GUIDE FOR ASME STAMP HOLDERS

Use of ASME Section VIII, Division 1 to Meet the EC Pressure Equipment Directive (97/23/EC)

The American Society of Mechanical Engineers

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FOREWORD

This Guide is a comprehensive review of the Pressure Equipment Directive (PED) and ASME Section VIII, Division 1.

ASME has received requests from all over the world to provide guidance to manufacturers who have been or will be impacted by the European PED. This document provides that guidance.

Manufacturers of Section VIII pressure vessels will find this document to be a useful tool when working with a notified body toward compliance with the PED and applying the CE mark to their products.

This document begins with an explanation of the European New Approach, and continues with the goals of the PED and a description of its scope of coverage. Then, the document offers an in-depth analysis of the PED concept of hazard categories and the various combinations of conformity assessment modules that can be used for each hazard category. Each of the PED Essential Safety Requirements are then covered, including materials, use of Notified Bodies, and requirements for CE marking.

The reader is next presented with a detailed comparison of the PED with Section VIII, Division 1, followed by a modified version of Annex Z for Section VIII, Division 1. This Annex Z provides instructions regarding what additional tasks must be completed to meet the administrative requirements of the PED.

As an added bonus, a list of interpretations developed in France is provided, with information on how to obtain copies of each.

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INTRODUCTION

With the adoption of 97/23/CE, the *EC Pressure Equipment Directive (PED)*, in May 1997, it soon became clear that pressure equipment designed and built to standards other than European standards could carry the CE mark. This was made possible by the European New Approach, in which Essential Safety Requirements (ESR) are established in the Directives, and standards are used to support them. Manufacturers in the US, Europe, and elsewhere approached ASME with requests to provide information on how they could use the ASME Boiler and Pressure Vessel Code to meet most of the ESR of the PED and thereby take advantage of improved movement of goods that is the goal of the New Approach.

Shortly after May 1999, ASME initiated sponsorship of a project conducted by the Pressure Vessel Research Council. The purpose of the project was to conduct a thorough analysis of the PED and compare its ESR with the design, construction, and administrative requirements of ASME Section VIII, Division 1. PVRC gathered experts on the PED and on Section VIII, Division 1 from Europe and the US to conduct this analysis. The result is this Guide, which is composed of three major portions. The first portion consists of Chapters I through X, which gives an overview of the PED, provides important basic information on the entire Directive, and identifies specific issues of higher importance. The next major portion is Chapters XI and XII, which provides a comparison of the PED and Section VIII, Division 1 requirements, including commentary on both, and an Annex Z for Section VIII, Division 1. Annex Z provides Section VIII Code users with instructions on how to augment their current practices to meet all ESRs of the PED. The third portion of this Guide gives a listing of approved CLAP interpretation sheets.

Because of the nature of ongoing learning regarding the application of the PED, the information contained in this Guide will need to be augmented and updated. ASME plans to issue such updates to the Guide in the future, as necessary. It is intended that this Guide will eventually form the basis for understanding between manufacturers and Notified Bodies regarding the use of ASME Section VIII, Division 1 as the basis for compliance with the PED. Having such a uniform approach will benefit not only manufacturers and Notified Bodies, but also users of pressure equipment.

The PED Information Resource Center website (ped.eurodyn.com) provides the latest information on the status of European approval of materials, names, contact information for all Notified Bodies, and other valuable news and developments

Updates to this Guide can be found at the ASME website at www.asme.org.

ASME acknowledges the efforts of the Pressure Vessel Research Council and its peer review groups, and especially Elmar Upitis, Kam Mokhtarian, and Francis Osweiller, for their efforts in developing this Guide.

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GUIDE FOR ASME STAMP HOLDERS

USE OF ASME SECTION VIII, DIVISION 1 TO MEET THE *EC PRESSURE EQUIPMENT DIRECTIVE (97/23/EC)*

CHAPTER I
THE EUROPEAN CONTEXT

1 MAIN CONCEPTS OF NEW APPROACH DIRECTIVES

(a) Before 1985, the European Directives were not mandatory, and many of them were not applied in European countries.

(b) In 1985 a *New Approach to Technical Harmonization and Standards* was established. The main objectives were to

(1) remove technical barriers to trade to permit free movement of goods throughout the European Union (EU)

(2) implement common regulations and common standards throughout the EU

(c) The fundamental principles of the *New Approach* are as follows:

(1) Directives are fully mandatory throughout the EU and supersede national regulations.

(2) Directives contain only Essential Safety Requirements (ESR), which are defined in terms of general safety objectives to enforce a common high level of protection in the EU regarding the hazards inherent to the product.

(3) EN-Standards will be explicit and quantify ESR to achieve these safety objectives. Use of these EN-Standards is not mandatory, but products complying with these standards are presumed to comply with the ESR of the Directive.

(4) Each Directive sets out Conformity Assessment Procedures to ensure that the product complies with all the requirements of the Directive. These procedures are selected from the European Council Decision on *Conformity Assessment Procedures* (July 1993) and are adapted to the products covered by each Directive.

(5) Each product covered by a Directive must be in full conformity with its specifications and must be CE marked, which will ensure free movement throughout the EU.

(6) A product may be subject to several Directives. Appendix X-3 in this Guide lists the *New Approach Directives*. Items appearing in boldface in Appendix X-3 apply to the PED and must be taken into account in the design and manufacture of pressure equipment, where applicable.

2 TERMS USED IN EUROPEAN DIRECTIVES

Appendix I-1 in this Guide gives a definition of the main terms used in the Directives, and especially in the PED. These terms are identified in this Guide by an initial capital letter (Notified Body, Marking, etc.).

Abbreviations are as follows:

ESR = Essential Safety Requirements
NB = Notified Body
EU = European Union
PED = Pressure Equipment Directive
EAM = European Approval for Materials
OJEC = Official Journal of European Communities

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APPENDIX I-1
GLOSSARY OF TERMS USED IN NEW APPROACH DIRECTIVES

CE marking: products in compliance with all the provisions of the applicable Directives, which provide for the CE marking, must bear this marking. Thus, the CE marking indicates, in particular, that the products comply with the essential requirements of all applicable Directives and that the products have been subject to a conformity assessment procedure provided for in the Directive. Furthermore, Member States are obliged to take appropriate measures to protect the CE marking.

conformity assessment procedures: before placing a product on the Community market, the Manufacturer must subject the product to a conformity assessment procedure provided for in the applicable Directive, with the intent of affixing the CE marking.

coordination of implementation: where the Member State or the Commission considers that a harmonized standard does not fully meet the essential requirements of a Directive, the matter will be brought to the attention of the committee set up by Directive 98/34/EC (i.e., Committee on technical standards and regulations). The Commission shall, taking into account the committee's opinion, notify the Member States to whether or not the standard should be withdrawn from the list published in the OJEC.

Many New Approach Directives provide for a Standing Committee, which may assist the Commission in delivering its opinion on the draft measures proposed to implement the provisions of the relevant Directive and to examine any matter relating to implementation and practical application of the Directive. Furthermore, regular meetings to discuss implementation issues take place as working groups, which are composed of representatives appointed by Member States and interest groups (e.g., notified bodies, standards organizations, manufacturers, distributors, and trade unions), chaired by the Commission.

essential safety requirements (ESR): essential requirements are set out in annexes to the Directives, and include all that is necessary to achieve the objectives of the Directive. Products may be placed on the market and put into service only if they are in compliance with the essential requirements.

New Approach Directives are generally designed to cover all typical risks related to public interest that the Directive intends to protect. Thus compliance with Community legislation often requires simultaneous application of several New Approach Directives and, possibly, other Community legislation. Furthermore, some elements may have been left outside the scope of the applicable Community legislation. This allows member states to draw up national legislation, in accordance with Articles 30 and 36 of the Treaty.

free movement: Member States must presume that products bearing CE marking comply with all provisions of the applicable Directives providing for its affixing. Accordingly, Member States may not prohibit, restrict, or impede the placing on the market and putting into service in their territory of products bearing CE marking, unless the provisions relating to CE marking are incorrectly applied.

As an exemption, Member States may prohibit, restrict, or impede the free movement of products bearing CE marking — in accordance with Articles 30 and 36 of the Treaty — because of risk that is not covered by the applicable Directives.

notified bodies (NB): third party conformity assessment is carried out by notified bodies, which have been designated by the Member States from the bodies, established on their territory, that fulfill the requirements specified in the Directive.

placing on the market and putting into service: Member States are obliged to take the necessary measures to ensure that products are placed on the market and put into service, only if they do not endanger the safety and health of persons, or other public interests covered by the Directive, when properly installed, maintained, and used for the intended purposes. This entails an obligation for market surveillance on the part of the Member States.

Member States are allowed to adopt, in Compliance with the Treaty (e.g., Articles 30 and 36), additional national provisions to protect, in particular, workers, consumers, or the environment. However, these provisions may neither require modifications of the product

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nor influence the conditions for its placing on the market.

presumption of conformity: products that comply with national standards, which have been incorporated into harmonized standards and the reference numbers of which have been published in the OJEC, are presumed to comply with the corresponding essential requirements. Where the Manufacturer has not applied, or has only partially applied such a standard, it must document the measures taken and their adequacy to comply with the essential requirements.

safeguard clause: Member States are obliged to take all appropriate measures to prohibit or restrict the placing on the market of products bearing CE marking or to withdraw them from the market, if these products may compromise the safety and health of individuals or other public interest covered by the applicable Directives, when the products are used for their intended purpose. Furthermore, the Member State must inform the Commission of such a measure. Where the Commission considers the national measure justified, it informs all Member States who must take appropriate action.

scope: defines the range of products covered by the Directive, or nature of hazards the Directive is intended to avert. It usually covers risks related to a product (i.e., product approach) or risks related to a phenomena (i.e., risk approach). Accordingly, a product may be covered by several Directives.

transposition and transitional provisions: Member States are required to incorporate the provisions of the Directives into their national legislation. They must inform the Commission of the measures taken.

Member States must permit the placing on the market products that are in compliance with regulations in force in their territory at the date of application of the Directive in question, until the date established by the Directive. Under certain restrictions, such products must also be permitted to be placed into service beyond that date.

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CHAPTER II
PED OVERVIEW

1 INTRODUCTION

1.1 General

Pressure components present inherent hazards due to the potential energy of their content, especially for gas. As a consequence, most industrial countries have regulated these products for many decades.

This is the case with the European countries that have developed national regulations, which often vary significantly. Some are very detailed (as in France), others contain only very general requirements (as in the UK), and some others have developed very detailed Conformity Assessment Procedures for Pressure Equipment (as in Germany). This profusion of different regulations leads to technical barriers to trade. In 1989 the EU decided to establish a *Pressure Equipment Directive* to eliminate these problems.

1.2 Intent

The PED has three intents:

(a) Adopt a common regulation for Pressure Equipment throughout EU.

(b) Eliminate the technical barriers to trade for this industrial sector and permit free movement of products throughout the EU.

(c) Ensure a high level of safety for Pressure Equipment throughout the EU.

The third intent is the most important one, as the PED has been built on this concept of safety level with the implementation of four Hazard Categories. Therefore, the PED is more a hazard-oriented than a product-oriented Directive. As a consequence, **the PED covers only the pressure hazard. Other Directives may be applicable to cover other hazards.**

A list of Directives that may also be applicable to Pressure Equipment is given in Appendix X-2 in this Guide. Manufacturers must not forget that when they affix the CE Marking, they implicitly declare that their equipment fully complies with all the Directives that apply to it.

1.3 Manufacturers

The liberal principles of the *New Approach* applied to the PED will lead to more freedom than before. The Manufacturers will be free to select

(a) their Notified Body: anywhere in the EU

(b) the Conformity Assessment Procedure: adapted to their fabrication

(c) how they will comply with the Essential Safety Requirements: use of the European Harmonized Standard or a National Code

1.4 Requirements

PED, like any European Directive, includes three types of requirements, which are

(a) legislative, as contained in Articles 1 to 21 of the PED

(b) devoted to Conformity Assessment Procedures (detailed in Annex III of the PED), which concern the responsibilities of Manufacturers and Notified Bodies

(c) devoted to the equipment itself and are called Essential Safety Requirements (detailed in Annex I of the PED)

2 GENERAL CONCEPTS

The *Pressure Equipment Directive* was adopted on May 29, 1997 and published in the Official Journal of European Communities (OJEC) on July 9, 1997 under the reference 97/23/CE.

The two main purposes of the PED are as follows:

(a) Set up in the 15 countries of the European Union (EU) a common regulation for all Pressure Equipment to ensure a high level of safety throughout the EU.

(b) Allow the free movement of Equipment in the EU to remove the technical barriers to trade.

This Directive came into force in November 1999 and will become fully mandatory in May 2002.

The purpose of this Guide is to make the users familiar with the key elements of the PED.

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2.1 Scope

The PED applies to all Equipment (pressure vessels, piping, boilers) subject to a pressure greater than 0.5 bar.

Despite several exclusions, such as nuclear field, this scope is very wide as it covers usual products (such as pressure-cookers) as well as large industrial Equipment (such as chemical reactors or liquefied gas vessels). The PED applies only to new Equipment.

2.2 Hazard Categories

Equipment that is above the thresholds specified by the PED is classified in four categories (I, II, III, and IV) according to their hazards, based on

(a) the nature of the fluid contained (more or less hazardous)

(b) the internal pressure (higher or lower)

(c) the internal volume (larger or smaller)

Equipment below these thresholds is not subject to the requirements in paras. 2.3 through 2.6.

2.3 Conformity Assessment Procedures

Each pressure equipment must be subject to a Conformity Assessment Procedure to verify that it complies with the specifications of the Directive. For each Hazard Category, one or several procedures are proposed to the Manufacturer. These procedures are more stringent for the higher categories. A reduction of stringency is provided for the Manufacturers who operate a Quality Assurance system.

2.4 Notified Body

The conformity assessment is performed by an independent inspection organization, notified by each of the Member States to the European Commission, who publishes the list in the OJEC. The Manufacturer may select any of the Notified Bodies from this list for the conformity assessment of the Equipment.

2.5 CE Marking

The CE Marking must be affixed on each piece of equipment, which complies with the specifications of the PED, ensuring the equipment the benefit of free movement in the EU.

2.6 Essential Safety Requirements

Each piece of equipment classified in one of the four Hazard Categories must fulfill all the Essential Safety Requirements specified in Annex I of the PED. These technical requirements cover the design, material, fabrication, testing, and inspection aspects for the equipment.

3 STRUCTURE OF PED

The PED has 21 Articles, which are listed in Appendix II-1 of this Guide.

The following articles form the cornerstone of the PED:

Article 1:	defines the Scope of PED.
Article 3:	defines the thresholds (pressure and volume) above which the Pressure Equipment will have to be classified in Hazard Categories and subject to Essential Safety Requirements, listed in Annex I of the PED
Article 9:	defines the four Hazard Categories (I, II, III, IV) that are obtained from graphs, given in Annex II of the PED
Article 10:	defines the Conformity Assessment Procedures, detailed in Annex III of the PED, which enable the NB to inspect the Equipment
Article 11:	defines *European Approval for Materials*
Article 12:	defines the role of the Notified Bodies
Article 20:	defines *Transitional Provisions*

These Articles are completed by seven Annexes of technical nature (Annexes I, II, III) or administrative nature (Annexes IV to VII), which are listed in Appendix II-1 of this Guide. Appendix II-2 presents a flowchart of the PED.

The remaining articles, which are of legal or administrative nature and are common to all New Approach Directives, are of little interest to Pressure Equipment Manufacturers:

(a) Articles devoted to Member States: Articles 2 (Market Surveillance), 4 (Free Movement), 5 (Presumption of Conformity), 8 (Safeguard Clause), 16, 17, 18, 19, and 21 of the PED.

(b) Articles of administrative nature: Articles 6 and 7 of the PED.

4 TRANSITIONAL PERIOD (ARTICLE 20 OF THE PED)

The PED was adopted on May 29, 1997. It was implemented on November 29, 1999 for a transitional period of 2.5 years, which shall end on May 29, 2002.

(a) Before May 29, 1999, each of the Member

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States must have incorporated the PED in its national regulation (Article 20-§1 of the PED).

(b) After November 29, 1999, beginning of the transitional period, the manufacturers of Pressure Equipment may choose between the following two items:

(1) Applying the PED. Each Pressure Equipment must bear the CE Marking and has the benefit of free movement within the EU.

(2) Applying the Present National Regulation. The Equipment cannot bear the CE Marking and will not have the free movement within the European Community.

(b) From May 30, 2002, end of the transitional period (Article 20-§3 of the PED):

(1) The application of the PED shall be fully mandatory in the 15 countries of EU and shall supersede the current National Regulations.

(2) Any Pressure Equipment within the scope of the PED shall have to comply with it and bear the CE Marking.

(3) The PED applies only to new Equipment. Equipment already in service shall not be subject to the PED, but will continue to meet the National Regulations.

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Article 2 Market surveillance
Article 3 Technical requirements*
Article 4 Free movement
Article 5 Presumption of conformity
Article 6 Committee on technical standard and regulations
Article 7 Committee on Pressure Equipment
Article 8 Safeguard clause
Article 9 Classification of Pressure Equipment*
Article 10 Conformity assessment*
Article 11 European approval for materials*
Article 12 Notified Bodies*
Article 13 Recognized third-party organizations*
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Annex II Conformity Assessment Tables*
Annex III Conformity Assessment Procedures*
Annex IV Criteria of the Notified Bodies
Annex V Criteria of the User Inspectorates
Annex VI CE Marking
Annex VII Declaration of Conformity

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* Article/Annex is referenced in this Guide.

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APPENDIX II-2
FLOWCHART FOR PRESSURE EQUIPMENT DIRECTIVE (97/23/CE)

The flowchart of the PED is presented on the following page.

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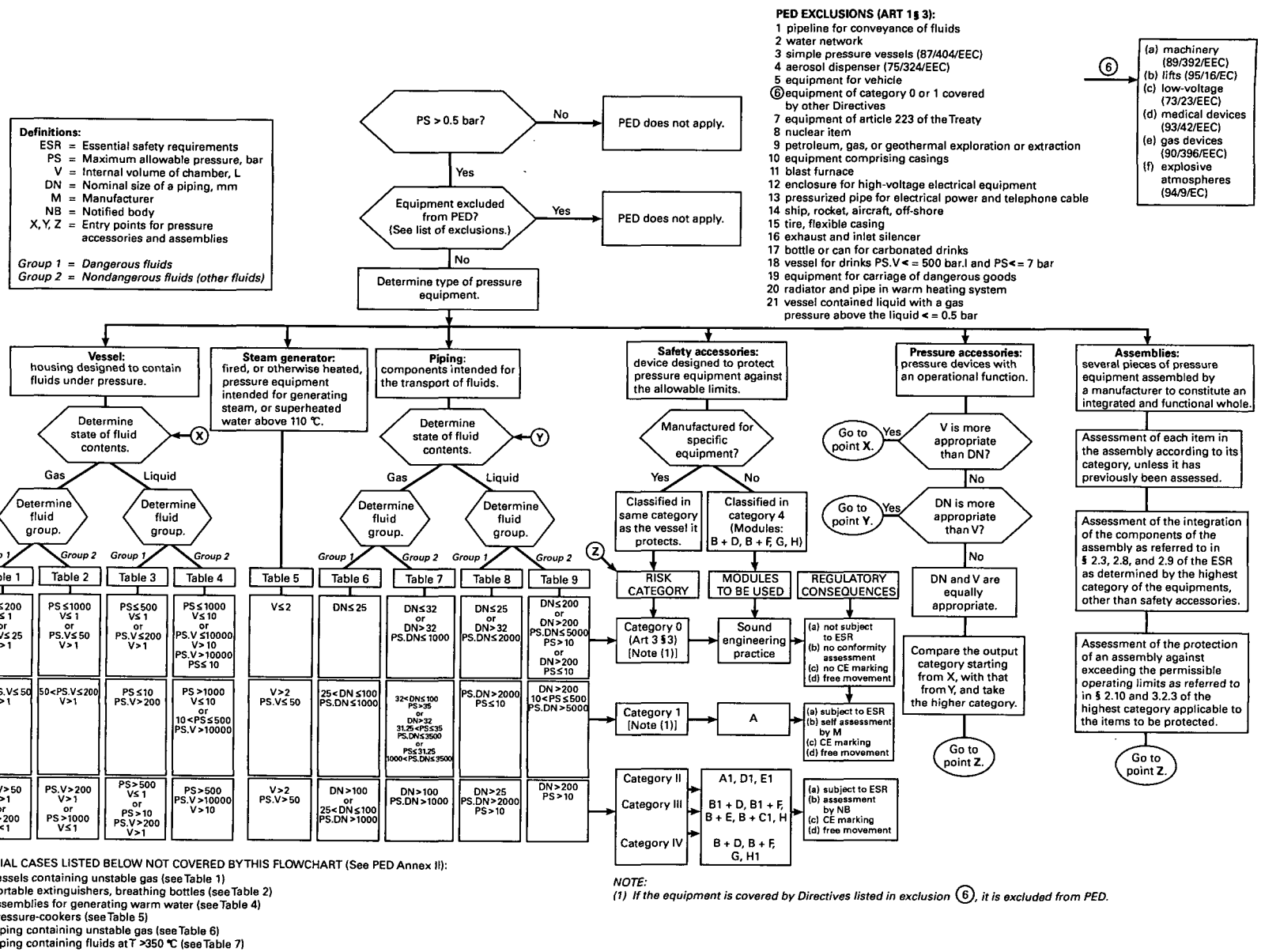

SPECIAL CASES LISTED BELOW NOT COVERED BY THIS FLOWCHART (See PED Annex II):

(a) vessels containing unstable gas (see Table 1)
(b) portable extinguishers, breathing bottles (see Table 2)
(c) assemblies for generating warm water (see Table 4)
(d) pressure-cookers (see Table 5)
(e) piping containing unstable gas (see Table 6)
(f) piping containing fluids at T >350 °C (see Table 7)

NOTE:
(1) If the equipment is covered by Directives listed in exclusion (6), it is excluded from PED.

FIG. II-2-1 FLOWCHART FOR THE PED

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CHAPTER III
SCOPE
(ARTICLE 1 OF THE PED)

1 SCOPE (ARTICLE 1-§1 OF THE PED)

The PED embraces all Pressure Equipment subject to an internal pressure of gas or fluid above 0.5 bar. It applies to new Equipment fabricated in the EU (and to new or used Equipment imported from countries outside the EU).

In-service inspection of operating Equipment is covered in the national regulations of each EU country. (It is not intended to develop an EU Directive covering in service inspection.)

All materials, metallic and nonmetallic are considered.

This scope is very wide as it covers any pressure containment above 0.5 bar from simple pressure cookers to large water-tube boilers.

2 TYPES OF EQUIPMENT COVERED (ARTICLE 1-§2 OF THE PED)

In the PED, the term *Pressure Equipment* covers the four following types:

vessel: a component intended to contain a fluid (gas or liquid) above 0.5 bar. This covers what was formerly called pressure vessels (unfired or fired).

piping: a component intended for the transport of fluids.

safety accessories: devices designed to protect the Equipment.

pressure accessories: devices with an operational function and subject to pressure (such as valves, pressure regulators, pressure gauges, filters, expansion joints, etc.).

Components (such as covers, collars, gaskets, flanges, bolts, and nozzles) are not considered as pressure accessories and cannot bear the CE Marking.

PED covers also Assemblies made of several parts of Pressure Equipment, assembled by the Manufacturer to constitute an integrated and functional whole, such as boilers.

These Assemblies are mentioned several times throughout the PED and are covered in Appendix X-1 of this Guide.

Only the above four types of Pressure Equipment (plus Assemblies) can bear the CE Marking and have the free movement throughout EU.

Equipment subject to less than 0.5 bar are not regulated by the PED, as they do not present a hazard.

3 PED EXCLUSIONS (ARTICLE 1-§3 OF THE PED)

Because the scope is very wide, many exclusions are listed in the PED (21 in total). They are of three types:

(a) Specific Equipment (e.g., pipelines, water networks, and nuclear sector), which are too difficult to regulate

(b) Equipment already covered by other Directives (e.g., Simple Pressure Vessels, Aerosol Dispensers, and Transportation of Dangerous Goods)

(c) Equipment that does not present significant hazards due to pressure (e.g., motor vehicles, tires, and gaseous bottles)

A list of these exclusions is provided in Appendix III-1 of this Guide.

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APPENDIX III-1
PED EXCLUSIONS
(ARTICLE 1-§3 OF THE PED)

(1) pipeline for conveyance of fluids

(2) water network

(3) simple pressure vessels (87/404/EEC)

(4) aerosol dispenser (75/324/EEC)

(5) equipment for vehicle

(6) equipment of Category 0 or I covered by other Directives

(7) equipment of article 223 of the Treaty

(8) nuclear item

(9) petroleum, gas, or geothermal exploration or extraction

(10) equipment comprising casings

(11) blast furnace

(12) enclosure for high-voltage electrical equipment

(13) pressurized pipe for electrical power and telephone cable

(14) ship, rocket, aircraft, off-shore

(15) tire, flexible casing

(16) exhaust and inlet silencer

(17) bottle or can for carbonated drinks

(18) vessel for drinks PS.V < 500 bar l and P < 7 bar

(19) equipment for carriage of dangerous goods

(20) radiator and pipe in warm heating system

(21) vessel contained liquid with a gas pressure above the liquid < 0.5 bar

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CHAPTER IV
HAZARD CATEGORIES
(ARTICLE 3, ARTICLE 9, ANNEX II OF THE PED)

1 LEVEL OF HAZARDS IN PRESSURE EQUIPMENT

PED is a hazard-directed Directive, rather than a product Directive. Its primary goal is to prevent potential hazards due to internal pressure in Equipment.

Several levels of hazards are considered in the PED, which have practical consequences for the Equipment both for the stringency of the Essential Safety Requirements and Conformity Assessment Procedures to be carried out.

Level 1 The pressure is 0.5 bar or lower: There is no significant hazard, and the equipment is outside the scope of the PED.

Level 2 The pressure is above 0.5 bar, but the Equipment presents only a minor pressure hazard, which does not require a Conformity Assessment. This is often called Category 0, which defines the threshold above which the Equipment is classified in Hazard Categories I, II, III, or IV.

Level 3 The pressure hazard level is low: The equipment is classified in Hazard Category I. There is no intervention of the NB.

Level 4 The pressure hazard level is moderate: The equipment is classified in Hazard Category II. The NB will check the Fabrication.

Level 5 The pressure hazard level is high: The equipment is classified in Hazard Category III. The NB will check the Design and the Fabrication.

Level 6 The pressure hazard level is very high: The equipment is classified in Hazard Category IV. The NB will perform increased check of the Design and Fabrication.

Therefore, there are two main cases for Pressure Equipment:

(a) the Equipment is below the thresholds of Category 0

(b) the Equipment is above the thresholds of Category 0

2 EQUIPMENT IN CATEGORY 0 (ARTICLE 3-§3 OF THE PED)

This concerns all the equipment that is at or below the thresholds defined in Article 3-§3 of the PED (see Fig. 1 in this Guide). These thresholds depend on the type of the Equipment, the dangerousness of the fluid, and the pressure (PS) and volume (V) of the Equipment. This is Category 0 (which does not appear as such in the PED) and is covered by Article 3-§3 of the PED.

Such equipment

(a) is not subject to the ESR: it must be constructed in accordance with Sound Engineering Practice

(b) is not subject to the Conformity Assessment Procedures

(c) is not subject to the Declaration of Conformity: it must only bear the identification of the manufacturer and be accompanied by instructions for use

(d) must not bear the CE Marking; however, it has the benefit of the free movement throughout the EU

3 EQUIPMENT IN HAZARD CATEGORIES I TO IV (ARTICLE 3-§1 OF THE PED)

Equipment that is above the thresholds defined in Article 3-§3 of the PED is classified in Hazard Category I to IV, depending on their level of hazard. This Equipment

(a) is subject to ESR

(b) is subject to the Conformity Assessment Procedure

(c) is subject to the Declaration of Conformity

(d) must bear the CE Marking

(e) has free movement throughout the EU

Hazard categories depend on the following factors:

(a) Type of Equipment: Vessel (fired on unfired), Piping, Safety Accessory, Pressure Accessory.

(b) Nature of Fluid:

(1) Gas in the sense of the PED (Article 3-§1.1a of the PED): gas, liquefied gas, gas dissolved under pressure, vapors, etc.

(2) Liquid in the sense of the PED (Article 3-

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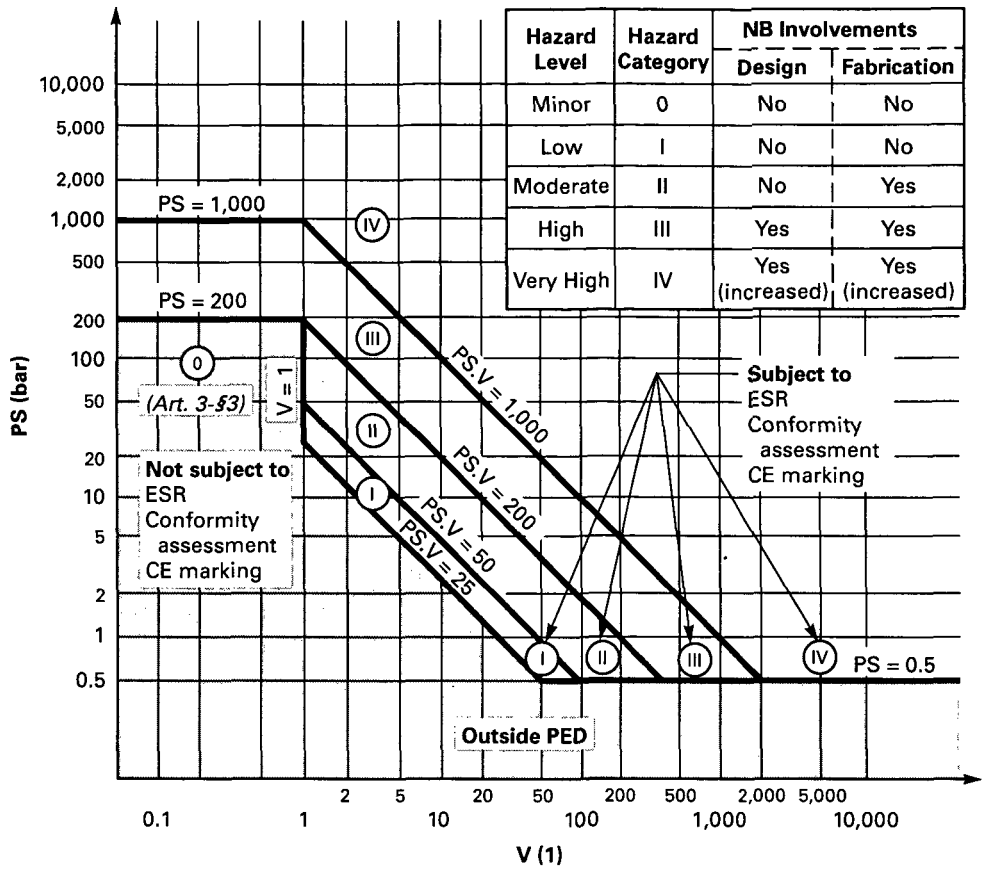

Hazard Level	Hazard Category	NB Involvements	
		Design	Fabrication
Minor	0	No	No
Low	I	No	No
Moderate	II	No	Yes
High	III	Yes	Yes
Very High	IV	Yes (increased)	Yes (increased)

FIG. 1 HAZARD CATEGORY FOR A VESSEL CONTAINING A DANGEROUS GAS (REFER TO TABLE 1 OF THE PED)

§1.1b of the PED): liquids having a vapor pressure 0.5 bar.

(c) Dangerousness of the fluid, which is classified into two groups (Article 9-§2 of the PED):

(1) Group 1: Dangerous fluids (explosives, flammable, toxic, oxidizing).

(2) Group 2: Nondangerous fluids (all others).

(d) Operations conditions characterized by the maximum allowable pressure, PS, and the internal volume, V (for Vessels), or the nominal diameter, DN (for Piping).

The hazard categories are defined in the PED by graphs (Tables 1 through 9 of Annex I of the PED). These graphs include some errors, which have been corrected in Appendix IV-1 of this Guide.

How to determine the hazard category is explained as follows for each type of Equipment.

4 VESSELS NOT SUBJECT TO FIRE OR HEAT (ARTICLE 3-§1.1 OF THE PED)

Figure 1 enables the determination of the Hazard Category of a vessel "not fired, nor heated with a risk of overheating" containing a dangerous gas, as a function of internal volume, V, and maximum allowable pressure, PS.

NOTE:

(1) If the vessel is composed of several chambers, the determination of the Hazard Category must be performed for each chamber and the higher hazard category is to be used.

(2) The volume, V, to be used is the total internal volume of the vessel or the chamber (not the volume occupied by the fluid).

(3) Each demarcation line pertains to the lower hazard category.

Three additional graphs, given by Tables 2, 3, and 4 of the PED (Annex II), cover vessels containing a

(a) nondangerous gas (Table 2)

(b) dangerous liquid (Table 3)

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(c) nondangerous liquid (Table 4)

5 VESSELS SUBJECT TO FIRE OR HEAT (ARTICLE 3-§1.2 OF THE PED)

This covers vessels subject to fire (e.g., boilers) and vessels subject to heat with the risk of overheating (e.g., pressure cookers) intended for generation of steam or superheated water (at T <110°C, or 230°F).

This is a nondangerous liquid, and only one graph (Table 5 of the PED) is sufficient to determine the Hazard Category.

6 PIPING (ARTICLE 3-§1.3)

As for unfired vessels, four graphs are necessary to determine the Hazard Category of piping given by Tables 6, 7, 8, and 9 of the PED.

7 SAFETY ACCESSORIES (ARTICLE 3-§1.4, ANNEX II-§2 OF THE PED)

According to the Hazard Category of the Equipment on which the safety accessory is fitted, the following two cases are possible:

(a) The equipment is in Category 0 (Article 3-§3 of the PED). The safety accessory is classified in Category 0, which indicates use of Sound Engineering Practice (instead of ESR). No Conformity Assessment and no CE Marking is required.

(b) The Equipment is in Hazard Category I, II, III, or IV (Annex II-§2 of the PED). Two cases are possible:

(1) The accessory is fabricated specifically for the Pressure Equipment: The safety accessory is in the same Hazard Category as the Equipment,

(2) The accessory is not fabricated specifically for the Pressure Equipment: The accessory is classified in Hazard Category IV.

8 PRESSURE ACCESSORIES (ARTICLE 3-§1.4, ANNEX II-§3 OF THE PED)

According to the Hazard Category of the Pressure Equipment on which the Pressure Accessory is fitted, the following two cases are possible (Annex II-§2 of the PED):

(a) The Equipment is in Category 0 (Article 3-§3 of the PED). The Pressure Accessory is in Category 0, which indicates use of Sound Engineering Practice (instead of ESR). No Conformity Assessment and no CE Marking is required.

(b) The Equipment is in Hazard Category I, II, III, or IV. The Accessory is classified using its pressure, PS, and its volume, V (using Table 1, 2, 3, 4, or 5 of the PED, as appropriate), or its nominal diameter, DN, (using Table 6, 7, 8, or 9 of the PED, as appropriate).

NOTE: If both V and DN are considered appropriate to define the Accessory, it is classified in the higher Hazard Category.

9 SUMMARY

The Hazard Category system forms the cornerstone of the PED both on technical and legal aspects. The Hazard Category has a significant impact on

(a) the severity level of the ESR applicable to the Equipment

(b) the stringency level of the Conformity Assessment Procedure to be performed by the NB and the Manufacturer

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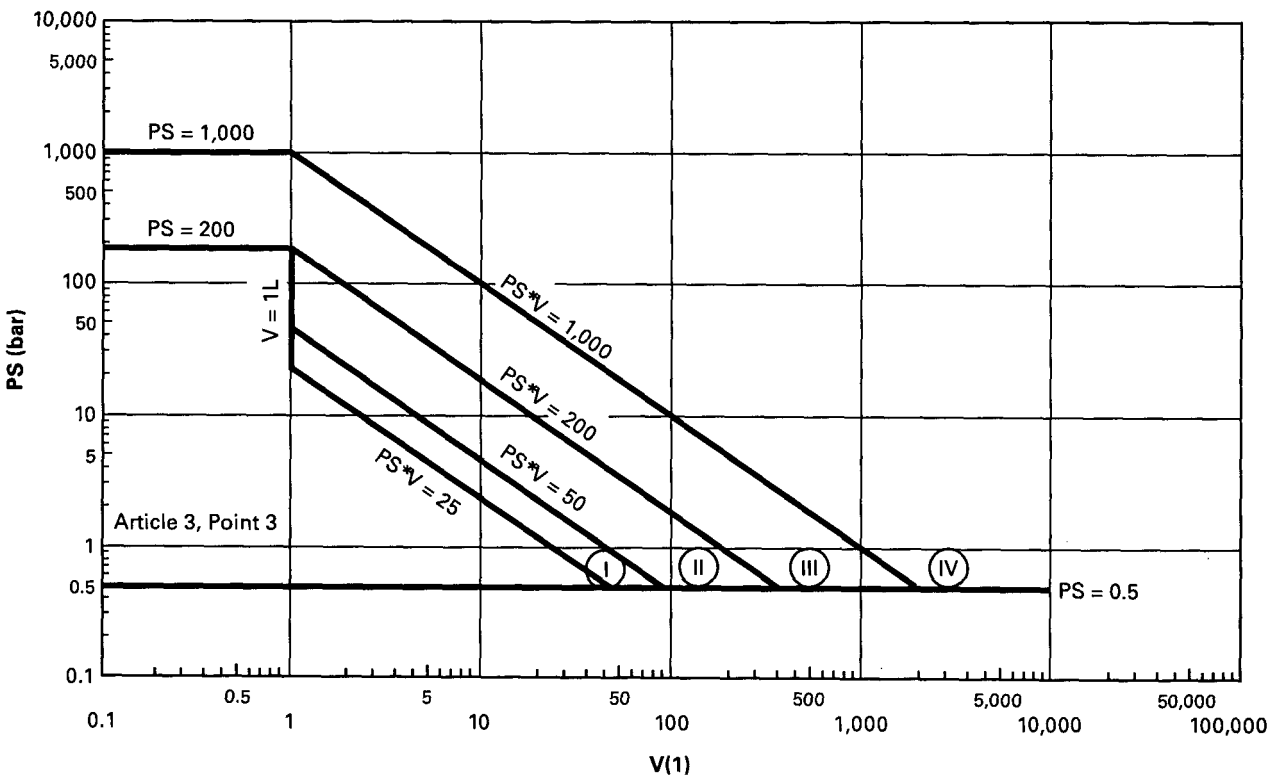
APPENDIX IV-1
GRAPHS FOR HAZARD CATEGORIES

The following graphs reproduce those given in the PED (Annex II, Tables 1 through 9), with correction of the errors.



GENERAL NOTE: Exceptionally, vessels intended to contain an unstable gas and falling within categories I or II on the basis of PED Table 1 must be classified in category III.

TABLE IV-1-1 VESSELS CONTAINING A DANGEROUS GAS

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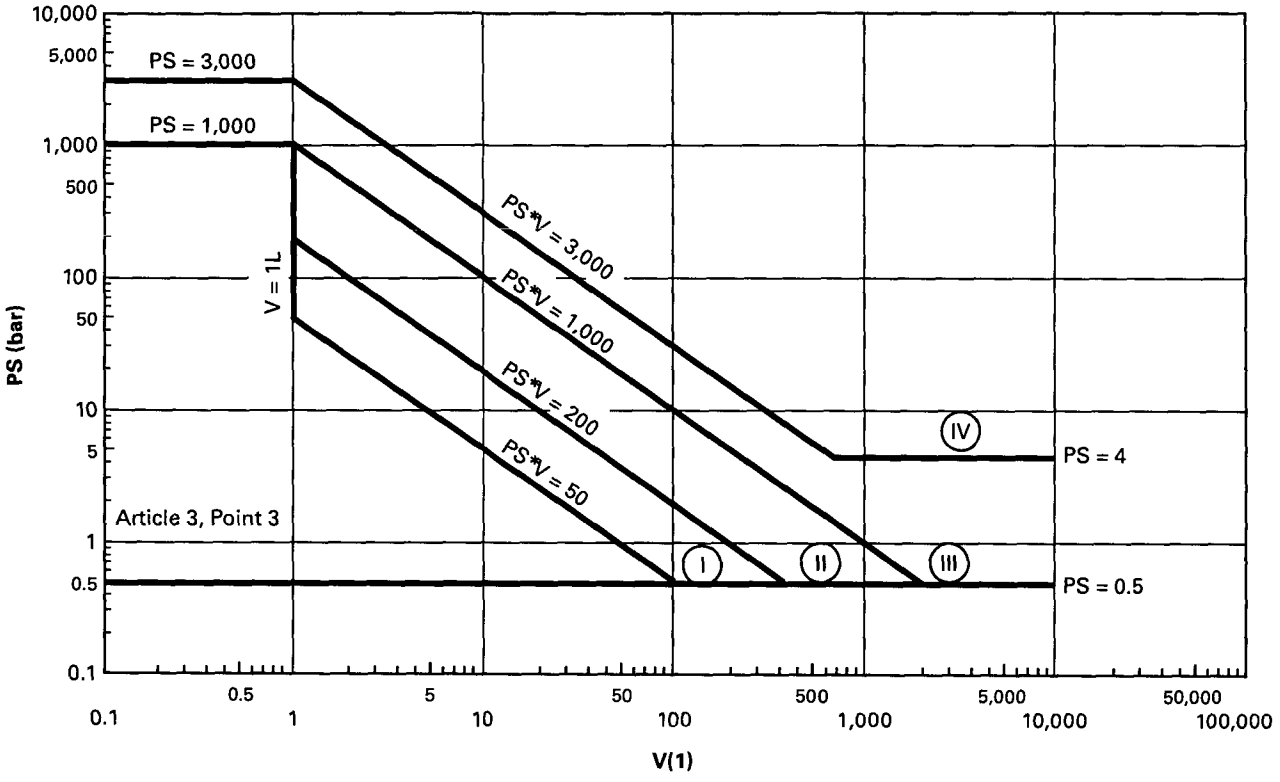

GENERAL NOTE: Exceptionally, portable extinguishers and bottles for breathing equipment must be classified at least in category III.

TABLE IV-1-2 VESSELS CONTAINING A NONDANGEROUS GAS

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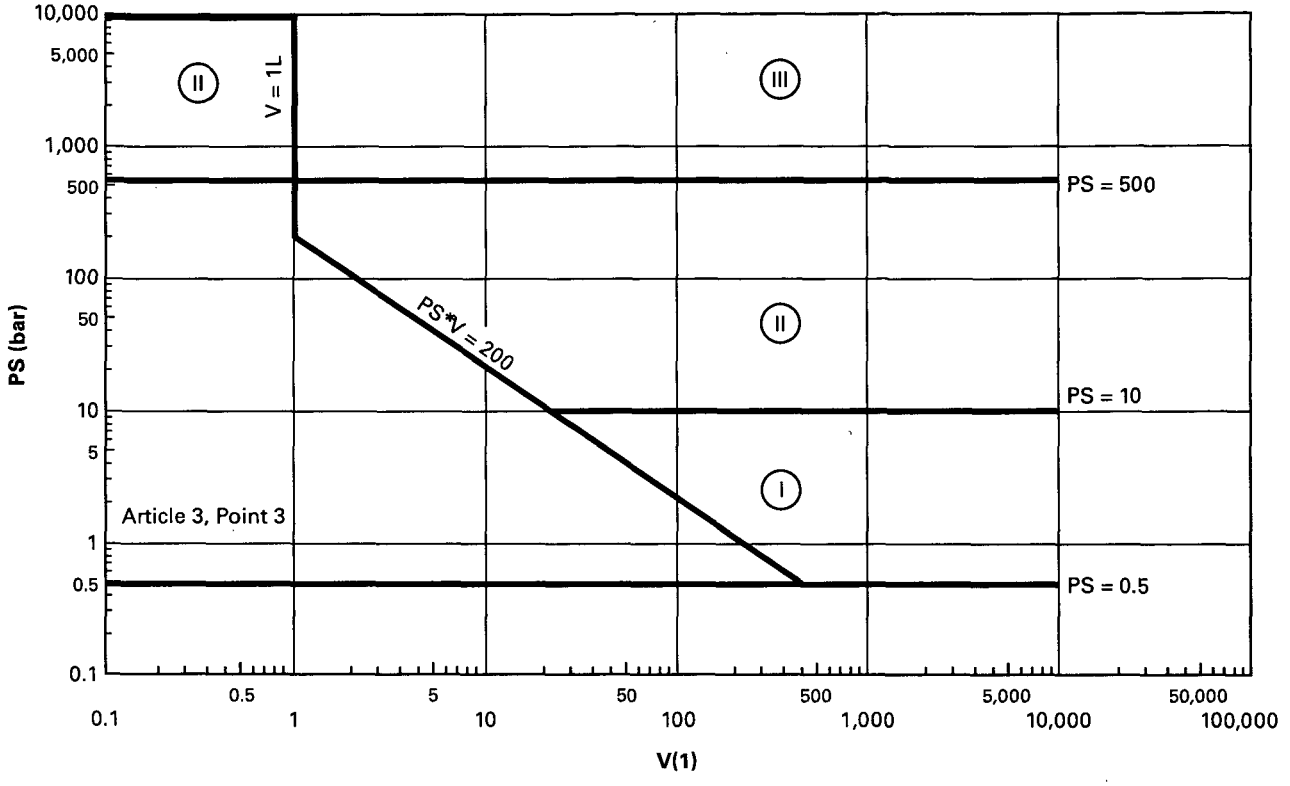

TABLE IV-1-3 VESSELS CONTAINING A DANGEROUS LIQUID

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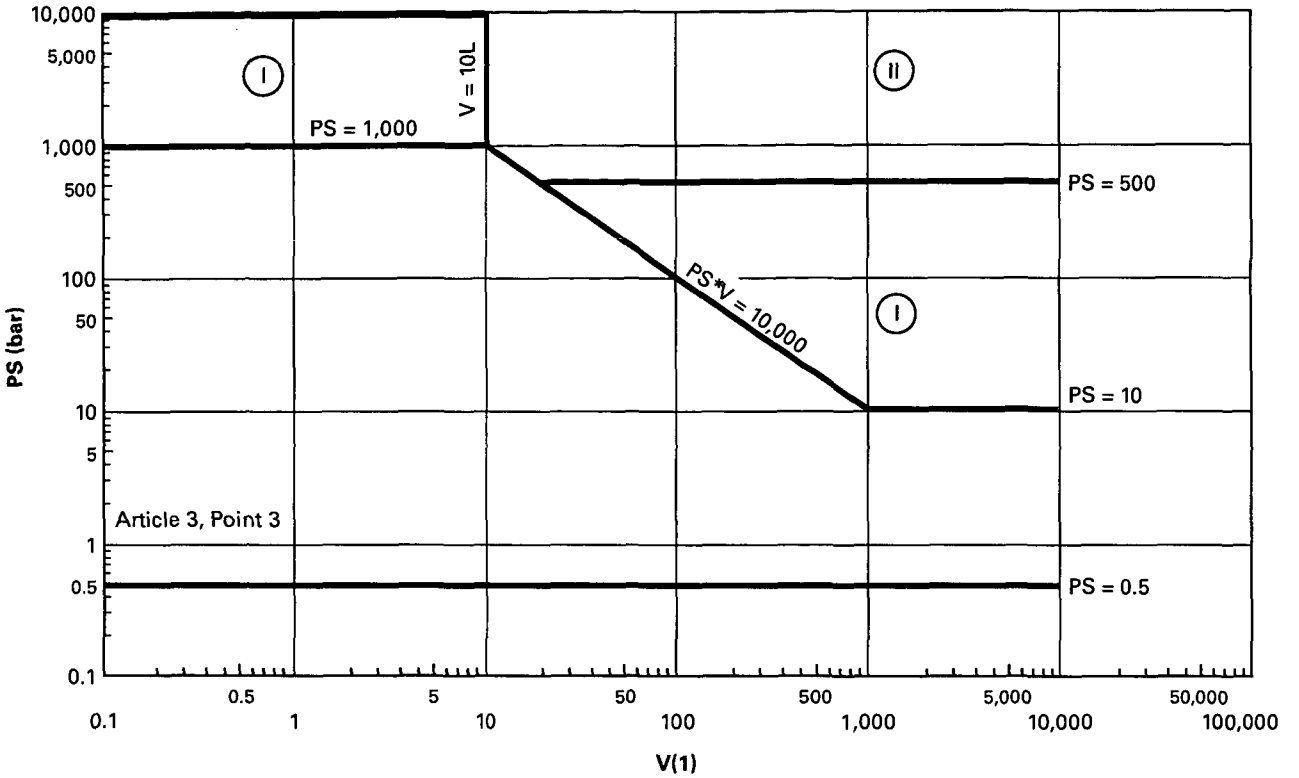

GENERAL NOTE: *Exceptionally, assemblies intended for generating warm water as referred to in* Article 3, Section 2.3, must be subject either to an EC design examination (Module B1) with respect to their conformity with the essential requirements referred to in Sections 2.10, 2.11, 3.4, 5(a), and 5(d) of Annex I, or to full quality assurance (Module H).

TABLE IV-1-4 VESSELS CONTAINING A NONDANGEROUS LIQUID

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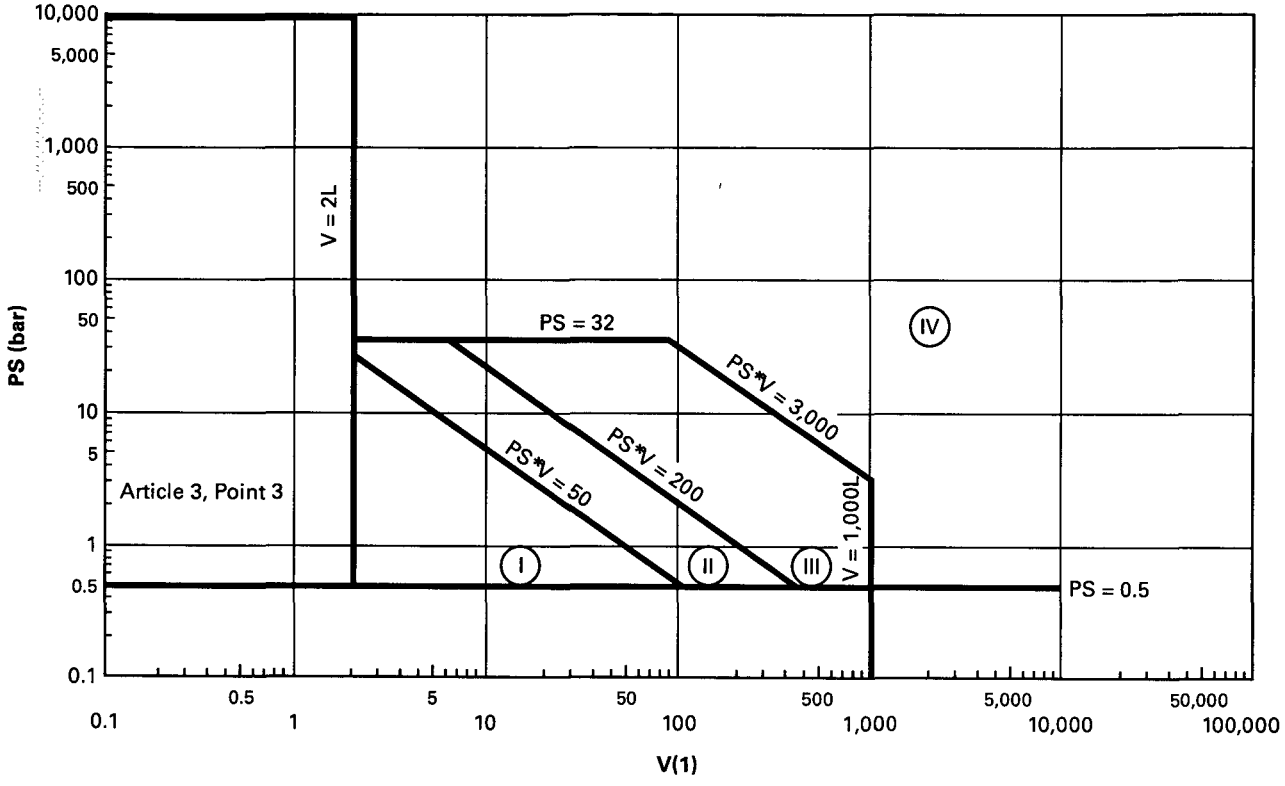

GENERAL NOTE: Exceptionally, the design of pressure-cookers must be subject to a conformity assessment procedure equivalent to at least one of the category III modules.

TABLE IV-1-5 BOILERS

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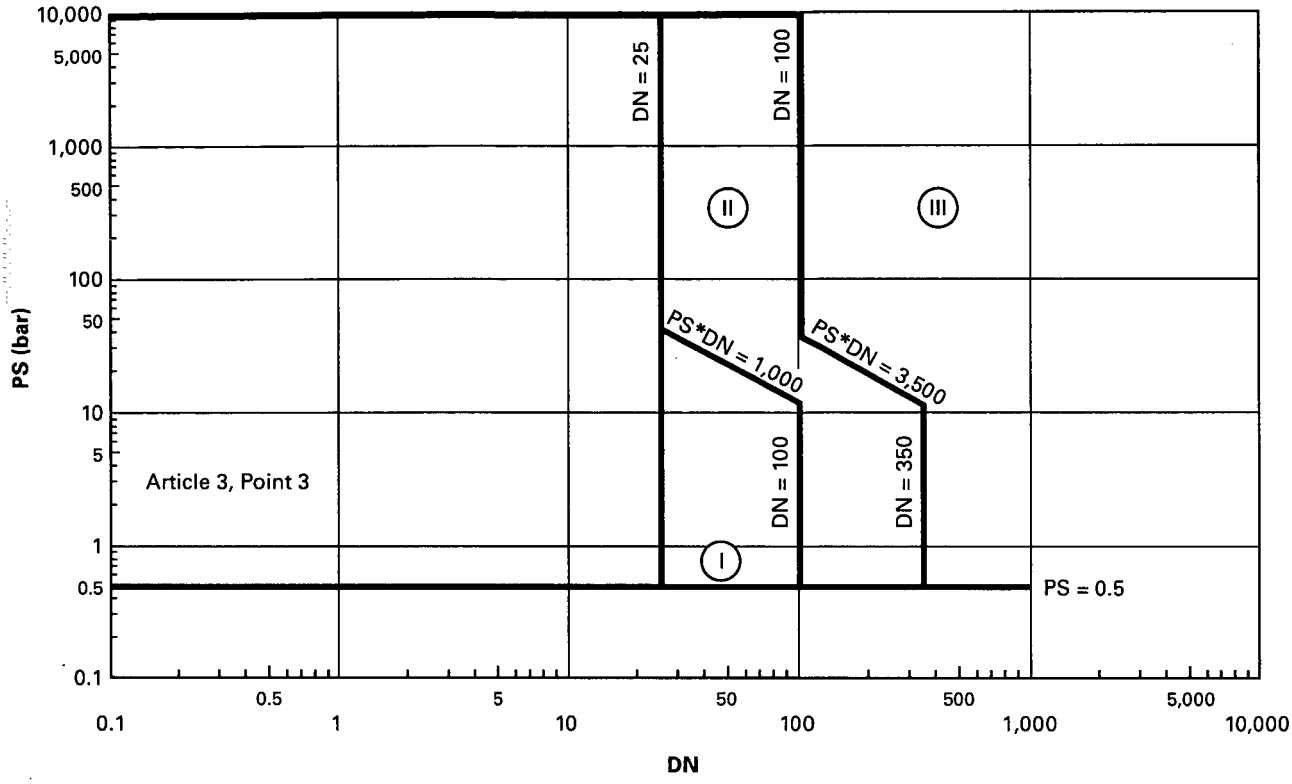

GENERAL NOTE: Exceptionally, piping intended for unstable gases and falling within categories I or II on the basis of PEDTable 6 must be classified in category III.

TABLE IV-1-6 PIPING CONTAINING A DANGEROUS GAS

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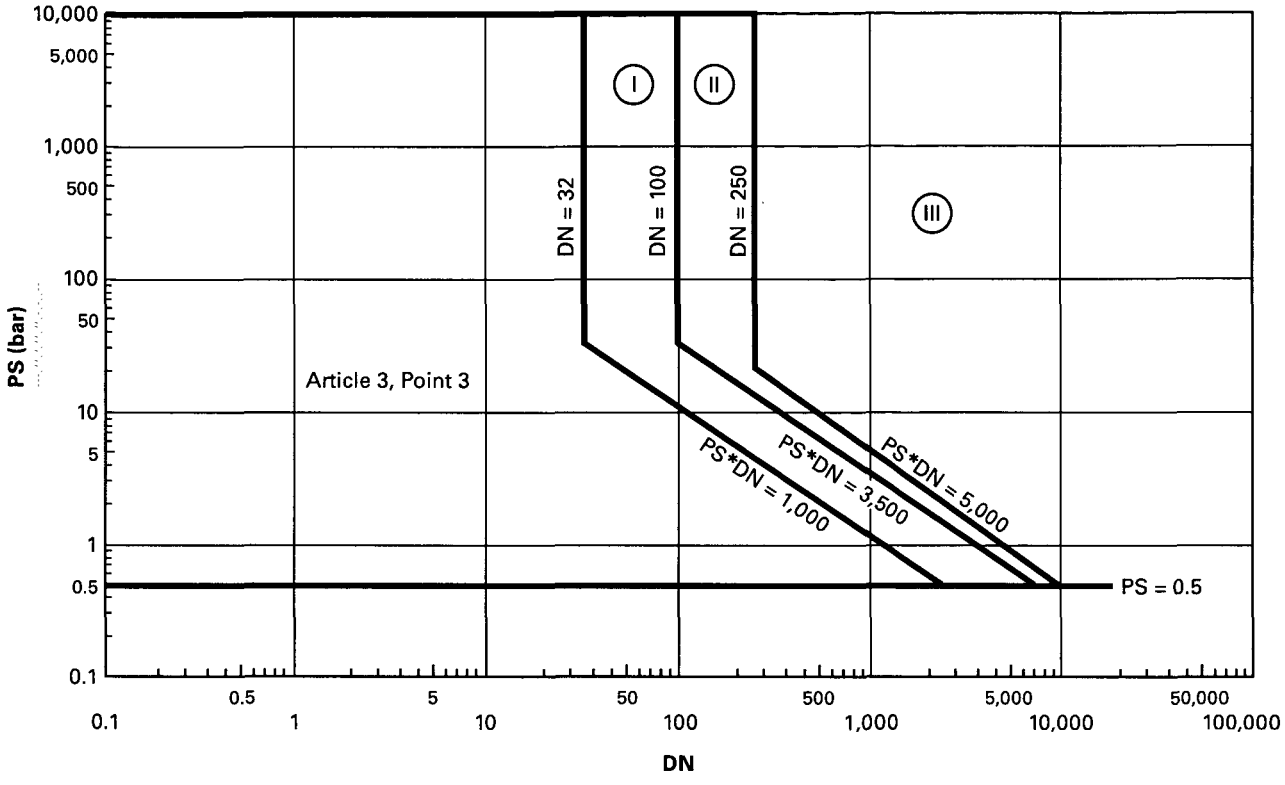

GENERAL NOTE: Exceptionally, all piping containing fluids at a temperature greater than 350°C and falling within category II on the basis of PED Table 7 must be classified in category III.

TABLE IV-1-7 PIPING CONTAINING A NONDANGEROUS GAS

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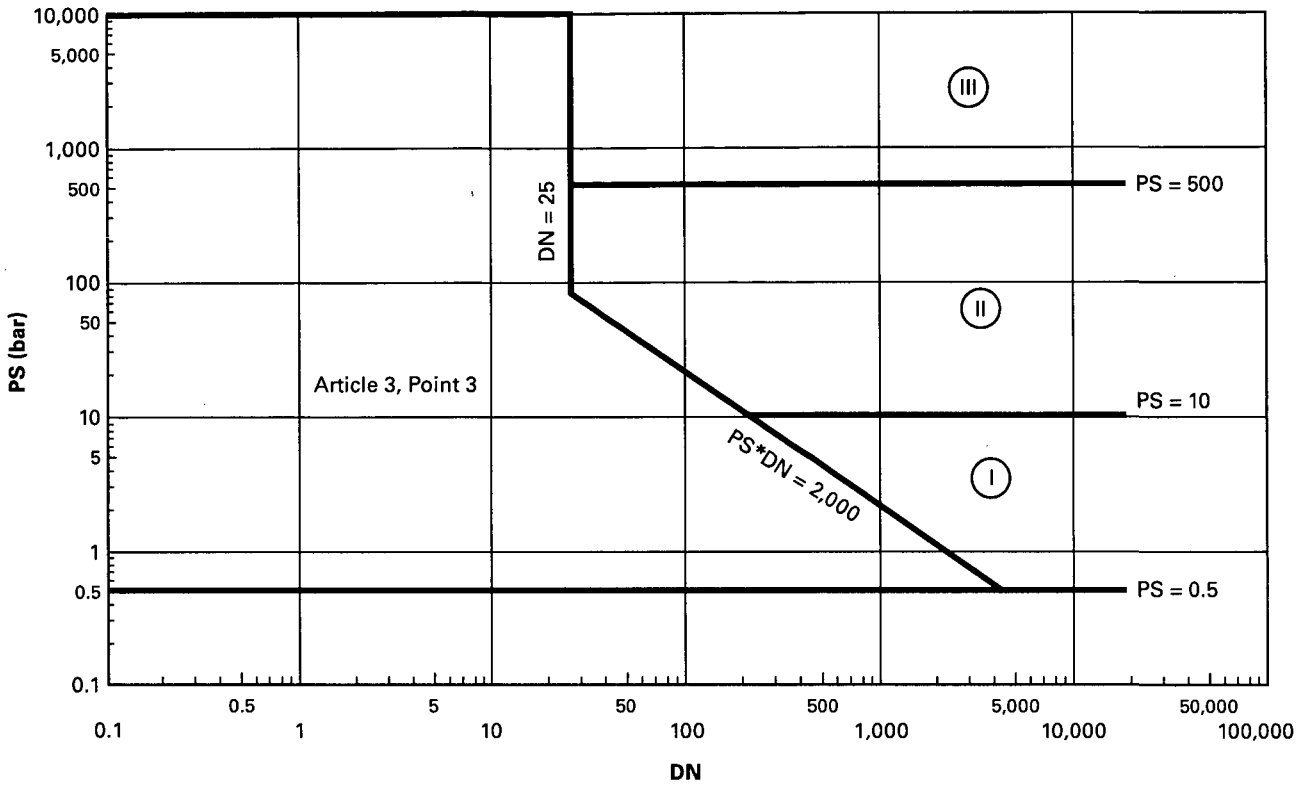

TABLE IV-1-8 PIPING CONTAINING A DANGEROUS LIQUID

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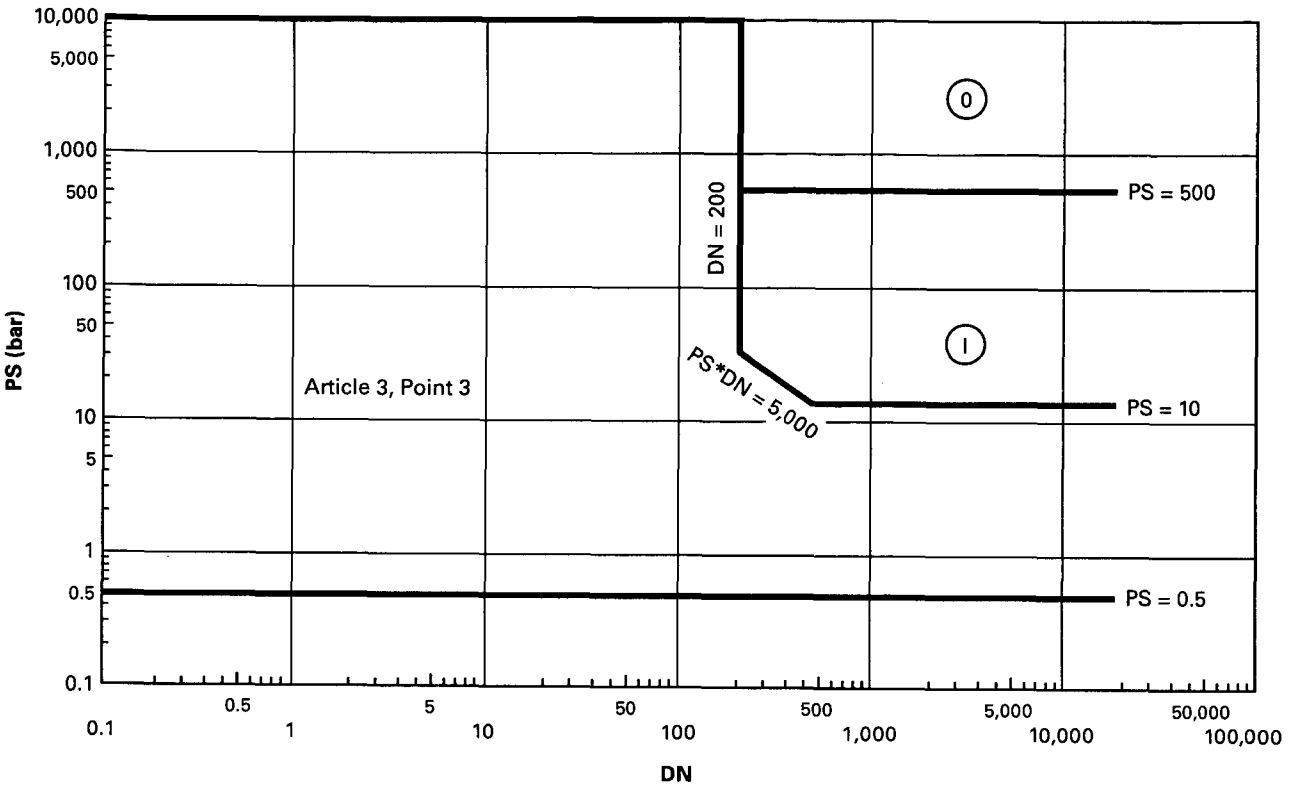

TABLE IV-1-9 PIPING CONTAINING A NONDANGEROUS LIQUID

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CHAPTER V
CONFORMITY ASSESSMENT PROCEDURES (ARTICLE 10, ANNEX III OF THE PED)

1 INTRODUCTION

(a) Any product regulated by a European Directive is subject to a Conformity Assessment to ensure that it complies with all the requirements of the PED, generally under the responsibility of a Notified Body (NB) (Article 10-§1 of the PED).

The European Council Decision of July 22, 1993 (93/465/EEC) contains a list of possible Conformity Assessment Procedures, which European Directives must refer to for the Conformity Assessment of the products they cover.

(b) Seven Conformity Assessment Procedures that are proposed conform to the following principles (see Table 1 of this Guide).

(1) Each procedure is divided into a design phase and a production phase.

(2) In each phase, the roles and responsibilities of the Manufacturer and the NB are detailed.

(3) Some procedures are better adapted to single production (procedures H, G).

Others are better adapted to series production (procedures B+C, B+E, B+F, B+D). In this case the procedure is divided in two modules covering separately the design phase and the production phase.

(4) The Manufacturer always has the choice between

(a) a Conformity Assessment Procedure without a QA system: the NB will check the product itself.

(b) a Conformity Assessment Procedure requiring a QA system: the NB will check the QA system more than the product itself.

(5) The Seven Conformity Assessment Procedures of Table 1 of this Guide imply an increasing involvement of the NB from procedure A to procedure H, depending on the level of hazard presented by the Equipment covered by the Directive.

(6) Each Manufacturer must select a Conformity Assessment Procedure among these seven procedures. Their application is mandatory for affixing the CE Marking (Article 10-§2 of the PED).

2 GENERAL CONCEPT (ARTICLE 10-§1.3 OF THE PED)

(a) The PED uses these seven conformity assessment procedures (A to H) plus six additional ones, (which are identified in Table 2 of this Guide), making a total of 13 procedures.

The multiplicity of these procedures results from the consensus between 15 countries and is justified by

(1) the diversity of types of Pressure Equipment

(2) the diversity of means of production (unit production, series production, with or without QA system)

(3) the diversity of hazard levels presented by these Equipment, which has led to four Hazard Categories in the PED

Table 2 of this Guide shows a general overview of these Conformity Assessment Procedures.

(b) In each Hazard Category one or several Conformity Assessment Procedures, of equivalent stringency, are proposed to the Manufacturer, depending on production (single or series) and if there is a QA system (see Table 3).

When the Hazard Category increases, the requirements of the procedures become more severe and there is more involvement of the NB:

Category I	No intervention by the NB (Procedure A)
Category II	No intervention by the NB at Design phase, but surveillance by the NB during production phase (A1) or surveillance by the NB of QA system (D1, E1)
Category III	Design examination by the NB and final assessment of the equipment (B+C1, B1+F). Surveillance of the QA system (B+E, B1+D, H)
Category IV	Increased intervention of the NB (B+F, G, B+D, H1)

The Manufacturer may always use a Conformity Assessment Procedure of a higher category level.

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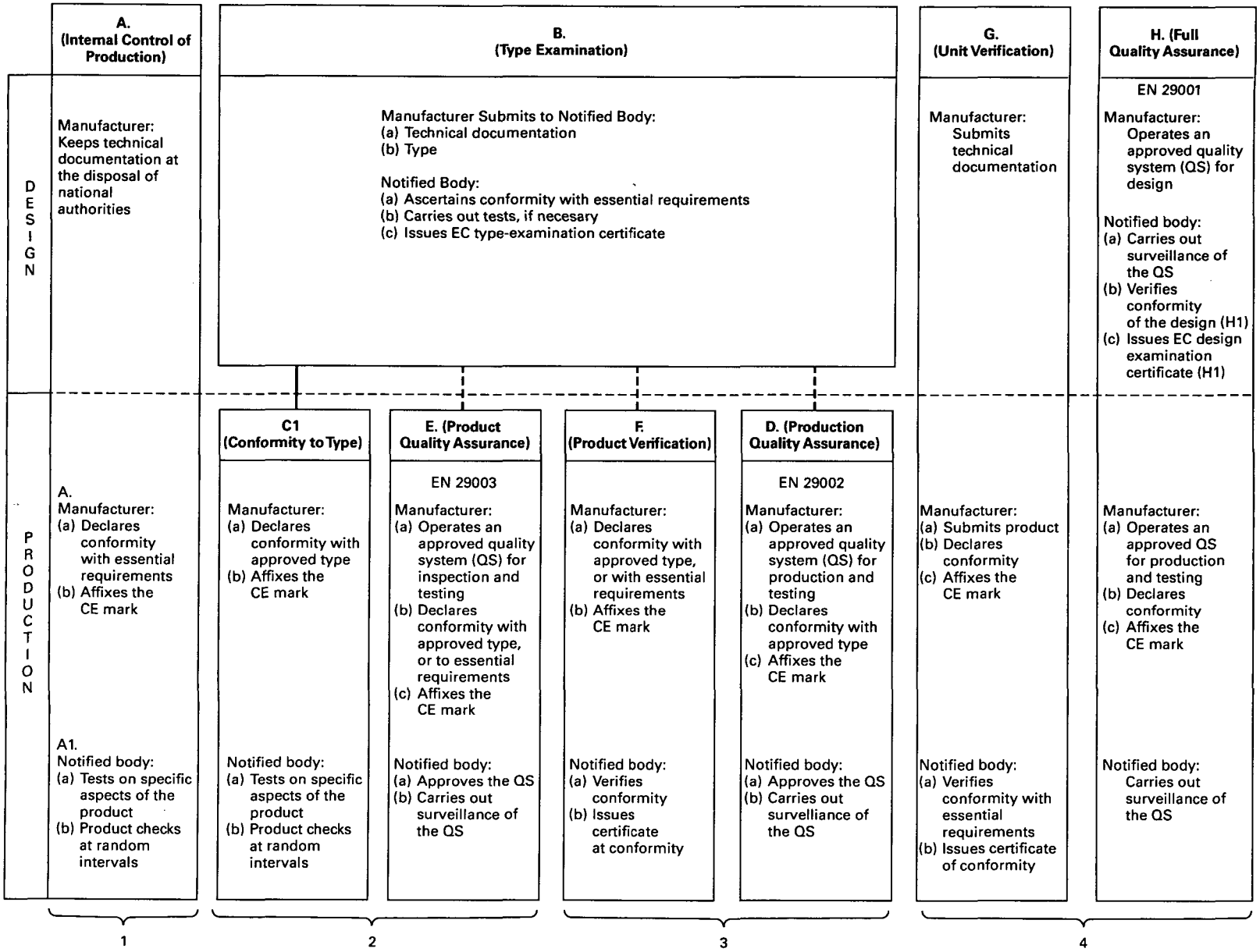

TABLE 1 CONFORMITY ASSESSMENT PROCEDURES

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TABLE 2 CONFORMITY ASSESSMENT PROCEDURES IN PED

Module	Risk Category	Design	Production
A	I	Technical documentation	Internal production control
A	II	Technical documentation	Internal production control with surveillance of the final assessment
B	III IV	Type examination	without QA: C or F with QA: E or D
B1	III	Design examination	without QA: F with QA: D
C	III	(Module B)	Conformity of the production to the type
D	III IV	(Module B or B1)	QA for production (ISO 29002)
D1	II	Technical documentation	QA for production (ISO 29002)
E	III	(Module B)	QA for final testing on products (ISO 29003)
E1	II	Technical documentation	QA for final testing on products (ISO 29003)
F	III IV	(Module B or B1)	Product verification
G	IV	Unit verification	Unit verification
H	III	QA for design	QA for prduction (ISO 29001)
H1	IV	QA for design, with design examination	QA for production with specific surveillance of final assessment (ISO 29001)

Adapted to SERIAL production

Adapted to UNIT production

Adapted to SERIAL or UNIT production

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TABLE 3 CONFORMITY ASSESSMENT PROCEDURE TO BE APPLIED IN EACH HAZARD CATEGORY

	Without QA		With QA	
Category	Series	Unit	Series	Unit
I	A	A	A	A
II	A1	A1	D1 or E1	D1 or E1
III	B + C B1 + F	B1 + F	B + E B1 + D	H B1 + D
IV	B + F	G	B + D	H1

3 STRUCTURE OF THE PROCEDURES

(a) Each Conformity Assessment Procedure is described in detail in Annex III of the PED and specifies the respective tasks and responsibilities of the manufacturer and of the NB for the Design and Production phases. For all Equipment

(1) the manufacturer must

(a) draw up the Technical Documentation

(b) ensure conformity to the ESR by drawing up a Declaration of Conformity (Annex VII of the PED)

(c) affix the CE Marking

(d) affix the identification number of the NB

(2) the NB must check the conformity of the Equipment with the ESR by applying the specifications of the Procedure. This check will differ according to whether the manufacturer uses a QA procedure.

(b) For the six Conformity Assessment Procedures without QA (A, A1, B+C, B+F, B1+F, G), the NB must examine the Design and the Fabrication of each Equipment, and perform appropriate tests, so as to check its conformity to the ESR, except for the following procedures:

(1) Procedure A. Self-certification by the Manufacturer.

(2) Procedure A1. Self-certification by the Manufacturer and surveillance by an NB that takes the form of unexpected visits.

(c) For the Seven Conformity Assessment Procedures with QA (D1, E1, B+E, B+D, B1+D, H, H1), the involvement of the NB on the Equipment itself is reduced, and the NB concentrates on the QA system. The NB

(1) assesses the adequacy of the QA system to the production

(2) carries out periodic audits to ensure that the Manufacturer applies the QA system

(3) applies the surveillance by unexpected visits to check that the QA systems works correctly

(d) Six procedures are devoted to unit production (A, A1, D1, E1, G, H, H1).

(e) Seven procedures are devoted to series production (B + C, B + D, B + E, B + F, B1 + D, B1 + F). They consist of a design module covering the design phase (modules B or B1) and a production module covering the production phase (modules C, D, E, and F).

4 REVIEW OF CONFORMITY ASSESSMENT MODULES

4.1 Conformity Assessment Modules

Module A	International Production Control
Module A1	International Manufacturing checks with monitoring final assessment
Module B	EC type examination
Module B1	EC design examination
Module C1	Monitoring conformity of the EC type
Module D	Quality assurance for production, final inspection, and testing
Module D1	Quality assurance for production, final inspection, and testing
Module E	Product quality assurance for final inspection and testing
Module E1	Quality assurance for final inspection and testing
Module F	Product verification
Module G	EC unit verification
Module H	Full quality assurance
Module H1	Full quality assurance with design examination and monitoring of the final assessment
Appendix I	Declaration of Conformity
Appendix II	Activities of Manufacturers and Notified Bodies in Accordance with Conformity Assessment Procedures

4.2 Module A: Internal Production Control

This module describes procedures by which Manufacturers, or their authorized representatives established in the European Community, ensure and declare that pressure equipment satisfy the requirements of the PED to which they apply. This module is applicable for Category I, for a production by series or unit, with or without a quality assurance system.

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4.2.1 Characteristics of the Module

(a) Internal Production Control by the Manufacturer

(b) No intervention of the NB

4.2.2 Role of the Manufacturer

(a) The Manufacturer must draw up the technical documentation (see Module A1) and must keep it at the disposal of the relevant national authorities for inspection purposes for 10 years after the last of the pressure equipment has been manufactured.

(b) The Manufacturer must affix the EC marking to each item of pressure equipment.

(c) The Manufacturer must draw up a written declaration of conformity.

(d) The Manufacturer must keep a copy of the declaration of conformity with the technical documentation.

4.3 Module A1: Internal Manufacturing Checks With Monitoring of Final Assessment

This module describes procedure by which the Manufacturer, or its authorized representative established in the Community, ensures and declares that pressure equipment of risk category II satisfies the requirements of the PED.

This module is applied for a production in series or by unit, without a quality assurance system.

4.3.1 Tasks of the Manufacturer

(a) The Manufacturer chooses an NB.

(b) The Manufacturer draws up technical documentation, as far as is relevant to such assessment, and covers the design, manufacture, and operation of the pressure equipment. The basic document is the general design drawing of the equipment completed if necessary by more detailed manufacturing drawings or diagrams of the subassemblies or circuits and commented if necessary by a written description. The technical documentation will contain

(1) name of the Manufacturer and site of production

(2) conceptual design and manufacturing drawings

(3) a list of harmonized standards applied and a description of the solutions adopted

(4) results of design calculation made and/or test reports

(c) The Manufacturer ensures that the manufacturing process complies with technical documentation.

(d) The Manufacturer affixes the EC marking and Notified Body identification number to each item.

(e) The Manufacturer draws up written declaration of conformity.

(f) Retain declaration of conformity and technical documentation for 10 years.

4.3.2 Tasks of the Notified Body

(a) Monitoring of final assessment by unexpected visits. The final assessment must include

(1) visual examination of the equipment

(2) hydraulic pressure test

(3) examination of safety devices

(b) Take samples of pressure equipment at manufacture or storage premises to conduct checks.

(c) Take appropriate action if items do not conform.

4.4 Module B: EC Type Examination

This module describes the part of the procedure by which an NB ascertains and attests that a representative example of the production meets the provisions of the PED to which they apply. This module is applied for risk category III and IV, for a production in series, with or without quality assurance.

4.4.1 Characteristics of the Module. This module is only applicable for the design examination. It is always associated with another module concerning the manufacturing of the pressure equipment (C1, E, F, or D).

4.4.2 Tasks of the Manufacturer

(a) The Manufacturer draws up the technical documentation that covers the design, manufacture, and operation of the pressure equipment. The documents to be given to the NB for a design examination are

(1) general description of the pressure equipment

(2) list of codes or harmonized standards applied and solution adopted

(3) design drawings, manufacturing drawings, diagram of components

(4) identification marking drawings (identity plate)

(5) list of materials used

(6) results of design calculation made and/or test reports

(7) forming procedures

(8) heat treatment procedures

(9) NDT procedures

(10) Qualification of permanent assemblies procedures: welding, braze-welding, brazing, expanding (dudjonning), and gluing

(11) Operating instructions

For calculation design, the results of the design calculation shall be given; for experimental design, the

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test reports shall be given, and for calculation design completed by experimental design, the results of the calculation shall be supplemented by the test reports.

These documents shall be given to the NB for this module, but also for and EC design examination (modules B1 and H1). They shall also be available in complement of the documents for the final assessment in modules A, A1, D1, E1, and H.

(b) The Manufacturer provides a representative example of production (a "type") to the NB.

(c) The Manufacturer retains documentation and copies of EC type-examination during 10 years.

4.4.3 Tasks of the Notified Body

(a) Examines the technical documentation

(b) Verify that the "type" is manufactured in conformity with the technical documentation

(c) Assess materials when they are not in conformity with harmonized standard or European Approval of Materials, and check material certificates

(d) Approve procedures for permanent joining or check they have been previously approved

(e) Verify staff are qualified or approved for permanent joining and nondestructive examination

(f) Issues EC type-examination certificate with a validity of 10 years

(g) Retain copy of documentation and EC type-examination certificate

4.5 Module B1: EC Design Examination

This module describes the part of the procedure where an NB ascertains and attests that the design of an item of pressure equipment meets the provisions of the PED to which they apply. This module is applied for risk category III, for production in series or by unit, with or without quality assurance.

4.5.1 Characteristics of the Module. This module is only applicable for design examination; it is always associated with another module concerning the manufacturing of a pressure equipment (F or D).

4.5.2 Tasks of the Manufacturer. The Manufacturer draw up the technical documentation as described in module B.

4.5.3 Tasks of the Notified Body. See module B (para. 4.4).

(a) Examine the technical documentation

(b) Issue EC design-examination certificate

4.6 Module C1: Monitoring Conformity to the EC Type

This module describes that part of procedure whereby the Manufacturer ensures and declare that pressure equipment is in conformity with the type as described in the EC type-examination certificates and satisfies the requirements of the PED to which they apply.

The Manufacturer must affix the EC marking to each item of pressure equipment and draw up a written declaration of conformity.

4.6.1 Characteristics of the Module. This module is only applicable for the manufacturing of the pressure equipment in series without quality assurance. It is always associated with the module B (EC type-examination).

4.6.2 Tasks of the Manufacturer

(a) Ensure that the manufacturing process produces pressure equipment that complies with the type as described in the EC type-examination certificate

(b) Choose an NB

(c) Affix CE marking and NB identification number

4.6.3 Tasks of the Notified Body

(a) Monitor the final assessment by unexpected visits

(b) Ensure that the Manufacturer performs the final assessment according to the PED

(c) Take samples of pressure equipment at manufacturing and storage premises to conduct checks

4.7 Module D: Quality Assurance for Production, Final Inspection, and Testing

This module describes procedures where the Manufacturer ensures and declares that the pressure equipment concerned is in conformity which the type described in the EC design-examination certificate and satisfies the requirements of the PED to which they apply.

4.7.1 Characteristics of this Module. This module is only applicable for the manufacturing of the pressure equipment in series or by unit, with quality assurance for risk categories III or IV. It is always associated with the module B (EC type examination), or B1 (EC design examination).

4.7.2 Tasks of the Manufacturer

(a) Set up and operate quality system for production, final inspection, and testing (e.g., ISO 9002), which ensures compliance of the pressure equipment with the type described in the EC type-examination certificate or the EC design-examination certificate.

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(b) Lodge application for assessment of quality system with an NB as described in module D1.

(c) Affix CE marking and NB identification number

(d) Draw up written declaration of conformity.

4.7.3 Tasks of the Notified Body

(a) Assess quality system including an inspection visit to the Manufacturer's premises.

(b) Carry out surveillance visits to ensure that the Manufacturer fulfills the obligation arising from the approved quality system.

(c) Carry out periodic audits such that a full reassessment is carried out.

(d) Carry out unexpected visits to verify that the quality system is functioning correctly.

(e) Notify the Manufacturer of assessment decision.

4.8 Module D1: Quality Assurance for Production, Final Inspection, and Testing

This module is applicable for conception and for the manufacturing of pressure equipment. It is not associated with another module.

4.8.1 Characteristics of the Module. This module is applicable for risk category II with quality assurance for production in series or by unit.

4.8.2 Tasks of the Manufacturer

(a) Draw up technical documentation covering design, manufacture, and final inspection. The documents given to the NB for final inspection shall contain

(1) certificates of qualification of NDT personnel, welders, brazing personnel

(2) data dealing with heat treatment (diagram of temperatures)

(3) inspection documents for the base materials and the consumables

(4) procedures for ensuring materials' traceability

(5) test reports of NDT, including radiographic films

(6) test reports of destructive tests

(7) forming conformity certificate

(b) Set up and operate quality system for production, final inspection and testing (e.g., ISO 9002), which ensures compliance of the pressure equipment with the PED.

(c) Give to the NB the documentation on the quality system including a description of quality objectives and organization structure.

(d) Affix EC marking and draw up written declaration of conformity.

4.8.3 Tasks of the Notified Body

(a) Assess quality system including an inspection visit to the manufacturer's premises.

(b) Carry out periodic audits such that a full reassessment is conducted.

(c) Carry out unexpected visits to verify that the quality system is functioning correctly.

(d) Notify the Manufacturer of assessment decision.

4.9 Module E: Product Quality Assurance and Quality Assurance for Final Inspection and Testing

This module is applicable only for the manufacturing of pressure equipment. It is associated with module B (conception).

4.9.1 Characteristics of the Module. This module is applicable for risk category III with quality assurance for production in series.

4.9.2 Tasks of the Manufacturer

(a) Set up and operate quality system for products (e.g., ISO 9003), which ensures compliance of the pressure equipment with the type described in the EC type examination certificate.

(b) Lodge application for assessment of quality system with an NB as described in module E1 (para. 4.10).

(c) Affix EC marking and notified body identification number.

(d) Draw up written declaration of conformity.

4.9.3 Tasks of the Notified Body

(a) Assess quality system, including technical aspect, with an inspection visit to the Manufacturer's premises.

(b) Carry out periodic audits such that a full reassessment is carried out.

(c) Carry out unexpected visits to verify that the quality system is functioning correctly.

(d) Notify the Manufacturer of assessment decision.

4.10 Module E1: Quality Assurance for Final Inspection and Testing

This module is applicable for conception and for manufacturing of pressure equipment. It is not associated with another module.

4.10.1 Characteristics of the Module. This module is applicable for risk category II with quality assurance for production in series and by unit.

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4.10.2 Tasks of the Manufacturer

(a) Draw up technical documentation covering design, manufacture, and final inspection.

(b) Set up a quality system for products (e.g., ISO 9003), and operate this quality assurance for final assessment and testing.

(c) Affix EC marking and notified body identification number.

(d) Draw up written declaration of conformity.

4.10.3 Tasks of the Notified Body

(a) Assess quality system, including technical aspect, with an inspection visit to the Manufacturer's premises.

(b) Carry out periodic audits such that a full reassessment is conducted.

(c) Carry out unexpected visits to verify that the quality system is functioning correctly.

(d) Notify the Manufacturer of assessment decision.

4.11 Module F: Product Verification

This module is applicable only for the manufacturing of pressure equipment. It is associated with module B or B1 (conception).

4.11.1 Characteristics of the Module. This module is applicable for risk category III or IV without quality assurance for production in series or by unit.

4.11.2 Tasks of the Manufacturer

(a) Ensure that the manufacturing process produces pressure equipment that is in conformity with the type described in the EC type-examination certificate (B), or EC design-examination certificate (B1).

(b) Choose an NB.

(c) Affix EC marking and notified body identification number.

(d) Draw up written declaration of conformity.

4.11.3 Tasks of the Notified Body

(a) Examine and test each item of pressure equipment, to verify that every item conforms to the type.

(b) Verify qualification of personnel responsible for permanent joining and NDT examination,

(c) Carry out final inspection and proof test.

(d) Draw up written certificate of conformity relating to the test.

4.12 Module G: EC Unit Verification

This module is applicable for design and manufacturing a pressure equipment. It is not associated with another module.

4.12.1 Characteristics of the Module. This module is applicable for risk category IV, without quality assurance and for production by unit.

4.12.2 Tasks of the Manufacturer

(a) Lodge application for unit verification with an NB that must include

(1) the technical documentation as described under module A1

(2) information relating to the approval of the manufacturing and test procedures

(3) information of the qualifications or approvals of staff carrying out permanent joining and nondestructive tests

(b) Affix EC marking.

(c) Draw up written declaration of conformity.

4.12.3 Tasks of the Notified Body

(a) Examine design and construction of each item.

(b) Examine technical documentation with respect to design and manufacturing procedures.

(c) Check certificates from material Manufacturers.

(d) Approve procedures for permanent joining of parts or check previous approval.

(e) Verify personnel responsible for permanent joining of parts and nondestructive testing.

(f) Perform during manufacture, appropriate tests set out in relevant harmonized standards or equivalent to ensure the conformity to the PED.

(g) Carry out final inspection and perform, or performed proof test.

(h) Examine the safety devices, if applicable.

(i) Affix identification number or have it affixed to the pressure equipment.

(j) Draw up certificate of conformity for the tests carried out.

4.13 Module H: Full Quality Assurance

This module is applicable for conception and for the manufacturing of pressure equipment. It is not associated with another module.

4.13.1 Characteristics of the Module. This module is applicable for risk category III with quality assurance for production by unit.

4.13.2 Tasks of the Manufacturer

(a) Implement an approved quality system for design, manufacture and final inspection and testing (e.g., ISO 9001), which must ensure compliance of the pressure equipment with the requirements of the PED that apply to it.

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(b) Lodge application for assessment of the quality system with an NB, which includes

(1) relevant information on the pressure equipment concerned

(2) documentation on the quality system including a description of quality objectives and organizational structure

(3) technical design specifications, including standards, that will be applied

(4) design control and technical verifications, process and systematic measures, particularly the procedures for permanent joining

(5) examinations and tests to be carried out

(6) quality records, such as inspection reports and test data, the qualifications or approvals of the personnel concerned particularly with permanent joining

(7) means of monitoring quality and quality system

(c) Undertake the fulfillment of obligations arising out of the quality system.

(d) Affix EC marking and identification number of the NB responsible for surveillance.

(e) Draw up declaration of conformity.

4.13.3 Tasks of the Notified Body

(a) Assess quality system including an inspection visit to the Manufacturer's premises.

(b) Presume conformity with respect to the elements of the quality system that implements a relevant harmonized standard (e.g., ISO 9001).

(c) Notify the Manufacturer of assessment decision.

(d) Carry out surveillance visits to ensure that the Manufacturer fulfills the obligations arising from the approved quality system.

(e) Carry out periodic audits such that a full reassessment is carried out every three years.

(f) Carry out unexpected visits to verify that the quality system is functioning correctly.

(g) Assess proposed changes to the quality system.

For category III and IV vessels for group 1 and group 2 gases and group 1 liquids and steam generators, the NB, when performing unexpected visits, must take a sample of equipment and perform or have performed, the proof test.

For one off production of category III steam generators, the NB must perform or have performed the proof test for each unit.

4.14 Module H1: Full Quality Assurance With Design Examination and Monitoring of the Final Assessment

This module is applicable in addition to the requirements of module H.

4.14.1 Tasks of the Manufacturer

(a) Lodge application for examination of the design with an NB. The application must enable the design, manufacture and operation of the pressure equipment to be understood and enable conformity with the relevant requirements of the PED to be assessed. It must include

(1) technical design specifications, including standards

(2) necessary supporting evidence for their adequacy, in particular where harmonized standards have not been applied in full

(b) Inform the NB of all modifications to the approved design.

4.14.2 Tasks of the Notified Body

(a) Examine the application and, if satisfied, issue an EC design examination certificate.

(b) Carry out surveillance of the final assessment in the form of unexpected visits, which must include examinations on the pressure equipment.

(c) Assess any modifications to the approved design and give additional approval.

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APPENDIX V-I
DECLARATION OF CONFORMITY

The EC declaration of conformity must contain the following:

(a) Name and address of the Manufacturer or of his authorized representative established within the Community

(b) Description of the pressure equipment or assembly

(c) Conformity assessment procedure followed

(d) In the case of assemblies, description of the pressure equipment constituting the assembly, and the conformity assessment procedures followed

(e) Where appropriate, name and address of the Notified Body that carried out the inspection

(f) Where appropriate, a reference to the EC type-examination certificate, EC design-examination certificate or EC certificate of conformity

(g) Where appropriate, name and address of the Notified Body monitoring the Manufacturer's quality assurance system

(h) Where appropriate, the references of harmonized standards applied

(i) Where appropriate, other technical standards and specifications used

(j) Where appropriate, the references of the others Community Directives applied

(k) Particulars of the signatory authorized to sign the legally binding declaration for the Manufacturer or his authorized representative established within the Community

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APPENDIX V-2
MANUFACTURERS AND NOTIFIED BODIES

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TABLE V-2-1 ACTIVITIES OF MANUFACTURERS AND NOTIFIED BODIES IN ACCORDANCE WITH CONFORMITY ASSESSMENT PROCEDURES

Range of Activities	Operation	Manufacturer and Notified Body Activities in Relation to Hazard Categories and Conformity Assessment Procedures								
		Hazard Categories								
		I	II	II	II	III	III	III	IV	IV
		Procedures								
		A	A1	D1	E1	B1+F	H	B1+D	G	H1
Design										
	Contractual documents	M	M	M	M	M	M	M	M	M
Design	Design review	M	M	M	M	M	M	M	M	M
	Design approval	...	...	...	...	NB	...	NB	NB	NB
Purchase and subcontracting specifications	Check									
	(a) purchase specifications	M	M	M	M	M	M	M	M	M
	(b) subcontracting specifications (including accessories)	M	M	M	M	M	M	M	M	M
Production technical specifications	Check									
	(a) forming procedures	M	M	M	M	NB	M	NB	NB	NB
	(b) welding procedures	M	M	M	M	NB	M	NB	NB	NB
	(c) testing procedures	M	M	M	M	NB	M	NB	NB	NB
	Issue of EC design-examination certificate	...	...	...	...	NB	...	NB	...	NB
Materials and Subcontracting										
Inspection at material Manufacturer's factory	Attendance when sampling intended to make specimens. Attendance during tests and destructive testing.	NA	NA				NA(1)			
Nondestructive testing of materials at material Manufacturer's factory	Check the validity of operator approvals, that nondestructive testing reports are issued, and that results conform to the purchase specifications.	M	M	M	M	NB	M	M	NB	M/NB (2)
Acceptance certificates for base materials	Check that information and test results recorded in the inspection documents conform to the purchase specifications.	M	M	M	M	NB	M	M	NB	M/NB (2)
Acceptance certificates for welding consumables	Check that information and test results recorded in the inspection documents conform to the purchase specifications.	M	M	M	M	NB	M	M	NB	M/NB (2)

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TABLE V-2-1 ACTIVITIES OF MANUFACTURERS AND NOTIFIED BODIES IN ACCORDANCE WITH CONFORMITY ASSESSMENT PROCEDURES (CONT'D)

Range of Activities	Operation	Manufacturer and Notified Body Activities in Relation to Hazard Categories and Conformity Assessment Procedures								
		Hazard Categories								
		I	II	II	II	III	III	III	IV	IV
		Procedures								
		A	A1	D1	E1	B1+F	H	B1+D	G	H1
Materials and Subcontracting (Cont'd)										
Check of products on stock	(a) Check that (1) satisfying inspection documents are issued (2) information and test results, recorded in the inspection documents, comply with the requirements of the Code.	M	M	M	M	NB	M	M	NB	M/NB (2)
	(b) When additional tests and testing are to be conducted, the following items apply: (1) *attendance when sampling intended to make specimens* (2) attendance during tests and testing (3) check of test and testing reports	M	M	M	M	NB	M	M	NB	M/NB
Identification of products (traceability)	(a) Check that the product identification and marking conform to the specification and inspection documents in accordance with the provisions of M1.9.	M	M/NB (3)	M	M	...	M	M	NB	M/NB (2)
	(b) Check the permanent identification procedure and transfer of marking during the fabrication is in accordance with the provisions of F1.2.2.	M	M/NB (3)	M	M	...	M	M	NB	M/NB (2)
Acceptance of subcontracted components	Same works as those performed for components carried out by the Manufacturer.	See activities related to corresponding works.								
Works Prior to Welding										
Welding procedure specifications	Check (a) of the validity of the welding procedure specification approved for the joint under consideration (b) that the welding procedure specification is within the scope of the welding procedure approval	M	M/NB (3)(4)	M (4)	M (4)	NB (4)	M (4)	NB (4)	NB (4)	M/NB (4)
Welding procedure approvals	Check that the welding procedures have been approved in accordance with the provisions of Annex FA2.	M	M/NB (3)(4)	M (4)	M (4)	NB (4)	M (4)	NB (4)	NB (4)	M/NB (4)

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TABLE V-2-1 ACTIVITIES OF MANUFACTURERS AND NOTIFIED BODIES IN ACCORDANCE WITH CONFORMITY ASSESSMENT PROCEDURES (CONT'D)

		Manufacturer and Notified Body Activities in Relation to Hazard Categories and Conformity Assessment Procedures								
		Hazard Categories								
		I	II	II	II	III	III	III	IV	IV
		Procedures								
Range of Activities	**Operation**	**A**	**A1**	**D1**	**E1**	**B1+F**	**H**	**B1+D**	**G**	**H1**
	Works Prior to Welding (Cont'd)									
Welders and operators approvals	Check (a) that the welders and operators have been approved in accordance with the provisions of F1.4.2 (b) the validity in time of approvals (c) the validity of the approval for the joint under consideration	M	M/NB (3)(4)	M (4)	M (4)	NB (4)	M (4)	NB (4)	NB (4)	M/NB (2)(4)
	Supervision During Fabrication									
Instructions	Check that instructions for fabrication and testing applicable to the poste de travail are issued.	M	M	M	M	M/NB	M	M	M/NB	M
Supervision during fabrication	Check that instructions for fabrication and testing are suitably applied. In particular, visual examination of welds before back welding and when completed.	M	M	M	M	M/NB	M	M	M/NB	M
	Destructive Testing of Welded Joints on Specimens									
Performance of specimens	(a) Attendance when sampling specimens and stamping.	M	M	M	M	NB	M	M	NB	M
	(b) Check of post-welding heat treatments carried out independently of the vessel.	M	M	M	M	NB	M	M	NB	M/NB (2)
Nondestructive testing of specimens	Examination of radiographs or attendance to ultrasonic examination.	M	M	M	M	NB	M	M	NB	M/NB (3)
Mechanical tests	(a) Stamping of specimens intended to mechanical tests.	M	M	M	M	NB	M	M	NB	M
	(b) Attendance to mechanical tests.	M	M	M	M	NB	M	M	NB	M/NB (3)
Testing and test reports	Examination of testing and test reports drawn up by the Manufacturer.	M	M/NB	M	M	NB	M	M	NB	M/NB (2)

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TABLE V-2-1 ACTIVITIES OF MANUFACTURERS AND NOTIFIED BODIES IN ACCORDANCE WITH CONFORMITY ASSESSMENT PROCEDURES (CONT'D)

Range of Activities	Operation	Manufacturer and Notified Body Activities in Relation to Hazard Categories and Conformity Assessment Procedures								
		Hazard Categories								
		I	II	II	II	III	III	III	IV	IV
		Procedures								
		A	A1	D1	E1	B1+F	H	B1+D	G	H1
Nondestructive Testing of Welded Joints										
Instructions and procedures	Check that (a) instruction and nondestructive testing procedure drawn up by the Manufacturer are issued and comply with the Code requirements	M	M/NB (3)	M	M	NB	M	NB	NB	NB (2)
	(b) the drafter is competent	M	M/NB (3)	M	M	NB	M	NB	NB	NB (2)
Testing operators	Check that the testing operators are approved.	M	M/NB	M	M	NB (4)	M (4)	NB (4)	NB (4)	NB (2)(4)
Nondestructive testing	(a) Examination of radiographs (b) Attendance to examination other than radiographic examination	M	M	M	M	M/NB	M	M	M/NB	M
Testing reports	Examination of testing and test reports drawn up by the Manufacturer.	M	M/NB (3)	M	M	NB	M	M	NB	M/NB (2)
Acceptance of the Vessel										
Technical documentation	Examination of the technical documentation	M	M	M	M	NB	M	M	NB	M
Calibration of measuring devices	Random examination of calibration reports related to measuring devices used for strength test, dimensional check, and other testing and tests.	M	M	M	M	NB	M	M	NB	M
Examination of the completed vessel	Visual examination of all accessible parts of the vessel prior to strength test and possible lining or painting.	M	M/NB (3)	M	M	NB	M/NB (3)(6)	M	NB	M/NB (3)
Strength test	(a) Check that test instructions are issued.	M	M/NB (3)	M	M	NB	M/NB (3)(6)	M	NB	M/NB (3)
	(b) Attendance to tests, visual examination of the vessel during and after the tests.	M	M/NB (3)	M	M	NB	M/NB (3)(6)	M	NB	M/NB (3)
	(c) Check of nameplate marking	M	M/NB (3)	M	M	NB	M/NB (3)(6)	M	NB	M/NB (3)

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TABLE V-2-1 ACTIVITIES OF MANUFACTURERS AND NOTIFIED BODIES IN ACCORDANCE WITH CONFORMITY ASSESSMENT PROCEDURES (CONT'D)

Range of Activities	Operation	Manufacturer and Notified Body Activities in Relation to Hazard Categories and Conformity Assessment Procedures								
		Hazard Categories								
		I	II	II	II	III	III	III	IV	IV
		Procedures								
		A	A1	D1	E1	B1+F	H	B1+D	G	H1
Acceptance of the Vessel (cont'd)										
Vessel acceptance	(a) Issue inspection and strength test certificate.	M	M	M	M	M	M	M	M	M
	(b) *Certificates of conformity to the Code and to the* Directive	M	M	M	M	M	M	M	M	M
Documents to be available	Examination of construction and Manufacturer documentation, and check that they comply with the Code requirements.	M	M/NB	M	M	NB	M/NB (3)(6)	M	NB	M/NB (3)
	CE marking (5)	M	M	M	M	M	M	M	M	M
	Certificate of conformity	...	...	...	...	NB	...	...	NB	...
	Affixing of the Notified Body identification number (5)	...	M/NB (3)	M	M	M/NB	M/NB (3)(6)	M	M/NB	M/NB (3)

GENERAL NOTES:
NB: *Notified Body 100%,*
M: Manufacturer 100%,
M/NB: Manufacturer 100%, Notified Body: random assessment on the basis of his knowledge of the Manufacturer *quality system (if applicable), or of procedures* in force.

NOTES:
(1) These are activities if the material Manufacturer does not apply a quality assurance system.
(2) This may performed during final assessment.
(3) Performed by unexpected visits of the Notified Body.
(4) *Approvals are witnessed by a recognized Third Party or by a Notified Body.*
(5) For the user inspectorate activity, there is no CE marking nor stamping of identification number.
(6) The Notified Body must perform or must have performed the final assessment for each equipment for the following:
(a) vessels and equipment of hazard category III fired or heated with the risk of overheating intended for generation of steam or super-heated water at temperatures *higher than 100 °C having a volume greater than 2L*
(b) pressure cookers, serially constructed in accordance with the procedure of the module H, for unit production using conformity assessment procedure H For this purpose, the Manufacturer must submit to the Notified Body the project of production program.

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CHAPTER VI
ESSENTIAL SAFETY REQUIREMENTS (ARTICLE 3, ANNEX I OF THE PED)

1 INTRODUCTION

The technical requirements concerning the Pressure Equipment itself are included in Annex I of the PED under the designation Essential Safety Requirements, (ESR). The following principles apply:

(a) All pressure equipment above the thresholds mentioned in Article 3 of the PED (i.e., classified in Hazard Category I, II, III, or IV) must comply with all these ESR. They concern the various steps of the construction: design, material selection, fabrication, inspection, and safety devices.

(b) These ESR are generally formulated in general terms of safety objectives, such as, "Pressure Equipment must be constructed in such a way to ensure its safety in reasonable foreseeable conditions."

The PED does not provide the means to achieve these requirements; this is the role of the Harmonized Standards. Some quantitative requirements are provided by PED §7 of Annex I, which "apply as a general rule." Manufacturers can depart from these quantitative requirements, but they must convince the NB that "they have taken appropriate measures to achieve an equivalent overall level of safety."

(c) It is the role of CEN Harmonized Standards (harmonized to the PED), such as draft Unfired Pressure Vessel (Pr. EN 15-443, in development by CEN/TC54), to quantify each of these requirements. As a consequence, this gives them a presumption of conformity to the PED (see PED Article 5-§2).

However, use of these Harmonized Standards is not compulsory. The Manufacturer may construct its pressure vessel using any Code or Standard but must be able to demonstrate to the NB that the vessel complies with each of the ESR of PED Annex I. Or, the Manufacturer must show that it has used a quantitative requirement different from the Harmonized Standards, provided an equivalent level of safety is acheieved.

(d) The Manufacturer is free to use one of the following three options to prove that this Equipment complies with the ESR:

(1) use of the EN Harmonized Standard, which will give presumption of conformity to the ESR

(2) use of a recognized Code like ASME Boiler and Pressure Vessel Code, CODAP, etc. (supplemented by additional requirements to ensure compliance with the PED).

(3) by applying directly the ESR and providing calculation sheets, carrying out tests, etc.

In options 2 and 3, the Manufacturer will have to convince the NB of its compliance with the ESR.

(e) The stringency of some of these ESR depend on the Hazard Category of the Equipment, especially

(1) approval of welding operating procedures (Annex I-§3.12 of the PED)

(2) approval of welders (Annex I-§3.12 of the PED)

(3) approval of nondestructive test personnel (Annex I-§3.13 of the PED)

(4) types of material certificate (Annex I-§4.3 of the PED)

2 GENERAL DISCUSSION OF ESR (ANNEX I OF THE PED)

2.1 Preliminary Remarks

(a) All equipment above the thresholds specified in PED Article 3-§1 (i.e. Equipment classified in Hazard Categories I, II, III, and IV) shall meet each of the essential safety requirements of Annex I of the PED. This applies to assemblies (Article 3-§2 of the PED), taking into account the derogation specified in clause Article 3-§2.3 (see Annex I-§2.8 of the PED).

(b) The Essential Safety Requirements are mandatory. These are expressed qualitatively in terms of general purposes. Only some numerical values are given in Annex I-§7 of the PED (joint efficiency, proof test pressure, etc.). The Manufacturer is not obliged to use these values provided an equivalent overall level safety has been achieved (Annex I-§7 of the PED).

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2.1.1 General (Annex I-§1 of the PED). Equipment must be constructed in such a way that their safety is ensured (Annex I-§1.1 of the PED). The Manufacturer shall carry out a hazard analysis, which shall be used as indicated in Annex I-§1.2 and Annex I-§1.3 of the PED.

2.1.2 Design (Annex I-§2 of the PED)

2.1.2.1 General (Annex I-§2.1 of the PED). Pressure equipment must be "properly designed" to ensure that the equipment will be safe throughout its intended life, taking into account

(a) suitable safety margins against the different failure modes

(b) loads corresponding to the intended use (pressure, temperature, wind, earthquake, etc.)

(c) expected working conditions (corrosion, erosion, fatigue, etc.), (Annex I-§2.2.1 of the PED)

2.1.2.2 Design Method. Two methods for design are proposed (Annex I-§2.2.2 of the PED):

(a) Calculation Method. This method is applicable to all cases (Annex I-§2.2.3 of the PED).

(1) This method must specify the maximal allowable stresses to prevent possible failure modes including creep, corrosion, fatigue, and instability (Annex I-§2.2.3.a of the PED).

(2) The allowable general membrane stress, S_a, is defined below, for each type of material (Annex I-§7.1.2 of the PED).

Material	Allowable General Membrane Stress, S_a
Ferritic steel	Lesser of $R_e/1.5$ and $R_m/2.4$
Austenitic steel if A > 30%	R_e
Austenitic steel if A > 35%	Lesser of $R_e/1.2$ and $R_m/3$
Cast steel	Lesser of $R_e/1.9$ and $R_m/3$
Aluminum	$R_e/1.5$
Aluminum alloys (not quenched)	Lesser of $R_e/1.5$ and $R_m/2.4$

A = elongation, %
R_e = specified minimum yield strength at operating temperature
R_m = specified minimum tensile strength at room temperature

NOTE: These stress values apply as a general rule. Other values may be used if an equivalent overall level of safety is achieved (PED Annex I-§7).

(3) The method shall take into account the following (PED Annex I-§2.2.3.b):

(a) the calculation pressure (greater than or equal to PS), the calculation temperature and the possible combinations

(b) the maximal stresses and stress concentrations

(c) the joint efficiency according to the level of testing of welded joints (Annex I-§7.2 of the PED)

Extent of Examination	Joint Efficiency
100% radiographic (RT) or ultrasonic (UT)	1.0
Spot examination by RT or UT	0.85
Visual examination only	0.70

NOTE: These joint efficiency values apply as a general rule. Greater values may be used if an equivalent overall level of safety has been achieved (Annex I-§7 of the PED).

(b) Experimental Method. This method is applicable only for (Annex I-§2.2.4 of the PED):

(1) vessels that have a PS x V less than 6000 bar L (3072 psi x ft^3)

(2) piping that has a PS x DN less than 3000 bar mm (1713 psi x in.)

This method does not apply when conformity assessment is carried out according to module B1. The Manufacturer shall draw up a test program on a representative sample, subjected to the agreement of the Notified Body in charge of the design assessment module.

2.1.2.3 Other requirements regarding design shall cover the following, if relevant (PED references are noted in parentheses):

(a) safety of handling and operation (Annex I-§2.3)

(b) means of inspection (Annex I-§2.4)

(c) means of draining and venting (Annex I-§2.5)

(d) corrosion and chemical attack (Annex I-§2.6)

(e) wear (Annex I-§2.7)

(f) reliability of assemblies (Annex I-§2.8)

(g) provisions for filling and discharge (Annex I-§2.9)

(h) protection against exceeding the allowable limits (Annex I-§2.10)

(i) safety accessories (Annex I-§2.11)

(j) external fire (Annex I-§2.12)

2.1.3 Fabrication (Annex I-§3 of the PED)

2.1.3.1 Manufacturing Procedures

(a) The Manufacturer must ensure that design specifications are effectively applied at fabrication stage (Annex I-§3.1 of the PED), especially regarding the following aspects (PED references are noted in parentheses):

(1) preparation of the component parts (Annex I-§3.1.1)

(2) permanent joining (Annex I-§3.1.2)

(3) heat treatments (Annex I-§3.1.4)

(4) traceability (Annex I-§3.1.5)

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(b) Permanent assemblies (Annex I-§3.1.2 of the PED) by welding, brazing, etc. shall be performed using qualified personnel and in accordance with qualified operating procedures. The Body in charge of the approval of these qualifications depends on the Hazard Category in which the pressure Equipment is classified:

Hazard Category of Equipment	Approval of Welding Procedure Qualification and Welder Qualification By	
Category I	Manufacturer	
Category II Category III Category IV	Notified Body (PED Article 12) or Third-party organization recognized by a Member State (PED Article 13)	Chosen by the Manufacturer

2.1.3.2 Nondestructive Testing (Annex I-§3.1.3 of the PED) shall be performed by qualified personnel. Body in charge of the approval of these qualifications depends on the Hazard Category in which the pressure Equipment is classified is as follows:

Equipment Hazard Category	Approval of NDE Personnel By
Category I Category II	Manufacturer
Category III Category IV	Third-party organization recognized by a Member State (PED Article 13)

2.1.3.3 Final Assessment (Annex I-§3.2 of the PED). Pressure Equipment must undergo a final assessment to ensure the compliance with the essential safety requirements. This final assessment must include a final examination and a proof test performed by the Manufacturer or the Notified body according to the assessment module that applies.

(a) Final examination (Annex I-§3.2.1 of the PED) comprises

(1) internal and external visual examination of the Equipment

(2) examination of the accompanying documents of the Equipment

(b) Proof test (Annex I-§3.2.2 of the PED), generally hydrostatic, carried out at a pressure P_t defined in Annex I-§7.4 of the PED. The test pressure shall be the larger of the following:

$$P_t = 1.25\, P_s \left(\frac{f_a}{f_t}\right)$$

$$P_t = 1.43\, P_s$$

where

P_s = allowable maximum operating pressure
f_a = nominal design stress at test temperature
f_t = nominal design stress at operating temperature

NOTE: Lower values may be used if an equivalent overall level of safety has been achieved. (Annex I-§7 of the PED).

(1) Exceptionally, where the hydrostatic pressure test is impractical, an "equivalent test" (e.g. a pneumatic test) may be performed.

(2) The test shall be performed for each equipment, unless the equipment is classified in category I (where the test may be carried out on a statistical basis).

(3) For assemblies, an examination of the safety accessories shall be performed additionally.

2.1.3.4 Marking and Operating Instructions

(a) In addition to CE Marking, information specified in PED Annex I-§3.3 shall be affixed on the Equipment.

(b) Pressure Equipment must be accompanied with instructions covering all information necessary for the user (mounting, start-up, use, maintenance). (See Annex I-§3.4 of the PED).

2.1.4 Materials (Annex I-§4 of the PED). The word *Material* includes the parent materials (i.e. base metals, such as steel, aluminum, etc.), as well as joining materials (for welding, brazing, etc.). Welding consumables and other joining materials are subject only to some of the parent material requirements.

2.1.4.1 Materials Intended for Pressure Parts (Annex I-§4.1 of the PED). Materials must have appropriate properties for all operating conditions reasonably foreseeable and for test conditions, especially regarding (Annex I-§7.5 of the PED):

(a) ductility: elongation after rupture, A% not less than 14%,

(b) toughness: impact test energy not less than 27 J.

NOTE: Lower values may be used if an equivalent overall level of safety has been achieved. (Annex I-§7 of the PED).

The materials must be sufficiently chemically resistant and not be affected by aging, etc.

2.1.4.2 Material Characteristics (Annex I-§4.2 of the PED)

(a) The Manufacturer must define material characteristics required by equipment design and material use (Annex I-§4.2.a of the PED).

(b) The Manufacturer must supply each specification for each material used which may be (Annex I-§4.2.b of the PED) one of the following:

(1) Material that complies with Harmonized Stan-

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dards. Thus, the material is presumed to comply with the Essential Safety Requirements (Article 5 of the PED)

(2) Material subject to a *European Approval for Materials* (Article 11 of the PED)

(3) Material subject to a "Particular Material Appraisal," which shall be carried out by a body depending on the Hazard Category in which the equipment is classified. (See below.)

Equipment Hazard Category	Particular Material Appraisal (PMA) Carried Out by
Category I Category II	Manufacturer
Category III Category IV	Notified Body in charge of evaluation and approval of the Pressure Equipment

(c) Materials shall be accompanied by an inspection document established by the material producer. For pressure parts the type of inspection document depends on the Equipment Hazard Category (Annex I-§4.3 of the PED), as follows:

Equipment Hazard Category	Type of Inspection Document (According to EN 10204)
Category I	Test report Type 2.2 (Certificate of Compliance)
Category II Category III Category IV	Inspection certificate Type 3.1A or 3.1B or 3.1C or 3.2

See Section VII of this Guide for more details regarding PED requirements for materials.

2.1.5 Specific Requirements Applicable to Fired Equipment (Annex I-§5 of the PED). This pressure equipment must be constructed so as to avoid or minimize risks of a significant loss of containment from overheating.

2.1.6 Specific Requirements Applicable to Piping (Annex I-§6 of the PED). This equipment must be constructed so as to ensure that the risks listed in subclauses (a) to (g) in PED Annex I-§6 are taken into account or minimized.

2.1.7 Specific Quantitative Requirements for All Equipment (Annex I-§7 of the PED)

(a) The quantitative requirements specified in this clause of Annex I may be superseded by other requirements (or other values) provided that these values result in an equivalent overall level of safety.

(b) These requirements have been included in Annex I-§7, subclauses 2, 3, and 4 of the PED. They deal with the following items:

(1) allowable stresses (Annex I-§7.1)
(2) joint coefficients (Annex I-§7.2)
(3) means of pressure limitation (Annex-§7.3)
(4) hydrostatic test pressure (Annex I-§7.4)
(5) material characteristics (Annex I-§7.5)

3 HAZARD ANALYSIS (PED ANNEX I)

Annex I of the PED (Preliminary Observations-§3) requires the Manufacturer to perform a hazard analysis to ensure safety of the Pressure Equipment during operation.

NOTE: Such a hazard analysis has no relationship with the Hazard Category concept, defined in PED Article 10, whose purpose is to determine the level of hazard presented by Pressure Equipment.

The hazard analysis should be performed as follows:

3.1 Identify the Hazard Due to Pressure

All potential failure mechanisms or dangers that can be anticipated during operation of the Pressure Equipment should be considered, such as

(a) effect of operating parameters (pressure, temperature, fluid, etc.)
(b) effect of static stresses
(c) effect of fluctuating stresses
(d) corrosion, erosion, abrasion
(e) creep
(f) modification of mechanical properties due to temperature, manufacturing process (forming, etc.), aging, etc.
(g) potential misuse of the Pressure Equipment during operation

NOTE: Only hazards due to pressure need to be considered for the PED. Other hazards (such as electrical hazards, electromagnetic hazards, transportation hazards) may be covered by other Directives (see the list in Appendix X-3 of this Guide).

3.2 Evaluation

Evaluate the hazards to determine if the hazards can be eliminated (using adequate safety margins in design, adequate materials, adequate testing and inspection, etc.) or reduced (PED Annex 1, §1.2, first indent).

NOTE: This is not a risk evaluation. The severity and probability of risk is not in the scope of the PED, which does not account for the consequences of a failure of the Pressure Equipment. This appears clearly in the determination of the Hazard Category of the Equipment.

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3.3 Reduction of Hazards

Reduce hazards that cannot be eliminated by applying protective measures during operation of the Equipment. The reduction of these hazards should appear in the Operating Instructions [PED Annex I, §1.2, second indent and §3.4(c)].

3.4 Informing Users

Inform Users of residual hazards so that they can take adequate measures (PED Annex I-§1.2, third indent). This also covers potential misuse of the Equipment by the User during operation (PED Annex I-§1.3).

3.5 Documentation

The results of the hazard analysis must be included in the Technical Documentation. The PED does not require the Manufacturer to provide the details of the hazard analysis.

The ESR contained in Annex I apply only when the corresponding hazards due to the pressure existing on the Pressure Equipment under operating conditions that are "reasonably foreseeable by the Manufacturer" (PED Annex I—Preliminary Observations, §2).

NOTE: Apart from the above, the User may perform a risk analysis by evaluating the probability and the consequences of possible failures or damages of the vessel itself on the people, the environment, etc. Such a risk analysis is outside of the scope of the PED and should be based on National regulations where the Pressure Equipment is being installed.

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CHAPTER VII
MATERIALS
(ARTICLE 11, ANNEX I OF THE PED)

1 GENERAL

(a) Before a material can be used in Pressure Equipment, it must comply with the applicable Essential Safety Requirements (ESR) specified in PED Annex I-§4 (also see Chapter VI, para. 2.1.4 of this Guide):

(1) The material must have appropriate properties for all foreseeable operating and test conditions.

(2) It must be sufficiently ductile: 14% minimum elongation for steel.

(3) It must have sufficient notch toughness: 27 J at 20°C (or 20 ft-lbs at 68°F) for steel.

(4) It must be sufficiently chemically resistant to the fluid contained in the pressure equipment.

(5) It must not be significantly affected by aging.

(6) It must be suitable for the intended processing procedures during manufacture of the pressure equipment.

(7) It must be selected to avoid undesirable effects when various materials are joined.

(8) It must be suitable for such application during the scheduled lifetime unless replacement is foreseen.

(b) For selecting a material for Pressure Equipment, the Manufacturer has three options (Annex I-§4.2b of the PED):

(1) Use material specification taken from an *EN Material Harmonized Standard.* Materials taken from these Standards are presumed to conform to the ESR and there will be no inspection from the NB.

(2) Use material covered by *European Approval for Materials (EAM)* as explained below. This procedure is only applicable for materials intended for repeated use.

(3) Use of material covered by a *Particular Material Approval.* This procedure is applicable for new material(s) that are not for repeated use.

2 MATERIALS THAT COMPLY WITH HARMONIZED MATERIALS STANDARDS

A European standard is called "Harmonized Standard" when the following conditions are fulfilled:

(a) Conforms to the addressed essential requirements

(b) Has an annex ZA

(c) Has been evaluated by the CEN consultant

(d) Is sent to the European Commission for publication in the OJEC.

Harmonized Standards for materials devoted to pressure equipment are issued by CEN. Examples are as follows:

(a) EN 10028 Series: Flat products made of steels for pressure purposes.

(b) EN 10216 Series: Seamless tubes for pressure purposes.

These standards are presumed to conform to the ESR and can be used to manufacture pressure equipment in accordance with the PED without any inspection by the NB.

3 EUROPEAN APPROVAL OF PRESSURE EQUIPMENT MATERIALS (ARTICLE 11 OF THE PED)

3.1 General

When the Pressure Equipment material is not covered by a Harmonized Standard, the Manufacturer of Pressure Equipment or materials can request an EAM to the NB.

The general procedure is as follows:

(a) The Manufacturer prepares a Data Sheet containing all the technical information relevant to the material specification.

(b) The NB performs appropriate inspections and tests to certify the conformity of the material to the applicable ESR. If the material was recognized as being safe before the implementation of the PED, the NB takes into account the existing data.

(c) The NB sends the material Data Sheet to the Member States and the European Commission who can disapprove the EAM within 3 months.

(d) If there is no disapproval during these 3 months the NB issues a EAM specification that will be published in the OJEC.

(e) This material specification is presumed to con-

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form to the applicable ESR and can be used at any time. It has therefore the same status as a Harmonized Standard material.

An EAM is a technical document defining the characteristics of materials intended for repeated use in the manufacture of pressure equipment that are not covered by any harmonized standard.

An EAM will be issued, at the request of one or more Manufacturers of materials or equipment, by an NB specifically designated for the task.

3.2 General Requirements for Obtaining European Approval (EAM) of Pressure Equipment Materials

3.2.1 European Approvals of Nationally Approved Specifications of EU Member Countries for Pressure Equipment Materials. EAMs are established by transforming the material specifications for pressure equipment originally covered in national standards of CEN member countries or in national technical material data sheets approved by the body competent for such approvals. The following requirements shall apply:

(a) The national material specification existed before the work on the relevant European Standard commenced.

(b) The material represents a real alternative to the materials covered in the relevant European Material Standard or an already existing European Approval for pressure equipment materials.

(c) The sampling and testing conditions are equivalent to or more stringent than those specified in the relevant European Material Standard.

(d) The requirements specified in the national specification shall in general be backed by statistical data.

3.2.2 European Approvals of Materials Covered in Non-EU Member Specifications. These EAMs are established on the basis of the material specifications prepared by national, regional, or international organizations outside CEN member countries.

An EAM of this type shall only be established for materials with which there is considerable experience in Europe and for which a similar material is covered in an European Material Standard.

The foreign specifications shall, where necessary, be restricted or be modified by supplementary requirements so that the material complies with both the foreign specification and the equivalent European Material Standard, including all the requirements of this European Standard. In any case, the provisions given in 1.1 under (c) to (f) shall be fulfilled.

The European Material Data Sheet shall include a comparison with the specifications of the equivalent European Material Standard.

3.2.3 Procedure for Incorporation of Existing National Material Specifications into European Material Data Sheets (EMDS)

3.2.3.1 Applications shall be made in writing to an NB for transformation of the material specification. An application form for preparation of a European material data sheet made from a European nationally approved material not covered in a European standard may contain the following information:

(a) Name and address of the applicant

(b) Number of nationally approved material specification

(c) Date of first and last edition

(d) Material group and material designation

(e) Product form and approved dimensions

(f) Material manufacturing process

(g) Comparable material specifications

(h) Basis of the approval

(i) Appraisal number (test report number) and date of issue, experience

3.2.3.2 The NB shall verify the requirements of 1.1 and, where appropriate, shall complete a questionnaire in the form of that given in 1.3.3 with the assistance of the applicant. After consideration the NB shall prepare a draft European Material Data Sheet. The draft EMDS may contain restrictions or supplementary requirements to ensure compliance of the specified material with the requirements of the main part.

The draft EMDS shall be submitted to the EU Member States and the European Commission.

3.2.3.3 The questionnaire for verifying the compliance of the nationally approved material specification with requirements for a European Material Data Sheet includes:

(a) Reference data for the national material specification

(b) Designation of nationally approved material specification

(c) Date of first and last edition

(d) Material Group and material designation

(e) Product form

(f) Approved dimensions

(g) Type of manufacture and deoxidization

(h) Delivery conditions

(i) Range of application

(j) Comparable material specifications

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(k) Indicate the reasons why this material is not inserted in a European standard

(l) Material specification existed prior to initiating work on the relevant European material standard

(m) The requirements are backed by statistical data

(n) Chemical composition

(o) Tensile properties at room temperatures, yield or proof strength, and tensile strength

(p) Elongation after fracture and reduction of area after rupture

(q) Tensile properties at elevated temperatures

(r) Impact properties

(s) Technological properties

(t) Comparison of the sampling and testing conditions between the national approved material specification and the relevant European material standard.

(u) Date

(v) Name and address of the NB

(w) Signature

The NB shall issue the final EMDS taking into account, where appropriate, comments of the EU member states and of the Commission and the opinion of the Standing Committee received within three months of the receipt of the request. A copy of the EMDS shall be sent to the EU Member States, the Notified Bodies, the Commission for publication of a reference in the OJEC.

4 PARTICULAR MATERIAL APPRAISAL (ANNEX I-§4.2c OF THE PED)

This approach is intended for a material that is not listed in a Harmonized Standard or for which an EAM has not been issued. The Particular Material Appraisal must be performed by

(a) the Manufacturer (or a subcontractor) if its equipment is in Hazard Categories I or II

(b) by the NB in charge of the Conformity Assessment Procedures if the equipment is in Hazard Categories III or IV

The material specification must be reviewed for compliance with the Essential Safety Requirements and, if necessary, additional tests must be carried out.

A Particular Material Appraisal indicates that the material complies with the applicable Essential Safety Requirements, but is limited to its application to the conditions specified. If the vessel manufacturer wants to use the material outside that range, he must reapply to the NB for extension of the approval. To grant approval, the NB may require additional tests to be carried out. Subject to these results, the NB may approve the use of the material for those particular conditions, but without an unconditional approval.

5 MATERIAL CERTIFICATES (ANNEX I-§4.3 OF THE PED)

All materials must have documentation, issued by the Material Manufacturer, which confirms compliance with an appropriate material specification. Where the component is a main pressure part of equipment in Category II, III, or IV, this documentation must be a Certificate of specific product control, e.g., EN 10204, Type 3.1A, 3.1B, or 3.1C or 3.2. Certificates of Conformity (e.g., Type 2.2) are acceptable only for pressure equipment in Category I.

6 MATERIAL MANUFACTURERS

Material certificates issued by Material Manufacturers that hold ISO 9000 Certification, issued by a European Accredited Certification Body, can be presumed by the Pressure Equipment Manufacturer to comply with the relevant material ESR.

Where the material manufacturer does not have such certification, its certificates are not presumed to comply with the relevant requirements and, therefore, it is up to the pressure equipment manufacturer to determine if the certificate is acceptable or if independent inspection is required. The Pressure Equipment Manufacturer may also have to convince the NB that the material manufacturer's certificates are acceptable. The draft supporting standard prEN 764-5 currently indicates that direct inspection by a Competent Body, appointed by the pressure equipment Manufacturer, is the appropriate route.

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CHAPTER VIII
NOTIFIED BODIES
(ARTICLE 12, ANNEX IV OF THE PED)

(a) The PED provides for the involvement of an NB to assess the conformity of the Equipment to the specifications of the PED.

(b) These NBs must comply with various requirements in terms of technical competence, organization, independence, etc. (See PED, Annex IV).

They are designated by the official authorities of each Member State, who notify the references of these bodies to the Commission of the European Communities.

The Commission publishes the list of the NB in the OJEC.

(c) The Manufacturer may select any of the NB from this list.

(d) According to the PED, the approval of joint procedures, joint operators (particularly welders) and non destructive testing operators may, in some cases, be performed by Recognized Third-Party Organizations (PED Article 13).

These entities must comply with criteria similar to those of the NB.

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CHAPTER IX
CE MARKING
(ARTICLE 15, ANNEX VI OF THE PED)

(a) The CE Marking is the visual symbol affixed on an Equipment placed on the EU market. It attests that the Equipment complies with all the provisions of the PED (Article 5-§1). This marking allows the free movement of the Equipment in the territory of the EU.

(b) The CE Marking is affixed by the Manufacturer, who takes in this way the responsibility to declare that the Equipment complies with the requirements of the Directive.

(c) A product may be subject simultaneously to various New Approach Directives. Thus, a piece of Equipment might be subject to the Machinery Directive if it is made of mobile parts, to the Low Voltage Directive if electrical energy is involved, etc. (see Appendix X-3).

In such cases, a single CE Marking must be affixed, which attests the compliance with all applicable Directives. It is therefore the responsibility of the Manufacturer to verify the list of Directives to which the equipment may be subjected.

The size of the CE Marking must meet certain rules (see PED Annex VI).

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CHAPTER X
SPECIFIC ISSUES

1 ASSEMBLIES (ARTICLE 10, ANNEX VI OF THE PED)

(a) PED covers also Assemblies, which are defined in the PED (Article 1-§2.1.5) as "several pieces of Pressure Equipment assembled by a Manufacturer to constitute an integrated and functional whole." Typical examples are pressure cookers and boilers. Two cases are possible:

(1) If the Manufacturer of an assembly intends to place it on the European Market and put it into service as an assembly (and not in the form of its constituent nonassembled elements), that assembly must comply with the PED.

(2) If the assembly of Pressure Equipment is performed by the user on its site and under its responsibility (as in the case of industrial installations), that assembly is outside the scope of the PED.

(b) The following requirements apply:

(1) Assemblies including at least a Pressure Equipment above the thresholds must comply with the ESR (Article 3-§2 of the PED).

(2) Assessment of the integration of the various Equipment of the assembly is determined by the highest Hazard Category of its Equipment, ignoring Safety Accessories (Article 10-§2b of the PED). Design must be conducted as stated in Annex I-§2.8 of the PED.

(c) Clauses of PED dealing with assemblies:

(1) Statement #5: Assemblies on Site
(2) Article 1-§2.1.5: Definition
(3) Article 3-§2: Boilers
(4) Article 10-§2: Conformity Assessment
(5) Article 15-§3: CE Marking
(6) Annex I-§2.8: Design
(7) Annex I-§3.2.3: Inspection of Safety Devices

2 USER INSPECTORATES (ARTICLE 14 OF THE PED)

(a) Member States may authorize in their territory the placing on the market, and the putting into service by Users, of Pressure Equipment whose conformity with the essential requirements has been assessed by a User Inspectorate (Article 14-§1 of the PED).

(b) Tasks and responsibilities of an NB may be transferred to a User Inspectorate under the following conditions:

(1) the User Inspectorate has been designated by one of the Member States (Article 14-§1 of the PED)

(2) the Equipment must be assessed according to one of the following modules: A1, C1, F, or G (Article 14-§6 of the PED)

(3) the User Inspectorate must act exclusively for the organization of which he or she is part

(c) The consequences are as follows:

(1) the Equipment so assessed shall not bear the CE Marking (Article 14-§3 of the PED)

(2) the Equipment may be used only in establishments operated by the group of which the User Inspectorate is part (Article 14-§4 of the PED)

3 SPECIFIC CASES

The following specific cases do not follow the general rules of the PED and the User should refer to the concerned Articles of the PED.

(a) Heat exchangers consisting of pipes for the purpose of cooling or heating air. (See Article 1-§2.1.2 of the PED.)

(b) Unfired Pressure Vessels and Boilers containing dangerous fluids (Group 1), classified in Hazard Category III or IV and assessed by QA procedures. (See Article 10-§1.5 of the PED.)

(c) Boilers of one-off production in Hazard Category III and module H. (See Article 10-§1.5 of the PED.)

(d) Vessels containing a dangerous unstable gas in Hazard Category I or II. (See Annex II, Table 2 of the PED.)

(e) Piping containing a dangerous unstable gas in Hazard Category I or II. (See Annex II, Table 6 of the PED.)

(f) Portable extinguishers and bottles for breathing Equipment. (See Annex II, Table 2 of the PED.)

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(g) Pressure-cookers. (See Annex II, Table 5 of the PED.)

(h) Piping containing gas at T <350°C, in Hazard Category II. (See Annex II, Table 7 of the PED.)

4 MANUFACTURER'S RESPONSIBILITY

(a) The PED, like all New Approach Directives, know only two responsible parties for the construction of Pressure Equipment:

(1) the Manufacturer who has the responsibility of the fabrication of the product

(2) the NB who has the responsibility of the Conformity Assessment of the product

In the New Approach, "the Manufacturer is the person who is responsible for designing and manufacturing a product with a view of placing it on the European Market on his behalf." This definition, which is not given in the PED, means that the Manufacturer is fully responsible for the design of the Pressure Equipment. There is no allowance made for sharing the responsibility with the User or an engineering contractor, or a designer.

The Manufacturer can subcontract the Design but will remain fully responsible for the Pressure Equipment when placed on the European market.

(b) The responsibility of the Manufacturer appears explicitly in the PED at the following clauses:

(1) Article 10-§1.1 and 1.4: "The Manufacturer shall subject each Pressure Equipment to one of the Conformity Assessment Procedures of Annex III, at its choice."

(2) Annex I, Preliminary Observations, §3: The Manufacturer is under an obligation to analyze the hazards in order to identify those which apply to his Equipment on account of pressure; he must then design and construct it taking account of his analysis."

(3) Annex I-§1 (General): shows the responsibility of the Manufacturer for what concerns the construction of his Equipment.

(4) Annex I-§2 (Design): shows the responsibility of the Manufacture for what concerns the Design of his Equipment, especially §2.1, 2.2.1, 2.2.3b, 2.6.

(5) Annex I-§4 (Materials): "Materials used for the manufacture for the Equipment must be suitable for such application during the scheduled lifetime."

Especially §4.1 and 4. "The Equipment Manufacturer must take appropriate measures to ensure that the material used conforms with the required specification."

(6) Annex III (Conformity Assessment Procedures): Whatever is the Conformity Assessment Procedures selected by the Manufacturer, its responsibilities are as follows:

"The Manufacturer ensures and declares that Pressure Equipment satisfies the requirements of the Directive which apply to it. The Manufacturer must affix the CE Marking to each Pressure Equipment and draw up a written Declaration of Conformity."

(7) More details on the Manufacturer's responsibility is given in Appendix X-1 of this Guide, which covers the following items:

(a) responsibility of the Manufacturer

(b) placing on the market and putting into service

(c) user

(c) The Manufacturer is also responsible to ensure its product complies to the obligations of all Directives which apply to it. By affixing the CE Marking the Manufacturer officially declares that its product complies with all relevant Directives.

Appendix X-3 of this Guide gives the list of all New Approach Directives, which may be applicable to Pressure Equipment.

5 OPERATING INSTRUCTIONS

When pressure equipment is placed on the market, it must be accompanied, as far as relevant, with instructions for the user, containing all the necessary safety information relating to:

(a) information as affixed to the equipment and required by Annex I, §3.3 of the PED (Marking and Labeling) with the exception of serial identification

(b) necessary safety information (see Annex I, §3.4 of the PED) relating to

(1) mounting including assembling of different pieces of pressure equipment

(2) putting into service

(3) use

(4) maintenance including checks by the user

(5) drawings necessary for a full understanding of the information, if applicable

(c) In particular, this information shall include the elements of the design files used for the in-service verification or for eventual modifications or repairs, such as materials nature, minimal design thicknesses, corrosion allowance, joints coefficients.

Where appropriate, this information must be accompanied by the technical documents for a full understanding of this information and instructions.

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Furthermore, for all the modules, a declaration of conformity (see Annex VII of the PED) is established by the Manufacturer and for modules F and G, a Certificate of Conformity is established by the NB.

The Directive does not specify that these two documents shall be given with the equipment but they can be furnished on request.

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APPENDIX X-1
RESPONSIBILITIES OF THE MANUFACTURER

X-1.1 MANUFACTURER

(a) A manufacturer, in the meaning of New Approach, is the person who is responsible for designing and manufacturing a product with a view of placing it on the Community market on his or her own behalf.

(b) The manufacturer has an obligation to ensure that a product intended to be placed on the Community market is designed and manufactured, and its conformity assessed to the essential requirements in accordance with the provisions of the applicable New Approach directive(s).

(c) The manufacturer may use finished products, ready-made parts or components or may subcontract tasks. However, the manufacturer must always retain overall control and have the necessary competence to take the responsibility for the product.

(d) The manufacturer is any natural or legal person who is responsible for designing or manufacturing a product with a view of placing it on the Community market under his or her own name.[1] The responsibilities of the manufacturer apply also to any natural or legal person who assembles, packs, processes, labels ready-made products with a view to their being placed on the Community market under his or her own name. Furthermore, the responsibility of the manufacturer is placed on any person who changes the intended use of a product in such a way that the different essential requirement will become applicable, or substantially modify or rebuild a product, thus creating a new product, with a view of placing it on the Community market.

(e) The manufacturer may design and manufacture the product. As an alternative, the manufacturer may have it designed, manufactured, assembled, packed, processed, and/or labeled with a view of placing it on the Community market under his or her own name, thus being presented as a manufacturer. Where subcontracting takes place, the manufacturer must retain the overall control for the product and ensure receipt of all the information that is necessary to fulfill the manufacturer's responsibilities according to New Approach directives.

(f) The manufacturer who subcontracts some or all activities may in no circumstances discharge himself from responsibilities (e.g., to an authorized representative, a distributor, or retailer, a wholesaler, a user or a subcontractor).

(g) The manufacturer has sole and ultimate responsibility for conformity of the product to the applicable directives. The manufacturer is responsible for

(1) designing and manufacturing the product in accordance with essential requirements laid down by the directive(s)

(2) carrying out conformity assessment in accordance with the procedure(s) laid down by the directive(s)

(h) The manufacturer is obliged to understand both the design and construction of the product to be able to take the responsibility for the product [i.e., for its being in compliance with all the provisions of the relevant New Approach directive(s)]. Regarding conformity assessment, the manufacturer's responsibility depends on the procedure applied. As a general rule, the manufacture must take all measures necessary to ensure that the manufacturing process assures compliance of the products (e.g., to operate a quality system), to affix the CE marking to the product, to establish a technical documentation, and to draw up EC declaration of conformity. Depending on the directive, the manufacturer may be required to submit the product to a third party (usually a notified body) for product testing and certification, or to have the quality system certified by a notified body. In addition, several directives set up complementary obligations (e.g., the requirement to accompany the product with specified information).[2]

(i) Directives usually require that manufacturer is identified on the product.[3] However, sometimes it is not possible to identify the person who, in reality, was in charge of designing and manufacturing the product.

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[1] The manufacturer is not defined in the New Approach directives, with the exemption of the directives relating to medical devices and in vitro diagnostic medical devices.

[2] For responsibilities of manufacturers and notified bodies according to each conformity assessment procedure, see Chapter V, para. 4 and Appendix V-2 of this Guide.

[3] See the applicable directives.

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In certain sectors this does not reduce the responsibilities of the person who placed the product on the Community market (e.g., any natural or legal person who imports a product from a third country with a view of placing it on the Community market). Accordingly, this person must ensure that the product complies with the applicable directives, and that the appropriate conformity assessment procedure has been conducted.[4]

(j) A product may be put into service without prior placing on the market (e.g., a product manufactured for own use). In such a case the person who puts the product into service must assume the responsibility of the manufacturer. Accordingly, this person must ensure that the product complies with the directive, and that the appropriate conformity assessment has been conducted.

(k) New approach directives do not require the manufacturer to be established in the community. Thus, the responsibilities of the manufacturer established outside the community are equal to those of the manufacturer established in a Member State.

X-1.2 PLACING ON THE MARKET AND PUTTING INTO SERVICE

(a) A product must comply with the applicable New Approach directives when it is placed on the Community market for the first time or put into service.

(b) Placing on the market is the initial action of making a product available for the first time on the Community market, with a view to distribution and/or use in the Community. Availability can be either for payment or free of charge.

(c) Placing into service takes place at the moment of first use within the Community by the end user. However, the need to ensure, in the framework of market surveillance, that products are in compliance with the provisions of the directive when being put into service is limited to products, which are not directly ready for use at the stage of placing on the market, whose compliance may be influenced by the distribution conditions, and/or which are not placed on the market prior to putting into service.

X-1.2.1 Placing on the Market[5]

(a) New Approach directives are designed to ensure free movement of products that comply with the high level of protection laid down in the applicable directives. Therefore, Member States may not prohibit, release, or impede the placing on the market of such products. However, Member States are allowed to adopt, in compliance with the Treaty (e.g., articles 30 and 36), additional national provisions regarding the use, and which are intended for the protection of workers or other users, or the environment.[6] Such national provisions may neither require modifications or a product manufactured in accordance with the provisions of the applicable directives, nor influence the conditions for its placing on the Community market.

(b) A product is placed on the Community market when it is made available for the first time. This is considered to take place when the product is transferred (or offered to be transferred) from the stage of manufacture with the intention of distribution and/or use on the Community market. Moreover, the concept of placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series.

(c) The transfer of the product takes place either from the manufacturer, or the authorized representative in the Community, to the importer established in the Community, or to the person responsible for distributing the product on the Community market. The transfer may also take place directly from the manufacturer, or the authorized representative in the Community, to the final consumer or user.

X-1.2.2 Putting into Service

Putting into service takes place at the moment of the first use within the Community by the end user. Products must comply with the provisions of the applicable New Approach directives and other Community legislation when they are put into service.

[4] This has explicitly been laid down in the directives relating to machinery and lifts. According to article 8(6) of the lift directive, regulations regarding the conformity assessment procedure fall to any person placing the product on the market in the Community, where neither the manufacturer nor his authorized representative established in the Community or the installer of the lift fulfills these obligations.

[5] Placing on the market has only been defined in very few sentences.

[6] See references in the directives relating to simple pressure vessels, construction products, machinery, personal protective equipment, potentially explosive atmospheres, recreational craft, lifts and pressure equipment. This may also become applicable in sectors covered by other directives.

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X-1.3 USER

(a) New Approach directives do not lay down obligations for users.[7]

(b) Community legislation concerning the health and safety of the workplace has an impact on the maintenance and use of products covered by New Approach directives that are used at the workplace.

(c) Many products covered by New Approach directives are used at the workplace. Employers have obligations regarding the use of work equipment in the workplace. An employer is considered any natural or legal person who has an employment relationship with a worker (i.e., any person employed by an employer), and has responsibility for the undertaking and/or establishment.

(d) According to the directive concerning minimum safety and health requirements for the use of work equipment by workers at work (89/655/EEC, modification 95/63/EC), the employer must take all measures necessary to ensure that work equipment (e.g., machinery and apparatus) is available to the workers suitable for the work carried out, and may be used by the workers without impairment to their safety or health. The employer may only obtain and/or use work equipment that complies with the provisions of the applicable directives, or, if no other directive is applicable or is so only partially, the minimum requirements laid down in the annex apply to the directive 89/655/EEC. The employer must also take the necessary measures to ensure that the work equipment is kept at such a level. Furthermore, the employer has an obligation to provide information and training for workers as regards to the use of work equipment.

(e) According to the directive concerning the minimum health and safety requirements for the use of personal protective equipment by workers in the workplace (89/656/EEC), such equipment must comply with the relevant Community provisions on design and manufacture with respect to safety and health (i.e., the New Approach directive relating to personal protective equipment). Furthermore, the equipment must be appropriate for the risk involved, correspond to existing conditions at the workplace, take into account ergonomic requirements and the worker's state of health, fit the wearer correctly, and be compatible where more than one equipment must be used simultaneously. The employer is required, before choosing the personal protective equipment, to assess that it satisfies the requirements.

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[7] As an exemption, according to the directive on pressure equipment, Member States may, under certain conditions, authorize in their territory, the placing on the market, and the putting into service by users.

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APPENDIX X-2
SIMULTANEOUS APPLICATION OF EUROPEAN DIRECTIVES

(a) Essential Requirements set up by New Approach directives may overlap and/or complement each other, depending on the risks related to the product in question.

(b) The placing on the market and putting into service can only take place, when the product complies with the provisions with all applicable directives, and when the conformity assessment has been carried out in accordance with all applicable directives.

(c) Where the same product or risk is carried by two or more directives, the application of other directives can sometimes be excluded, for instance following a risk analysis of the product.

(d) New approach directives cover a wide range of products and/or risks, which both overlap and complement each other. As a result several directives may have to be taken into consideration for one product, since the placing on the market and putting into service can only take place when the product complies with all applicable provisions.

(e) Risks covered by the essential requirements of the directives concern different aspects that in many cases complement each other (e.g., the directive relating to machinery covers in particular mechanical hazards, the directive relating to low voltage electrical hazards, and the directive relating to electromagnetic compatibility, electromagnetic disturbance and immunity), which calls for a joint application of the directives. Accordingly, the product has to be designed and manufactured in accordance with all applicable directives, as well as undergo the conformity assessment procedures according to all applicable directives, unless otherwise provided for.

(f) Certain directives make a direct reference to require the application of other directives (e.g., the directives relating to machinery, and the directive relating to telecommunications terminal equipment to the directive relating to low voltage equipment). Although such a reference has not been included in a number of directives, the general principle of simultaneous application still applies where the essential requirements of the directives are complementary to each other.

(g) The same product or risk can be covered by two or more directives. In such a case, the application of other directives is often limited by excluding certain products from the field of application of the other directives, or by giving preference to the more specified directive. This usually requires a risk analysis of the product, or sometimes an analysis of the intended purpose of the product, which then determines the applicable directive.

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APPENDIX X-3
NEW APPROACH DIRECTIVES

	Directive	Number of Directive	Date of Application	End of Transitional Period
1.	**Electrical equipment designed for use within certain voltage limits** (*"low voltage equipment"*)	73/23/EEC	19/08/74	01/01/97
		93/68/EEC	*01/01/95*	*01/01/97*
2.	Simple pressure vessels	87/404/EEC	01/07/90	01/07/92
		90/488/EEC	*01/07/91*	. . .
		93/68/EEC	*01/01/95*	*01/01/97*
3.	Safety of toys	88/378/EEC	01/01/90	. . .
		93/68/EEC	*01/01/95*	*01/01/97*
4.	Construction products	89/106/EEC	27/06/91	. . .
		93/68/EEC	*01/01/95*	*01/01/97*
5.	**Electromagnetic compatibility**	89/336/EEC	01/01/92	*31/12/95*
		92/31/EEC	*28/10/92*	. . .
		93/68/EEC	*01/01/95*	*01/01/97*
		98/13/EC	*06/11/92*	. . .
6.	**Machinery**	98/37/EC	01/01/93	31/12/94
			01/01/93	31/12/94
			01/01/95	*31/12/96*
			01/01/95	*01/01/97*
7.	Personal protective equipment	89/686/EEC	01/07/92	30/06/95
		93/68/EEC	*01/01/95*	*01/01/97*
		93/95/EEC	*29/01/94*	. . .
		96/58/EC	*01/01/97*	. . .
8.	Nonautomatic weighing instruments	90/384/EEC	01/01/93	01/07/02
		93/68/EEC	*01/01/95*	*01/01/97*
9.	Active implantable medical devices	90/385/EEC	01/01/93	31/12/94
		93/42/EEC	*01/01/95*	*14/06/98*
		93/68/EEC	*01/01/95*	*01/01/97*
10.	Appliances burning gaseous fuels (*"gas appliances"*)	90/396/EEC	01/01/92	31/12/95
		93/68/EEC	*01/01/95*	*01/01/97*
11.	Explosives for civil use (*"civil explosives"*)	93/15/EEC	01/01/95	31/12/02
12.	Medical devices	93/42/EEC	01/01/95	14/06/98
13.	**Equipment and protective systems intended for use in potentially explosive atmospheres** (*"potentially explosive atmospheres"*)	94/9/EC	01/03/96	30/06/03
14.	Recreational craft	94/25/EC	16/06/96	16/06/98
15.	Packaging and packaging waste	94/62/EC	30/06/96	31/12/97
16.	Lifts	95/16/EC	01/07/97	30/06/99
17.	Pressure equipment	97/23/EC	29/11/99	29/05/02
18.	Telecommunications terminal equipment and satellite earth station equipment (*"telecommunications terminal equipment"*)	98/13/EC	06/11/92	. . .
		. . .	*01/05/92*	. . .
		. . .	*01/01/95*	. . .
19.	In vitro diagnostic medical devices	98/XX/EC	XX	YY
20.	**New hot water boilers fired with liquid or gaseous fuels** (*"hot water boilers"*)	92/42/EEC	01/01/94	31/12/97
		93/68/EEC	*01/01/95*	*01/01/97*
21.	**Transportable pressure equipment**	99/36/EC	01/07/01	01/07/03

GENERAL NOTES:
(a) Directives that may be applicable to PED Equipment are in bold.
(b) Italicized items indicate amendments.

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CHAPTER XI
COMPARISON OF ASME AND PED REQUIREMENTS

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TABLE 4
COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I

PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
1	**GENERAL REQUIREMENTS** **PRELIMINARY OBSERVATIONS**						
1.	The obligations arising from the essential requirements listed in this Annex for pressure equipment also apply to assemblies where the corresponding hazard exists.	Assembly 1	See Article 1, para. 2.1.5 for definition of "assemblies"		UG-11		
2.	The essential requirements laid down in the directive are compulsory. The obligations laid down in these essential requirements apply only if the corresponding hazard exists for the pressure equipment in question when it is used under the conditions that are reasonably foreseeable by the manufacturer.		Informative statement				
3.	The manufacturer is under an obligation to analyze the hazards to identify those that apply to the equipment on account of pressure.	Req't 1.a		None		Sect. VIII, Div. 1 does not require hazard analysis.	Note (1)
	The manufacturer must then design and construct it, taking account of this analysis.	Req't 1.b		None			Note (2)
4.	The general requirements are to be interpreted and applied in such a way as to take account of the state of the art and current practice at the time of design and manufacture as well as of technical and economical considerations that are consistent with a high degree of health and safety protection.	Statement	Informative statement	Yes	U-1(a)(3) U-2(a)(1) U-2(a)(2) U-2(g) UW-2(a)	Note (A)	

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TABLE 4
COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
1.	GENERAL						
1.1	Pressure equipment must be designed, manufactured, checked, and, if applicable, equipped and installed in such a way as to ensure its safety when put into service in accordance with the manufacturer's instructions, or in reasonably foreseeable conditions.	Req't 2		Partial	U-1(a)(3) U-2(a)	Note (B)	Note (3) and (4)
1.2	In choosing the most appropriate solutions, the manufacturer must comply with the principles set out below in the following order:	Req't 3	This supplements Req't 1. (There is no reference to User in the PED.)	Partial			Note (5)
	(a) Eliminate or reduce hazards as far as is reasonably practicable	Req't 3.a	Hazards during operation of the vessel.	Yes	U-2(a), UW-2	U-2(a) refers to User, whereas PED refers to Manufacturer.	
	(b) Apply appropriate protection measures against hazards that cannot be eliminated.	Req't 3.b	Pressure relief, thermocouples, corrosion allowance, etc.	Yes	UW-2(a), App. D, E, F, & T UG-4(f)		
	(c) Where appropriate, inform users of residual hazards and indicate whether it is necessary to take appropriate special measures to reduce risks at the time of installation and/or use.	Req't 3.c	Remaining hazards after Req'ts 3.a and 3.b have been met.	None			
1.3	Where the potential for misuse is known or can be clearly foreseen, the pressure equipment must be designed to prevent danger from such misuse, or,	Req't 4.a		Partial	UG-20(b), UG-125		Note (6)
	if that is not possible, adequate warning (must be) given that the pressure equipment must not be used in that way.	Req't 4.b		Partial	UG-116	Note (B)	

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TABLE 4
COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
2	DESIGN REQUIREMENTS						
2.	DESIGN						
2.1	General						
	The pressure equipment must be properly designed, taking all relevant factors into account to ensure that the equipment will be safe throughout its intended life.	Req't 5		*Partial*	U-2(a), UG-20, UG-21,22 UW-2, UCS-56, UCS-66	*Note (C)*	*Note (4)*
	The design must incorporate appropriate safety coefficients using comprehensive methods known to incorporate adequate safety margins against all relevant failure modes in a consistent manner.	Req't 6	(The PED does not define how this is to be accomplished in a "consistent manner.")	Yes		Note (D)	
2.2	Design for Adequate Strength						
2.2.1	The pressure equipment must be designed for loadings appropriate to its intended use and other reasonably foreseeable operating conditions. In particular, the following factors must be taken into account:	Req't 7		Partial	UG-22		
	(a) internal/external pressure	Req't 7a		Yes	UG-22(a)		
	(b) ambient and operational temperatures	Req't 7b		Yes	UG-22(h)		
	(c) static pressure and mass of contents in operating and in test conditions	Req't 7c		Yes	UG-22(b)		
	(d) traffic, wind, earthquake loading	Req't 7d		Partial	UG-22(f)	Except traffic.	
	(e) reaction forces and moments that result from the supports, attachments, piping, etc.	Req't 7e		Yes	UG-22(d)		
	(f) corrosion and erosion, fatigue, etc.	Req't 7f		Yes	UG-22(e), UG-25(b)		
	(g) decomposition of unstable fluids.	Req't 7g		No		Note (E)	Note (7)

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TABLE 4
COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	Various loadings that can occur at the same time must be considered, taking into account the probability of their simultaneous occurrence.	Req't 8		Yes	UG-22, UG-23(d)		
2.2.2	Design for adequate strength must be based on	Req't 9					
	(a) as a general rule a calculation method, as described in 2.2.3, and	Req't 9		Yes	UG-27 through 55		
	supplemented if necessary by an experimental design method as described in 2.2.4, or			Partial	UG-19(c), UG-101		Note (8)
	(b) an experimental design method without calculation, as described in 2.2.4, when the product of the maximum allowable pressure PS and the volume V is less than 6000 bar x L, or the product PS x DN less than 3000 bar.	Req't 9b		Partial		There is no limit on pressure and volume in UG-101	
2.2.3	Calculation method						
	(a) Pressure containment and other loading aspects		See Req't 9a				
	The allowable stresses for pressure equipment must be limited having regard to reasonably foreseeable failure modes under operating conditions.	Req't 10a		Yes	UG-23		
	To this end, safety factors must be applied to eliminate fully any uncertainty arising out of manufacture, actual operational conditions, stresses, calculation models, and the properties and behavior of the material.	Req't 10(b)	(It is not possible to fully eliminate any uncertainty.)	Yes	UG-23		
	These calculations methods must provide sufficient safety margins consistent, where applicable, with the requirements of Section 7.	Req't 10c	See Q1 and Table Q1	Yes	Sect. II, Part D, App. 1		
	The requirements set out above may be met by applying one of the following methods, as appropriate, if necessary as a supplement to or in combination with another method:	Req't 11					

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TABLE 4
COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	(1) design by formula	Req't 11a		Yes	UG-27 to UG-55		
	(2) design by analysis	Req't11 b		Yes	U-2(g)		
	(3) design by fracture mechanics	Req't 11c	Not applicable				
	(b) Resistance						
	Appropriate design calculations must be used to establish the resistance of the pressure equipment concerned.	Req't 12		Yes			
	In particular:						
	(1) the calculation pressures must not be less than the maximum allowable pressures and	Req't 13		Yes	UG-21		
	take into account static head and	Req't 14a		Yes	UG-22(b),		
	dynamic fluid pressures and	Req't 14b		Yes	UG-22(b)		
	the decomposition of unstable fluids.	Req't 14c		None		Note (E)	Note (7)
	Where a vessel is separated into individual pressure-containing chambers, the partition wall must be designed on the basis of the highest possible chamber pressure relative to the lowest pressure possible in the adjoining chamber.	Req't 15		Yes	UG-19(a)		
	(2) the calculation temperatures must allow for appropriate safety margins	Req't 16		Yes	UG-20		
	(3) the design must take appropriate account of all possible combinations of temperature and pressure that might arise under reasonably foreseeable operating conditions for the equipment	Req't 17		Yes	UG-20, UG-21		
	(4) the maximum stresses and peak stress combinations must be kept within safe limits	Req't 18		Yes	UG-22, UG-23		

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COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	(5) the calculation for pressure containment must utilize the values appropriate to the properties of the material, based on the documented data	Req't 19a		Yes	Sect. VIII, Div. 1, App P. Sect. II, Part D, App. 1		
	having regard to the provisions set out in Section 4 together with the appropriate safety factors.	Req't 19b	See Table Q1 for design factors.	Yes			
	Material characteristics to be considered, where applicable, include:	Req't 20		Partial			
	(a) yield strength, 0.2% or 1.0% proof strength as appropriate at the calculation temperature	Req't 20a		Yes	UG-4, UG-23.		
	(b) tensile strength	Req't 20b		Yes	UG-23, Sect. VIII, Div. 1, App. P.		
	(c) time-dependent strength, i.e. creep strength	Req't 20c		Yes	UG-23, App. P, Sect. II, Part D, App. 1.		
	(d) fatigue data	Req't 20d		Yes	UG-22	Note (F)	
	(e) Young's modulus (modulus of elasticity)	Req't 20e		Yes	Sect. II, Part D, App. 5		
	(f) appropriate amount of plastic strain	Req't 20f		Partial		Note (G)	Note (9)
	(g) impact strength	Req't 20g		Yes	UG-84		
	(h) fracture toughness	Req't 20h		Yes	UCS-66, UG-84, etc.		

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	(6) appropriate joint factors must be applied to the materials properties depending, for example, on the type of nondestructive testing, the materials joined and the operating conditions envisaged	Req't 21	See Q2 and Table Q2	Yes	UW-2(a), UW-12	Note (H)	
	(7) the design must take appropriate account of all reasonably foreseeable degradation mechanisms (e.g., corrosion, creep, fatigue) commensurate with the intended use of the equipment	Req't 22		Yes	UG-25, App. E Sect. II, Part D, App. 6	Note (I)	
	Attention must be drawn, in the instructions referred to in Section 3.4, to particular features of the design, which is relevant to the life of the equipment, for example:	Req't 23					Note (3)
	(a) for creep: design hours of operation at specified temperatures	Req't 23a		Partial		Note (J)	Note (10)
	(b) for fatigue: design number of cycles at the specified stress levels	Req't 23b		Partial		Note (J)	Note (10)
	(c) for corrosion: design corrosion allowance	Req't 23c		Yes	UG-25, App. E	Note (K)	
	(c) Stability Aspects						
	Where the calculated thickness does not allow for adequate structural stability,	Req't 24a		Yes	UG-22, UG-28		
	the necessary measures must be taken to remedy the situation, taking into account the risks from transport and handling.	Req't 24b	Including transport of original vessel	None		Note (L)	Note (11)
2.2.4	Experimental design method						
	The design of the equipment may be validated, in all or in part, by an appropriate test program carried out on a sample representative of the equipment or the category of equipment.	Req't 25		Yes	UG-101		

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	The test program must be clearly defined prior to testing and accepted by the notified body responsible for the design conformity assessment module, where it exists.	Req't 25a		None		Note (M)	Note (12)
	This program must define test conditions and criteria for acceptance or refusal.	Req't 25b		Yes	UG-101		
	The actual values of the essential dimensions and characteristics of the materials, which constitute the equipment tested, shall be measured before the test.	Req't 25c		Yes	UG-101(j)		
	Where appropriate, during tests, it must be possible to observe the critical zones of the pressure equipment with adequate instrumentation capable of registering strains and stresses with sufficient precision.	Req't 25d		Yes	UG-101(j) UG-101(n)		
	The test program must include:						
	(a) A pressure strength test, the purpose of which is to check that, at a pressure with a defined safety margin in relation to the maximum allowable pressure, the equipment does not exhibit sufficient leaks or deterioration exceeding a determined threshold.	Req't 25e		Partial	UG-101(m)	Notes (N) and (O)	Note (13)
	The test pressure must be determined on the basis of the differences between the values of the geometrical and material characteristics measures under test conditions and the values used for design purposes	Req't 25f		Yes	UG-101	Note (P)	
	it must take into account the differences between the test and design temperatures	Req't 25g		Yes	UG-101(k)		
	(b) Where the risk of creep or fatigue exists, appropriate tests determined on the basis of the service conditions laid down for the equipment, for instance, hold time at specified temperatures, number of cycles at specified stress-levels, etc;	Req't 25h		None		Note (J)	Note (8)

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	(c) Where necessary, additional tests concerning other factors referred to in 2.2.1 such as corrosion, external damage, etc.	Req't 25i		None			Note (8)
2.3	Provisions to ensure safe handling and operation						
	The method of operation specified for pressure equipment must be such as to preclude any reasonable foreseeable risk in operation of the equipment. Particular attention must be paid, where appropriate, to	Req't 26		None		Note (Q)	Note (14)
	(a) closures and openings	Req't 26a	Also see Req't 27a and Req't 27b.	Yes	UG-35.2, App. S		
	(b) dangerous discharge of pressure relief blow-off	Req't 26b		None			
	(c) devices to prevent physical access while pressure or vacuum exists	Req't 26c		None			
	(d) surface temperature taking into consideration the intended use	Req't 26d		None			
	(e) decomposition of unstable fluids	Req't 26e		None			
	In particular, pressure equipment fitted with an access door must be equipped with an automatic or manual device enabling the user easily "to ascertain that the opening will not present any hazard."	Req't 27a		None		Note (R)	Note (15)
	Furthermore, where the opening can be operated quickly, the pressure equipment must be fitted with a device to prevent it being opened whenever the pressure or temperature of the fluid presents a hazard.	Req't 27b		Yes	UG-35(a), UG-35(b), UG-35(c)		
2.4	Means of examination						
	(a) Pressure equipment must be designed and constructed so that all necessary examinations to ensure safety can be conducted.	Req't 28		Yes	Part UG, Part UW	That is implied in Code rules.	

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	(b) Means of determining the internal condition of the equipment must be available, where it is necessary to ensure the continued safety of the equipment, such as access openings allowing physical access to the inside of the pressure equipment so that appropriate examinations can be conducted safely and ergonomically.	Req't 29a		Yes	UG-46	Note (S)	
	(c) Other means of ensuring the safe condition of the pressure equipment may be applied:	Req't 29b		Yes			
	(1) where it is too small for physical internal access, or	Req't 29b1		Yes	UG-46(b), UG-46(i)		
	(2) where opening the pressure equipment would adversely affect the inside, or	Req't 29b2		None		This is not addressed in Sect. VIII, Div. 1.	Note (16)
	(3) where the substance contained has been shown not to be harmful to the material from which the pressure equipment is made and no other internal degradation mechanisms are reasonably foreseeable.	Req't 29b3		Yes	UG-46(c)		
2.5	Means of draining and venting						
	Adequate means must be provided for draining and venting of pressure equipment where necessary:	Req't 30		Partial	UG-25(f)	Note (T)	Note (17)
	(a) to avoid harmful effects such as water hammer, vacuum collapse, corrosion, and uncontrolled chemical reactions.	Req't 30a		Partial	UG-25(f)	Note (U) Note (V)	
	All stages of operations and testing, particularly pressure testing, must be considered.	Req't 30b		Partial	UG-99(i)	In-service operation is not addressed in Sect. VIII, Div. 1.	
	(b) to permit cleaning, inspection, and maintenance in a safe manner.	Req't 30c		Yes	UG-46		

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
2.6	Corrosion or other chemical attack						
	Where necessary, adequate allowance or protection against corrosion or other chemical attack must be provided, taking account of the intended and reasonably foreseeable use.	Req't 31		Partial	UG-25, UCS-25, UCL-25, Apps. D, E, and F, etc.	Other forms of chemical attack than corrosion are not addressed in Sec. VIII, Div. 1.	Note (18)
2.7	Wear						
	Where severe conditions of erosion or abrasion may arise, adequate measures must be taken to	Req't 32		None	UG-26	Note (W)	Note (19)
	(a) minimize the effect by appropriate design (e.g., additional material thickness, or by the use of liners or cladding materials)	Req't 32a		Partial	UG-26		
	(b) permit replacement of parts that are most affected	Req't 32b		None			
	(c) draw attention, in the instructions referred to in para. 3.4, to measures necessary for continued safe use	Req't 32c		None		Note (B)	Note (3)
2.8	Assemblies						
	Assemblies must be so designed that	Assembly 2				Note (X)	Note (20)
	(a) the components to be assembled together are suitable and reliable for their duty			Yes	UG-11 UG-120(c)		
	(b) all the components are properly integrated and assembled in an appropriate manner			Yes			

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
2.9	Provisions for filling and discharge						
	Where appropriate, the pressure equipment must be so designed and provided with accessories, or provisions made for their fitting, to ensure safe filling and discharge with respect to such hazards as:	Req't 33		None		Note (Y)	Note (21)
	(a) on filling:						
	(1) overfilling or overpressurization having regard in particular to the filling ratio and to vapor pressure at the reference temperature,	Req't 33a		None			
	(2) instability of the pressure equipment	Req't 33b		None			
	(b) on discharge: the uncontrolled release of the pressurized fluid	Req't 33c		None			
	(c) on filling or discharge: unsafe connection and disconnection	Req't 33d		None			
3	**SAFETY DEVICES REQUIREMENTS**						
2.10	Protection against exceeding the allowable limits of pressure equipment						
	Where under reasonably foreseeable conditions, the allowable limits could be exceeded, the pressure equipment must be fitted with, or provisions made for the fitting of, suitable protective devices, within an assembly.	Req't 34		Yes	UG-125 through UG-128		
	The suitable device or combination of such devices must be determined on the basis of the particular characteristics of the equipment or assembly.			Yes	UG-125 through UG-128		

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	Suitable protective devices and combinations thereof comprise:						
	(a) safety accessories as defined in Article 1, section 2.1.3	Req't 35a		Yes	UG-125, CC 2211		
	(b) where appropriate, adequate monitoring devices such as indicators and/or alarms that enable adequate action to be taken either automatically or manually to keep the pressure equipment within the allowable limits	Req't 35b		None		Note (Z)	Note (22)
2.11	Safety accessories						
2.11.1	*Safety accessories must*						
	(a) be designed and constructed to be reliable and suitable for their intended duty and take into account the maintenance and testing requirements of the devices, where applicable	Req't 36a		Yes	UG-126, UG-131, UG-132		
	(b) be independent of other functions, unless their safety function cannot be affected by such other functions	Req't 36b		Yes	UG-125		
	(c) comply with the appropriate design principles to obtain suitable and reliable protection. These principles include, in particular, fail-safe modes, redundancy, diversity, and self-diagnosis	Req't 36c		Partial	UG-125, App. M	Note (AA)	Note (23)
2.11.2	*Pressure limiting devices*						
	The devices must be so designed that the pressure will not permanently exceed the maximum allowable pressure PS; however, a short duration pressure surge in keeping with the specifications in para. 7.3 is allowable, where appropriate.	Req't 37a Req't 37b	See Q3. (Pressure surge is limited to 10% by Q3).	Yes	UG-125		
2.11.3	*Temperature monitoring devices*						
	These devices must have an adequate response time on safety grounds, consistent with the measurement function.	Req't 38		Yes	App. C, App. T	Note (BB)	Note (24)

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
2.12	External fire						
	Where necessary, pressure equipment must be so designed and, where appropriate, fitted with suitable accessories, or provision made for their fitting, to meet damage-limitation requirements in the event of external fire, having particular regard to the intended use.	Req't 39		Yes	UG-125(c)(2)		
4	**FABRICATION REQUIREMENTS**						
3	MANUFACTURING						
3.1	Manufacturing procedures						
	The manufacturer must ensure the competent execution of the provisions set out at the design stage by applying the appropriate techniques and relevant procedures, especially with consideration of the following.	Req't 40		Yes	UG-75, UG-78, UG-93,95 UG-117		
3.1.1	*Preparation of the component parts*						
	Preparation of the component parts (e.g., forming and chamfering) must not give rise to defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the pressure equipment.	Req't 41		Yes	UG-11, UG-76, UG-95, UW-31,32		
3.1.2	*Permanent joining*						
	Permanent joints and adjacent zones must be free of any surface or internal defects detrimental to the safety of the equipment.	Req't 42		Yes	UW-11,32 UW-35,36 UW-37(a)–37(e), UW-51		

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	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.	Req't 43		Yes	UW-28	Note (CC)	
	For pressure equipment, permanent joining of components that contribute to the pressure resistance of the equipment and components that are directly attached to them must be carried out by suitably qualified personnel	Req't 44a		Yes	UW-28,29		
	according to suitable operating procedures.	Req't 44b		Yes	UW-37 UW-46,47 UW-48		
	For pressure equipment in categories II, III, and IV, operating procedures and personnel must be approved by a competent third party, which, at the manufacturer's discretion, may be						
	(a) a notified body	Req't 45a	See definition in PED, Article 12	None			Note (25)
	(b) a third party organization recognized by a Member State as provided in Article 13	Req't 45b	See definition in PED, Article 13	None			
	To carry out these approvals the third party must perform examinations and tests as set out in the appropriate harmonized standards or	Req't 46a	See EN 287 for qualification of welders & EN288 for qualification of operating procedure.	None			Note (26)
	equivalent examinations and tests or	Req't 46b		None			
	must have them performed.	Req't 46c		None			

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
3.1.3	*Nondestructive tests*						
	For pressure equipment, non-destructive tests of permanent joints must be carried out by suitable qualified personnel.	Req't 47		Yes	UW-51(a) App. 6, 8 App. 12		
	For pressure equipment in categories III and IV the personnel must be approved by a third party organization recognized by a Member State pursuant to Article 13 of the PED.	Req't 48		None			Note (27)
3.1.4	*Heat treatment*						
	Where there is a risk that the manufacturing process will change the material properties to an extent that would impair the safety of the pressure equipment, suitable heat treatment must be applied at the appropriate stage of manufacture.	Req't 49		Yes	UG-85, UCS-85, UHT-5(e), UHT-51		
3.1.5	*Traceability*						
	Suitable procedures must be established and maintained for identifying the material making up the components of the equipment that contribute to pressure resistance by suitable means from receipt, through production, up to the final test of the manufactured pressure equipment.	Req't 50		Yes	UG-93, UG-94, App. 10		
5	**INSPECTION REQUIREMENTS**						
3.2	Final assessment						
	Pressure equipment must be subjected to final assessment as described as follows:	Statement	Final inspection plus proof test				

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
3.2.1	*Final inspection*						
	Pressure equipment must undergo a final inspection to assess visually and	Req't 51a		Yes	UG-90(c)(1), UG-99(g),		Note (28)
	by examination of the accompanying documents compliance with the requirements of the Directive. Test carried out *during manufacture may be taken into account.*	Req't 51b		Partial	UG-90, UG-100(d), UG-120, App.W		
	As far as is necessary on safety grounds, the final inspection must be carried out internally and externally on every part of the equipment, where appropriate during manufacture (e.g., where examination during the final inspection is no longer possible).	Req't 52		Yes	UG-90, UG-96, UG-97		
3.2.2	*Proof test*	Req't 53					
	Final assessment of pressure equipment must include a test for the pressure containment aspect, which will normally take the form hydrostatic pressure test at a pressure at least equal, where appropriate, to the value in para. 7.4.	Req't 53a		None	UG-99	Note (DD)	Note (29)
	For category I series produced equipment, this test may be *performed on a statistical basis.*	Req't 53b		N/A		Not permitted in Sect. VIII, Div. 1.	
	Where the hydrostatic pressure test is harmful or impractical, other tests of a recognized value may be carried out. For test other than the hydrostatic pressure test, additional measures, such as nondestructive tests or other methods of equivalent validity, must be applied before those tests are carried out.	Req't 53c		Yes	UG-100, UW-50		Note (30)
3.2.3	*Inspection of safety devices*						
	For assemblies, the final assessment must also include a check of the safety devices intended to check full compliance with the requirements referred to in para. 2.10.	Assembly -3		Partial	UG-136, UG-137	Note (Z)	

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PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
3.3	Marking and labeling				UG-116,		
	In addition to the CE marking referred to in Article 15 of the PED, the following information must be provided:	Req't 54		Partial	UG-118-119, UG-129,		This can be on one or more name plates.
	(a) For all pressure equipment			Partial			
	(1) the name and address or other means of identification of the manufacturer and, where appropriate, of its authorized representative established within the Community	Req't 54a		Partial		Note (EE)	Note (31)
	(2) the year of manufacture	Req't 54b		Yes	UG-116		
	(3) identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number	Req't 54c		Partial	UG-116	Not required in Section VIII, Division 1.	
	(4) essential maximum/minimum allowable limits	Req't 54d		Yes	UG-116		
	(b) Depending on the type of pressure equipment, further information necessary for safe installation, operation or use, and, where applicable, maintenance and periodic inspection such as			None		Not required in Section VIII, Division 1.	Note (31)
	(1) the volume V of the pressure equipment in L	Req't 54e					
	(2) the nominal size for piping DN	Req't 54f					
	(3) the test pressure PT applied in bar and date	Req't 54g					
	(4) safety device set pressure in bar	Req't 54h					
	(5) output of the pressure equipment in kW	Req't 54i					
	(6) supply voltage in V (volts)	Req't 54j					
	(7) intended use	Req't 54k					
	(8) filling ratio kg/L	Req't 54l					
	(9) maximum filling mass in kg	Req't 54m					
	(10) tare mass in kg	Req't 54n					
	(11) the product group	Req't 54o					

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PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	(c) where necessary, warnings fixed to the pressure equipment drawing attention to misuse, which experience has shown might occur.	Req't 54p		None		Not required in Section VIII, Division 1.	Note (32)
	The CE marking and the required information must be given to the pressure equipment or on a dataplate firmly attached to it, with the following exceptions:	Req't 55		Partial	UG-119	Sect. VIII, Div. 1 does not cover CE marking.	Note (33)
	(1) where applicable, appropriate documents may be used to avoid repetitive marking of individual parts such as piping components, intended for the same assembly. This applies to CE marking and other marking and labeling referred to in this Annex	Req't 55a		None	UG-119		
	(2) where the pressure equipment is too small, e.g., accessories, the information referred to in (b) may be given on a label attached to that pressure equipment	Req't 55b		None		Labels are not addressed in Sec. VIII, Div. 1.	
	(3) labeling or other adequate means may be used for the mass to be filled and the warnings referred to in (c), provided it remains legible for the appropriate period of time.	Req't 55c		None			
3.4	Operating instructions			None		Note (B)	Note (3)
	(a) When pressure equipment is placed on the market, it must be accompanied, as far as relevant, with instructions for the user, containing all the necessary safety information relating to:	Req't 56					
	(1) mounting including assembling of different pieces of pressure equipment	Req't 56a					
	(2) putting into service	Req't 56b					
	(3) use	Req't 56c					
	(4) maintenance including checks by the user	Req't 56d					

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PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	(b) Instructions must cover information affixed to the pressure equipment in accordance with para. 3.3, with the exception of serial identification, and	Req't 56e					
	must be accompanied, where appropriate,	Req't 56f					
	by the technical documents,	Req't 56g					
	drawings, and diagrams necessary for a full understanding of these instructions.	Req't 56h					
	(c) If appropriate, these instructions must also refer to hazards arising from misuse in accordance with para. 1.3 and	Req't 56i					
	particular features of the design in accordance with para. 2.2.3.	Req't 56j					
6	**MATERIAL REQUIREMENTS**						
4	MATERIALS						
	Materials used for the manufacture of pressure equipment must be suitable for such application during the scheduled lifetime unless replacement is foreseen.	Req't 57		Partial	UG-4–UG-8, UG-10, Sect. II, App. 6.	Although that is the intent of the Code, it has no specific Code requirements.	Note (34)
	Welding consumables and other joining materials need to fulfill only the relevant requirements of 4.1, 4.2(a), and the first paragraph of 4.3, in an appropriate way, both individually and in a joined structure.	Req't 58	Requirements 43, 59 to 64, 65, 67, and 69 apply.	Partial	UG-9, UW-26, Sect. II, Part C.		Note (35)
4.1	Materials for pressurized parts must	Req't 59		Partial			
	(a) have appropriate properties for all operating conditions that are reasonably foreseeable and for all test conditions, and	Req't 59a		Partial	UG-4, Sect. II,	See ASME Sect. II, Parts A, B, C, and D for materials properties. Some materials may not meet PED requirements.	Note (36)
	in particular they should be sufficiently ductile and tough.	Req't 59b	Elongation A ≥ 14%.	Partial	Parts, A, B, C, D.		
		Req't 59c	J ≥ 27 J (20 ft-lbs) at ≤ 20°C (68°F).	Partial	UG-84, UCS-66, UHT-6		Note (37)

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TABLE 4
COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	Where appropriate, the characteristics of the materials must comply with the requirements of para. 7.5.	Req't 59d	See PED Section 7.5	Partial			Note (38)
	Moreover, due care should be exercised in particular in selecting materials to prevent brittle-type fracture where necessary,	Req't 60a		Partial	UG-84	Sect. VIII, Div. 1 toughness requirements do not meet all PED requirements.	
	where for specific reasons brittle material has to be used appropriate measures must be taken.	Req't 60b		None		The Code does not address brittle materials.	
	(b) be sufficiently chemically resistant to the fluid contained in the pressure equipment;	Req't 61a		Partial	UG-16(e), UG-25, Sect. II, Part D, App. 5, 6.	Note (FF)	Note (36)
	the chemical and physical properties necessary for operational safety must not be significantly affected within the scheduled lifetime of the equipment;	Req't 61b		Partial		Note (FF)	
	(c) not be significantly affected by aging	Req't 62		Partial	Sect. II, Part D, App. 5, 6.		Note (36)
	(d) be suitable for the intended processing procedures	Req't 63	(Fabrication)	Yes	UG-79, UCS-85, UHT-81		
	(e) be selected to avoid significant undesirable effects when the various materials are put together	Req't 64		Yes	UG-18		

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COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
4.2	(a) The pressure equipment manufacturer must define in an appropriate manner the values necessary for the design calculations referred to in para. 2.2.3 and	Req't 65a		Yes	UG-23		
	the essential characteristics of the materials and	Req't 65b		Partial			Notes (36)
	their treatment referred to in para. 4.1	Req't 65c		Partial			and (38)
	(b) The manufacturer must provide in technical documentation elements relating to compliance with the material specification of the Directive in one of the following forms by						Note (39)
	(1) using materials that comply with harmonized standards	Req't 66a		None			
	(2) using materials covered by a European approval of pressure equipment materials in accordance with Article 11 of the PED	Req't 66b		None			
	(3) a particular material appraisal	Req't 66c	Performed by the NB for category III and IV vessels	None			
	(c) For pressure equipment in categories III and IV, particular appraisal as referred to in the third indent of (b) must be performed by the notified body in charge of the conformity assessment procedures for the pressure equipment.			None			Note (40)
4.3	The equipment manufacturer must take appropriate measures to ensure that the material used conforms with the required specification.	Req't 67a		Yes		UG-93	
	In particular, documentation prepared by the material manufacturer affirming compliance with the specification must be obtained for all materials.	Req't 67b		Yes		UG-23(a), UG-93	

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	For the main pressure bearing parts of equipment in categories II, III, and IV, this must take the form of certificate of specific product control.	Req't 68		None	UG-93		Note (41)
	Where a material manufacturer has an appropriate quality-assurance system, certified by a competent body established within the Community and having *undergone a specific assessment for materials*, certificates issued by the manufacturer are presumed to certify conformity with relevant requirements of this section.	Req't 69		None			Note (42)
7.	**SPECIFIC REQUIREMENTS FOR HEATED PRESSURE VESSELS**						
	SPECIFIC PRESSURE EQUIPMENT REQUIREMENTS						
	In addition to the applicable requirements of sections 1 through 4, the following requirements apply to the pressure equipment covered by sections 5 and 6.	Statement	These requirements are in addition to requirements 1 to 72				
5.	FIRED OR OTHERWISE HEATED PRESSURE EQUIPMENT WITH RISK OF OVERHEATING AS REFERRED TO IN ARTICLE 3 (1)			N/A			
	This pressure equipment includes:	Req't 70					
	(a) Steam and hot water generators as referred to in Article 3, section 1.2, such as fired steam and hot-water boilers, superheaters and reheaters, waste-heat boilers, waste incineration boilers, electrode or immersion-type electrically heated boilers, pressure cookers, with their accessories, and, where applicable, their systems for treatment of feedwater and for fuel supply	Req't 70a	In principle, these items are in the scope of the Code				

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COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	(b) Process heating equipment for other than steam and hot water generation falling under Article 3, section 1.1, such as heaters for chemical and other similar processes and pressurized food-processing equipment.	Req't 70b					
	This pressure equipment must be calculated, designed, and constructed to avoid or to minimize risks of a significant loss of containment from overheating.	Req't 71					
	In particular it must be ensured, where applicable, that	Req't 72					
	(a) appropriate means of protection are provided to restrict operating parameters such as heat input, heat take-off, and, where applicable, fluid level to avoid any risk of local and general overheating	Req't 72a					
	(b) sampling points are provided where required to allow evaluation of the properties of the fluid to avoid risks related to deposits and/or corrosion	Req't 72b					
	(c) adequate provisions are made to eliminate risks of damage from deposits	Req't 72c					
	(d) safe removal of residual heat after shutdown are provided	Req't 72d					
	(e) steps are taken to avoid a dangerous accumulation of ignitable mixtures and combustible substances and air, or flame flowback	Req't 72e					

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
6.	PIPING AS REFERRED TO IN ARTICLE 3, SECTION 1.3			N/A			
	Design and construction must ensure that		Not in the scope of Section VIII, Division 1.				
	(a) the risk of overstressing from inadmissible free movement or excessive forces being produced (e.g., on flanges, connections, bellows, or hoses) is adequately controlled by means such as support, constraint, anchoring, alignment, and pre-tension						
	(b) where there is a possibility of condensation occurring inside pipes for gaseous fluids, means are provided for drainage and removal of deposits from low areas to avoid damage from water hammer or corrosion						
	(c) consideration is given to the potential damage from turbulence and formation of vortices; the relevant parts of para. 2.7 are applicable						
	(d) consideration is given to the risk of fatigue due to vibrations in pipes						
	(e) where fluids of Group 1 are contained in the piping, appropriate means are provided to isolate "take-off" pipes, the size of which represents a significant risk						
	(f) the risk of inadvertent discharge is minimized; the take-off points must be clearly marked on the permanent side, indicating the fluid contained						
	(g) the position and route of underground piping is at least recorded in the technical documentation to facilitate safe maintenance, inspection, or repair						

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
8.	**QUANTITATIVE REQUIREMENTS**						
7.	SPECIFIC QUANTITATIVE REQUIREMENTS FOR CERTAIN PRESSURE EQUIPMENT						
	The following provisions apply as a general rule. However, where they are not applied, including in cases where materials are not specifically referred to and no harmonized standards are applied, the manufacturer must demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.	Statement	Manufacturer can depart from these quantitative requirements, but they will have to prove to the N.B. that an equivalent level of safety is achieved.				Note (43)
	This section is an integral part of PED Annex I. The provisions in this section supplement the essential requirements of sections 1 through 6 for the pressure equipment to which they apply.	Statement					
7.1	Allowable stresses						Note (44)
7.1.1	*Symbols*						
	$R_{e/t}$, yield limit, indicates the value at the calculation temperature of: (a) upper flow limit for a material presenting upper and lower flow limits (b) the 1.0% proof strength of austenitic steel and nonalloyed aluminum (c) the 0.2% proof strength in other cases	Statement	These quantitative requirements have been reincorporated in the previous sections at the right place.				
	$R_{m/20}$ indicates the minimum value of the ultimate strength at 20°C.						
	$R_{m/t}$ designates the ultimate strength at the calculation temperature.						

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
7.1.2	The permissible general membrane stress for predominantly static loads and for temperatures outside the range in which creep is significant must not exceed the smaller of the following values, according to the material used:	Quantitative Req't Q1	Also included in Req't 10c. See Table Q1.	Yes	Section II, Part D, Table 1A and App. 1.		Note (45)
	(a) in the case of ferritic steel including normalized (normalized rolled) steel and excluding fine grain steel and specially heat-treated steel, $^2/_3$ of $R_{e/t}$ and $^5/_{12}$ of $R_{m/20}$	Req't Q1a					
	(b) for austenitic steel:	Q1b				Note (GG)	Note (46)
	(1) if its elongation after rupture exceeds 30%, $^2/_3$ of $R_{e/t}$	Q1b1					Note (47)
	(2) or, alternatively, and if its elongation after rupture exceeds 35%, $^5/_6$ of $R_{e/t}$ and $^1/_3$ of $R_{m/20}$	Q1b2					
	(c) for nonalloy or low alloy cast steel, 10/19 of $R_{e/t}$ and $^1/_3$ of $R_{m/20}$	Req't Q1c					
	(d) for aluminum, $^2/_3$ of $R_{e/t}$	Q1d					
	(e) for aluminum alloys, excluding precipitation hardening alloys, $^2/_3$ of $R_{e/t}$ and $^5/_{12}$ of $R_{m/20}$	Q1d					
7.2	*Joint coefficients*						
	For welded joints, the joint coefficient must not exceed the following values:	Req't Q2	See Table Q2.	Yes	Table UW-12		
	(a) for equipment subject to destructive and nondestructive tests that confirm that the whole series of joints show no significant defects: 1	Req't Q2a	Also included in Req't 21.				
	(b) for equipment subject to random nondestructive testing: 0.85	Q2b					

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PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
	(c) for equipment not subject to nondestructive testing other than visual inspection: 0.7	Q2c					
	If necessary, the type of stress and the mechanical and technological properties of the joint must also be taken into account,	Q2d	(Need clarification of the intent of this paragraph).				
7.3	Pressure limiting devices, particularly for pressure vessels						
	The momentary pressure surge referred to in para. 2.11.2 must be kept to 10% of the maximum allowable pressure.	Req't Q3	Also included in Req't 37b	Partial	UG-125	UG-125(c) limits this to 10%, or 3 psi, whichever is greater.	Note (48)
7.4	Hydrostatic test pressure						
	For pressure vessels, the hydrostatic test pressure referred to in para. 3.2.2 must be no less than	Req't Q4	See Table Q3				
	(a) that corresponding to the maximum loading to which the pressure equipment may be subject in service, taking into account its maximum allowable pressure and its maximum allowable temperature, multiplied by the coefficient 1.25, or	Q4a	Also included in Req't 53a. See Table Q3.	Yes	UG-99		
	(b) the maximum allowable pressure multiplied by the coefficient 1.43, whichever is the greater	Q4b		None			Note (29)

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COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

PED Requirements				ASME Section VIII, Div. 1 Requirements			
PED Para.	Annex I Essential Safety Requirements	Grouping	Comments	Yes, None, Partial	Code Reference	Comments	Additional Considerations for PED, Annex 1
1	2	3	4	5	6	7	8
7.5	Material characteristics						
	Unless other values required in accordance with other criteria must be taken into account, a steel is considered as sufficiently ductile to satisfy 4.1(a) if, in a tensile test carried out by a standard procedure, its elongation after rupture is no less than 14% and	Req't Q5	Also included in Req't 59b.	Partial			Note (38)
	its bending rupture energy measured on an ISO V test-piece is no less than 27 J, at a temperature no greater than 20°C but not higher than the lowest scheduled operating temperature.	Req't Q6	Also included in Req't 59c	Partial		Sect. VIII, Div. 1, UG-84, UCS-66 and UHT-6 have different toughness criteria than PED. Some materials may not meet the PED requirements.	Note (37)

GENERAL NOTE: Any reference to the Code in this table means ASME Section VIII, Division 1.

NOTES:

(A) ASME Section VIII, Division 1 (the Code) is based on "design by rule." It requires the use of the design rules provided in the Code. Other methods may be used only if no rules are provided in the Code.

(B) ASME Section VIII, Division 1 does not require the Manufacturer to issue Operating Instructions or warnings regarding potential hazards or misuse of pressure equipment.

(C) Section VIII, Division 1 includes requirements for new construction. It does not include specific requirements for in-service degradation. The User is generally responsible for adequate corrosion/erosion allowances and selection of suitable materials for the intended.

(D) Safety factors are built into the Section VIII, Division 1 allowable design stresses, notch toughness requirements, joint efficiencies/NDE requirements, etc. The Code does not include margins for in-service degradation.

(E) Section VIII, Division 1 does not address decomposition of unstable fluids.

(F) Section VIII, Division 1 does not have rules for fatigue analysis but does require consideration of cyclic and dynamic loading in design of pressure equipment (UG-22).

(G) Section VIII, Division 1 does not have a direct limit on plastic strain, except in the creep range, but other limits indirectly control this.

(H) Certain operating conditions, such as lethal service, require 100% RT and also requires specific weld types and thereby influences the appropriate joint efficiency [UW-2(a)].

(I) Corrosion and fatigue must be taken into account in Section VIII, Division 1 by the Code design requirements for a particular vessel. Creep is taken into account by the Code design basis for establishing the allowable stresses in the creep range.

(J) Section VIII, Division 1 does not require design for specific hours in the creep range, nor specific number of cycles at specified stress levels. UG-22(e), however, requires consideration of cyclic loads in the design.

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TABLE 4 COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

NOTES (CONT'D):

(K) Section VIII, Division 1 requires the corrosion allowance to be shown on the Data Report for in-service use. It provides guidance for corrosion allowance and corrosion resistant metal linings (Appendix E, Appendix F), and states that vessels or parts of vessels subject to thinning by corrosion, erosion, or mechanical abrasion shall have provision made for the desired life of the vessel [UG-25(b)]. The Code does not require operating instructions nor specific instructions related to the life of the equipment. See UG-25, UCS-25, UCL-25, UHT-25, UB-13, and Appendix E, as appropriate.

(L) Section VIII, Division 1 does not address transport or handling loads. Non-stationary vessels are being removed from Section VIII and will be included in Section XII.

(M) UG-101(b) requires witnessing the tests and acceptance of the test results by the Authorized Inspector (AI), but not acceptance of the test program by the AI prior to testing.

(N) ASME Section VIII, Division 1 does not include requirements for leakage.

(O) Corrosion and other in-service deterioration are not included in Section VIII, Division 1, UG-101.

(P) These requirements are included in UG-101(d)(2), UG-101(j), UG-101(n)(4), and in UG-101(o)(4).

(Q) Section VIII, Division 1 has no specific requirements for the items listed in Annex I, para. 2.3.

(R) Section VIII, Division 1 has no specific requirements for access doors to be fitted with devices "to ascertain that the opening will not present a hazard" or to prevent from opening quick opening closures when the pressure or temperature of the fluid may present a hazard.

(S) Section VIII, Division 1 provides for inspection openings but does not address internal examination via the access openings.

(T) Section VIII, Division 1 does not address venting, except during pressure testing.

(U) Water hammer and uncontrolled chemical reactions are not addressed in Section VIII, Division 1.

(V) Section VIII, Division 1 does not specifically address vacuum vents.

(W) Erosion is not specifically addressed in Section VIII, Division 1.

(X) Section VIII, Division 1 does not address assemblies, but does address parts. The Code requirements are intended to apply also to assemblies.

(Y) ASME Section VIII, Division 1 does not require accessories "to assure safe filling and discharge" with respect to the hazards listed in 2.9 of PED Annex I.

(Z) Section VIII, Division 1 has no specific requirements for monitoring devices, such as indicators and alarms referred to in 2.10(b) of PED Annex I.

(AA) Fail-safe modes, redundancy, diversity, and self-diagnosis are not specifically addressed in Section VIII, Division 1.

(BB) The response time of temperature-monitoring devices is not specifically addressed in Section VIII, Division 1.

(CC) Section VIII, Division 1 requires the minimum tensile properties of the weld metal to meet the specified minimum tensile properties of the base metal (except for welded 9% Nickel steels). See Section II, Part D, Table 1A.

(DD) Section VIII, Division 1 test pressure factor of 1.3 times the maximum allowable working pressure for hydrostatic test does not meet the 1.43 factor required by PED. Annex I does not specify test pressure for a pneumatic test, but does require additional NDE for pneumatic test.

(EE) The Section VIII, Division 1 requirements for marking and Data Reports are included in UG-116, UG-118, and UG-119. Vessels intended for lethal service must include the letter "L" in the marking. Marking of pressure relief devices is included in UG-129. The requirements for Data Reports are included UG-120 and in Appendix W. The name and address of the vessel Manufacturer must be listed in the Section VIII, Division 1 Data Reports. The name and address of Manufacturer's representative in the European Community is as additional requirement.

(FF) Chemical and physical properties for operational safety are implied in Section VIII, Division 1, but the Code has no specific rules for this.

(GG) Section VIII, Part ULT provides an alternate design basis that permits the use of higher design stresses at low temperatures for certain materials because of increased strength in these materials at low temperatures.

(1) The Manufacturer must perform hazards analysis in accordance with Article 3, Article 9, and Annex II of the PED. (See Chapter VI, para. 3 of this Guide.)

(2) The Manufacturer is required to design and construct the pressure equipment to comply with all the Essential Safety Requirements in PED Annex I. This Annex does not assign any responsibility to User. It makes it the duty of the manufacturer to achieve safety and comply with the Essential Safety Requirements.

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COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

NOTES (CONT'D):

(3) The Manufacturer shall prepare, as far as relevant, instructions for the User, containing the necessary safety information listed in PED, Annex I §3.4. (See PED Annex IST-§3.4 and Chapter X, para. 5 of this Guide). The instructions shall include the following:
  (a) Marking and labeling as required by PED §3.3 of Annex I of the PED.
  (b) Installation instructions, including assembling different pieces of pressure equipment
  (c) Putting into service
  (d) Use
  (e) Maintenance, including checks by the User
  (f) Drawings necessary for full understanding of the information, if applicable
  (g) *Design information for in-service verification, modification or repairs*
  (h) Warnings to prevent the danger of misuse of the equipment
  (i) Declaration of Conformity

(4) The Manufacturer must also consider the following (not specifically addressed in ASME Section VIII, Division 1):
  (a) Inform Users of residual hazards
  (b) Prevent dangers from foreseeable misuse
  (c) Take into account foreseeable degradation mechanisms
  (d) Ensure safety throughout the intended life of the pressure equipment

(5) The Manufacturer must
  (a) eliminate or reduce hazards as far as it is reasonably possible
  (b) apply appropriate protection measures against hazards that cannot be eliminated
  (c) where appropriate, inform Users of any residual hazards and any additional measures to be taken to reduce risks during installation and/or use

(6) The manufacturer must provide the necessary safeguards (e.g., safety relief vents, temperature measuring devices and other sensors, etc.) where there is potential for misuse or improper use of the pressure equipment (e.g., different service conditions or more hazardous fluids, pressure or temperature surges, auto-refrigeration, etc.).

(7) Annex I of the PED requires consideration of decomposition of unstable fluids in the design.

(8) An experimental design method, as described in para. 2.2.4, may require additional test for fatigue, creep, corrosion rates, and impose additional limitations consistent with those in the PED (e.g., hold time at temperature, number of fatigue cycles at a given stress level, corrosion rates, etc.).

(9) The design calculations should include the amount of plastic strain, where appropriate.

(10) Any limitations on design life from operation at the design temperature in creep range, fatigue cycles, and corrosion allowance must be specified in Operating Instructions.

(11) The design calculations must take into account structural stability, including during transport and handling, as appropriate.

(12) The manufacturer must obtain approval from the Notified Body responsible for the conformity assessment module, if one exists for the experimental test program.

(13) The experimental design method must take into account leakage and deterioration of pressure equipment (e.g., corrosion, etc.).

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TABLE 4
COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

NOTES (CONT'D):

(14) The Manufacturer must consider the following aspects to ensure safe handling and preclude risk during operation from:
  (a) closures and openings
  (b) discharge of pressure relief blowoff
  (c) access while pressure or vacuum exists in the pressure equipment
  (d) surface temperature, taking into account the intended use of the equipment
  (e) decomposition of unstable fluids

(15) Pressure equipment fitted with access doors must be equipped with automatic or manual devices enabling the User "to ascertain that the opening will not present any hazards."

(16) Provisions for safe condition inside the vessel, where applicable, must be included in Operating Instructions.

(17) The vessel Manufacturer must provide adequate means for venting and draining (including vacuum vents), as required by PED Annex I, §2.5 for all stages of operation and testing. The Manufacturer must also avoid harmful effects, such as water hammer, corrosion, uncontrolled chemical reaction, etc.

(18) Consideration must also be given to other forms of chemical attack besides corrosion, where appropriate, as required by PED Annex I, §2.6.

(19) Erosion must be considered in the design, where appropriate, to meet the requirements of PED, Annex I, §2.7.

(20) The Section VIII, Division 1 requirements implicitly apply also to assemblies. The Manufacturer must make certain that all assemblies comply with the requirements of Annex I, §2.8. (The PED defines assemblies as several pieces of pressure equipment assembled by the Manufacturer to constitute an integral and functional whole).

(21) The Manufacturer must provide the necessary accessories in accordance with PED, Annex I, §2.9 to assure safe filling and discharge, prevent uncontrolled release of pressurized fluid, and prevent unsafe connection and disconnection.

(22) The Manufacturer must provide the necessary indicators and alarms to meet the requirements of PED Annex I, §2.10.

(23) The design of accessories shall comply with the requirements of PED Annex I §2.11, including fail safe modes, redundancies, diversity, and self-diagnosis.

(24) Temperature monitoring devices must have adequate response time, consistent with the measurement function.

(25) See PED Article 12 for Notified Bodies and Article 13 for recognized third party organizations. (See Chapter VIII of this Guide for additional information.)

(26) For pressure equipment in Categories II, III and IV, qualification of welders and welding operators must meet the requirements of EN 287 and qualification of welding procedures the requirements of EN 288. (EN 287 and EN 288 are European harmonized standards). The welder, welding operator and welding procedure qualifications must be approved by a Notified Body or an approved third party organization. To carry out these approvals, the third party must perform (or have performed) examinations and tests as set out in the approved European harmonized standards or equivalent examinations and tests.

(27) For pressure equipment in Categories III and IV, the NDE personnel must be approved by an approved third party organization recognized by a Member State in the European Community. (See PED Article 13 for recognized third party organizations.)

Note: The PED does not provide any specific requirements for qualification of NDE personnel; therefore, the qualification in accordance with Recommended Practice No. SNT-TC-1A should be acceptable for radiographic examination of Category I and II pressure equipment.

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TABLE 4
COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

NOTES (CONT'D):

(28) The Manufacturer must provide the additional documentation to demonstrate compliance with the PED. This includes (but is not limited to) the following:
- (a) Qualifications of NDT personnel
- (b) Qualifications of welders and welding operators
- (c) Welding procedure qualifications
- (d) Heat treat procedures and data
- (e) Material certification and inspection documents for base metal and welding consumables
- (f) Procedures for ensuring material traceability
- (g) NDT reports, including radiographic films
- (h) Test reports of mechanical tests (e.g., on test coupons)
- (i) Reports on defects and deviations during manufacture
- (j) Forming and other manufacturing procedures
- (k) Other technical documentation in accordance with the applicable Conformity Assessment Module

(29) The Manufacturer must use the test pressures specified in §7.4 of PED Annex I for the hydrostatic test. (The hydrostatic test pressure requirement in the 1999 Addenda to Section VIII, Division 1 does not meet the PED Annex I §7.4, test pressure requirement of 1.43 times the maximum allowable pressure.)

(30) Annex I does not specify pneumatic test pressure. An agreement should be obtained from the Notified Body in charge of conformity assessment (Article 12 of the PED) or the third party organization in charge of the proof test (Article 13 of the PED) for a pneumatic test (e.g., in accordance with Section VIII, Division 1, UG-100).

(31) In addition to the CE marking, the vessel Manufacturer must provide the additional information provided in PED Annex I §3.3(a) and §3.3(b), as applicable.

(32) Based on the type of equipment and intended service, warning labels shall be attached to the pressure equipment giving warnings about potential misuse of the pressure equipment, based on past experience. (Examples of such misuse are auto-refrigeration, etc., without having considered it in the design of the pressure equipment.)

(33) The Manufacturer needs to provide the necessary CE marking and labels (where applicable) in accordance with the requirements in PED Annex I, §3.3.

(34) The PED requires the manufacturer to select material, which is suitable for the scheduled lifetime of the vessel, therefore specific consideration must be given to various degradation mechanisms, such as creep, fatigue, embrittlement, etc., some of which are not addressed in ASME Section VIII, Division 1. (See Annex I, §3.1.4, 4.1. 4.2, 4.3, 7.1, and 7.5 for additional requirements and Chapter VII of this Guide for additional information.)

(35) The properties of permanent welded joints (weld metal and heat affected zones) must meet the required minimum properties for the materials (including elongation and impact test requirements) to be joined unless other relevant property values are specifically taken into account in the design.

(36) Although it is implied by other considerations in Section VIII, Division 1, some of the materials requirements in PED §4.1 of Annex I are not specifically addressed in the Code, such as aging and the materials being sufficiently resistant of fluids contained in the pressure equipment. The PED requires the manufacturer to be responsible for material selection for the intended service that meets the requirements of PED Annex I, §4.1(a) through §4.1(e).

(37) Annex I, §7.5 of the PED requires materials to have minimum average impact test value of 27 J (20 ft-lbs) at 20°C (68°F). Fig. UG-84 in Section VIII, Division 1 accepts lower values for certain materials (e.g. 15 ft-lbs). Fig. UCS-66 includes impact test exemption curves, which exempt certain materials from impact testing at warmer temperatures, therefore, some ASME materials may not meet the PED Annex I toughness requirements. Also, Part UHT has different toughness requirements for Part UHT materials (mils lateral expansion instead of ft-lbs).

Note: Subsize impact test specimen are not addressed in PED Annex I. (7.5 x 10 mm and 5 x 10 mm impact test specimen are addressed in the draft CEN pressure vessel standard prEN 13445:1999; the subsize energy values exceed those in SA-20).

(38) Materials will only be approved if they have the following properties:
- (a) Have appropriate properties for all foreseeable operating and test conditions
- (b) Are sufficiently ductile (14% min. elongation for steel)
- (c) Are sufficiently tough (27 J minimum average for steel) at 20°C (68°F), or at the lowest operating temperature

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TABLE 4
COMPARISON OF ASME SECTION VIII, DIVISION 1 REQUIREMENTS WITH PED 97/23/EC, ANNEX I (CONT'D)

NOTES (CONT'D):

(39) Materials must conform to one of the following:
  (a) Materials that are specified in a European harmonized product standard
  (b) Materials that are covered by a European Approval of pressure equipment materials
  (c) Materials that are issued with a Particular Material Appraisal, for equipment in Category III and IV. (See Chapter VII of this Guide for European Approval of Material and for approval of material by Particular Material Appraisal.)

(40) If the pressure equipment is classified in Category III or Category IV, the particular material appraisal (PMA) of the material must be by the Notified Body in charge of the conformity assessment procedure for that pressure equipment. (See Chapter VI, para. 2.1.4 of this Guide.)

(41) The manufacturer must ensure that the material conforms to one of the appropriate specifications and is supported by appropriate certification:
  (a) For main pressure parts in Categories II, III, and IV the test certificates shall be EN 10204, Types 3.1A, 3.1B, 3.1C, or 3.2. (Certificates of Compliance are not acceptable.)
  (b) Certificates of Type 2.2 are acceptable for Category I equipment.
  (c) Certificates of Type 2.2 are acceptable for welding consumables for pressure equipment in all categories.
  (See Chapter VII of this Guide for the types of EN 10204 material certificates required for material used in pressure equipment, depending on hazard category.)

(42) If the material manufacturer holds accredited certification to ISO 9000 from a Certification Body established within the European community, a material certificate of the EN 10204, 3.1.B is acceptable. Where the material manufacturer does not hold such a certification, the pressure equipment manufacturer is responsible for determining the certification requirements.

(43) The specified quantitative requirements apply as a general rule. Other values may be used, but the Manufacturer must be able to demonstrate to the Notified Body that the appropriate measures have been taken to demonstrate that equivalent overall levels of safety have been achieved.

(44) For the materials listed in § 7.1, the allowable stresses are let to the Manufacturer, who must demonstrate that an overall safety has been achieved. For this objective, the Manufacturer may refer to Harmonized Standards, codes and specifications approved by the CEN Technical Committee (e.g., prEN 13345, draft CEN pressure Vessel Standard).

(45) The permissible general membrane stresses used in the calculations must conform to the following:
  (a) For ferritic steel, including normalized steel and excluding fine grain steel and specially heat treated steel, the lesser of
  (b) $^{2}/_{3}$ of the specified minimum yield strength ($R_{e/t}$)
  (c) $^{5}/_{12}$ of the specified minimum ambient temperature tensile strength ($R_{m/20}$)
  In general, the allowable design stresses in ASME Section II, Part D, are acceptable. However, the Code allows the design stresses to be 90% of the specified minimum yield strength for certain materials (stainless steel and some strain hardening materials). The manufacturer shall verify that the ASME Code allowable design stresses meet the PED criteria in each particular case.
  Note: Although not stated in PED Annex I, the allowable stresses for ferritic steels also apply to fine grain steels. (See Chapter XI of this Guide.)

(46) The provisions of Section VIII, Division 1, Part ULC may not meet the specified criteria in PED Annex I.

(47) ASME Section VIII, Division 1 permits allowable stress, $S \leq 0.9\ S_Y$ for certain austenitic stainless steels. This exceeds the allowable stresses permitted in PED §7.1 of Annex I.

(48) Pressure limiting devices must not exceed the maximum allowable pressure by more than 10%. (Section VIII, Division 1, UG-125 allows the greater of 10% and 3 psi).

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TABLE Q1 SAFETY FACTORS FOR ALLOWABLE STRESSES

Material	Allowable Stress, S_a
Ferritic steel and low alloy steel	Lesser of $R_e/1.5$ and $R_m/2.4$
Fine grain steel	Allowable stresses are not given in the PED
Austenitic steel with $A > 30\%$	$R_e/1.5$
Austenitic steel with $A > 35\%$	Lesser of $R_e/1.2$ and $R_m/3$
Cast steel	Lesser of $R_e/1.9$ and $R_m/3$
Aluminum	$R_e/1.5$
Aluminum alloys (not quenched)	Lesser of $R_e/1.5$ and $R_m/2.4$

GENERAL NOTES:
A = elongation, %
R_e = specified minimum yield strength at design temperature
R_m = specified minimum tensile strength at room temperature

TABLE Q2 JOINT EFFICIENCIES

Extent of Examination	Joint Efficiency
100% RT or UT	1.0
Spot examination by RT or UT	0.85
Visual examination only	0.70

TABLE Q3 FORMULA FOR CALCULATING HYDROSTATIC TEST PRESSURE

Test pressure, P_t, shall be the larger of:

$P_t = 1.25\ P_s \left(\frac{S_t}{S}\right)$ and

$P_t = 1.43\ P_s$

P_s = maximum allowable operating pressure

S_t = allowable nominal design stress at test temperature

S = allowable nominal design stress at design temperature

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CHAPTER XII
ANNEX Z, ADDITIONAL CONSIDERATIONS FOR APPLICATION OF ASME SECTION VIII, DIVISION 1 VESSELS WITHIN THE SCOPE OF PED 97/23/EC, ANNEX I

Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
	PRELIMINARY OBSERVATIONS		
1.	The obligations arising from the essential requirements listed in this Annex for pressure equipment also apply to assemblies where the corresponding hazard exists.	UG-11	
2.	The essential requirements laid down in the directive are compulsory. The obligations laid down in these essential requirements apply only if the corresponding hazard exists for the pressure equipment in question when it is used under the conditions that are reasonably foreseeable by the Manufacturer.		
3.	The Manufacturer is under an obligation to analyze the hazards to identify those that apply to equipment on account of pressure; the Manufacturer must then design and construct it, taking account of the analysis.	(None)	The Manufacturer must perform hazards analysis in accordance with Article 3, Article 9, and Annex II of the PED. The Manufacturer is required to design and construct the pressure equipment to comply with all the Essential Safety Requirements in PED Annex I.
4.	The general requirements are to be interpreted and applied in such a way as to take account of the state of the art and current practice at the time of design and manufacture as well as of technical and economical considerations that are consistent with a high degree of health and safety protection.	U-1(a)(3) U-2(a)(1) U-2(a)(2) U-2(g) UW-2(a)	
1.	**GENERAL**		
1.1	Pressure equipment must be designed, manufactured, checked, and, if applicable, equipped and installed in such a way as to ensure its safety when put into service in accordance with the Manufacturer's instructions, or in reasonably foreseeable conditions.	U-1(a)(3), U-2(a) (Partial)	The Manufacturer must prepare instructions for the User containing the necessary safety information in accordance with PED §3.4 of Annex I. The Manufacturer must also consider the following: (a) Inform Users of residual hazards (b) Prevent dangers from foreseeable misuse (c) Take into account foreseeable degradation mechanisms (d) Ensure safety throughout the intended life of the pressure equipment

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
1.2	In choosing the most appropriate solutions, the Manufacturer must comply with the principles set out below in the following order:		The Manufacturer must
	(a) Eliminate or reduce hazards as far as is reasonably practicable.	U-2(a) UW-2	(a) eliminate or reduce hazards as far as it is reasonably practical
	(b) Apply appropriate protection measures against hazards that cannot be eliminated.	UW-2(a) (Partial) (None)	(b) apply appropriate protection measures against hazards that cannot be eliminated
	(c) Where appropriate, inform users of residual hazards and indicate whether it is necessary to take appropriate special measures to reduce risks at the time of installation and/or use.		(c) where appropriate, inform users of any residual hazards and any additional measures to be taken to reduce risks during installation and/or use
1.3	Where the potential for misuse is known or can be clearly foreseen, the pressure equipment must be designed to prevent danger from such misuse or,	UG-20(b) (Partial)	The Manufacturer must provide the necessary safeguards (e.g., safety relief vents, temperature measuring devices, and other sensors) where there is potential for misuse of the pressure equipment (e.g., different service conditions or more hazardous fluids, auto-refrigeration).
	if that is not possible, adequate warning (must be) given that the pressure equipment must not be used in that way.	UG-116 (Partial)	Where necessary, the Manufacturer must provide appropriate warnings in Operating Instructions regarding improper use of the equipment. (See PED §3.4 of Annex I).
2.	**DESIGN**		
2.1	The pressure equipment must be properly designed taking all relevant factors into account to ensure that the equipment will be safe throughout its intended life.	U-2(a), UG-20, UG-21,22 UW-2, UCS-56, UCS-66 (Partial)	The Manufacturer must also consider the following factors in the design of the equipment: (a) Take into account foreseeable degradation mechanisms (b) Ensure safety throughout the intended life of the pressure equipment
	The design must incorporate appropriate safety coefficients using comprehensive methods that are known to incorporate adequate safety margins against all relevant failure modes in a consistent manner.	Section II, Part D, Appendix 1	
2.2	Design for adequate strength		
2.2.1	The pressure equipment must be designed for loadings appropriate to its intended use and other reasonably foreseeable operating conditions. In particular, the following factors must be taken into account:	UG-22	
	(a) internal/external pressure	UG-22(a)	
	(b) ambient and operational temperatures	UG-22(h)	
	(c) static pressure and mass of contents in operating and test conditions	UG-22(b)	
	(d) traffic, wind, earthquake loading	UG-22(f) (Partial)	(Note: Section VIII, Division 1 does not cover transportable vessels. These will be covered in the proposed new Section XII.)

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
22.1 Cont'd	(e) reaction forces and moments that result from the supports, attachments, piping, etc.	UG-22(d)	
	(f) corrosion, erosion, fatigue, etc. (g) decomposition of unstable fluids	UG-22(e), UG-25(b) (None)	The design must take into account decomposition of unstable fluids.
	Various loadings that can occur at the same time must be considered, taking into account the probability of their simultaneous occurrence.	UG-22, UG-23(d)	
2.2.2	Design for adequate strength must be based on		
	(a) as a general rule a calculation method, described in 2.2.3, and supplemented, if necessary, by an experimental design method as described in 2.2.4, or	UG-19(c), UG-101 (Partial)	An experimental design method, as described in PED §2.2.4 of Annex I may require additional tests for fatigue, creep, corrosion rates, and may have to impose additional limitations consistent with those in the PED.
	(b) an experimental design method without calculation, as described in 2.2.4, when the product of the maximum allowable pressure, PS, and the volume, V, is less than 6000 bar x L, or the product PS x DN (is) less than 3000 bar.		The Manufacturer must assure that the limitations on the allowable pressure, PS, and on volume, V, are not exceeded.
2.2.3	*Calculation Method*		
	(a) Pressure containment and other loading aspects The allowable stresses for pressure equipment must be limited having regard to reasonably foreseeable failure modes under operating conditions. To this end, safety factors must be applied to eliminate fully any uncertainty arising out of manufacture, actual operational conditions, stresses, calculation models, and the properties and behavior of the material.	UG-23	
	These calculation methods must provide sufficient safety margins consistent, where applicable, with the requirements of Section 7.	Section II, Part D, Appendix 1	
	The requirements set out above may be met by applying one of the following methods, as appropriate, if necessary as a supplement to or in combination with another method:		
	(1) design by formula	UG-27 to UG-55	
	(2) design by analysis	U-2(g)	
	(3) design by fracture analysis	N/A	
	(b) Resistance		

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
22.3 Cont'd	Appropriate design calculations must be used to establish the resistance of the pressure equipment concerned.		
	In particular:		
	(1) the calculation pressures must not be less than the maximum allowable *pressures and take into* account static head and dynamic fluid pressures and the decomposition of unstable fluids.	UG-21, UG-22(b) (None)	The design calculations must include the condition of decomposition of unstable fluids, where appropriate.
	Where a vessel is separated into individual pressure containing chambers, the partition wall must be designed on the basis of the highest possible chamber pressure relative to the lowest pressure possible in the adjoining chamber.	UG-19(a)	
	(2) the calculation temperatures must allow for appropriate safety margins.	UG-20	
	(3) the design must take appropriate account of all possible combinations of *temperature and pressure that might* arise under reasonably foreseeable operating conditions for the equipment.	UG-20, UG-21	
	(4) the maximum stresses and peak stress combinations must be kept within safe limits.	UG-22, UG-23	
	(5) the calculation for pressure equipment must utilize the values appropriate to the properties of the material, based on the documented data, having regard to the provisions set out in Section 4 together with *the appropriate safety factors.* Material characteristics to be considered, where applicable, include:	Section VIII, Division 1, Appendix P, Section II, Part D, Appendix 1	
	(a) yield strength, 0.2% or 1.0% proof strength, as appropriate, at calculation temperature (b) tensile strength (c) time-dependent strength, i.e. creep strength	UG-4, UG-23, Section VIII, Division 1, Appendix P, Section II. Part D, Appendix 1	
	(d) fatigue data (e) Young's modulus (modulus of elasticity) (f) appropriate amount of plastic strain (g) impact strength (h) fracture toughness	UG-22 Section II, Part D, Appendix 5 (Partial) UG-84 UG-84, UCS-66, etc. UW-2(a),	The design calculations should include the *amount of plastic strain, where appropriate.*

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
22.3 Cont'd	(6) Appropriate joint factors must be applied to the materials properties, depending, for example, on the type of nondestructive testing, the materials joined, and the operating conditions envisioned.	UW-12	
	(7) The design must take appropriate account of all reasonably foreseeable degradation mechanisms (e.g., corrosion, creep, fatigue) commensurate with the intended use of the equipment.	UG-25, Section VIII, Division 1, Appendix E, Section II. Part D, Appendix 6	
	Attention must be drawn, in the instructions referred to in 3.4, to the particular features of the design, which is relevant to the life of the equipment, for example:		
	(a) for creep: design hours of operation at specified temperatures	(Partial)	Any limitations on design life from operation at design temperature in creep range, fatigue cycles, and corrosion allowance must be specified in Operating Instructions.
	(b) for fatigue: design number of cycles at the specified stress levels	(Partial)	
	(c) for corrosion: design corrosion allowance	UG-25, Appendix E	
	(c) Stability Aspects		
	Where the calculated thickness does not allow for adequate structural stability, the necessary measures must be taken to remedy the situation, taking into account the risks from transport and handling.	(None)	The design calculations must take into account structural stability, including transport and handling of vessels and assemblies.
2.2.4	*Experimental Design Method*		
	The design of the equipment must be validated, in all or in part, by an appropriate test program carried out on a sample representative of the equipment or the category of the equipment.	UG-101	
	The test program must be clearly defined prior to testing and accepted by the Notified Body responsible for the conformity assessment module, where it exists.	(None)	The Manufacturer must obtain approval from the Notified Body responsible for the conformity assessment module, if one exists, for the experimental test program.
	The program must define test conditions and criteria for acceptance and refusal.	UG-101	
	The actual values of the essential dimensions and characteristics of the materials that constitute the equipment tested shall be measured before the test.	UG-101(j)	
	Where appropriate, during tests, it must be possible to observe the critical zones of the pressure equipment with adequate instrumentation capable of registering strains and stresses with sufficient precision.	UG-101(j), UG-101(n)	

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
2.2.4 Cont'd	The test program must include:		
	(a) A pressure strength test, the purpose of which is to check that, at a pressure with a defined safety margin in relation to the maximum allowable pressure, the equipment does not exhibit sufficient leaks or deterioration exceeding a determined threshold.	UG-101(m) (Partial)	The experimental design method must take into account leakage and deterioration of pressure equipment (e.g., corrosion, etc.).
	The test pressure must be determined on the basis of the differences between the values of the geometrical and material characteristics measures under test conditions and the values used for design purposes;	UG-101	
	it must take into account the differences between the test and design temperatures.	UG-101(k)	
	(b) Where the risk of creep or fatigue exists, appropriate tests determined on the basis of the service conditions laid down for the equipment, for instance, hold time at specified temperatures, number of cycles at specified stress-levels, etc;	(None)	An experimental design method, as described in 2.2.4 of Annex I of the PED may require additional tests and impose additional limitations consistent with those in the PED (hold time at specified temperatures, number of fatigue cycles at a given stress level, corrosion rates, external damage, etc.)
	(c) Where necessary, additional tests concerning other factors referred on 2.2.1, such as corrosion, external damage, etc.	(None)	
2.3	**Provisions to Ensure Safe Handling and Operation**		
	The method of operation specified for pressure equipment must be such as to preclude any reasonable foreseeable risk in operation of the equipment. Particular attention must be paid, where appropriate, to (a) closures and openings (b) dangerous discharge of pressure relief blowoff (c) access while pressure or vacuum exists in the pressure equipment (d) surface temperature, taking into account the intended use of the equipment (e) decomposition of unstable fluids	(None)	The Manufacturer must consider the following aspects to ensure safe handling and preclude risk during operation (a) closures and openings (b) dangerous discharge of pressure relief blowoff (c) access while pressure or vacuum exists in the pressure equipment (d) surface temperature, taking into account the intended use of the equipment (e) decomposition of unstable fluids
	In particular, pressure equipment fitted with an access door must be equipped with an automatic or manual device enabling the user easily "to ascertain that the opening will not present any hazard."	(None)	Pressure equipment fitted with access doors must be equipped with automatic or manual devices to enable the User to ascertain that the opening will not present any hazards.
	Furthermore, where the opening can be operated quickly, the pressure equipment must be fitted with a device to prevent it being opened whenever the pressure or temperature of the fluid presents a hazard.	UG-35(a) through UG-35(c)	

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
2.4	**Means of Examination**		
	(a) Pressure equipment must be designed and constructed so that all necessary examinations to ensure safety can be conducted.	Part UG, Part UW	
	(b) Means of determining the internal condition of the equipment must be available, where it is necessary to ensure the continued safety of the equipment, such as access openings allowing physical access to the inside of the pressure equipment so that appropriate examinations can be carried out safely and ergonomically.	UG-46	
	(c) Other means of ensuring the safe condition of the pressure equipment may be applied:		
	(1) where it is too small for physical internal access, or	UG-46(b), UG-46(i)	
	(2) where the opening of the pressure equipment would adversely affect the inside, or	(None)	Provisions for safe conditions inside the vessel, where applicable, must be included in Operating Instructions.
	(3) where the substance contained has been shown not to be harmful to the material from which the pressure equipment is made and no other internal degradation mechanisms are reasonably foreseeable.	UG-46(c)	
2.5	**Means of Venting and Draining**		
	Adequate means must be provided for draining and venting of pressure equipment, where necessary:		
	(a) to avoid harmful effects, such as water hammer, vacuum collapse, corrosion, and uncontrolled chemical reactions. All stages of operations and testing, particularly pressure testing, must be considered.	UG-25(f) (Partial)	The vessel Manufacturer must provide adequate means for venting and draining for all stages of operation and testing, including vacuum vents. The Manufacturer must also avoid harmful effects, such as water hammer, corrosion, and uncontrolled chemical reactions.
	(b) to permit cleaning, inspection, and maintenance in a safe manner.	UG-46	
2.6	**Corrosion or Other Chemical Attack**		
	Where necessary, adequate allowance or protection against corrosion or other chemical attack must be provided, taking due account of the intended and reasonably foreseeable use.	UG-25, UCS-25, UCL-25, Appendix D, E, F (Partial)	Considerations must also be given for other forms of chemical attack besides corrosion, where appropriate, as required by PED Annex I, §2.6.

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
2.7	**Wear**		
	Where severe conditions of erosion or abrasion may arise, adequate measures must be taken to		
	(a) minimize the effect by appropriate design (e.g., additional material thickness, or by the use of liners or cladding materials)	UG-26 (Partial)	Erosion and abrasion must be considered in the design, where appropriate.
	(b) permit replacement of parts that are most affected		
	(c) draw attention, in the instructions referred to in para. 3.4, to measures necessary for continued safe use	(None)	The Manufacturer shall prepare instructions for the User the of pressure equipment containing the necessary safety information in accordance with PED §3.4 of Annex I, and include considerations for wear, where applicable, in accordance with §2.7.
2.8	**Assemblies**		
	Assemblies must be so designed that: (a) the components to be assembled together are suitable and reliable for their duty, (b) all the components are properly integrated and assembled in an appropriate manner.	UG-21, UG-120(c)	The Manufacturer must make certain that all assemblies are so designed that they comply with the applicable PED requirements. (Note: PED defines "Assemblies" as several pieces of pressure equipment assembled by a Manufacturer to constitute an integrated and functional whole.)
2.9	**Provisions for Filling and Discharge**		
	Where appropriate, the pressure equipment must be so designed and provided with accessories, or provisions made for their fitting, as to ensure safe filling and discharge with respect to such hazards as:		Provide the necessary accessories in accordance with the requirements of PED, to ensure safe filling and discharge, prevent uncontrolled release of pressurized fluid, and prevent unsafe connection and disconnection.
	(a) on filling:		
	(1) overfilling or overpressurization having regard in particular to the filling ratio and to the vapor pressure at the reference temperature	(None)	
	(2) instability of pressure equipment	(None)	
	(b) on discharge: the uncontrolled release of the pressurized fluid	(None)	
	(c) on filling or discharge: unsafe connection and disconnection	(None)	
2.10	**Protection Against Exceeding the Allowable Limits of Pressure Equipment**		
	Where under reasonably foreseeable conditions, the allowable limits could be exceeded, the pressure equipment must be	UG-125 through UG-128	

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
2.10 Cont'd	fitted with, or provisions made for the fitting of, suitable protective devices, within an assembly.		
	The suitable device or combination of such devices must be determined on the basis of the particular characteristics of the equipment or assembly.	UG-125 through UG-128	
	Suitable protective devices and combination thereof comprise:		
	(a) safety accessories as defined in Article 1, section 2.1.3	UG-125, CC 2211	
	(b) where appropriate, adequate monitoring devices such as indicators and/or alarms that enable adequate action to be taken either automatically or manually to keep the pressure equipment within the allowable limits		The Manufacturer must provide the necessary indicators and alarms to comply with the requirements of PED Annex I, §2.10.
2.11	**Safety Accessories**		The design of safety accessories must comply with the requirements of PED Annex I, §2.11. (Note: Fail-safe modes, redundancy, diversity and self-diagnosis are not specifically addressed in Section VIII, Division 1.)
2.11.1	*Safety accessories must*		
	(a) be designed and constructed to be reliable and suitable for their intended duty and take into account the maintenance and testing requirements of the devices, where applicable	UG-126, UG-131, UG-132 UG-125	
	(b) be independent of other functions, unless their safety function cannot be affected by such other functions		
	(c) comply with the appropriate design principles to obtain suitable and reliable protection. These principles include, in particular, fail-safe modes, redundancy, diversity, and self-diagnosis	UG-125, Appendix M (Partial)	The design of safety accessories shall comply with the appropriate design principles in the PED, including fail-safe modes, redundancy, diversity and self-diagnosis.
2.11.2	*Pressure limiting devices*		
	The devices must be so designed that the pressure will not permanently exceed the maximum allowable pressure, PS; however, a short duration pressure surge in keeping with the specifications in para. 7.3 is allowable, where appropriate.	UG-125 (Partial)	(Note: Section VIII, Division 1, UG-125(c) allows 10% or 3 psi, whichever is greater, above the MAWP; UG-125(c)(1) allows 16%, or 4 psi, whichever is greater, above the MAWP. Both may exceed the PED maximum limitation of 10% in Annex I, 7.3.)
2.11.3	*Temperature monitoring devices*		
	These devices must have an adequate response time on safety grounds, consistent with the measurement function.	Appendix C, Appendix T (Partial)	The Manufacturer must provide temperature monitoring devices that have adequate response time, consistent with the measurement function.

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
3.	**MANUFACTURING**		
3.1	**Manufacturing Procedures**		
	The Manufacturer must ensure the competent execution of the provisions set out in the design stage by applying the appropriate techniques and relevant procedures especially with consideration of the following:	UG-75, UG-78, UG-93, UG-95, UG-117	
3.1.1	*Preparation of the component parts*		
	Preparation of the component parts (e.g., forming and chamfering) must not give rise to defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the pressure equipment.	UG-11, UG-76, UG-95, UW-31, UW-32	
3.1.2	*Permanent joining*	UW-11,32 UW-35,36	
	Permanent joints and adjacent zones must be free of any surface or internal defects detrimental to the safety of the equipment.	UW-37(a) – 37(e), UW-51	
	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.	UG-28	
	For pressure equipment, permanent joining of components that contribute to pressure resistance of the equipment and components which are directly attached to them must be carried out by suitably qualified personnel according to suitable operating procedures.	UW-28, UW-29, UW-37, UW-46, UW-47, UW-48	
	For pressure equipment in categories II, III, and IV, operating procedures and personnel must be approved by a competent third party, which, at the Manufacturer's discretion, may be		See PED, Article 12 for notified bodies and Article 13 for recognized third party organizations for approval of welding procedure and welder qualifications for Category II, III, and IV pressure equipment. (Note: The Manufacturer can use ASME welding procedure and welder qualifications for Category I vessels).
	(a) a Notified Body	(None)	
	(b) a third party organization recognized by a Member State as provided in PED Article 13	(None)	
	To carry out these approvals the third party must perform examinations and tests as set out in the appropriate harmonized standards, or equivalent tests or must have them performed.	(None)	For pressure equipment in Categories II, III, and IV, qualification of welders and welding operators must meet the requirements of EN 287 and qualification of welding procedures the requirements of EN 288. The welder, welding operator, and welding procedure qualifications must be approved by a Notified Body or an approved third party organization. Welded joints (weld metal and heat affected zones) must meet the same specified minimum

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
3.1.2 Cont'd			properties (elongation and impact test requirements) as the base metal.
3.1.3	*Nondestructive tests*		
	For pressure equipment in categories III and IV the personnel must be approved by a third party organization recognized by a Member State pursuant to PED Article 13.	(None)	For pressure equipment in Categories III and IV, the NDE personnel must be approved by an approved third party organization recognized by a Member State in the European Community. (Note: The Manufacturer may use the certification required by ASME, Section VIII, para. UW-51(a)(2) for pressure equipment in Categories I and II for radiographic examination.)
3.1.4	*Heat treatment*		
	Where there is a risk that the manufacturing process will change the material properties to an extent that would impair the safety of the pressure equipment, suitable heat treatment must be applied at the appropriate stage of the manufacture.	UG-85, UCS-85, UHT-5(e), UHT-51	
3.1.5	*Traceability*		
	Suitable procedures must be established and maintained for identifying the material making up the components of the equipment that contribute to the pressure resistance by suitable means from receipt, through production, up to the final test of the manufactured pressure equipment.	UG-93, UG-94, Section VIII, Division 1, Appendix 10	
3.2	**Final Assessment**		
	Pressure equipment must be subjected to the final assessment described as follows:		
3.2.1	*Final inspection*		
	Pressure equipment must undergo a final inspection to access visually and by examination of the accompanying documents compliance with the requirements of the Directive. Test carried out during manufacture may be taken into account.	UG-90, UG-90(c)(1) UG-99(g), UG-100(d), UG-120, Appendix W (Partial)	The Manufacturer must provide documentation to demonstrate compliance with the Directive. This shall include (a) qualifications of the NDT personnel (b) qualification of welders and welding operators (c) welding procedure qualifications (d) heat treat procedures and data (e) material certification and inspection documents for base metal and welding consumables (f) procedures for ensuring material traceability (g) NDT reports, including radiographic films, (h) test reports of mechanical tests (e.g., coupons) (i) reports on defects and deviations during manufacture (j) forming and other manufacturing procedures
	As far as necessary on safety grounds, the final inspection must be carried out internally and externally on every part of the equipment, where appropriate during manufacture (e.g., where examination during the final inspection is no longer possible).	UG-90, UG-96, UG-97	

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
3.2.1 Cont'd			(k) other technical documentation in accordance with the appropriate conformity assessment module
3.2.2	*Proof test*		
	Final assessment of pressure equipment must include a test for the pressure containment aspect, which will normally take the form of a hydrostatic pressure test at a pressure at least equal, where appropriate, to the value in para. 7.4.	(None)	The Manufacturer must use the test pressures specified in PED 7.4 of Annex I for the hydrostatic test. (Note: The hydrostatic test pressure factor of 1.3 in UG-99 of the Code does not meet the PED requirement.)
	For category I series produced equipment, this test may be performed on a statistical basis.	(N/A)	The test pressure for a pneumatic test is not specified in §7.4 of Annex I. An agreement must be obtained for a pneumatic test from the Notified Body (see PED Article 12) in charge of the conformity assessment or the third party organization (see PED Article 13) in charge of the proof test.
	Where a hydrostatic test pressure is harmful or impractical, other tests of a recognized value may be carried out. For test other than the hydrostatic pressure test, additional measures, such as nondestructive tests or other methods of equivalent validity, must be applied before those tests are carried out.	UG-100, UW-50	
3.2.3	*Inspection of safety devices*		
	For assemblies, the final assessment must also include a check of the safety devices intended to check full compliance with the requirements referred to in para. 2.10.	UG-136, UG-137 (Partial)	This includes a check of monitoring devices, such as indicators and/or alarms for safety accessories to prevent exceeding the allowable pressure and temperature limits. [See PED Annex I, §2.10(b).]
3.3	**Marking and Labeling**		
	In addition to the CE marking referred to in Article 15, the following information must be provided:		
	(a) For all pressure equipment (1) the name and address or other means of identification of the Manufacturer and, where appropriate, of his authorized representative established within the Community (2) the year of manufacture (3) identification of the pressure equipment according to its nature, such as type, series or batch identification, and serial number (4) the essential maximum/minimum allowable limits	UG-116, UG-118,-UG-119, UG-129 (Partial)	In addition to the CE marking, the vessel Manufacturer must provide the additional information required by PED Annex I, §3.3(a) and §3.3(b), as applicable.
	(b) Depending on the type of pressure equipment, further information necessary for safe installation, operation or use and, where applicable, maintenance and periodic inspection such as (1) the volume, V, of the pressure equipment in L	(None)	

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
3.3 Cont'd	(2) the nominal size for piping, DN (3) the test pressure, PT, applied in bar and date (4) safety device set pressure in bar (5) output of pressure equipment in kW (6) supply voltage in, V (volts) (7) intended use (8) filling ratio kg/L (9) maximum filling mass in kg (10) tare mass in kg (11) the product group		
	(c) Where necessary, warnings fixed to the pressure equipment drawing attention to misuse which experience has shown might occur.	(None)	Based on the type of equipment and intended service, warning labels shall be attached to the pressure equipment giving warnings about potential misuse of the pressure equipment, based on past experience.
	The CE marking and the required information must be given to the pressure equipment or on a dataplate firmly attached to it, with the following exceptions:	UG-119 (Partial)	The Manufacturer needs to provide the necessary CE marking in accordance with the requirements of PED Annex I, §3.3.
	(1) where applicable, appropriate documents may be used to avoid repetitive marking of individual parts such as piping components, intended for the same assembly. This applies to CE marking and other marking and labeling referred to in this Annex	(None)	
	(2) where the pressure equipment is too small, (e.g., accessories), the information referred to in (b) may be given on a label attached to that pressure equipment	(None)	
	(3) labeling or other adequate means may be used for the mass to be filled and the warnings referred to in (c), provided it remains legible for the appropriate period of time	(None)	
3.4	**Operating Instructions**		
	(a) When pressure equipment is placed on the market, it must be accompanied, as far as relevant, with instructions for the user, containing all the necessary safety information relating to: (1) mounting including assembling of different pieces of pressure equipment (2) putting into service (3) use (4) maintenance including checks by user	(None)	The Manufacturer shall prepare, as far as relevant, instructions for the User, containing the necessary safety information listed in §3.4, and if appropriate, refer to hazards arising from potential misuse of the equipment in accordance with §1.3, to any particular features of the design in accordance with §2.2.3, and to wear in accordance with §2.7 of Annex I of the PED. The instructions shall include: (a) marking and labeling as required by 3.3 (b) installation instructions, including assembling different pieces of pressure equipment (c) putting into service

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
3.4 Cont'd			(d) use (e) maintenance, including checks by the User (f) drawings necessary for full understanding of the information, if applicable (g) design information for in-service verification, modifications or repairs (h) warnings to prevent the danger of misuse of the equipment (i) declaration of Conformity
	(b) Instructions must cover information affixed to the pressure equipment in accordance with 3.3, with the exception of serial identification, and must be accompanied, where appropriate, by the technical documents, drawings, and diagrams necessary for a full understanding of these instructions.	(None)	
	(c) If appropriate, these instructions must also refer to hazards arising from misuse in accordance with para. 1.3 and particular features of the design in para. 2.2.3.accordance with	(None)	
4.	**MATERIALS**		
	Materials used for manufacturing of pressure equipment must be suitable for such application during the scheduled lifetime unless replacement is foreseen.	UG-4 – UG-8, UG-10, Section II and Section II, Part D, Appendix 6. (Partial)	The PED requires the Manufacturer to select material (including bolting) which is suitable for the scheduled lifetime of the vessel, therefore specific consideration must also be given to various degradation mechanisms, such as creep, embrittlement, etc. (See Annex I, §3.1.4, 4.1. 4.2, 4.3, 7.1, and 7.5 for additional requirements.)
	Welding consumables and other joining materials need to fulfill only the relevant requirements of 4.1, 4.2(a), and the first paragraph of 4.3, in an appropriate way, both individually and in a joined structure.	UG-9, UG-26 (Partial)	The properties of permanent welded joints (weld metal and heat affected zones) must meet the specified minimum properties (including elongation and impact test requirements) for the materials to be joined unless other relevant property values are specifically taken into account in the design.
4.1	**Materials for Pressurized Parts Must**		
	(a) have appropriate properties for all operating conditions that are reasonably foreseeable and for all test conditions, and	UG-4, Section II, Parts A, B, C, and D (Partial)	The Manufacturer of pressure equipment is responsible for material selection for the intended service. The materials must meet the requirements of Annex I, §4.1(a) through §4.1(e).
	in particular they should be sufficiently ductile and tough.	UG-84, UCS-66, UHT-6, etc. (Partial)	7.5 of Annex I requires materials to have 14% minimum elongation and to meet a minimum average value of 27 J (20 ft-lbs) at 20°C (68°F).

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
4.1 Cont'd	Where appropriate, the characteristics of the materials must comply with the requirements of 7.5. Moreover, due care should be exercised in particular in selecting materials to prevent brittle type fracture where necessary, where for specific reasons brittle material has to be used appropriate measures must be taken.	Section II, Parts A, B, C, and D (Partial)	Materials will only be approved if they have the following properties: (a) Have appropriate properties for all foreseeable operating and test conditions, (b) Are sufficiently ductile (14% min. elongation for steel), (c) Are sufficiently tough (27 J min. average for steel) at 20°C, or at the lowest operating temperature.
	(b) be sufficiently chemically resistant to the fluid contained in the pressure equipment; the chemical and physical properties necessary for operational safety must not be significantly affected within the scheduled lifetime of the equipment	UG-16(e), UG-25, Section II, Part D, Appendix 5, 6 (Partial)	The PED requires the Manufacturer to be responsible for material selection for the intended service. The materials must meet the requirements of §4.1(a) through 4.1(e) in Annex I. (Note: This is implied in Section VIII, Division 1, but the Code has no specific rules for this.)
	(c) not be significantly affected by aging	Section II, Part D, Appendix 5, 6 (Partial)	(Note: This is implied in Section VIII, Division 1, but the Code has no specific requirements for aging.)
	(d) be suitable for the intended processing procedures	UG-79, UCS-85, UHT-81	
	(e) be selected to avoid significant undesirable effects when the various materials are put together	UG-18	
4.2	(a) The pressure equipment Manufacturer must define in an appropriate manner the values necessary for the design calculations referred to in 2.2.3 and the essential characteristics of the materials and their treatment referred to in 4.1.	UG-23 (Partial)	(a) Materials will only be approved if they: (1) have appropriate properties for all foreseeable operating and test conditions (2) are sufficiently ductile (14% min. elongation for steel) (3) are sufficiently tough (27 J min. average for steel) at 20°C, or at the lowest operating temperature
	(b) The Manufacturer must provide in technical documentation elements relating to compliance with the material specification of the Directive in one of the following forms by	(None)	(b) Materials must conform to one of the following: (1) Materials that are specified in a European harmonized product standard (2) Materials that are covered by a European Approval of pressure equipment materials (3) Materials that are issued with a Particular Material Appraisal, for equipment in Category III and IV. The Particular Material Appraisal (PMA) must be carried out by the Notified Body responsible for the conformity assessment of that equipment. (Note: Currently there are no ASME material specifications with European Approval. Consult ASME staff regarding European Approval of ASME material specifications).
	(1) using materials that comply with harmonized standards	(None)	
	(2) using materials covered by a European approval of pressure equipment materials in accordance with Article 11	(None)	
	(3) a particular appraisal	(None)	

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4.2 Cont'd	(c) For pressure equipment in categories III and IV, particular appraisal as referred to in (b)(3) must be performed by the Notified Body in charge of the conformity assessment procedures for he pressure equipment.	(None)	If the pressure equipment is classified in Category III or Category IV, the Particular Material Appraisal (PMA) of the material must be by the Notified Body (NB) in charge of the conformity assessment procedure for that pressure equipment.
4.3	The equipment Manufacturer must take appropriate measures to ensure that the material used conforms with the required specification.	UG-93	
	In particular, documentation prepared by the material Manufacturer affirming compliance with the specification must be obtained for all materials.	UG-23(a), UG-93	
	For the main pressure bearing parts of equipment in categories II, III, and IV, this must take the form of certificate of specific product control.	(None)	The Manufacturer must ensure that the material conforms to one of the appropriate specifications and is supported by appropriate certification. (a) For main pressure parts of pressure equipment in Categories II, III, and IV the test certificates shall be EN 10204, Types 3.1A, 3.1B, 3.1C, or 3.2. (b) Certificates of Type 2.2 are acceptable for Category I equipment. (c) Certificates of Type 2.2 are acceptable for welding consumables for pressure equipment in all categories.
	Where the material Manufacturer has an appropriate quality-assurance system, certified by a competent body established within the Community and having undergone a specific assessment of materials, certificates issued by the Manufacturer are presumed to certify the conformity with relevant requirements of this section.	(None)	If the material Manufacturer holds accredited certification to ISO 9000 from a Certification Body established within the European community, a material certificate of the EN 10204, 3.1.B is acceptable. Where the material Manufacturer does not hold such a certification, the pressure equipment Manufacturer is responsible for determining the certification requirements.
7.	**SPECIFIC QUANTITIVE REQUIREMENTS FOR CERTAIN PRESSURE EQUIPMENT**		
	The following provisions apply as a general rule. However, where they are not applied, including in cases where materials are not specifically referred to and no harmonized standards are applied, the Manufacturer must demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.		The specified quantitative requirements apply as a general rule. Other values may be used but the Manufacturer must be able demonstrate to the Notified Body that appropriate measures have been taken to demonstrate that equivalent overall level of safety has been achieved.
	This section is an integral part of PED Annex I. The provisions in this section supplement the essential requirements of sections 1 through 6 for the pressure equipment to which they apply.		

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Annex I Paragraph	Annex I Essential Safety Requirements	Section VIII, Division 1 Reference	Additional Considerations
7.1	**Allowable Stresses**		For the materials not listed in §7.1, the allowable stresses are left to the Manufacturer, who must demonstrate that an equivalent overall safety has been achieved. For this objective, the Manufacturer may refer to Harmonized standards, codes and specifications approved by the CEN Technical Committee (e.g., prEN 13345, the draft CEN Pressure Vessel Standard).
7.1.1	*Symbols* $R_{e/t}$, yield limit, indicates the value at the calculation temperature of: (a) The upper flow limit for a material presenting upper and lower flow limits (b) The 1.0% proof strength of austenitic steel and nonalloyed aluminum (c) The 0.2% proof strength in other cases $R_{m/20}$ indicates the minimum value of the ultimate strength at 20°C. $R_{m/t}$ designates the ultimate strength at the calculation temperature.		
7.1.2	The permissible general membrane stress for predominantly static loads and for temperatures outside the range in which creep is significant must not exceed the smaller of the following values, according to the material used:	Section II, Part D, Table 1A, and Appendix 1	(Note: In general, the allowable design stresses in ASME Section II, Part D, are acceptable. The Manufacturer must verify that the ASME Code allowable design stresses meet the PED criteria in each particular case.)
	(a) in the case of ferritic steel including normalized (normalized rolled) steel and excluding fine grain steel and specially heat-treated steel, $^2/_3$ of $R_{e/t}$ and $^5/_{12}$ of $R_{m/20}$	(Partial)	
	(b) for austenitic steel	(Partial)	(Note: The Code allows the design stresses to be 90% of the specified minimum yield strength for certain materials (stainless steel and some strain hardening materials), which does not meet the limitations in PED §7.1.2 of Annex I. Also, the provisions of Section VIII, Division 1, Part ULC may not meet the criteria specified in PED, Annex I.)
	(1) if its elongation after rupture exceeds 30%, $^2/_3$ of $R_{e/t}$		
	(2) or, alternatively, and if its elongation after rupture exceeds 35%, $^5/_6$ of $R_{e/t}$ and $^1/_3$ of $R_{m/20}$		
	(c) for nonalloy or low alloy cast steel, $^{10}/_{19}$ of $R_{e/t}$ and $^1/_3$ of $R_{m/20}$		
	(d) for aluminum, $^2/_3$ of $R_{e/t}$		
	(e) for aluminum alloys, excluding precipitation hardening alloys, $^2/_3$ of $R_{e/t}$ and $^5/_{12}$ of $R_{m/20}$		
7.3	**Pressure Limiting Devices, Particularly for Pressure Vessels**		
	The momentary surge referred to in para. 2.22.2 must be kept to 10% of the maximum allowable pressure.	(Partial)	The Manufacturer must verify that the Section VIII, Division 1, UG-125 set pressure complies with the Annex I requirement in each case.

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7.3 Cont'd			[Note: Section VIII, Division 1, UG-125(c) allows 10% or 3 psi, whichever is greater, above the MAWP.]
7.4	**Hydrostatic Test Pressure**		
	For pressure vessels, the hydrostatic test pressure referred to in para. 3.2.2 must be no less than		
	(a) that corresponding to the maximum loading to which the pressure equipment may be subject in service, taking into account its maximum allowable pressure and its maximum allowable temperature, multiplied by a coefficient of 1.25, or	UG-99	
	(b) the maximum allowable pressure multiplied by the coefficient 1.43, whichever is greater.	(None)	The hydrostatic test pressure in the 1999 Addenda to Section VIII, Division 1 does not meet the PED Annex I, para. 7.4, test pressure requirement for 1.43 times the maximum allowable pressure.
7.5	Unless other values required in accordance with other criteria must be taken into account, a steel is considered as sufficiently ductile to satisfy 4.1(a) if, in a tensile test carried out by a standard procedure, its elongation after rupture is no less than 14% and	(Partial)	Materials will only be approved if they (a) have appropriate properties for all foreseeable operating and test conditions (b) are sufficiently ductile (14% min. elongation for steel) (c) are sufficiently tough (27 J, or 20 ft-lbs minimum average for steel) at 20°C (68°F), or at the lowest operating temperature
	its bending rupture energy measured on an ISO V test-piece is no less than 27 J, at a temperature no greater than 20°C but not higher than the lowest scheduled operating temperature.	(Partial)	[Note: Section VIII, Division 1 permits lower energy values than 27 J (20 ft-lbs) for certain materials. Fig. UCS-66 includes impact test exemption curves, which exempt certain materials from impact testing at warmer temperatures. Part UHT requires 15 mils minimum lateral expansion for high strength steels. Some ASME materials, therefore, may not meet the toughness requirements of PED, Annex I, §7.5.] Alternate toughness requirements may be acceptable, but must be shown to achieve an equivalent overall safety and agreed to by the Notified Body.

Note: Any reference to the Code in this table indicates ASME Section VIII, Division 1.

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CHAPTER XIII
INTERPRETATIONS OF THE PED

The European Commission has set up a Committee Working Group "Pressure" (WG"P") to answer questions and provide clarifications and interpretations regarding the requirements in the PED 97/23/EC. A number of interpretations have been prepared by the French Comite de liaison Appareils a Pression (CLAP) regarding the intent of the requirements in this PED. The following is a list of the CLAP interpretations that provides clarification of the PED requirements pertinent to ASME Section VIII, Division 1 pressure vessels.

CLAP Interpretations

CLAP 6, Version 2: Responsibility of EC marking
CLAP 7, Version 2: Notified Bodies for equipments concerned by more than one directive.
CLAP 9, Version 7: Joining operation on site.*
CLAP 10, Version 2: Specific quantitative requirements.
CLAP 12, Version 4: Inspection documents for materials.
CLAP 14, Version 5: Harmonized standard for materials.*
CLAP 16, Version 3: Taking into account the EN ISO 9000 certifications.*
CLAP 19, Version 2: Documents to be given for a design examination.
CLAP 20, Version 4: Documents to be given for the final inspection.*
CLAP 21, Version 3: Documents to be with the equipment placed on the market = operating instructions to be given with the equipment.
CLAP 26, Version 3: Pressure gages.*
CLAP 28, Version 3: Forming procedures.*
CLAP 30, Version 4: Technical competence of the manufacturer.
CLAP 31, Version 2: Clarification of the different bodies defined in PED.
CLAP 32, Version 3: Modules adopted to the type of production.
CLAP 33, Version 4: Permanent joints.*
CLAP 34, Version 2: Grouping of fluids.
CLAP 35, Version 5: Certification of Personnel by Visual Examination.
CLAP 36, Version 3: Qualification of procedures for permanent joints.
CLAP 38, Version 2: Identification, conformity verification and traceability of the materials for the main pressure bearing parts.
CLAP 44, Version 2: Different modules for an equipment with sub-contracted part.
CLAP 46, Version 2: Different modules for an assembly.
CLAP 47, Version 2: Activities of the inspection bodies.
CLAP 48, Version 4: Welding materials and other permanent joining materials.
CLAP 50, Version 3: Final assessment.
CLAP 54, Version 2: Moving parts of a valve.
CLAP 56, Version 3: Heat exchanger.*
CLAP 57, Version 3: Proof test pressure.
CLAP 61, Version 2: Risk analysis.
CLAP 64, Version 2: In-service inspection.
CLAP 65, Version 2: Assembly.
CLAP 66, Version 2: Boilers.
CLAP 70, Version 1: Replacements, repairs or modifications
CLAP 72, Version 1: Pressure accessory.*
CLAP 73, Version 1: Piping components.*
CLAP 75, Version 1: Classification of pressure accessories.*
CLAP 76, Version 1: Conformity assessment procedure for assemblies even if the assembly is done under the responsibility of the user.*
CLAP 82, Version 1: Sound engineering practice.*
CLAP 83, Version 2: Harmonized standard for materials.

* The WG"P" has officially approved this interpretation.

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CLAP 84, Version 2: Main pressure-bearing part.
CLAP 86, Version 2: Specific assessment of material manufacturer.
CLAP 87, Version 2: Unstable gas.
CLAP 88, Version 2: Bolting parts.
CLAP 90, Version 2: Allowable stresses for materials.
CLAP 91, Version 1: Fine grain steels. (Need English language text)
CLAP 92, Version 2: Monitors.
CLAP 93, Version 3: Vessels containing two phases, one liquid and one gaseous.
CLAP 94, Version 1: Determination of maximum allowable pressure
CLAP 95, Version 1: (Need English language text)
CLAP 96, Version 1: Marking of product group
CLAP 98, Version 1: Sampling on a statistical basis
CLAP 108, Version 2: Particular material appraisal by a User Inspectorate

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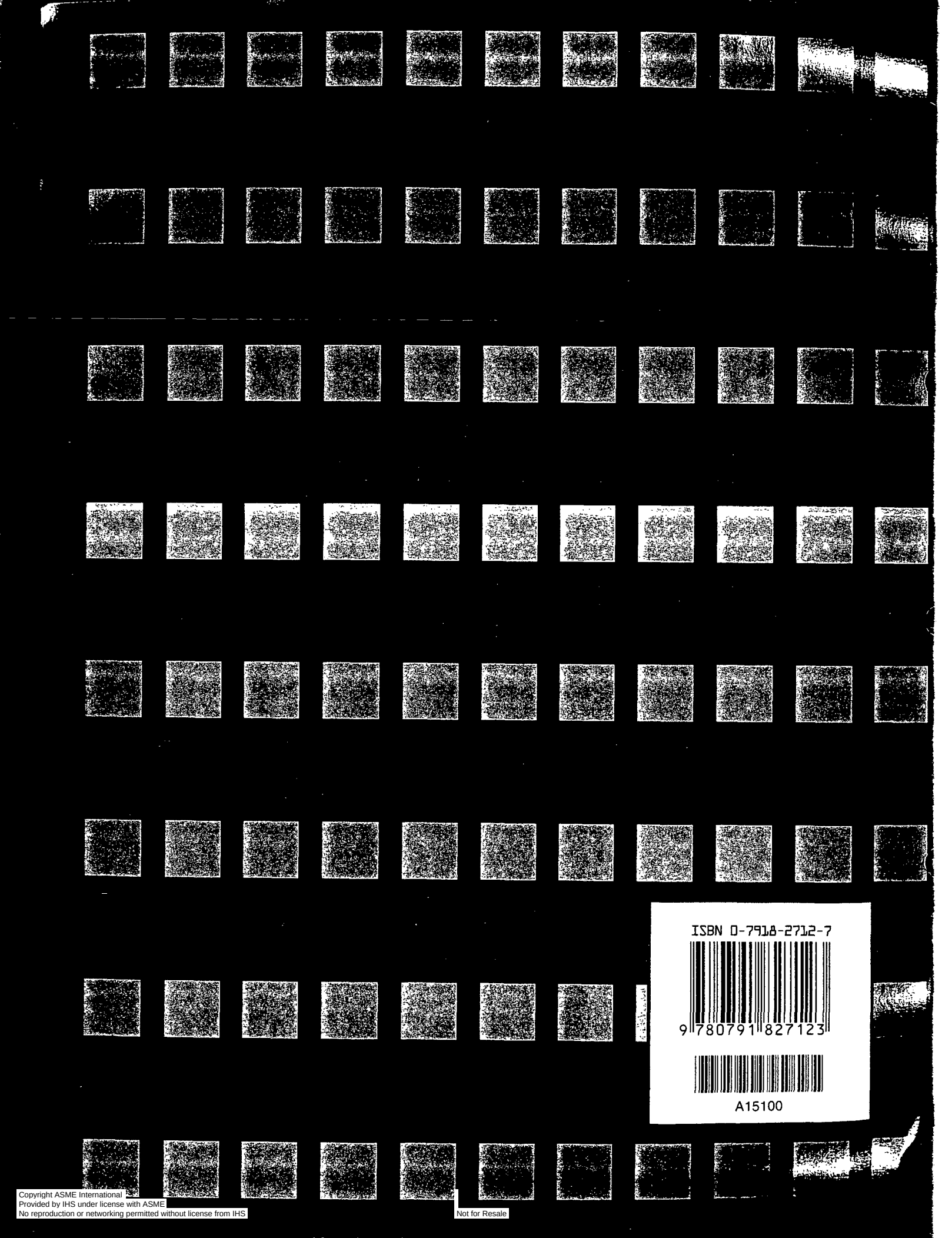

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