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.

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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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

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

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.

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.

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), 15, 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

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.

APPENDIX II-1
CONTENTS OF THE PED

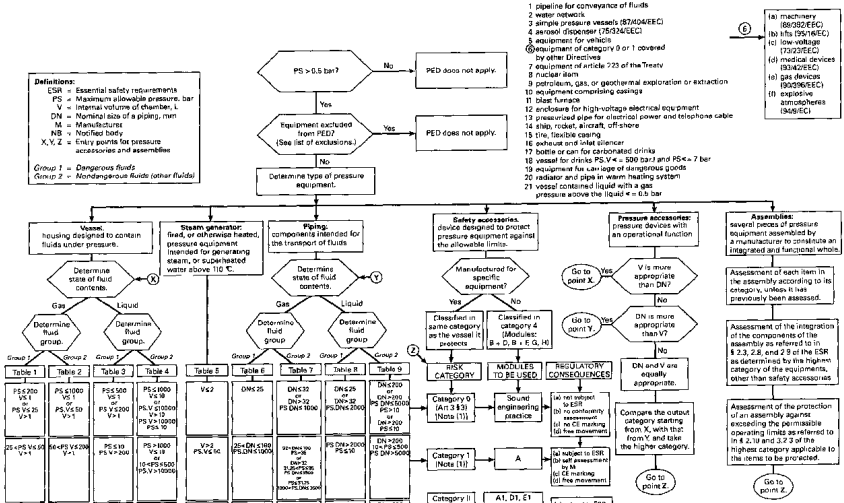
ARTICLES

ANNEXES

* Article/Annex is referenced in this Guide.

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

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



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 (E), it is excluded from PED

FIG. II-2-1 FLOWCHART FOR THE PED

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.