

dti

PRODUCT STANDARDS

Pressure Equipment

GUIDANCE NOTES ON THE
UK REGULATIONS

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This document is intended to help suppliers of pressure equipment and enforcement authorities to understand, in general terms, the main features of the Pressure Equipment Regulations 1999 ("the PER"). It is informative and for guidance only and cannot act as a substitute for the Regulations which constitute the law. The guide has no legal authority and is not an authoritative interpretation of the Regulations, which is a matter for the Courts. You should always refer to the PER themselves for a full statement of the legal requirements and, if appropriate, seek your own independent legal advice. The PER may be revised from time to time so users should keep themselves informed. In this regard information may be obtained from the DTI's Standards and Technical Regulations Directorate.

Pressure Equipment

- Essential features of the law

The Pressure Equipment Regulations 1999 (“the PER” – SI 1999/2001) implemented the Pressure Equipment Directive (“PED” 97/23/EC) in the United Kingdom and entered fully into force on 29 November 1999. The PER were amended in two respects by the Pressure Equipment (Amendment) Regulations 2002 (SI 2002/1267) with effect from 30 May 2002. (For more details see pages 6 and 15 below under ‘Exclusions’ and ‘Penalties’ respectively).

From **30 May 2002**, pressure equipment and assemblies placed on the market and put into service in the United Kingdom must comply with the PER.

General Requirements

Subject to the exclusions described below, the PER make it an offence for a ‘responsible person’ (see page 6) to place on the market, put into service or otherwise supply pressure equipment and assemblies above specified pressure/volume thresholds unless:

- they are safe;
- they meet essential safety requirements covering design, manufacture and testing;
- they satisfy appropriate conformity assessment procedures and are accompanied by a declaration of conformity; and
- they carry the CE marking and other information in English.

Pressure equipment and assemblies below specified pressure/volume thresholds must:

- be safe;
- be designed and manufactured according to ‘sound engineering practice’ (SEP);
- be accompanied by adequate instructions for use; and
- bear specified markings (but not the CE marking).

Common requirements apply throughout the European Economic Area (EEA) so that pressure equipment complying with the PER may be placed on the market or put into service anywhere in the EEA.

Failure to comply with the PER:

- ❑ means that such pressure equipment or assemblies cannot legally be placed on the market or put into service in the UK or the Community or EEA.
- ❑ could result in prosecution and penalties on conviction of a fine or imprisonment or both.

Free movement of goods

Achieving the free movement of goods - one of the four basic freedoms - lies at the heart of the drive to create the single European market. In May 1985, European Community Ministers agreed on a 'New Approach to Technical Harmonisation and Standards' to fulfil this objective.

'New Approach' Directives (that is Community laws) set out '**Essential Requirements**' (for safety, for example), written in general terms, which must be met before products may be supplied in the United Kingdom or anywhere else in the Community. Harmonised European standards then fill in the detail. Conformity with such standards is the main way for business to comply with the 'Essential Requirements'. The Directives also state how manufacturers should demonstrate that products meet the 'Essential Requirements'. Products meeting these requirements carry **CE marking**, which means they can be sold anywhere in the Community or European Economic Area (EEA)¹.

The Pressure Equipment Directive 97/23/EC (PED) has been implemented in United Kingdom law by the Pressure Equipment Regulations 1999 (SI 1999/2001). These Regulations have been amended by the Pressure Equipment (Amendment) Regulation 2002 (SI 2002/1267).

¹ There are twenty-five members of the Community - Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the UK. The EEA adds Iceland, Liechtenstein and Norway. Directive 97/23/EC has been adopted by the EEA Joint Committee and extends to the EEA.

The Pressure Equipment Regulations 1999 (SI 1999/2001)

APPLICATION

Entry into force:

Regulations 1, 2, 20 and 22	31 st August 1999
Remaining regulations	29 th November 1999

PRODUCTS AFFECTED BY THE REGULATIONS

Scope: the PER apply to the design, manufacture and conformity assessment of pressure equipment and assemblies of pressure equipment with a maximum allowable pressure greater than 0.5 bar. The PER do not apply to excluded pressure equipment and assemblies (see page 6), pressure equipment and assemblies placed on the market before 29th November 1999 or pressure equipment or assemblies placed on the market on or before 29th May 2002 if they comply with the safety provisions in force in the UK on 29th November 1999 and do not bear a CE marking (unless required by another Community Directive or any indication of compliance with the PED).

Definitions:

- ❑ **Pressure equipment** is defined as vessels, piping, safety accessories and pressure accessories.

Where applicable, pressure equipment includes elements attached to pressurised parts such as flanges, nozzles, couplings, supports, lifting lugs etc.

- ❑ **Vessel** is defined as a housing designed and built to contain fluids under pressure.

A vessel includes its direct attachments up to the coupling point connecting it to other equipment. A vessel may be composed of more than one chamber.

- ❑ **Piping** is defined as piping components intended for the transport of fluids when connected together for integration into a pressure system.

Piping includes a pipe or system of pipes, tubing, fittings, expansion joints, hoses, or other pressure-bearing components as appropriate. Heat exchangers consisting of pipes for the purpose of cooling or heating air shall be considered as piping.

- ❑ **Safety accessories** are defined as devices designed to protect pressure equipment against the allowable limits being exceeded.

Such devices include devices for direct pressure limitation, such as safety valves and bursting discs, etc, and limiting devices which either activate the means for correction or provide for shutdown or shutdown and lock out, such as pressure switches or temperature switches, etc.

- Pressure accessories** are defined as devices with an operational function and having pressure-bearing housings.
- Assemblies** are defined as several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole.

The Regulations do not apply to the assembly of pressure equipment on the site(s) and under the responsibility of the user, as in the case of industrial installations. In such cases, the Pressure Systems Safety Regulations 2000 which contain “in use” provisions will apply (see page 16).

General duties of manufacturers, authorised representatives and others

The duty to comply with the PER rests on any “**responsible person**” who places pressure equipment and assemblies on the market or puts it into service. A “responsible person” is defined in the Regulations as:

- the manufacturer or his authorised representative established within the Community;
- where neither the manufacturer nor his authorised representative is established within the Community, the person who places the pressure equipment or assembly on the market or puts it into service.

The responsible person may arrange for any, or all, of the activities involved in the design and manufacture of an item of pressure equipment or an assembly to be carried out by others. However, the responsible person retains overall responsibility.

Exclusions

The Regulations do **not** apply to equipment and assemblies:

- listed at Annex A;
- manufactured for use outside the EEA and placed on the market outside the EEA;
- exhibited at trade fairs subject to certain conditions;
- placed on the market before 29th May 2002 and which complied with the requirements legally applicable for placing on the market before 28th November 1999.**

However, any subsequent major repair or modification to such a product with the intention of placing it on the market may bring it within the scope of the PER and it will be required to comply with the requirements. The Commission's Guide to the Implementation of directives based on the New Approach and the Global Approach sets out further detail on the scope of New Approach directives relating to used and second-hand products and products imported from third countries. More information on this publication and how to acquire it can be found on page 19.

- ❑ placed on the market after use "otherwise than in the course of business" at all times since manufacture or import (see Regulation 2(4) introduced by SI 2002/1267).

PRODUCT CLASSIFICATION

In order to know how the PER will apply to specific items of pressure equipment, the manufacturer will need to classify the equipment according to its perceived level of hazard by reference to the charts reproduced in Annex B. Equipment of a relatively low hazard will be required to be manufactured according to 'sound engineering practice' (SEP) (see page 10). Equipment that is classified as a higher hazard than SEP is required to meet the relevant essential safety requirements of the PER and, on that account, to be CE marked. It is allocated, in ascending order of that hazard, to one of Categories I, II, III, or IV and the implications of this categorisation are further explained on page 12. The following table shows which chart in Annex B should be used for the various types of equipment.

	VESSELS				STEAM GENERATORS	PIPING			
State of contents	Gas		Liquid		↓ ↓ ↓ ↓	Gas		Liquid	
Fluid Group	1	2	1	2		1	2	1	2
Chart	1	2	3	4	5	6	7	8	9

Therefore, in order to classify pressure equipment, the manufacturer will need to know:

- a) The type of equipment concerned, i.e. vessel, steam generator or piping (see below for pressure accessories and safety accessories);

A steam generator is a particular type of vessel and means fired or otherwise heated pressure equipment with the risk of overheating intended for generation of steam or super-heated water at temperatures higher than 110° C.

- b) The state of the intended fluid contents - gas or liquid;

*If a fluid has a vapour pressure at the maximum allowable temperature of the equipment of greater than 0.5 bar above normal atmospheric pressure (1 013 mbar), it is treated as a **gas**, otherwise it is treated as a **liquid**.*

- c) The fluid group of the intended contents - Group 1 or Group 2.

Group 1 comprises those fluids classified, according to the EC Directive on the classification of dangerous substances, as:*

*explosive;
extremely flammable;
highly flammable;
flammable (where the maximum allowable temperature is above flashpoint);
very toxic;
toxic;
oxidising.*

Group 2 comprises all other fluids including steam.

*Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances as last amended by Council Directive 96/56/EC and last adapted to technical progress by Commission Directive 96/54/EC.

These Directives have been implemented in Great Britain by the Chemicals (Hazard Information and Packaging for Supply) Regulations 1994 (as amended) (CHIP). A useful introduction to CHIP is available as a downloadable 12-page booklet at

<http://www.hse.gov.uk/pubns/indg350.pdf>.

Further references to CHIP are also available on the Health and Safety Executive (HSE) CHIP site at <http://www.hse.gov.uk/chip/index.htm>. A free leaflet or a priced guidance book on CHIP is available from HSE Books, PO Box 1999, Sudbury, Suffolk CO10 2WA, tel: 01787 881165, fax: 01787 313995, or from the HSE website at:

<http://www.hsebooks.co.uk>

With this information the manufacturer can identify the relevant chart in Annex B (see table on previous page), and determine the correct classification of the equipment by plotting the maximum allowable pressure and, in the case of vessels, the volume in litres or, for piping, the nominal size (DN).

The maximum allowable pressure (PS) is the maximum pressure for which the equipment is designed, as specified by the manufacturer.

Nominal size (DN) means a numerical designation of size which is common to all components in a piping system other than components indicated by outside diameter or by thread size; that is to say a convenient round number for reference purposes which is only loosely related to manufacturing dimensions and designated by the letters “DN” followed by a number. Reference may be made to Guideline 2/2, available on the Commission’s Pressure Equipment Directive website at <http://ped.eurodyn.com>, to determine the classification of tubular products or accessories for which the notion of DN does not exist.

For **pressure accessories**, the manufacturer will need to know:

- a) The state of the intended fluid contents - gas or liquid;
- b) The classification of the intended fluid contents - Group 1 or Group 2;
- c) The maximum allowable pressure; and
- d) The volume in litres or the nominal size (DN), as appropriate.

If the volume measurement is appropriate for the accessory concerned, the category of the equipment should be determined by plotting the maximum allowable pressure and volume on the relevant **vessels** chart in Annex B (see table on page 7).

If the nominal size is appropriate, the category of the equipment should be determined by plotting the maximum allowable pressure and the nominal size (DN) on the relevant **pipings** chart (see table on page 7).

Where both the volume and the nominal size are considered appropriate, both the relevant vessels and piping charts should be used and the pressure accessory classified in the highest resulting category.

Safety accessories: are generally classified under Category IV unless they are manufactured to protect specific pressure equipment in which case they may be classified in the same category as the equipment they protect.

Assemblies: special provisions apply to assemblies (see under Technical Requirements and Conformity Assessment below).

Product classification is shown in diagrammatic form in Annex C.

TECHNICAL REQUIREMENTS

The Regulations require that all pressure equipment and assemblies within their scope must be safe when placed on the market and put into service.

‘Safe’ pressure equipment and assemblies are those which, when properly installed and maintained and used for their intended purpose, will not endanger the health and safety of persons and, where appropriate, domestic animals or property.

Sound Engineering Practice (SEP)

Equipment classified according to the charts in Annex B as 'SEP' will be required simply to be designed and manufactured according to 'sound engineering practice'. SEP equipment will need to be accompanied by adequate instructions for use and must bear markings to permit identification of the manufacturer or authorised representative established within the Community. CE marking must not be affixed to SEP equipment.

Essential safety requirements

Equipment classified in Categories I to IV will be required to meet requirements for design, manufacture, testing, marking, labelling, instructions and materials which are considered to be essential for safety reasons (reproduced in Annex D). The Regulations require safety accessories and pressure accessories intended for equipment classified in Categories I to IV to meet the essential safety requirements.

Assemblies which include at least one item of pressure equipment classified in Categories I to IV which the manufacturer intends to be placed on the market and put into service as assemblies, will also be required to meet the essential safety requirements.

In addition:

assemblies intended for generating steam or superheated water at a temperature higher than 110°C comprising at least one item of fired or otherwise heated pressure equipment presenting a risk of overheating and which include at least one item of pressure equipment classified in Categories I to IV will be required to meet the essential safety requirements; and

assemblies intended for generating warm water at temperatures not greater than 110°C which are manually fed with solid fuels and have a product of pressure and volume greater than 50 bar litres will be required to meet essential safety requirements 2.10, 2.11, 3.4, 5(a) and 5(d).

Equipment manufactured to mandated harmonised European standards developed in support of the PED will be presumed to comply with the essential safety requirements which those standards address.

The European Committee for Standardisation (CEN) is working to produce a series of harmonised European standards in support of the Pressure Equipment Directive. The work programme includes product and supporting standards. The reference numbers of harmonised European standards with Annex ZAs referring to the PED are published in the Official Journal of the European Communities. The current position regarding harmonised and mandated standards for the Directive can be ascertained from the Commission's website:

<http://www.newapproach.org/Directives/DirectiveList.asp>

Harmonised European standards are reproduced as British Standards and the reference numbers of these standards will be available from BSI Business Information. Enquiries on the progress of these standards should also be addressed to the BSI Information Centre (see page 18).

CONFORMITY ASSESSMENT

In order to demonstrate that the essential safety requirements are satisfied, equipment will be subject to conformity assessment based on EC Decision 93/465/EEC of 22 July 1993 which set down a framework of conformity assessment 'modules' intended for use in New Approach Directives. According to the category of the equipment, manufacturers will be given a choice of 'modules' described in Annex E.

The higher the category, and therefore the greater the hazard, the more demanding are the requirements. Equipment in Category I will be subject to the manufacturer's own internal production control. The modules for products in Categories II, III & IV will require the involvement of '**notified bodies**', appointed by Member States, either in the approval and monitoring of the manufacturers' quality assurance system or in direct product inspection.

In addition to notified bodies, '**Recognised third-party organisations**' may also be appointed by Member States specifically to carry out the approval of welding procedures and personnel and non-destructive testing personnel as required for pressure equipment and assemblies in Categories II, III and IV by sections 3.1.2 and 3.1.3 of the essential safety requirements (notified bodies may also be appointed for these procedures in addition to the wider conformity assessment procedures).

'**User inspectorates**' may also be appointed by Member States to carry out the tasks of notified bodies within their own organisations under Modules A1, C1, F and G only. The CE marking should not be affixed to pressure equipment and assemblies assessed by user inspectorates.

In the United Kingdom, notified bodies, recognised third-party organisations and user inspectorates are appointed by the Secretary of State for Trade and Industry. These bodies are collectively known as "Conformity Assessment Bodies" (CABs). A list of the United Kingdom CABs can be found on the STRD website at <http://www.dti.gov.uk/strd/pdncab.pdf>

Organisations interested in applying for notified body, recognised third-party organisation or user inspectorate status will be assessed against the criteria set down in the UK Guidelines on the appointment of Conformity Assessment Bodies – Ref. URN99/1051, which incorporates the minimum criteria set out in the Directive. A copy of the Guidelines is available on the STRD website at <http://www.dti.gov.uk/strd/pedcabgd.pdf>

The conformity assessment modules available for the different categories of equipment are detailed below, along with a brief description in the key (fuller details are provided in Annex E). Manufacturers may choose the module(s) which best suit them, e.g. a manufacturer of Category II equipment may choose A1, D1 or E1.

Category I	Category II	Category III	Category IV
Module	Modules	Modules	Modules
A	A1	B1 + D	B + D
	D1	B1 + F	B + F
	E1	B + E	G
		B + C1	H1
		H	

Key

Module	Design	Production
A	Technical documentation	Internal production control
A1	Technical documentation	Internal production control with monitoring of the final assessment
B	Type examination	
B1	Design examination	
C1		Monitoring of final assessment
D		Quality assurance for production, final inspection and test
D1	Technical documentation	Quality assurance for production, final inspection and test
E		Quality assurance for final inspection and test
E1	Technical documentation	Quality assurance for final inspection and test
F		Product verification
G	Unit verification	Unit verification
H	Quality assurance for design,	manufacture, final inspection and test
H1	Quality assurance for design, with design examination and	manufacture, final inspection and test monitoring of final assessment

A summary of the module requirements is given in Annex E.

Manufacturers may choose to apply one of the procedures for a higher category but this will not alter the category of their product (see Guideline 2/25 on the European Commission's Pressure Equipment Directive website <http://ped.eurodyn.com>).

Assemblies will need to be subject to the following three-stage conformity assessment procedure:

- a) each item making up an assembly will need to be assessed as described above;

- b) the integration of the component parts of the assembly (as referred to in sections 2.3, 2.8 and 2.9 of the essential safety requirements) will need to be assessed according to the highest category applicable to the equipment concerned (except that the category of any safety accessories is disregarded when establishing the category of this assessment); and
- c) the protection of the assembly against exceeding the permissible operating limits (as referred to in sections 2.10 and 3.2.3 of the essential safety requirements) will need to be assessed according to the highest category applicable to the equipment to be protected.

CE marking requirements

Once conformity assessment has been completed, and if the equipment or assembly complies with the provisions of the PER, the manufacturer will be required to affix the CE marking to each item of pressure equipment or assembly and draw up a declaration of conformity (see section below). The CE marking is as illustrated in diagram 1 below. It should not be smaller than 5mm in its vertical height and the proportions, as shown in diagram 2, should be maintained whatever its size. The grid is for information only, and does not form part of the marking. The CE marking will need to be affixed in a visible, easily legible and indelible fashion.



Diagram 1

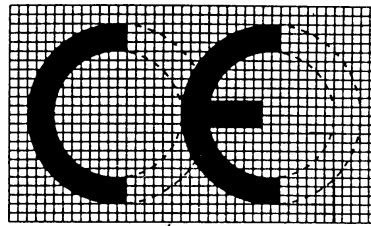


Diagram 2

The CE marking will need to be accompanied by the identification number of the notified body if it is involved at the production control phase (i.e. monitoring of final assessment, product verification or surveillance of an approved quality assurance system).

The CE marking must not be affixed to 'SEP' equipment.

CE marking is a visible declaration by the manufacturer or his authorised representative that the pressure equipment to which it relates satisfies all the provisions of the Regulations. Equipment bearing the mark will be taken as meeting the requirements and thereby entitled to free circulation throughout the EEA provided that the equipment does in fact satisfy those requirements.

By affixing CE marking to pressure equipment the manufacturer is making a statement that his equipment meets the requirements of all relevant Directives. It is for the manufacturer to decide which other Directives are relevant to his equipment. However, where a particular Directive provides a transitional period which allows a manufacturer the choice of which provisions to apply, the manufacturer must indicate which Directive(s) have been applied. This information must be given in the documents, notices or instructions that accompany the pressure equipment.

The presence of CE marking does not mean that the pressure equipment cannot be challenged by an enforcement authority if they have reasonable grounds for suspecting an infringement of the Regulations.

Suppliers should note that CE marking is not a European safety mark or quality symbol intended for consumers and should not be presented as such. Its purpose is to indicate to enforcement authorities that the pressure equipment to which it relates is intended for sale in the Community and the EEA and signifies a declaration, which is rebuttable, by the manufacturer or his authorised representative that the equipment satisfies the requirements and is entitled to access those markets. It should also be noted that CE marking is specific only to a range of Directives. It can only be applied to products covered by such Directives and under the conditions contained in them. While it is not an offence under the Regulations to affix **CE marking** to items which are not pressure equipment or covered by another Directive requiring **CE marking**, such an action could constitute an offence under section 1 of the Trade Descriptions Act 1968 and may result in prosecution and a subsequent fine. This can apply to any person in the supply chain.

EC Declaration of Conformity

An EC Declaration of Conformity is a written declaration by the manufacturer or his authorised representative that the equipment to which the CE marking has been affixed complies with the requirements of the Regulations.

A copy of the EC Declaration of Conformity is not required to accompany each product but a copy should be retained by the responsible person who first places the equipment on the market in the Community or EEA.

The declaration of conformity will need to contain the information set out in Annex F.

ENFORCEMENT

In Great Britain the Health and Safety Executive (HSE), and, for Northern Ireland, the Health and Safety Executive for Northern Ireland (HSENI), are responsible for enforcing the Regulations in relation to pressure equipment and assemblies for use in the workplace.

In Great Britain trading standards authorities, and in Northern Ireland district councils, are responsible for enforcing the Regulations in relation to pressure equipment used in a non-work environment.

The HSE has 7 regions with offices throughout Great Britain and, in Northern Ireland which is treated as one region, the HSENI office in Belfast. Each of these offices can advise suppliers of equipment for use at work regarding current standards and relevant legislation. HSE inspectors may also make preventive or reactive visits to suppliers.

Suppliers of equipment wishing to ensure that their products meet the requirements of the Regulations can make enquiries to one of the Notified Bodies, to HSE's Infoline Service (Tel: 0845 345 0055) or to their nearest HSE office or, in Northern Ireland, the Health and Safety Executive for Northern Ireland's Information and Advice Helpline (Tel: 0800 032 0121). Clearly it is in the supplier's own interest to discuss at an early stage any problems they may be having in applying the Regulations to their products.

Penalties

If tried in a Magistrates Court, the maximum penalty for contravening the Regulations is currently a fine of £5,000 or, in some cases, imprisonment for up to 3 months, or both.

If tried in a Crown Court, the penalty for contravening the Regulations is currently an unlimited fine or, in some cases, imprisonment for up to 2 years, or both.

It is for the courts to decide the penalty in each instance taking into account the severity of the offence. The Pressure Equipment (Amendment) Regulations 2002 (SI 2002/1267) provides for cases to be tried in either the Magistrates or Crown Courts.

The Regulations provide a defence of due diligence.

Free circulation

Member States may not, on grounds of the hazards due to pressure, prohibit, restrict or impede the placing on the market and putting into service of pressure equipment and assemblies which comply with the provisions of the PED. Member States are to presume that pressure equipment and assemblies bearing the CE marking satisfy the provisions of the PED. The Member State in which the equipment is eventually used can stipulate in which official language(s) of the European Community the accompanying documentation is to be provided.

Safeguard procedure

Member States are required to take all appropriate measures to withdraw from the market pressure equipment or assemblies bearing the CE marking which, when used in accordance with its intended purpose, is liable to endanger the safety of people and, where appropriate, domestic animals or property. The Member State must immediately inform the European Commission of such action and give reasons. Where, after consultation with the parties concerned, the Commission finds that the measures are justified, it must inform the Member State taking the action and the other Member States.

Member States are required to take action against anyone who affixes the CE marking to pressure equipment or an assembly which does not comply and must inform the Commission and other member States of the action taken.

OTHER LEGISLATION

Simple Pressure Vessels Directive

Certain vessels for air or nitrogen are covered by the Simple Pressure Vessels Directive (“SPVD”) and are thus excluded from the PER The Simple Pressure Vessels Directive (87/404/EEC as amended), implemented in the United Kingdom by The Simple Pressure Vessels (Safety) Regulations (SI 1991/2749) as amended, continues to apply to these products. A booklet describing its precise scope and requirements, ‘Product Standards - Simple Pressure Vessels’, is available from the STRD website at <http://www.dti.gov.uk/strd/spvps.pdf> and from the DTI Publications Orderline on 0845 015 0010.

The Pressure Systems Safety Regulations

The Pressure Systems Safety Regulations 2000 (“PSSR”) (SI 2000/128) applies to the design and construction of pressure equipment not covered by the Pressure Equipment Regulations. PSSR applies to the **use** and ongoing integrity of pressure systems.

The PSSR can be obtained from:

The Stationery Office Ltd (TSO)
51 Nine Elms Lane
London
SW8 5DR
Tel: 0870 600 5522
Fax: 0870 600 5533
E-Mail: <mailto:customer.services@tso.co.uk>

A copy of the Regulations may also be downloaded from the HMSO’s website
<http://www.legislation.hmso.gov.uk/si/si2000/20000128.htm>

The “Safety of Pressure Systems” Approved Code of Practice (ACOP) L122 SI 2000 No. 128, which describes the PSSR for prospective users, is available at a charge from:

HSE Books
PO Box 1999
Sudbury
Suffolk
CO10 2WA

Tel: 01787 881165
Fax: 01787 313995

or from the HSE website at: <http://www.hsebooks.co.uk>

USEFUL INFORMATION AND CONTACTS

Availability of the text of the Regulations and the Directive

The Pressure Equipment Regulations 1999 (SI 1999/2001) and the amending regulations (SI 2002/1267) can be obtained from:

The Stationery Office Ltd (TSO)
51 Nine Elms Lane
London
SW8 5DR

Tel: 0870 600 5522
Fax: 0870 600 5533
E-Mail <mailto:customer.services@tso.co.uk>

A copy of the Regulations may also be downloaded from the HMSO's website
<http://www.hmso.gov.uk/stat.htm>

The complete text of the Pressure Equipment Directive was published in the Official Journal of the European Communities (No. L181 of 9 July 1997 - ISBN 011 916 0927). Copies of the Official Journal can be obtained from The Stationery Office as above. A copy of the Directive can be downloaded from the Commission's website <http://ped.eurodyn.com>.

Please note that DTI does not supply copies of the Regulations, of standards or of Directives.

Action Single Market

Where compliant equipment is denied proper access to the market in other EEA countries, Action Single Market will offer advice and assistance.

Action Single Market
Department of Trade & Industry
Bay 4121
1 Victoria Street
London
SW1H 0ET
Tel: 020 7215 2833
Fax: 020 7215 2234

E-mail: <mailto:asm@dti.gsi.gov.uk>

Website: <http://www.dti.gov.uk/europe/asm>

FURTHER INFORMATION

Enquiries relating to the Regulations:

Department of Trade & Industry
Standards & Technical Regulations Directorate
Bay 331
151 Buckingham Palace Road
London SW1W 9SS

Tel: 0207 215 1437
Fax: 0207 215 1529

Website: <http://www.dti.gov.uk/strd>

Enquiries relating to Enforcement:

HSE Infoline

Tel: 0845 345 0055

Website: <http://www.hse.gov.uk>

Enquiries relating to standards which may be used to demonstrate conformity:

Charles Barker
BSI Information Centre
389 Chiswick High Road
London W4 4AL

Tel: 0208 996 7474
Fax: 0208 996 7048

Website: <http://www.bsi-global.com>

Enquiries relating to the interpretation of the Directive across the European Union and the implementation of the Regulations in other Member States:

A series of guidelines in the form of specimen 'Questions and Answers' has been developed by the European Commission in cooperation with government representatives from the Member States and other parties with an interest in the practical application of the Directive, e.g. industry, users and CABs. These are organised into a series of headings and can be accessed on the European Commission's pressure equipment website <http://ped.eurodyn.com>. This site also contains details of contacts with responsibility for the PED in other Member States and useful links e.g. to the CEN website.

Guidance on the scope, philosophy and application of New Approach Directives is available in the “Guide to the implementation of directives based on the New Approach and Global Approach” (the Blue Guide) at the European Commission’s website:

<http://europa.eu.int/comm/enterprise/newapproach/legislation/guide/index.htm>

Further copies of this booklet can be obtained from the DTI’s Publications Orderline by quoting the URN reference given at the beginning of this booklet:

DTI Publications Orderline
ADMAIL 528
London SW1W 8YT
Tel: 0845 015 0010
Fax: 0845 015 0020

This booklet can also be downloaded from the Department’s website:
<http://www.dti.gov.uk/strd/ped.pdf>

Equipment excluded from the scope of the Regulations

- 1 pipelines comprising piping or a system of piping designed for the conveyance of any fluid or substance to or from an installation (onshore or offshore) starting from and including the last isolation device located within the confines of the installation, including all the annexed equipment designed specifically for pipelines. This exclusion does not apply to standard pressure equipment such as may be found in pressure reduction stations or compression stations;
- 2 networks for the supply, distribution and discharge of water and associated equipment and headraces such as penstocks, pressure tunnels, pressure shafts for hydroelectric installations and their related specific accessories;
- 3 equipment covered by Directive 87/404/EEC on simple pressure vessels;
- 4 equipment covered by Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the member States relating to aerosol dispensers ⁽¹⁾;
- 5 equipment intended for the functioning of vehicles defined by the following Directives and their Annexes:
 - ❑ Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the member States relating to the type-approval of motor vehicles and their trailers ⁽²⁾,
 - ❑ Council Directive 74/150/EEC of 4 March 1974 on the approximation of the laws of the member States relating to the type-approval of wheeled agricultural or forestry tractors ⁽³⁾,
 - ❑ Council Directive 92/61/EEC of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles ⁽⁴⁾;
- 6 equipment classified as no higher than Category I under Article 9 of the PED and covered by one of the following Directives:
 - ❑ Council Directive 98/37/EC of 14 June 1989 on the approximation of the laws of the member States relating to machinery ⁽⁵⁾,
 - ❑ European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the member States relating to lifts ⁽⁶⁾,

⁽¹⁾ OJ No L 147, 9.6.1975, p. 40. as last amended by Commission Directive 94/1/EC
⁽²⁾ OJ No L 42, 23.2.1970, p. 1. as last amended by Commission Directive 95/54/EC
⁽³⁾ OJ No L 84, 28.3.1974, p. 10. as last amended by the 1994 Act of Accession.
⁽⁴⁾ OJ No L 225, 10.8.1992, p. 72. as last amended by the 1994 Act of Accession.
⁽⁵⁾ OJ No L 207, 23.7.1998, p. 1.
⁽⁶⁾ OJ No L 213, 7.9.1995, p. 1.

- ❑ Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the member States relating to electrical equipment designed for use within certain voltage limits ⁽⁷⁾,
 - ❑ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽⁸⁾,
 - ❑ Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the member States relating to appliances burning gaseous fuels ⁽⁹⁾,
 - ❑ Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the member States concerning equipment and protective systems intended for use in potentially explosive atmospheres ⁽¹⁰⁾;
- 7 equipment covered by Article 296 (1) (b) of the Treaty (i.e. specifically designed and constructed for military purposes);
- 8 items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;
- 9 well-control equipment used in the petroleum, gas or geothermal exploration and extraction industry and in underground storage which is intended to contain and/or control well pressure. This comprises the wellhead (Christmas tree), the blow out preventers (BOP), the piping manifolds and all their equipment upstream;
- 10 equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor. Such equipment may include:
- ❑ engines including turbines and internal combustion engines,
 - ❑ steam engines, gas/steam turbines, turbogenerators, compressors, pumps and actuating devices;
- 11 blast furnaces including the furnace cooling system, hot-blast recuperators, dust extractors and blast-furnace exhaust-gas scrubbers and direct reducing cupolas, including the furnace cooling, gas converters and pans for melting, re-melting, de-gassing and casting of steel and non-ferrous metals;
- 12 enclosures for high-voltage electrical equipment such as switchgear, control gear, transformers, and rotating machines;

⁽⁷⁾ OJ No L 77, 26.3.1973, p. 29. as last amended by Directive 93/68/EEC

⁽⁸⁾ OJ No L 169, 12.7.1993, p. 1. as last amended by Directive 98/79/EC

⁽⁹⁾ OJ No L 196, 26.7.1990, p. 15. as last amended by Directive 93/68/EEC

⁽¹⁰⁾ OJ No L 100, 19.4.1994, p. 1.

- 13 pressurized pipes for the containment of transmission systems, e.g. for electrical power and telephone cables;
- 14 ships, rockets, aircraft and mobile off-shore units, as well as equipment specifically intended for installation on board or the propulsion thereof;
- 15 pressure equipment consisting of a flexible casing, e.g. tyres, air cushions, balls used for play, inflatable craft, and other similar pressure equipment;
- 16 exhaust and inlet silencers;
- 17 bottles or cans for carbonated drinks for final consumption;
- 18 vessels designed for the transport and distribution of drinks having a PS•V of not more than 500 bar•L and a maximum allowable pressure not exceeding 7 bar;
- 19 equipment covered by the ADR ⁽¹⁾, the RID ⁽²⁾, the IMDG ⁽³⁾ and the ICAO Convention ⁽⁴⁾;
- 20 radiators and pipes in warm water heating systems;
- 21 vessels designed to contain liquids with a gas pressure above the liquid of not more than 0.5 bar.

⁽¹⁾ ADR = European Agreement concerning the International Carriage of Dangerous Goods by Road.
⁽²⁾ RID = Regulations concerning the International Carriage of Dangerous Goods by Rail.
⁽³⁾ IMDG = International Maritime Dangerous Goods Code.
⁽⁴⁾ ICAO = International Civil Aviation Organization.

Classification Charts

(See Page 7)

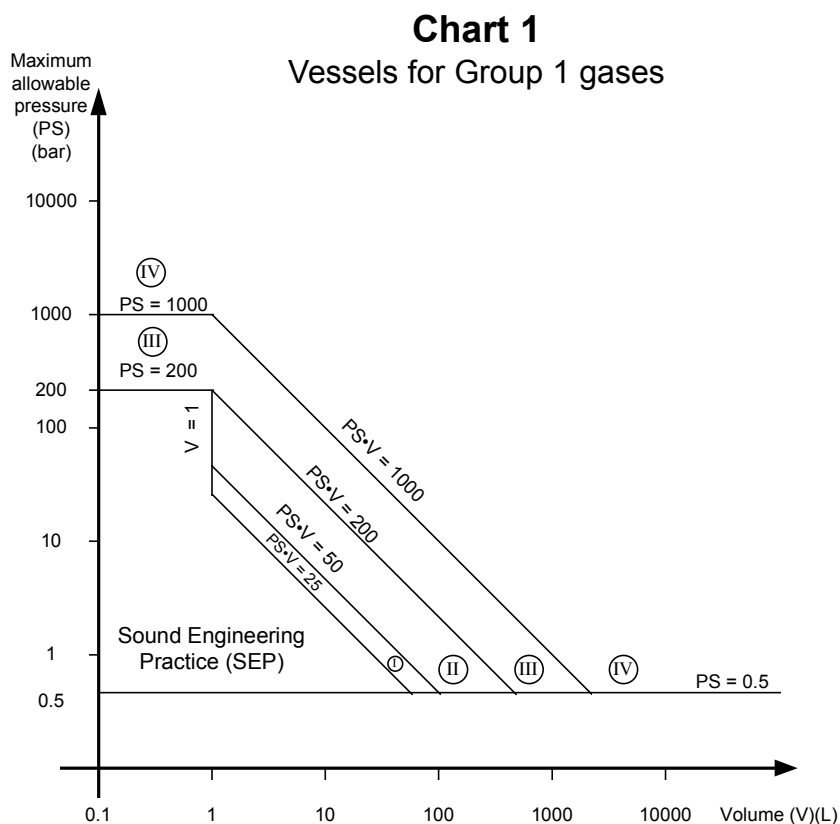
Notes:

The demarcation lines in the following charts indicate the upper limit for each category. The charts are called tables in the Directive implementing the PER.

Charts for gases include gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure at the maximum allowable temperature is greater than 0.5 bar above normal atmospheric pressure (1 013 mbar).

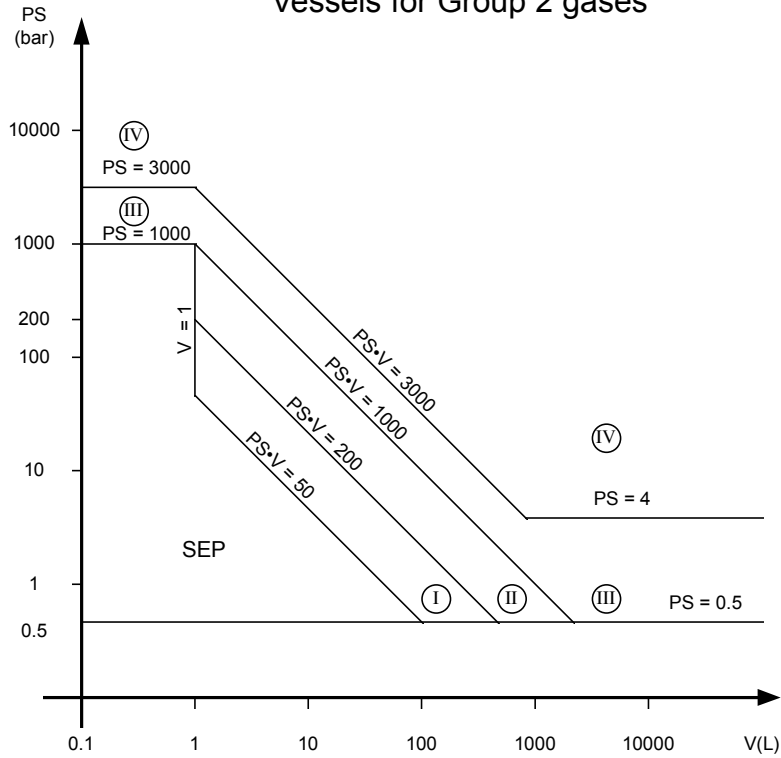
Charts for liquids include liquids having a vapour pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure (1 013 mbar).

The charts assign each piece of equipment to a firm category. Over classification of equipment, e.g. declaring it to be category IV when it is category II, is expressly prohibited. See Commission's Guideline 2/25 on the <http://ped.eurodyn.com> website.



Exceptionally, vessels intended to contain an unstable gas and falling within categories I or II on the basis of Chart 1 must be classified in category III

Chart 2
Vessels for Group 2 gases



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

Chart 3
Vessels for Group 1 liquids

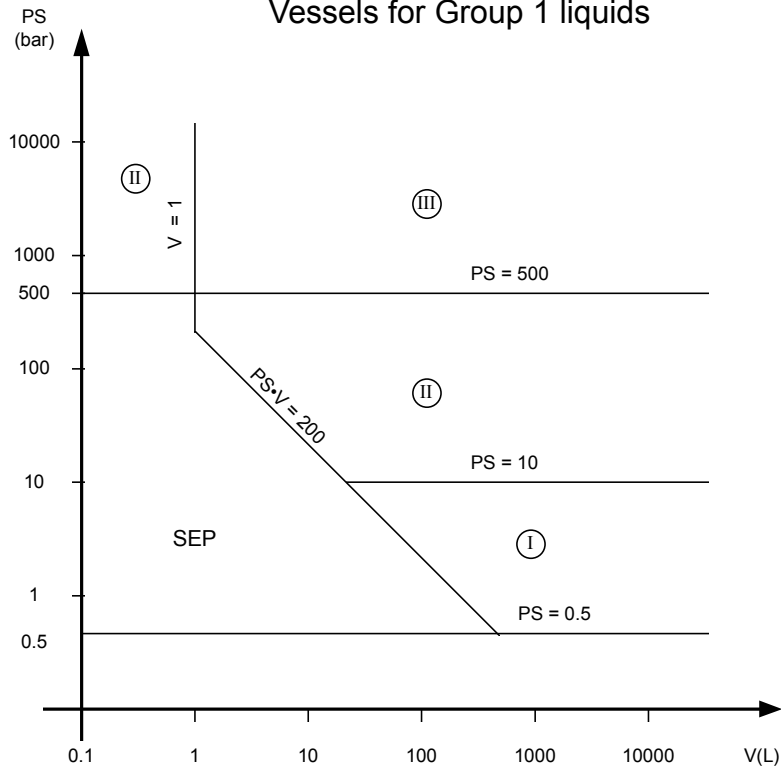
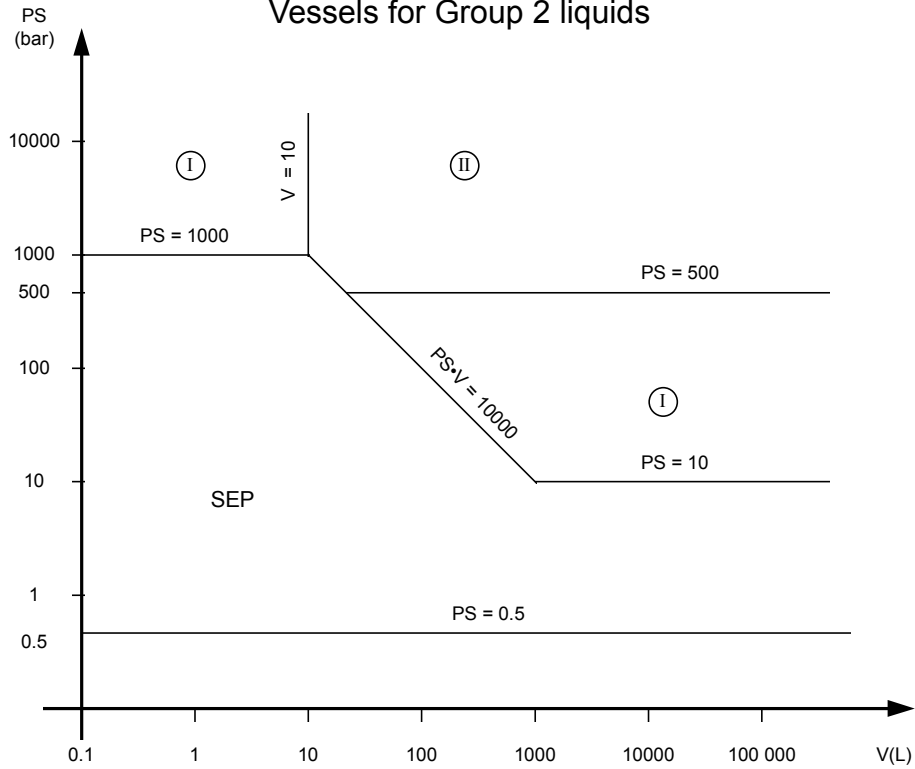
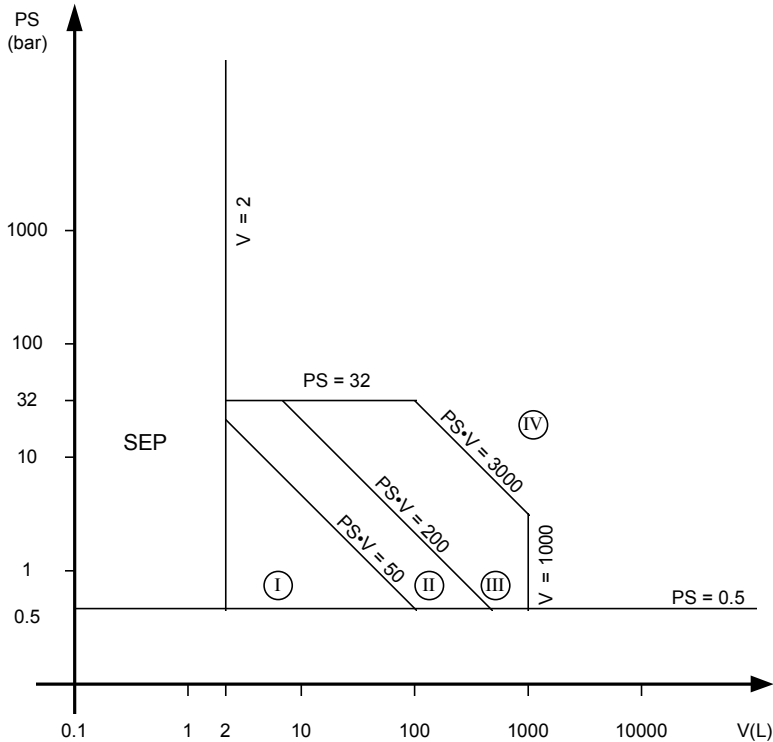


Chart 4
Vessels for Group 2 liquids



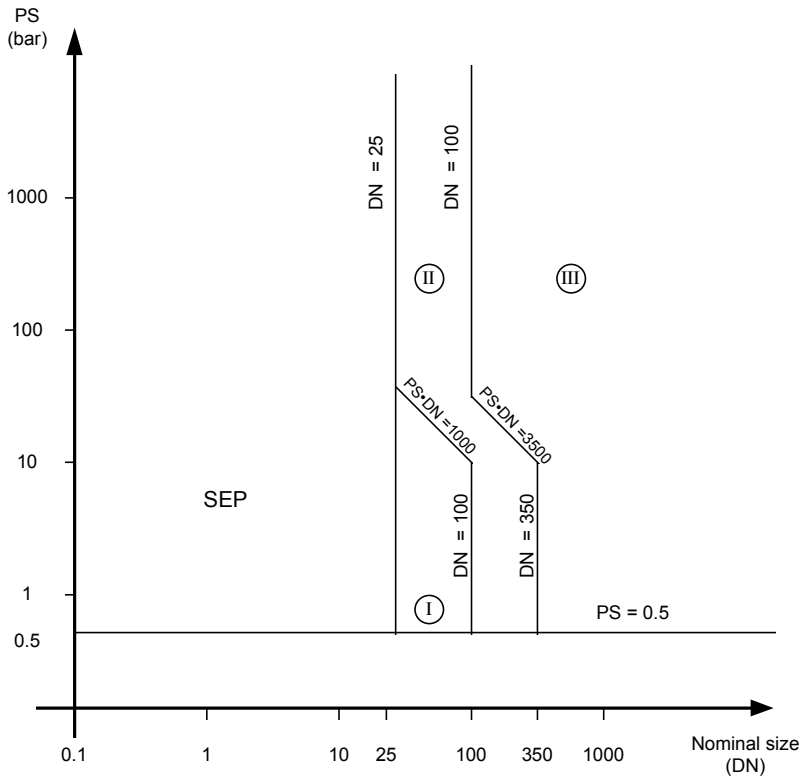
Exceptionally, assemblies intended for generating warm water at temperatures not greater than 110°C which are manually fed with solid fuels and have a product of pressure and volume greater than 50 bar litres, must be subject either to an EC design examination (Module B1) with respect to their conformity with Sections 2.10, 2.11, 3.4, 5(a) and 5(d) of the essential safety requirements, or to full quality assurance (Module H).

Chart 5
Steam Generators



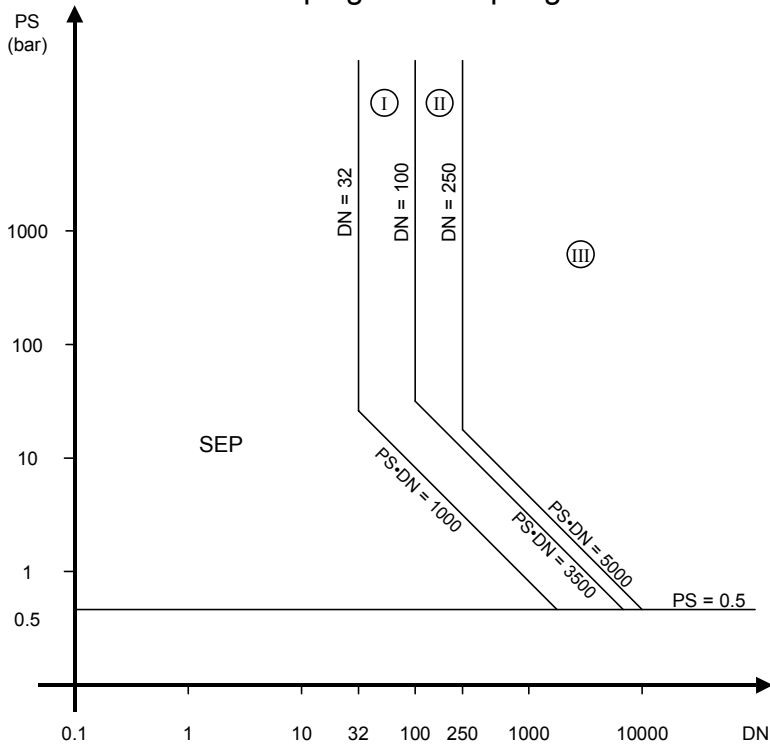
Exceptionally, the design of pressure cookers must be subject to a conformity assessment procedure equivalent to at least one of the category III modules.

Chart 6
Piping for Group 1 gases



Exceptionally, piping intended for unstable gases and falling within categories I or II must be classified in category III.

Chart 7
Piping for Group 2 gases



Exceptionally, all piping containing fluids at a temperature greater than 350°C and falling within category II must be classified in category III.

Chart 8
Piping for Group 1 liquids

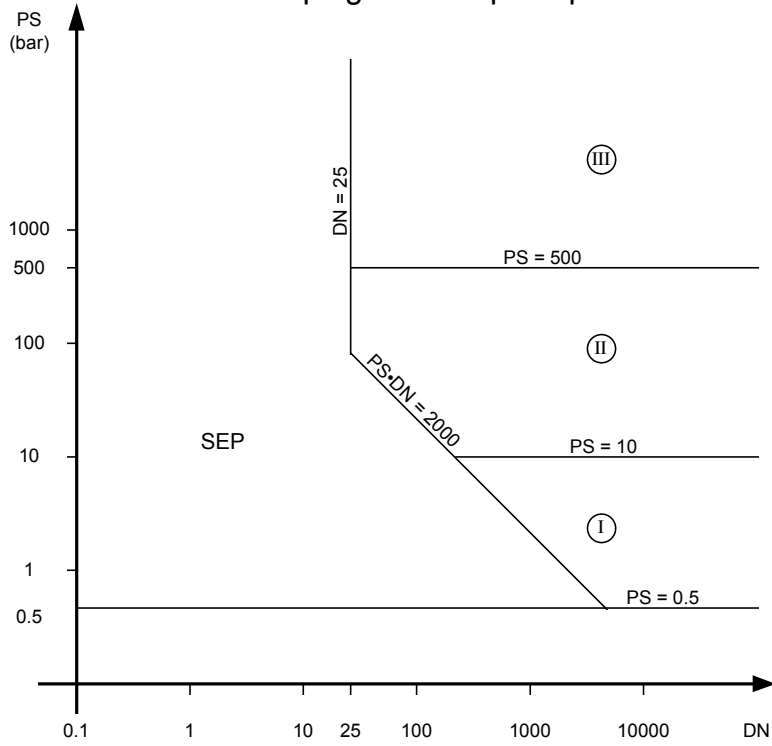
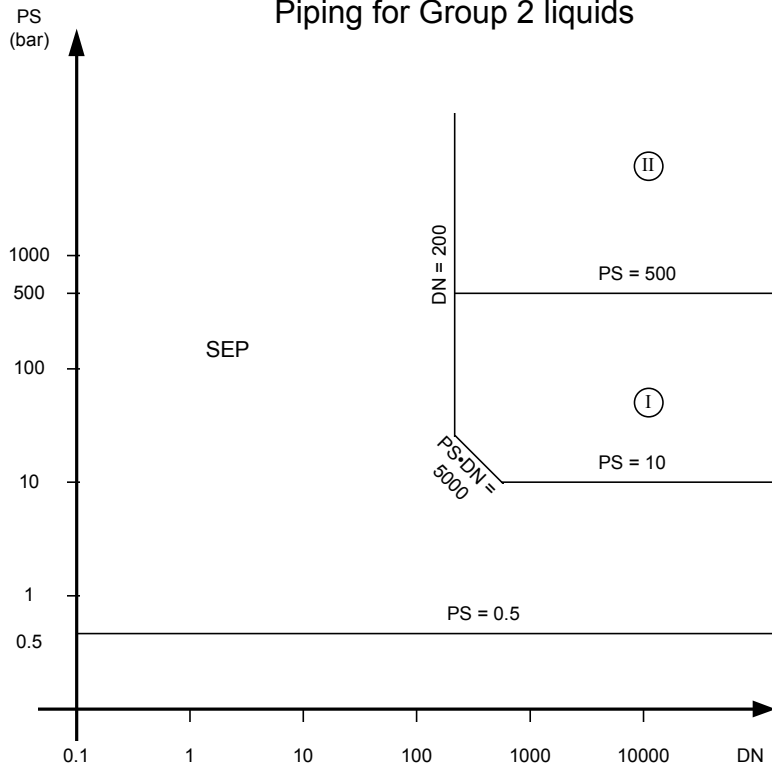
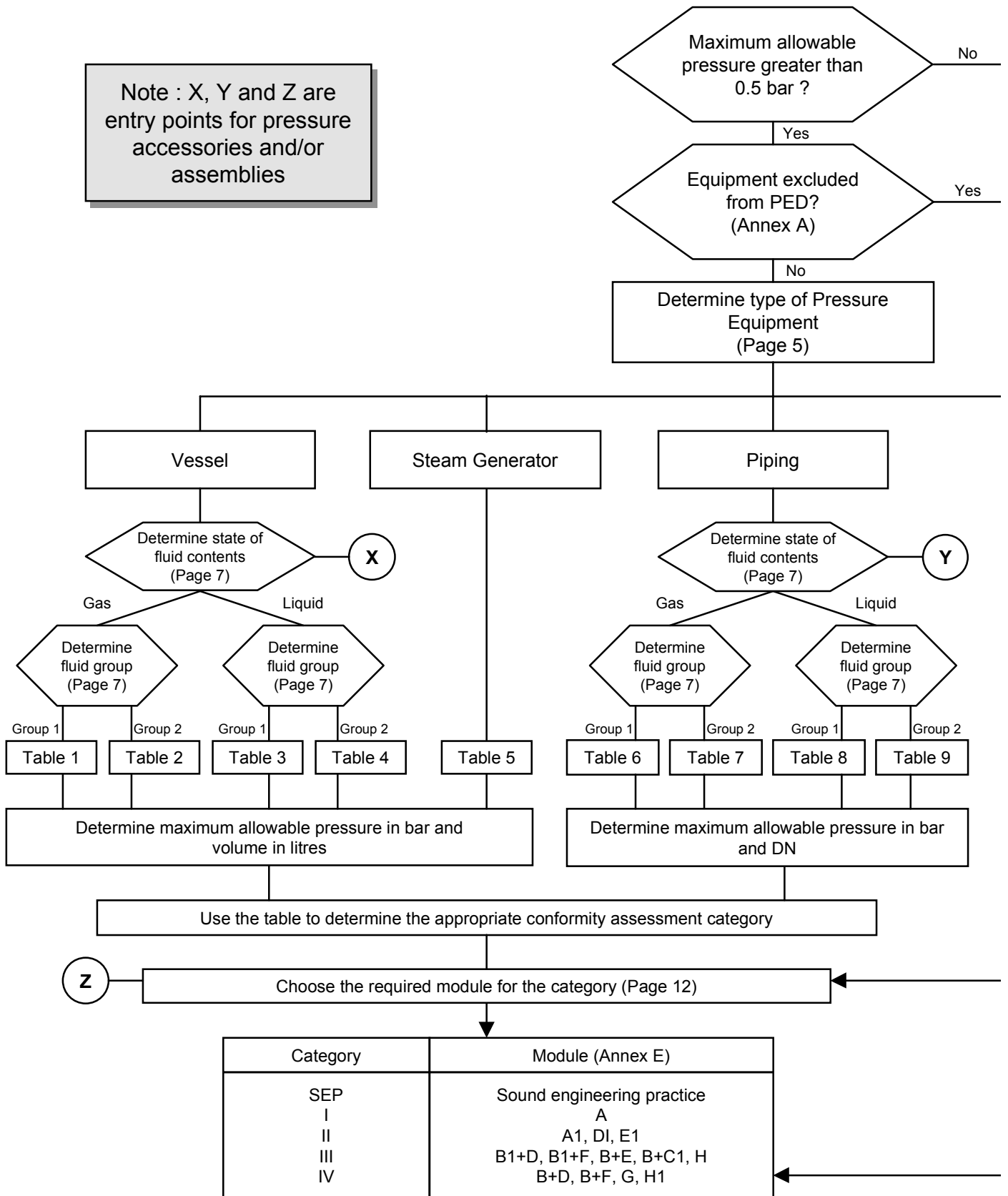


Chart 9
Piping for Group 2 liquids

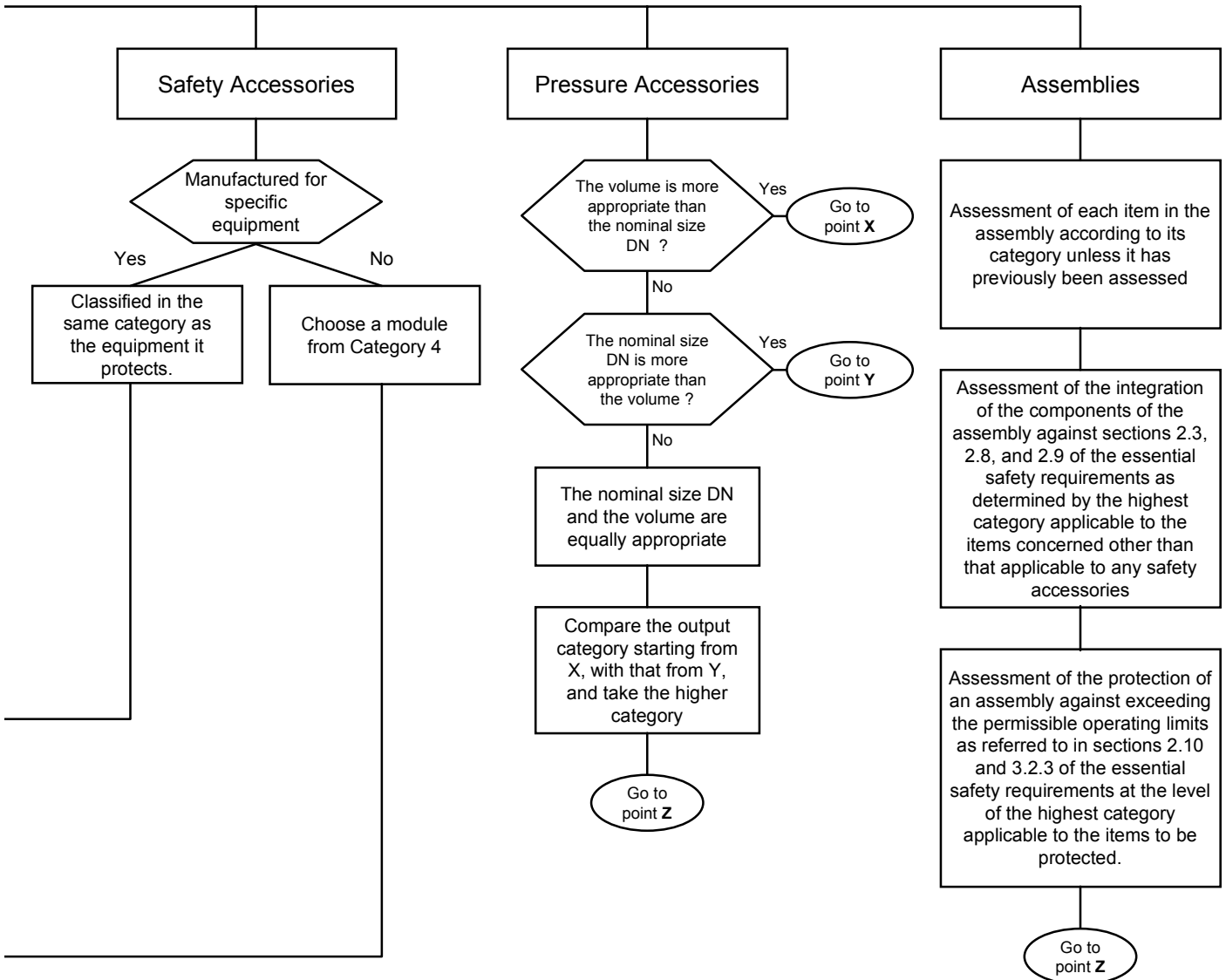
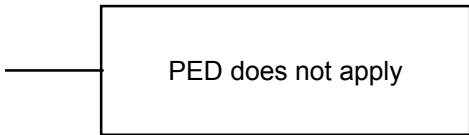
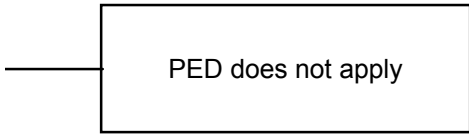


PRESSURE EQUIPMENT CLASSIFICATION

Note : X, Y and Z are entry points for pressure accessories and/or assemblies



AND CONFORMITY ASSESSMENT



ESSENTIAL SAFETY REQUIREMENTS

(See Page 10)

Note: Interpretation of some of the concepts used in the Essential Safety Requirements can be found under headings 4, 5 and 6 of the European Commission Guidelines on the <http://ped.eurodyn.com> website.

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.
2. The essential requirements laid down in the Regulations 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 conditions which are reasonably foreseeable by the manufacturer.
3. The manufacturer is under an obligation to analyse 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.
4. The essential 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 economic considerations which are consistent with a high degree of health and safety protection.

1. GENERAL

- 1.1. Pressure equipment must be designed, manufactured and 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.
- 1.2. In choosing the most appropriate solutions, the manufacturer must apply the principles set out below in the following order:
 - eliminate or reduce hazards as far as is reasonably practicable,
 - apply appropriate protection measures against hazards which cannot be eliminated,
 - where appropriate, inform users of residual hazards and indicate whether it is necessary to take appropriate special measures to reduce the risks at the time of installation and/or use.
- 1.3. Where the potential for misuse is known or can be clearly foreseen, the pressure equipment must be designed so as to prevent danger from such misuse or, if that is not possible, adequate warning given that the pressure equipment must not be used in that way.

2. DESIGN

2.1 General

The pressure equipment must be properly designed taking all relevant factors into account in order to ensure that the equipment will be safe throughout its intended life.

The design must incorporate appropriate safety coefficients using comprehensive methods which are known to incorporate adequate safety margins against all relevant failure modes in a consistent manner.

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:

- internal/external pressure,
- ambient and operational temperatures,
- static pressure and mass of contents in operating and test conditions,
- traffic, wind, earthquake loading,
- reaction forces and moments which result from the supports, attachments, piping, etc.
- corrosion and erosion, fatigue, etc.
- decomposition of unstable fluids.

Various loadings which can occur at the same time must be considered, taking into account the probability of their simultaneous occurrence.

2.2.2. Design for adequate strength must be based on:

- as a general rule, a calculation method, as described in 2.2.3, and supplemented if necessary by an experimental design method as described in 2.2.4, or
- 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 6 000 bar•L or the product $PS \cdot DN$ less than 3 000 bar.

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 behaviour of the material.

These calculation methods must provide sufficient safety margins consistent, **where applicable**, with the requirements of section 7.

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:

- design by formula,
 - design by analysis,
 - design by fracture mechanics;
- (b) Resistance

Appropriate design calculations must be used to establish the resistance of the pressure equipment concerned.

In particular:

- ❑ 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. 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,
- ❑ the calculation temperatures must allow for appropriate safety margins,
- ❑ the design must take appropriate account of all possible combinations of temperature and pressure which might arise under reasonably foreseeable operating conditions for the equipment,
- ❑ the maximum stresses and peak stress concentrations must be kept within safe limits,
- ❑ the calculation for pressure containment must utilise the values appropriate to the properties of the material, based on documented data, having regard to the provisions set out in section 4 together with appropriate safety factors. Material characteristics to be considered, where applicable, include:
 - yield strength, 0.2% or 1.0% proof strength as appropriate at calculation temperatures:
 - tensile strength,
 - time-dependent strength, i.e. creep strength,
 - fatigue data,
 - Young's modulus (modulus of elasticity),
 - appropriate amount of plastic strain,
 - impact strength,
 - fracture toughness,
- ❑ appropriate joint factors must be applied to the material properties depending, for example, on the type of non-destructive testing, the materials joined and the operating conditions envisaged
- ❑ 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. Attention must be drawn, in the instructions referred to in section 3.4, to particular features of the design which are relevant to the life of the equipment, for example:
 - for creep: design hours of operation at specified temperatures:
 - for fatigue: design number of cycles at specified stress levels:
 - for corrosion: design corrosion allowance

(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.

2.2.4. Experimental design method

The design of the equipment may be validated, in all or in part, by an appropriate test programme carried out on a sample representative of the equipment or the category of equipment.

The test programme must be clearly defined prior to testing and accepted by the notified body responsible for the design conformity assessment module, where it exists.

This programme must define test conditions and criteria for acceptance or refusal. The actual values of the essential dimensions and characteristics of the materials which constitute the equipment tested shall be measured before the test.

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.

The test programme 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 significant leaks or deformation exceeding a determined threshold.

The test pressure must be determined on the basis of the differences between the values of the geometrical and material characteristics measured under test conditions and the values used for design purposes; it must take into account the differences between the test and design temperatures;

- (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;
- (c) where necessary, additional tests concerning other factors referred to in 2.2.1 such as corrosion, external damage, etc.

2.3. Provisions to ensure safe handling and operation

The method of operation specified for pressure equipment must be such as to preclude any reasonably foreseeable risk in operation of the equipment. Particular attention must be paid, where appropriate, to:

- closures and openings,
- dangerous discharges of pressure relief blow off,
- devices to prevent physical access whilst pressure or a vacuum exists,
- surface temperature taking into consideration the intended use,
- 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. 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.

2.4. Means of examination

- (a) Pressure equipment must be designed and constructed so that all necessary examinations to ensure safety can be carried out;
- (b) Means of determining the internal condition of the equipment must be available, where this 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;
- (c) Other means of ensuring the safe condition of the pressure equipment may be applied:
 - where it is too small for physical internal access, or
 - where opening the pressure equipment would adversely affect the inside, or
 - 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.

2.5. Means of draining and ventilating

Adequate means must be provided for the draining and venting of pressure equipment where necessary:

- to avoid harmful effects such as water hammer, vacuum collapse, corrosion and uncontrolled chemical reactions. All stages of operation and testing, particularly pressure testing, must be considered,
- to permit cleaning, inspection and maintenance in a safe manner.

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.

2.7. Wear

Where severe conditions of erosion or abrasion may arise, adequate measures must be taken to:

- minimise that effect by appropriate design, e.g. additional material thickness, or by the use of liners or cladding materials,
- permit replacement of parts which are most affected,
- draw attention, in the instructions referred to in 3.4, to measures necessary for continued safe use.

2.8. Assemblies

Assemblies must be so designed that:

- the components to be assembled together are suitable and reliable for their duty,
- all the components are properly integrated and assembled in an appropriate manner.

2.9. Provisions for filling and discharge

Where appropriate, the pressure equipment must be so designed and provided with accessories, or provision made for their fitting, as to ensure safe filling and discharge in particular with respect to hazards such as:

- (a) on filling:
 - overfilling or overpressurisation having regard in particular to the filling ratio and to vapour pressure at the reference temperature,
 - Instability of the pressure equipment;
- (b) on discharge: the uncontrolled release of the pressurised fluid;
- (c) on filling or discharge: unsafe connection and disconnection.

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 provision made for the fitting of, suitable protective devices, unless the equipment is intended to be protected by other 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.

Suitable protective devices and combinations thereof comprise:

- (a) safety accessories;
- (b) where appropriate, adequate monitoring devices such as indicators and/or alarms which enable adequate action to be taken either automatically or manually to keep the pressure equipment within the allowable limits.

2.11. Safety accessories

2.11.1. *Safety accessories must:*

- be so designed and constructed as to be reliable and suitable for their intended duty and take into account the maintenance and testing requirements of the devices, where applicable,
- be independent of other functions, unless their safety function cannot be affected by such other functions,
- comply with appropriate design principles in order to obtain suitable and reliable protection. These principles include, in particular, fail-safe modes, redundancy, diversity and self-diagnosis.

2.11.2. *Pressure limiting devices*

These 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 laid down in 7.3 is allowable, where appropriate.

2.11.3. *Temperature monitoring devices*

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

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 its intended use.

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 a view to the aspects set out below.

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.

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.

The properties of permanent joints must meet the minimum properties specified for the materials to be joined unless other relevant property values are specifically taken into account in the design calculations.

For pressure equipment, permanent joining of components which contribute to the pressure resistance of equipment and components which are directly attached to them must be carried out by suitably qualified personnel according to suitable operating procedures.

For pressure equipment in categories II, III and IV operating procedures and personnel must be approved by a competent third party which, at the manufacturers discretion, may be:

- a notified body ⁽¹⁾,
- a third-party organisation recognised by a member State ⁽¹⁾.

To carry out these approvals the third party must perform examinations and tests as set out in the appropriate harmonised standards or equivalent examinations and tests or must have them performed.

3.1.3. *Non-destructive tests*

For pressure equipment, non-destructive tests of permanent joints must be carried out by suitably qualified personnel. For pressure equipment in categories III and IV, the personnel must be approved by a third-party organisation recognised by a member State ⁽¹⁾.

3.1.4 *Heat treatment*

Where there is a risk that the manufacturing process will change the material properties to an extent which would impair the safety of the pressure equipment, suitable heat treatment must be applied at the appropriate stage of manufacture.

3.1.5. *Traceability*

Suitable procedures must be established and maintained for identifying the material making up the components of the equipment which contribute to pressure resistance by suitable

⁽¹⁾ See Page 11

means from receipt through production, up to the final test of the manufactured pressure equipment.

3.2. Final assessment

Pressure equipment must be subjected to final assessment as described below.

3.2.1. Final inspection

Pressure equipment must undergo a final inspection to assess visually and by examination of the accompanying documents compliance with the requirements of the Regulations. Tests carried out during manufacture may be taken into account. 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 in the course of manufacture (e.g. where examination during the final inspection is no longer possible).

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 laid down in 7.4.

For category I series-produced pressure equipment, this test may be performed on a statistical basis.

Where the hydrostatic pressure test is harmful or impractical, other tests of a recognised value may be carried out. For tests other than the hydrostatic pressure test, additional measures, such as non destructive tests or other methods of equivalent validity, must be applied before those tests are carried out.

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 2.10.

3.3. Marking and labelling ⁽¹⁾

In addition to the CE marking, the following information must be provided:

(a) for all pressure equipment:

- the name and address or other means of identification of the manufacturer and, where appropriate, of his authorised representative established within the Community,
- the year of manufacture,
- identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number,
- essential maximum/minimum allowable limit;

(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:

- the volume V of the pressure equipment in L,
- the nominal size for piping DN,

⁽¹⁾ The Regulations require that where the equipment is to be placed on the market and put into service in the UK, the instructions, marking, labelling and information are in English. Other member States may require that such information is provided in the official language of that member State.

- the test pressure PT applied in bar and date,
 - safety device set pressure in bar,
 - output of the pressure equipment in kW,
 - supply voltage in V (volts),
 - intended use,
 - filling ratio kg/L,
 - maximum filling mass in kg,
 - tare mass in kg,
 - the product group;
- (c) where necessary, warnings fixed to the pressure equipment drawing attention to misuse which experience has shown might occur.

The CE marking and the required information must be given on the pressure equipment or on a dataplate firmly attached to it with the following exceptions:

- where applicable appropriate documentation 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 labelling referred to in this Annex;
- 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:
- labelling 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.

3.4. **Operating instructions** ⁽¹⁾

- (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:
- mounting including assembling of different pieces of pressure equipment,
 - putting into service,
 - use,
 - maintenance including checks by the user;
- (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;
- (c) If appropriate, these instructions must also refer to hazards arising from misuse in accordance with 1.3 and particular features of the design in accordance with 2.2.3.

⁽¹⁾ *The Regulations require, to the extent that it is needed for safe and correct use of pressure equipment and assemblies, that where equipment is to be placed on the market in the UK, the information required in Sections 3.3 and 3.4 is to be provided in English. Other member States may require that such information is provided in the official language of that member State.*

4. MATERIALS

Materials used for the manufacture of pressure equipment must be suitable for such application during the scheduled lifetime unless replacement is foreseen.

Welding consumables and other joining materials need fulfil 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.

4.1. Materials for pressurised parts must:

- (a) have appropriate properties for all operating conditions which are reasonably foreseeable and for all test conditions, and in particular they should be sufficiently ductile and tough. 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 in order to prevent brittle-type fracture where necessary; where for specific reasons brittle material has to be used appropriate measures must be taken;
- (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;
- (c) not be significantly affected by ageing;
- (d) be suitable for the intended processing procedures;
- (e) be selected in order to avoid significant undesirable effects when the various materials are put together.

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;

(b) the manufacturer must provide in his technical documentation elements relating to compliance with the materials specifications of the Directive in one of the following forms:

- by using materials which comply with harmonised standards,
- by using materials covered by a European approval of pressure equipment materials ⁽¹⁾,
- by a particular material appraisal;

(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 conformity assessment procedures for the pressure equipment.

4.3. The equipment manufacturer must take appropriate measures to ensure that the material used conforms with the required specification. In particular, documentation prepared by the material manufacturer affirming compliance with a specification must be obtained for all materials.

⁽¹⁾ A European approval for materials (EAM) is a technical document defining the characteristics of materials intended for repeated use in the manufacture of pressure equipment which are not covered by any harmonised standard. European approvals for materials will be issued in draft form, at the request of one or more manufacturers of materials or equipment, by a notified body specifically designated for the task and will then be subject to the approval of the procedure laid down in Article 11 of the PED.

For the main pressure bearing parts of equipment in categories II, III and IV, this must take the form of a certificate of specific product control.

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 the relevant requirements of this section.

SPECIFIC PRESSURE EQUIPMENT REQUIREMENTS

In addition to the applicable requirements of sections 1 to 4, the following requirements apply to the pressure equipment covered by sections 5 and 6.

5. FIRED OR OTHERWISE HEATED PRESSURE EQUIPMENT WITH A RISK OF OVERHEATING

This pressure equipment includes:

- steam and hot-water generators, 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, together with their accessories and where applicable their systems for treatment of feedwater and for fuel supply, and
- process-heating vessels for other than steam and hot water generation, such as heaters for chemical and other similar processes and pressurised food-processing equipment.

This pressure equipment must be calculated, designed and constructed so as to minimise risks of a significant loss of containment from overheating. In particular it must be ensured, where applicable, that:

- (a) appropriate means of protection are provided to restrict operating parameters such as heat input, heat take-off and, where applicable, fluid level so as to avoid any risk of local and general overheating,
- (b) sampling points are provided where required to allow evaluation of the properties of the fluid so as to avoid risks related to deposits and or corrosion,
- (c) adequate provisions are made to eliminate risks of damage from deposits,
- (d) means of safe removal of residual heat after shutdown are provided,
- (e) steps are taken to avoid a dangerous accumulation of ignitable mixtures of combustible substances and air, or flame blowback.

6. PIPING

Design and construction must ensure:

- (a) that 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) that 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) that due consideration is given to the potential damage from turbulence and formation of vortices; the relevant parts of 2.7 are applicable;
- (d) that due consideration is given to the risk of fatigue due to vibrations in pipes;
- (e) that, 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) that the risk of inadvertent discharge is minimised; the take-off points must be clearly marked on the permanent side, indicating the fluid contained;
- (g) that the position and route of underground piping is at least recorded in the technical documentation to facilitate safe maintenance, inspection or repair.

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 harmonised standards are applied, the manufacturer must demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.

This section is an integral part of this Annex. The provisions laid down in this section supplement the essential requirements of sections 1 to 6 for the pressure equipment to which they apply.

7.1. Allowable stresses

7.1.1. Symbols

$R_{e/t}$, yield limit, indicates the value at the calculation temperature of:

- the upper flow limit for a material presenting upper and lower flow limits
- the 1.0% proof strength for austenitic steel and non-alloyed aluminium
- the 0.2% proof strength in other cases.

$R_{m/20}$ indicates the minimum value of the ultimate strength 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:

- in the case of ferritic steel including normalized (normalized rolled) steel and excluding fine-grained steel and specially heat-treated steel, $\frac{2}{3}$ of $R_{e/t}$ and $\frac{5}{12}$ of $R_{m/20}$;
- in the case of austenitic steel:
 - if its elongation after rupture exceeds 30%, $\frac{2}{3}$ of $R_{e/t}$
 - or, alternatively, and if its elongation after rupture exceeds 35%, $\frac{5}{6}$ of $R_{e/t}$ and $\frac{1}{3}$ of $R_{m/t}$;
- in the case of non-alloy or low alloy cast steel, $\frac{10}{19}$ of $R_{e/t}$ and $\frac{1}{3}$ of $R_{m/20}$;
- in the case of aluminium $\frac{2}{3}$ of $R_{e/t}$;
- in the case of aluminium alloys excluding precipitation hardening alloys $\frac{2}{3}$ of $R_{e/t}$ and $\frac{5}{12}$ of $R_{m/20}$.

7.2. **Joint coefficients**

For welded joints, the joint coefficient must not exceed the following values:

- for equipment subject to destructive and non-destructive tests which confirm that the whole series of joints show no significant defects :1,
- for equipment subject to random non-destructive testing: 0.85,
- for equipment not subject to non-destructive testing other than visual inspection: 0.7.

If necessary, the type of stress and the mechanical and technological properties of the joint must also be taken into account.

7.3 **Pressure limiting devices, particularly for pressure vessels.**

The momentary pressure surge referred to in 2.11.2 must be kept to 10% of the maximum allowable pressure.

7.4. **Hydrostatic test pressure**

For pressure vessels, the hydrostatic test pressure referred to in 3.2.2 must be no less than:

- 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
- the maximum allowable pressure multiplied by the coefficient 1.43, whichever is the greater.

7.5. **Material characteristics**

Unless other values are required in accordance with other criteria that 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 its bending rupture energy measured on ISO V test piece is no less than 27 J, at a temperature not greater than 20°C but not higher than the lowest scheduled operating temperature.

Conformity Assessment Procedures

(see page 11)

Note: This annex contains a summary of the conformity assessment procedures contained in Schedule 4 of the Pressure Equipment Regulations (Annex III of the PED). Readers should refer to the Regulations themselves for a full statement of the requirements.

Module A Internal production control

This module describes the procedure by which manufacturer, or his authorised representative established in the Community, ensures and declares that pressure equipment satisfies the requirements of the Regulations which apply to it. It does **not** require the involvement of a notified body.

Manufacturer:

- draw up technical documentation which must enable an assessment to be made of the conformity of the pressure equipment with the requirements of the Regulations which apply to it. It must, as far as is relevant to such assessment, cover the design, manufacture and operation of the pressure equipment and contain:
 - a general description of the pressure equipment
 - conceptual design and manufacturing drawings
 - descriptions and explanations necessary for an understanding of the drawings and the operation of the pressure equipment
 - a list of the harmonised standards applied and a description of the solutions adopted to meet the essential safety requirements where harmonised standards have not been applied
 - results design calculations made, examinations carried out etc
 - test reports
- ensure manufacturing process complies with technical documentation
- affix CE marking
- draw up written declaration of conformity
- retain declaration of conformity and technical documentation for 10 years

Module A1 Internal production control with monitoring of final assessment

In addition to the requirements of Module A:

Manufacturer:

- choose a Notified Body

Notified Body:

- monitor final assessment & monitor by unexpected visits
- ensure manufacturer performs final assessment according to Section 3.2 of the essential safety requirements
- take samples of pressure equipment at manufacture or storage premises to conduct checks
- assess number to sample and whether it is necessary to perform or have performed, all or part of final assessment on the samples
- take appropriate action if items do not conform

Manufacturer:

- affix Notified Body identification number to each item

Module B EC type - examination

This module describes the part of the procedure whereby a Notified Body ascertains and attests that a representative example of the production meets the provisions of the Regulations which apply to it.

Manufacturer:

- lodge application for EC type-examination with a Notified Body which must include
 - the technical documentation as described under Module A
 - information on the tests provided for during manufacture
 - information on the qualifications or approvals of staff carrying out permanent joining and non-destructive tests
 - information on the operating procedures for permanent joining
- provide a representative example of production (a 'type') to the Notified Body

Notified Body:

- examine technical documentation
- verify type is manufactured in conformity with the technical documentation
- identify parts designed in accordance with harmonised & other relevant standards
- assess materials when not in conformity with harmonised standard or European approval and check material certificates
- approve procedures for permanent joining or check they have been previously approved
- verify that staff are qualified or approved for permanent joining and non-destructive testing
- where harmonised standards have been applied, perform appropriate examinations and tests to establish that they have actually been applied

- where harmonised standards have not been applied, perform appropriate examinations and tests to establish whether the essential safety requirements have been met
- if satisfied, issue EC type-examination certificate (valid 10 years)
- if an EC type-examination certificate is refused, provide detailed reasons
- additional approval of modifications
- retain copies of documentation and EC type-examination certificate

Manufacturer:

- inform Notified Body of any modifications
- retain documentation and copies of EC type-examination certificate for 10 years

Module B1 EC design-examination

This module describes the part of the procedure whereby a Notified Body ascertains and attests that the design of an item meets the provisions of the Regulations which apply to it.

Manufacturer:

- lodge application for EC design examination with Notified Body which must include
 - technical documentation as described under Module A
 - supporting evidence for the adequacy of the design solution
 - information on the qualifications or approvals of staff carrying out permanent joining and non-destructive tests
 - information on the operating procedures for permanent joining

Notified Body:

- examine technical documentation
- identify components which are designed in accordance with harmonised standards and those which are not
- assess materials not in conformity with harmonised standards or European approval
- approve procedures for permanent joining or check previous approvals
- verify staff are qualified or approved for permanent joining & non-destructive testing
- where harmonised standards have been applied, perform appropriate examinations to establish that they have been applied properly
- where harmonised standards have not been applied, perform appropriate examinations to establish whether the essential safety requirements have been met
- if satisfied, issue EC design-examination certificate

- if an EC design-examination certificate is refused, provide detailed reasons
- additional approval of modifications
- retain copies of documentation and EC design-examination certificate

Manufacturer:

- inform Notified Body of modifications to approved design
- keep technical documentation and copies of EC design-examination certificate for 10 years

Module C1

Monitoring of final assessment

This module describes procedures whereby the manufacturer, or authorised representative established in the Community, ensures and declares that the pressure equipment is in conformity with the type as described in the EC type-examination certificate (see Module B) and satisfies the requirements of the Regulations which apply to it.

Manufacturer:

- ensure that the manufacturing process produces pressure equipment which complies with the type as described in the EC type-examination certificate and with the requirements of the Regulations
- choose a Notified Body

Notified Body:

- monitor final assessment by unexpected visits
- ensure manufacturer performs final assessment according to Section 3.2 of the essential safety requirements
- take samples of pressure equipment at manufacturing and storage premises to conduct checks
- take appropriate action when equipment does not conform

Manufacturer:

- affix CE marking and Notified Body's identification number
- draw up written declaration of conformity
- hold copy of declaration of conformity for 10 years

Module D

Quality assurance for production, final inspection and testing

This module describes procedures whereby the manufacturer ensures and declares that the pressure equipment conforms with the type described in the EC type-examination certificate (see Module B) or the EC design-examination certificate (see Module B1) and satisfies the requirements of the Regulations which apply to it.

Manufacturer

- operate an approved quality system for production, final inspection and testing (eg 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 and with the requirements of the Regulations which apply to it
- lodge application for assessment of quality system with a Notified Body as described under Module D1 below but with the addition of technical documentation for the approved type and a copy of the EC type-examination certificate or EC design-examination certificate
- undertake to fulfil obligations arising from the quality system

Notified Body:

- assess quality system including an inspection visit to the manufacturers' premises
- include in the auditing team at least one member with experience of assessing the pressure equipment technology
- presume conformity in respect of the elements of the quality system which implement a relevant harmonised standard (eg ISO 9002)
- notify the manufacturer of assessment decision
- carry out surveillance visits to ensure that the manufacturer fulfils the obligations arising from the approved quality system
- carry out periodic audits such that a full reassessment is carried out every 3 years
- carry out unexpected visits to verify that the quality system is functioning correctly
- assess proposed changes to the quality system

Manufacturer:

- affix CE marking and identification number of Notified Body responsible for surveillance
- draw up written declaration of conformity
- inform the Notified Body of intended adjustments to the quality system
- hold documentation for 10 years.

NB For category III and IV vessels for Group 1 gases, Group 2 gases and Group 1 liquids and steam generators, the Notified Body, when performing unexpected visits, must take a sample of equipment and perform or have performed, the proof test referred to in Section 3.2.2 of the essential safety requirements

Module D1

Quality assurance for production, final inspection and testing

This module describes procedures whereby the manufacturer ensures and declares that the items of pressure equipment satisfy the requirements of the Regulations which apply to them.

Manufacturer:

- draw up technical documentation covering design, manufacture and operation as described under Module A
- operate an approved quality system for production, final inspection and testing (eg ISO 9002) which must ensure compliance of the pressure equipment with the requirements of the Regulations which apply to it.
- lodge application for assessment of quality system with a Notified Body which includes
 - relevant information on the pressure equipment concerned
 - documentation on the quality system including a description of
 - quality objectives and organisational structure
 - manufacturing, quality control and quality assurance techniques to be used
 - examinations and tests to be carried out
 - quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly with permanent joining
 - means of monitoring quality and the quality system
- undertake to fulfil obligations arising from the quality system

Notified Body:

- assess quality system including an inspection visit to the manufacturers' premises
- include in the auditing team at least one member with experience of assessing the pressure equipment technology
- presume conformity in respect of the elements of the quality system which implement a relevant harmonised standard (eg ISO 9002)
- notify the manufacturer of assessment decision
- carry out surveillance visits to ensure that the manufacturer fulfils the obligations arising from the approved quality system
- carry out periodic audits such that a full reassessment is carried out every 3 years
- carry out unexpected visits to verify that the quality system is functioning correctly
- assess proposed changes to the quality system

Manufacturer:

- affix CE marking and identification number of Notified Body responsible for surveillance
- draw up written declaration of conformity
- inform the Notified Body of intended adjustments to the quality system
- hold documentation for 10 years.

NB For category III and IV vessels for Group 1 gases, Group 2 gases and Group 1 liquids and steam generators, the Notified Body, when performing unexpected visits, must take a sample of equipment and perform or have performed, the proof test referred to in Section 3.2.2 of the essential safety requirements

Module E

Quality assurance for final inspection and testing

This module describes the procedures whereby the manufacturer ensures and declares the equipment is in conformity with the type described in the EC type-examination certificate (see Module B) and satisfies the requirements of the Regulations which apply to it.

Manufacturer:

- operate an approved quality system for final inspection and testing (eg ISO 9003) under which each item of pressure equipment must be examined and appropriate tests carried out to ensure its conformity with the requirements of the Regulations which apply to it.
- lodge application for assessment of quality system with a Notified Body as described under Module E1 below but with the addition of technical documentation for the approved type and a copy of the EC type-examination certificate
- undertake to discharge obligations arising from the quality system
- examine and test equipment as set out in relevant harmonised standard, or equivalent and, particularly, carry out final assessment as referred to in Section 3.2 of the essential safety requirements

Notified Body:

- assess quality system including an inspection visit to the manufacturers' premises
- include in the auditing team at least one member with experience of assessing the pressure equipment technology
- presume conformity in respect of the elements of the quality system which implement a relevant harmonised standard (e.g. ISO 9003)
- notify the manufacturer of assessment decision
- carry out surveillance visits to ensure that the manufacturer fulfils the obligations arising from the approved quality system
- carry out periodic audits such that a full reassessment is carried out every 3 years
- carry out unexpected visits to verify that the quality system is functioning correctly

- assess proposed changes to the quality system

Manufacturer:

- affix CE marking and identification number of Notified Body responsible for surveillance
- draw up written declaration of conformity
- inform the Notified Body of intended adjustments to the quality system
- hold documentation for 10 years.

NB For category III and IV vessels for Group 1 gases, Group 2 gases and Group 1 liquids and steam generators, the Notified Body, when performing unexpected visits, must take a sample of equipment and perform or have performed, the proof test referred to in Section 3.2.2 of the essential safety requirements

Module E1

Quality assurance for final inspection and testing

This module describes the procedure whereby the manufacturer ensures and declares that the equipment satisfies the requirements of the Regulations that apply to it.

Manufacturer:

- draw up technical documentation covering design, manufacture and operation as described under Module A
- operate an approved quality system for final inspection and testing (eg ISO 9003) under which each item of pressure equipment must be examined and appropriate tests carried out to ensure its conformity with the requirements of the Regulations which apply to it.
- lodge application for assessment of quality system with a Notified Body which includes
 - relevant information on the pressure equipment concerned
 - documentation on the quality system including a description of
 - quality objectives and organisational structure
 - procedures for the permanent joining of parts
 - examinations and tests to be carried out after manufacture
 - quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly with permanent joining
 - means of monitoring quality and the quality system
- undertake to discharge obligations arising from the quality system

Notified Body:

- assess quality system including an inspection visit to the manufacturers' premises
- include in the auditing team at least one member with experience of assessing the pressure

equipment technology

- presume conformity in respect of the elements of the quality system which implement a relevant harmonised standard (eg ISO 9003)
- notify the manufacturer of assessment decision
- carry out surveillance visits to ensure that the manufacturer fulfils the obligations arising from the approved quality system
- carry out periodic audits such that a full reassessment is carried out every 3 years
- carry out unexpected visits to verify that the quality system is functioning correctly
- assess proposed changes to the quality system

Manufacturer:

- affix CE marking and identification number of Notified Body responsible for surveillance
- draw up written declaration of conformity
- inform the Notified Body of intended adjustments to the quality system
- hold documentation for 10 years.

NB For category III and IV vessels for Group 1 gases, Group 2 gases and Group 1 liquids and steam generators, the Notified Body, when performing unexpected visits, must take a sample of equipment and perform or have performed, the proof test referred to in Section 3.2.2 of the essential safety requirements

Module F

Product verification

This module describes the procedure whereby the manufacturer, or his authorised representative established in the Community, ensures and declares the pressure equipment is in conformity with the type as described in the EC type-examination certificate or the EC design-examination certificate and satisfies the requirements of the Regulations which apply to it.

Manufacturer:

- ensure that the manufacturing process produces pressure equipment which is in conformity with the type described in the EC type-examination certificate (see Module B) or EC design examination certificate (see Module B1) and the requirements of the Regulations which apply to it
- choose a Notified Body

Notified Body:

- examine and test each item of pressure equipment, as set out in the relevant harmonised standard or equivalent, to verify that every item conforms to the type and the requirements of the Regulations
- verify qualifications of personnel responsible for permanent joining of parts and non-destructive

examination

- verify material manufacturers' certificates
- carry out, or have carried out, final inspection and proof test as referred to in Section 3.2 of the essential safety requirements
- examine safety devices, if applicable
- draw up written certificate of conformity relating to the tests
- affix or have affixed its identification number to each item.

Manufacturer:

- affix the CE marking
- draw up written declaration of conformity
- ensure that the certificates of conformity issued by the Notified Body are available on request
- keep copy of the declaration of conformity for 10 years

Module G

Unit verification

This module describes the procedure whereby the manufacturer ensures and declares the pressure equipment which has been issued with a certificate of conformity for tests carried out satisfies the requirements of the Regulations which apply to it.

Manufacturer:

- lodge application for unit verification with a Notified Body which must include
 - the technical documentation as described under Module A
 - information relating to the approval of the manufacturing and test procedures
 - information on the qualifications or approvals of staff carrying out permanent joining and non-destructive tests
 - information on the operating procedures for permanent joining

Notified Body:

- examine design and construction of each item
- examine technical documentation with respect to design and manufacturing procedures
- assess materials used where they do not conform to a relevant harmonised standard or European materials approval
- check certificates from material manufacturers
- approve procedures for permanent joining of parts or check previous approval
- verify personnel responsible for permanent joining of parts and non-destructive testing

- perform, during manufacture, appropriate tests set out in relevant harmonised standards or equivalent to ensure conformity with Regulations
- carry out final inspection and perform, or have performed, proof test
- examine the safety devices, if applicable
- affix identification number or have it affixed to the pressure equipment
- draw up certificate of conformity for the tests carried out

Manufacturer:

- affix CE marking
- draw up written declaration of conformity
- ensure that the certificates of conformity and declaration of conformity are available on request

Module H

Full quality assurance

This module describes the procedures whereby the manufacturer ensures and declares that the pressure equipment satisfies the requirements of the Regulations which apply to it.

Manufacturer:

- implement an approved quality system for design, manufacture and final inspection and testing (eg ISO 9001) which must ensure compliance of the pressure equipment with the requirements of the Regulations which apply to it
- lodge application for assessment of the quality system with a Notified Body which includes
 - relevant information on the pressure equipment concerned
 - documentation on the quality system including a description of
 - quality objectives and organisational structure
 - technical design specifications, including standards, that will be applied
 - design control and verification techniques, processes and systematic measures, particularly with regard to materials
 - manufacturing, quality control and quality assurance techniques to be used, particularly the procedures for permanent joining
 - examinations and tests to be carried out
 - quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly with permanent joining

- means of monitoring quality and the quality system
- undertake to fulfil obligations arising out of quality system

Notified Body:

- assess quality system including an inspection visit to the manufacturers' premises
- include in the auditing team at least one member with experience of assessing the pressure equipment technology
- presume conformity in respect of the elements of the quality system which implement a relevant harmonised standard (eg ISO 9001)
- notify the manufacturer of assessment decision
- carry out surveillance visits to ensure that the manufacturer fulfils the obligations arising from the approved quality system
- carry out periodic audits such that a full reassessment is carried out every 3 years
- carry out unexpected visits to verify that the quality system is functioning correctly
- assess proposed changes to the quality system

Manufacturer:

- affix CE marking and identification number of Notified Body responsible for surveillance
- draw up written declaration of conformity
- inform the Notified Body of intended adjustments to the quality system
- hold documentation for 10 years.

NB *For category III and IV vessels for Group 1 gases, Group 2 gases and Group 1 liquids and steam generators, the Notified Body, when performing unexpected visits, must take a sample of equipment and perform or have performed, the proof test referred to in Section 3.2.2 of the essential safety requirements*

For one-off production of category III steam generators the Notified Body must perform or have performed the proof test referred to in Section 3.2.2 of the essential safety requirements for each unit

Module H1

Full quality assurance with design examination and monitoring of the final assessment

In addition to the requirements of Module H:

Manufacturer:

- lodge application for examination of the design with a Notified Body. The application must enable the design, manufacture & operation of the pressure equipment to be understood and enable conformity with the relevant requirements of the Regulations to be assessed. It must include
 - technical design specifications, including standards
 - necessary supporting evidence for their adequacy, in particular where harmonised standards have not been applied in full
- inform the Notified Body of all modifications to the approved design

Notified Body:

- examine the application and, if satisfied, issue an EC design-examination certificate
- carry out increased surveillance of the final assessment in the form of unexpected visits which must include examinations on the pressure equipment
- assess any modifications to the approved design and give additional approval

DECLARATION OF CONFORMITY

(See Page 14)

The EC declaration of conformity must contain the following particulars:

- name and address of the manufacturer or of his authorized representative established within the Community,
- description of the pressure equipment or assembly,
- conformity assessment procedure followed,
- in the case of assemblies, description of the pressure equipment constituting the assembly, and the conformity assessment procedures followed,
- where appropriate, name and address of the notified body which carried out the inspection,
- where appropriate, a reference to the EC type-examination certificate, EC design-examination certificate or EC certificate of conformity,
- where appropriate, name and address of the notified body monitoring the manufacturer's quality assurance system,
- where appropriate, the references of the harmonized standards applied,
- where appropriate, other technical standards and specifications used,
- where appropriate, the references of the other Community Directives applied,
- particulars of the signatory authorized to sign the legally binding declaration for the manufacturer or his authorized representative established within the Community.