or all-weld metal as appropriate
- Tensile properties of all-weld metal: tensile and yield strength, elongation
- Impact properties of all-weld metal at temperature according to designation.

Test results are based on non-specific inspection and testing. They can be given for example as typical values based on quality control tests.

Acceptedby WPG on:	2002-06-19
Acceptedby Working Group "pressure" on:	2002-10-03

7.11. Guideline 7/11

Guideline related to: Annex I

Question: Do the essential safety requirements of annex I apply to pressure equipment manufactured from plastic, GRP and other non metallic materials?

Answer: Yes.

Acceptedby WPG on:	1999-12-15
Acceptedby Working Group "pressure" on:	2000-06-29

7.12. Guideline 7/12

Guideline related to: Annex I section 4

Question: Shall welding consumables and other joining materials comply with harmonised standards, European approvals of materials or particular material appraisal?

Answer: No.

Reason: The PED does not require that these materials fulfil the requirement of Annex I. 4.2b).

Note : The joining components referred to in Guideline 7/8 (bolting parts) are not permanent joining materials.

Accepted by WPG on: 2013-04-25, adopted by WGP 2014-03-20	2000-02-17, editorial amendment (note) by WPG
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Accepted by Working Group "pressure" on:	2000-06-29
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7.13. Guideline 7/13

Guideline related to: Annex I, Sections 4.1a and 7.5

Question: What is meant by *Where appropriate*, in the context of section 4.1a when it refers to the quantitative values of section 7.5?

Answer: *Where appropriate* refers to steel, since this is the only material cited in 7.5.

For impact properties see also guideline 7/17.

Accepted by WPG on:	2002-12-05
Accepted by Working Group “ pressure ” on:	2003-01-27

7.14. Guideline 7/14

Guideline related to: Annex I section 7.1.2

Question: What does the exclusion of fine-grained steel in the first dash of section 7.1.2 of Annex I of the directive mean?

Answer: Those fine grained steels are micro-alloyed steels for pressure purposes as, for example, those given in EN 10028-3 or in EN 10222-4.

For these steels, the quantitative value of permissible membrane stress stated in Annex I section 7.1.2 does not apply. However an equivalent overall level of safety must be achieved (refer to guideline 8/6).

Acceptedby WPG on:	2001-01-11
Acceptedby Working Group "pressure" on:	2001-06-26

7.15. Guideline 7/15

Guideline related to: Annex I, section 4.2.b)

Question: Annex I, section 4.2.b), first indent authorises the use of materials which comply with harmonized standards.

Is this route still valid for a material for which the specification includes complementary requirements or improved properties to those of a grade in a harmonized EN material standard?

Answer: Yes.

Provided all the value limits stated for the particular grade in the harmonized EN material standard are met.

Moreover the material manufacturer shall affirm compliance with both the harmonized standard and the additional specification, as requested by Annex I, section 4.3.

See also guideline [7/1](#).

Accepted by WPG on :	2001-04-24
Accepted in principle by Working Group “pressure” on : 2001-04-03 – Wording reviewed by WPG on 2001-04-24	

7.16. Guideline 7/16

Guideline related to: Annex I, section 4.3

Question: The Directive 97/23/CE considers the case of “a material manufacturer who has an appropriate quality-assurance system, certified by a competent body established within the Community and having undergone a specific assessment for materials”. How should this requirement be understood in practice?

Answer: In practice, this requirement is satisfied when the material manufacturer has a quality assurance system of at least EN ISO 9001 type, certified by a competent body (according to the definition given in guideline 7/2) established as a legal entity within the European Community, and when the field of validity of the certification specifies production of material indicating the relevant material types.

The specific assessment of the quality system shall properly cover all the relevant processes and material properties referred to in the material specifications, and attested in the material certificates.

A single reference to section 4.3 of Annex I of PED is not sufficient to validate the quality assurance system of the material manufacturer. The reference document for quality assurance system which has been used shall be identified. Reference to the PED in the quality assurance system certification is not a mandatory requirement.

Note: See also guidelines 7/5, 7/7 and 9/5.

Accepted by WPG on : 2005-11-28 editorially amended by WPG on 2012-09-12 and WGP on 2013-03-07
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Accepted by Working Group “ pressure ” on : 2006-03-31
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7.17. Guideline 7/17

Guideline related to: Annex I section 4.1a and Annex I section 7.5

Question: What approach can be used to decide if a steel grade selected for a pressurized part requires specific impact properties?

Answer: 1. The philosophy of the approach outlined below takes account of the hazard analysis performed by the manufacturer in relation to the toughness necessary for the identified failure modes (e.g. brittle fracture) in the finished pressure equipment.

2. The exception concerns “ductile materials which are not subject to a ductile/brittle transition at the foreseeable conditions the equipment will be exposed to”.

Examples of such materials are: austenitic stainless steels.

Some design codes provide specific rules for the avoidance of brittle fracture that takes account of the anticipated or actual operating conditions prevailing, e.g. material, thickness, temperature, etc. Where the application of these rules indicate that the material will not behave in a brittle manner and all aspects of the chosen design code have been followed, sufficient confidence is gained in the behaviour of the material not to require specified impact properties. When these design codes are applied also other items need to be taken into account (see item 3 below).

3. The justification for omission of the impact properties shall be based on the most adverse possible combination of all elements of the steel grade specification, such as:

- the full permissible range of the chemical analysis,
- the extreme mechanical properties,

as documented and permissible in the specification and not on the values of the actual deliveries.

The consequence of the worst combination of chemistry must be considered because the specified range of chemical analysis for some materials could result in brittle behaviour,. Where appropriate, such materials could be accepted if the chemical composition and mechanical properties are restricted in the purchase order and in the particular material appraisal to such levels that, from experience, do not give rise to brittle fracture.

EXAMPLES include Manganese-Carbon ratio, Carbon, Sulphur, Phosphorus content, Aluminium to Nitrogen ratio.

Other restrictions may include:

- avoiding inter-metallic phases,
- avoiding large grain sizes,
- placing limits on mechanical properties.

Manufacturers and Notified Bodies must demonstrate that they have taken such factors into account in documenting the necessary PMAs.

4. Furthermore subsequent manufacturing processes affecting the impact properties of the material shall be taken into account, when making the above assessment.

Following all the rules in the design code should generally ensure that this requirement is met; however additional requirements may also be necessary to ensure that all relevant ESRs have been met.

EXAMPLES: forming, heat treatment, welding.

5. However, verification testing of specified impact property may not be required in cases where there is no doubt about the fulfilment of the essential safety requirement on sufficient toughness to avoid brittle fracture.

EXAMPLES : Most Austenitic Stainless Steels.

Reason: Impact property values are the most common way to fulfil the essential safety requirement of toughness specified in annex I Section 4.1a.

Although impact testing of materials is the commonly accepted route to demonstrate materials have specified minimum toughness, it is not the only route.

EXAMPLES: Restrictions on operating temperatures, Fracture mechanics.

Note 1: Every harmonized European steel standard has specified impact properties.

Note 2: A “history of safe use” alone cannot replace the need for the specification of impact properties. This notion is inextricably linked to a particular code, set of safety factors and safety philosophy and can therefore not necessarily be transferred to a different safety philosophy/concept.

Following the requirements of an established design Code alone does not provide a “presumption of conformity” and a simple claim by the manufacturer that they “have followed the specified Code” is not in itself justification. Established Codes may be used as the basis for meeting the essential safety requirements however it is necessary to compare the selected Code requirements to the essential safety requirements and identify and address any deviations. This requires those using the Code to have a good understanding of the principles involved, rather than mechanistic following of rules.

Accepted by WPG on:	2007-01-30
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7.18. Guideline 7/18

Guideline related to: Annex I section 4.1 and Annex I section 7.5

Question: Do the essential safety requirements on materials specified in Annex I section 4.1 and section 7.5 apply to the base material or to the pressure equipment?

Answer: They apply to the pressure equipment in its entirety, i.e. also to the heat affected zones of a weldment, but not to the non pressure-bearing parts.

Note: Subsequent manufacturing processes affecting properties of the base material shall be taken into account when specifying the properties of the base material, as per Annex I, sections 3.1.1, 3.1.2 and 3.1.4 of PED.

Accepted by WPG on:	2001-11-22
Accepted by Working Group "pressure" on:	2002-02-27

7.19. Guideline 7/19

Guideline related to: Article 1, paragraph 2.1.2, Annex I, sections 3.1, 4.3 and 7.2

Question: Which requirements apply to components, such as dished ends, bolts, flanges, welded fittings etc, which are placed on the market as such?

Answer: To be incorporated into an item of pressure equipment, components which are manufactured from materials such as plates, coils and bars shall meet all the relevant essential safety requirements related to the manufacturing process used ; for instance in the manufacturing of welded dished ends, sections 3.1 and 7.2 of Annex I are relevant in addition to section 4.

In order to prove the conformity to the PED of the pressure equipment containing the component the equipment manufacturer will need relevant documents from the component supplier:

- Material certificates (of the plates, coils, bars ...),

and as relevant :

- Welding procedure approvals,
- Welder/welding operator approvals,
- Non Destructive Testing operator qualifications,
- Non Destructive Testing reports,
- Destructive Testing reports,
- Forming and heat treatment information,
- etc.

This information may be in the form of a component certificate.

The requirement in Annex I section 4.3 is not however intended for a component manufacturer, who is not a material manufacturer in the context of PED, even if he modifies the mechanical properties of the material.

Forgings (including forged flanges), castings and seamless tubes are generally considered to be materials. Fittings made from these “materials” without subsequent welding or other process which could alter the material characteristics are also considered to be materials. As regard welded tubes, see guideline 7/25.

Note: Current practice may require components to be delivered with certificates based on standard EN 10204 *Metallic products. Types of inspection documents* or corresponding requirement when they are placed on the market as such. The PED does not preclude supplying such certificates with components.

See also guidelines [1/9](#), [1/22](#), [4/3](#), [7/5](#), [7/6](#), [7/8](#), [7/18](#) and [7/25](#).

Accepted by WPG on:	2004-12-15
Accepted by Working Group “pressure” on:	2005-01-19

7.20. Guideline 7/20

Guideline 7/20 has been withdrawn.

7.21. Guideline 7/21

Guideline related to: Article 11, Annex I section 4.2b

Question: May a notified body perform a particular material appraisal at the request of a material manufacturer?

Answer: No.

If the material manufacturer wants to have his material approved by a notified body the proper way to proceed is to request European approval for material in accordance with Article 11, if the material is not covered by a European harmonised standard under the PED and cited in Official Journal of the European Union (OJEU).

Note 1: See guideline 9/13 for further information regarding PMA.

Note 2: For further guidance about the process and the content of a PMA refer to the Guiding principles in document PE-03-28 approved by the Working Group Pressure (downloadable from the PED website).

Accepted by WPG on: 2010-09-21 (editorial amendment of version of 2007-04-18) + editorial amendment by WPM on 2010-10-05	
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Accepted by the Working Group "pressure" on:	2010-11-24
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7.22. Guideline 7/22

Guideline related to: Annex I sections 4.1 and 7.5

Question: What is meant by the following two terms: *Other values*, and *other criteria*, in the context of section 7.5?

Answer: *Other criteria* refers to further criteria depending e.g. on the type/dimension/product form and resistance level of steel or mode of operation, which shall be taken into account to prove its toughness and ductility.

Other values refers to those other criteria which can result in more demanding values for elongation or bending rupture energy or specified values for additional properties.

See also guideline 8/6 for the application of section 7.

Accepted by WPG on:	2003-03-06
Accepted by Working Group "pressure" on:	2003-04-28

7.23. Guideline 7/23

Guideline related to: Annex I section 4

Question: With which requirements of Annex I section 4 does the material used for a gasket have to comply?

Answer: The main function of a gasket is to ensure tightness. Its material needs to fulfil only the relevant requirements of 4.1, 4.2 (a) and the first paragraph of 4.3.

Acceptedby WPG on:	2003-03-06
Acceptedby Working Group "pressure" on:	2003-04-28

7.24. Guideline 7/24

Guideline related to: Annex I, sections 2.2.3 and 4.3

Question: Annex I section 4.3 of the Pressure Equipment Directive (PED) requires that the material manufacturer must prepare documentation affirming compliance with the specification required by the equipment manufacturer.

Does this requirement mean that material properties used in the design of the pressure equipment must be based on those affirmed (guaranteed) by the material manufacturer?

Answer: Yes, the material properties used in design of the equipment, e.g. yield strength and impact properties, must be based on those of the specification which are affirmed by the material manufacturer.

Note 1: This does not mean that the values of the specification need to be written on the certificate. It is sufficient for the material manufacturer's certificate to make reference to the specification where the appropriate values are included. See also guideline 7/17 for the need of verification testing of specified impact properties.

Note 2: See also guideline 7/18 for the relationship between the essential safety requirements and the properties of the base material.

Accepted by WPG on:	2003-06-19
Accepted by Working Group "pressure" on: editorially amended by WPG on 2003-12-17, confirmed by WGP on 2004-03-17	2003-11-03,

7.25. Guideline 7/25

Guideline related to: Annex I, sections 3.1.2, 3.1.3 and 4.3

Question: How shall welded tubes be considered for the application of the Pressure Equipment Directive (PED)?

Answer: Continuously machine-welded tubes, i.e. tubes made from coils as starting materials in an automatic process, which are usually heat treated after welding shall be in the terms of certification procedures considered as materials provided the essential safety requirements (ESRs) of Annex I section 4 “Materials” as well as applicable ESRs of Annex I section 3 “Manufacturing” (in particular 3.1.2 and 3.1.3) are fulfilled.

Further the manufacturer of such tubes shall affirm compliance of the welded tube to the specification.

In general, the inspection document shall take the form of a certificate of specific product control, where shall be found the references to the competent third party approval of welding procedures and personnel and to the recognised third party approval of non destructive personnel (for categories III and IV).

When the use of the welded tube is limited to pressure equipment of category I, a statement in the test report confirming that personnel and welding procedures are qualified according to suitable internal operating procedures is sufficient.

In application of guideline [7/16](#), where the welded tube manufacturer has a certified quality system, this system shall properly cover not only the relevant material properties referred to in the tube specifications, but also the manufacturing process of the welded tubes (in particular welding and NDT).

Note: This implies that e.g. tubes made from plates are to be considered components, see guideline [7/19](#).

Accepted by WPG on:	2004-04-15
Accepted by Working Group “pressure” on:	2004-09-07

7.26. Guideline 7/26

Guideline related to: Article 1 paragraph 2.9 and Article 11

Question: What type of material may follow the European Approval for Materials (EAM) route?

Answer: An EAM may be issued for a special or novel material grade not included in a European material standard harmonized under the Pressure Equipment Directive (PED). Such a material grade shall have a specification associated with particular chemistry and/or conferring specific mechanical properties or characteristics such as corrosion resistance. These mechanical properties or characteristics shall be supplementary to those in similar harmonised standards. See also PED Guideline [7/15](#).

An EAM is a route to facilitate the use of safe materials in absence of harmonized standards and to encourage material technology development and innovation.

An EAM shall not be issued for:

1. a grade of material listed in a current or former national material standard that has a specification covered by a harmonised European material standard.
2. a grade of material which was previously included in a European national material standard but which was not included in the harmonised European material standard which has replaced the European national material standard.

In those cases a PMA is to be drawn up, see PED guidelines [7/21](#) and [9/13](#).

Note 1: A “grade of material” may be designated by use of a material number in accordance with EN 10027-2 in the case of metallic materials.

Note 2: The Pressure Equipment Directive (PED) states that European Approval for Materials (EAMs) shall be withdrawn by the notified body if the type of material is covered by a harmonized standard.

Accepted by WPM on:	2010-10-05
Accepted by Working Group "pressure" on:	2010-11-24

7.27. Guideline 7/27

Guideline related to: Annex I section 4.3

Question: When an equipment manufacturer receives a certificate type 3.1 according to EN 10204:2004 by the material manufacturer, in pursuance of the third paragraph of section 4.3 of Annex I, what evidence of compliance with these requirements shall be recorded in the technical documentation?

Answer: The equipment manufacturer shall be able to confirm that the material manufacturer's quality system certificate meets the requirements of the third paragraph of section 4.3 of Annex I (field of validity of the certification, range of validity of certification, establishment of the competent body as a legal entity within the European Community, accreditation).

The equipment manufacturer should keep track of such information which may be requested by the market surveillance authority. To fulfil this requirement the equipment manufacturer should keep in its technical documentation the appropriate quality system certificate of the material manufacturer or other equally objective evidence.

See also Guideline 7/2 and Guideline 7/16.

Accepted by WPG on:	2013-01-17
Accepted by Working Group "Pressure" on:	2013-03-07

7.28. Guideline 7/28

Guideline related to: Annex I section 7.5

Question: How to apply Annex I, section 7.5 on the bending rupture energy measured on an ISO V test piece for base materials whose, due to its thickness, the collection of a test piece of section 10 mm x 10 mm is not possible?

Answer: The value of 27 Joules required on Annex 1, section 7.5, means the use of test piece of section 10 mm x 10 mm and an impact test KV according EN ISO 148-1:2010, Metallic materials – Charpy pendulum impact test – Part 1: Test method.

When a standard size test piece of 10mm x 10mm cannot be obtained, it is recommended to use a sub-sized specimen with a cross section of 7,5mm (7,5mm x 10mm) or 5mm (5mm x 10mm) and to adjust the value of impact test (see EN 13445-2 and EN 13480-2).

When a sub-sized specimen (5mm x 10mm) cannot be obtained due to the dimensions of the material, the verification of the specified 27 Joules is not relevant but the properties of the material are still to be guaranteed by the material manufacturer.

See also Guidelines [7/17](#) and [7/13](#).

Accepted by WPG on:	2013-04-25
Accepted by Working Group “pressure” on:	2014-03-20

7.29. Guideline 7/29 (pending)

7.30. Guideline 7/30

Guideline related to: Annex I; section 4.3

Question: A manufacturer produces material only to a chemical analysis without mechanical testing and without affirmation of compliance to a material specification and/or grade.

An entity intends to purchase the material and affirm compliance to a material specification by performing the mechanical tests as required by that material specification. There will be no further processing, other than cutting to size. Is this procedure acceptable and may this material be used in pressure equipment under the PED?

Answer: No, even if the mechanical tests are recorded in an EN 10204 inspection certificate which describes the testing entity as the manufacturer of the material.

Reason: Paragraph 4.3 Annex I of the PED requires the material manufacturer to affirm the compliance with a specification. Any entity who is not involved in the material manufacturing process cannot be considered as a material manufacturer.

Accepted by WPG on:	2013-09-18
Accepted by Working Group “pressure” on:	2014-03-20

8. INTERPRETATION OF OTHER ESSENTIAL SAFETY REQUIREMENTS

1	SCOPE AND EXCLUSIONS OF THE DIRECTIVE
2	CLASSIFICATION AND CATEGORIES
3	ASSEMBLIES
4	EVALUATION ASSESSMENT PROCEDURES
5	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON DESIGN
6	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MANUFACTURING
7	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MATERIALS
8	INTERPRETATION OF OTHER ESSENTIAL SAFETY REQUIREMENTS
9	MISCELLANEOUS
10	GENERAL-HORIZONTAL QUESTIONS

8.1. Guideline 8/1

Guideline related to: Symbol for litre

Question: In the linguistic versions of the directive the symbol for the unit for volume (litre) is not consistent (big L, small l). Which symbol should be used?

Answer: The big “L” should be used. This should be taken into account by the Member States when transposing the directive.

Reason: In the field of pressure equipment the symbol for litre is mainly used in connection with numbers. The letter “l” and the figure “1” look often identically so that misunderstandings between figures and the symbol can occur. Often the marking on nameplates is stamped so it is important that the symbol is easy readable.

Accepted by WPG on:	1998-10-12
Accepted by Working Group “pressure” on:	1999-01-29

8.2. Guideline 8/2

Guideline related to: Annex I, sections 3.2.2 and 7.4

Question: Final assessment (Annex I, section 3.2.2) of pressure equipment must include a test for pressure containment at a pressure at least equal, where appropriate, to the value laid down in section 7.4. This section only refers to pressure vessels. Does this mean that 7.4 does not apply to piping, and pressure and safety accessories?

Answer: In accordance with Annex I, 3.2.2 in the course of the final assessment pressure equipment must be subjected to a test for the pressure containment aspect. As a rule, this test for the pressure containment aspect is supposed to be carried out in the form of a hydrostatic pressure test. Where this is not possible or disadvantageous other procedures are permissible.

The pressure value chosen for carrying out a hydrostatic pressure test must be such as to assure testing the pressure containment aspect of the pressure equipment with due consideration of the determined safety factors without causing a damage to the pressure equipment. Annex I, 7.4 provides additional formulas which may be applied only in due consideration of the above described general criteria (3.2.2). The formulas in Annex I, section 7.4 should be considered for all items of pressure equipment, not only pressure vessels.

Accepted by WPG on:	1999-07-16
Accepted by Working Group "pressure" on:	1999-11-08

8.3. Guideline 8/3

Guideline related to: Annex I points 3.3 and 3.4.

Question: What safety information must be given to the user in relation to Annex I points 3.3 and 3.4 ?

Answer: When pressure equipment is placed on the market, the manufacturer is required by the PED to ensure that it is accompanied by instructions for the user containing certain safety information; such information is mandatory. Additional information may be requested by the user or recommended by the manufacturer, and agreed as part of the order or contract; this information is not a PED requirement and therefore is optional. Both types of information are elaborated below.

The following are **required by the PED**:

- Details accompanying the CE mark, per clause 3.3a, 3.3b and 3.3c
- Operating instructions for mounting, putting into service, use and maintenance, per clause 3.4a, which include as far as relevant to the equipment:
 - safe operating limits and design basis (includes anticipated operating and assumed design conditions, intended life, design code used, joint coefficients and corrosion allowances)
 - features of the design relevant to the life of the equipment per clause 2.2.3b last indent
 - residual hazards not prevented by design or protective measures, that might arise from foreseeable misuse, per clause 1.3, 3.3c, and 3.4c
 - technical documents, drawings and diagrams necessary for a full understanding of these instructions, as per clause 3.4b
 - information about replaceable parts, for example per clause 2.7

Note 1: Where an assembly of pressure equipment includes a number of different PS, it is acceptable not to provide these different PS on the assembly marking but they must be provided by other suitable means for example on an assembly layout diagram accompanying the operating instructions.

Note 2: Without prejudice of clause 3.4a, other information, not required by the PED, may be included by contractual agreement, such as: hazard analysis, material test certificates, detailed design calculations, “as built” drawings, heat treatment records, welding records, NDT results, results of dimensional check, full records of proof test, details and results of special checks, details of any corrective repair or modifications, full documentation of any concessions made.

Accepted by WPG on: 2013-09-18
Accepted by Working Group “pressure” on: 2014-03-20

8.4. Guideline 8/4

Guideline related to: Annex I, 2nd and 3rd preliminary observations

Question: What shall be the extent of the hazard analysis specified in the third preliminary observation of Annex I?

How shall it be documented?

Answer: The hazard analysis shall enable the manufacturer to identify and to determine the potential modes of failure due to loading of pressure equipment which could occur when this equipment is installed and used in reasonably foreseeable operating conditions.

After the manufacturer has fixed the limits of the equipment, he must complete a hazard analysis which will enable him to identify the essential requirements which are applicable to the equipment.

The results of this analysis (applicable essential requirements in relation to the foreseeable operating conditions) shall be included in the technical documentation, but the inclusion of full details of the analysis in the documentation is not required by PED.

Accepted by WPG on:	1999-09-02
Accepted by Working Group "pressure" on:	1999-11-08

8.5. Guideline 8/5

Guideline related to: Annex I, section 3.4

Question: Does the strength of the foundations (concrete plates, tightened gravel, piling etc), where the pressure equipment is erected, belong to the details to be considered under PED?

Answer: The strength of the foundations does not belong to the details to be checked by notified bodies in modules B1, G etc. But the manufacturer, obliged by section 3.4 of Annex I of PED, must give relevant information (support forces etc) so that the body responsible for installation of the pressure equipment can design the grounding (see Annex I, section 2.2.1).

Note: This information should also be made available to the user with 'as built' drawings, see guideline 8/3.

Accepted by WPG on:	1999-09-03
Accepted by Working Group “ pressure ” on:	1999-11-08

8.6. Guideline 8/6

Guideline related to: Annex I section 7

Question: The first paragraph Annex I section 7 explicitly provides for exceptions to the general rules specified subsequently. How should the achievement of “an equivalent overall level of safety” in such a case be demonstrated?

Answer: The specific quantitative requirements given in section 7 of Annex I are related to particular failure modes. If different values are used, the corresponding failure modes and their combination shall be identified and the measures taken to maintain an equivalent level of safety shall be provided in the technical documentation, with appropriate justifications.

The achievement of “an equivalent overall level of safety” may be assumed if the measures taken provide adequate safety margins against all relevant failure modes in a consistent manner. Safety margins are adequate, and deviation from a particular value is justified:

- a) by a reduced risk in the respective failure mode, or
- b) by additional means to ensure no increase of the risk.

When using a harmonised standard for pressure equipment which has been published in the Official Journal of the European Communities, no further justification is needed for the quantitative values which have been used as regards Annex I section 7 (refer also to guideline [7/1](#)).

The requirement to demonstrate an equivalent overall level of safety applies to the product itself, and to the measures taken to meet the essential safety requirements. The use of a "recognised" code is not, in itself, sufficient to demonstrate an equivalent overall level of safety (see also guideline [9/5](#)).

Accepted by WPG on:	2002-04-10
Accepted by Working Group “pressure” on:	2002-05-23

8.7. Guideline 8/7

Guideline related to: Article 1 paragraph 2.2, Article 1 paragraph 2.3, Annex I section 1.1, Annex I section 1.3, Annex I section 2.2.1

Question: What conditions should be considered to determine the maximum allowable pressure PS of an equipment?

Answer: All the reasonably foreseeable conditions shall be taken into account, which occur during operation (starting, operation, stop) and standby (storage, transport, maintenance, emptying, blanketing or inerting).

Note 1: The operating instructions shall identify the reasonably foreseeable hazards arising from misuse which were not possible to eliminate during the design (see Annex I section 1.3).

Note 2: The maximum allowable pressure is used to determine the test pressure, not vice versa.

Note 3: "Pressure related to atmospheric pressure", as defined in Article 1 paragraph 2.2, is the pressure inside the envelope. It shall not be interpreted as "differential pressure between atmospheric pressure and absolute pressure prevailing inside the equipment" for the purposes of classification.

Example: Blanketing (inerting) at more than 0,5 bar of an equipment which operates at less than 0,5 bar will have the consequence of including the equipment in the scope of the directive, if not otherwise excluded.

Accepted by WPG on:	2000-11-29, editorially amended on 2004-06-15
Accepted by Working Group "pressure" on:	2001-10-19, confirmed by WGP on 2004-09-07

8.8. Guideline 8/8

Guideline related to: Article 9 paragraphs 1 and 2, Annex I, section 3.3 b, last indent

Question: What does “product group” mean?

Answer: “Product group” is not defined in the directive but in the context of Article 9 paragraphs 1 and 2 it shall be taken to mean the “fluid group” which is used for the purposes of classification.

Note: Moreover, for equipment designed for a specific fluid, the manufacturer shall indicate, where necessary, in order to draw the attention of user, the name of the fluid on the equipment and in the operating instructions (annex I section 3.3 b and annex I section 3.4 respectively).

Accepted by WPG on:	2000-11-29
Accepted by Working Group “pressure” on:	2001-10-19

8.9. Guideline 8/9

Guideline related to: Annex I, section 3.3 a)

Question: **Must an individual serial number always be provided, even if the items of pressure equipment are manufactured in batches or series?**

Answer: No.

For items of pressure equipment manufactured in batches or series (such as portable extinguishers or valves) the identification may be limited to the batch or series number. It is not always necessary to provide an individual serial number on each item of pressure equipment.

Notes:

1. When a national authority applies the safeguard clause the decision will relate to all products belonging to the same batch or series. Similarly, if a manufacturer withdraws non-compliant or defective products from the market this will relate to all products belonging to the same batch or series.
2. It should be noted that some linguistic versions are unclear on this point.
3. Sufficient identification shall be possible according to the nature of the equipment.

Accepted by WPG on:	2001-11-22
Accepted by Working Group "pressure" on:	2002-02-28

8.10. Guideline 8/10

Guideline related to: Article 3 paragraph 1.2; Annex I section 3.3

Question: Does the directive require a specific format for marking the year of manufacture of pressure cookers?

Answer: No.

The year of manufacture could be for example given as a 4-digit (year of manufacture: yyyy) or limited to 2 digits, associated with the serial number (xxxx/yy).

Acceptedby WPG on:	2001-12-18
Acceptedby Working Group "pressure" on:	2002-02-28

8.11. Guideline 8/11

Guideline related to: Annex I, preliminary observation 3

Question: For products built according to a harmonized standard, is the manufacturer still obliged to perform the hazard analysis required by Annex I preliminary observation 3 of the PED?

Answer: Yes.

The manufacturer has

- first to identify the hazards;
- second to determine those essential safety requirements (ESRs) which apply to his product.

Then, a comparison with Annex ZA of an existing harmonized standard will allow him to decide whether this standard fully covers the relevant ESRs for his product.

See also Guideline **8/4**.

Acceptedby WPG on:	2002-06-18
Acceptedby Working Group "pressure" on:	2002-10-03

8.12. Guideline 8/12

Guideline related to: Annex I, section 3.3

Question: Which are the essential maximum/minimum allowable limits to be marked according to Annex I section 3.3 a) of Pressure Equipment Directive (PED)?

Answer: All pressure equipment shall be marked with the maximum allowable pressure PS, unless this might be misleading for safe use (see for instance guideline 8/18 for bottles for breathing apparatus).

Depending on the type of pressure equipment, its operating conditions and the results of hazard analysis there may be other essential maximum/minimum allowable limits or combinations thereof, such as

- maximum or minimum allowable temperature;
- maximum or minimum fluid level

Note: Further information may be required (see PED Annex I sections 3.3.b and c).

Accepted by WPG on:	2008-09-11
Accepted by Working Group "pressure" on:	2015-03-11

8.13. Guideline 8/13

Guideline related to: Annex I, section 3.3, Annex VI

Question: Which provisions are to be followed for the CE marking of small pressure accessories and safety accessories, the dimensions of which do not allow fulfilment of the requirements of:

- annex I, section 3.3.a) about the minimum information required,
- annex VI about the minimum size of the CE marking of 5 mm.

Answer: Where these requirements are a physical impossibility, the marking may be given on a label attached to the accessory.

For example if a safety accessory has an external diameter of 8 mm and an internal diameter of 3,7 mm, the whole marking is given on a label.

Reason: Even though the 2nd indent of the last paragraph of section 3.3 of Annex I refers only to the information under 3.3.b) to be given on a label, in case of technical impossibility it is allowed to give all the information on a label as provided for in the Guide for the New Approach Directives.

Accepted by WPG on:	2003-05-14
Accepted by Working Group "pressure" on: editorially amended on 2005-06-28	2003-11-03,

8.14. Guideline 8/14

Guideline related to: Annex I section 3.2.2

Question: Is it possible to undertake statistical proof testing of series-produced safety valves?

Answer: Yes, when the body of the safety valve classified according to Annex II section 3 does not exceed category I and subject it is supported by the hazard analysis.

Reason: The proof test is intended to verify the pressure containment aspect of the item of pressure equipment. The proof test does not address the safety function which is covered by Annex I section 2.11.1.

Note 1: The safety function of such safety valves needs to be assessed according to category IV (except for safety valves manufactured for specific equipment of category lower than IV).

Note 2: The same reasoning is not applicable to the other items of pressure equipment which are classified by the PED in a higher category than the category derived from their intrinsic characteristics.

Accepted by WPG on:	2004-12-16
Accepted by Working Group "pressure" on:	2005-01-19

8.15. Guideline 8/15

Guideline related to: Annex I sections 1.1, 1.2, 1.3, 2.9, 2.10, 2.11, 3.4, 5

Question: How should the ESRs (essential safety requirements) of Annex I be interpreted in regard of boilers for generating steam or superheated water intended for operation without continuous supervision?

Answer: All the ESRs from Annex I apply if the corresponding hazards exist. The following observations, which are **not necessarily exhaustive**, explain how some of the ESRs can be understood in the context of operation without continuous supervision.

ESRs	Explanation
1.1	The boiler shall be able to operate automatically, and include a control mode “operation without continuous supervision”.
1.3, 5a	The heating system shall be able to operate only if all the boiler safety systems are operational.
2.10	Protection against exceeding allowable limits on pressure, temperature and water level shall be ensured by safety accessories (see also guideline 1/43).
2.10	When specific aspects of water quality are subject to rapid variation giving rise to dangerous situations within the period of unattended operation, protection against exceeding such limit shall be ensured by safety accessories.
2.10	Adequate monitoring devices, which enable adequate action to be taken automatically to keep the boiler within the allowable limits, shall be provided.
2.10	Warning devices, such as indicators or alarms, which enable the origin of anomalies to be displayed, shall be provided.
2.10	In the case of failure of the power supply to electrical boilers a safe shutdown or continuous operation of the control circuit of the boiler shall be ensured.
2.11	Safety accessories shall be designed to cause a safe shutdown of all or part of the boiler, in case of failure of their power supply.
2.11.1	If for certain operations, the boiler shall be able to operate with some safety accessories neutralised, this shall simultaneously disable the control mode “operation without continuous supervision”.
3.4, 1.2	<p>The instructions for use shall explicitly state that the boiler is designed and equipped to be operated without continuous supervision. It shall inform of residual hazards and special measures to be taken during operation to eliminate them. It shall state:</p> <ul style="list-style-type: none"> - how to test the safety accessories (logic diagram for instance) and what are the recommended intervals for such inspections; - the requirements for boiler feedwater;

	- the instructions to restart the boiler, for every stop origin.
5a	After a boiler shutdown caused by anomaly, the boiler shall not be able to restart automatically.
5d	After shutdown, residual heat shall be safely removed without human intervention.
5e	After a heating system has been locked in the stop position due to failure in its supply, a manual reset shall be necessary to unlock it.

The following examples are frequently used requirements to check the function of the safety system periodically as stated in guideline **9/20**. The requirements are related to ESRs section 5 and section 2.11.1 of Annex I:

24 hours operation without continuous supervision is permitted if functional tests of the limiting devices are carried out periodically at adequate intervals.

A functional test carried out by the boiler attendant includes the shut down of the burner-valves, or, when the boiler is fed by solid fuels, the stopping of the conveyor system. This functional test also includes checking of the quality of water. Member states may have specific requirements to allow duration greater than 24 hours, e.g. provision of a device for automatic monitoring of water quality.

Accepted by WPG on:	2004-02-25
Accepted by Working Group "pressure" on:	2004-03-18

8.16. Guideline 8/16

Guideline related to: Annex I sections 3.2.2 and 7.4

Question: If the hydrostatic pressure test required by Annex I section 3.2.2 is replaced by a pneumatic pressure test because filling with water is harmful or impractical, what value has to be used for the pressure test?

Answer: Either the values given in Annex I section 7.4 are to be used for the pneumatic pressure test or the manufacturer has to achieve an equivalent level of safety using other appropriate means.

See guideline [8/2](#).

Note 1: Whether the test is pneumatic or hydrostatic, when the value of the pressure deviates from the value of Annex 1 section 7.4, additional measures must be applied to verify the pressure containment aspect including tightness (see guideline [5/3](#)).

Note 2: Attention is drawn to the fact that pneumatic testing can be highly dangerous. Reference should be made to the appropriate national authorities for regulation or guidance on the procedures to be followed.

Accepted by WPG on:	2004-12-16
Accepted by Working Group "pressure" on:	2005-01-19

8.17. Guideline 8/17

Guideline related to: Article 15 paragraph 2, Annex I section 3.3

Question: Is it possible to provide the marking and labelling required by Annex I section 3.3 on a sticker?

Answer: Yes, provided the sticker is non-removable, indelible, legible and firmly attached to the pressure equipment, for the intended lifetime and foreseeable conditions of use.

Note: When using stickers, account has to be taken of limited durability in practice. For most types of pressure equipment, industrial practice is to use rigid data plates.

See also guideline **8/13**.

Acceptedby WPG on:	2004-10-06
Acceptedby Working Group "pressure" on:	2005-01-19

8.18. Guideline 8/18

Guideline related to: Annex I, section 3.3

Question: What shall be the information about pressure and temperature to be marked on bottles for breathing apparatus according to PED?

Answer: Bottles for breathing apparatus shall be marked with the working pressure (PW) as defined in RID/ADR, chapter 1.2.

Minimum and maximum allowable temperatures TS shall also be marked

Instead of the test pressure PT referred to in PED (3rd indent of 3.3.b in Annex I) the test pressure (PH) as defined in RID/ADR, chapter 1.2 shall be marked.

Note: 1. Further information may be required (see PED Annex I sections 3.3.b and c).

2. The manufacturer shall explain the marking of pressure and temperature parameters in the instructions for filling and periodic inspection.

3. According to RID/ADR , PW is the settled pressure, expressed in bar, of a compressed gas at a reference temperature of +15 °C in a full pressure receptacle, and PH is the required pressure, also expressed in bar, applied during a pressure test for initial or periodic inspection. PW and PH being the abbreviations for working pressure and test pressure as per RID/ADR, 6.2.2.7.3.

4. The answer is given on the basis that the standards referenced in ADR are normally used for the design of bottles for breathing apparatus and that appropriate impact properties are specified to demonstrate an overall level of safety equivalent to that of the PED.

Accepted by WPG on:	2014-07-01
Accepted by Working Group "pressure" on:	2015-03-11

8.19. Guideline 8/19

Guideline related to: Article 15 paragraph 2, Annex I section 3.3 and 3.4

Question: What is the marking information to be put on the constituent parts of pressure equipment intended for domestic use?

Answer: Only the complete pressure equipment can be conformity assessed, and only one CE marking shall be affixed, preferably on the constituent part that is not supposed to be replaced.

The constituent parts of such pressure equipment, which can be sold separately, as spare parts for instance, should have a marking allowing them to be identified unambiguously. They shall not carry a CE marking additional to the marking of the complete equipment.

The declaration of conformity and instructions for use shall describe in an appropriate manner the components making up this equipment. The operating instructions for use shall give the list of spare parts (where appropriate); how to identify them, in particular their marking information.

See also Guideline [1/22](#), [1/47](#), [4/11](#)

Note: An example would be a pressure cooker constituting a body and lid.

Accepted by WPG on:	2011-01-27
Accepted by Working Group "pressure" on:	2012-03-06

9. MISCELLANEOUS

1	SCOPE AND EXCLUSIONS OF THE DIRECTIVE
2	CLASSIFICATION AND CATEGORIES
3	ASSEMBLIES
4	EVALUATION ASSESSMENT PROCEDURES
5	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON DESIGN
6	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MANUFACTURING
7	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MATERIALS
8	INTERPRETATION OF OTHER ESSENTIAL SAFETY REQUIREMENTS
9	MISCELLANEOUS
10	GENERAL-HORIZONTAL QUESTIONS

9.1. Guideline 9/1

Guideline related to: Article 3, paragraph 3

Question: What is to be understood by "sound engineering practice"?

Answer: Sound engineering practice” means, without prejudice to article 4, paragraph 1.2, that such pressure equipment is designed taking into account all relevant factors influencing its safety. Furthermore, such equipment is manufactured, verified and delivered with instructions for use in order to ensure its safety during its intended life, when used in foreseeable or reasonably foreseeable conditions. The manufacturer is responsible for the application of sound engineering practice.

Acceptedby WPG on:	1998-09-18
Acceptedby Working Group "pressure" on:	1999-01-29

9.2. Guideline 9/2

Guideline related to: Article 11, Paragraph 1

Question: What does “material recognised as being safe to use before 29 November 1999” in Article 11, first paragraph mean ?

Answer: Recognised as being safe to use means a material

- with well-known characteristics, and
- with a well-established history of safe use in the pressure equipment field.

To be approved under Article 11, such a material must fulfil the relevant essential safety requirements of Annex I.

Accepted by WPG on:	1999-06-10
Accepted by Working Group “pressure” on:	1999-11-08

9.3. Guideline 9/3

Guideline related to: Article 11, Paragraph 1

Question: Is the approval of a material manufacturer part of the European Approval of Material procedure for “a material recognised as being safe to use before 29 November 1999”?

Answer: No, the purpose of such a European Approval of Material is to certify the conformity of types of materials with the corresponding requirements of the Directive, not to approve a material manufacturer.

Accepted by WPG on:	1999-02-26
Accepted by Working Group “pressure” on:	1999-11-08

9.4. Guideline 9/4

Guideline related to: Article 11, Paragraph 1

Question: May a European Approval of Material for a “material recognised as being safe to use before 29 November 1999”, be restricted to one or more material manufacturers?

Answer: No, see guideline 9/3.

Note: If a material which is covered by a European Approval of Material is patented, or has a patent pending, this information shall be included in the European Approval of Material.

Accepted by WPG on:	2000-02-17
Accepted by Working Group “pressure” on:	2000-06-29

9.5. Guideline 9/5

Guideline related to: Article 5

Question: In which conditions is it possible to use a document other than a harmonised standard (national standard, professional code or private technical document) for the design and manufacture of pressure equipment for the application of PED?

Answer: 1) The use of the harmonised standard is not mandatory.
2) However, the directive did not include provisions to give presumption of conformity to documents other than harmonised standards.

A manufacturer using another document shall describe in his technical documentation the solutions adopted to meet the essential requirements of the directive.

The notified body (or the user inspectorate) shall validate, if required by the module chosen, these solutions.

3) The technical requirements of the Directive are given in Annex I. When using a national standard, a professional code or a private technical document for fulfilling Annex I, only the technical content of this document is relevant. Further provisions of this document (e.g. about bodies or certification procedures) are not relevant for the application of PED.

Note: See also guideline 9/6.

Accepted by WPG on:	1999-07-15
Accepted by Working Group "pressure" on:	1999-11-08

9.6. Guideline 9/6

Guideline related to: Article 5

Question: Is it possible to use partially one or more harmonised standards, codes or specifications to design and manufacture a pressure equipment conform to the Pressure Equipment Directive?

Answer: The different parts (design, manufacture, inspection, ...) of an harmonised standard, a code or a specification for pressure equipment form a consistent set of documents which should be followed.

Nevertheless, the partial use of an harmonised standard, a code or a specification is not forbidden.

In these conditions, the essential requirements covered by the part(s) of harmonised standards, codes or specifications used shall be identified.

The essential requirements not covered by the part(s) of harmonised standards, codes or specifications shall be subject to an analysis to judge the validity of the adopted solutions.

Then, if several different parts of harmonised standards, codes or specifications are used, it shall be verified that there are no incompatibility or inconsistency between these parts, particularly for the application data (permissible stress, safety coefficient, extent of the inspection, ...).

Note: See also guideline 9/5.

Accepted by WPG on:	1999-06-10
Accepted by Working Group "pressure" on:	1999-11-08

9.7. Guideline 9/7

Guideline related to: Article 1 paragraph 2.1.3, Article 3 paragraphs 1.4 and 3

Question: Under what circumstances shall safety accessories placed on the market not bear the CE marking according to the PED?

Answer: Safety accessories exclusively manufactured and put on the market for specific pressure equipment or assemblies covered by Article 3 paragraph 3 of the PED shall not bear the CE marking under the PED (but see Note 2).

Furthermore, safety accessories exclusively intended for equipment not covered by the PED are also not covered by the PED.

Also safety accessories covered by the PED and assessed by a user inspectorate shall not bear the CE marking.

Note 1: The specific use shall be clearly mentioned by the manufacturer of the safety accessory in the instructions.

Note 2: This does not forbid the use of a CE-marked safety accessory on an Article 3 paragraph 3 equipment.

Accepted by WPG on:	2003-05-14
Accepted by Working Group “ pressure ” on:	2003-11-03

9.8. Guideline 9/8

Guideline related to: Article 15.2

Question: Conformity with the PED is required for some piping per Article 3.1.3, which are part of an industrial installation. May all such piping for a given installation be covered by a single CE marking?

Answer: Yes, providing the CE marking is prominently displayed and the accompanying documentation supplied by the manufacturer to the user clearly defines the boundary of the installation.

Accepted by WPG on:	1999-09-03
Accepted by Working Group “pressure” on:	1999-11-08

9.9. Guideline 9/9

Guideline related to: Article 3.3

Question: If an item of pressure equipment is covered by Article 3.3, and there exists an EN product standard for this type of pressure equipment, does this mean that the EN standard explains the meaning of the sound engineering practice?

Answer: Not necessarily.

The manufacturer is always responsible for the application of all relevant procedures and techniques, whether they are given in the standard or not, in order to fulfil the requirement of Article 3.3. Standards and other professional codes are useful frame of reference in this context. See also guideline [9/1](#).

Accepted by WPG on:	1999-12-14
Accepted by Working Group "pressure" on:	2000-06-29

9.10. Guideline 9/10

Guideline related to: Annex I, section 4.2 b, 3rd indent, Annex III module B, 4.1 2nd indent and module B1, 4.1 1st indent

Question: When performing an EC type examination or an EC design-examination by using particular appraisals for materials, are these appraisals applicable to all items of pressure equipment covered by this examination?

Answer: Yes.

Accepted by WPG on:	1999-12-15
Accepted by Working Group "pressure" on:	2000-06-29

9.11. Guideline 9/11

Guideline related to: Annex I, 4.2.b third indent

Question: When performing a particular appraisal for materials recognized as being safe to use before 29.11.1999, shall the existing data for these materials be taken into account when assessing the suitability of this material?

Answer: Yes, and if this data as referred to in Guideline 9/2 is sufficient for the proof of conformity, in principle no additional testing should be performed.

The manufacturer (and the Notified Body) shall take into account the material properties of the actual deliveries when claiming the history of safe use for a particular material, if its specification has significantly wider limits.

Reasons: 1. Even though the PED does not specify the content of a particular material appraisal, the concept of safe history applies similarly as for EAMs.

2. It would be incorrect to assume that every batch supplied to the wider specification has equally good properties.

For example, in many steel specifications, sulphur may be permitted up to 0,030%, but modern steelmaking techniques produce lower sulphur levels consistently less than 0,010%. The good impact toughness associated with the low sulphur content will not be obtained if another batch of steel is supplied at or near 0,030% sulphur.

Note: Where such commonly used materials are not covered by harmonised standards or EAM, particular material appraisal is the only other route that remains.

Accepted by WPG on:	2001-11-21
Accepted by Working Group "pressure" on:	2002-02-28

9.12. Guideline 9/12

Guideline related to: Article 3.3, Annex I.4

Question: Do the requirements of Annex I.4 regarding materials also apply to pressure equipment described in Article 3.3 (Sound engineering practice)?

Answer: No.

Any pressure equipment covered in Article 3.3 does not have to meet the Essential Safety Requirements of Annex I and consequently does not fall under the regime of the material requirements contained therein.

See also guideline [9/1](#).

Accepted by WPG on:	2000-02-18
Accepted by Working Group “pressure” on:	2000-06-29

9.13. Guideline 9/13

Guideline related to: Annex I section 4.2b 3rd indent, and Annex I section 4.2c

Question: What are the formal requirements of a particular material appraisal (PMA)?

Answer: The PMA shall describe the material properties in a manner that is concise, complete and correct for the foreseen application (see also PED Guideline 7/18). It shall comprise qualitative and quantitative data providing evidence that the relevant Essential Safety Requirements (ESR) of PED Annex I are met.

The responsibility for drawing up the PMA lays with the pressure equipment manufacturer.

The PMA shall be part of the technical documentation.

The PED only requires a particular appraisal of a PMA by a notified body for pressure equipment in category III and IV.

Note 1: The PED uses the word "appraisal" in two contexts which are unclear in some linguistic versions: (i) the PMA (which is the material datasheet) and (ii) the appraisal of the PMA.

Note 2: For further guidance about the process and the content of a PMA refer to the Guiding principles in document PE-03-28 approved by the Working Group Pressure ([current version](#) downloadable from the PED website).

Note 3: When European harmonised material standards are available for materials similar to a material grade covered by the PMA, the material characteristics (e.g. rupture energy, elongation after fracture, corrosion resistance,...) included in this European harmonised material standard are to be considered in the PMA. See also PED Guideline 7/1.

Accepted by WPG on:	2012-09-12
Accepted by Working Group "pressure" on:	2013-03-07

9.14. Guideline 9/14

Guideline related to: Article 14 section 1, Annex I section 4.2

Question : May the particular material appraisal (referred in the third indent of 4.2 b) of Annex I) be carried out by a user inspectorate as part of the conformity assessment of pressure equipments based on modules A1, C1, F or G?

Answer: Yes for module G.

Indeed, article 14 indicates that, by way of derogation from the provisions relating to the tasks carried out by the notified bodies, the conformity of pressure equipment can be assessed by a user inspectorate. And so the particular appraisal referred in annex I 4.2 c) can be carried out by a user inspectorate if, in accordance with article 14, it has been appointed for module G.

Note 1: For module A1, the particular appraisal is carried out by the manufacturer. For module C1 and F, the particular appraisal was carried out previously as part of modules for design.

Note 2: The PED uses the word "appraisal" in two contexts which are unclear in some linguistic versions: (i) the PMA (which is the material datasheet) and (ii) the appraisal of the PMA.

Accepted by WPG on: amendment by WPG on 2001-01-10 and 2013-04-25	2000-10-03, with editorial
Accepted by Working Group "pressure" on:	2000-11-08

9.15. Guideline 9/15

Guideline related to: Article 14

Question: A user places an order for Pressure Equipment on a manufacturer in Member State 'A', where the Member State has chosen *not* to implement Article 14; but the Pressure Equipment is intended to be put into service as part of an industrial installation in Member State 'B', where Article 14 is implemented. May Member State 'A' refuse to allow the user's inspectorate, which has been authorized according to Art. 14 in another Member State, to operate on its territory, thus preventing the User Inspectorate from undertaking conformity assessment of the Pressure Equipment?

Answer: No, provided the transfer takes place directly from the manufacturer to the user, and it takes place in Member State 'B' the User Inspectorate may legally undertake the conformity assessment activities in Member State 'A'.

Reason: Article 14, Paragraph 1 says: “.... Member States may authorize *in their territory the placing on the market, and the putting into service* by users, of Pressure Equipment which has been assessed by a User Inspectorate designated in accordance with the criteria”

It is clear that the *putting into service* will take place in Member State 'B' and therefore can be authorized in conformity with the Directive.

Acceptedby WPG on:	2001-01-10
Acceptedby Working Group "pressure" on:	2001-10-19

9.16. Guideline 9/16

Guideline related to: Article 4 paragraph 1.1; Article 5 paragraph 1; Annex VII

Question: Must a CE-marked item of pressure equipment, or an assembly, be supplied with an EC declaration of conformity, when it is placed on the market?

Answer: The manufacturer of CE-marked pressure equipment or assembly should be aware that the declaration of conformity must be made available for national authorities immediately upon request. Otherwise the presumption of conformity as provided for in Article 5, paragraph 1, is in doubt. For this purpose the manufacturer or his authorised representative established within the Community must draw up a written declaration of conformity and keep a copy of it for a period of ten years after the last pressure equipment has been manufactured.

However, Article 4, paragraph 1.1 requires that Member States provide free movement for pressure equipment and assemblies which comply with the PED and bear a CE mark, but there is no provision in the PED that an EC declaration of conformity must be mandatorily supplied with the pressure equipment or assembly in order to comply with the PED.

In addition, the manufacturer should be aware that the declaration of conformity is a helpful document to the distributor or user because it is a summary of design, manufacture and conformity assessment.

The manufacturer should also be aware that some Member States require that the declaration of conformity is available at the user premises at the time of putting into service and for subsequent in-service inspections of the pressure equipment.

The manufacturer should also be aware that the EC declaration of conformity is an essential document for the manufacturer of an assembly into which a CE-marked item of pressure equipment is to be integrated.

It is therefore highly recommended to provide the EC declaration of conformity for all products which are intended to be put into service as such, with the product.

Note: The EC declaration of conformity does not need to be a separate document; it may be included in the instructions for use.

Accepted by WPG on:	2001-05-16
Accepted in principle by Working Group "pressure" on:	2001-06-27

9.17. Guideline 9/17

Guideline related to: Article 3 paragraph 3

Question: How shall a manufacturer established outside the European Economic Area (EEA) fulfil the requirement of the sound engineering practice (SEP) of a Member State?

Answer: A manufacturer outside of EEA may choose the SEP of one of the Member States.

SEP from countries outside EEA does not automatically fulfil the requirement of Article 3, paragraph 3.

However, as a general rule, it can be assumed that the SEP of a Member State is met if:

- the product has been legally marketed in one Member State of EEA for many years, or
- the product fulfils technical specifications recognised by one Member State of EEA.

Refer also to guidelines [9/1](#) and [9/9](#).

Reason: Article 3 paragraph 3 of PED stipulates mutual recognition of SEP of Member States in order to avoid barriers of trade. The level of safety is assumed to be sufficient in all Member States. So the equipment must in be fact safe.

Accepted by WPG on:	2001-02-21
Accepted by Working Group “pressure” on:	2001-11-28

9.18. Guideline 9/18

Guideline related to: Article 4 paragraph 1

Question: Article 4.1 of PED provides for free placing on the market or putting into service of CE-marked pressure equipment. Under what circumstances can the application of national regulations (e.g. by public authorities or private authorised bodies) on periodic testing constitute a barrier to trade?

Answer: Differentiation between in-service inspection periods for similar CE-marked items of pressure equipment for the same purpose should be based on technical reasoning and the conditions of use of the equipment.

Specification of **formal** requirements for:

- the involvement of a specific notified body or bodies,
- the compliance with a specific (e.g. national) design code to the exclusion of other technically justifiable/equivalent solutions would constitute a barrier to trade.

Acceptedby WPG on:	2003-05-14
Acceptedby Working Group "pressure" on:	2003-11-03

9.19. Guideline 9/19

Guideline related to: Article 3, paragraph 3; Article 4, paragraph 1.2

Question: What information should be supplied with an item of pressure equipment, or an assembly, which falls under article 3, paragraph 3 (sound engineering practice, SEP) when it is placed on the market, to indicate that it complies with the provisions of article 3, paragraph 3?

Answer: There are no specific provisions in the directive on how the manufacturer must indicate that such equipment complies with the PED.

Nevertheless, the manufacturer must supply adequate instructions for use, and provide markings to permit identification of the manufacturer or its authorized representative established within the Community.

However, manufacturers should be aware that it is likely to be helpful if they include with the product a reference to the PED indicating that the requirement of sound engineering practice of a Member State (see guideline 9/1) has been met. This can for example be achieved by a statement included with the instructions of use, by a separate document attached to the equipment, or by an addition to the marking.

Note: The manufacturer must not draw up, an EC declaration of conformity, nor affix the CE-mark for such equipment in the context of PED.

Accepted by WPG on:	2001-05-16
Accepted by Working Group "pressure" on:	2001-11-28

9.20. Guideline 9/20

Guideline related to: Article 2 paragraph 2, Article 4 paragraph 1.1, Annex I sections 2.3, 2.10b and 2.11.1

Question: Are national requirements additional to the Pressure Equipment Directive (PED) for the design, conformity assessment and installation of safety systems of CE-marked boilers for generating steam or superheated water intended for operation without continuous supervision permissible?

Answer: No.

When

- the boiler is intended for operation without continuous supervision
- the specific hazards due to this situation are taken into account in the hazard analysis and design of the assembly and its safety systems
- this assembly meets all relevant provisions of the PED (including a description of the intended operation mode and of the associated safety systems in the instructions for use)

any additional design requirements would constitute a restriction on or impediment to the placing of this product on the market.

National requirements may oblige the user to check the function of the safety system periodically. The requirements shall be based on technical criteria of the design of the safety system in order to guarantee that for similar safety systems the same operational requirements apply.

See also guidelines [3/4](#), [8/3](#) and [9/18](#).

Note: Guideline [8/15](#) identifies significant ESRs applicable to boilers intended for operation without continuous supervision.

Acceptedby WPG on:	2003-06-19
Acceptedby Working Group "pressure" on:	2003-11-03, updated on 2004-03-18

9.21. Guideline 9/21

Guideline related to: Article 4, paragraph 2, Annex I sections 3.1, 3.3 and 3.4

Question: Article 4 of the Pressure Equipment Directive allows Member States to require the information for pressure equipment described in Annex 1 sections 3.3 and 3.4 to be provided in the language of the country in which the equipment or assembly reaches the final user. If so required, does this impose the task of translating on the manufacturer?

Answer: The PED allows Member States to require translation and consequently to take restrictive measures if this requirement is not fulfilled. Manufacturers, distributors and importers should be aware of this requirement.

If the national legislation requires the translation, it has to be fulfilled. When the equipment is not placed on the market in the Member State of the final user, the person introducing the equipment in the linguistic area (e.g. the importer, the distributor, the manufacturer of an assembly including such equipment) must ensure the requirement is fulfilled.

For pressure equipment specifically manufactured for a defined end user which is subject to contract between the supplier and user, they can also contractually agree who shall do the translation(s) taking into account the national law.

Accepted by WPG on:	2003-05-15
Accepted by Working Group "pressure" on:	2003-11-03

9.22. Guideline 9/22

Guideline related to: Article 10 paragraph 4, Annex VII

Question: In which language must the EC declaration of conformity be written?

Answer: The EC declaration of conformity shall be drawn up in one of the official languages of the European Union, as chosen by the manufacturer or agreed by contract with the client.

See the guide to the implementation of directives based on New approach and Global approach § 5.4.

Note: In the process of the market surveillance, a national authority may request a translation of the EC declaration of conformity into its official language (see the guide to the implementation of directives based on New approach and Global approach § 8.2).

Accepted by WPG on:	2003-11-13
Accepted by Working Group "pressure" on:	2004-03-18

Reservation from Belgium

9.23. Guideline 9/23

Guideline related to: Article 4 paragraph 1, article 5 paragraph 1

Question: What aspects must not be assessed during inspections under national legislation before putting into service products falling in the scope of the Pressure Equipment Directive (PED)?

Answer: Pressure equipment and assemblies bearing the CE mark and the EC declaration of conformity are presumed to conform with the requirements of the PED. Therefore, during inspections under national legislation of such products, performed before putting into service, it is not permissible that:

- the fulfilment of essential requirements of the PED, e.g. integrity of welds or the sustainability of the design, is assessed again.
- product-related documentation (other than operating instructions and the EC declaration of conformity) is required to be provided by the user or manufacturer.

Note 1: The said inspections may e.g. verify whether the pressure equipment or assemblies have suffered from transport damage, whether their integration in the surrounding environment and/or their joining to the rest of the installation has been performed correctly according to national legislation or whether the operators have sufficient expertise.

Note 2: Any re-assessment of essential safety requirements already covered by the conformity assessment of the PED would be illicit double testing and constitute an impediment of the putting into service of equipment complying with the PED.

Note 3: This guideline does not address market surveillance activities, under the responsibility of public authorities, by application of Article 2.

Note 4: See also guidelines [1/3](#) and [8/3](#).

Accepted by WPG on:	2004-02-24
Accepted by Working Group "pressure" on:	2004-03-18

9.24. Guideline 9/24

Guideline related to: Article 1, article 2 paragraph 2, article 3, article 4 paragraph 1, article 5 paragraph 1

Question: What additional requirements for the design, manufacture and assessment of pressure equipment and assemblies covered by the Pressure Equipment Directive (PED) containing explosive/inflammable fluids are allowed in national regulations in addition to the requirements of the PED?

Answer: (1) All technical (design, manufacturing, conformity assessment) requirements addressing hazards related to pressure are covered by the PED. Any additional national requirements related to pressure would constitute an impediment of the free movement of products falling into the scope of the PED and are not permissible. The following are examples of non-permissible additional requirements:

- Specific requirements for protection against the release of the fluid
- Specific requirements for materials due to the nature of the fluid
- Specific requirements to avoid explosions/fires triggered by pressure (e.g. local heating due to pressure energy converted into thermal energy)

These aspects shall have been taken into account by the manufacturer as part of the hazard analysis.

(2) The PED does not consider the prevention of and protection against explosions/inflammations, which are not triggered by pressure (e.g. electrostatic ignition of an explosive fluid, etc.). These hazards may be addressed by national legislation, unless it is covered by other European legislation (e.g. ATEX Directive).

Note 1: This question is of particular relevance for national legislation on LPG, natural gas and hydrogen installations.

Note 2: The PED provisions on risk analysis and categories for conformity assessment take into account the explosive/inflammable nature of the fluid.

Note 3: However, national requirements can address installation conditions of the pressure equipment or assembly, e.g. in order to protect operators, environment or the pressure equipment / assembly itself.

Accepted by WPG on:	2004-02-25
Accepted by Working Group "pressure" on:	2004-03-18

10. GENERAL-HORIZONTAL QUESTIONS

1	SCOPE AND EXCLUSIONS OF THE DIRECTIVE
2	CLASSIFICATION AND CATEGORIES
3	ASSEMBLIES
4	EVALUATION ASSESSMENT PROCEDURES
5	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON DESIGN
6	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MANUFACTURING
7	INTERPRETATION OF THE ESSENTIAL SAFETY REQUIREMENTS ON MATERIALS
8	INTERPRETATION OF OTHER ESSENTIAL SAFETY REQUIREMENTS
9	MISCELLANEOUS
10	GENERAL-HORIZONTAL QUESTIONS

10.1. Guideline 10/1

Guideline related to: Horizontal guidelines

Question: Must the pressure equipment directive be applied to used pressure equipment imported from outside the European Economic Area?

Answer: Yes.

Reason: Blue guide, point 2.1 "Products submitted to directives";
Blue guide, point 7.2 "Products to be CE-marked"

Accepted by WPG on:
Accepted by Working Group "pressure" on: 1999-01-28

10.2. Guideline 10/2

Guideline related to: Horizontal guidelines

Question: Must the pressure equipment directive be applied to used pressure equipment imported from another country of the European Economic Area (EEA), if it was not manufactured under the regime to PED?

Answer: No, but national legislation of the receiving country will apply.

Reason: Guide to the Implementation of Directives Based on New Approach and Global Approach, point 2 "Scope of New Approach directives" (footnote 20 to be noted) and point 9.1 "The agreement on the European Economic Area".

Accepted by WPG on:	1999-01-28
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Accepted by Working Group "pressure" on: 1999-01-28, editorially amended on 2005-03-16 by WPG, confirmed on 2005-06-28 by WGP.
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10.3. Guideline 10/3

Guideline related to: Article 20, section 3

Question: Article 20, section 3 states that the transition period extends up to and includes 29 May 2002. If a manufacturer intends to place pressure equipment or assemblies on the market according to pre-PED national Regulations during the transition period, what conditions must be met?

Answer: 1. A necessary condition is that all manufacturing and conformity assessment operations required by the pre-PED national Regulations have been completed on or before 29 May 2002.

2. In addition, given that one of the purposes of including a transition period in the Directive is to provide time for manufacturers to reduce stocks, items of pre-PED pressure equipment must be physically transferred to the customer or distribution chain on or before 29 May 2002, unless the transfer of ownership has occurred before this date.

Supplementary points: Provided the conditions in 1 and 2 have been met, there are no restrictions on the subsequent sale of pre-PED pressure equipment (through a distribution chain for example) or when such equipment is eventually put into service within the respective Member state.

If a manufacturer retains some stocks of pre-PED pressure equipment or assemblies after 29 May 2002, then they can only be subsequently placed on the market if they are shown to be in compliance with the PED (This is not necessary if the items are intended for export to a country outside the Community). For subsequent use of such an item of pressure equipment in an assembly, refer to guideline 3/11.

Accepted by WPG on:	2000-10-02
Accepted by Working Group "pressure" on:	2000-11-08

10.4. Guideline 10/4

Guideline related to: Article 1 paragraph 2.1.5, Article 3 paragraph.2.2

Question: When an assembly is built by a subsidiary or affiliated company of the final user, is such an assembly covered by the PED?

Answer: Yes.

As the subsidiary or affiliate company is a separate legal entity – even if it is part of the same industrial group – the assembly is transferred between the two companies and hence is placed on the market. The subsidiary or affiliate company is to be considered the manufacturer.

Note: If the subsidiary or affiliate company acts under the overall responsibility of the user (as an installer or sub-contractor), the PED does not apply to this "installation" (see guideline [3/2](#)).

Accepted by WPG on:	2001-08-31
Accepted by Working Group “pressure” on:	2001-11-28

10.5. Guideline 10/5

Guideline related to: Article 5 and recitals 16 & 17

Question: **Harmonized standards frequently use normative references to other EN and non-EN standards. Do these referenced standards also confer presumption of conformity to the ESRs?**

Answer: It depends on the type of reference:

1. When a reference (which is contained in a part of a standard which provides presumption of conformity) to a particular, limited section of another standard, is used as a particular description in the harmonized standard, then the presumption of conformity extends to this reference.

In exceptional cases, an entire standard can be used as a particular description in the harmonized standard (test standards for instance).

In both cases, the referenced standards shall be dated. If it is not dated, the version valid at the time of publication of the standard containing the reference shall be used.

It should be noted, that the presumption of conformity is not valid for the referenced parts or standards independently, but only when applied in the context of the harmonized standard containing the references.

2. Other references, such as:

- references contained in an informative part,
- references with no direct relevance to harmonized normative parts,
- references to informative parts/documents,
- reference to pre-standards (ENV), technical specifications (TS); or other deliverables such as Technical reports (TR) or CEN workshop agreements (CWA),
- references to non EN standards, non ISO/IEC standards which do not comply with the applicable CEN/CENELEC rules (see note 1), do not confer this presumption of conformity.

It should also be noted that the entire reference list, which typically is given as clause 2 of EN standards, does not in itself confer presumption of conformity.

Note 1: Applicable CEN/CENELEC rules require the following:

- ensure that no suitable CEN, CENELEC, ETSI, ISO or IEC documents are available and confirm that there is a necessity to refer to a document other than those developed by CEN, CENELEC, ETSI, ISO and IEC;
- confirm that it is impractical to include the relevant text in full;
- justify the need for making reference to a document other than those developed by CEN, CENELEC, ETSI, ISO and IEC;
- ensure and confirm that the referenced document shall:
 - have wide acceptance;

- not be in contradiction with the European legislation, nor create regulatory problems when the EN is implemented by CEN/CENELEC members;
- have been prepared in accordance with the principles set in the ISO/IEC Guide 59 - Code of Practice for Standardization - (with the definitions of EN 45020) and in the ISO/IEC Directives;
- have clearance in respect of possible IPR (Intellectual Property Rights) issues as prescribed in CEN/CENELEC Memorandum 8;
- not be a draft, but shall be an adopted document with an identified and dated issue;
- be publicly available in official CEN/CENELEC languages, at least in English.

Note 2: For a harmonized standard whose reference is published in the OJEC, the annex ZA gives the relation between the ESR's covered by the standard and the corresponding clauses of this standard.

Accepted by WPG on:	2001-08-30
Accepted by Working Group "pressure" on:	2001-11-29

10.6. Guideline 10/6

Guideline related to: Annex VII

Question: What is the information to be given in the Declaration of Conformity in order to comply with indents 8 and 9 of Annex VII?

Answer: The harmonised standard or specification referred to is the governing document(s) embracing all aspects of materials, design, manufacture and testing of the item of pressure equipment or assembly.

If the governing document is an internal specification or a published technical code, this information shall also be given.

However, as regards conditions related to the use of such documents, see also guidelines 9/5 and 9/6 particularly.

Reason: According to paragraph 5.4 of the “Guide to implementation of directives based on New Approach and Global Approach”, the standards or other documents (such as published technical codes and internal specifications) used should be described in a precise, complete and clearly defined way; It is not requested to give the complete list of the standards used in combination with the governing document.

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10.7. Guideline 10/7

Guideline related to: Annex III, modules D, D1, E, E1, H and H1

Question: In Annex III, for modules D, D1, E, E1, H and H1, specific documentation is required to be retained for a period of 10 years after the last date of manufacture.

The text specifically requires that 'documentation concerning the quality system' be retained. Does this also include quality records such as material certificates, test reports etc?

Answer: Yes.

The provisions concerning the retention of records shall be described in the manufacturer's quality system documentation. The description of technical documentation, in section 3 of module A, should act as the guiding principle for the other modules. This includes results of examinations, test reports, material certificates, etc. and has to be kept by the manufacturer, or his authorised representative, for 10 years after the last of the pressure equipment has been manufactured.

See also the Guide to the Implementation of Directives based on New Approach and Global Approach, sub-clause 5.3.

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10.8. Guideline 10/8

Guideline related to: Annex VII

Question: What is the information to be given in the Declaration of Conformity of assemblies in order to comply with the 4th indent of Annex VII?

Answer: The declaration of conformity of assemblies must contain a description of all items of pressure equipment constituting the assembly together with, for each PED item, the conformity assessment procedure followed.

Note: This description includes the identification of the items of pressure equipment falling under category I to IV.

The other items taken into account in the assessment of the integration of the PED assembly (including Art 3 paragraph 3 equipment or pressure equipment excluded from the PED) shall also be described as part of this assembly. This latter description may be by reference to appropriate information in the instructions for use (e.g. component lists, drawings). See also guideline **3/13**.

See also paragraph 5.4 of the “Guide to implementation of directives based on New Approach and Global Approach”.

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