
STATUTORY INSTRUMENTS

1999 No. 2001

HEALTH AND SAFETY

The Pressure Equipment Regulations 1999

<i>Made</i>	- - - -	<i>15th July 1999</i>
<i>Laid before Parliament</i>		<i>19th July 1999</i>
<i>Coming into force</i>		
<i>regulations 1, 2, 20 and 22</i>		<i>31st August 1999</i>
<i>remaining regulations</i>		<i>29th November 1999</i>

The Secretary of State, being a Minister designated⁽¹⁾ for the purposes of section 2(2) of the European Communities Act 1972⁽²⁾ in relation to measures relating to pressure equipment and assemblies, in exercise of the powers conferred on him by that section and of all his other enabling powers, hereby makes the following Regulations:

PART I
PRELIMINARY

Citation and commencement

- 1.—(1) These Regulations may be cited as the Pressure Equipment Regulations 1999.
- (2) This regulation, regulations 2, 20 and 22 shall come into force on 31st August 1999.
- (3) The remaining regulations shall come into force on 29th November 1999.

Interpretation

- 2.—(1) In these Regulations—
 - (a) the “Pressure Equipment Directive” means Directive [97/23/EC](#) of the European Parliament and of the Council on the approximation of the laws of the Member States relating to pressure equipment⁽³⁾;

⁽¹⁾ [S.I. 1998/2793](#).

⁽²⁾ [1972 c. 68](#).

⁽³⁾ [OJ No. L181, 9.7.97, p. 1](#).

- (b) except for the references to the European Communities in the definition of “the Commission” and in relation to the Official Journal, a reference to the Community includes a reference to the EEA, and a reference to a member State includes a reference to an EEA State: for this purpose—
- (i) the “EEA” means the European Economic Area;
 - (ii) an “EEA State” means a State which is a Contracting Party to the EEA Agreement; and
 - (iii) the “EEA Agreement” means the Agreement on the European Economic Area signed at Oporto on 2nd May 1992 as adjusted by the Protocol signed at Brussels on 17th March 1993(4); and
- (c) unless the context otherwise requires, a reference to a numbered regulation or Schedule is a reference to the regulation or Schedule so numbered in these Regulations and a reference—
- (i) to a paragraph in a regulation is a reference to a paragraph in that regulation;
 - (ii) to an Annex is a reference to an Annex of the Pressure Equipment Directive: for the purposes of these Regulations, Annexes I, II, III, VI and VII are respectively set out in Schedules 2, 3, 4, 5, and 6;
 - (iii) to an Article in an Annex is a reference to the Article so numbered in the Pressure Equipment Directive and a reference to a section of an Article shall be construed accordingly;
 - (iv) to a section or a paragraph in an Annex is a reference to a section or a paragraph in that Annex as set out in the relevant Schedule; and
 - (v) to “the Directive” in an Annex is a reference to the Pressure Equipment Directive.
- (2) In these Regulations, unless the context otherwise requires—
- “assembly” means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole;
- “business” includes a profession and an undertaking;
- “CE marking” means the CE marking referred to in regulation 16 consisting of the initials “CE” in the form shown in Schedule 5;
- “the Commission” means the Commission of the European Communities;
- “enforcement authority” means—
- (a) in the case of pressure equipment and assemblies for use in the workplace—
 - (i) in Great Britain, the Health and Safety Executive established under section 10 of the Health and Safety at Work etc. Act 1974(5) and
 - (ii) in Northern Ireland, the Health and Safety Executive for Northern Ireland established under Article 12 of the Health and Safety at Work (Northern Ireland) Order 1978(6);
 - (b) in the case of pressure equipment and assemblies for private use or consumption—
 - (i) in Great Britain, weights and measures authorities; and
 - (ii) in Northern Ireland, every district council;
- “essential requirements” means the requirements set out in Schedule 2;

(4) The application of the Pressure Equipment Directive was extended to the EEA from 26th September 1998 by virtue of Decision 82/98 of the EEA Joint Committee which inserted a reference to that Directive after point 6 in Chapter VIII of Annex II to the EEA Agreement.

(5) 1974 c. 37.

(6) S.I. 1978/1039 (N.I. 9); Article 12 was amended by S.I. 1998/2795 (N.I. 18) Article 6(1) and paragraph 8 of Schedule 1.

“European approval for materials” or “European approval for pressure equipment 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 harmonised standard as referred to in paragraph 4.2(b) of Schedule 2;

“fluid” means gases, liquids and vapours in pure phase as well as mixtures thereof; a fluid may contain a suspension of solids;

“fluid in Group 1” means a fluid being a dangerous fluid, that is to say a substance or preparation covered by the definitions of Article 2(2) of Council Directive [67/548/EEC](#) of 27th June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances⁽⁷⁾ as specified in that Article as:

- explosive,
- extremely flammable,
- highly flammable,
- flammable (where the maximum allowable temperature is above flashpoint),
- very toxic,
- toxic, or
- oxidising;

“fluid in Group 2” means a fluid which is not a fluid in Group 1;

“harmonised standard” means a technical specification adopted by the European Committee for Standardisation or the European Committee for Electrotechnical Standardisation or both, upon a mandate from the Commission in accordance with Directive [98/34/EC](#) of 22nd June 1998 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⁽⁸⁾, and of which the reference number is published in the Official Journal of the European Communities;

“maximum allowable pressure” or “PS” means the maximum pressure for which the equipment is designed, as specified by the manufacturer, defined at a location specified by the manufacturer, being the location of connection of protective or limiting devices or the top of equipment or, if either of the foregoing are not appropriate, any point specified by the manufacturer;

“maximum or minimum allowable temperature” or “TS” means the maximum or minimum temperatures, as the case may be, for which the equipment is designed, as specified by the manufacturer;

“nominal size” or “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; that is to say a convenient round number for reference purposes which is only loosely related to manufacturing dimensions and designated by the letters “DN” followed by a number;

“notified body” shall be construed in accordance with regulation 18;

“permanent joints” means joints which cannot be disconnected except by destructive methods;

“piping” means piping components intended for the transport of fluids when connected together for integration into a pressure system, such components include in particular a pipe or system of pipes, tubing, fittings, expansion joints, hoses, other pressure-bearing components as appropriate or heat exchangers consisting of pipes for the purpose of cooling or heating air;

⁽⁷⁾ OJ No. 196, 16.8.1967, p. 1. Directive as last amended by Commission Directive [94/69/EC](#) (OJ No. L381, 31.12.1994, p. 1).

⁽⁸⁾ OJ No. L204, 21.7.98, p. 37. Directive [98/34/EC](#) was amended by Directive [98/48/EC](#) of the European Parliament and of the Council (OJ No. L217, 5.8.98, p. 18).

“pressure” means pressure relative to atmospheric pressure being gauge pressure; vacuum is designated by a negative value;

“pressure accessories” means devices with an operational function and having pressure-bearing housings;

“pressure equipment” means vessels, piping, safety accessories and pressure accessories; where applicable, pressure equipment include elements attached to pressurised parts, such as flanges, nozzles, couplings, supports, lifting lugs, and similar;

“recognised third-party organisation” shall be construed in accordance with regulation 19;

“relevant essential requirements” in relation to pressure equipment or an assembly, means those provisions of the essential requirements which are applicable to that particular pressure equipment or assembly, as the case may be;

“responsible person” means—

- (a) the manufacturer or his authorised representative established within the Community; or
- (b) where neither the manufacturer nor his authorised representative is established within the Community, the person who places the pressure equipment or assembly on the market or puts it into service as the case may be;

“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;

“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, 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 devices;

“standard” means a technical specification approved by a recognised standardising body for repeated or continuous application, with which compliance is not compulsory: and, for the avoidance of doubt, includes a harmonised standard or a transposed harmonised standard;

“supply” includes offering to supply, agreeing to supply, exposing for supply and possessing for supply and cognate expressions shall be construed accordingly;

“transposed harmonised standard” means a national standard of a member State which transposes a harmonised standard;

“user inspectorate” shall be construed in accordance with regulation 22;

“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; and

“volume” or “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) For the purposes of these Regulations, pressure equipment or assemblies shall not be regarded as having been put into service where a person—

- (a) being a manufacturer of pressure equipment or an assembly for his own use; or
- (b) having imported pressure equipment or an assembly from a country or territory outside the Community for his own use

puts that pressure equipment or assembly into service otherwise than in the course of business.

PART II

APPLICATION

Pressure equipment and assemblies

3. Subject to regulations 4, 5, and 6, these Regulations apply to pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar.

Excluded pressure equipment and assemblies

4.—(1) These Regulations shall not apply to the products listed in Schedule 1.

(2) For the avoidance of doubt these Regulations shall not apply to the assembly of pressure equipment on the site and under the responsibility of the user.

Pressure equipment and assemblies placed on the market before 29th November 1999

5. These Regulations shall not apply to pressure equipment and assemblies placed on the market before 29th November 1999.

Exclusion until 30th May 2002 of pressure equipment and assemblies complying with provisions in force on 28th November 1999

6.—(1) Subject to paragraph (2), these Regulations shall not apply to pressure equipment and assemblies placed on the market on or before 29th May 2002 which comply with any safety provisions with which they would have been required to comply for them to be placed on the market in the United Kingdom on 28th November 1999.

(2) The exclusion provided in paragraph (1) shall not apply in the case of pressure equipment or an assembly which—

- (a) unless required to bear the CE marking pursuant to any other Community obligation, bears the CE marking or an inscription liable to be confused with it; or
- (b) bears or is accompanied by any other indication, howsoever expressed, that it complies with the Pressure Equipment Directive.

PART III

GENERAL REQUIREMENTS

General duty relating to the placing on the market or putting into service of pressure equipment

7.—(1) Subject to regulation 11, no person who is a responsible person shall place on the market or put into service any pressure equipment described in paragraph 2 unless the requirements of paragraph (3) have been complied with in relation to it.

(2) For the purposes of paragraph (1), the following are pressure equipment—

- (a) vessels, except those referred to in sub-paragraph (b), for—
 - (i) 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—

- (aa) for fluids in Group 1, with a volume greater than 1L and a product of PS and V greater than 25 bar-L, or with a pressure PS greater than 200 bar;
 - (bb) for fluids in Group 2, with a volume greater than 1L and a product 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;
 - (ii) 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—
 - (aa) for fluids in Group 1, with a volume greater than 1L and a product of PS and V greater than 200 bar-L, or with a pressure PS greater than 500 bar;
 - (bb) 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;
 - (b) 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⁽⁹⁾ having a volume greater than 2L, and all pressure cookers;
 - (c) piping intended for—
 - (i) gases, liquefied 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—
 - (aa) for fluids in Group 1, with a DN greater than 25;
 - (bb) for fluids in Group 2, with a DN greater than 32 and a product of PS and DN greater than 1 000 bar;
 - (ii) 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—
 - (aa) for fluids in Group 1, with a DN greater than 25 and a product of PS and DN greater than 2 000 bar;
 - (bb) 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;
 - (d) subject to regulation 9, safety and pressure accessories intended for equipment covered by sub-paragraphs (a), (b) and (c), including where such equipment is incorporated into an assembly.
- (3) The requirements in respect of pressure equipment described in paragraph 2 are that—
- (a) it satisfies the relevant essential requirements and for the purpose of satisfying those requirements where a transposed harmonised standard covers one or more of the relevant essential requirements, any pressure equipment constructed in accordance with that transposed harmonised standard shall be presumed to comply with that or, as the case may be, those essential requirements;
 - (b) the appropriate conformity assessment procedure in respect of the pressure equipment has been carried out in accordance with regulation 13(1);
 - (c) the CE marking has been affixed to it by the manufacturer of the pressure equipment or his authorised representative established within the Community in accordance with regulation 16 and Schedule 5;

(9) Corrigendum to Directive 97/23/EC published at OJ No. L265, 27.9.97, p. 110.

- (d) a declaration of conformity has been drawn up in respect of it by the manufacturer of the pressure equipment or his authorised representative established within the Community containing the information listed in Schedule 6; and
- (e) it is in fact safe.

(4) 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) In respect of pressure equipment to be placed on the market and put into service in the United Kingdom, where the requirements of paragraphs 3.3 and 3.4 of Schedule 2 are to be met, the marking, labelling, information and instructions shall be in English.

General duty relating to the placing on the market or putting into service of assemblies

8.—(1) Subject to regulation 11, no person who is a responsible person shall place on the market or put into service an assembly described in paragraph 2 unless the requirements of paragraph (3) have been complied with in relation to it.

(2) For the purposes of paragraph (1), an assembly is—

- (a) an assembly which includes at least one item of pressure equipment described in paragraph (2) of regulation 7 and—
 - (i) is intended for generating steam or superheated water at a temperature higher than 110°C⁽¹⁰⁾ comprising at least one item of fired or other heated pressure equipment presenting a risk of overheating; or
 - (ii) not being a product included in sub-paragraph (i) above, is intended by the manufacturer to be placed on the market and put into service as an assembly; or
- (b) an assembly which is intended for generating warm water at temperatures not greater than 110°C, which is manually fed with the solid fuels and has a PS.V greater than 50 bar-L.

(3) (a) The requirements in respect of an assembly described in paragraph (2)(a) are that—

- (i) it satisfies the relevant essential requirements and for the purpose of satisfying those requirements where a transposed harmonised standard covers one or more of the relevant essential requirements, any assembly constructed in accordance with that transposed harmonised standard shall be presumed to comply with that or, as the case may be, those essential safety requirements;
- (ii) the appropriate conformity assessment procedure in respect of the assembly has been carried out in accordance with regulation 14;
- (iii) the CE marking has been affixed to it by the manufacturer of that assembly or his authorised representative established within the Community in accordance with regulation 16 and Schedule 5;
- (iv) a declaration of conformity has been drawn up in respect of it by the manufacturer of the assembly or his authorised representative established within the Community containing the information listed in Schedule 6; and
- (v) it is in fact safe.

(b) The requirements in respect of any assembly described in paragraph (2)(b) are that—

- (i) it satisfies the essential requirements referred to in paragraphs 2.10, 2.11, 3.4, 5(a) and 5(d) of Schedule 2, and

(ii) it complies with the requirements listed in sub-paragraphs (a)(ii) to (v) inclusive above.

(4) Any technical documentation or other information in relation to an assembly 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) In respect of an assembly to be placed on the market in the United Kingdom, where the requirements of paragraphs 3.3 and 3.4 of Schedule 2 are to be met, the marking, labelling, information and instructions shall be in English.

Requirement for pressure equipment or assemblies to comply with sound engineering practice

9.—(1) Subject to regulation 11, no person who is a responsible person shall place on the market or put into service any pressure equipment or assembly to which these Regulations apply below or equal to the limits in regulations 7(2)(a), (b) or (c) or regulation 8(2) unless the requirements of paragraph (2) below have been complied with in relation to it.

- (2) The requirements referred to in paragraph (1) are that the pressure equipment or assembly—
- (a) is designed and manufactured in accordance with sound engineering practice in order to ensure safe use;
 - (b) must be accompanied by adequate instructions for use;
 - (c) must bear markings to permit identification of the manufacturer or of his authorised representative established within the Community; and
 - (d) be safe.

(3) For the avoidance of doubt, pressure equipment or assemblies to which this regulation applies shall not bear the CE marking.

General duty relating to the supply of pressure equipment and assemblies

10. Subject to regulation 11, no person, who is not a responsible person, shall supply any pressure equipment or assembly unless that pressure equipment or assembly is safe.

Exceptions to placing on the market or supply in respect of certain pressure equipment and assemblies

11. For the purposes of regulation 7, 8, 9, or 10, pressure equipment or an assembly shall not be regarded as being placed on the market or supplied, as the case may be—

- (a) where that pressure equipment or assembly—
 - (i) will be put into service in a country outside the Community; or
 - (ii) is imported into the Community for re-export to a country outside the Community, save that this paragraph shall not apply if the CE marking, or any inscription liable to be confused therewith, is affixed thereto; or
- (b) by the exhibition at trade fairs and exhibitions of that pressure equipment or an assembly, in respect of which the provisions of these Regulations are not satisfied, if—
 - (i) a notice is displayed in relation to the pressure equipment or assembly in question to the effect—
 - (aa) that it does not satisfy those provisions; and

- (bb) that it may not be placed on the market or supplied until those provisions are satisfied by the manufacturer of pressure equipment or assembly or his authorised representative established within the Community; and
- (ii) appropriate safety measures are taken when demonstrating such pressure equipment or assembly to ensure the safety of persons.

Classification of pressure equipment

12.—(1) For the purposes of regulation 13, pressure equipment referred to in regulation 7(2) shall be classified by category in accordance with Schedule 3 according to ascending level of hazard.

(2) The appropriate table for pressure equipment coming within regulation 7(2)(a) to (c) inclusive shall be as follows:

for pressure equipment coming within,

- (a) regulation 7(2)(a)(i)(aa), table 1;
- (b) regulation 7(2)(a)(i)(bb), table 2;
- (c) regulation 7(2)(a)(ii)(aa), table 3;
- (d) regulation 7(2)(a)(ii)(bb), table 4;
- (e) regulation 7(2)(b), table 5;
- (f) regulation 7(2)(c)(i)(aa), table 6;
- (g) regulation 7(2)(c)(i)(bb), table 7;
- (h) regulation 7(2)(c)(ii)(aa), table 8; or
- (i) regulation 7(2)(c)(ii)(bb), table 9.

(3) For pressure equipment coming within regulation 7(2)(d), the category shall be determined in accordance with paragraphs 2 and 3 of Schedule 3.

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

Conformity assessment procedures for pressure equipment

13.—(1) For the purposes of regulation 7(3)(b), the appropriate conformity assessment procedure for pressure equipment shall be one of the procedures set out in Schedule 4 as determined in accordance with paragraph (3).

(2) The manufacturer shall apply either,

- (i) one of the conformity assessment procedures which may be chosen from among those laid down in paragraph (3) for the category in which the pressure equipment is classified, or
- (ii) one of the procedures which apply to a higher category of pressure equipment, if available.

(3) The relevant conformity assessment procedures set out in Schedule 4 to be applied for the various categories of pressure equipment determined in accordance with regulation 12 above are as follows:

- (i) for category I, module A;
- (ii) for category II, any of the following modules:
 - A1,
 - D1, or
 - E1;

(iii) for category III, any of the following modules:

- B1 plus D,
- B1 plus F,
- B plus E,
- B plus C1, or
- H;

(iv) for category IV, any of the following modules:

- B plus D,
- B plus F,
- G, or
- H1.

Conformity assessment procedure for assemblies

14. For the purposes of regulation 8(3)(a)(ii), the relevant conformity assessment procedure to be applied by the manufacturer in respect of the assembly shall be a global conformity assessment procedure comprising:

- (a) assessment of each item of pressure equipment making up the assembly and referred to in regulation 7(2)(a) to (d) 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;
- (b) the assessment of the integration of the various components of the assembly as referred to in paragraphs 2.3, 2.8 and 2.9 of Schedule 2 which shall be determined by the highest category applicable to the equipment concerned other than that applicable to any safety accessories;
- (c) the assessment of the protection of an assembly against exceeding the permissible operating limits as referred to in paragraphs 2.10 and 3.2.3 of Schedule 2 shall be conducted in the light of the highest category applicable to the items of equipment to be protected.

Exclusion for pressure equipment and assemblies for use for experimentation

15.—(1) Regulations 13 and 14 shall not apply to an item of pressure equipment or an assembly the use of which is in the interests of experimentation.

(2) For the purpose of this regulation “experimentation” means pressure equipment or an assembly designed or adapted for the purpose only of conducting any test or measurement in relation to that pressure equipment or assembly.

CE marking

16.—(1) The CE marking shall be accompanied by the identification number of the notified body involved at the production control phase.

(2) Subject to paragraph (3), the CE marking shall be affixed in a visible, easily legible and indelible fashion to each item of pressure equipment referred to in regulation 7, or assembly referred to in regulation 8 which is complete or is in a state permitting final assessment as described in paragraph 3.2 of Schedule 2.

(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 8 but individual items of pressure

equipment already bearing the CE marking when incorporated into the assembly shall continue to bear that marking.

(4) Subject to paragraph (5), where the pressure equipment or assembly is subject to other 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 those other Directives.

(5) Where one or more of the other Directives referred to in paragraph (4) allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only with the Directives applied by the manufacturer, and in this case, particulars of the Directives applied, 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.

(6) The affixing of markings on pressure equipment or an assembly which are likely to mislead third parties as to the meaning or form of the CE marking is prohibited.

(7) Any other marking may be affixed to pressure equipment or an assembly provided that the visibility and legibility of the CE marking is not thereby reduced.

European approval for materials

17. European approval for materials shall be issued, at the request of one or more manufacturers of materials or equipment, by one of the notified bodies referred to in regulation 18 specifically designated for that task and in accordance with the procedures set out in Schedule 7.

Notified bodies

18. For the purposes of these Regulations, a notified body is a body which has been appointed to carry out one or more of the conformity assessment procedures mentioned or referred to in regulation 13 or 14 or to issue a European approval for materials as referred to in regulation 17 and which has been—

- (a) appointed as a notified body in the United Kingdom pursuant to regulation 20; or
- (b) appointed by a member State other than the United Kingdom, and has been notified by the member State concerned to the Commission and the other member States pursuant to Article 12 of the Pressure Equipment Directive.

Recognised third-party organisations

19. For the purposes of these Regulations, a recognised third-party organisation, is an organisation which has been appointed for the purposes of carrying out the tasks referred to in paragraphs 3.1.2(11) and 3.1.3 of Schedule 2, and which has been—

- (a) appointed as a recognised third-party organisation in the United Kingdom pursuant to regulation 20; or
- (b) appointed by a member State other than the United Kingdom, and has been notified by the member State concerned to the Commission and the other member States pursuant to Article 12 of the Pressure Equipment Directive.

Notified bodies and recognised third-party organisations appointed by the Secretary of State

20.—(1) The Secretary of State may from time to time appoint such persons as he thinks fit to be notified bodies or recognised third-party organisations for the purposes of these Regulations.

(11) There is an error in the English text of the Pressure Equipment Directive. The text uses “3.2.2” instead of “3.1.2”.

- (2) An appointment—
- (a) may relate to all descriptions of pressure equipment or assemblies or such descriptions (which may be framed by reference to any circumstances whatsoever) of pressure equipment or assemblies as the Secretary of State may from time to time determine;
 - (b) may be made subject to such conditions as the Secretary of State may from time to time determine, and such conditions may include conditions which are to apply upon or following termination of the appointment;
 - (c) shall, without prejudice to the generality of sub-paragraph (b) and subject to paragraph (4), require that body to carry out the procedures and specific tasks for which it has been appointed including (where so provided as part of those procedures) surveillance to ensure that the manufacturer of the pressure equipment or assemblies or his authorised representative established within the Community or the importer, as the case may be, duly fulfils the obligations arising out of the relevant conformity assessment procedure;
 - (d) shall be terminated upon 90 days' notice in writing to the Secretary of State at the request of the notified body or recognised third-party organisation; and
 - (e) may be terminated if it appears to the Secretary of State that any of the conditions of the appointment are not complied with.
- (3) Subject to paragraphs (2)(d) and (e), an appointment under this regulation may be for the time being or for such period as may be specified in the appointment.
- (4) A notified body or recognised third-party organisation appointed by the Secretary of State shall not be required to carry out the functions referred to in paragraph (2)(c) if—
- (a) the documents submitted to it in relation to carrying out such functions are not in English or another language acceptable to that body;
 - (b) the person making the application has not submitted with his application the amount of the fee which the body requires to be submitted with the application pursuant to regulation 21; or
 - (c) the body reasonably believes that, having regard to the number of applications made to it in relation to its appointment under these Regulations which are outstanding, it will be unable to commence the required work within three months of receiving the application.
- (5) If for any reason the appointment of a notified body or recognised third-party organisation is terminated under this regulation, the Secretary of State may—
- (a) give such directions (either to the body the subject of the termination or to another notified body or recognised third-party organisation) for the purpose of making such arrangements for the determination of outstanding applications as he considers appropriate; and
 - (b) without prejudice to the generality of the foregoing, authorise another notified body or recognised third-party organisation to take over its functions in respect of such cases as he may specify.
- (6) Where a notified body is minded to refuse to issue an EC type-examination certificate or EC design-examination certificate⁽¹²⁾ it shall—
- (a) give notice in writing to the applicant of the reasons why it is minded to do so; and
 - (b) give the applicant the opportunity to make representations within a period of 28 days of the said notice being given and consider any representations made within that period by the applicant.

(12) Module B and Module B1 in Schedule 4, respectively, concern the application for and issue of an EC type examination certificate and an EC design-examination certificate.

(7) In the framework of quality assurance procedures for pressure equipment in categories III and IV referred to in regulations (2)(a)(i) and (ii)(aa) and (b) the notified body shall,

- (a) 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 paragraph 3.2.2 of Schedule 2 and to this end, the manufacturer shall inform the notified body of the intended schedule of production, and
- (b) shall carry out at least two visits during the first year of manufacturing, the frequency of subsequent visits being determined by the notified body on the basis of the criteria set out in section 4.4 of the relevant modules.

(8) In the case of one-off production of vessels and pressure equipment in category III referred to in regulation 7(2)(b) under the module H procedure, the notified body shall perform or have performed the final assessment, as referred to in paragraph 3.2.2 of Schedule 2, for each unit and to this end, the manufacturer shall communicate the intended schedule of production to the notified body.

Fees

21.—(1) Without prejudice to the power of the Secretary of State, where he is appointed as a notified body in the United Kingdom, to charge fees pursuant to regulations made under section 56 of the Finance Act 1973⁽¹³⁾ and subject to paragraph (2), a notified body or recognised third-party organisation appointed by the Secretary of State may charge such fees in connection with, or incidental to, carrying out its duties in relation to the functions referred to in regulation 20(2)(c) as it may determine; provided that such fees shall not exceed the sum of the following—

- (a) the costs incurred or to be incurred by the notified body or recognised third-party organisation in performing the relevant function; and
- (b) an amount on account of profit which is reasonable in the circumstances having regard to—
 - (i) the character and extent of the work done or to be done by the body on behalf of the applicant; and
 - (ii) the commercial rate normally charged on account of profit for that work or similar work.

(2) The power in paragraph (1) includes the power to require the payment of fees or a reasonable estimate thereof in advance of carrying out the work requested by the applicant.

User inspectorates

22.—(1) For the purposes of these Regulations, a user inspectorate is a body which has been appointed to carry out one or more of the conformity assessment procedures referred to in regulations 13 and 14 and as more specifically defined in paragraph (7) and, which has been—

- (a) appointed in the United Kingdom pursuant to paragraph (2); or,
- (b) appointed by a member State other than the United Kingdom, and has been notified by the member State concerned to the Commission and other member States pursuant to Article 12 of the Pressure Equipment Directive.

(2) The Secretary of State may from time to time appoint such persons and on such conditions as he thinks fit to be a user inspectorate.

(3) No body shall be appointed under this regulation unless the Secretary of State is satisfied that the group of which the user inspectorate is part applies a common safety policy as regards the

(13) 1973 c. 51.

technical specifications for the design, manufacture, inspection, maintenance and use of pressure equipment and assemblies.

(4) An appointment—

- (a) may relate to all descriptions of pressure equipment or assemblies or such descriptions (which may be framed by reference to any circumstances whatsoever) of pressure equipment or assemblies as the Secretary of State may from time to time determine;
- (b) may be made subject to such conditions as the Secretary of State may from time to time determine, and such conditions may include conditions which are to apply upon or following termination of the appointment;
- (c) shall, without prejudice to the generality of sub-paragraph (b) above, require that body, subject to paragraph (10), to carry out the procedures and specific tasks for which it has been appointed including (where so provided as part of those procedures) surveillance to ensure that the manufacturer of the pressure equipment or assemblies or his authorised representative established within the Community or the importer, as the case may be, duly fulfils the obligations arising out of the relevant conformity assessment procedure;
- (d) shall be terminated upon 90 days' notice in writing to the Secretary of State at the request of the user inspectorate; and
- (e) may be terminated if it appears to the Secretary of State that any of the conditions of the appointment are not complied with.

(5) Subject to paragraphs (4)(d) and (e), an appointment under this regulation may be for the time being or for such period as may be specified in the appointment.

(6) The user inspectorates shall act exclusively for the group of which they are part.

(7) The conformity assessment procedures applicable by user inspectorates shall be modules A1, C1, F and G, as described in Schedule 4 and for this purpose references in those modules to “notified body” shall be read as if they are references to “user inspectorate”.

(8) The pressure equipment and assemblies to which the application relates may be used only in establishments operated by the group of which the user inspectorate is part.

(9) The pressure equipment and assembly, the conformity of which has been assessed by a user inspectorate, shall not bear the CE marking.

(10) A user inspectorate appointed by the Secretary of State shall not be required to carry out the functions referred to in paragraph (4)(c) if the documents submitted to it in relation to carrying out such functions are not in English or another language acceptable to that body.

Conditions for pressure equipment and assemblies being taken to conform with the provisions of these Regulations

23.—(1) Subject to paragraph (2), any pressure equipment or assembly which—

- (a) bears the CE marking in accordance with regulation 7(3)(c) or 8(3)(a)(iii); and
- (b) is accompanied by an EC declaration of conformity in accordance with regulation 7(3)(d) or 8(3)(a)(iv),

shall be taken to conform with all the provisions of these Regulations which apply to it, including the appropriate conformity assessment procedure specified in regulation 13, unless there are reasonable grounds for suspecting that it does not so conform.

(2) Paragraph (1) does not apply in relation to an enforcement authority where a person fails or refuses to make available to the enforcement authority the documentation which he is required, by the conformity assessment procedure which applies to that pressure equipment or assembly, to retain a copy thereof.

PART IV ENFORCEMENT

Application of Schedule 8

24.—(1) Subject to paragraph (2), Schedule 8 shall have effect for the purposes of providing for the enforcement of these Regulations and for matters incidental thereto.

(2) Except in the case of pressure equipment or an assembly which, in the opinion of an enforcement authority, is liable to endanger the safety of persons and, where appropriate, domestic animals or property, where an enforcement authority has reasonable grounds for suspecting that the CE marking has been affixed to pressure equipment or an assembly and in relation to which any provision of these Regulations has not been complied with it may serve notice in writing on—

- (a) the manufacturer of the pressure equipment or assembly or his authorised representative established within the Community; or
- (b) in a case where neither the manufacturer of the pressure equipment or assembly nor his authorised representative established within the Community has placed the pressure equipment or assembly on the market, the person who places it on the market in the United Kingdom;

and subject to paragraph (3), no other action pursuant to Schedule 8 may be taken, and no proceedings may be brought pursuant to regulation 25, in respect of that pressure equipment or assembly until such notice has been given and the person to whom it is given has failed to comply with its requirements.

(3) Notwithstanding the provisions of paragraph (2), for the purposes of ascertaining whether or not the CE marking has been correctly affixed, action may be taken pursuant to section 20 of the Health and Safety at Work etc. Act 1974⁽¹⁴⁾ or, in Northern Ireland, pursuant to Article 22 of the Health and Safety at Work (Northern Ireland) Order 1978⁽¹⁵⁾ or section 29 of the Consumer Protection Act 1987⁽¹⁶⁾, as they are applied by Schedule 8.

(4) A notice which is given under paragraph (2) shall—

- (a) state that the enforcement authority suspects that the CE marking has not been correctly affixed to the pressure equipment or assembly;
- (b) specify the respect in which it is so suspected and give particulars thereof;
- (c) require the person to whom the notice is given—
 - (i) to secure that any pressure equipment or assembly to which the notice relates conforms as regards the provisions concerning the correct affixation of the CE marking within such period as may be specified in the notice; or
 - (ii) to provide evidence within that period, to the satisfaction of the enforcement authority, that the CE marking has been correctly affixed; and
- (d) warn that person that if the non-conformity continues after, or if satisfactory evidence has not been provided within, the period specified in the notice, further action may be taken under these Regulations in respect of that pressure equipment or assembly or pressure equipment or assembly of the same type placed on the market by that person.

Offences

25. Any person who—

⁽¹⁴⁾ 1974 c. 37.

⁽¹⁵⁾ S.I. 1978/1039 (N.I. 9).

⁽¹⁶⁾ 1987 c. 43.

- (a) contravenes or fails to comply with regulation 7(1), 8(1), 9(1) or 10,
- (b) fails to supply or retain a copy of the declaration of conformity as required by regulation 7(4); or
- (c) fails to comply with the requirements of regulation 7(5) or 8(5),

shall be guilty of an offence.

Penalties

26.—(1) A person guilty of an offence under regulation 25(a) shall be liable on summary conviction—

- (a) to imprisonment for a term not exceeding 3 months; or
- (b) to a fine not exceeding level 5 on the standard scale,

or to both.

(2) A person guilty of an offence under regulation 25(b) or (c) shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Defence of due diligence

27.—(1) Subject to the following provisions of this regulation, in proceedings against any person for an offence under regulation 25 above it shall be a defence for that person to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) Where in any proceedings against any person for such an offence the defence provided by paragraph (1) involves an allegation that the commission of the offence was due—

- (a) to the act or default of another; or
- (b) to reliance on information given by another,

that person shall not, without the leave of the court, be entitled to rely on the defence unless, not less than seven clear days before the hearing of the proceedings (or, in Scotland, the trial diet), he has served a notice under paragraph (3) on the person bringing the proceedings.

(3) A notice under this paragraph shall give such information identifying or assisting in the identification of the person who committed the act or default or gave the information as is in the possession of the person serving the notice at the time he serves it.

(4) It is hereby declared that a person shall not be entitled to rely on the defence provided by paragraph (1) by reason of his reliance on information supplied by another, unless he shows that it was reasonable in all the circumstances for him to have relied on the information, having regard in particular—

- (a) to the steps which he took, and those which might reasonably have been taken, for the purpose of verifying the information; and
- (b) to whether he had any reason to disbelieve the information.

Liability of persons other than the principal offender

28.—(1) Where the commission by any person of an offence under regulation 25 is due to the act or default committed by some other person in the course of any business of his, the other person shall be guilty of the offence and may be proceeded against and punished by virtue of this paragraph whether or not proceedings are taken against the first-mentioned person.

(2) Where a body corporate is guilty of an offence under these Regulations (including where it is so guilty by virtue of paragraph (1)) in respect of any act or default which is shown to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any

director, manager, secretary or other similar officer of the body corporate or any person who was purporting to act in any such capacity he, as well as the body corporate, shall be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

(3) Where the affairs of a body corporate are managed by its members, paragraph (2) shall apply in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(4) In this regulation, references to a “body corporate” include references to a partnership in Scotland and, in relation to such partnership, any reference to a director, manager, secretary or other similar officer of a body corporate is a reference to a partner.

Consequential amendments

29.—(1) In the Provision and Use of Work Equipment Regulations 1998(**17**), at the end of column (1) of Schedule 1, there shall be added the words “The Pressure Equipment Regulations 1999” and at the end of column (2) the words “[S.I. 1999/2001](#)”.

(2) In the Provision and Use of Work Equipment Regulations (Northern Ireland) 1999(**18**), at the end of column (1) of Schedule 2, there shall be added the words “The Pressure Equipment Regulations 1999” and at the end of column (2) the words “[S.I. 1999/2001](#)”.

(3) In regulation 10(1) of the Pressure Vessels (Verification) Regulations 1988(**19**) there shall be inserted after the words “pressure vessel” the words “, not being one to which the Pressure Equipment Regulations 1999 apply,”.

(4) In regulation 10(1) of the Pressure Vessels (Verification) Regulations (Northern Ireland) 1993(**20**) there shall be inserted after the words “pressure vessel” the words “, not being one to which the Pressure Equipment Regulations 1999 apply,”.

15th July 1999

John Battle,
Minister for Energy & Industry,
Department of Trade and Industry

(17) [S.I. 1998/2306](#).

(18) [S.R. 1999 No. 305](#)

(19) [S.I. 1988/896](#).

(20) [S.R. 1992 No. 79](#), as amended by [S.R. 1999 No. 126](#).

SCHEDULE 1

Regulation 4(1)

EXCLUDED PRESSURE EQUIPMENT AND ASSEMBLIES

1. Pipelines comprising piping or a system of piping designed for the conveyance of any fluid or substance to or from an installation (onshore or offshore) starting from and including the last isolation device located within the confines of the installation, including all the annexed equipment designed specifically for pipelines. This exclusion does not apply to standard pressure equipment such as may be found in pressure reduction stations or compression stations;

2. Networks for the supply, distribution and discharge of water and associated equipment and headraces such as penstocks, pressure tunnels, pressure shafts for hydroelectric installations and their related specific accessories;

3. Equipment covered by Directive [87/404/EEC](#)(**21**) on simple pressure vessels;

4. Equipment covered by Council Directive [75/324/EEC](#) of 20 May 1975 on the approximation of the laws of the member States relating to aerosol dispensers(**22**);

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(**23**);

— 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(**24**);

— Council Directive [92/61/EEC](#) of 30 June 1992 relating to the type-approval of two or three-wheel motor vehicles(**25**);

6. Equipment classified as no higher than category I under Article 9 of this Directive 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(**26**);

— 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(**27**);

— Council Directive [73/23/EEC](#) of 19 February 1973 on the harmonisation of the laws of the member States relating to electrical equipment designed for use within certain voltage limits(**28**);

— Council Directive [93/42/EEC](#) of 14 June 1993 concerning medical devices(**29**);

— 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(**30**);

— Directive [94/9/EC](#) of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the member States concerning equipment and protective systems intended for use in potentially explosive atmospheres(**31**);

(21) OJ No. L220, 8.8.87, p. 48.

(22) OJ No. L147, 9.6.1975, p. 40. Directive as last amended by Commission Directive [94/1/EC](#) (OJ No. L23, 28.1.1994, p. 28).

(23) OJ No. L42, 23.2.1970, p. 1. Directive as last amended by Commission Directive [95/54/EC](#) (OJ No. L266, 8.11.1995, p. 1).

(24) OJ No. L84, 28.3.1974, p. 10. Directive as last amended by the 1994 Act of Accession.

(25) OJ No. L225, 10.8.1992, p. 72. Directive as last amended by the 1994 Act of Accession.

(26) OJ No. L207, 23.7.98, p. 1.

(27) OJ No. L213, 7.9.1995, p. 1.

(28) OJ No. L77, 26.3.1973, p. 29. Directive as last amended by Directive [93/68/EEC](#) (OJ No. L220, 30.8.1993, p. 1).

(29) OJ No. L169, 12.7.1993, p. 1.

(30) OJ No. L196, 26.7.1990, p. 15. Directive as last amended by Directive [93/68/EEC](#) (OJ No. L220, 30.8.1993, p. 1).

(31) OJ No. L100, 19.4.1994, p. 1.

7. Equipment covered by Article 296(1)(b) of the Treaty;
8. Items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;
9. Well-control equipment used in the petroleum, gas or geothermal exploration and extraction industry and in underground storage which is intended to contain and/or control well pressure, that is to say the wellhead (Christmas tree), the blow out preventers (BOP), the piping manifolds and all their equipment upstream;
10. Equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor, such equipment may include:
 - engines including turbines and internal combustion engines,
 - steam engines, gas/steam turbines, turbo-generators, compressors, pumps and actuating devices;
11. Blast furnaces including the furnace cooling system, hot-blast recuperators, dust extractors and blast-furnace exhaust-gas scrubbers and direct reducing cupolas, including the furnace cooling, gas converters and pans for melting, re-melting, de-gassing and casting of steel and non-ferrous metals;
12. Enclosures for high-voltage electrical equipment such as switchgear, control gear, transformers, and rotating machines;
13. Pressurised pipes for the containment of transmission systems, including for example electrical power and telephone cables;
14. Ships, rockets, aircraft and mobile off-shore units, as well as equipment specifically intended for installation on board or the propulsion thereof;
15. Pressure equipment consisting of a flexible casing, including for example tyres, air cushions, balls used for play, inflatable craft, and other similar pressure equipment;
16. Exhaust and inlet silencers;
17. Bottles or cans for carbonated drinks for final consumption;
18. Vessels designed for the transport and distribution of drinks having a PS.V of not more than 500 bar-L and a maximum allowable pressure not exceeding 7 bar;
19. Equipment covered by the ADR(32), the RID(33), the IMDG(34) and the ICAO Convention(35);
20. Radiators and pipes in warm water heating systems;
21. Vessels designed to contain liquids with a gas pressure above the liquid of not more than 0.5 bar.

(32) ADR=European Agreement concerning the International Carriage of Dangerous Goods by Road.

(33) RID=Regulations concerning the International Carriage of Dangerous Goods by Rail.

(34) IMDG=International Maritime Dangerous Goods Code.

(35) ICAO=International Civil Aviation Organisation.

SCHEDULE 2

Regulations 2(2), 7(5), 8(5), 14, 16(1), 19,
20(7)(a)

(Annex I to the Pressure Equipment Directive) ESSENTIAL SAFETY REQUIREMENTS

PRELIMINARY OBSERVATIONS

1. The obligations arising from the essential requirements listed in this Annex for pressure equipment also apply to assemblies where the corresponding hazard exists.
2. The essential requirements laid down in the Directive are compulsory. The obligations laid down in these essential requirements apply only if the corresponding hazard exists for the pressure equipment in question when it is used under 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

1.1. 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

2.1. General

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

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

2.2. Design for adequate strength

(2.2.1) The pressure equipment must be designed for loadings appropriate to its intended use and other reasonably foreseeable operating conditions. In particular, the following factors must be taken into account:

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

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

(2.2.2) Design for adequate strength must be based on:

- as a general rule, a calculation method, as described in 2.2.3, and supplemented if necessary by an experimental design method as described in 2.2.4, or
- an experimental design method without calculation, as described in 2.2.4, when the product of the maximum allowable pressure PS and the volume V is less than 6 000 bar-L or the product $PS-DN$ less than 3 000 bar.

(2.2.3) Calculation method

(a) Pressure containment and other loading aspects

The allowable stresses for pressure equipment must be limited having regard to reasonably foreseeable failure modes under operating conditions. To this end, safety factors must be applied to eliminate fully any uncertainty arising out of manufacture, actual operational conditions, stresses, calculation models and properties and behaviour of the material.

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

The requirements set out above may be met by applying one of the following methods, as appropriate, if necessary as a supplement to or in combination with another method:

- design by formula,
- design by analysis,
- design by fracture mechanics;

(b) Resistance

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

In particular:

- the calculation pressures must not be less than the maximum allowable pressures and take into account static head and dynamic fluid pressures and the decomposition of unstable fluids. Where a vessel is separated into individual pressure-containing chambers, the partition wall must be designed on the basis of the highest possible chamber pressure relative to the lowest pressure possible in the adjoining chamber,
- the calculation temperatures must allow for appropriate safety margins,

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- the design must take appropriate account of all possible combinations of temperature and pressure which might arise under reasonably foreseeable operating conditions for the equipment,
- the maximum stresses and peak stress concentrations must be kept within safe limits,
- the calculation for pressure containment must utilise the values appropriate to the properties of the material, based on documented data, having regard to the provisions set out in section 4 together with appropriate safety factors. Material characteristics to be considered, where applicable, include:
 - yield strength, 0.2% or 1.0% proof strength as appropriate at calculation 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, 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 under 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 2.2.1 such as corrosion, external damage, etc.

2.3. Provisions to ensure safe handling and operation

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

- closures and openings,
- dangerous 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:

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

2.6. Corrosion or other chemical attack

Where necessary, adequate allowance or protection against corrosion or other chemical attack must be provided, taking due account of the intended and reasonably foreseeable use.

2.7. Wear

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

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

2.8. Assemblies

Assemblies must be so designed that:

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

2.9. Provisions for filling and discharge

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

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

2.10. Protection against exceeding the allowable limits of pressure equipment

Where, under reasonably foreseeable conditions, the allowable limits could be exceeded, the pressure equipment must be fitted with, or provision made for the fitting of, suitable protective devices, unless the equipment is intended to be protected by other protective devices within an assembly.

The suitable device or combination of such devices must be determined on the basis of the particular characteristics of the equipment or assembly.

Suitable protective devices and combinations thereof comprise:

- (a) safety accessories as defined in Article 1, section 2.1.3,
- (b) where appropriate, adequate monitoring devices such as indicators and/or alarms which enable adequate action to be taken either automatically or manually to keep the pressure equipment within the allowable limits.

2.11. Safety accessories

(2.11.1) Safety accessories must:

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

(2.11.2) Pressure limiting devices

These devices must be so designed that the pressure will not permanently exceed the maximum allowable pressure PS; however a short duration pressure surge in keeping with the specifications laid down in 7.3 is allowable, where appropriate.

(2.11.3) Temperature monitoring devices

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

2.12. External fire

Where necessary, pressure equipment must be so designed and, where appropriate, fitted with suitable accessories, or provision made for their fitting, to meet damage-limitation requirements in the event of external fire, having particular regard to its intended use.

3 MANUFACTURING

3

3.1. Manufacturing procedures

The manufacturer must ensure the competent execution of the provisions set out at the design stage by applying the appropriate techniques and relevant procedures, especially with a view to the aspects set out below.

(3.1.1) Preparation of the component parts

Preparation of the component parts (e.g. forming and chamfering) must not give rise to defects or cracks or changes in the mechanical characteristics likely to be detrimental to the safety of the pressure equipment.

(3.1.2) Permanent joining

Permanent joints and adjacent zones must be free of any surface or internal defects detrimental to the safety of the equipment.

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

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

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

- a notified body,
- a third-party organisation recognised by a Member State as provided for in Article 13.

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

(3.1.3) Non-destructive tests

For pressure equipment, non-destructive tests of permanent joints must be carried out by suitable qualified personnel. For pressure equipment of categories III and IV, the personnel must be approved by a third-party organisation recognised by a Member State pursuant to Article 13.

(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. Test carried out during manufacture may be taken into account. As far as is necessary on safety grounds, the final inspection must be carried out internally and externally on every part of the equipment, where appropriate in the course of manufacture (e.g. where examination during the final inspection is no longer possible).

(3.2.2) Proof test

Final assessment of pressure equipment must include a test for the pressure containment aspect, which will normally take the form of a hydrostatic pressure test at a pressure at least equal, where appropriate, to the value laid down in 7.4.

For category 1 series-produced pressure equipment, this test may be performed on a statistical basis.

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

(3.2.3) Inspection of safety devices

For assemblies, the final assessment must also include a check of the safety devices intended to check full compliance with the requirements referred to in 2.10.

3.3. Marking and labelling

In addition to the CE marking referred to in Article 15, the following information must be provided:

- (a) for all pressure equipment:
 - the name and address or other means of identification of the manufacturer and, where appropriate, of his authorised representative established within the Community,
 - the year of manufacture,
 - identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number,

- essential maximum/minimum allowable 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 Annex;
- where the pressure equipment is too small, e.g. accessories, the information referred to in (b) may be given on a label attached to that pressure equipment;
- labelling or other adequate means may be used for the mass to be filled and the warnings referred to in (c), provided it remains legible for the appropriate period of time.

3.4. Operating instructions

- (a) When pressure equipment is placed on the market, it must be accompanied, as far as relevant, with instructions for the user, containing all the necessary safety information relating to:
 - mounting including assembling of different pieces of pressure equipment,
 - putting into service,
 - use,
 - maintenance including checks by the user;
- (b) Instructions must cover information affixed to the pressure equipment in accordance with 3.3, with the exception of serial identification, and must be accompanied, where appropriate, by the technical documents, drawings and diagrams necessary for a full understanding of these instructions;
- (c) If appropriate, these instructions must also refer to hazards arising from misuse in accordance with 1.3 and particular features of the design in accordance with 2.2.3.

4 MATERIALS

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

Welding consumables and other joining materials need fulfil only the relevant requirements of 4.1, 4.2(a) and the first paragraph of 4.3, in an appropriate way, both individually and in a joined structure.

4.1 Materials for pressurised parts must:

- (a) have appropriate properties for all operating conditions which are reasonably foreseeable and for all test conditions, and in particular they should be sufficiently ductile and tough. Where appropriate, the characteristics of the materials must comply with the requirements of 7.5. Moreover, due care should be exercised in particular in selecting materials in order to prevent brittle-type fracture where necessary; where for specific reasons brittle material has to be used appropriate measures must be taken;
 - (b) be sufficiently chemically resistant to the fluid contained in the pressure equipment; the chemical and physical properties necessary for operational safety must not be significantly affected within the scheduled lifetime of the equipment;
 - (c) not be significantly affected by ageing;
 - (d) be suitable for the intended processing procedures;
 - (e) be selected in order to avoid significant undesirable effects when the various materials are put together.
- (a) (a) The pressure equipment manufacturer must define in an appropriate manner the values necessary for the design calculations referred to in 2.2.3 and the essential characteristics of the materials and their treatment referred to in 4.1;
 - (b) the manufacturer must provide in his technical documentation elements relating to compliance with the materials specification of the Directive in one of the following forms:
 - by using materials which comply with harmonised standards,
 - by using materials covered by a European approval of pressure equipment materials in accordance with Article 11,
 - 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, the following requirements apply to the pressure equipment covered by sections 5 and 6.

5 FIRED OR OTHERWISE HEATED PRESSURE EQUIPMENT WITH A RISK OF OVERHEATING AS REFERRED TO IN ARTICLE 3(1)

5

This pressure equipment includes:

- steam and hot-water generators as referred to in Article 3, section 1.2, such as fired steam and hot-water boilers, superheaters and reheaters, waste-heat boilers, waste incineration boilers, electrode or immersion-type electrically heated boilers, pressure cookers, 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 Article 3, section 1.1, such as heaters for chemical and other similar processes and pressurised food-processing equipment.

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

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

6 PIPING AS REFERRED TO IN ARTICLE 3, SECTION 1.3

6

Design and construction must ensure:

- (a) that the risk of overstressing from inadmissible free movement or excessive forces being produced, e.g. on flanges, connections, bellows or hoses, is adequately controlled by means such as support, constraint, anchoring, alignment and pre-tension;
- (b) that where there is a possibility of condensation occurring inside pipes for gaseous fluids, means are provided for drainage and removal of deposits from low areas to avoid damage from water hammer or corrosion;
- (c) that due consideration is given to the potential damage from turbulence and formation of vortices; the relevant parts of 2.7 are applicable;
- (d) that due consideration is given to the risk of fatigue due to vibrations in pipes;
- (e) that, where fluids of Group 1 are contained in the piping, appropriate means are provided to isolate 'take-off' pipes the size of which represents a significant risk;
- (f) that the risk of inadvertent discharge is minimised; the take-off points must be clearly marked on the permanent side, indicating the fluid contained;
- (g) that the position and route of underground piping is at least recorded in the technical documentation to facilitate safe maintenance, inspection or repair.

7 SPECIFIC QUANTITATIVE REQUIREMENTS FOR CERTAIN PRESSURE EQUIPMENT

7

The following provisions apply as a general rule. However, where they are not applied, including in cases where materials are not specifically referred to and no harmonised standards are applied, the manufacturer must demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.

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

7.1. Allowable stresses

(7.1.1) Symbols

R_e/t , yield limit, indicates the value at the calculation temperature of:

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

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

R_m/t designates the ultimate strength at the calculation temperature.

(7.1.2) The permissible general membrane stress for predominantly static loads and for temperatures outside the range in which creep is significant must not exceed the smaller of the following values, according to the material used:

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

7.2. Joint coefficients

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

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

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

7.3. Pressure limiting devices, particularly for pressure vessels

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

7.4. Hydrostatic test pressure

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

- that corresponding to the maximum loading to which the pressure equipment may be subject in service taking into account its maximum allowable pressure and its maximum allowable temperature, multiplied by the coefficient 1.25 or
- the maximum allowable pressure multiplied by the coefficient 1.43, whichever is the greater.

7.5. Material characteristics

Unless other values are required in accordance with other criteria that must be taken into account, a steel is considered as sufficiently ductile to satisfy 4.1(a) if, in a tensile test carried out by a standard procedure, its elongation after rupture is no less than 14% and its bending rupture energy measured on an ISO IV 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 3

Regulation 12

(Annex II to the Pressure Equipment Directive) CONFORMITY ASSESSMENT TABLES

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

- I = Module A
- II = Modules 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 Article 1, Section 2.1.3, and referred to in Article 3, Section 1.4, 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 Article 1, Section 2.1.4, and referred to in Article 3, Section 1.4, 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.

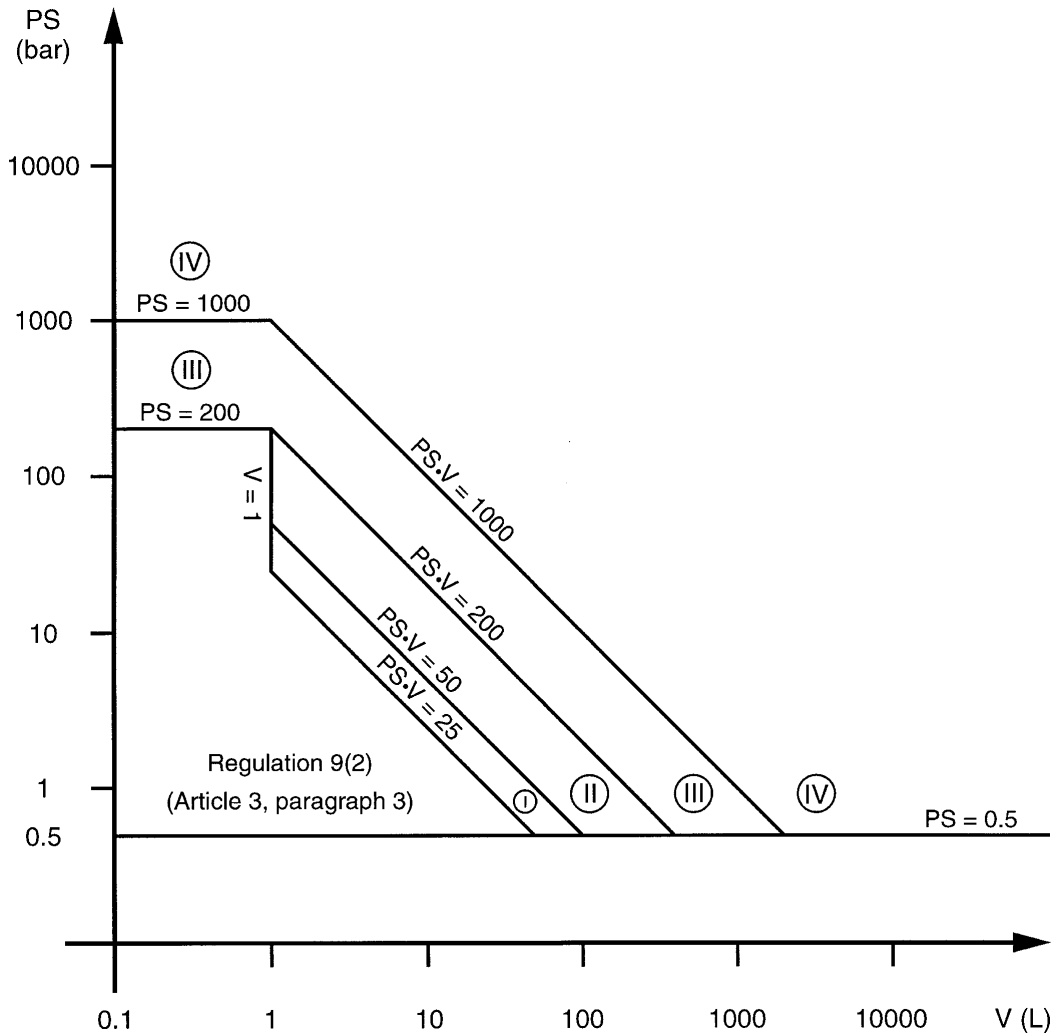
Where both the volume and the nominal size are considered appropriate in the second indent, the pressure accessory must be classified in the highest category.

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

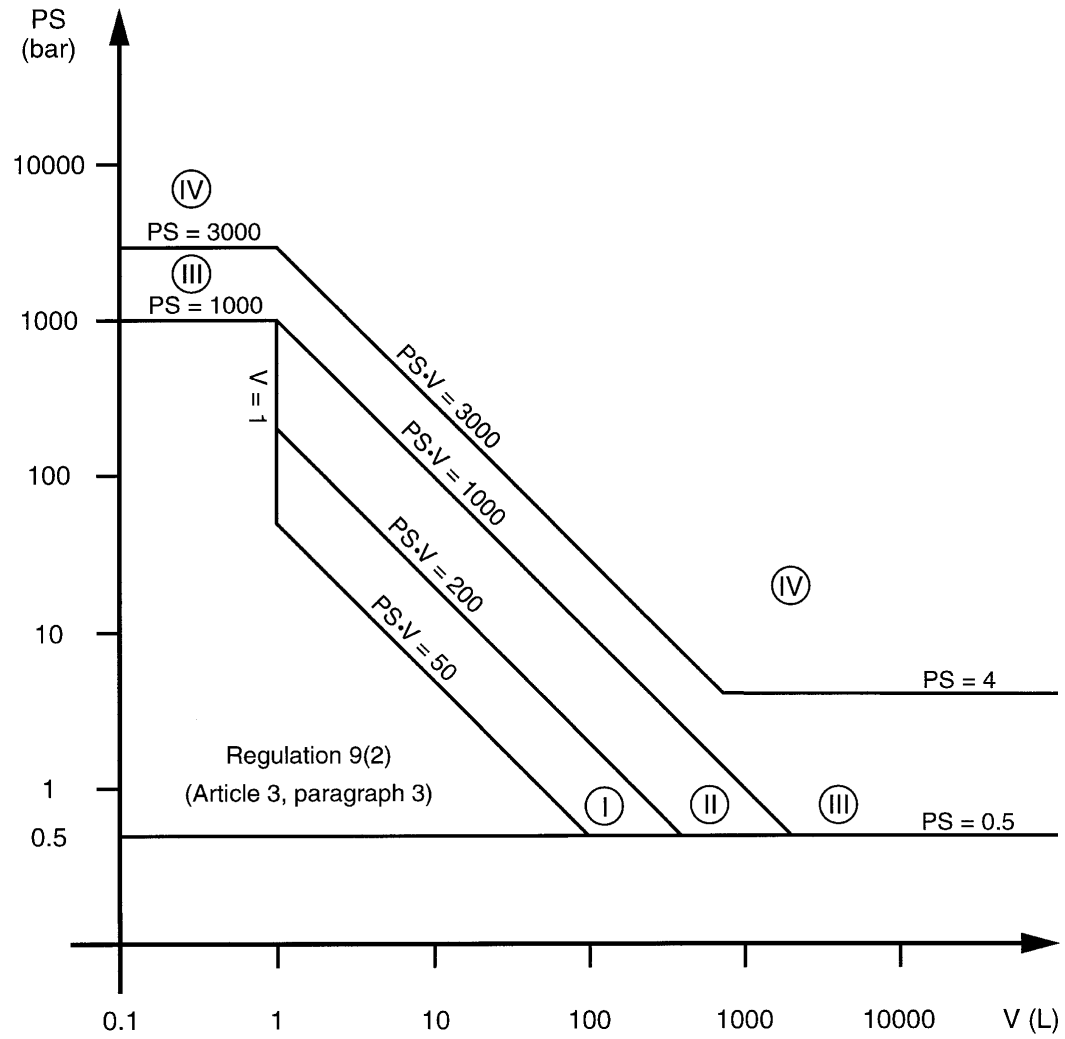
Vessels referred to in Article 3, Section 1.1(a), first indent

Table 1 Vessels referred to in Article 3, Section 1.1(a), 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.

Status: This is the original version (as it was originally made).

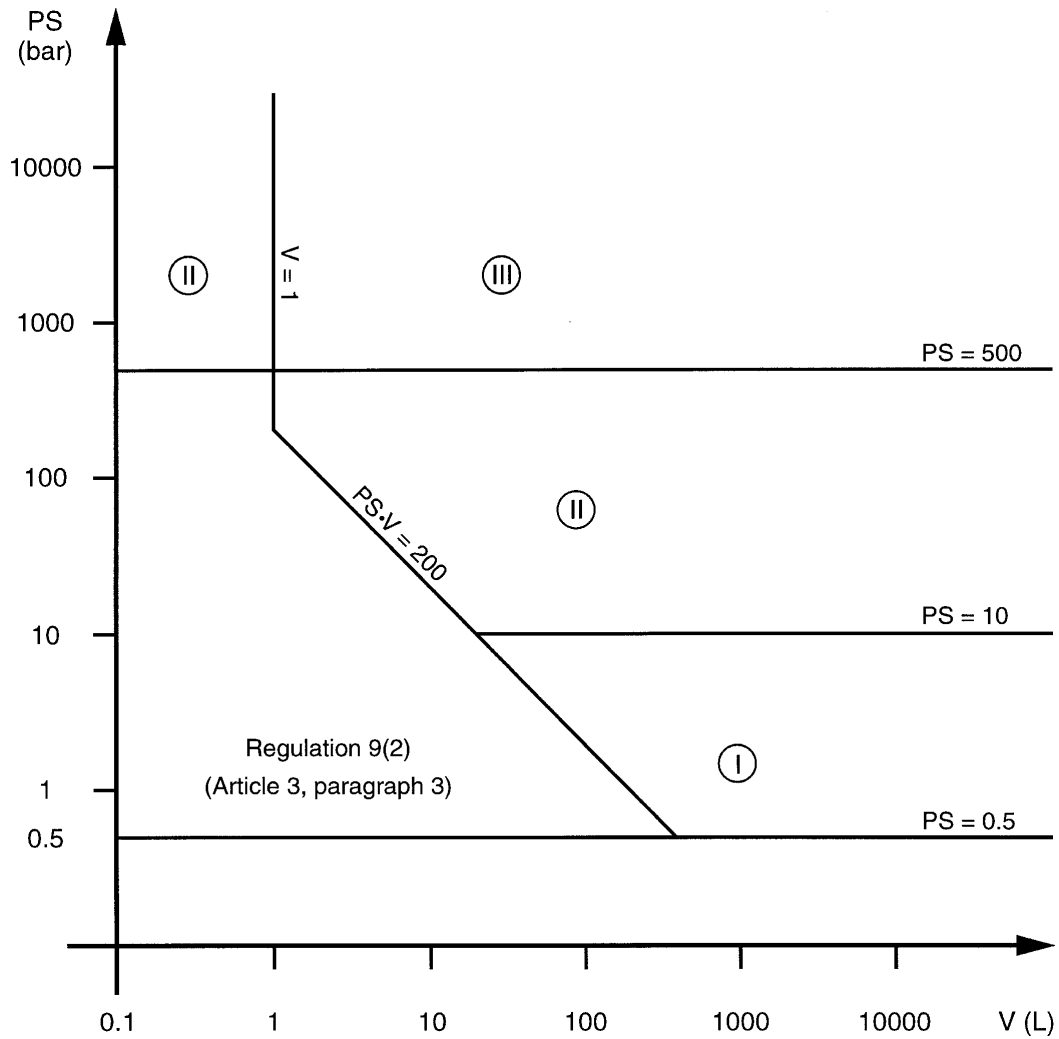


Vessels referred to in Article 3, Section 1.1(a), second indent
 Table 2 Vessels referred to in Article 3, Section 1.1(a), second indent Exceptionally, portable extinguishers and bottles for breathing equipment must be classified at least in category III



Vessels referred to in Article 3, Section 1.1(b), first indent
Table 3 Vessels referred to in Article 3, Section 1.1(b), first indent

Status: This is the original version (as it was originally made).



Vessels referred to in Article 3, Section 1.1(b), second indent

Table 4 Vessels referred to in Article 3, Section 1.1(b), second indent Exceptionally, assemblies intended for generating warm water as referred to in Article 3, Section 2.3, must be subject either to an EC design examination (Module B1) with respect to their conformity with the essential requirements referred to in Sections 2.10, 2.11, 3.4, 5(a) and 5(d) of Annex I, or to full quality assurance (Module H).

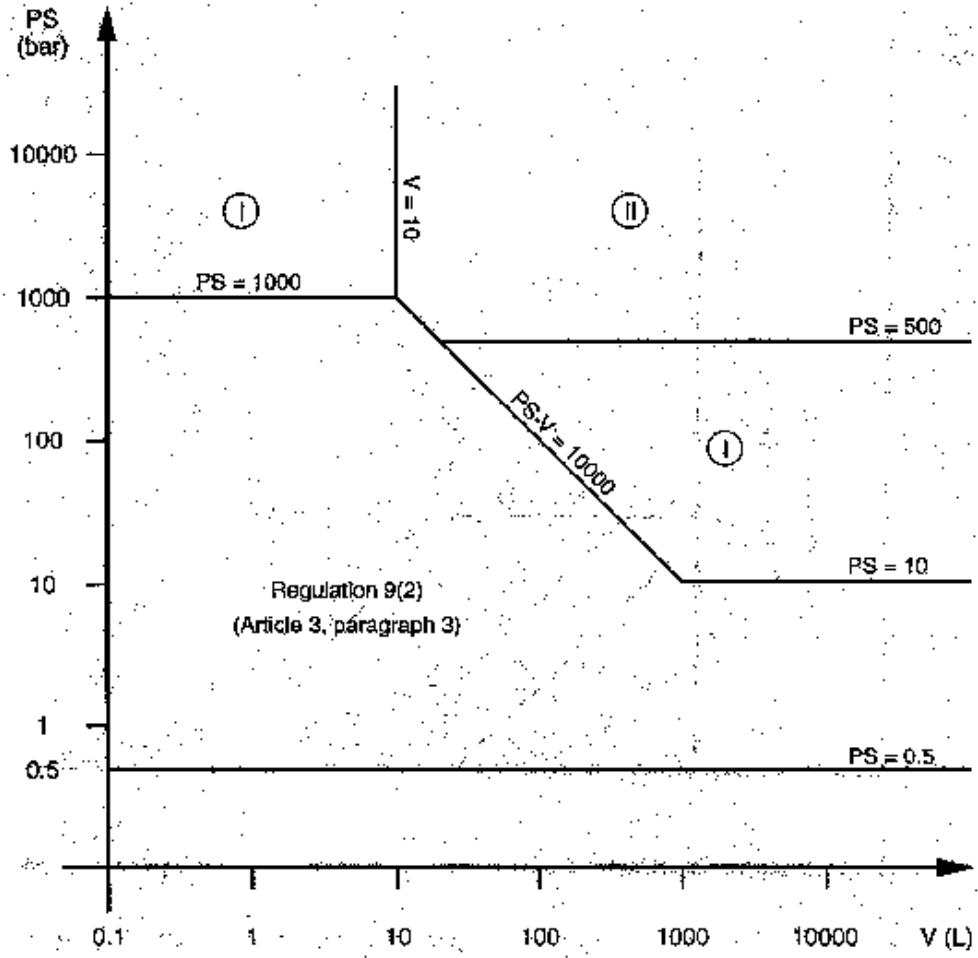


Table 4

Pressure equipment referred to in Article 3, Section 1.2

Table 5 Pressure equipment referred to in Article 3, Section 1.2 Exceptionally, the design of pressure-cookers must be subject to a conformity assessment procedure equivalent to at least one of the category III modules.

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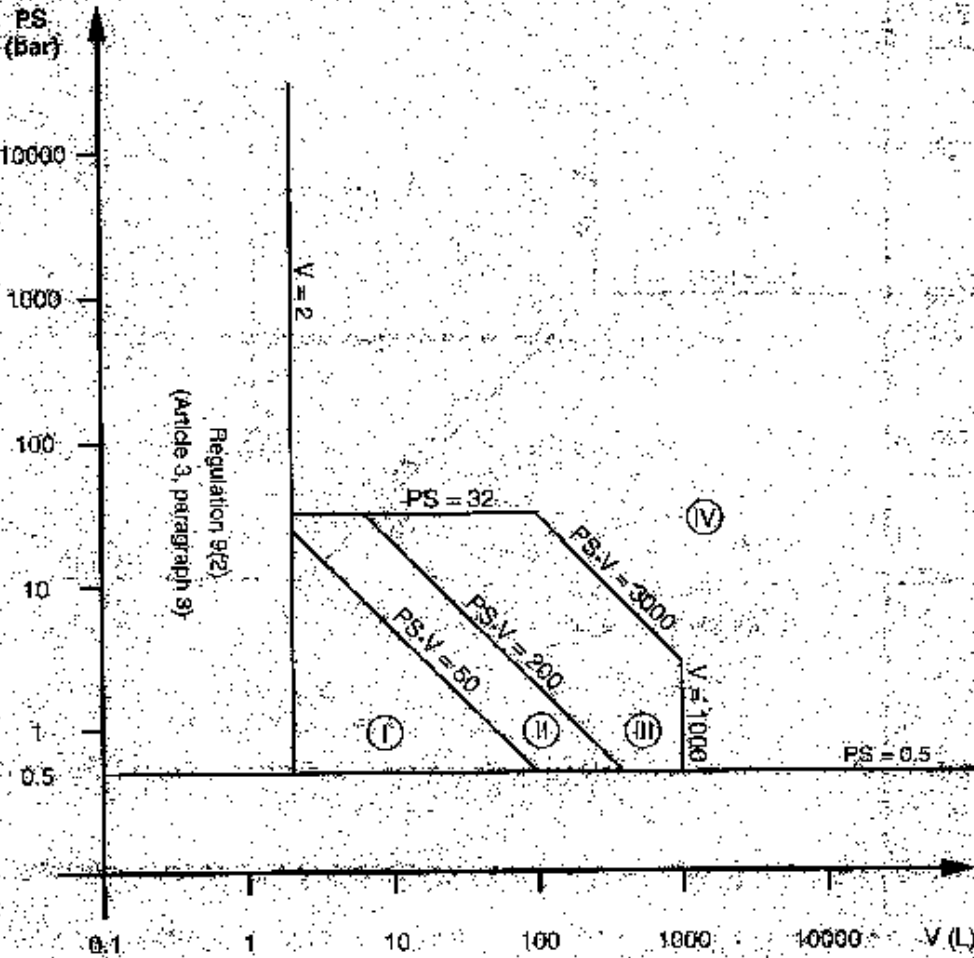


Table 5

Piping referred to in Article 3, Section 1.3(a), first indent
 Table 6 Piping referred to in Article 3, Section 1.3(a), 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.

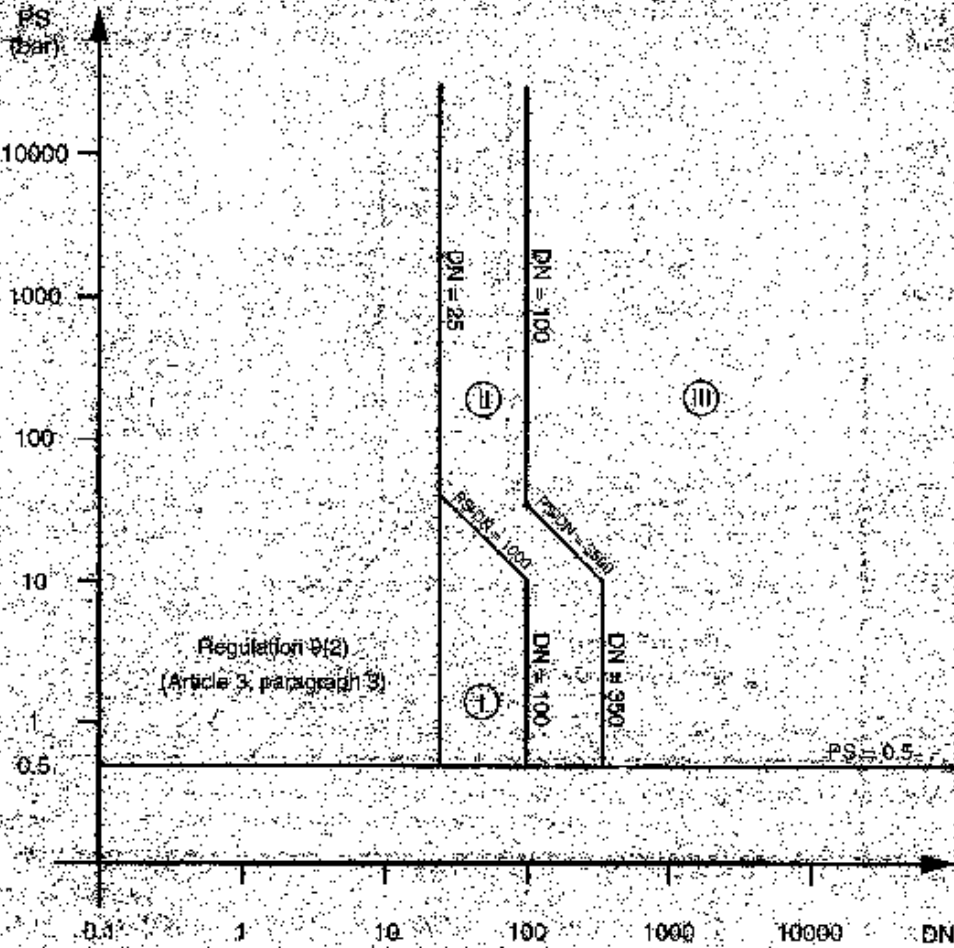


Table 6

Piping referred to in Article 3, Section 1.3(a), second indent

Table 7 Piping referred to in Article 3, Section 1.3(a), 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 category III.

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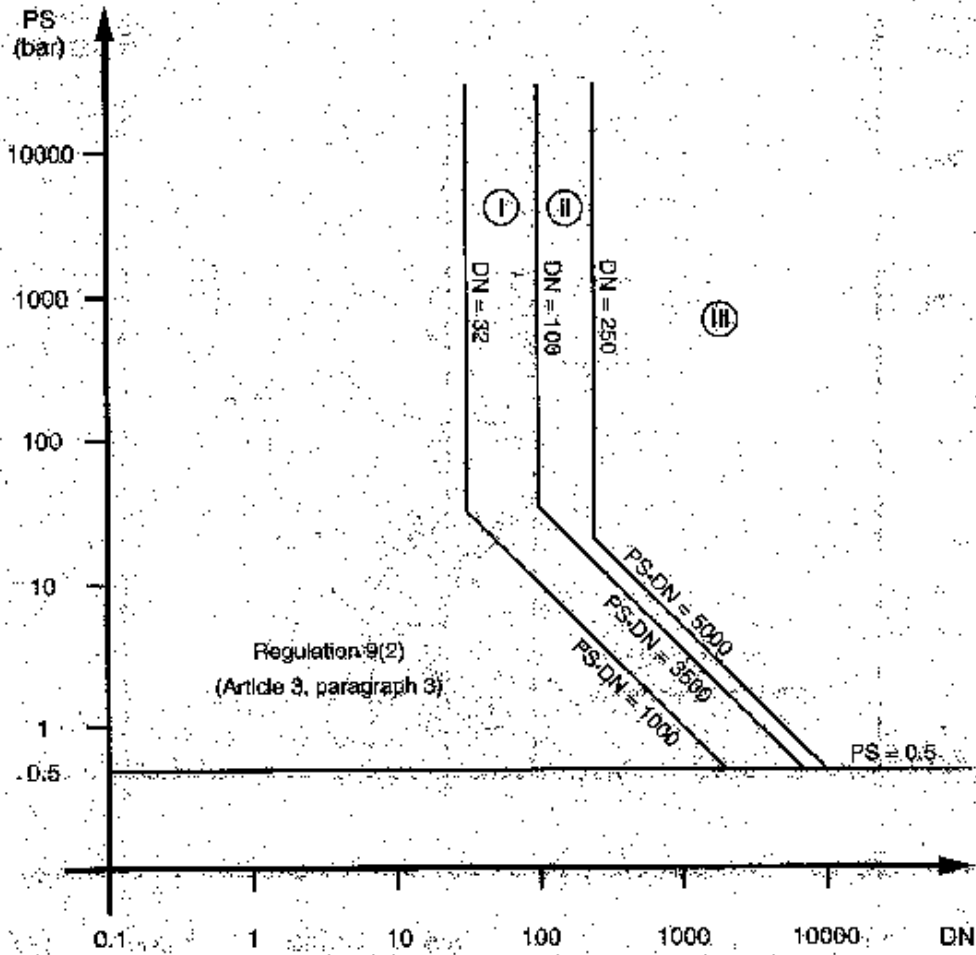


Table 7

Piping referred to in Article 3, Section 1.3(b), first indent

Table 8 Piping referred to in Article 3, Section 1.3(b), first indent

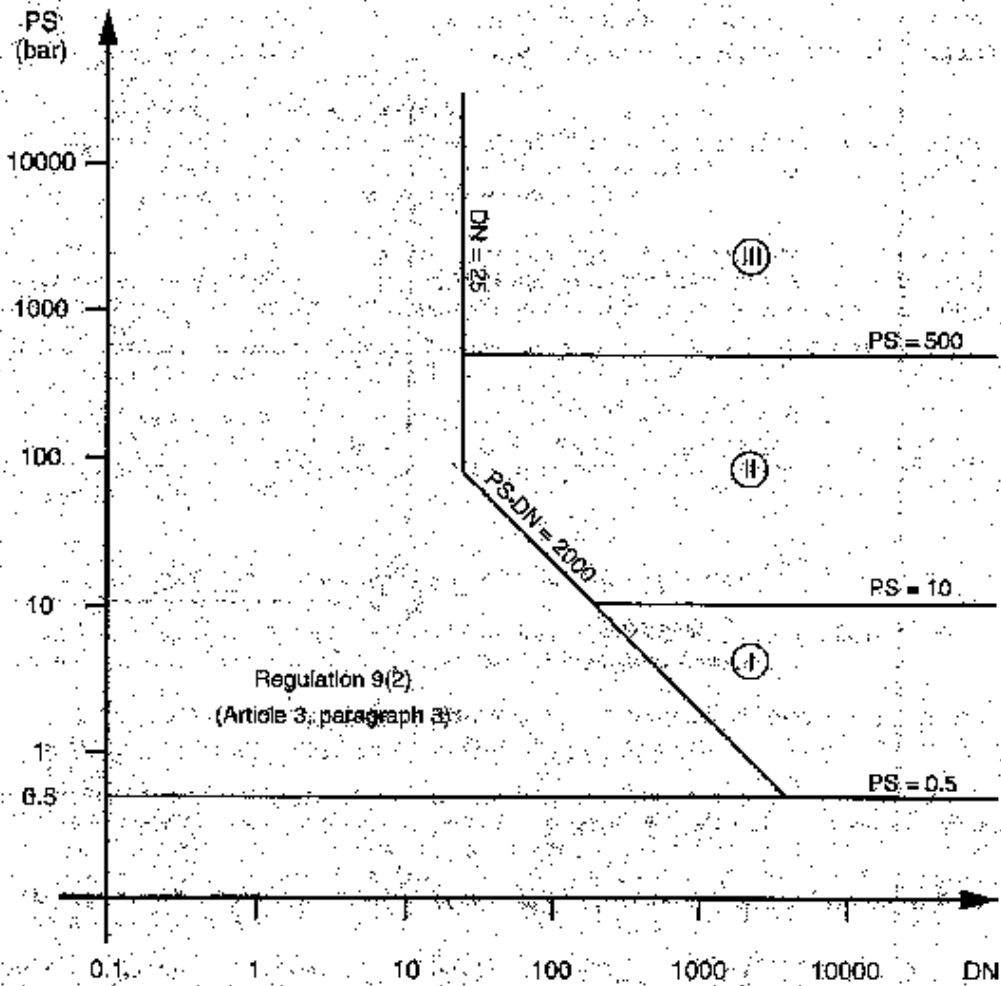
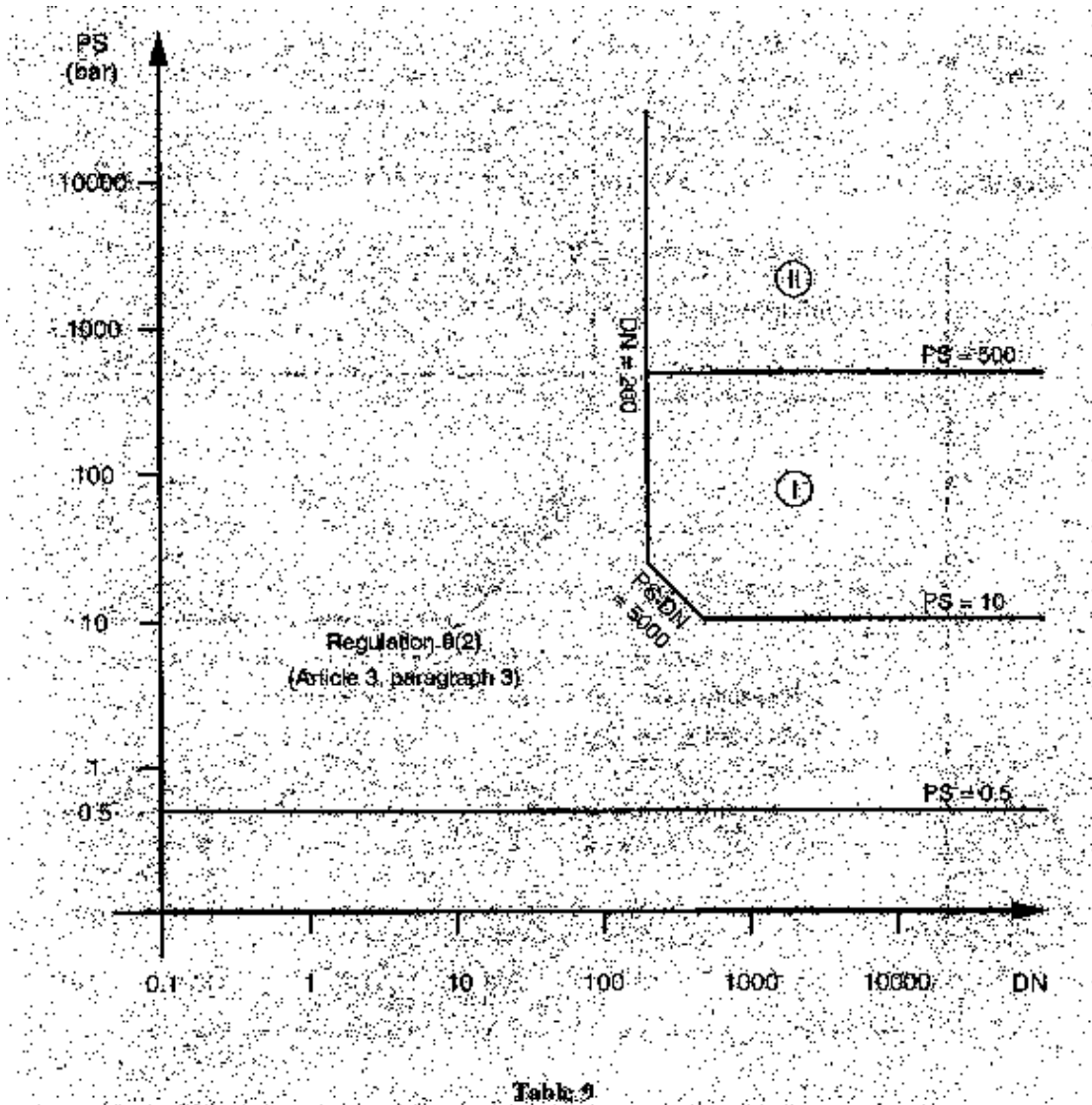


Table 8

Piping referred to in Article 3, Section 1.3(b), second indent
Table 9 Piping referred to in Article 3, Section 1.3(b), second indent

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SCHEDULE 4

Regulation 13

(Annex III to the Pressure Equipment Directive)
CONFORMITY ASSESSMENT PROCEDURES

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

Module A (internal production control)

1. This module describes the procedure whereby the manufacturer or his authorised representative established within the Community who carries out the obligations laid down in section 2 ensures and declares that pressure equipment satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the

Community, 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 and either the manufacturer or his authorised representative established within the Community 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 authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the pressure equipment on the Community market.

3. The technical documentation must enable an assessment to be made of the conformity of the pressure equipment with the requirements of the Directive 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 Article 5, applied in full or in part, and a description of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

2. The manufacturer, or his authorised representative established within the Community, must keep a copy of the declaration of conformity with the technical documentation.

5. 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 and with the requirements of the Directive 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 section 3.2 of Annex I,
- 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 Directive which apply to it.

2. The application for EC type-examination must be lodged by the manufacturer or by his authorised representative established within the Community 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 authorised 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.

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.

3. The technical documentation must enable an assessment to be made of the conformity of the pressure equipment with the requirements of the Directive 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 Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 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 sections 3.1.2 and 3.1.3 of Annex I.

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 Article 5, 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 harmonised standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with section 4.3 of Annex I,

- approve the procedures for the permanent joining of pressure equipment parts, or check that they have been previously approved in accordance with section 3.1.2 of Annex I,
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with sections 3.1.2 or 3.1.3 of Annex I.

(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 Directive where the standards referred to in Article 5 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 Directive 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 authorised representative established within the Community, 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 authorised representative established within the Community, 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 authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community 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 Directive which apply to it.

Status: This is the original version (as it was originally made).

The experimental design method provided for in section 2.2.4 of Annex I may not be used in the context of this module.

2. The manufacturer, or his authorised representative established within the Community, 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 authorised 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.

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 Directive 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 Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 have not been applied,
- the necessary supporting evidence for the adequacy of the design solution, in particular where the standards referred to in Article 5 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 sections 3.1.2 and 3.1.3 of Annex 1.

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 Article 5, 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 harmonised 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 section 3.1.2 of Annex I,
- verify that the personnel undertaking the permanent joining of pressure equipment parts and the non-destructive tests are qualified or approved in accordance with sections 3.1.2 and 3.1.3 of Annex I.

(4.2) perform the necessary examinations to establish whether the solutions adopted by the manufacturer meet the essential requirements of the Directive where the standards referred to in Article 5 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 Directive 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 authorised representative established within the Community, 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 Directive 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 authorised representative established within the Community, 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 authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.

Module C1 (conformity to type)

1. This module describes that part of the procedure whereby the manufacturer, or his authorised representative established within the Community, 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 Directive which apply to it. The manufacturer, or his authorised representative established within the Community, 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 Directive which apply to it.

3. The manufacturer, or his authorised representative established within the Community, 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.

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Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the pressure equipment on the Community 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 section 3.2 of Annex I,
- 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 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 Directive which apply to it. The manufacturer, or his authorised representative established within the Community, 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.

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

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 Directive 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 organisational 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 section 3.1.2 of Annex I,
- 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 sections 3.1.2. and 3.1.3 of Annex I,
- 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 3.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in 3.2.

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 authorised representative established within the Community, 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 3.2 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

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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 organisation, 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 3.1;
- the adjustments referred to in the second paragraph of 3.4;
- the decisions and reports from the notified body which are referred to in the last paragraph of 3.3, the last paragraph of 3.4, and in 4.3 and 4.4.

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 ensures and declares that the items of pressure equipment concerned satisfy the requirements of the Directive which apply to them. The manufacturer, or his authorised representative established within the Community, 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.

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 Directive 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 Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 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 and be subject to surveillance as specified in section 5.

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 Directive 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 organisational 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 section 3.1.2 of Annex I,
- 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 section 3.1.2 of Annex I,
- 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 4.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in 4.2.

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 authorised representative established within the Community, 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 4.2 or whether a reassessment is required.

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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 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 organisation, 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,
- the documentation referred to in the second indent of 4.1,
- the adjustments referred to in the second paragraph of 4.4,
- the decisions and reports from the notified body which are referred to in the last paragraph of 4.3, the last paragraph of 4.4, and in 5.3 and 5.4.

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 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 which apply to it. The manufacturer, or his authorised representative established within the Community, 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.

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

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 Article 5, or equivalent tests, particularly final assessment as referred to in section 3.2 of Annex I, must be carried out in order to ensure its conformity with the requirements of the Directive 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 organisational 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 sections 3.1.2 and 3.1.3 of Annex I.

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

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 authorised representative established within the Community, 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 3.2 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 organisation, 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 3.1,
- the adjustments referred to in the second paragraph of 3.4,
- the decisions and reports from the notified body which are referred to in the last paragraph of 3.3, the last paragraph of 3.4, and in 4.3 and 4.4.

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 ensures and declares that the pressure equipment satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community 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.

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 Directive 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 Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 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 and be subject to surveillance as specified in section 5.

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 Article 5, or equivalent tests, and particularly final assessment as referred to in section 3.2 of Annex I, must be carried out in order to ensure its conformity with the requirements of the Directive 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 organisational 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 section 3.1.2 of Annex I,
- 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 section 3.1.2 of Annex I.

(4.3) The notified body must assess the quality system to determine whether it satisfies the requirements referred to in 4.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in 4.2.

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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 authorised representative established within the Community, 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 4.2 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 organisation, 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,
- the documentation referred to in the second indent of 4.1,

- the adjustments referred to in the second paragraph of 4.4,
- the decisions and reports from the notified body which are referred to in the last paragraph of 4.3, the last paragraph of 4.4 and in 5.3 and 5.4.

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 authorised representative established within the Community, ensures and declares that the pressure equipment subject to the provisions of section 3 is in conformity with the type described:

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

and satisfies the requirements of the Directive 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 Directive which apply to it.

The manufacturer, or his authorised representative established within the Community, 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 Directive by examining and testing every product in accordance with section 4.

The manufacturer, or his authorised representative established within the Community, 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 Article 5 or equivalent examinations and tests in order to verify that it conforms to the type and the requirements of the Directive 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 sections 3.1.2 and 3.1.3 of Annex I,
- verify the certificate issued by the materials manufacturer in accordance with section 4.3 of Annex I,
- carry out or have carried out the final inspection and proof test referred to in section 3.2 of Annex I 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 authorised representative established within the Community, 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 satisfies the requirements of the Directive 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 Directive 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 Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive where the standards referred to in Article 5 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 sections 3.1.2 and 3.1.3 of Annex I.

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 Article 5 of the Directive, or equivalent examinations and tests, to ensure its conformity with the requirements of the Directive 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 harmonised standards or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with section 4.3 of Annex I,
- approve the procedures for the permanent joining of parts or check that they have been previously approved in accordance with section 3.1.2 of Annex I,

- verify the qualifications or approvals required under sections 3.1.2 and 3.1.3 of Annex I,
- carry out the final inspection referred to in section 3.2.1 of Annex I, perform or have performed the proof test referred to in section 3.2.2 of Annex I, 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 authorised representative established within the Community, 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 ensures and declares that the pressure equipment in question satisfies the requirements of the Directive which apply to it. The manufacturer, or his authorised representative established within the Community, 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.

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

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 Directive 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 organisational 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 Article 5 are not applied in full, the means that will be used to ensure that the essential requirements of the Directive 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 section 4 of Annex I,
- 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 section 3.1.2 of Annex I,

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- 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 sections 3.1.2 and 3.1.3 of Annex I,
- 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 3.2. The elements of the quality system which conform to the relevant harmonised standard are presumed to comply with the corresponding requirements referred to in 3.2.

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 authorised representative established within the Community, 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 3.2 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, report 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 organisation, 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 3.1;
- the adjustments referred to in the second subparagraph of 3.4;
- the decisions and reports from the notified body which are referred to in the last subparagraph of 3.3, the last subparagraph of 3.4, and in 4.3 and 4.4.

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 Directive 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 Article 5 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 Directive which apply to it issue an EC design-examination certificate to the applicant. The certificate must contain the conclusions of the examination, the conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the functioning of the pressure equipment or accessories;
 - (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 the Directive 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;

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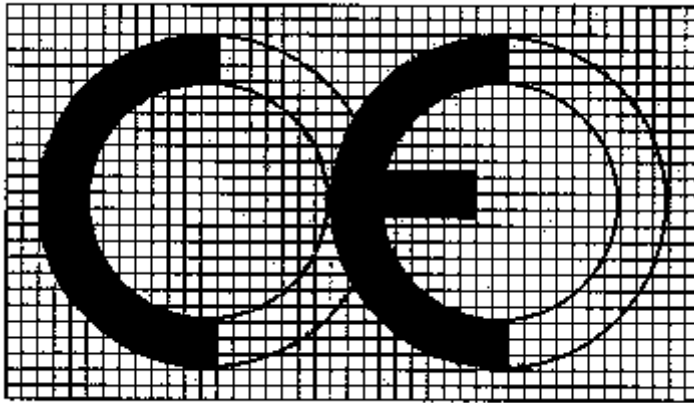
- (e) each notified body must also communicate to the other notified bodies the relevant information concerning the EC design-examination certificates it has withdrawn or refused.
- 2. Final assessment as referred to in section 3.2 of Annex I is subject to increased surveillance in the form of unexpected visits by the notified body. In the course of such visits, the notified body must conduct examinations on the pressure equipment.

SCHEDULE 5

Regulations 2(2), 7(3)(c), 8(3)(a)(iii)

(Annex VI to the Pressure Equipment Directive)
CE MARKING

- 1. The CE marking shall consist of the initials “CE” taking the following form:



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

SCHEDULE 6

Regulations 7(3)(d), 8(3)(a)(iv)

(Annex VII to the Pressure Equipment Directive)
EC DECLARATION OF CONFORMITY

The EC declaration of conformity must contain the following particulars:

- name and address of the manufacturer or of his authorised representative established within the Community,
- description of the pressure equipment or assembly,
- conformity assessment procedure followed,
- in the case of assemblies, description of the pressure equipment constituting the assembly, and the conformity assessment procedures followed,
- where appropriate, name and address of the notified body which carried out the inspection,

- where appropriate, a reference to the EC type-examination certificate, EC design-examination certificate or EC certificate of conformity,
- where appropriate, name and address of the notified body monitoring the manufacturer's quality assurance system,
- where appropriate, the references of the harmonised standards applied,
- where appropriate, other technical standards and specifications used,
- where appropriate, the references of the other Community Directives applied,
- particulars of the signatory authorised to sign the legally binding declaration for the manufacturer or his authorised representative established within the Community.

SCHEDULE 7

Regulation 17

EUROPEAN APPROVAL FOR MATERIALS

1. 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, and in the case of materials recognised as being safe to use before 29th November 1999, the notified body shall take account of the existing data when certifying such conformity.

2. The notified body shall not issue a European approval for materials until it has:

- (a) informed the Member States and the Commission by sending them the appropriate information;
- (b) allowed a period of three months to elapse in order that a member State or the Commission may refer the matter to the Standing Committee set up by Article 5 of Directive [98/34/EC](#);
- (c) taken into account, where appropriate, the opinion of the Committee and the comments submitted.

3. A copy of the European approval for pressure equipment materials shall be sent to the member States, the notified bodies and the Commission.

4. 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 Schedule 2.

5. 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 if the type of materials is covered by a harmonised standard and shall immediately inform the other member States, the notified bodies and the Commission of any withdrawal of an approval.

SCHEDULE 8

Regulation 24

ENFORCEMENT

Enforcement in Great Britain

1. In Great Britain, in relation to pressure equipment or assemblies for use in the workplace—

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- (a) it shall be the duty of the Executive to make adequate arrangements for the enforcement of these Regulations, and accordingly a reference in the provisions applied for the purposes of such enforcement by sub-paragraph (b) to an “enforcing authority” shall be construed as a reference to the Executive;
- (b) sections 19 to 28(36), 33 to 35(37), 38, 39, 41 and 42 of the 1974 Act shall apply for the purposes of providing for the enforcement of these Regulations and in respect of proceedings for contravention thereof as if—
 - (i) references to relevant statutory provisions were references to those sections as applied by this paragraph and to these Regulations;
 - (ii) references to articles, substances, articles and substances, or plant, were references to pressure equipment or assemblies;
 - (iii) references to the field of responsibility of an enforcing authority, however expressed, were omitted;
 - (iv) in section 20, subsection (3) was omitted;
 - (v) in section 23, subsections (3), (4) and (6) were omitted;
 - (vi) in section 33—
 - (aa) in subsection (1) the whole of paragraphs (a) to (d) were omitted;
 - (bb) subsection (1A) was omitted;
 - (cc) in subsection (2), the reference to paragraph (d) of subsection (1) was omitted;
 - (dd) subsection (2A) was omitted;
 - (ee) for subsection (3) there was substituted the following:—
 - “(3) A person guilty of an offence under any paragraph of subsection (1) above not mentioned in subsection (2) above or of an offence under subsection (1)(e) above not falling within that subsection shall be liable—
 - (a) on summary conviction, to a fine not exceeding level 5 on the standard scale; or
 - (b) on conviction on indictment—
 - (i) in the case of an offence under subsection (1)(g), (j) or (o), to imprisonment for a term not exceeding two years, or a fine, or both; or
 - (ii) in all other cases, to a fine.”; and
 - (ff) subsection (4) was omitted;
 - (vii) in section 34—
 - (aa) paragraphs (a) and (b) were omitted from subsection (1); and
 - (bb) in subsection (3) for “six months” there was substituted “twelve months”; and

(36) In section 22, subsections (1) and (2) were amended and subsection (4) was added by paragraph 2, of Schedule 3 to, and section 36 of, the Consumer Protection Act 1987 (c. 43). Sections 25A and 27A were inserted by paragraphs 3 and 4 respectively, and section 28(1)(a) was amended by paragraph 5 of Schedule 3 to and section 36 of, 1987 c. 43; section 27 was amended by the repeal of subsection (2)(b) and the word “or” immediately preceding it by section 29(3) and (4) of, paragraph 10(1) and (2) of Schedule 6 and Schedule 7 to, the Employment Act 1989 (c. 38), and in subsection (3) by section 33(1) of, and paragraph 7(a) of Part II of Schedule 3 to, the Employment Act 1988 (c. 19) and section 29(3) of, and paragraph 10(3) of Schedule 6 to, 1989 c. 38.

(37) Section 33 was amended in subsection (1) in paragraph (h) by section 36 of, and paragraph 6 of Schedule 3 to, 1987 c. 43, and in paragraph (m) by section 30 of, and Part I of the Schedule to, the Forgery and Counterfeiting Act 1981 (c. 45); in subsection (2) as it applies to England and Wales by section 46 of the Criminal Justice Act 1982 (c. 48).

- (viii) in section 42, subsections (4) and (5) were omitted;
 - (c) sections 36(1) and (2) and 37 shall apply in relation to offences under section 33 as applied by sub-paragraph (b)(vi); and
 - (c) Any function of the Health and Safety Commission under the 1974 Act which is exercisable in relation to the enforcement by the Executive of the relevant statutory provisions shall be exercisable in relation to the enforcement by the Executive of these Regulations.
2. In Great Britain, in relation to pressure equipment or assemblies for private use or consumption—
- (a) it shall be the duty of every weights and measures authority to enforce these Regulations within their area and a reference in the provisions applied to these Regulations by sub-paragraph (b) to an “enforcement authority” shall be construed accordingly;
 - (b) sections 14, 15, 28 to 35, 37, 38, 44 and 47 of the 1987 Act shall apply for the purposes of providing for the enforcement of these Regulations and in respect of proceedings for contravention thereof as if—
 - (i) references to safety provisions were references to these Regulations;
 - (ii) references to goods were references to pressure equipment or assemblies as the context may require;
 - (iii) in section 14, in sub-section (6), for “six months” there was substituted “three months”;
 - (iv) in sections 28, 29, 30, 33, 34 and 35, the words “or any provision made by or under Part III of this Act” on each occasion that they occur, were omitted;
 - (v) in section 28, sub-sections (3), (4) and (5) were omitted;
 - (vi) in section 29, sub-section (4) was omitted;
 - (vii) in section 30, sub-sections (7) and (8) were omitted; and
 - (viii) in section 38(1), paragraphs (a) and (b) were omitted;
 - (d) sections 39 and 40 of the 1987 Act shall apply to offences under section 32 of that Act as it is applied to these Regulations by sub-paragraph (b); and
 - (e) in England and Wales, a magistrates' court may try an information in respect of an offence committed under these Regulations if the information is laid within twelve months from the time when the offence is committed, and in Scotland summary proceedings for such an offence may be begun at any time within twelve months from the time when the offence is committed.

Enforcement in Northern Ireland in relation to pressure equipment or assemblies

3.—(1) In Northern Ireland it shall be the duty of the Health and Safety Executive for Northern Ireland to make adequate arrangements for the enforcement of these Regulations in relation to pressure equipment or assemblies for use in the workplace and a reference in the provisions applied to these Regulations by sub-paragraph (2) below to an “enforcing authority” or to its “field of responsibility” (however expressed) shall be construed accordingly.

- (a) (2) (a) For the purposes of providing for the enforcement of these Regulations and in respect of proceedings for contravention thereof, Articles 21 to 33(38), 35, 36, 38 and 39 of the Order shall apply as if—

(38) Article 24(1) and (2) was amended, and Article 24(3) substituted, by Article 28 of, and paragraph 3 of Schedule 2 to, the Consumer Protection (Northern Ireland) Order 1987 [S.I. 1987/2049 \(N.I. 20\)](#). Article 26(4) was repealed by Article 35 of, and Schedule 4 to, the Industrial Training (Northern Ireland) Order 1984 [S.I. 1984/1159 \(N.I. 9\)](#). Articles 27A and 29A were

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- (i) references to relevant statutory provisions were references to those Articles as applied by this paragraph and to these Regulations;
 - (ii) references to articles, substances, articles and substances, or plant, were references to pressure equipment or assemblies;
 - (iii) in Article 22, paragraph (3) was omitted;
 - (iv) in Article 25, paragraphs (3), (4) and (5) were omitted;
 - (v) in Article 31—
 - (aa) in paragraph (1), the whole of sub-paragraphs (a) to (d) were omitted;
 - (bb) paragraph (1A) was omitted;
 - (cc) in paragraph (2), the reference to sub-paragraph (d) of paragraph (1) was omitted;
 - (dd) paragraph (2A) was omitted;
 - (ee) paragraph (3) was omitted;
 - (ff) for paragraph (4) there was substituted the following:—
 - “(4) A person guilty of an offence under any sub-paragraph of paragraph (1) not mentioned in paragraph (2) or of an offence under paragraph (1)(e) not falling within paragraph (2) shall be liable—
 - (a) on summary conviction, to a fine not exceeding level 5 on the standard scale; or
 - (b) on conviction on indictment—
 - (i) in the case of an offence under paragraph (1)(g), (j) or (o), to imprisonment for a term not exceeding two years, or a fine, or both; or
 - (ii) in all other case, to a fine.”; and
 - (gg) paragraph (5) was omitted;
 - (vi) in Article 32—
 - (aa) sub-paragraph (a) and (b) were omitted from paragraph (1); and
 - (bb) in paragraph (3), for “six months” there was substituted “twelve months”; and
 - (vii) in Article 39, paragraphs (4) and (5) were omitted; and
- (b) Articles 34(1) and (2) shall apply in relation to offences under Article 31 as it is applied by sub-paragraph (2)(a)(v).
- (3) In Northern Ireland, in relation to pressure equipment or assemblies for private use or consumption—
- (a) it shall be the duty of every district council to enforce these Regulations within their area and a reference in the provisions applied to these Regulations by sub-paragraph (b) to an “enforcement authority” shall be construed accordingly;

inserted, and Articles 30(1)(a) and 31(1)(h) amended, by Article 28 of, and paragraphs 4, 5, 6 and 7 respectively of Schedule 2 to, *S.I. 1987/2049 (N.I. 20)*. Article 29(2) to (4) was repealed by Article 10(1)(c) of the Statistics of Trade and Employment (Northern Ireland) Order 1988 *S.I. 1988/595 (N.I. 3)*. Article 31(1)(m) was amended by Article 10(1)(c) of *S.I. 1988/595 (N.I. 3)*; Article 31(1)(j) was amended by Article 13(3) of, and Schedule 5 to, the Criminal Justice (Northern Ireland) Order 1986 *S.I. 1986/1883 (N.I. 15)*; Article 31(1A) and (2A) was respectively inserted by Article 6(3) and (4) of the Offshore, and Pipelines, Safety (Northern Ireland) Order 1992 *S.I. 1992/1728 (N.I. 17)*; Article 31(4) was amended by Article 6(5) of *S.I. 1992/1728 (N.I. 17)*; Article 31(5)(d) and (6) was repealed by Article 6(6) of *S.I. 1992/1728 (N.I. 17)*; and Article 31(7) was repealed by section 30 of, and Part III of the Schedule to, the Forgery and Counterfeiting Act 1981 (c. 45). There are other amendments to Articles 31 and 32 which are not relevant to these Regulations.

- (b) the provisions of paragraph 2(b) and (c) of this Schedule shall have effect; and
- (c) a magistrates' court may try a complaint in respect of an offence committed under these Regulations if the complaint is made within twelve months from the time when the offence is committed.

Forfeiture of pressure equipment or assemblies for private use or consumption: England and Wales and Northern Ireland

4.—(1) An enforcement authority in England and Wales or Northern Ireland may apply under this paragraph for an order for the forfeiture of any pressure equipment or assembly for private use or consumption on the grounds that there has been a contravention in relation thereto of regulation 7, 8, 9 or 10.

(2) An application under this paragraph may be made—

- (a) where proceedings have been brought in a magistrates' court in respect of an offence in relation to some or all of the pressure equipment or assemblies under regulation 25 to that court; and
- (b) where no application for the forfeiture of the pressure equipment or assembly has been made under sub-paragraph (a), by way of complaint to a magistrates' court.

(3) On application under this paragraph the court shall make an order for the forfeiture of the pressure equipment or assembly if it is satisfied that there has been a contravention in relation thereto of regulation 7, 8, 9 or 10.

(4) For the avoidance of doubt it is hereby declared that a court may infer for the purposes of this paragraph that there has been a contravention in relation to any pressure equipment or assembly of regulation 7, 8, 9 or 10 if it is satisfied that those regulations have been contravened in relation to an item of pressure equipment or assembly which is representative of that pressure equipment or assembly (whether by reason of being of the same design or part of the same consignment or batch or otherwise).

(5) Any person aggrieved by an order made under this paragraph by a magistrates' court, or by a decision of such court not to make such an order, may appeal against that order or decision—

- (a) in England and Wales, to the Crown Court
- (b) in Northern Ireland, to the county court,

and an order so made may contain such provision as appears to the court to be appropriate for delaying the coming into force of an order pending the making and determination of any appeal (including any application under section 111 of the Magistrates' Court Act 1980⁽³⁹⁾, or article 146 of the Magistrates' Courts (Northern Ireland) Order 1981⁽⁴⁰⁾ (statement of case)).

(6) Subject to sub-paragraph (7), where any pressure equipment or assembly is forfeited under this paragraph it shall be destroyed in accordance with such directions as the court may give.

(7) On making an order under this paragraph a magistrates' court may, if it considers it appropriate to do so, direct that the pressure equipment or assembly to which the order relates shall (instead of being destroyed) be released, to such person as the court may specify, on condition that that person—

- (a) does not supply the pressure equipment or assembly to any person otherwise than—
 - (i) to a person who carries on a business of buying pressure equipment or assemblies of the same description as the first mentioned product and repairing or reconditioning it; or

⁽³⁹⁾ 1980 c. 43.

⁽⁴⁰⁾ S.I. 1981/1675 (N.I. 26).

- (ii) as scrap (that is to say, for the value of materials included in the pressure equipment or assembly rather than for the value of the pressure equipment or assembly itself); and
- (b) complies with any order to pay costs or expenses which has been made against that person in the proceedings for the order for forfeiture.

Forfeiture of pressure equipment or assemblies for private use or consumption: Scotland

5.—(1) In Scotland a sheriff may make an order for forfeiture of any pressure equipment or assembly for private use or consumption in relation to which there has been a contravention of any provision of regulation 7, 8, 9 or 10—

- (a) on an application by the procurator-fiscal made in the manner specified in section 134 of the Criminal Procedure (Scotland) Act 1995(41); or
- (b) where a person is convicted of any offence in respect of any such contravention, in addition to any other penalty which the sheriff may impose.

(2) The procurator-fiscal making an application under sub-paragraph (1)(a) shall serve on any person appearing to him to be the owner of, or otherwise to have an interest in, the pressure equipment or assembly to which the application relates a copy of the application, together with a notice giving him the opportunity to appear at the hearing of the application to show cause why the pressure equipment or assembly should not be forfeited.

(3) Service under sub-paragraph (2) shall be carried out, and such service may be proved, in the manner specified for citation of an accused in summary proceedings under the Criminal Procedure (Scotland) Act 1995.

(4) Any person upon whom a notice is served under sub-paragraph (2) and any other person claiming to be the owner of, or otherwise to have an interest in, the pressure equipment or assembly to which an application under this paragraph relates shall be entitled to appear at the hearing of the application to show cause why the pressure equipment or assembly as the case may be should not be forfeited.

(5) The sheriff shall not make an order following an application under sub-paragraph (1)(a)—

- (a) if any person on which notice is served under sub-paragraph (2) does not appear, unless service of the notice on that person is proved; or
- (b) if no notice under sub-paragraph (2) has been served, unless the court is satisfied that in the circumstances it was reasonable not to serve notice on any person.

(6) The sheriff shall make an order under this paragraph only if he is satisfied that there has been a contravention in relation to the pressure equipment or assemblies of regulation 7, 8, 9 or 10.

(7) For the avoidance of doubt it is declared that the sheriff may infer for the purposes of this paragraph that there has been a contravention in relation to any pressure equipment or assembly of regulation 7, 8, 9 or 10 if he is satisfied that those regulations have been contravened in relation to an item of pressure equipment or assembly which is representative of that pressure equipment or assembly (whether by reason of being of the same design or part of the same consignment or batch or otherwise).

(8) Where an order for the forfeiture of any pressure equipment or assembly is made following an application by the procurator-fiscal under sub-paragraph (1)(a), any person who appeared, or was entitled to appear, to show cause why it should not be forfeited may, within twenty-one days of the making of the order, appeal to the High Court by Bill of Suspension on the ground of an alleged miscarriage of justice; and section 182(5)(a) to (e) of the Criminal Procedure (Scotland) Act 1995 shall apply to an appeal under this sub-paragraph as it applies to a stated case under Part X of that Act.

(41) 1995 c. 46.

- (9) An order following an application under sub-paragraph (1)(a) shall not take effect—
- (a) until the end of the period of twenty-one days beginning with the day after the day on which the order is made; or
 - (b) if an appeal is made under sub-paragraph (8) within that period, until the appeal is determined or abandoned.
- (10) An order under sub-paragraph (1)(b) shall not take effect—
- (a) until the end of the period within which an appeal against the order could be brought under the Criminal Procedure (Scotland) Act 1995; or
 - (b) if an appeal is made within that period, until the appeal is determined or abandoned.
- (11) Subject to sub-paragraph (12), pressure equipment or assemblies forfeited under this paragraph shall be destroyed in accordance with such directions as the sheriff may give.
- (12) If he thinks fit, the sheriff may direct the pressure equipment or assemblies to be released to such person as he may specify, on condition that that person does not supply it to any person otherwise than—
- (a) to a person who carries on a business of buying pressure equipment or assemblies of the same description as the first-mentioned pressure equipment or assemblies and repairing or reconditioning it; or
 - (b) as scrap (that it to say, for the value of materials included in the pressure equipment or assemblies rather for the value of the pressure equipment or assembly itself).

Duty of enforcement authority to inform Secretary of State of action taken

6. An enforcement authority shall, where action has been taken by it to prohibit or restrict the placing on the market, the supply or putting into service (whether under these Regulations or otherwise) of any pressure equipment or assembly which bears the CE marking, forthwith inform the Secretary of State of the action taken, and the reasons for it, with a view to this information being passed by him to the Commission.

Savings

7. Nothing in these Regulations shall authorise an enforcement authority to bring proceedings in Scotland for an offence.

Interpretation

8. In this Schedule—

“the 1974 Act” means the Health and Safety at Work etc. Act 1974(42);

“the 1987 Act” means the Consumer Protection Act 1987(43);

“the Executive” means the Health and Safety Executive established under section 10 of the 1974 Act;

“the Order” means the Health and Safety at Work (Northern Ireland) Order 1978; and

“pressure equipment or assemblies” means pressure equipment or assemblies, as the case may be, to which these Regulations apply.

(42) 1974 c. 37.

(43) 1987 c. 43.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement the European Parliament and Council Directive [97/23/EC](#) (OJ No. L181, 9.7.97, p. 1) on the approximation of the laws of the member States concerning pressure equipment (“the Directive”). They come into force on 29th November 1999 except regulations 1, 2, 20 and 22 which come into force on 31st August.

For the purposes of the Regulations, relevant definitions are contained in regulation 2.

Part II provides for the application of the Regulations. They apply to pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar (regulation 3).

The Regulations do not apply to:

- (a) the products listed in Schedule 1 (regulation 4);
- (b) pressure equipment or assemblies placed on the market before 29th November 1999 (regulation 5); or
- (c) pressure equipment or assemblies placed on the market on or before 29th May 2002 if they comply with the safety provisions in force in the United Kingdom on 28th November 1999 and do not bear the CE marking (unless required by another Community Directive) or any indication of compliance with the Directive (regulation 6).

Part III sets out the general requirements relating to the placing on the market or putting into service of pressure equipment and assemblies by a “responsible person” (as defined). A person is deemed to be a “responsible person” when he manufactures pressure equipment or assemblies for his own use or imports pressure equipment or assemblies from a third country, where it is in the course of business (regulation 2(3)). Pressure equipment or assemblies must satisfy the relevant essential requirements and be safe; in addition, the appropriate conformity assessment procedure (regulations 13 and 14) must have been carried out, unless the equipment is to be used for experimentation (regulation 15), a declaration of conformity drawn up in respect of the product, and the CE marking must have been affixed to the product by the “responsible person” (regulations 7 and 8). Where pressure equipment or assemblies fall below the limits in regulations 7(2) and 8(2) the pressure equipment or assembly must be designed and manufactured in accordance with sound engineering practice, be accompanied by adequate instructions for use, bear markings to permit identification of the manufacturer or his authorised representative established within the Community, and be safe (regulation 9). Any person, other than the “responsible person”, who supplies pressure equipment or assemblies, must ensure that it is safe (regulation 10). Pressure equipment or assemblies shall not be regarded as being placed on the market or supplied in the circumstances described in regulation 11.

The essential safety requirements are set out in Schedule 2, and in that connection, there is a definition of “relevant essential requirements” in regulation 2. There is a presumption that the relevant essential requirements are met if the pressure equipment or assembly complies with transposed harmonised standards (regulations 7(3)(a) and 8(3)(a)(i) and (b)(i)). Regulation 13 describes the various conformity assessment procedures available in respect of pressure equipment (Schedule 4) as determined by the category into which the item of pressure equipment is classified (regulation 12). Regulation 14 describes the conformity assessment procedure for assemblies. The content of the EC declaration of conformity which is to be drawn up in respect of pressure equipment or assemblies is set out in Schedule 6. Requirements relating to the CE marking and other inscriptions for these products are set out in regulation 16 and Schedule 5. For the purposes of these Regulations there is a definition of “safe” in regulation 2.

Regulation 18 describes a body which can be a “notified body” for the purpose of these Regulations and regulation 19 describes a body which can be a “recognised third-party organisation” for the purposes of these Regulations, and the provisions of regulation 20 relate to “notified bodies” and “recognised third-party organisations” appointed by the Secretary of State. Regulation 21 provides for the United Kingdom notified bodies to charge fees. Regulation 17 provides for the issue in accordance with Schedule 7 of European approvals for materials by notified bodies designated for that task. Regulation 22 provides for the appointment of “user inspectorates” (as defined) to carry out specified conformity assessment procedures.

Regulation 23 describes the circumstances under which pressure equipment or assemblies might be taken to conform with the provisions of the Regulations.

Part IV and Schedule 8 provide for the enforcement of the Regulations. In Great Britain, the Health and Safety Executive are to enforce the Regulations in respect of pressure equipment and assemblies intended for use in the workplace and the weights and measures authorities are the enforcement authorities in respect of such products for private use; in Northern Ireland, the Health and Safety Executive for Northern Ireland is the enforcement authority for products intended for use in the workplace, and district councils are the enforcement authorities for products for private use. Except in the case of pressure equipment or assemblies which are considered to be unsafe, where an enforcement authority suspects that the CE marking has been incorrectly affixed to an item of pressure equipment or an assembly a notice may be served requiring compliance with the provisions of the Regulations; it is only following a breach of that notice that enforcement action can be taken in those circumstances. However, specific enforcement provisions can be used for the purpose of ascertaining whether or not the CE marking has been correctly affixed. Any person who contravenes regulations 7, 8, 9 or 10 shall be guilty of an offence under regulation 25 and the penalties attracted by those offences are set out in regulation 26. A defence of due diligence is provided in regulation 27 and the liability of persons other than the principal offender is set out in regulation 28.

Some consequential amendments are made by regulation 29.

A Regulatory Impact Assessment in respect of these Regulations is available and a copy can be obtained from the Department of Trade and Industry, Standards and Technical Regulations Directorate, 3rd Floor, 151 Buckingham Palace Road, London, SW1W 9SS. A copy has also been placed in the libraries of both Houses of Parliament.

Copies of relevant documents may be obtained as follows—

- (a) Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) [ISBN 0-11-550814-7], from Her Majesty’s Stationery Office;
- (b) the International Maritime Dangerous Goods Code [ISBN 92 801 1125 6], from the International Maritime Organisation, 4 Albert Embankment, London SE1 7SR.
- (c) the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) [ISBN-011-550735-3], from Her Majesty’s Stationery Office.
- (d) A copy of the Chicago Convention (numbered Doc. 7300/6) can be obtained from the Civil Aviation Authority, Printing and Publications Service, Greville House, 37 Gratten Road, Cheltenham, Glos. GL50 2BN.