Supplment tal-Gazzetta tal-Gvern ta' Malta, Nru. 17,285, 3 ta' Settembru, 2002
Taqsima B

L.N. 248 of 2002

PRODUCT SAFETY ACT (ACT NO. V OF 2001)

Pressure Equipment Regulations, 2002

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Economic Services, on the advice of the Malta Standards Authority, has made the following regulations:-

Citation and commencement.

1.1. The title of these regulations is the Pressure Equipment Regulations, 2002.

1.2. These regulations shall become operative on the 1st September, 2002, which date shall be notified by the Authority in the Gazette.

1.2.1. Provided that the requirement of regulation 5 of these regulations and the CE marking shall not be obligatory prior to the 1st January, 2003 in respect of:

1.2.1.1. pressure equipment already placed on the market prior to the 1st September, 2002;

1.2.1.2. pressure equipment ordered before the 1st September, 2002 and imported into Malta up to the 31st August, 2002.

1.2.2. Provided that the requirement of regulation 5 of these regulations and the CE marking shall not be obligatory prior to the 1st January, 2003 in respect of pressure equipment manufactured in Malta up to 31st December, 2002 and which is in compliance with other Orders and/or regulations currently in force in Malta.

1.2.3. Provided that the requirement to provide information to the European Commission referred to in regulation 13.4 of these regulations shall come into force on such date as the Minister responsible for consumer affairs, after consultation with the Malta Standards Authority, may prescribe.

Scope.

2.1. These regulations shall apply to the design, manufacture and conformity assessment of pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar.

2.2. The following are excluded from the scope of these regulations:

2.2.1. 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;

2.2.2. 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;

2.2.3. equipment covered by Directive 87/404/EEC on simple pressure vessels as implemented by L.N. 229 of 1998: Simple Pressure Vessels Order 1998 (Order No. M35 of 1998);

2.2.4. 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], as implemented by L.N. 145 of 2002: Aerosol Dispensers Regulations, 2002;

2.2.5. 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], as implemented by L.N. 95 of 2002: Motor Vehicles (EC Type-Approval) Regulations, 2002,

- 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], as implemented by L.N. 97 of 2002: Wheeled Agricultural or Forestry Tractors (EC Type-Approval) Regulations, 2002,

[1]OJ No. L 147, 09.06.75, p. 40. Directive as last amended by Commission Directive 94/1/EC (OJ No. L 23, 28.01.94, p. 28).
[2]OJ No. L 42, 23.02.70, p. 01. Directive as last amended by Commission Directive 95/54/EC (OJ No L 266, 08.11.95, p. 01).
[3]OJ No. L 84, 28.03.74, p. 10. Directive as last amended by the 1994 Act of Accession.

- Council Directive 92/61/EEC of 30 June, 1992 relating to the type-approval of two or three-wheel motor vehicles[4], as implemented by L.N. 96 of 2002: Two or Three-Wheel Motor Vehicles (EC Type-Approval) Regulations, 2002,

2.2.6. equipment classified as no higher than category I under regulation 9 of these regulations and covered by one of the following Directives:

- Council Directive 89/392/EEC of 14 June, 1989 on the approximation of the laws of the Member States relating to machinery[5], as implemented by L.N. 250 of 2001: Machinery Regulations, 2001,

- 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], as implemented by L.N. 249 of 2001: Lifts Regulations, 2001,

- 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], as implemented by L.N. 23 of 1999: Low Voltage Electrical Equipment Order 1999 (Order No. M37 of 1999),

- Council Directive 93/42/EC of 14 June, 1993 concerning medical devices[8], as implemented by L.N. 67 of 2001: Medical Devices Regulations, 2001,

- 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], as implemented by L.N. 52 of 1996: Appliances Burning Gaseous Fuels Order 1996 (Order No. M33 of 1996),

- 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 the use in potentially explosive atmospheres[10], as implemented by L.N. 107 of 1999: The Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres Order 1999 (Order No. M42 of 1999);

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[4]OJ No. L 225, 10.08.92, p. 72. Directive as last amended by the 1994 Act of Accession.
[5]OJ No. L 183, 29.06.89, p. 09. Directive as last amended by Directive 93/68/EEC (OJ No L 220, 30.08.93, p. 01).
[6]OJ No. L 213, 07.09.95, p. 01.
[7]OJ No. L 77, 26.03.73, p. 29. Directive as last amended by Directive 93/68/EEC (OJ No L 220, 30.08.93, p. 01).
[8]OJ No. L 169, 12.07.93, p. 01.
[9]OJ No. L 196, 26.07.90, p. 15. Directive as last amended by Directive 93/68/EEC (OJ No. L 220, 30.08.93, p. 01).
[10]OJ No. L 100, 19.04.94, p. 01.

2.2.7. equipment covered by Article 223 (1) (b) of the Treaty;

2.2.8. items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;

2.2.9. 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;

2.2.10. 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, turbo-generators, compressors, pumps and actuating devices;

2.2.11. 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;

2.2.12. enclosures for high-voltage electrical equipment such as switchgear, control gear, transformers, and rotating machines;

2.2.13. pressurized pipes for the containment of transmission systems, e.g. for electrical power and telephone cables;

2.2.14. ships, rockets, aircraft and mobile off-shore units, as well as equipment specifically intended for installation on board or the propulsion thereof;

2.2.15. pressure equipment consisting of a flexible casing, e.g. tyres, air cushions, balls used for play, inflatable craft, and other similar pressure equipment;

2.2.16. exhaust and inlet silencers;

2.2.17. bottles or cans for carbonated drinks for final consumption;

2.2.18. vessels designed for the transport and distribution of drinks having a PS 7V of not more than 500 bar 7L and a maximum allowable pressure not exceeding 7 bar;

2.2.19. equipment covered by the ADR[11], the RID[12], the IMDG[13] and the ICAO Convention[14];

2.2.20. radiators and pipes in warm water heating systems;

2.2.21. vessels designed to contain liquids with a gas pressure above the liquid of not more than 0.5 bar.

3.1. For the purposes of these regulations, the following definitions shall apply: Definitions.

3.1.1. "The Directive" means Council Directive 97/23/EC[15] of the European Parliament and of the Council on the approximation of the laws of the Member States concerning pressure equipment.

3.1.2. "Pressure equipment" means vessels, piping, safety accessories and pressure accessories.

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

3.1.2.1. "Vessel" means a housing designed and built to contain fluids under pressure including its direct attachments up to the coupling point connecting it to other equipment. A vessel may be composed of more than one chamber.

3.1.2.2. "Piping" means piping components intended for the transport of fluids, when connected together for integration into a pressure system. Piping includes in particular 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.

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[11]ADR = European Agreement concerning the International Carriage of Dangerous Goods by Road.
[12]RID = Regulations concerning the International Carriage of Dangerous Goods by Rail.
[13]IMDG = International Maritime Dangerous Goods Code.
[14]ICAO = International Civil Aviation Organization.
[15]OJ No. L 181, 09.07.97, p. 01.

3.1.2.3. "Safety accessories" means devices designed to protect pressure equipment against the allowable limits being exceeded. Such devices include:

- devices for direct pressure limitation, such as safety valves, bursting disc safety devices, buckling rods, controlled safety pressure relief systems (CSPRS), and

- limiting devices, which either activate the means for correction or provide for shutdown or shutdown and lockout, such as pressure switches or temperature switches or fluid level switches and 'safety related measurement control and regulation (SRMCR)' devices.

3.1.2.4. "Pressure accessories" means devices with an operational function and having pressure-bearing housings.

3.1.2.5. "Assemblies" means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole.

3.1.3. "Pressure" means pressure relative to atmospheric pressure, i.e. gauge pressure. As a consequence, vacuum is designated by a negative value.

3.1.4. "Maximum allowable pressure PS" means the maximum pressure for which the equipment is designed, as specified by the manufacturer.

3.1.4.1. It is defined at a location specified by the manufacturer. This must be the location of connection of protective and/or limiting devices or the top of equipment or if not appropriate any point specified.

3.1.5. "Maximum/minimum allowable temperature TS" means the maximum/minimum temperatures for which the equipment is designed, as specified by the manufacturer.

3.1.6. "Volume (V)" means the internal volume of a chamber, including the volume of nozzles to the first connection or weld and excluding the volume of permanent internal parts.

3.1.7. "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 diameters or by thread size. It is a convenient round number for reference purposes and is only loosely

related to manufacturing dimensions. The nominal size is designated by DN followed by a number.

3.1.8. "Fluids" means gases, liquids and vapours in pure phase as well as mixtures thereof. A fluid may contain a suspension of solids.

3.1.9. "Permanent joints" means joints which cannot be disconnected except by destructive methods.

3.1.10. "European approval for materials" means a technical document defining the characteristics of materials intended for repeated use in the manufacture of pressure equipment which are not covered by any harmonized standard.

3.1.11. "Harmonised Standard" means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), upon a remit from the European Commission in accordance with Directive 98/34/EC[16] of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and regulations as amended by Directive 98/48/EC[17] of the European Parliament and of the Council.

3.1.12. "National Standard transposing the Harmonised Standard" means a Standard issued by one of the members of CEN/ CENELEC/ETSI which is declared and noted to be technically equivalent to the Harmonised Standard originally issued by CEN/ CENELEC/ETSI.

3.1.13. "OJ" means the Official Journal of the European Communities.

3.1.14. "Community" means the European Community.

3.1.15. "Essential health and safety requirements" means the requirements in Annex I of the Directive, which is set out in Schedule I hereto;

3.1.16. "Notified body" means a body responsible for carrying out functions relating to the conformity assessment procedures set out in Article 10 of the Directive and described in regulation 10 of these regulations which has been notified by the Member State concerned to

[16]OJ No. L 204, 21.07.98, p. 37.
[17]OJ No. L 217, 05.08.98, p. 18.

the Commission and the other Member States pursuant to Article 12 (1) of the Directive;

3.1.17. "CE marking" means the CE conformity marking consisting of the symbol "CE" as set out in Schedule VI to these regulations;

3.1.18. "Manufacturer" means the person:

3.1.18.1. who is primarily responsible for the design and construction of pressure equipment so that it complies with the requirements of these regulations;

3.1.18.2. who is responsible for "re-building" or modifying existing pressure equipment, and who in so doing is creating "as-new" pressure equipment;

3.1.18.3. who takes responsibility for the appraisal of the design, construction and any necessary modification of used imported pressure equipment.

3.1.19. "Local authorised representative" means any person (or organisation) established in Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations;

3.1.20. "Importer" means any person who places pressure equipment from a foreign country on to the Maltese market so that he supplies such pressure equipment on the first occasion that it is supplied in Malta;

3.1.21. "Person who supplies pressure equipment" means wholesalers, distributors, retailers etc.

3.1.22. "Supply" includes offering to supply, agreeing to supply, exposing for supply and possessing for supply, and cognate expressions shall be construed accordingly:

Provided that "supply" does not include exhibition at trade fairs and exhibitions of pressure equipment in respect of which the provisions of these regulations are not satisfied if a notice is displayed in relation to the product in question to the effect:–

3.1.22.1. that it does not satisfy those provisions; and

3.1.22.2. that it may not lawfully be supplied until the responsible person has ensured that those provisions are satisfied;

3.1.23. "Responsible person" in relation to pressure equipment means:

3.1.23.1. the manufacturer thereof;

3.1.23.2. the manufacturer's local authorised representative; or

3.1.23.3. where the manufacturer is not established in Malta and he has not appointed a local authorised representative, the person who places the pressure equipment on the local market.

3.1.24. "Placing on the market" means importation, wholesale, retail, sale and distribution free of charge.

3.1.25. "Safe" in relation to pressure equipment or an assembly, means that the pressure equipment or assembly when properly installed and maintained and used for its intended purpose is not liable to endanger the health or safety of persons and, where appropriate, domestic animals or property, and, where the context admits, cognate expressions shall be construed accordingly;

Applicability.

4.1. The provisions of these regulations are applicable to all imported pressure equipment as well as to that manufactured for the local market.

4.1.1. No person may construct, import, place on the market or put into service any pressure equipment which does not comply with the provisions of these regulations.

4.2. The free movement, placing on the market or putting into service in the Maltese territory of products which satisfy the provisions of these regulations shall not be impeded.

General requirements.

5.1. No person shall place on the market any pressure equipment to which these regulations apply unless the requirements of regulation 5.2 of these regulations below have been complied with in relation to it.

5.2. The requirements in respect of any pressure equipment are that:

5.2.1. it satisfies the essential safety requirements which are applicable to that pressure equipment and, for the purpose of satisfying those requirements where a transposed harmonised standard covers one

or more of the essential safety requirements, a product which conforms with that standard shall be presumed to comply with that or, as the case may be, those essential safety requirements;

5.2.2. the appropriate conformity assessment procedure in respect of the pressure equipment has been carried out in accordance with regulation 10 of these regulations;

5.2.3. the CE marking has been affixed to it by the manufacturer of the pressure equipment or his authorised representative in accordance with regulation 14 and Schedule VI to these regulations;

5.2.4. a declaration of conformity has been drawn up in respect of it by the manufacturer of the pressure equipment or his authorised representative containing the information listed in Schedule VII to these regulations; and

5.2.5. it is in fact safe.

5.3. Any technical documentation or other information in relation to an item of pressure equipment required to be retained under the conformity assessment procedure used shall be retained by the person specified in that respect in that conformity assessment procedure for any period specified in that procedure.

5.4. In respect of pressure equipment to be placed on the market and put into service in Malta, where the requirements of paragraphs 3.3 and 3.4 of Schedule I to these regulations are to be met, the marking, labelling, information and instructions shall be in either Maltese and/or English.

Technical requirements.

6.1. The pressure equipment referred to in regulations 6.1.1, 6.1.2, 6.1.3 and 6.1.4 of these regulations must satisfy the essential requirements set out in Annex I of the Directive, which is set out in Schedule I hereto.

6.1.1. Vessels, except those referred to in 6.1.2 for:

6.1.1.1. 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) within the following limits:

- for fluids in Group 1 with a volume greater than 1 L and pressure equipment of PS and V greater than 25 bar L, or with a

pressure PS greater than 200 bar (Annex II, table 1 of the Directive, which is set out in Schedule II hereto),

- for fluids in Group 2, with a volume greater than 1 L and pressure equipment of PS and V greater than 50 bar L, or with a pressure PS greater than 1 000 bar, and all portable extinguishers and bottles for breathing apparatus (Annex II, table 2 of the Directive, which is set out in Schedule II hereto);

6.1.1.2. liquids having a vapour pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:

- for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 200 bar L, or with a pressure PS greater than 500 bar (Annex II, table 3 of the Directive, which is set out in Schedule II hereto),

- for fluids in Group 2 with a pressure PS greater than 10 bar and a product of PS and V greater than 10 000 bar L, or with a pressure PS greater than 1 000 bar (Annex II, table 4 of the Directive, which is set out in Schedule II hereto).

6.1.2. 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 having a volume greater than 2L, and all pressure cookers (Annex II, table 5 of the Directive, which is set out in Schedule II hereto).

6.1.3. Piping intended for:

6.1.3.1. gases, liquified gases, gases dissolved under pressure, vapours and those liquids whose vapour pressure at the maximum allowable temperature is greater than 0.5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:

- for fluids in Group 1 with a DN greater than 25 (Annex II, table 6 of the Directive, which is set out in Schedule II hereto),

- for fluids in Group 2 with a DN greater than 32 and a product of PS and DN greater than 1 000 bar (Annex II, table 7 of the Directive, which is set out in Schedule II hereto);

6.1.3.2. liquids having a vapour pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure (1 013 mbar), within the following limits:

- for fluids in Group 1 with a DN greater than 25 and a product of PS and DN greater than 2 000 bar (Annex II, table 8 of the Directive, which is set out in Schedule II hereto),

- for fluids in Group 2 with a PS greater than 10 bar, a DN greater than 200 and a product of PS and DN greater than 5 000 bar (Annex II, table 9 of the Directive, which is set out in Schedule II hereto).

6.1.4. Safety and pressure accessories intended for equipment covered by regulations 6.1.1, 6.1.2 and 6.1.3 of these regulations, including where such equipment is incorporated into an assembly.

6.2. The assemblies defined in regulation 3.1.2.5 of these regulations, which include at least one item of pressure equipment covered by regulation 6.1 of these regulations and which are listed in regulations 6.2.1, 6.2.2 and 6.2.3 of these regulations must satisfy the essential requirements set out in Annex I of the Directive which is set out in Schedule I hereto.

6.2.1. 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.

6.2.2. Assemblies other than those referred to in regulation 6.2.1 of these regulations, if the manufacturer intends them to be placed on the market and put into service as assemblies.

6.2.3. By way of derogation from the introductory paragraph to this section, assemblies intended for generating warm water at temperatures not greater than 110°C which are manually fed with solid fuels and have a PS 7V greater than 50 bar 7L must comply with the essential requirements referred to in Annex I, sections 2.10, 2.11, 3.4, 5 (a) and 5 (d) of this Directive, which is set out in Schedule I hereto.

6.3. Pressure equipment and/or assemblies below or equal to the limits in regulations 6.1.1, 6.1.2 and 6.1.3 of these regulations respectively must be designed and manufactured in accordance with the sound engineering practice in Malta and/or in a Member State in order to ensure safe use. Pressure equipment and/or assemblies must be accompanied by adequate instructions for use and must bear markings to permit identification of the manufacturer or of his authorised representative. Such equipment and/or assemblies must not bear the CE marking referred to in regulation 14 of these regulations.

Free movement.

7.1. The placing on the market or putting into service under the conditions specified by the manufacturer of pressure equipment or assemblies referred to in regulation 3 of these regulations which comply with these regulations and bear the CE marking indicating that they have undergone conformity assessment in accordance with regulation 10 of these regulations, shall not be prohibited, restricted or impeded on grounds of the hazards due to pressure.

7.1.1. The placing on the market or putting into service of pressure equipment or assemblies which comply with regulation 6.3 or these regulations, shall not be prohibited, restricted or impeded on grounds of the hazards due to pressure.

7.2. The information referred to in Annex I, sections 3.3 and 3.4 of the Directive, which is set out in Schedule I hereto, to be provided in Maltese and/or English, may be required for safe and correct use of pressure equipment and assemblies.

Presumption of conformity.

8.1. Pressure equipment and assemblies bearing the CE marking provided for in regulation 14 of these regulations and the EC declaration of conformity provided for in Annex VII of the Directive, which is set out in Schedule VII hereto, shall be regarded as conforming to all the provisions of these regulations, including the conformity assessment provided for in regulation 10 of these regulations.

8.2. Pressure equipment and assemblies which conform to the national standards transposing the harmonized standards, the reference numbers of which have been published in the Official Journal of the European Communities shall be presumed to conform to the essential requirements referred to in regulation 6 of these regulations.

Classification of pressure equipment.

9.1. Pressure equipment referred to in regulation 6.1 of these regulations shall be classified by category in accordance with Annex II of the Directive, which is set out in Schedule II hereto according to ascending level of hazard.

For the purposes of such classification, fluids shall be divided into two groups in accordance with regulations 9.1.1 and 9.1.2 of these regulations.

9.1.1. Group 1 comprises dangerous fluids. A dangerous fluid is a substance or preparation covered by the definitions in Article 2 (2) of 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[18], as implemented by regulation 3.2 of the Dangerous Substances (Notification) Regulations, 2002 (L.N. 318 of 2001).

[18]OJ No. 196, 16.08.67, p. 01. Directive as last amended by Commission Directive 94/69/EC (OJ No. L 381, 31.12.94, p. 01).

Group 1 comprises fluids defined as:

- explosive,

- extremely flammable,

- highly flammable,

- flammable (where the maximum allowable temperature is above flashpoint),

- very toxic,

- toxic,

- oxidizing.

9.1.2. Group 2 comprises all other fluids not referred to in regulation 9.1.1 of these regulations.

9.2. Where a vessel is composed of a number of chambers, it shall be classified in the highest category applicable to the individual chambers. Where a chamber contains several fluids, classification shall be on the basis of the fluid which requires the highest category.

Conformity assessment.

10.1. Before placing pressure equipment on the market, the manufacturer shall subject each item of equipment to one of the conformity assessment procedures described in Annex III of the Directive, which is set out in Schedule III hereto, according to the conditions given in regulation 10 of these regulations.

10.1.1. The conformity assessment procedures to be applied to an item of pressure equipment with a view to affixing the CE marking shall be determined by the category, as defined in regulation 9 of these regulations, in which the equipment is classified.

10.1.2. The conformity assessment procedures to be applied for the various categories are as follows:

- category I
  Module A

- category II
  Module A1
  Module D1
  Module E1

- category III
  - Module B1 + D
  - Module B1 + F
  - Module B + E
  - Module B + C1
  - Module H

- category IV
  - Module B + D
  - Module B + F
  - Module G
  - Module H1

10.1.3. Pressure equipment shall be subjected to one of the conformity assessment procedures which may be chosen by the manufacturer among those laid down for the category in which it is classified. The manufacturer may also choose to apply one of the procedures which apply to a higher category, if available.

10.1.4. The framework of quality assurance procedures for equipment in categories III and IV referred to in regulation 6.1.1.1 and 6.1.1.2, first indent and regulation 6.1.2 of these regulations, the notified body shall, when performing unexpected visits, take a sample of equipment from the manufacturing or storage premises in order to perform, or have performed the final assessment as referred to in Annex I, section 3.2.2 of the Directive, which is set out in Schedule I hereto. To this end, the manufacturer shall inform the notified body of the intended schedule of production. The notified body shall carry out at least two visits during the first year of manufacturing. The frequency of subsequent visits shall be determined by the notified body on the basis of the criteria set out in section 4.4 of the relevant modules.

10.1.5. In the case of one-off production of vessels and equipment in Category III referred to in regulation 6.1.2 of these regulations under the module H procedure, the notified body shall perform or have performed the final assessment, as referred to in Annex I, section 3.2.2 of this Directive, which is set out in Schedule I hereto, for each unit. To this end, the manufacturer shall communicate the intended schedule of production to the notified body.

10.2. Assemblies referred to in regulation 6.2 of these regulations shall be subjected to a global conformity assessment procedure comprising:

10.2.1. assessment of each item of pressure equipment making up the assembly and referred to in regulation 6.1 of these regulations

which has not been previously subjected to a conformity assessment procedure and to a separate CE marking; the assessment procedure shall be determined by the category of each item of equipment;

10.2.2. the assessment of the integration of the various components of the assembly as referred to in Annex I, sections 2.3, 2.8 and 2.9 of the Directive, which is set out in Schedule I hereto, which shall be determined by the highest category applicable to the equipment concerned other than that applicable to any safety accessories;

10.2.3. the assessment of the protection of an assembly against exceeding the permissible operating limits as referred to in AnnexI, sections 2.10 and 3.2.3 of the Directive, which is set out in Schedule I hereto, shall be conducted in the light of the highest category applicable to the items of equipment to be protected.

10.3. The Director of Consumer Affairs may, were justified, by way of derogation from regulations 10.1 and 10.2 of these regulations allow the placing on the market and putting into service of individual pressure equipment items and assemblies referred to in regulation 3.1 of these regulations, in respect of which the procedures referred to in regulations 10.1 and 10.2 of these regulations have not been applied and the use of which is in the interests of experimentation.

10.4. Records and correspondance relating to conformity assessment shall be drawn up in either Maltese and/or English.

European approval for materials.

11.1. European approval for materials, as defined in regulation 3.1.10 of these regulations, shall be issued at the request of one or more manufacturers of materials or equipment, by a notified body specifically designated for that task. The notified body shall determine and perform, or arrange for the performance of, the appropriate inspections and tests to certify the conformity of the types of material with the corresponding requirements of these regulations; in the case of materials recognized as being safe to use before 29 November 1999, the notified body shall take account of the existing data when certifying such conformity.

11.2. The materials used for the manufacture of pressure equipment conforming with European approvals for materials, the references of which have been published in the *Official Journal of the European Communities*, shall be presumed to conform to the applicable essential requirements of Annex I of the Directive, which is set out in Schedule I hereto.

11.3. The notified body which issued the European approval for pressure equipment materials shall withdraw that approval if it finds

that it should not have been issued or if the type of materials is covered by a harmonized standard. It shall immediately inform the other Member States, the notified bodies and the Commission of any withdrawal of an approval.

User inspectorates.

12.1. By way of derogation from the provisions relating to the tasks carried out by the notified bodies, the Director of Consumer Affairs may authorize the placing on the market, and the putting into service by users, of pressure equipment or assemblies referred to in regulations 2 and 3 of these regulations of which conformity with the essential requirements has been assessed by a user inspectorate designated in accordance with the criteria referred to in regulation 12.7 of these regulations.

12.2. When a user inspectorate has been designated in accordance with the criteria set out in regulation 12 of these regulations, the Director of Consumer Affairs may not, on grounds of the hazards due to pressure, prohibit, restrict or impede the placing on the market or putting into service, under the conditions provided for in regulation 12 of these regulations, of pressure equipment or assemblies the conformity of which has been assessed by a user inspectorate designated by an other Member State in accordance with the criteria set out in regulation 12 of these regulations.

12.3. Pressure equipment and assemblies the conformity of which has been assessed by a user inspectorate shall not bear the CE marking.

12.4. The pressure equipment and assemblies referred to may be used only in establishments operated by the group of which the inspectorate is part. The group shall apply a common safety policy as regards the technical specifications for the design, manufacture, inspection, maintenance and use of pressure equipment and assemblies.

12.5. The user inspectorates shall act exclusively for the group of which they are part.

12.6. The conformity assessment procedures applicable by user inspectorates shall be modules A1, C1, F and G, as described in Annex III of the Directive, which is set out in Schedule III hereto.

12.7. The criteria listed in Annex V of the Directive, which is set out in Schedule V hereto, shall be applied in designating the user inspectorates and it shall be ensured that the group of which the inspectorate is part applies the criteria referred to in the second sentence of regulation 12.4 of these regulations.

12.8. The authorisation of a user inspectorate shall be withdrawn if the user inspectorate no longer meets the criteria referred to in regulation 12.7 of these regulations.

Withdrawal and prohibition from market.

13.1. Where it is ascertained that pressure equipment or assemblies referred to in regulations 2 and 3 of these regulations and bearing the CE marking referred to in Schedule VI to these regulations, when correctly constructed, installed, maintained and used in accordance with their intended purpose may endanger the safety and health of persons, property or the environment, the Director of Consumer Affairs shall take all appropriate measures to withdraw such equipment or assemblies from the market, prohibit the placing on the market, putting into service or use thereof, or restrict free movement thereof.

13.1.1. The Director of Consumer Affairs shall immediately inform the Consumer and Industrial Goods Directorate[19] of the Malta Standards Authority of any such measure, indicating the reason for its decision and, in particular, whether non-conformity is due to:-

13.1.1.1. failure to satisfy the essential requirements referred to in regulation 6 of these regulations;

13.1.1.2. incorrect application of the standards referred to in regulation 8.2 of these regulations;

13.1.1.3. shortcomings in the standards themselves referred to in regulation 8.2 of these regulations;

13.1.1.4. shortcomings in the European approval of pressure equipment materials as referred to in regulation 11 of these regulations.

13.2. Where a non-complying pressure equipment or assembly, referred to in regulation 6 of these regulations bears the CE marking, the Director of Consumer Affairs shall take appropriate action against whom so ever has affixed the marking or drawn up the declaration and shall so inform the Consumer and Industrial Goods Directorate of the Malta Standards Authority.

13.3. Any decision taken pursuant to these regulations which restricts the placing on the market and putting into service of products shall state the exact grounds on which it is based.

13.3.1. Such a decision shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the

[19]L.N. 213 of 2000 – Malta Standards Authority (Establishment of Directorates) Order, 2000, published in the Government Gazette No. 17,002 of 20th October, 2000.

legal remedies available to him under the laws in force in Malta and of the time limits to which such remedies are subject.

13.4. The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulations 13.1.1. and 13.2. of these regulations.

13.5. All appropriate measures shall be taken to encourage the local authorities responsible for implementing these regulations to cooperate with each other and provide each other with information in order to assist the functioning of these regulations.

CE Marking.

14.1. The CE marking consists of the initials "CE" in accordance with the model in Annex VI of the Directive, which is set out in Schedule VI hereto.

14.1.1. The CE marking shall be accompanied by the identification number, as referred to in Article 12 (1) of the Directive, of the notified body involved at the production control phase..

14.2. The CE marking shall be affixed in a visible, easily legible and indelible fashion to each

- item of pressure equipment referred to in regulation 6.1 of these regulations, or

- assembly referred to in regulation 6.2 of these regulations which is complete or is in a state permitting final assessment as described in Annex I, section 3.2 of the Directive, which is set out in Schedule I hereto.

14.3. It is not necessary for the CE marking to be affixed to each individual item of pressure equipment making up an assembly as referred to in regulation 6.2 of these regulations. Individual items of pressure equipment already bearing the CE marking when incorporated into the assembly shall continue to bear that marking.

14.4. Subject to regulation 14.5 below, where any pressure equipment or assembly is subject to other directive or directives covering other aspects which provide for the affixing of the CE marking, the latter shall indicate that the pressure equipment or assembly in question is also presumed to conform to the provisions of that other directive or those directives.

14.5. Where one or more of the other directives referred to in regulation 14.4 of these regulations, allow the manufacturer during a transitional period to choose which arrangements to apply, the CE marking shall indicate conformity only with the directive or directives applied by the manufacturer. In this case, the particulars of the said directives, as published in the Official Journal of the European Communities, must be given in the documents, notices or instructions required by the directives and accompanying the pressure equipment or assembly in question.

14.6. No person shall affix on any pressure equipment or assemblies, to which these regulations apply, any markings or inscriptions which are likely to mislead third parties with regard to the meaning or the form of the CE marking.

14.7. Without prejudice to regulation 14.6 of these regulations, nothing in these regulations shall prohibit the affixing on any pressure equipment or assemblies, or on the packaging of any such pressure equipment, of any other markings, provided that the visibility and legibility of the CE marking are not thereby reduced.

14.8. Without prejudice to regulation 13:

14.8.1. where it is established that the CE marking has been affixed wrongly, the manufacturer or his authorized representative shall be obliged to end the infringement under conditions laid down by the Director of Consumer Affairs;

14.8.2. where non-compliance continues, the Director of Consumer Affairs shall take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market, in accordance with the procedure laid down in regulation 13 of these regulations.

SCHEDULE I

Based on Annex I of the Directive

ESSENTIAL SAFETY REQUIREMENTS

PRELIMINARY OBSERVATIONS

1. The obligations arising from the essential requirements listed in this Schedule 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 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 point 2.2.3 of this Schedule, and supplemented if necessary by an experimental design method as described in point 2.2.4 of this Schedule, or

- an experimental design method without calculation, as described in point 2.2.4 of this Schedule, when the product of the maximum allowable pressure PS and the volume V is less than 6 000 bar 7L or the product PS 7DN 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 of this Schedule.

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 utilize the values appropriate to the properties of the material, based on documented data, having regard to the provisions set out in section 4 of this Schedule 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 temperature,

- 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 of this Schedule, 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 measures 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 point 2.2.1 of this Schedule 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 discharge 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 it is necessary to ensure the continued safety of the equipment, such as access openings allowing physical access to the inside of the pressure equipment so that appropriate examinations can be carried out safely and ergonomically;

(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 venting

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:

- minimize 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 section 3.4 of this Schedule 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 overpressurization 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 pressurized 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 as defined in regulation 3.1.2.3 of these regulations,

(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 section 7.3 of this Schedule 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 who, at the manufacturer's discretion, may be:

- a notified body,

- a third-party organization recognized by a Member State as provided for in Article 13 of the Directive.

To carry out these approvals the third party must perform examinations and tests as set out in the appropriate harmonized 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 suitable qualified personnel. For pressure equipment in categories III and IV, the personnel must be approved by a third-party organization recognized by a Member State pursuant to Article 13 of the Directive.

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 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 Directive. 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 section 7.4 of this Schedule.

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

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

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 section 2.10 of this Schedule.

3.3 Marking and labelling

In addition to the CE marking referred to in regulation 14 of these regulations, 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 authorized representative,

- the year of manufacture,

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

- essential maximum/minimum allowable limits;

(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,

- 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 Schedule;

- 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

(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 section 3.3 of this Schedule, 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 section 1.3 of this Schedule and particular features of the design in accordance with point 2.2.3 of this Schedule.

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 sections 4.1, 4.2 (a) and the first paragraph of 4.3 of this Schedule, in an appropriate way, both individually and in a joined structure.

4.1. Materials for pressurized 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 section 7.5 of this Schedule. 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. The pressure equipment manufacturer must define in an appropriate manner the values

(a) necessary for the design calculations referred to in point 2.2.3 of this Schedule and the essential characteristics of the materials and their treatment referred to in section 4.1 of this Schedule;

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

- by using materials which comply with harmonized standards,

- by using materials covered by a European approval of pressure equipment materials in accordance with regulations 11 of these regulations,

- 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.

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 of this Schedule, the following requirements apply to the pressure equipment covered by sections 5 and 6 of this Schedule.

5. FIRED OR OTHERWISE HEATED PRESSURE EQUIPMENT WITH A RISK OF OVERHEATING AS REFERRED TO IN REGULATION 6.1 OF THESE REGULATIONS.

This pressure equipment includes:

- steam and hot-water generators as referred to in regulation 6.1.2 of these regulations such as fired steam and hotwater 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 equipment for other than steam and hot water generation falling under regulation 6.1.1 of these regulations, such as heaters for chemical and other similar processes and pressurized foodprocessing equipment.

This pressure equipment must be calculated, designed and constructed so as to avoid to minimize 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 AS REFERRED TO IN REGULATION 6.1.3. OF THESE REGULATIONS

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 section 2.7 of this Schedule 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 minimized; 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 harmonized 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 Schedule I. 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

Re/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 of austenitic steel and non-alloyed aluminium,

- the 0.2 % proof strength in other cases.

Rm/20 indicates the minimum value of the ultimate strength 20°C.

Rm/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, 2/3 of Re/t and 5/12 of Rm/20;

- in the case of austenitic steel:

- if its elongation after rupture exceeds 30 %, 2/3 of Re/t

- or, alternatively, and if its elongation after rupture exceeds 35 %, 5/6 of Re/t and 1/3 of Rm/t ;

- in the case of non-alloy or low-alloy cast steel, 10/19 of Re/t and 1/3 of Rm/20 ;

- in the case of aluminium, 2/3 of Re/t ;

- in the case of aluminium alloys excluding precipitation hardening alloys 2/3 of Re/t and 5/12 of Rm/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 point 2.11.2 of this Schedule 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 point 3.2.2 of this Schedule 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 section 4.1 (a) of this Schedule 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 an 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.

SCHEDULE II

Based on Annex II of the Directive

CONFORMITY ASSESSMENT TABLES

1. The references in the tables to categories of modules are the following:

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

2. The safety accessories defined in regulation 3.1.2.3 of these regulations and referred to in regulation 6.1.4 of these regulations are classified in category IV. However, by way of exception, safety accessories manufactured for specific equipment may be classified in the same category as the equipment they protect.

3. The pressure accessories defined in regulation 3.1.2.4 of these regulations and referred to in regulation 6.1.4 of these regulations, are classified on the basis of:

- their maximum allowable pressure PS, and

- their volume V or their nominal size DN, as appropriate, and

- the group of fluids for which they are intended, and the appropriate table for vessels or piping is to be used to determine the conformity assessment category.

4. Where both the volume and the nominal size are considered appropriate in the second indent, the pressure accessory must be classified in the highest category.

5. The demarcation lines in the following conformity assessment tables indicate the upper limit for each category.

Table 0: Product Classifications and relevant tables

	VESSELS				STEAM GENERATORS	PIPING			
State of Contents	Gas		Liquid			Gas		Liquid	
Fluid Group	Dang.	Oth.	Dang.	Oth.		Dang.	Oth.	Dang.	Oth.
Refer to Table/Graph of this Schedule	1	2	3	4	5	6	7	8	9

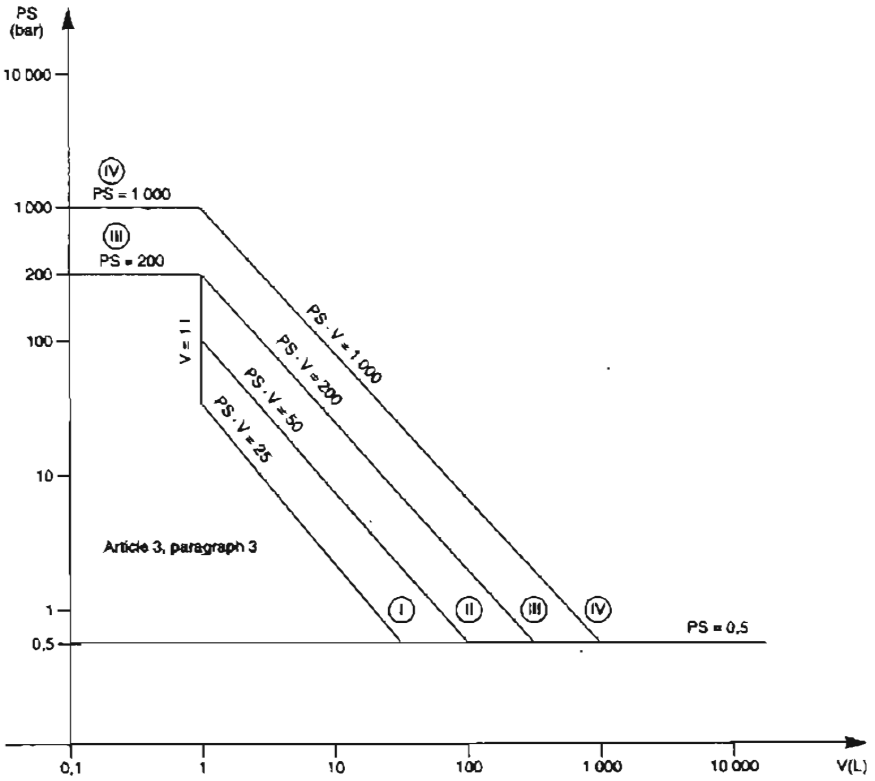


Table 1

Vessels referred to in regulation 6.1.1.1 of these regulations, first indent

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

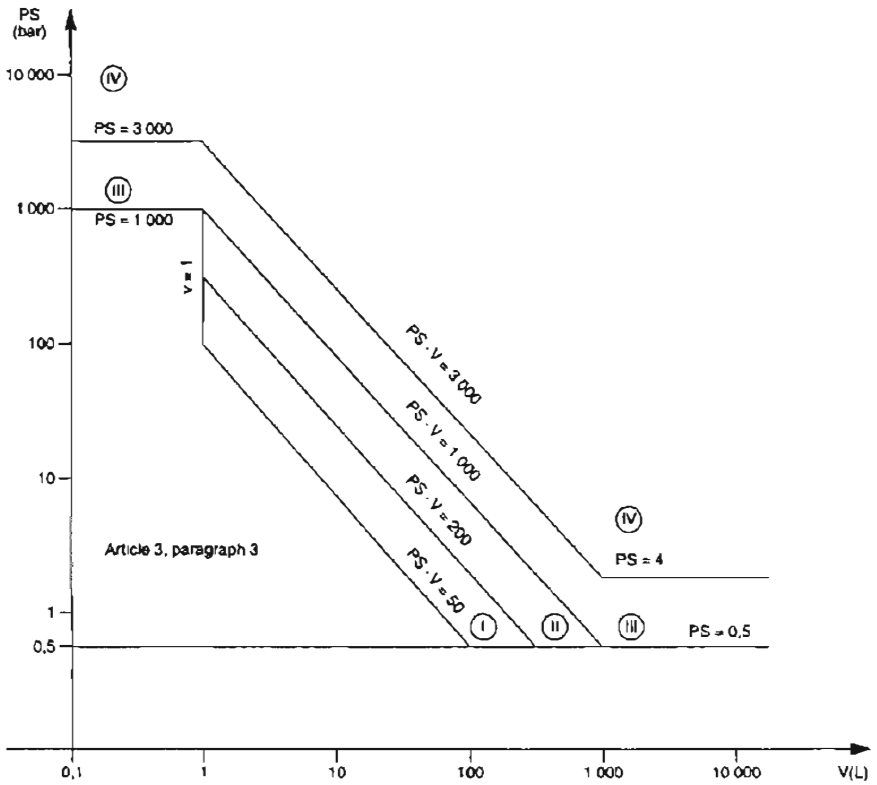


Table 2

Vessels referred to in regulation 6.1.1.1 of these regulations, second indent

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

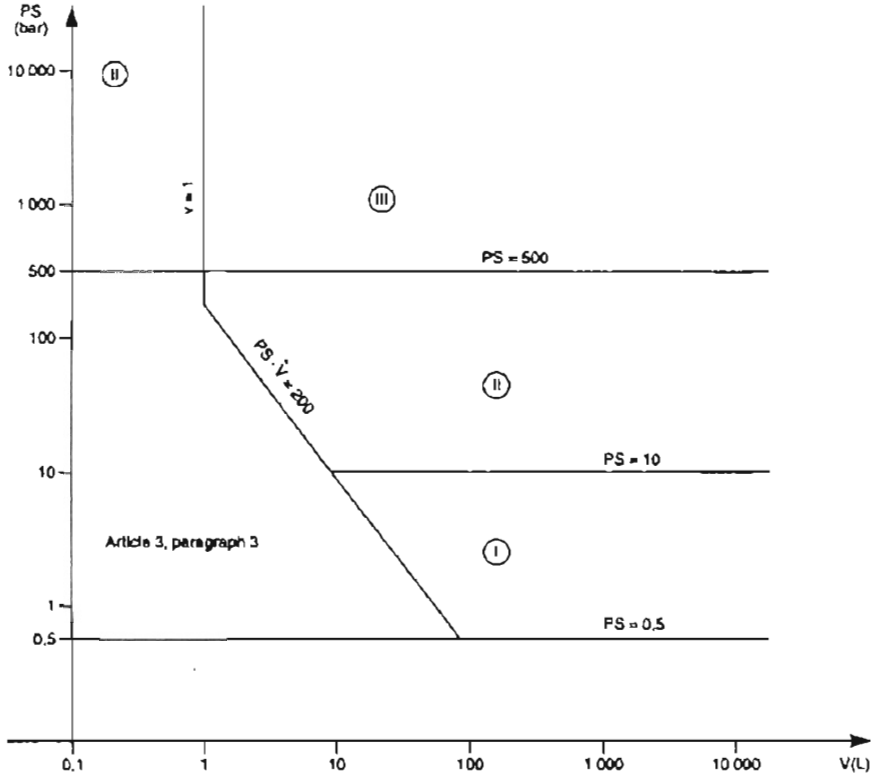


Table 3

Vessels referred to in regulation 6.1.1.2 of these regulations, first indent

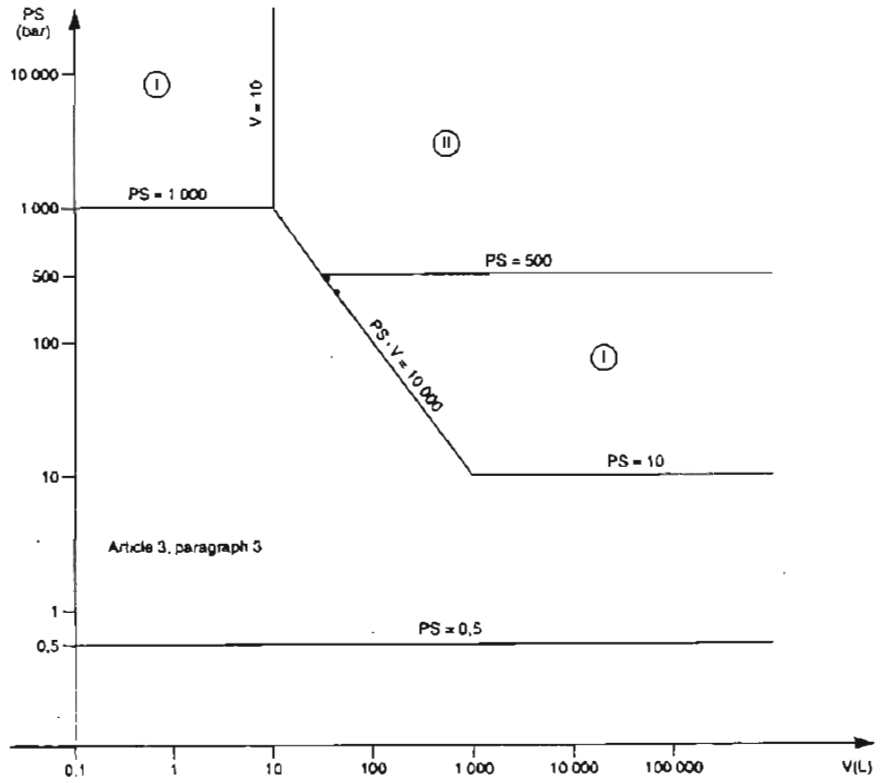


Table 4

Vessels referred to in regulation 6.1.1.2 of these regulations, second indent

Exceptionally, assemblies intended for generating warm water as referred to in regulation 6.2.3 of these regulations must be subject either to an EC design examination (Module B1) with respect to their conformity with the essential requirements referred to in Annex I, sections 2.10, 2.11, 3.4, 5 (a) and 5 (d) of the Directive, which is set out in Schedule I hereto, or to full quality assurance (Module H).

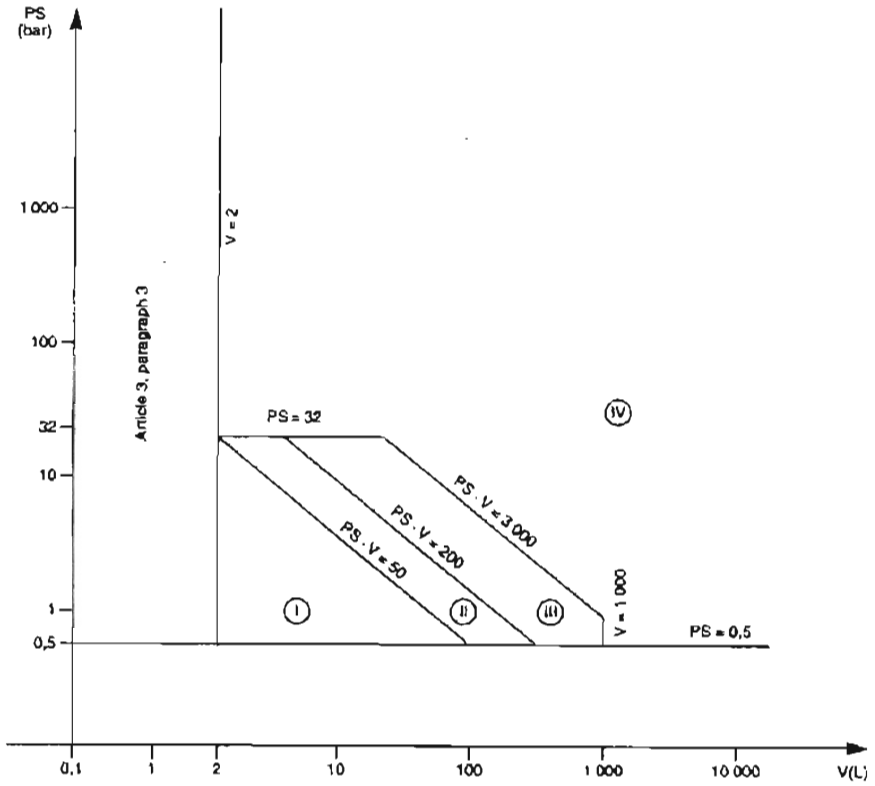


Table 5

Pressure equipment referred to in regulation 6.1.2 of these regulations

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

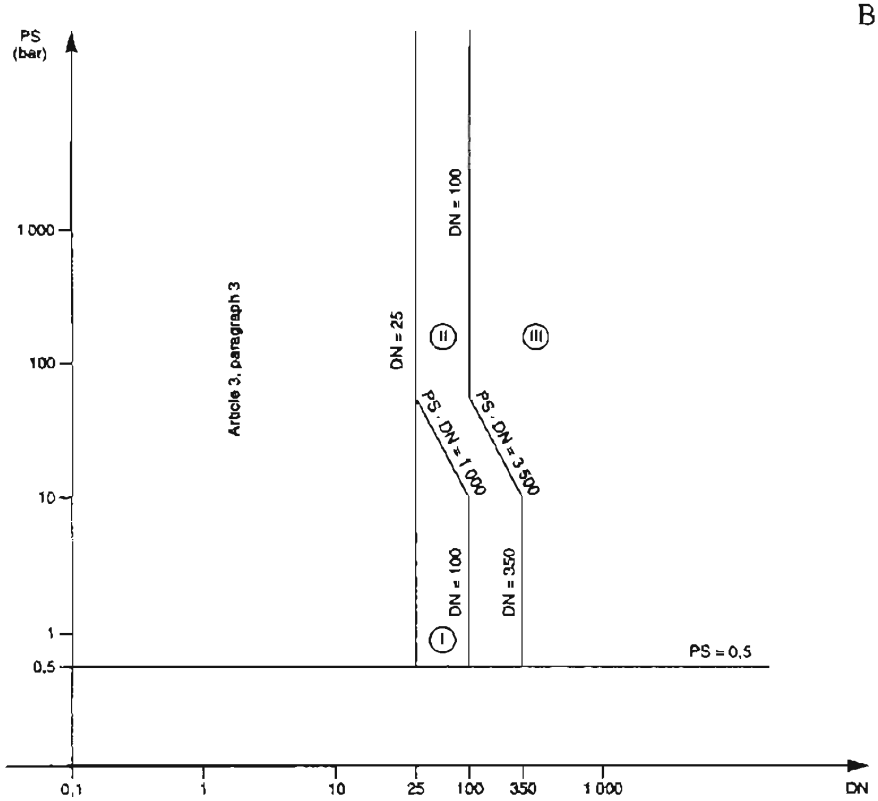


Table 6

Piping referred to in regulation 6.1.3.1 of these regulations, first indent

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

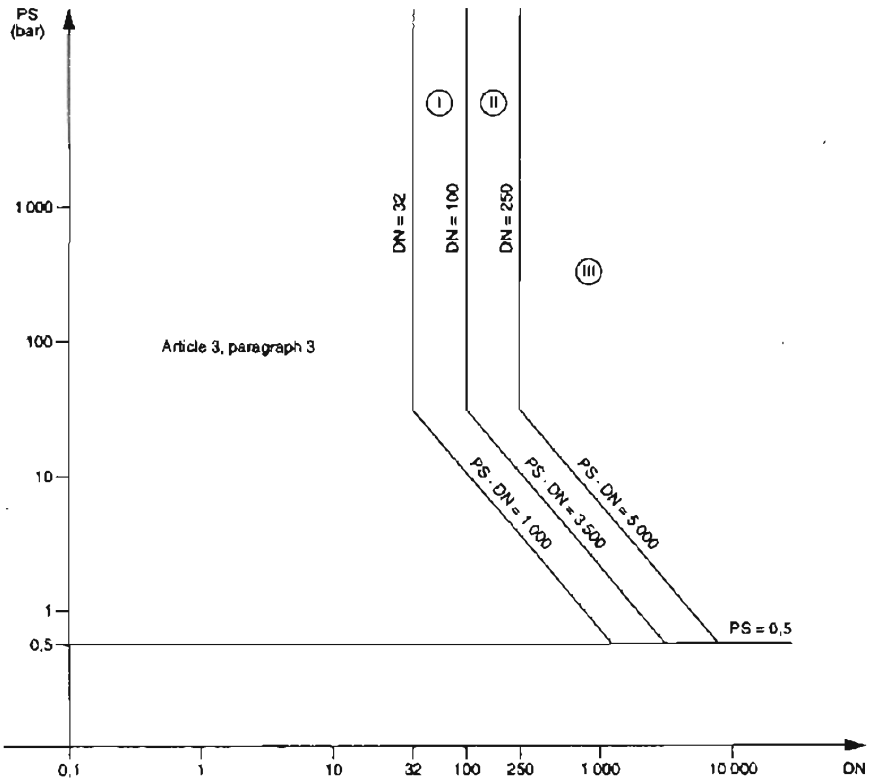


Table 7

Piping referred to in regulation 6.1.3.1 of these regulations, second indent

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

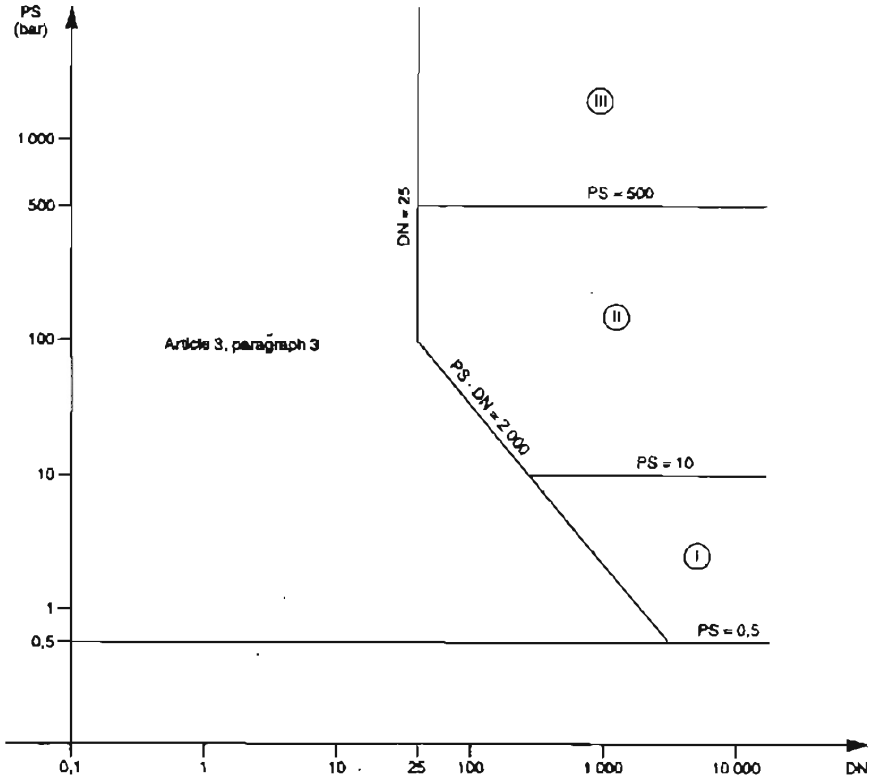


Table 8

Piping referred to in Regulation 6.1.3.2 of these regulations, first indent

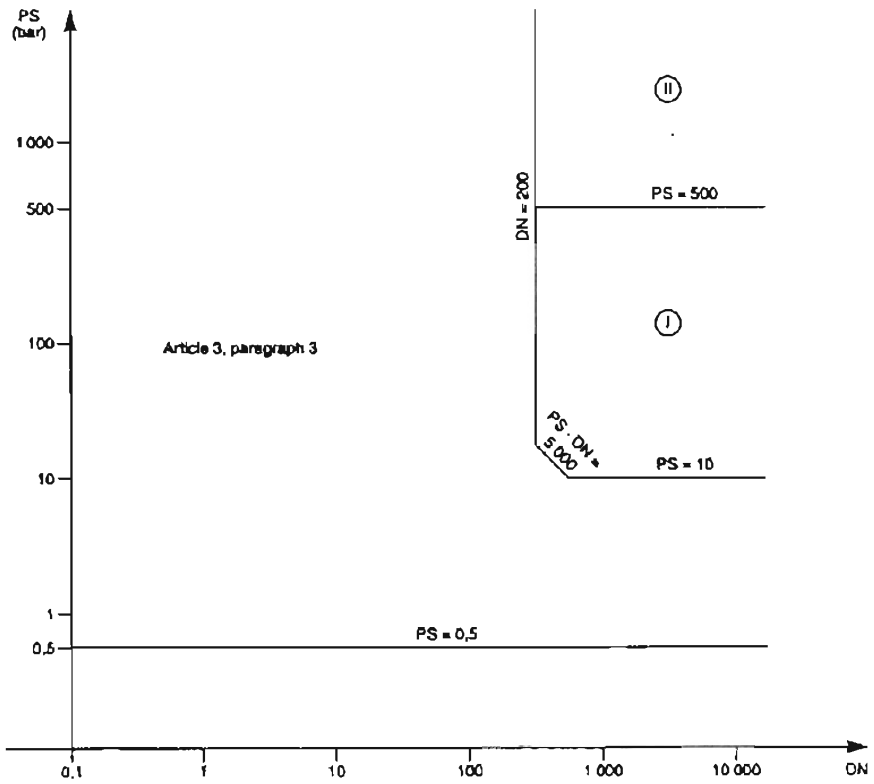


Table 9

Piping referred to in Regulation 6.1.3.2

SCHEDULE III

Based on Annex III of the Directive

CONFORMITY ASSESSMENT PROCEDURES

The obligations arising from the provisions on pressure equipment in this Schedule also apply to assemblies.

Table 10: summary of Modules for each category

Safety Hazard	Conformity Assessment Modules
I	A
II	A1 D1 E1
III	B1 + D B1 + F B + E B + C1 H
IV	B + D B + F G H1

Module A (internal production control)

1. This module describes the procedure whereby the manufacturer or his authorized representative who carries out the obligations laid down in section 2 of this Schedule ensures and declares that pressure equipment satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorized representative, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity.

2. The manufacturer must draw up the technical documentation described in section 3 of this Schedule and either the manufacturer or his authorized representative must keep it at the disposal of the relevant national authorities for inspection purposes for a period of ten years after the last of the pressure equipment has been manufactured.

Where neither the manufacturer nor his authorized representative is established in Malta, the obligation to keep the technical documentation available is the responsibility of the person who places the pressure equipment on the market.

3. The technical documentation 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 for 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 and diagrams of components, sub-assemblies, circuits, etc.,

descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,

- a list of the standards referred to in regulation 8 of these regulations, applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the regulations where the standards referred to in regulation 8 of these regulations have not been applied,

- results of design calculations made, examinations carried out, etc.,

- test reports.

The manufacturer, or his authorized representative, must keep a copy of the declaration of conformity with the technical documentation.

The manufacturer must take all measures necessary to ensure that the manufacturing process requires the manufactured pressure equipment to comply with the technical documentation referred to in section 2 of this module and with the requirements of the regulations which apply to it.

Module A1 (internal manufacturing checks with monitoring of the final assessment)

In addition to the requirements of module A, the following applies.

Final assessment must be performed by the manufacturer and monitored by means of unexpected visits by a notified body chosen by the manufacturer.

During such visits the notified body must:

- establish that the manufacturer actually performs final assessment in accordance with Annex I, section 3.2 of the Directive, which is set out in Schedule I hereto.

- take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks.

The notified body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the pressure equipment samples.

Should one or more of the items of pressure equipment not conform, the notified body must take appropriate measures.

On the responsibility of the notified body, the manufacturer must affix the former's identification number on each item of pressure equipment.

Module B (EC-type examination)

1. This module describes the part of the procedure by which a notified body ascertains and attests that a representative example of the production in question meets the provisions of the regulations which apply to it.

2. The application for EC type-examination must be lodged by the manufacturer or by his authorized representative with a single notified body of his choice.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well,

- a written declaration that the same application has not been lodged with any other notified body,

- the technical documentation described in section 3 if this module.

3. The applicant must place at the disposal of the notified body a representative example of the production envisaged, hereinafter called 'type'. The notified body may request further examples should the test programme so require.

A type may cover several versions of pressure equipment provided that the differences between the versions do not affect the level of safety.

The technical documentation 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 for such assessment, cover the design, manufacture and operation of the pressure equipment and contain:

- a general description of the type,

- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,

- a list of the standards referred to in regulation 8 of these regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the regulations where the standards referred to in regulation 8 of these regulations have not been applied,

- results of design calculations made, examinations carried out, etc.,

- test reports,

- information concerning the tests provided for in manufacture,

- information concerning the qualifications or approvals required under of Annex I, sections 3.1.2 and 3.1.3 of the Directive, which is set out in Schedule I hereto.

4. The notified body must:

4.1 examine the technical documentation, verify that the type has been manufactured in conformity with it and identify the components designed in accordance with the relevant provisions of the standards referred to in regulation 8 of these regulations as well as those designed without applying the provisions of those standards.

In particular, the notified body must:

- examine the technical documentation with respect to the design and the manufacturing procedures,

- assess the materials used where these are not in conformity with the relevant harmonized standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with Annex I, section 4.3 of the Directive, which is set out in Schedule I hereto.

- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with Annex I, section 3.1.2 of the Directive, which is set out in Schedule I hereto.

- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with Annex I, sections 3.1.2 or 3.1.3 of the Directive, which is set out in Schedule I hereto.

4.2. perform or have performed the appropriate examinations and necessary tests to establish whether the solutions adopted by the manufacturer meet the essential requirements of the regulations where the standards referred to in regulation 8 of these regulations have not been applied.

4.3. perform or have performed the appropriate examinations and necessary tests to establish whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied.

4.4. agree with the applicant the location where the examinations and necessary tests are to be carried out.

5. Where the type satisfies the provisions of the regulations which apply to it, the notified body must issue an EC type-examination certificate to the applicant. The certificate, which should be valid for ten years and be renewable, must contain the name and address of the manufacturer, the conclusions of the examination and the necessary data for identification of the approved type.

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body.

If the notified body refuses to issue an EC type-examination certificate to the manufacturer or to his authorized representative, that body must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved pressure equipment; these are subject to additional approval where they may affect conformity with the essential requirements or the prescribed conditions for use of the pressure equipment. This additional approval must be given in the form of an addition to the original EC type-examination certificate.

7. Each notified body must communicate to the Member States the relevant information concerning EC type-examination certificates which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the EC type-examination certificates it has withdrawn or refused.

8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The annexes to the certificates must be held at the disposal of the other notified bodies.

9. The manufacturer, or his authorized representative, must keep with the technical documentation copies of EC type-examination certificates and their additions for a period of ten years after the last of the pressure equipment has been manufactured.

Where neither the manufacturer nor his authorized representative is established in Malta, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the market.

Module B1 (EC design-examination)

1. This module describes the part of the procedure whereby a notified body ascertains and attests that the design of an item of pressure equipment meets the provisions of the regulations which apply to it.

The experimental design method provided for in Annex I section 2.2.4 of the Directive, which is set out in Schedule I hereto, may not be used in the context of this module.

2. The manufacturer, or his authorized representative, must lodge an application for EC design examination with a single notified body.

The application must include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address as well,

- a written declaration that the same application has not been lodged with any other notified body,

- the technical documentation described in section 3 of this module.

The application may cover several versions of the pressure equipment provided that the differences between the versions do not affect the level of safety.

3. The technical documentation 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 for 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 and diagrams of components, sub-assemblies, circuits, etc.,

- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,

- a list of the standards referred to in regulation 8 of these regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the regulations where the standards referred to in regulation 8 of these regulations have not been applied,

- the necessary supporting evidence for the adequacy of the design solution, in particular where the standards referred to in regulation 8 of these regulations have not been applied in full; this supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf,

- results of design calculations made, examinations carried out, etc.,

- information regarding the qualifications or approvals required under Annex I, sections 3.1.2 and 3.1.3 of the Directive, which is set out in Schedule I hereto.

4. The notified body must:

4.1. examine the technical documentation and identify the components which have been designed in accordance with the relevant provisions of the standards referred to in regulation 8 of these regulations, as well as those which have been designed without applying the relevant provisions of those standards.

In particular, the notified body must:

- assess the materials where these are not in conformity with the relevant harmonized standards or with a European approval for pressure equipment materials,

- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with Annex I, section 3.1.2 of the Directive, which is set out in Schedule I hereto.

- verify that the personnel undertaking the permanent joining of pressure equipment parts and the nondestructive tests are qualified or approved in

accordance with Annex I, sections 3.1.2 and 3.1.3 of the Directive, which is set out in Schedule I hereto.

4.2. perform the necessary examinations to establish whether the solutions adopted by the manufacturer meet the essential requirements of the regulations where the standards referred to in regulation 8 of these regulations have not been applied.

4.3. perform the necessary examinations to establish whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied.

5. Where the design meets the provisions of the regulations which apply to it, the notified body must issue an EC design-examination certificate to the applicant.

The certificate must contain the name and address of the applicant, the conclusions of the examination, conditions for its validity and the necessary data for identification of the approved design.

A list of the relevant parts of the technical documentation must be annexed to the certificate and a copy kept by the notified body.

If the notified body refuses to issue an EC design-examination certificate to the manufacturer or to his authorized representative, that body must provide detailed reasons for such refusal. Provision must be made for an appeals procedure.

6. The applicant must inform the notified body that holds the technical documentation concerning the EC design-examination certificate of all modifications to the approved design; these are subject to additional approval where such changes may affect the conformity of the pressure equipment with the essential requirements of the regulations or the prescribed conditions for use of the equipment. This additional approval must be given in the form of an addition to the original EC design-examination certificate.

7. Each notified body must communicate to the Member States the relevant information concerning EC design-examination certificates which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the EC design-examination certificates it has withdrawn or refused.

8. The other notified bodies may on request obtain the relevant information concerning:

- the EC design-examination certificates and additions granted,

- the EC design-examination certificates and additions withdrawn.

9. The manufacturer, or his authorized representative, must keep with the technical documentation referred to in section 3 copies of EC design-examination certificates and their additions for a period of ten years after the last of the pressure equipment has been manufactured. Where neither the manufacturer nor his authorized representative is established in Malta, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the market.

Module C1 (conformity to type)

1. This module describes that part of the procedure whereby the manufacturer, or his authorized representative, ensures and declares that pressure equipment is in conformity with the type as described in the EC type-examination certificate and satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorized representative, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity.

2. The manufacturer must take all measures necessary to ensure that the manufacturing process requires the manufactured pressure equipment to comply with the type as described in the EC type-examination certificate and with the requirements of the regulations which apply to it.

3. The manufacturer, or his authorized representative, must keep a copy of the declaration of conformity for a period of ten years after the last of the pressure equipment has been manufactured.

Where neither the manufacturer nor his authorized representative is established in Malta, the obligation to keep the technical documentation available is the responsibility of the person who places the pressure equipment on the market.

4. Final assessment must be subject to monitoring in the form of unexpected visits by a notified body chosen by the manufacturer.

During such visits, the notified body must:

- establish that the manufacturer actually performs final assessment in accordance with Annex I, section 3.2 of the Directive, which is set out in Schedule I hereto.

- take samples of pressure equipment at the manufacturing or storage premises in order to conduct checks. The notified body must assess the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of final assessment on the pressure equipment samples.

Should one or more of the items of pressure equipment not conform, the notified body must take appropriate measures.

On the responsibility of the notified body, the manufacturer must affix the former's identification number on each item of pressure equipment.

Module D (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 of this module ensures and declares that the pressure equipment concerned is in conformity with the type described in the EC type-examination certificate or EC design-examination certificate and satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorized representative, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 4 of this module.

2. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in section 3 of this Schedule and be subject to surveillance as specified in section 4 of this module.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice.

The application must include:

- all relevant information on the pressure equipment concerned,

- the documentation concerning the quality system,

- the technical documentation for the approved type and a copy of the EC type-examination certificate or EC design-examination certificate.

3.2. The quality system must ensure compliance of the pressure equipment with the type described in the EC type-examination certificate or EC design-examination certificate and with the requirements of the regulations which apply to it.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,

- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with Annex I, section 3.1.2 of the Directive, which is set out in Schedule I hereto,

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the joining of parts and the non-destructive tests in accordance with Annex I, sections 3.1.2 and 3.1.3 of the Directive, which is set out in Schedule I hereto,

- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in section 3.2 of this module. The elements of the quality system which conform to the relevant harmonized standard are presumed to comply with the corresponding requirements referred to in section 3.2 of this module.

The auditing team must have at least one member with experience of assessing the pressure equipment technology concerned. The assessment procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

Provision must be made for an appeals procedure.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in section 3.2 of this module or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- the quality system documentation,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

4.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

4.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:

- the category of the equipment,

- the results of previous surveillance visits,

- the need to follow up corrective action,

- special conditions linked to the approval of the system, where applicable,

- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may, if necessary, carry out or have carried out tests to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of ten years after the last of the pressure equipment has been manufactured, hold at the disposal of the national authorities:

- the documentation referred to in the second indent of section 3.1 of this module;

- the adjustments referred to in the second paragraph of section 3.4 of this module;

- the decisions and reports from the notified body which are referred to in the last paragraph of section 3.3, the last paragraph of section 3.4 and in sections 4.3 and 4.4 of this module.

6. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module D1 (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 3 of this module ensures and declares that the items of pressure equipment concerned satisfy the requirements of the regulations which apply to them. The manufacturer, or his authorized representative, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 5 of this module.

2. The manufacturer must draw up the technical documentation described below. The technical documentation 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 for 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 and diagrams of components, sub-assemblies, circuits, etc.,

- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,

- a list of the standards referred to in regulation 8 of these regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the regulations where the standards referred to in regulation 8 of these regulations have not been applied,

- results of design calculations made, examinations carried out, etc.,

- test reports.

3. The manufacturer must operate an approved quality system for production, final inspection and testing as specified in section 4 of this module and be subject to surveillance as specified in section 5 of this module.

4. Quality system

4.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice.

The application must include:

- all relevant information on the pressure equipment concerned,

- the documentation concerning the quality system.

4.2. The quality system must ensure compliance of the pressure equipment with the requirements of the regulations which apply to it.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,

- the manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with Annex I, section 3.1.2 of the Directive, which is set out in Schedule I hereto,

- the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts in accordance with Annex I, section 3.1.2 of the Directive, which is set out in Schedule I hereto,

- the means of monitoring the achievement of the required quality and the effective operation of the quality system.

4.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 4.2 of this module. The elements of the quality system, which conform to the relevant harmonized standard, are presumed to comply with the corresponding requirements referred to in point 4.2 of this module.

The auditing team must have at least one member with experience of assessing the pressure equipment technology concerned. The assessment procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

4.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the amended quality system will still satisfy the requirements referred to in point 4.2 of this module or whether a reassessment is required.

If must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

5. Surveillance under the responsibility of the notified body

5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

5.2. The manufacturer must allow the notified body access for inspection purposes to the locations of manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- the quality system documentation,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

5.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

5.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:

- the category of the equipment,

- the results of previous surveillance visits,

- the need to follow up corrective action,

- special conditions linked to the approval of the system, where applicable,

- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may, if necessary, carry out or have carried out tests to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

6. The manufacturer must, for a period of ten years after the last of the pressure equipment has been manufactured, hold at the disposal of the national authorities:

- the technical documentation referred to in section 2 of this module,

- the documentation referred to in the second indent of point 4.1 of this module,

- the adjustments referred to in the second paragraph of point 4.4 of this module,

- the decisions and reports from the notified body which are referred to in the last paragraph of point 4.3, the last paragraph of point 4.4, and in points 5.3 and 5.4 of this module.

7. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module E (product quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 of this module ensures and declares that the pressure equipment is in conformity with the type as described in the EC type-examination certificate and satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorized representative, must affix the CE marking to each product and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 4 of this module.

2. The manufacturer must operate an approved quality system for the final pressure equipment inspection and testing as specified in section 3 of this module and be subject to surveillance as specified in section 4 of this module.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system for the pressure equipment with a notified body of his choice.

The application must include:

- all relevant information on the pressure equipment concerned,

- the documentation concerning the quality system,

- the technical documentation for the approved type and a copy of the EC type-examination certificate.

3.2. Under the quality system, each item of pressure equipment must be examined and appropriate tests as set out in the relevant standard(s) referred to in regulation 8 of these regulations, or equivalent tests, particularly final assessment as referred to in Annex I, section 3.2 of the Directive, which is set out in Schedule I hereto, must be carried out in order to ensure its conformity with the requirements of the regulations which apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,

- the examinations and tests to be carried out after manufacture,

- the means of monitoring the effective operation of the quality system,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with Annex I, sections 3.1.2 and 3.1.3 of the Directive, which is set out in Schedule I hereto.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this module. The elements of the

quality system, which conform to the relevant harmonized standard, are presumed to comply with the corresponding requirements referred to in point 3.2 of this module.

The auditing team must have at least one member with experience of assessing the pressure equipment technology concerned. The assessment procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to discharge the obligations arising from the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative, must inform the notified body which has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the modified quality system will still satisfy the requirements referred to in point 3.2 of this module or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of inspection, testing and storage and provide it with all necessary information, in particular:

- the quality system documentation,

- the technical documentation,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

4.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

4.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on

the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:

- the category of the equipment,

- the results of previous surveillance visits,

- the need to follow up corrective action,

- special conditions linked to the approval of the system, where applicable,

- significant changes in manufacturing organization, policy or techniques.

During such visits, the notified body may, if necessary carry out or have carried out tests to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of ten years after the last of the pressure equipment has been manufactured, hold at the disposal of the national authorities:

- the documentation referred to in the second indent of point 3.1 of this module,

- the adjustments referred to in the second paragraph of point 3.4 of this module,

- the decisions and reports from the notified body which are referred to in the last paragraph of point 3.3, the last paragraph of point 3.4, and in points 4.3 and 4.4 of this module.

6. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module E1 (product quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 3 of this module ensures and declares that the pressure equipment satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorized representative, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity.

The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 5 of this module.

2. The manufacturer must draw up the technical documentation described below.

The technical documentation 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 for 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 and diagrams of components, sub-assemblies, circuits, etc.,

- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,

- a list of the standards referred to in regulation 8 of these regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the regulations where the standards referred to in regulation 8 of these regulations have not been applied,

- results of design calculations made, examinations carried out, etc.,

- test reports.

3. The manufacturer must operate an approved quality system for the final pressure equipment inspection and testing as specified in section 4 of this module and be subject to surveillance as specified in section 5 of this module.

4. Quality system

4.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice.

The application must include:

- all relevant information on the pressure equipment concerned,

- the documentation concerning the quality system.

4.2. Under the quality system, each item of pressure equipment must be examined and appropriate tests as set out in the relevant standard(s) referred to in regulation 8 of these regulations, or equivalent tests, and particularly final assessment as referred to in Annex I, section 3.2 of the Directive, which is set out in Schedule I hereto, must be

carried out in order to ensure its conformity with the requirements of the regulations which apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment,

- the procedures used for the permanent joining of parts as approved in accordance with Annex I, section 3.1.2 of the Directive, which is set out in Schedule I hereto,

- the examinations and tests to be carried out after manufacture,

- the means of monitoring the effective operation of the quality system,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts in accordance with Annex I, section 3.1.2 of the Directive, which is set out in Schedule I hereto.

4.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 4.2 of this module. The elements of the quality system, which conform to the relevant harmonized standard, are presumed to comply with the corresponding requirements referred to in point 4.2 of this module.

The auditing team must have at least one member with experience of assessing the pressure equipment technology concerned. The assessment procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision. Provision must be made for an appeals procedure.

4.4. The manufacturer must undertake to discharge the obligations arising from the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative, must inform the notified body which has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the modified quality system will still satisfy the requirements referred to in point 4.2 of this module or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

5. Surveillance under the responsibility of the notified body

5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

5.2. The manufacturer must allow the notified body access for inspection purposes to the locations of inspection, testing and storage and provide it with all necessary information, in particular:

- the quality system documentation,

- the technical documentation,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

5.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

5.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:

- the category of the equipment,

- the results of previous surveillance visits,

- the need to follow up corrective action,

- special conditions linked to the approval of the system, where applicable,

- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may, if necessary, carry out or have carried out tests to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

6. The manufacturer must, for a period of ten years after the last of the pressure equipment has been manufactured, keep at the disposal of the national authorities:

- the technical documentation referred to in section 2 of this module,

- the documentation referred to in the second indent of point 4.1 of this module,

- the adjustments referred to in the second paragraph of point 4.4 of this module,

- the decisions and reports from the notified body which are referred to in the last paragraph of point 4.3, the last paragraph of point 4.4 and in points 5.3 and 5.4 of this module.

7. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module F (product verification)

1. This module describes the procedure whereby a manufacturer, or his authorized representative, ensures and declares that the pressure equipment subject to the provisions of section 3 of this module is in conformity with the type described:

- in the EC type-examination certificate, or in the EC design examination certificate

- in the EC design-examination certificate and satisfies the requirements of the regulations which apply to it.

2. The manufacturer must take all measures necessary to ensure that the manufacturing process requires the pressure equipment to comply with the type described

- in the EC type-examination certificate, or

- in the EC design-examination certificate and with the requirements of the regulations which apply to it.

The manufacturer, or his authorized representative, must affix the CE marking to all pressure equipment and draw up a declaration of conformity.

3. The notified body must perform the appropriate examinations and tests in order to check the conformity of the pressure equipment with the relevant requirements of the regulations by examining and testing every product in accordance with section 4 of this module.

The manufacturer, or his authorized representative, must keep a copy of the declaration of conformity for a period of ten years after the last of the pressure equipment has been manufactured.

4. Verification by examination and testing of each item of pressure equipment

4.1. Each item of pressure equipment must be individually examined and must undergo appropriate examinations and tests as set out in the relevant standard(s) referred to in regulation 8 of these regulations or equivalent examinations and tests in order to verify that it conforms to the type and the requirements of the regulations which apply to it.

In particular, the notified body must:

- verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved in accordance with Annex I, sections 3.1.2 and 3.1.3 of the Directive, which is set out in Schedule I hereto,

- verify the certificate issued by the materials manufacturer in accordance with Annex I, section 4.3 of the Directive, which is set out in Schedule I hereto,

- carry out or have carried out the final inspection and proof test referred to in Annex I, section 3.2 of the Directive, which is set out in Schedule I hereto, and examine the safety devices, if applicable.

4.2. The notified body must affix its identification number or have it affixed to each item of pressure equipment and draw up a written certificate of conformity relating to the tests carried out.

4.3. The manufacturer, or his authorized representative, must ensure that the certificates of conformity issued by the notified body can be made available on request.

Module G (EC unit verification)

1. This module describes the procedure whereby the manufacturer ensures and declares that pressure equipment which has been issued with the certificate referred to in section 4.1 of this module satisfies the requirements of the regulations which apply to it. The manufacturer must affix the CE marking to the pressure equipment and draw up a declaration of conformity.

2. The manufacturer must apply to a notified body of his choice for unit verification.

The application must contain:

- the name and address of the manufacturer and the location of the pressure equipment,

- a written declaration to the effect that a similar application has not been lodged with another notified body,

- technical documentation.

3. The technical documentation must enable the conformity of the pressure equipment with the requirements of the regulations which apply to it to be assessed and the design, manufacture and operation of the pressure equipment to be understood.

The technical documentation must contain:

- a general description of the pressure equipment,

- conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, etc.,

- descriptions and explanations necessary for an understanding of the said drawings and diagrams and the operation of the pressure equipment,

- a list of the standards referred to in regulation 8 of these regulations, applied in full or in part and descriptions of the solutions adopted to meet the essential requirements of the regulations where the standards referred to in regulation 8 of these regulations have not been applied,

- results of design calculations made, examinations carried out, etc.,

- test reports,

- appropriate details relating to the approval of the manufacturing and test procedures and of the qualifications or approvals of the personnel concerned in accordance with Annex I, sections 3.1.2 and 3.1.3 of the Directive, which is set out in Schedule I hereto.

4. The notified body must examine the design and construction of each item of pressure equipment and during manufacture perform appropriate tests as set out in the relevant standard(s) referred to in regulation 8 of these regulations, or equivalent examinations and tests, to ensure its conformity with the requirements of the regulations which apply to it.

In particular the notified body must:

- examine the technical documentation with respect to the design and the manufacturing procedures,

- assess the materials used where these are not in conformity with the relevant harmonized standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with Annex I, section 4.3 of the Directive, which is set out in Schedule I hereto,

- approve the procedures for the permanent joining of parts or check that they have been previously approved in accordance with Annex I, section 3.1.2 of the Directive, which is set out in Schedule I hereto,

- verify the qualifications or approvals required under Annex I, sections 3.1.2 and 3.1.3 of the Directive, which is set out in Schedule I hereto,

- carry out the final inspection referred to in Annex I, section 3.2.1 of the Directive, which is set out in Schedule I hereto, perform or have performed the proof test referred to in Annex I, section 3.2.2 of the Directive, which is set out in Schedule I hereto, and examine the safety devices, if applicable.

4.1. The notified body must affix its identification number or have it affixed to the pressure equipment and draw up a certificate of conformity for the tests carried out. This certificate must be kept for a period of ten years.

4.2. The manufacturer, or his authorized representative, must ensure that the declaration of conformity and certificate of conformity issued by the notified body can be made available on request.

Module H (full quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 of this module ensures and declares that the pressure equipment in question satisfies the requirements of the regulations which apply to it. The manufacturer, or his authorized representative, must affix the CE marking to each item of pressure equipment and draw up a written declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in section 4 of this module.

2. The manufacturer must implement an approved quality system for design, manufacture, final inspection and testing as specified in section 3 of this module and be subject to surveillance as specified in section 4 of this module.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice.

The application must include:

- all relevant information concerning the pressure equipment in question,

- the documentation concerning the quality system.

3.2. The quality system must ensure compliance of the pressure equipment with the requirements of the regulations which apply to it.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the procedural and quality measures such as programmes, plans, manuals and records.

It must contain in particular an adequate description of:

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the quality of the design and to product quality,

- the technical design specifications, including standards, that will be applied and, where the standards referred to in regulation 8 of these regulations are not applied in full, the means that will be used to ensure that the essential requirements of the regulations which apply to the pressure equipment will be met,

- the design control and design verification techniques, processes and systematic measures that will be used when designing the pressure equipment, particularly with regard to materials in accordance with Annex I, section 4 of the Directive, which is set out in Schedule I hereto,

- the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic measures that will be used, particularly the procedures for the permanent joining of parts as approved in accordance with Annex I, section 3.1.2 of the Directive, which is set out in Schedule I hereto,

- the examinations and tests to be carried out before, during, and after manufacture, and the frequency with which they will be carried out,

- the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications or approvals of the personnel concerned, particularly those of the personnel undertaking the permanent joining of parts and the non-destructive tests in accordance with Annex I, sections 3.1.2 and 3.1.3 of the Directive, which is set out in Schedule I hereto,

- the means of monitoring the achievement of the required pressure equipment design and quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2 of this module. The elements of the quality system which conform to the relevant harmonized standard are presumed to comply with the corresponding requirements referred to in point 3.2 of this module.

The auditing team must have at least one member with experience of assessing the pressure equipment technology concerned. The assessment procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

Provision must be made for an appeals procedure.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative, must inform the notified body that has approved the quality system of any intended adjustment to the quality system.

The notified body must assess the proposed changes and decide whether the modified quality system will still satisfy the requirements referred to in point 3.2 of this module or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of this surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body access for inspection purposes to the locations of design, manufacture, inspection, testing and storage and provide it with all necessary information, in particular:

- the quality system documentation,

- the quality records provided for in the design part of the quality system, such as results of analyses, calculations, tests, etc.,

- the quality records provided for in the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel concerned, etc.

4.3. The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and provide the manufacturer with an audit report. The frequency of periodic audits must be such that a full reassessment is carried out every three years.

4.4. In addition the notified body may pay unexpected visits to the manufacturer. The need for such additional visits, and the frequency thereof, will be determined on the basis of a visit control system operated by the notified body. In particular, the following factors must be considered in the visit control system:

- the category of the equipment,

- the results of previous surveillance visits,

- the need to follow up corrective action,

- special conditions linked to the approval of the system, where applicable,

- significant changes in manufacturing organization, policy or techniques.

During such visits the notified body may, if necessary, carry out or have carried out tests to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period of ten years after the last of the pressure equipment has been manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of the second subparagraph of point 3.1 of this module;

- the adjustments referred to in the second subparagraph of point 3.4 of this module;

- the decisions and reports from the notified body which are referred to in the last subparagraph of point 3.3, the last subparagraph of point 3.4, and in points 4.3 and 4.4 of this module.

6. Each notified body must communicate to the Member States the relevant information concerning the quality system approvals which it has withdrawn, and, on request, those it has issued.

Each notified body must also communicate to the other notified bodies the relevant information concerning the quality system approvals it has withdrawn or refused.

Module H1 (full quality assurance with design examination and special surveillance of the final assessment)

1. In addition to the requirements of module H, the following apply:

(a) the manufacturer must lodge an application for examination of the design with the notified body;

(b) the application must enable the design, manufacture and operation of the pressure equipment to be understood, and enable conformity with the relevant requirements of the regulations to be assessed.

It must include:

- the technical design specifications, including standards, which have been applied,

- the necessary supporting evidence for their adequacy, in particular where the standards referred to in regulation 8 of these regulations have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf;

(c) the notified body must examine the application and where the design meets the provisions of the regulations which apply to it issue an EC design-examination certificate to the applicant. The certificate must contain the conclusions of the examination, the conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the functioning of the pressure equipment or accessories;

(d) the applicant must inform the notified body that has issued the EC design-examination certificate of all modifications to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design-examination certificate where they may affect conformity with the essential requirements of these regulations or the prescribed conditions for use of the pressure equipment. This additional approval must be given in the form of an addition to the original EC design-examination certificate;

(e) each notified body must also communicate to the other notified bodies the relevant information concerning the EC design-examination certificates it has withdrawn or refused.

2. Final assessment as referred to in Annex I, section 3.2 of the Directive, which is set out in Schedule I hereto, is subject to increased surveillance in the form of unexpected visits by the notified body. In the course of such visits, the notified body must conduct examinations on the pressure equipment.

Table 11: Summary of Conformity Assessment Procedure for each module

Module	Conformity Assessment Procedure	Description
A	Internal production control.	This module describes the procedure by which the manufacturer ensures and declares that pressure equipment satisfies the requirements of the Directive/Regulation which apply to it.
A1	Internal production control with monitoring of final assessment.	As above but in addition includes monitoring of final assessment by notified body.
B	EC type – examination.	Describes the part of the procedure where a notified body ascertains and attests that a representative example of the production meets the provisions of the Directive/Regulation which apply to it.
B1	EC design – examination.	Describes the part of the procedure where a notified body ascertains and attests that the design of an item meets the provisions of the Directive/ Regulation which apply to it
C1	Monitoring of final assessment.	Describes procedures where the manufacturer, or authorised representative ensures and declares that the pressure equipment is in conformity with the type as described in the EC type examination certificate and satisfies the requirements of the Directive/ Regulation which apply to it.
D	Quality assurance for production, final inspection and testing.	Describes procedures where the manufacturer ensures and declares that the pressure equipment conforms with the type described in the EC type examination certificate or the EC design certificate and satisfies the requirements of the Directive/Regulation which apply to it.

D1	Quality assurance for production, final inspection and testing.	This module describes the procedure by which manufacturer ensures and declares that pressure equipment satisfies the requirements of the Directive/Regulation which apply to it.
E	Quality assurance for final inspection and testing.	Describes procedures where the manufacturer ensures and declares that the equipment is in conformity with the type described in the EC type examination certificate and satisfies the requirements of the Directive/ Regulation which apply to it.
E1	Quality assurance for final inspection and testing.	Describes the procedure where the manufacturer ensures and declares that the equipment satisfies the requirements of the Directive/Regulation that apply to it.
F	Product verification.	Describes the procedure where the manufacturer or authorised representative ensures and declares the pressure equipment is in conformity with the type as described in the EC type examination certificate or the EC design certificate and satisfies the requirements of the Directive/Regulation.
G	Unit verification.	Describes the procedure where 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 Directive/ Regulation.
H	Full quality assurance	Describes the procedure where the manufacturer ensures and declares the pressure equipment satisfies the requirements of the Directive/ Regulation.
H1	Full quality assurance with design examination and monitoring of final assessment.	As above.

Schedule IV

Based on Annex IV of the Directive

MINIMUM CRITERIA TO BE MET WHEN DESIGNATING THE NOTIFIED BODIES AND THE RECOGNIZED THIRD-PARTY ORGANIZATIONS

1. The body, its director and the personnel responsible for carrying out the assessment and verification operations may not be the designer, manufacturer, supplier, installer or user of the pressure equipment or assemblies which that body inspects, nor the authorized representative of any of those parties. They may not become directly involved in the design, construction, marketing or maintenance of the pressure equipment or assemblies, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer of pressure equipment or assemblies and the notified body.

2. The body and its personnel must carry out the assessments and verifications with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of verifications.

3. The body must have at its disposal the necessary personnel and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with the inspection and surveillance operations, it must also have access to the equipment required to perform special verifications.

4. The personnel responsible for inspection must have:

- sound technical and vocational training,

- satisfactory knowledge of the requirements of the inspections they carry out and adequate experience of such operations,

- the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. The impartiality of the inspection personnel must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of such inspections.

6. The body must take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the inspections.

7. The personnel of the body must observe professional secrecy with regard to all information gained in carrying out their tasks (except vis-a-vis the competent administrative authorities of the State in which their activities are carried out) under the regulations or any provision of national law giving effect to it.

Schedule V

Based on Annex V of the Directive

CRITERIA TO BE MET WHEN AUTHORIZING USER INSPECTORATES REFERRED TO IN REGULATION 12 OF THESE REGULATIONS

1. The user inspectorate must be organizationally identifiable and have reporting methods within the group of which it is part which ensure and demonstrate its impartiality. It must not be responsible for the design, manufacture, supply, installation, operation or maintenance of the pressure equipment or assemblies, and must not engage in any activities that might conflict with its independence of judgment and integrity in relation to its inspection activities.

2. The user inspectorate and its personnel must carry out the assessments and verifications with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of verifications.

3. The user inspectorate must have at its disposal the necessary personnel and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with the inspection and surveillance operations; it must also have access to the equipment required to perform special verifications.

4. The personnel responsible for inspection must have:

- sound technical and vocational training,

- satisfactory knowledge of the requirements of the inspections they carry out and adequate experience of such operations,

- the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

5. The impartiality of inspection personnel must be guaranteed. Their remuneration must not depend on the number of inspections carried out, nor on the results of such inspections.

6. The user inspectorate must have adequate liability insurance unless liability is assumed by the group of which it is part.

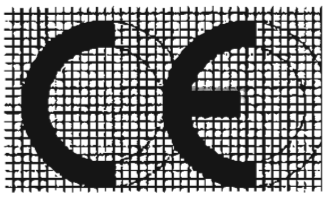
7. The personnel of the user inspectorate must observe professional secrecy with regard to all information gained in carrying out their tasks (except vis-a-vis the competent administrative authorities of the State in which their activities are carried out) under the regulations or any provision of national law giving effect to it.

Schedule VI

Based on Annex VI of the Directive

CE MARKING

The CE marking consists of the initials "CE" taking the following form:



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the CE marking.

If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected. The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm.

Schedule VII

Based on Annex VII of the Directive

DECLARATION OF CONFORMITY

The EC declaration of conformity must contain the following particulars:

- name and address of the manufacturer or of his authorized representative,

- 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.

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