STATUTORY INSTRUMENTS

2016 No. 1105

CONSUMER PROTECTION
HEALTH AND SAFETY

The Pressure Equipment (Safety) Regulations 2016

Made - - - -	*15th November 2016*
Laid before Parliament	*16th November 2016*
Coming into force - -	*8th December 2016*

The Secretary of State is a Minister designated [M1] for the purposes of section 2(2) of the European Communities Act 1972 [M2] in relation to pressure equipment and assemblies of pressure equipment.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for certain references to provisions of EU instruments to be construed as references to those provisions as amended from time to time.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of, and paragraph 1A [M3] of Schedule 2 to, the European Communities Act 1972.

Marginal Citations

M1 S.I. 1998/2793.

M2 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c.51) and by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7). The enabling powers of section 2(2) were extended by virtue of the amendment of section 1(2) by section 1 of the European Economic Area Act 1993 (c.51).

M3 Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory reform Act 2006 and amended by Part 1 of the Schedule to the European Union (Amendment) Act 2008.

PART 1

Preliminary

Citation and commencement

1. These Regulations may be cited as the Pressure Equipment (Safety) Regulations 2016 and come into force on 8th December 2016 ("the commencement date").

Interpretation E+W+S

2.—(1) In these Regulations—

"the 1974 Act" means the Health and Safety at Work etc Act 1974 [M4];

"the 1978 Order" means the Health and Safety at Work (Northern Ireland) Order 1978 [M5];

"the 1987 Act" means the Consumer Protection Act 1987 [M6];

"the 1999 Regulations" means the Pressure Equipment Regulations 1999 [M7];

[F1]…

[F2]…

"applicant" means any person making an application for a conformity assessment procedure to be carried out by a notified body;

"assembly" means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole;

[[F3]"authorised representative" means a person established within the **[**[F4]United Kingdom**]** appointed in accordance with regulation 19(1) (manufacturer's authorised representative);**]**

[F5]…

[F6]…

"conformity assessment" means the process demonstrating whether the essential requirements relating to pressure equipment or assemblies have been fulfilled;

"conformity assessment activities" means any activities involved in conformity assessment, including calibration, testing, certification and inspection;

"conformity assessment body" means a person that performs conformity assessment activities;

[[F7]"conformity assessment procedure" means a procedure for conformity assessment set out in Schedule 1A;**]**

"conformity assessment procedure" means a procedure for conformity assessment set out in Annex III to the Directive (as amended from time to time);

[[F8]"declaration of conformity" means a declaration of conformity drawn up in accordance with regulation 48 (declaration of conformity);**]**

[[F8]"designated standard" has the meaning given to it in regulation 2A;**]**

"the Directive" means Directive 2014/68/EU of the European Parliament and of the Council of 15th May 2014 on the harmonisation of the laws of the member States relating to the making available on the market of pressure equipment (recast) [M8]**[**[F9](as it has effect immediately before IP completion day)**]**;

"designating authority" means the Secretary of State;

"distributor" means any person in the supply chain, other than the manufacturer or the importer, who makes pressure equipment or an assembly available on the market;

"district council" means a district council within the meaning of the Local Government Act (Northern Ireland) 1972 [M9];

"economic operator" means a manufacturer, an importer or a distributor;

"enforcing authority" means any person enforcing these Regulations under regulation 67 (enforcement);

"essential safety requirements" means the requirements set out in Schedule 2;

F10 …

F11 …

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

"fluid in Group 1" has the meaning set out in paragraph 3(1) of Schedule 3;

"fluid in Group 2" has the meaning set out in paragraph 3(2) of Schedule 3;

F12 …

[F13"importer" means a person who—

(a) is established in the United Kingdom and places pressure equipment or an assembly from a country outside of the United Kingdom on the market; or

(b) is established in Northern Ireland and places pressure equipment or an assembly on the market that has been supplied to them for distribution, consumption or use in the course of a commercial activity, whether in return for payment or free of charge from an EEA state;**]**

"make available on the market" means the supply of pressure equipment or an assembly for distribution, consumption or use on the **[**F14market of Great Britain**]** in the course of a commercial activity, whether in return for payment or free of charge, and related expressions are to be construed accordingly;

"manufacturer" means a person who—

(c) manufactures pressure equipment or an assembly, or has such equipment or assembly designed or manufactured; and either—

(d) markets that pressure equipment under that person's name or trade mark; or

(e) uses it for his own purposes;

"market surveillance authority" has the meaning set out in regulation 66 (designation of market surveillance authority);

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

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

F15 …

"nominal size (DN)" means a numerical designation of size which is common to all components in a piping system other than components indicated by outside diameters or by thread size; it is a convenient round number for reference purposes and is only loosely related to manufacturing dimensions; the nominal size is designated by DN followed by a number;

F16 …

"notified body requirements" means the requirements set out in Schedule 4;

F17 …

"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; piping includes in particular a pipe or system of pipes, tubing, fittings, expansion joints, hoses or other pressure-bearing components as appropriate; heat exchangers consisting of pipes for the purpose of cooling or heating air are to be considered as piping;

"place on the market" means make pressure equipment or an assembly available on the **[**F18market of Great Britain**]** for the first time, and related expressions are to be construed accordingly;

"pressure" means pressure relative to atmospheric pressure, i.e. gauge pressure; and as a consequence, 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, including, where applicable, elements attached to pressurised parts such as flanges, nozzles, couplings, supports and lifting lugs;

"putting into service" means the first use of pressure equipment or an assembly by its user, and related expressions are to be construed accordingly;

"RAMS" means Regulation (EC) 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93[M10];

"recall" means the taking of any measure aimed at achieving the return of pressure equipment or an assembly that has already been made available to the end-user and related expressions are to be construed accordingly;

"recognised third party organisation" is a body within the meaning set out in regulation 52;

"relevant conformity assessment procedure" means a conformity assessment procedure appropriate for the classification of the pressure equipment, as set out in regulation 42;

"relevant economic operator" means, in relation to pressure equipment or an assembly, an economic operator who has obligations in respect of that pressure equipment or assembly under these Regulations;

"safety accessories" means devices designed to protect pressure equipment against the allowable limits being exceeded, including devices for direct pressure limitation, such as safety valves, bursting disc safety devices, buckling rods, controlled safety pressure relief systems (CSPRS), and limiting devices, which either activate the means for correction or provide for shutdown or shutdown and lockout, such as pressure switches or temperature switches or fluid level switches and safety related measurement control and regulation (SRMCR) devices;

"technical documentation" has the meaning set out in regulation 10(2) (technical documentation and conformity assessment);

"technical specification" means a document that prescribes technical requirements to be fulfilled by pressure equipment or an assembly;

[F19"UK marking" means the marking in the form set out in Annex 2 of RAMS;**]**

"user inspectorate" is a body within the meaning set out in regulation 53 (User inspectorates);

"user inspectorate requirements" means the requirements set out in Schedule 5;

"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;

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

"weights and measures authority" means a local weights and measures authority within the meaning of section 69 of the Weights and Measures Act 1985 [M11];

"withdrawal", when used in relation to pressure equipment or an assembly, means the taking of any measure aimed at preventing pressure equipment or an assembly in the supply chain from being made available on the market, and related expressions must be construed accordingly.

(2) In these Regulations, a reference to pressure equipment being "in conformity with Part 2" means that—

(a) pressure equipment is in conformity with the essential safety requirements; and

(b) each relevant economic operator has complied, or is complying, with the obligations imposed on them under Part 2 of these Regulations which must be satisfied at or before the time at which they made the pressure equipment or assembly available on the market.

(3) In regulations 16 and 26, "risk" means a risk which could arise from lawful and readily predictable human behaviour.

(4) In the other provisions of these Regulations (except Schedule 2), "risk" means a risk—

(a) which could arise from lawful and readily predictable human behaviour; and

(b) which may result in harm to any of the following interests—

(i) the health and safety of persons;

(ii) domestic animals; or

(iii) property.

[F20](5) . . . . . .

(6) In these Regulations, the definition of a manufacturer does not include a private person who manufactures pressure equipment or an assembly on an occasional basis for their own use in a non-commercial context.

[F21](7) . . . . . .

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F1 Words in reg. 2(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F2 Words in reg. 2(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F3 Words in reg. 2(1) substituted (26.12.2017) by The Radio Equipment Regulations 2017 (S.I. 2017/1206), regs. 1, **82(2)(a)(i)** (with regs. 3-5, 77)

F4 Words in reg. 2(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), **Sch. 5 para. 1(1)(e)**

F5 Words in reg. 2(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(d)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F6 Words in reg. 2(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(e)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F7 Words in reg. 2(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(f)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F8 Words in reg. 2(1) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(g)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F9 Words in reg. 2(1) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(h)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2 and S.I. 2020/852, reg. 4(2), Sch. 1 para. 1(m)(ii)); 2020 c. 1, Sch. 5 para. 1(1)

F10 Words in reg. 2(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(i)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F11 Words in reg. 2(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(j)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F12 Words in reg. 2(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(k)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F13 Words in reg. 2(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(l)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/1460, **Sch. 3 para. 16(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 2(1) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 24 para. 2(2)(m) (as substituted by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), **4(12)(a)**)

F15 Words in reg. 2(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(n)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F16 Words in reg. 2(1) omitted (26.12.2017) by virtue of The Radio Equipment Regulations 2017 (S.I. 2017/1206), regs. 1, **82(2)(a)(ii)** (with regs. 3-5, 77)

F17 Words in reg. 2(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(o)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F18 Words in reg. 2(1) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 24 para. 2(2)(p) (as substituted by The Product Safety and Metrology etc. (Amendment to Extent and Meaning of Market) (EU Exit) Regulations 2020 (S.I. 2020/676), regs. 1(1), **4(12)(b)**)

F19 Words in reg. 2(1) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(2)(q)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F20 Reg. 2(5) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(3)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F21 Reg. 2(7) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 2(3)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Marginal Citations

M4 1974 c.37.
M5 S.I. 1978/1039 (N.I. 9).
M6 1987 c.43.
M7 S.I. 1999/2001 as amended by S.I. 2002/1267, S.I. 2008/1597, 2012/1809, S.I. 2014/469, S.I. 2015/399.
M8 OJ No L 189, 27.6.2014, p. 164, as corrected by OJ No L 157, 23.6.2015, p112.
M9 1972 c.9.
M10 OJ No L 218, 13.8.2008, p. 30.
M11 1985 c.72; section 69 was amended by the Statute Law (Repeals) Act 1989 (c.43), Schedule 1, paragraph 4, the Local Government etc. (Scotland) Act 1994 (c.39), Schedule 13, paragraph 144 and the Local Government (Wales) Act 1994 (c.19), Schedule 16, paragraph 75.

Interpretation N.I.

2.—(1) In these Regulations—

"the 1974 Act" means the Health and Safety at Work etc Act 1974 [F182];

"the 1978 Order" means the Health and Safety at Work (Northern Ireland) Order 1978 [F183];

"the 1987 Act" means the Consumer Protection Act 1987 [F184];

"the 1999 Regulations" means the Pressure Equipment Regulations 1999 [F185];

"accreditation" has the meaning set out in point 10 of Article 2 of RAMS;

"accreditation certificate" means a certificate, issued by the United Kingdom Accreditation Service or a national accreditation body in another **[**[F186]relevant state**]**, attesting that a conformity assessment body meets the notified body requirements or the user inspectorate requirements;

"applicant" means any person making an application for a conformity assessment procedure to be carried out by a notified body;

"assembly" means several pieces of pressure equipment assembled by a manufacturer to constitute an integrated and functional whole;

[[F187]"authorised representative" means a person established **[**[F188]in a relevant state**]** appointed in accordance with regulation 19(1) (manufacturer's authorised representative);**]**

"CE marking" means a marking which takes the form set out in Annex II of RAMS (as amended from time to time);

"Commission" means the European Commission;

"conformity assessment" means the process demonstrating whether the essential requirements relating to pressure equipment or assemblies have been fulfilled;

"conformity assessment activities" means any activities involved in conformity assessment, including calibration, testing, certification and inspection;

"conformity assessment body" means a person that performs conformity assessment activities;

"conformity assessment procedure" means a procedure for conformity assessment set out in Annex III to the Directive (as amended from time to time);

"the Directive" means Directive 2014/68/EU of the European Parliament and of the Council of 15th May 2014 on the harmonisation of the laws of the member States relating to the making available on the market of pressure equipment (recast) [F189];

"designating authority" means the Secretary of State;

"distributor" means any person in the supply chain, other than the manufacturer or the importer, who makes pressure equipment or an assembly available on the market;

"district council" means a district council within the meaning of the Local Government Act (Northern Ireland) 1972 [F190];

"economic operator" means a manufacturer, **[**[F191]an authorised representative,**]** an importer or a distributor;

"enforcing authority" means any person enforcing these Regulations under regulation 67 (enforcement);

"essential safety requirements" means the requirements set out in Schedule 2;

"EU declaration of conformity" means a declaration of conformity drawn up in accordance with regulation 48 (EU declaration of conformity);

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

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

"fluid in Group 1" has the meaning set out in paragraph 3(1) of Schedule 3;

"fluid in Group 2" has the meaning set out in paragraph 3(2) of Schedule 3;

"harmonised standard" has the meaning set out in Article 2(1)(c) of Regulation (EU) 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation [F192] (as amended from time to time);

"importer" means any person who—

(a) is established in **[**[F193]a relevant state**]**; and

(b) places pressure equipment or an assembly from a third country on the **[**[F194]relevant**]** market;

"make available on the market" means the supply of pressure equipment or an assembly for distribution, consumption or use on the **[**[F195]relevant**]** market in the course of a commercial activity, whether in return for payment or free of charge, and related expressions are to be construed accordingly;

"manufacturer" means a person who—

(c) manufactures pressure equipment or an assembly, or has such equipment or assembly designed or manufactured; and either—

(d) markets that pressure equipment under that person's name or trade mark; or

(e) uses it for his own purposes;

"market surveillance authority" has the meaning set out in regulation 66 (designation of market surveillance authority);

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

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

"national accreditation body" has the meaning set out in point 11 of Article 2 of RAMS;

"nominal size (DN)" means a numerical designation of size which is common to all components in a piping system other than components indicated by outside diameters or by thread size; it is a convenient round number for reference purposes and is only loosely related to manufacturing dimensions; the nominal size is designated by DN followed by a number;

F196 ...

"notified body requirements" means the requirements set out in Schedule 4;

"Official Journal" means the Official Journal of the European Union;

"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; piping includes in particular a pipe or system of pipes, tubing, fittings, expansion joints, hoses or other pressure-bearing components as appropriate; heat exchangers consisting of pipes for the purpose of cooling or heating air are to be considered as piping;

"place on the market" means make pressure equipment or an assembly available on the **[**F197relevant**]** market for the first time, and related expressions are to be construed accordingly;

"pressure" means pressure relative to atmospheric pressure, i.e. gauge pressure; and as a consequence, 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, including, where applicable, elements attached to pressurised parts such as flanges, nozzles, couplings, supports and lifting lugs;

"putting into service" means the first use of pressure equipment or an assembly by its user, and related expressions are to be construed accordingly;

"RAMS" means Regulation (EC) 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93F198;

"recall" means the taking of any measure aimed at achieving the return of pressure equipment or an assembly that has already been made available to the end-user and related expressions are to be construed accordingly;

"recognised third party organisation" is a body within the meaning set out in regulation 52;

"relevant conformity assessment procedure" means a conformity assessment procedure appropriate for the classification of the pressure equipment, as set out in regulation 42;

"relevant economic operator" means, in relation to pressure equipment or an assembly, an economic operator who has obligations in respect of that pressure equipment or assembly under these Regulations;

[F199"relevant market" means—

(a) the market in Northern Ireland; and

(b) the markets of the EEA states;

"relevant state" means—

(a) Northern Ireland; or

(b) any EEA state;**]**

"safety accessories" means devices designed to protect pressure equipment against the allowable limits being exceeded, including devices for direct pressure limitation, such as safety valves, bursting disc safety devices, buckling rods, controlled safety pressure relief systems

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

"technical documentation" has the meaning set out in regulation 10(2) (technical documentation and conformity assessment);

"technical specification" means a document that prescribes technical requirements to be fulfilled by pressure equipment or an assembly;

[[F200]"UK(NI) indication" means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020;**]**

"user inspectorate" is a body within the meaning set out in regulation 53 (User inspectorates);

"user inspectorate requirements" means the requirements set out in Schedule 5;

"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;

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

"weights and measures authority" means a local weights and measures authority within the meaning of section 69 of the Weights and Measures Act 1985 [F201];

"withdrawal", when used in relation to pressure equipment or an assembly, means the taking of any measure aimed at preventing pressure equipment or an assembly in the supply chain from being made available on the market, and related expressions must be construed accordingly.

(2) In these Regulations, a reference to pressure equipment being "in conformity with Part 2" means that—

(a) pressure equipment is in conformity with the essential safety requirements; and

(b) each relevant economic operator has complied, or is complying, with the obligations imposed on them under Part 2 of these Regulations which must be satisfied at or before the time at which they made the pressure equipment or assembly available on the market.

(3) In regulations 16 and 26, "risk" means a risk which could arise from lawful and readily predictable human behaviour.

(4) In the other provisions of these Regulations (except Schedule 2), "risk" means a risk—

(a) which could arise from lawful and readily predictable human behaviour; and

(b) which may result in harm to any of the following interests—

(i) the health and safety of persons;

(ii) domestic animals; or

(iii) property.

[F202](5) . . . . . .

(6) In these Regulations, the definition of a manufacturer does not include a private person who manufactures pressure equipment or an assembly on an occasional basis for their own use in a non-commercial context.

[[F203](7) In these Regulations (except Part 4 (notification of conformity assessment bodies) and Schedules 4 (notified body requirements) and 6 (operational obligations of notified bodies, recognised third party organisations and user inspectorates)), "notified body" means—

(a) a notified body within the meaning set out in regulation 51 (notified bodies), or

(b) a notified body under the laws of any other **[**[F204]relevant state**]** which implement the Directive.**]**

Extent Information

E67 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F182 1974 c.37.

F183 S.I. 1978/1039 (N.I. 9).

F184 1987 c.43.

F185 S.I. 1999/2001 as amended by S.I. 2002/1267, S.I. 2008/1597, 2012/1809, S.I. 2014/469, S.I. 2015/399.

F186 Words in reg. 2(1) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(1)(a)**

F187 Words in reg. 2(1) substituted (26.12.2017) by The Radio Equipment Regulations 2017 (S.I. 2017/1206), regs. 1, **82(2)(a)(i)** (with regs. 3-5, 77)

F188 Words in reg. 2(1) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(1)(b)**

F189 OJ No L 189, 27.6.2014, p. 164, as corrected by OJ No L 157, 23.6.2015, p112.

F190 1972 c.9.

F191 Words in reg. 2(1) inserted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(1)(c)**

F192 OJ No L 316, 14.11.2012, p12.

F193 Words in reg. 2(1) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(1)(d)(i)**

F194 Word in reg. 2(1) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(1)(d)(ii)**

F195 Word in reg. 2(1) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(1)(e)(i)**

F196 Words in reg. 2(1) omitted (26.12.2017) by virtue of The Radio Equipment Regulations 2017 (S.I. 2017/1206), regs. 1, **82(2)(a)(ii)** (with regs. 3-5, 77)

F197 Word in reg. 2(1) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(1)(e)(ii)**

F198 OJ No L 218, 13.8.2008, p. 30.

F199 Words in reg. 2(1) inserted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(1)(f)**

F200 Words in reg. 2(1) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), **Sch. 2 para. 10(2)**

F201 1985 c.72; section 69 was amended by the Statute Law (Repeals) Act 1989 (c.43), Schedule 1, paragraph 4, the Local Government etc. (Scotland) Act 1994 (c.39), Schedule 13, paragraph 144 and the Local Government (Wales) Act 1994 (c.19), Schedule 16, paragraph 75.

F202 Reg. 2(5) omitted (N.I.) (31.12.2020) by virtue of The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(2)**

F203 Reg. 2(7) inserted (26.12.2017) by The Radio Equipment Regulations 2017 (S.I. 2017/1206), regs. 1, **82(2)(b)** (with regs. 3-5, 77)

F204 Words in reg. 2(7)(b) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(3)**

[[F22]**Designated standard**

2A.—(1) Subject to paragraphs (6) and (7), in these Regulations a "designated standard" means a technical specification which is—

(a) adopted by a recognised standardisation body **[**F23or an international standardising body**]**, for repeated or continuous application, with which compliance is not compulsory; and

(b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

(2) For the purposes of paragraph (1), a "technical specification" means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

(a) the characteristics required of a product, including—

(i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions; and

(ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; or

(b) production methods and processes relating to the product, where these have an effect on the characteristics of the product.

(3) For the purposes of this regulation a "recognised standardisation body" means any one of the following organisations—

(a) the European Committee for Standardisation (CEN);

(b) the European Committee for Electrotechnical Standardisation (Cenelec);

(c) the European Telecommunications Standards Institute (ETSI);

(d) the British Standards Institution (BSI).

[

F24(3A) In this regulation "international standardising body" has the same meaning as it has for the purposes of the Agreement on Technical Barriers to Trade, part of Annex 1A to the agreement establishing the World Trade Organisation signed at Marrakesh on 15 April 1994 (as modified from time to time).**]**

(4) When considering whether the publication is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

(5) Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with **[**F25such**]** technical specifications adopted by the other standardisation organisations **[**F26or by international standardising bodies as the Secretary of State considers to be relevant**]**.

(6) The Secretary of State may remove from publication the reference to a standard that has been published in accordance with paragraph (1)(b).

(7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

(8) In this regulation, a reference to a "product" is a reference to a product to which these Regulations apply.

(9) The Secretary of State may be regulations amend paragraph (3) to reflect any changes in the name or structure of the recognised standardisation bodies.

(10) Regulations made under paragraph (9) are to be made by statutory instrument.

(11) A statutory instrument containing regulations made under paragraph (9) is subject to annulment in pursuance of a resolution of either House of Parliament.**]**

F22 Reg. 2A inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 3** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F23 Words in reg. 2A(1)(a) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 13(a)**; S.I. 2020/1662, reg. 2(ee)

F24 Reg. 2A(3A) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 13(b)**; S.I. 2020/1662, reg. 2(ee)

F25 Word in reg. 2A(5) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 13(c)(i)**; S.I. 2020/1662, reg. 2(ee)

F26 Words in reg. 2A(5) inserted (31.12.2020) by European Union (Future Relationship) Act 2020 (c. 29), s. 40(7), **Sch. 4 para. 13(c)(ii)**; S.I. 2020/1662, reg. 2(ee)

Pressure equipment and assemblies

3.—(1) Subject to paragraph (2) and regulation 4, these Regulations apply to pressure equipment and assemblies with a maximum allowable pressure PS greater than 0.5 bar.

(2) These Regulations apply to pressure equipment and assemblies placed on the market on or after the commencement date.

Excluded pressure equipment and assemblies

4.—(1) These Regulations do not apply to the items listed in Schedule 1.

(2) These Regulations do not apply to the assembly of pressure equipment on the site of and under the responsibility of a user who is not the manufacturer.

Exception for trade fairs, exhibitions and demonstrations

5. Nothing in these Regulations prevents the showing and use of pressure equipment and assemblies, which is not in conformity with Part 2, at a trade fair, exhibition or demonstration for the marketing of pressure equipment, provided that a visible sign clearly indicates—

(a) that the pressure equipment or assembly is not in conformity with Part 2; and

(b) that the pressure equipment or assembly must not be made available on the market or put into service until brought into conformity.

Pressure equipment and assemblies subject to essential safety requirements

6. The following pressure equipment must satisfy the essential safety requirements set out in Schedule 2—

(a) vessels, except those referred to in subparagraph (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 (1013 mbar) within the following limits—

(aa) for fluids in Group 1 with a volume greater than 1 L 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 1 L and a product of PS and V greater than 50 bar·L or with a pressure PS greater than 1000 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 (1013 mbar) within the following limits—

(aa) for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 200 bar·L, or with a pressure PS greater than 500 bar;

(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 1000 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 having a volume greater than 2 L, 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 (1013 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 1000 bar;

(ii) liquids having a vapour pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure (1013 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 2000 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 5000 bar;

(d) safety and pressure accessories intended for equipment covered by (a) to (c) above including where such equipment is incorporated into an assembly.

7.—(1) The following assemblies which include at least one item of pressure equipment covered by regulation 6 must satisfy the essential safety requirements set out in Schedule 2—

(a) assemblies intended for generating steam or superheated water at a temperature higher than 110 °C comprising at least one item of fired or otherwise heated pressure equipment presenting a risk of overheating;

(b) assemblies other than those referred to in subparagraph (a), if the manufacturer intends them to be made available on the market and put into service as assemblies.

(2) By way of derogation from subparagraph (1)(a) above, assemblies intended for generating warm water at temperatures not greater than 110°C which are manually fed with solid fuels and have a PS·V greater than 50 bar·L must comply with only those essential safety requirements referred to in paragraphs 14, 15, 30, 33(2)(a) and 33(2)(d) of Schedule 2.

Requirement for pressure equipment and assemblies to comply with sound engineering practice **E+W+S**

8.—(1) This regulation applies to pressure equipment and assemblies to which these Regulations apply and which are below or equal to the limits set out in regulations 6(a) to (c) or regulation 7, as applicable.

(2) Pressure equipment and assemblies to which this regulation applies must be—

(a) designed and manufactured in accordance with **[**[F27]sound engineering practice**]** in order to ensure safe use; and

(b) accompanied by adequate instructions for use.

[[F28](3) Pressure equipment and assemblies to which this regulation applies must not bear the UK marking referred to in regulation 49 unless required to do so by other applicable UK legislation.**]**

(4) In this regulation, "safe" 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 applicable, domestic animals or property.

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F27 Words in reg. 8(2)(a) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 4(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F28 Reg. 8(3) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 4(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Requirement for pressure equipment and assemblies to comply with sound engineering practice N.I.

8.—(1) This regulation applies to pressure equipment and assemblies to which these Regulations apply and which are below or equal to the limits set out in regulations 6(a) to (c) or regulation 7, as applicable.

(2) Pressure equipment and assemblies to which this regulation applies must be—

(a) designed and manufactured in accordance with the sound engineering practice of a **[**[F205]relevant state**]** in order to ensure safe use; and

(b) accompanied by adequate instructions for use.

(3) Pressure equipment or assemblies to which this regulation applies must not bear the CE marking referred to in Regulation 49 unless required to do so by other applicable EU legislation.

(4) In this regulation, "safe" 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 applicable, domestic animals or property.

Extent Information

E68 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F205 Words in reg. 8(2)(a) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 2(3)**

[[F29]Power to reclassify pressure equipment and assemblies

8A.—(1) Where the condition in paragraph (2) is met, the Secretary of State may by regulations make provision that pressure equipment or assemblies referred to in regulation 8 are to satisfy the essential requirements in Schedule 2.

(2) The condition referred to in paragraph (1) is that the Secretary of State considers that the provision is required to mitigate the effects of very serious safety concerns.

(3) Regulations made under paragraph (1)—

(a) are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament; and

(b) include power—

(i) to make different provision for different cases; and

(ii) to make such supplemental, consequential and transitional provision as the Secretary of State considers appropriate.**]**

F29 Reg. 8A inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 5** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

PART 2

Obligations of economic operators

Manufacturers

Design and manufacture in accordance with essential safety requirements

9.—(1) Before placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market or using it for their own purposes, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential safety requirements.

(2) Before placing pressure equipment or an assembly referred to in regulation 8 on the market or using it for their own purposes, a manufacturer must ensure that it complies with regulation 8(2).

Technical documentation and conformity assessment E+W+S

10.—(1) Before placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market or using it for their own purposes, a manufacturer must—

(a) classify it using the categories set out in Schedule 3 (classification of pressure equipment), according to an ascending level of hazard;

(b) determine the conformity assessment procedures to apply to the pressure equipment or assembly in accordance with regulation 41 (conformity assessment procedure);

(c) carry out the relevant conformity assessment procedure in respect of that pressure equipment or assembly, or have such a procedure carried out; and

(d) draw up the relevant technical documentation referred to in the conformity assessment module followed in accordance with regulation 41.

(2) For the purposes of paragraph (1)(d), the relevant technical documentation is the following with reference to the modules set out in **[**F30Schedule 1A to these Regulations**]**—

(a) where Module A is followed, the technical documentation is the technical documentation referred to in point 2 under Module A (Internal production control);

(b) where Module A2 is followed, the technical documentation is the technical documentation referred to in point 2 under Module A2 (Internal production control plus supervised pressure equipment checks at random intervals);

(c) where Module B (production type) is followed, the technical documentation is the technical documentation referred to in point 3 under Module B (**[**F31Type**]** examination – production type);

(d) where Module B (design type) is followed, the technical documentation is the technical documentation referred to in point 3 under Module B (**[**F31Type**]** examination – design type);

(e) where Module G is followed, the technical documentation is the technical documentation referred to in point 2 under Module G (Conformity based on unit verification);

(f) where Module H is followed, the technical documentation is the technical documentation referred to in point 3 under Module H (Conformity based on full quality assurance);

(g) where Module H1 is followed, the technical documentation is the technical documentation referred to in point 3 under Module H1 (Conformity based on full quality assurance plus design examination).

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F30 Words in reg. 10(2) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 6(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F31 Word in reg. 10(2) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 6(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Technical documentation and conformity assessment N.I.

10.—(1) Before placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market or using it for their own purposes, a manufacturer must—

(a) classify it using the categories set out in Schedule 3 (classification of pressure equipment), according to an ascending level of hazard;

(b) determine the conformity assessment procedures to apply to the pressure equipment or assembly in accordance with regulation 41 (conformity assessment procedure);

(c) carry out the relevant conformity assessment procedure in respect of that pressure equipment or assembly, or have such a procedure carried out; and

(d) draw up the relevant technical documentation referred to in the conformity assessment module followed in accordance with regulation 41.

(2) For the purposes of paragraph (1)(d), the relevant technical documentation is the following with reference to the modules set out in Annex III to the Directive (as amended from time to time)—

(a) where Module A is followed, the technical documentation is the technical documentation referred to in point 2 under Module A (Internal production control);

(b) where Module A2 is followed, the technical documentation is the technical documentation referred to in point 2 under Module A2 (Internal production control plus supervised pressure equipment checks at random intervals);

(c) where Module B (production type) is followed, the technical documentation is the technical documentation referred to in point 3 under Module B (EU-type examination – production type);

(d) where Module B (design type) is followed, the technical documentation is the technical documentation referred to in point 3 under Module B (EU-type examination – design type);

(e) where Module G is followed, the technical documentation is the technical documentation referred to in point 2 under Module G (Conformity based on unit verification);

(f) where Module H is followed, the technical documentation is the technical documentation referred to in point 3 under Module H (Conformity based on full quality assurance);

(g) where Module H1 is followed, the technical documentation is the technical documentation referred to in point 3 under Module H1 (Conformity based on full quality assurance plus design examination).

Extent Information

E69 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F32Declaration] of conformity and [F33UK] marking E+W+S

11.—(1) Where the conformity of pressure equipment or an assembly referred to in regulation 6 or 7 with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the pressure equipment or assembly on the market—

(a) draw up a declaration of conformity in accordance with regulation 48 (F34... declaration of conformity);

(b) affix the **[**F35UK**]** marking in accordance with regulation 49 (CE marking); and

(c) where applicable, ensure that the identification number of the **[**F36approved**]** body is affixed in accordance with regulation 49.

(2) The requirement in paragraph (1)(b) does not apply in cases where—

(a) the conformity assessment procedure followed in accordance with regulation 41 is either module A2, C2, F or G; and

(b) the conformity assessment procedure has been carried out by a user inspectorate.

(3) The manufacturer must keep the F37... declaration of conformity up-to-date.

[F38(4) Where pressure equipment or an assembly is subject to more than one enactment requiring the drawing up of a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment by its title.**]**

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F32 Word in reg. 11 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 7(a)(i)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F33 Word in reg. 11 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 7(a)(ii)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F34 Word in reg. 11(1)(a) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 7(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F35 Word in reg. 11(1)(b) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 7(c)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F36 Word in reg. 11(1)(c) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 24 para. 7(ca) (as inserted by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(3), **14(a)**; 2020 c. 1, Sch. 5 para. 1(1))

F37 Word in reg. 11(3) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 7(d)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F38 Reg. 11(4) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 7(e)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

EU declaration of conformity and CE marking N.I.

11.—(1) Where the conformity of pressure equipment or an assembly referred to in regulation 6 or 7 with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the pressure equipment or assembly on the market—

(a) draw up a declaration of conformity in accordance with regulation 48 (EU declaration of conformity);

(b) affix the CE marking in accordance with regulation 49 (CE marking); and

(c) where applicable, ensure that the identification number of the notified body is affixed in accordance with regulation 49.

(2) The requirement in paragraph (1)(b) does not apply in cases where—

(a) the conformity assessment procedure followed in accordance with regulation 41 is either module A2, C2, F or G; and

(b) the conformity assessment procedure has been carried out by a user inspectorate.

(3) The manufacturer must keep the EU declaration of conformity up-to-date.

(4) Where pressure equipment or an assembly is subject to more than one EU instrument requiring a declaration of conformity to be drawn up, the manufacturer must draw up a single declaration of conformity which—

(a) identifies the EU instruments; and

(b) includes references to the publication of those EU instruments in the Official Journal.

Extent Information

E70 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Duty to keep technical documentation and F39... declaration of conformity E+W+S

12. A manufacturer must keep the technical documentation and the F40... declaration of conformity drawn up in respect of pressure equipment or an assembly and make them available for

inspection by the enforcing authorities for a period of 10 years beginning on the day on which the pressure equipment or assembly is placed on the market.

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F39 Word in reg. 12 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 8** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F40 Word in reg. 12 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 8** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Duty to keep technical documentation and EU declaration of conformity N.I.

12. A manufacturer must keep the technical documentation and the EU declaration of conformity drawn up in respect of pressure equipment or an assembly and make them available for inspection by the enforcing authorities for a period of 10 years beginning on the day on which the pressure equipment or assembly is placed on the market.

Extent Information

E71 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Labelling of pressure equipment and assemblies E+W+S

13.—(1) Before placing pressure equipment or an assembly on the market, a manufacturer must—

(a) ensure that it bears a type, batch or serial number or other element allowing its identification; and

(b) ensure that it is marked with—

(i) the name, registered trade name or registered trade mark of the manufacturer; and

(ii) a single postal address at which the manufacturer can be contacted.

(2) Where it is not possible for information specified in paragraph (1)(a) and (b) to be indicated on the pressure equipment or assembly, the manufacturer must ensure that the information is indicated on its packaging or in a document accompanying the pressure equipment or assembly.

[[F41](3) The details set out in paragraph (1)(b) must be clear, legible and in easily understandable English.**]**

Extent Information

E6 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F41 Reg. 13(3) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 9** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Labelling of pressure equipment and assemblies N.I.

13.—(1) Before placing pressure equipment or an assembly on the market, a manufacturer must—

(a) ensure that it bears a type, batch or serial number or other element allowing its identification; and

(b) ensure that it is marked with—

(i) the name, registered trade name or registered trade mark of the manufacturer; and

(ii) a single postal address at which the manufacturer can be contacted.

(2) Where it is not possible for information specified in paragraph (1)(a) and (b) to be indicated on the pressure equipment or assembly, the manufacturer must ensure that the information is indicated on its packaging or in a document accompanying the pressure equipment or assembly.

(3) The details set out in paragraph (1)(b) must be in a language which can be easily understood by consumers, other users and market surveillance authorities in the **[**F206relevant state**]** in which it is to be made available to such users.

Extent Information

E72 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F206 Words in reg. 13(3) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(1)**

Instructions and safety information E+W+S

14.—(1) When placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market, a manufacturer must ensure that it is accompanied by instructions and safety information **[**F42that are clear, legible and in easily understandable English**]**.

(2) The instructions and safety information referred to in paragraph (1) must include the information listed in paragraphs 29 and 30 of Schedule 2.

(3) When placing pressure equipment or an assembly covered by regulation 8 on the market, a manufacturer must ensure that it is accompanied by adequate instructions for use **[**F43that are clear, legible and in easily understandable English**]**.

F44(4) . . . . . .

F44(5) . . . . . .

Extent Information

E7 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F42 Words in reg. 14(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 10(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F43 Words in reg. 14(3) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 10(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F44 Reg. 14(4)(5) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 10(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Instructions and safety information N.I.

14.—(1) When placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market, a manufacturer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users.

(2) The instructions and safety information referred to in paragraph (1) must include the information listed in paragraphs 29 and 30 of Schedule 2.

(3) When placing pressure equipment or an assembly covered by regulation 8 on the market, a manufacturer must ensure that it is accompanied by adequate instructions for use in a language which can be easily understood by consumers and other users.

(4) Where the pressure equipment or assembly is placed on the market in **[**F207Northern Ireland**]**, the language referred to in paragraphs (1) and (3) must be English.

(5) Instructions and safety information must be clear, understandable and intelligible.

Extent Information

E73 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F207 Words in reg. 14(4) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(2)**

Compliance procedures for series production E+W+S

15.—(1) A manufacturer of pressure equipment or assemblies which are manufactured by series production must ensure that procedures are in place to ensure that any pressure equipment or assemblies so manufactured will be in conformity with Part 2.

(2) In doing so, the manufacturer must take adequate account of—

(a) any change in pressure equipment or assembly design or characteristics; and

(b) any change in a **[**F45designated**]** standard or in another technical specification by reference to which the F46... declaration of conformity was drawn up.

Extent Information

E8 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F45 Word in reg. 15(2)(b) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 11(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F46 Word in reg. 15(2)(b) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 11(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Compliance procedures for series production N.I.

15.—(1) A manufacturer of pressure equipment or assemblies which are manufactured by series production must ensure that procedures are in place to ensure that any pressure equipment or assemblies so manufactured will be in conformity with Part 2.

(2) In doing so, the manufacturer must take adequate account of—

(a) any change in pressure equipment or assembly design or characteristics; and

(b) any change in a harmonised standard or in another technical specification by reference to which the EU declaration of conformity was drawn up.

Extent Information

E74 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Monitoring

16.—(1) When appropriate, with regard to the risks to the health and safety of consumers and other users presented by pressure equipment or assemblies, the manufacturer must—

(a) carry out sample testing of pressure equipment or assemblies made available on the market;

(b) investigate complaints that pressure equipment or assemblies are not in conformity with Part 2;

(c) keep a register of—

(i) complaints that pressure equipment or assemblies are not in conformity with Part 2;

(ii) pressure equipment or assemblies which are found not to be in conformity with Part 2; and

(iii) pressure equipment or assemblies recalls; and

(d) keep distributors informed of any monitoring carried out under this regulation.

(2) The manufacturer must keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

Duty to take action in respect of pressure equipment or assemblies placed on the market which are considered not to be in conformity E+W+S

17.—(1) A manufacturer who considers, or has reason to believe, that pressure equipment or an assembly which that manufacturer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

(a) bring the pressure equipment or assembly into conformity;

(b) withdraw the pressure equipment or assembly; or

(c) recall the pressure equipment or assembly.

(2) Where pressure equipment or an assembly presents a risk, the manufacturer must immediately inform the market surveillance authority[F47]... of the risk, giving details of—

(a) the respect in which the pressure equipment or assembly is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Extent Information

E9 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F47 Words in reg. 17(2) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 12** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Duty to take action in respect of pressure equipment or assemblies placed on the market which are considered not to be in conformity N.I.

17.—(1) A manufacturer who considers, or has reason to believe, that pressure equipment or an assembly which that manufacturer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

(a) bring the pressure equipment or assembly into conformity;

(b) withdraw the pressure equipment or assembly; or

(c) recall the pressure equipment or assembly.

(2) Where pressure equipment or an assembly presents a risk, the manufacturer must immediately inform the market surveillance authority, and the competent national authorities of any other **[**[F208]relevant state**]** in which the manufacturer made the pressure equipment or assembly available on the market, of the risk, giving details of—

(a) the respect in which the pressure equipment or assembly is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Extent Information

E75 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F208 Words in reg. 17(2) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(1)**

Provision of information and cooperation

18.—(1) Further to a request from an enforcing authority, and within such period as the authority may specify, a manufacturer must provide the authority with all the information and documentation necessary to demonstrate that pressure equipment or an assembly is in conformity with Part 2.

(2) A request referred to in paragraph (1)—

(a) may only be made during the period of 10 years beginning on the day the pressure equipment or assembly was placed on the market; and

(b) must be accompanied by the reasons for making the request.

(3) The information and documentation referred to in paragraph (1)—

(a) may be provided electronically; and

(b) must be in a language which can be easily understood by the enforcing authority.

(4) A manufacturer must, at the request of the enforcing authority, cooperate with that authority on any action taken to—

(a) evaluate pressure equipment or an assembly in accordance with regulation 70 (evaluation of pressure equipment or assemblies presenting a risk); or

(b) eliminate the risks posed by pressure equipment or an assembly which the manufacturer has placed on the market.

Manufacturer's authorised representatives E+W+S

19.—(1) A manufacturer may, by written mandate, appoint a person as their authorised representative to perform specified tasks on the manufacturer's behalf.

(2) The mandate must allow the authorised representative to do at least the following in relation to pressure equipment or assemblies covered by the mandate—

(a) perform the manufacturer's obligations under regulation 12 (duty to keep technical documentation and [F48]... declaration of conformity); and

(b) perform the manufacturer's obligations under regulation 18 (provision of information and cooperation).

(3) The obligations laid down in regulation 9 (design and manufacture in accordance with the essential safety requirements) and regulation 10(1)(b) (technical documentation and conformity assessment) must not form part of an authorised representative's mandate.

(4) An authorised representative must comply with all the duties imposed on the manufacturer in relation to each obligation under these Regulations that the representative is appointed by the manufacturer to perform and, accordingly as far as those duties, as well as the penalties for failure to comply with those duties, are concerned, references in these Regulations (except in this regulation) to the manufacturer are to be taken as including a reference to the authorised representative.

(5) A manufacturer who has appointed an authorised representative to perform on the manufacturer's behalf an obligation under these Regulations remains responsible for the proper performance of that obligation.

Extent Information

E10 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F48 Word in reg. 19(2)(a) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 13** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Manufacturer's authorised representatives N.I.

19.—(1) A manufacturer may, by written mandate, appoint a person as their authorised representative to perform specified tasks on the manufacturer's behalf.

(2) The mandate must allow the authorised representative to do at least the following in relation to pressure equipment or assemblies covered by the mandate—

(a) perform the manufacturer's obligations under regulation 12 (duty to keep technical documentation and EU declaration of conformity); and

(b) perform the manufacturer's obligations under regulation 18 (provision of information and cooperation).

(3) The obligations laid down in regulation 9 (design and manufacture in accordance with the essential safety requirements) and regulation 10(1)(b) (technical documentation and conformity assessment) must not form part of an authorised representative's mandate.

(4) An authorised representative must comply with all the duties imposed on the manufacturer in relation to each obligation under these Regulations that the representative is appointed by the manufacturer to perform and, accordingly as far as those duties, as well as the penalties for failure to comply with those duties, are concerned, references in these Regulations (except in this regulation) to the manufacturer are to be taken as including a reference to the authorised representative.

(5) A manufacturer who has appointed an authorised representative to perform on the manufacturer's behalf an obligation under these Regulations remains responsible for the proper performance of that obligation.

Extent Information

E76 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Importers

Prohibition on placing on the market pressure equipment or assemblies which are not in conformity

20. An importer must not place pressure equipment or an assembly on the market unless it is in conformity with Part 2.

Requirements which must be satisfied before an importer places pressure equipment or assemblies on the market E+W+S

21.—(1) Before placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market, an importer must ensure that—

(a) the relevant conformity assessment procedure has been carried out;

(b) the manufacturer has drawn up the technical documentation;

(c) the pressure equipment or assembly—

(i) bears the **[**F49UK**]** marking; and

(ii) is accompanied by the required documents; and

(d) the manufacturer has complied with the requirements of regulation 13 (labelling).

(2) The requirement in paragraph (1)(c)(i) does not apply in cases where—

(a) the conformity assessment procedure followed in accordance with regulation 41 is either module A2, C2, F or G; and

(b) the conformity assessment procedure has been carried out by a user inspectorate.

(3) Before placing pressure equipment or an assembly referred to in regulation 8 on the market, an importer must ensure that—

(a) the manufacturer has drawn up the technical documentation;

(b) the pressure equipment or assembly is accompanied by adequate instructions for use and any required documents; and

(c) the manufacturer has complied with the requirements of regulation 13 (labelling).

(4) In paragraphs (1)(c)(ii) and (3)(b), "required documents" means any documents that the manufacturer is required to provide with pressure equipment or an assembly pursuant to regulation 13(2) (labelling) and 14 (instructions and safety information).

Extent Information

E11 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F49 Word in reg. 21(1)(c)(i) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 14** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Requirements which must be satisfied before an importer places pressure equipment or assemblies on the market N.I.

21.—(1) Before placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market, an importer must ensure that—

(a) the relevant conformity assessment procedure has been carried out;

(b) the manufacturer has drawn up the technical documentation;

(c) the pressure equipment or assembly—

(i) bears the CE marking; and

(ii) is accompanied by the required documents; and

(d) the manufacturer has complied with the requirements of regulation 13 (labelling).

(2) The requirement in paragraph (1)(c)(i) does not apply in cases where—

(a) the conformity assessment procedure followed in accordance with regulation 41 is either module A2, C2, F or G; and

(b) the conformity assessment procedure has been carried out by a user inspectorate.

(3) Before placing pressure equipment or an assembly referred to in regulation 8 on the market, an importer must ensure that—

(a) the manufacturer has drawn up the technical documentation;

(b) the pressure equipment or assembly is accompanied by adequate instructions for use and any required documents; and

(c) the manufacturer has complied with the requirements of regulation 13 (labelling).

(4) In paragraphs (1)(c)(ii) and (3)(b), "required documents" means any documents that the manufacturer is required to provide with pressure equipment or an assembly pursuant to regulation 13(2) (labelling) and 14 (instructions and safety information).

Extent Information

E77 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Prohibition on placing on the market pressure equipment or assemblies considered not to be in conformity with the essential safety requirements

22.—(1) Where an importer considers, or has reason to believe, that pressure equipment or an assembly referred to in Regulation 6 or 7 is not in conformity with the essential safety requirements, the importer must not place the pressure equipment or assembly on the market.

(2) Where pressure equipment or an assembly presents a risk, the importer must inform the manufacturer and the market surveillance authority of that risk.

Information identifying importer E+W+S

23.—(1) Before placing pressure equipment or an assembly on the market, an importer must indicate on the pressure equipment or assembly—

(a) the name, registered trade name or registered trade mark of the importer; and

(b) a postal address at which the importer can be contacted.

(2) The information specified in paragraph (1) must be in a language which can be easily understood by consumers and other users and the market surveillance authority [F50]....

[[F51](3) Paragraph (1) does not apply where—

(a) either—

(i) it is not possible to set out the information referred to in paragraph (1) on the pressure equipment or assembly, or

(ii) the importer has imported the pressure equipment or assembly from an EEA state or Switzerland and places it on the market within the period of **[**[F52]seven years**]** beginning with IP completion day, and

(b) before placing the pressure equipment or assembly on the market, the importer sets out the information referred to in paragraph (1) on the packaging of the pressure equipment or assembly or in a document accompanying the pressure equipment or assembly.**]**

Extent Information

E12 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F50 Words in reg. 23(2) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 15(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F51 Reg. 23(3) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 15(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), **2**, S.I. 2019/1246, regs. 1(3), **5**, 6(3), S.I. 2020/852, regs. 1, 4(2), **Sch. 1 para. 1(m)(iii)** and S.I. 2020/1460, reg. 1(5), **Sch. 3 para. 2(2)(b)**); 2020 c. 1, Sch. 5 para. 1(1)

F52 Words in reg. 23(3)(a)(ii) substituted (E.W.S.) (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 4, **Sch. 3 para. (k)**

Modifications etc. (not altering text)

C1 Reg. 23 modified (temp.) by S.I. 2019/392, **reg. 6** (as inserted (10.9.2019) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(2)(4), **2(3)** (with reg. 18))

Information identifying importer N.I.

23.—(1) Before placing pressure equipment or an assembly on the market, an importer must indicate on the pressure equipment or assembly—

(a) the name, registered trade name or registered trade mark of the importer; and

(b) a postal address at which the importer can be contacted.

(2) The information specified in paragraph (1) must be in a language which can be easily understood by consumers and other users and the market surveillance authority in the **[**[F209]relevant state**]** in which it is to be made available to such users.

(3) Where it is not possible to indicate the information specified in paragraph (1) on **[**[F210]the pressure equipment or assembly**]**, the importer must indicate that information—

(a) on the packaging; or

(b) in a document accompanying the pressure equipment or assembly.

Extent Information

E78 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F209 Words in reg. 23(2) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(1)**

F210 Words in reg. 23(3) substituted (10.9.2019) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(2), **3**

Modifications etc. (not altering text)

C2 Reg. 23 modified (temp.) by S.I. 2019/392, reg. 6 (as inserted (10.9.2019) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(2)(4), **2(3)** (with reg. 18))

Instructions and safety information E+W+S

24.—(1) When placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market, an importer must ensure that it is accompanied by instructions and safety information **[**[F53]that are clear, legible and in easily understandable English**]**.

(2) The instructions and safety information referred to in paragraph (1) must include the information listed in paragraphs 29 and 30 of Schedule 2.

(3) When placing pressure equipment or an assembly covered by regulation 8 on the market, an importer must ensure that it is accompanied by instructions and safety information **[**[F54]that are clear, legible and in easily understandable English**]** .

[F55](4) . . . . . .

Extent Information

E13 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F53 Words in reg. 24(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 16(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F54 Words in reg. 24(3) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 16(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F55 Reg. 24(4) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 16(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Instructions and safety information N.I.

24.—(1) When placing pressure equipment or an assembly referred to in regulation 6 or 7 on the market, an importer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users.

(2) The instructions and safety information referred to in paragraph (1) must include the information listed in paragraphs 29 and 30 of Schedule 2.

(3) When placing pressure equipment or an assembly covered by regulation 8 on the market, an importer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by consumers and other users.

(4) Where the pressure equipment or assembly is placed on the market in **[**F211Northern Ireland**]**, the language referred to in paragraphs (1) and (3) must be English.

Extent Information

E79 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F211 Words in reg. 24(4) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(2)**

Storage and transport

25. Where an importer has responsibility for pressure equipment or an assembly referred to in Regulation 6 or 7, the importer must ensure that the conditions under which the pressure equipment or assembly is stored or transported do not jeopardise its conformity with the essential safety requirements.

Monitoring

26.—(1) Where appropriate, having regard to the risks to the health and safety of consumers and other users presented by the pressure equipment or assemblies, the importer must—

(a) carry out sample testing of pressure equipment and assemblies made available on the market by the importer;

(b) investigate complaints of pressure equipment and assemblies made available on the market by the importer which are not in conformity with Part 2;

(c) keep a register of—

(i) complaints that pressure equipment or assemblies are not in conformity with Part 2;

(ii) pressure equipment or assemblies which are found not to be in conformity with Part 2; and

(iii) pressure equipment or assemblies recalls; and

(d) keep distributors informed of any monitoring carried out under this regulation.

(2) The importer must keep an entry made in the register for a period of at least 10 years beginning on the day on which the obligation to make the entry arose.

Duty to take action in respect of pressure equipment or assemblies placed on the market considered not to be in conformity E+W+S

27.—(1) An importer who considers, or has reason to believe, that pressure equipment or an assembly which that importer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

(a) bring that pressure equipment or assembly into conformity;

(b) withdraw the pressure equipment or assembly; or

(c) recall the pressure equipment or assembly.

(2) Where the pressure equipment or assembly presents a risk, the importer must immediately inform the market surveillance authority and the competent national authorities [F56]... of the risk, giving details of—

(a) the respect in which the pressure equipment or assembly is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Extent Information

E14 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F56 Words in reg. 27(2) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 17** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Duty to take action in respect of pressure equipment or assemblies placed on the market considered not to be in conformity N.I.

27.—(1) An importer who considers, or has reason to believe, that pressure equipment or an assembly which that importer has placed on the market is not in conformity with Part 2 must immediately take the corrective measures necessary to—

(a) bring that pressure equipment or assembly into conformity;

(b) withdraw the pressure equipment or assembly; or

(c) recall the pressure equipment or assembly.

(2) Where the pressure equipment or assembly presents a risk, the importer must immediately inform the market surveillance authority and the competent national authorities of any other **[**[F212]relevant state**]** in which the importer made the pressure equipment or assembly available on the market of the risk, giving details of—

(a) the respect in which the pressure equipment or assembly is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Extent Information

E80 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F212 Words in reg. 27(2) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(1)**

Retention of technical documentation and [F57]... declaration of conformity E+W+S

28. An importer must, for a period of 10 years beginning on the day on which pressure equipment or an assembly is placed on the market, keep and, upon request, make available to an enforcing authority the following in relation to the pressure equipment or assembly—

(a) a copy of the [F58]... declaration of conformity; and

(b) the technical documentation.

Extent Information

E15 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F57 Word in reg. 28 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 18** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F58 Word in reg. 28(a) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 18** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Retention of technical documentation and EU declaration of conformity N.I.

28. An importer must, for a period of 10 years beginning on the day on which pressure equipment or an assembly is placed on the market, keep and, upon request, make available to an enforcing authority the following in relation to the pressure equipment or assembly—

(a) a copy of the EU declaration of conformity; and

(b) the technical documentation.

Extent Information

E81 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Provision of information and cooperation E+W+S

29.—(1) Following a request from an enforcing authority, and within such period as the authority may specify, an importer must provide the authority with all the information and documentation necessary to demonstrate that pressure equipment or an assembly is in conformity with Part 2.

(2) A request referred to in paragraph (1)—

(a) may only be made during the period of 10 years beginning on the day the importer places the pressure equipment or assembly on the market; and

(b) must be accompanied by the reasons for making the request.

(3) The information and documentation referred to in paragraph (1)—

(a) may be provided electronically; and

(b) **[**[F59]must be clear, legible and in easily understandable English**]**.

(4) An importer must, at the request of the enforcing authority, cooperate with that authority on any action taken to—

(a) evaluate pressure equipment or assemblies in accordance with regulation 70 (evaluation of pressure equipment or assemblies presenting a risk); or

(b) eliminate the risks posed by pressure equipment or assemblies which the importer has placed on the market.

Extent Information

E16 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F59 Words in reg. 29(3)(b) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 19** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Provision of information and cooperation N.I.

29.—(1) Following a request from an enforcing authority, and within such period as the authority may specify, an importer must provide the authority with all the information and documentation necessary to demonstrate that pressure equipment or an assembly is in conformity with Part 2.

(2) A request referred to in paragraph (1)—

(a) may only be made during the period of 10 years beginning on the day the importer places the pressure equipment or assembly on the market; and

(b) must be accompanied by the reasons for making the request.

(3) The information and documentation referred to in paragraph (1)—

(a) may be provided electronically; and

(b) must be in a language which can be easily understood by the enforcing authority.

(4) An importer must, at the request of the enforcing authority, cooperate with that authority on any action taken to—

(a) evaluate pressure equipment or assemblies in accordance with regulation 70 (evaluation of pressure equipment or assemblies presenting a risk); or

(b) eliminate the risks posed by pressure equipment or assemblies which the importer has placed on the market.

Extent Information

E82 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Distributors

Duty to act with due care

30. When making pressure equipment or an assembly available on the market, a distributor must act with due care to ensure that it is in conformity with Part 2.

Requirements which must be satisfied before a distributor makes pressure equipment or assemblies available on the market) E+W+S

31.—(1) Before making pressure equipment or an assembly referred to in regulation 6 or 7 available on the market, the distributor must verify that—

(a) the pressure equipment or assembly—

(i) bears the **[**F60UK**]** marking;

(ii) is accompanied by the required documents;

[F61(iii) is accompanied by instructions and safety information that are clear, legible and in easily understandable English;**]**

(b) the manufacturer has complied with the requirements of regulation 13 (labelling of pressure equipment and assemblies); and

(c) the importer has complied with the requirements of regulation 23 (information identifying importer).

(2) In paragraph (1)(a)(ii), "required documents" means the documents that the manufacturer or importer is required to provide with pressure equipment or assemblies pursuant to—

(a) regulation 13 (labelling of pressure equipment and assemblies);

(b) regulation 23 (information identifying importer);

(c) regulation 14 or 24 (instructions and safety information); and

(d) regulation 49 (**[**F62UK**]** marking).

F63(3) . . . . . .

Extent Information

E17 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F60 Word in reg. 31(1)(a)(i) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 20(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F61 Reg. 31(1)(a)(iii) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 20(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F62 Word in reg. 31(2)(d) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 20(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F63 Reg. 31(3) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 20(c)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Requirements which must be satisfied before a distributor makes pressure equipment or assemblies available on the market) N.I.

31.—(1) Before making pressure equipment or an assembly referred to in regulation 6 or 7 available on the market, the distributor must verify that—

(a) the pressure equipment or assembly—

(i) bears the CE marking;

(ii) is accompanied by the required documents;

(iii) the instructions and safety information are in a language which can be easily understood by consumers and other users in the **[**F213relevant state**]** in which the pressure equipment or assembly is to be made available on the market;

(b) the manufacturer has complied with the requirements of regulation 13 (labelling of pressure equipment and assemblies); and

(c) the importer has complied with the requirements of regulation 23 (information identifying importer).

(2) In paragraph (1)(a)(ii), "required documents" means the documents that the manufacturer or importer is required to provide with pressure equipment or assemblies pursuant to—

(a) regulation 13 (labelling of pressure equipment and assemblies);

(b) regulation 23 (information identifying importer);

(c) regulation 14 or 24 (instructions and safety information); and

(d) regulation 49 (CE marking).

(3) Where the pressure equipment or assembly is made available on the market in **[**F214Northern Ireland**]**, the language referred to in paragraph (1)(a)(iii) must be English.

Extent Information

E83 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F213 Words in reg. 31(1)(a)(iii) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(1)**

F214 Words in reg. 31(3) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(2)**

Storage and transport

32. Where a distributor has responsibility for pressure equipment or an assembly referred to in Regulation 6 or 7, the distributor must ensure that the conditions under which the pressure equipment or assembly is stored or transported do not jeopardise its conformity with the essential safety requirements.

Prohibition on making available on the market where pressure equipment or assemblies are not considered to be in conformity with essential safety requirements

33.—(1) Where a distributor considers, or has reason to believe, that pressure equipment or an assembly referred to in Regulation 6 or 7 is not in conformity with the essential safety requirements, the distributor must not make the pressure equipment or assembly available on the market until it has been brought into conformity.

(2) Where the pressure equipment or assembly presents a risk, the distributor must inform the following persons of the risk—

(a) the manufacturer or the importer; and

(b) the market surveillance authority.

Duty to take action in respect of pressure equipment made available on the market which are not in conformity E+W+S

34.—(1) A distributor who considers, or has reason to believe, that pressure equipment or assemblies which the distributor has made available on the market is not in conformity with Part 2 must make sure that the necessary corrective measures are taken to—

(a) bring that pressure equipment or assembly into conformity;

(b) withdraw the pressure equipment or assembly; or

(c) recall the pressure equipment or assembly.

(2) Where the pressure equipment or assembly presents a risk, the distributor must immediately inform the market surveillance authority, and the competent national authorities F64..., of that risk, giving details of—

(a) the respect in which pressure equipment is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Extent Information

E18 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F64 Words in reg. 34(2) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 21** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Duty to take action in respect of pressure equipment made available on the market which are not in conformity N.I.

34.—(1) A distributor who considers, or has reason to believe, that pressure equipment or assemblies which the distributor has made available on the market is not in conformity with Part 2 must make sure that the necessary corrective measures are taken to—

(a) bring that pressure equipment or assembly into conformity;

(b) withdraw the pressure equipment or assembly; or

(c) recall the pressure equipment or assembly.

(2) Where the pressure equipment or assembly presents a risk, the distributor must immediately inform the market surveillance authority, and the competent national authorities of the **[**F215relevant states**]** in which the distributor has made the pressure equipment or assembly available on the market, of that risk, giving details of—

(a) the respect in which pressure equipment is considered not to be in conformity with Part 2; and

(b) any corrective measures taken.

Extent Information

E84 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F215 Words in reg. 34(2) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(3)**

Provision of information and cooperation E+W+S

35.—(1) Following a request from an enforcing authority, and within such period as the authority may specify, a distributor must provide the authority with all the information and documentation necessary to demonstrate that pressure equipment or an assembly is in conformity with Part 2.

(2) The information referred to in paragraph (1)—

(a) may be provided electronically; and

(b) **[**F65must be clear, legible and in easily understandable English**]**.

(3) A distributor must, at the request of the enforcing authority, cooperate with that authority on any action taken to—

(a) evaluate pressure equipment in accordance with regulation 70 (evaluation of pressure equipment or assemblies presenting a risk); or

(b) eliminate the risks posed by pressure equipment or assemblies which the distributor has made available on the market.

Extent Information

E19 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F65 Words in reg. 35(2)(b) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 22** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Provision of information and cooperation N.I.

35.—(1) Following a request from an enforcing authority, and within such period as the authority may specify, a distributor must provide the authority with all the information and documentation necessary to demonstrate that pressure equipment or an assembly is in conformity with Part 2.

(2) The information referred to in paragraph (1)—

(a) may be provided electronically; and

(b) must be in a language which can be easily understood by the enforcing authority.

(3) A distributor must, at the request of the enforcing authority, cooperate with that authority on any action taken to—

(a) evaluate pressure equipment in accordance with regulation 70 (evaluation of pressure equipment or assemblies presenting a risk); or

(b) eliminate the risks posed by pressure equipment or assemblies which the distributor has made available on the market.

Extent Information

E85 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

All economic operators

Cases in which obligations of manufacturers apply to importers and distributors

36. An importer or distributor ("A") is to be considered a manufacturer for the purposes of these Regulations, and is subject to the obligations of the manufacturer under this Part, where A—

(a) places pressure equipment or an assembly on the market under A's own name or trademark; or

(b) modifies pressure equipment or an assembly already placed on the market in such a way that it may affect whether the pressure equipment or assembly is in conformity with Part 2.

Translation of F66... declaration of conformity E+W+S

37.—(1) Before making pressure equipment or an assembly available on the market, an economic operator must ensure that the F67... declaration of conformity is **[**F68in English**]**.

F69(2) . . . . . .

Extent Information

E20 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F66 Word in reg. 37 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 23(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F67 Word in reg. 37(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 23(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F68 Words in reg. 37(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 23(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F69 Reg. 37(2) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 23(c)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Translation of EU declaration of conformity N.I.

37.—(1) Before making pressure equipment or an assembly available on the market, an economic operator must ensure that the EU declaration of conformity is prepared in, or translated into, the language required by the **[**[F216]relevant state**]** in which it is to be made available on the market.

(2) Where the pressure equipment or assembly is to be made available on the market in **[**[F217]Northern Ireland**]**, the language required is English.

Extent Information

E86 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F216 Words in reg. 37(1) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(1)**

F217 Words in reg. 37(2) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 3(2)**

Identification of economic operators

38.—(1) An economic operator ("E") who receives a request in relation to pressure equipment or an assembly from the market surveillance authority before the end of the relevant period must, within such period as that authority may specify, identify to the authority—

(a) any other economic operator who has supplied E with the pressure equipment or assembly; and

(b) any other economic operator to whom E has supplied the pressure equipment or assembly.

(2) The relevant period is—

(a) for information under paragraph (1)(a), 10 years beginning on the day on which E was supplied with the pressure equipment or assembly; and

(b) for information under paragraph (1)(b), 10 years beginning on the day on which E supplied the pressure equipment or assembly.

Prohibition on improper use of [F70UK] marking E+W+S

39.—(1) An economic operator must not affix the **[**F71UK**]** marking to pressure equipment or an assembly unless—

(a) that economic operator is the manufacturer of the pressure equipment or assembly; and

(b) the conformity of the pressure equipment or assembly with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure.

(2) An economic operator must not affix the **[**F71UK**]** marking to pressure equipment or an assembly where—

(a) the conformity assessment procedure followed in accordance with regulation 41 is either module A2, C2, F or G; and

(b) the conformity assessment procedure has been carried out by a user inspectorate.

(3) An economic operator must not affix to pressure equipment or an assembly a marking which—

(a) is not the **[**F71UK**]** marking; but

(b) purports to attest that the pressure equipment or assembly is in conformity with the essential safety requirements.

(4) An economic operator must not affix to pressure equipment or an assembly a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the **[**F71UK**]** marking.

(5) An economic operator must not affix to pressure equipment or an assembly any other marking if the visibility, legibility and meaning of the **[**F71UK**]** marking would be impaired as a result.

Extent Information

E21 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F70 Word in reg. 39 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 24** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F71 Word in reg. 39 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 24** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Prohibition on improper use of CE marking N.I.

39.—(1) An economic operator must not affix the CE marking to pressure equipment or an assembly unless—

(a) that economic operator is the manufacturer of the pressure equipment or assembly; and

(b) the conformity of the pressure equipment or assembly with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure.

(2) An economic operator must not affix the CE marking to pressure equipment or an assembly where—

(a) the conformity assessment procedure followed in accordance with regulation 41 is either module A2, C2, F or G; and

(b) the conformity assessment procedure has been carried out by a user inspectorate.

(3) An economic operator must not affix to pressure equipment or an assembly a marking which—

(a) is not the CE marking; but

(b) purports to attest that the pressure equipment or assembly is in conformity with the essential safety requirements.

(4) An economic operator must not affix to pressure equipment or an assembly a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking.

(5) An economic operator must not affix to pressure equipment or an assembly any other marking if the visibility, legibility and meaning of the CE marking would be impaired as a result.

Extent Information

E87 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F72Obligations which are met by complying with the obligations in the Directive

39A.—(1) In this regulation—

(a) any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive;

(b) "CE marking" has the meaning given to it in Article 2(31); and

(c) "pressure equipment and assemblies" means the pressure equipment and assemblies referred to in Article 4(1) and (2).

(2) Paragraph (3) applies where, before placing pressure equipment or an assembly on the market, the manufacturer—

(a) ensures that the pressure equipment or assembly has been manufactured in accordance with the essential safety requirements set out in Annex I;

(b) ensures that the relevant conformity assessment procedures referred to in Article 14 have been carried out;

(c) draws up the technical documentation referred to in Annex III;

(d) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;

(e) affixes a CE marking and the identification number of the notified body (where that body is involved in the product control phase) in accordance with Articles 18 and 19(1) to (4);

(f) draws up an EU declaration of conformity, in accordance with Article 17; and

(g) ensures that the EU declaration of conformity is prepared in or translated into English.

(3) Where this paragraph applies—

(a) the requirements of regulations 9(1), 10 and 11(1) are to be treated as being satisfied;

(b) regulations 2(2)(a), 11(3), 12, 15(2), 19(2) and 39 apply subject to the modifications in paragraph (8); and

(c) Part 3 does not apply;

(d) regulation 74 does not apply.

(4) Paragraph (5) applies where, before placing pressure equipment or an assembly on the market, the importer ensures that—

(a) the relevant conformity assessment procedure referred to in Article 14 has been carried out;

(b) the manufacturer has drawn up the technical documentation referred to in Annex III; and

(c) the pressure equipment or assembly bears the CE marking and any notified body identification number.

(5) Where this paragraph applies—

(a) the requirements of regulation 21(1)(a) to (c) are to be treated as being satisfied; and

(b) regulations 2(2)(a), 22(1), 25 and 28 apply subject to the modifications in paragraph (8).

(6) Paragraph (7) applies where, before making pressure equipment or an assembly available on the market, a distributor ensures that the pressure equipment or assembly bears the CE marking.

(7) Where this paragraph applies—

(a) regulation 31(1)(a)(i) is to be treated as being satisfied; and

(b) regulations 2(2)(a) and 33(1) apply subject to the modifications in paragraph (8).

(8) The modifications referred to in sub-paragraphs (3)(b), (5)(b) and (7)(b) are that—

(a) any reference to "declaration of conformity" is to be read as a reference to the EU declaration of conformity;

(b) any reference to "UK marking" is to be read as a reference to the CE marking;

(c) any reference to "essential safety requirements" is to be read as a reference to the essential safety requirements referred to in Annex I;

(d) any reference to "designated standard" is to be read as a reference to a harmonised standard within the meaning of Article 2(24); and

(e) any reference to "relevant conformity assessment procedure" is to be read as a reference to the relevant conformity assessment procedures referred to in Article 14.

F72 Regs. 39A-39D inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 25** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 16(3)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Conformity assessment procedure obligation which is met by complying with the Directive.

39B .—(1) In this regulation any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive.

(2) Paragraph (3) applies where, prior to the manufacture of pressure equipment or an assembly, the manufacturer ensures that the conformity assessment procedure that applies to that pressure equipment or assembly in accordance with Article 14(2), referred to as Module B and set out in Annex III, has been carried out.

(3) Where this paragraph applies—

(a) the requirement in regulation 42 to follow the conformity assessment procedure referred to in that regulation as Module B is to be treated as being satisfied;

(b) any reference to "relevant conformity assessment procedure" in regulations 10(1)(c), 11(1), 21(1)(a), 39(1)(b) and 48(b) is to be read as including the conformity assessment procedure referred to in Article 14(2), referred to as Module B and set out in Annex III; and

(c) any reference to "technical documentation" in regulations 10(1)(d), 21(1)(b) and 28(b) is to be read as including the technical documentation relating to the design of the pressure equipment or assembly referred to as Module B as set out in Annex III.

F72 Regs. 39A-39D inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 25** (with Sch.

24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 16(3)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Expiry of regulations 39A and 39B

39C.—(1) Subject to paragraph (2), regulation 39A ceases to have effect at the end of the period of **[**[F73]four years**]** beginning with IP completion day.

(2) Notwithstanding the expiry of regulation 39A—

(a) any pressure equipment or assembly which was placed on the market pursuant to regulation 39A may continue to be made available on the market on or after the expiry of regulation 39A;

(b) any obligation to which a person was subject under regulation 39A in respect of any pressure equipment or assembly placed on the market pursuant to regulation 39A continues to have effect after the expiry of regulation 39A, in respect of that equipment or assembly.

(3) Subject to paragraph (4), regulation 39B ceases to have effect at the end of the period of **[**[F74]four years**]** beginning with IP completion day.

(4) Where a conformity assessment procedure has been completed pursuant to regulation 39B in relation to a pressure equipment or an assembly prior to the expiry of regulation 39B, regulation 39B continues to apply in respect of that pressure equipment or assembly where—

(a) the manufacturer arranges for the EU-Type examination certificate and any annexes to be transferred to an approved body;

(b) the approved body referred to in sub-paragraph (a) accepts responsibility for the EU-Type examination certificate; and

(c) the approved body issues a Type-examination certificate relying, or relying in part, on any examinations or tests undertaken prior to the issue of the EU-Type examination certificate.

(5) In paragraph (4) "EU-Type examination certificate" means a certificate issued after the conformity assessment referred to in the Directive as Module B and set out in Annex III of the Directive, has been carried out.

F72 Regs. 39A-39D inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 25** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 16(3)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F73 Words in reg. 39C(1) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, **Sch. 1** para. (n)

F74 Words in reg. 39C(3) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 2, **Sch. 1** para. (n)

Qualifying Northern Ireland Goods

39D.—(1) Where paragraph (2) applies any pressure equipment or assembly is to be treated as being in conformity with Part 2.

(2) This paragraph applies where—

(a) any pressure equipment or assembly—

(i) is in conformity with Part 2, as that Part applies in Northern Ireland; and

(ii) is qualifying Northern Ireland goods; and

(b) an importer has complied with the obligations set out in paragraph (3).

(3) The obligations referred to in paragraph (2)(b) are that, before placing the pressure equipment or assembly on the market, the importer—

(a) complies with regulation 23;

(b) ensures that—

(i) the relevant conformity assessment procedure has been carried out in accordance with Part 3, as that Part applies in Northern Ireland;

(ii) the manufacturer has drawn up the technical documentation; and

(iii) the pressure equipment or assembly bears the CE marking.

(4) In this regulation—

"CE marking" has the meaning given to it in regulation 2(1), as it applies in Northern Ireland;

"qualifying Northern Ireland goods" has the meaning given to it in regulations made under section 8C(6) of the European Union (Withdrawal) Act 2018;

"technical documentation" has the meaning given to it in regulation 2(1), as it applies in Northern Ireland.**]**

F72 Regs. 39A-39D inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 25** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/1460, reg. 1(4), **Sch. 3 para. 16(3)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

PART 3

Conformity assessment

Presumption of conformity E+W+S

40.—(1) Pressure equipment or an assembly which is in conformity with a **[**[F75]designated**]** standard (or part of such a standard) [F76]... is to be presumed to be in conformity with the essential safety requirements covered by that standard (or that part of that standard).

[F77](2) . . . . . .

[[F78](3) The presumption in paragraph (1) is rebuttable.**]**

Extent Information

E22 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F75 Word in reg. 40(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 26(a)(i)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F76 Words in reg. 40(1) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 26(a)(ii)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F77 Reg. 40(2) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 26(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F78 Reg. 40(3) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 26(c)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Presumption of conformity N.I.

40.—(1) Pressure equipment or an assembly which is in conformity with a harmonised standard (or part of such a standard) the reference to which has been published in the Official Journal is to be presumed to be in conformity with the essential safety requirements covered by that standard (or that part of that standard).

(2) The materials used for the manufacture of pressure equipment or an assembly which are in conformity with a European approval for materials, the reference to which has been published in the Official Journal, are to be presumed to be in conformity with the essential safety requirements applicable to that European approval for materials.

(3) The presumptions in paragraph (1) and (2) are rebuttable.

Extent Information

E88 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Conformity assessment procedures

41. For the assessment of conformity of pressure equipment falling within regulation 6, the manufacturer must determine the applicable category in accordance with the procedure set out in Schedule 3.

E+W+S

42.—(1) The manufacturer must follow one of the following conformity assessment procedures referred to in **[**[F79]Schedule 1A to these Regulations**]** according to the category in which the equipment is classified—

(a) Category I: Module A;

(b) Category II: Module A2; or, at the choice of the manufacturer, Module D1; or Module E1;

(c) Category III: Modules B (design type) + D; or, at the choice of the manufacturer, Modules B (design type) + F; or Modules B (production type) + E; or Modules B (production type) + C2; or Module H;

(d) Category IV: Modules B (production type) + D; or, at the choice of the manufacturer, Modules B (production type) + F; or Module G; or Module H1.

(2) The manufacturer may also choose to apply one of the procedures which apply to a higher category, if available.

Extent Information

E23 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F79 Words in reg. 42(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 27** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

N.I.

42.—(1) The manufacturer must follow one of the following conformity assessment procedures referred to in Annex III to the Directive (as amended from time to time) according to the category in which the equipment is classified—

(a) Category I: Module A;

(b) Category II: Module A2; or, at the choice of the manufacturer, Module D1; or Module E1;

(c) Category III: Modules B (design type) + D; or, at the choice of the manufacturer, Modules B (design type) + F; or Modules B (production type) + E; or Modules B (production type) + C2; or Module H;

(d) Category IV: Modules B (production type) + D; or, at the choice of the manufacturer, Modules B (production type) + F; or Module G; or Module H1.

(2) The manufacturer may also choose to apply one of the procedures which apply to a higher category, if available.

Extent Information

E89 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F80Power to amend applicable module

42A.—(1) Where in order to mitigate the effects of very serious safety concerns the Secretary of State considers that an item or family of pressure equipment are to be subject to different categories of modules, the Secretary of State may by regulations make such provision.

(2) Regulations made under paragraph (1)—

(a) are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament; and

(b) include power—

(i) to make different provision for different cases; and

(ii) to make such supplemental, consequential and transitional provision as the Secretary of State considers appropriate.**]**

F80 Reg. 42A inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 28** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

E+W+S

43.—(1) The notified body or user inspectorate must, when performing unexpected visits in the framework of quality assurance procedures for pressure equipment in categories III and IV in regulation 6(a)(i), 6(a)(ii)(aa) or 6(b), 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 25 of Schedule 2.

(2) The manufacturer must inform the notified body or user inspectorate of the intended schedule of production.

(3) The notified body or user inspectorate must carry out at least two visits during the first year of manufacturing.

(4) The notified body or user inspectorate must determine the frequency of subsequent visits on the basis of the criteria set out in point 4.4. of modules D, E and H and point 5.4 of module H1 in **[**[F81]Schedule 1A to these Regulations**]**.

Extent Information

E24 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F81 Words in reg. 43(4) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 29** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

N.I.

43.—(1) The notified body or user inspectorate must, when performing unexpected visits in the framework of quality assurance procedures for pressure equipment in categories III and IV in regulation 6(a)(i), 6(a)(ii)(aa) or 6(b), 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 25 of Schedule 2.

(2) The manufacturer must inform the notified body or user inspectorate of the intended schedule of production.

(3) The notified body or user inspectorate must carry out at least two visits during the first year of manufacturing.

(4) The notified body or user inspectorate must determine the frequency of subsequent visits on the basis of the criteria set out in point 4.4. of modules D, E and H and point 5.4 of module H1 in Annex III to the Directive (as amended from time to time).

Extent Information

E90 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

44. In the case of one-off production of vessels and pressure equipment in category III referred to in regulation 6(b) under the module H procedure, the notified body or user inspectorate must perform or have performed the final assessment, as referred to in paragraph 25 of Schedule 2, for each unit.

E+W+S

45. For the assessment of conformity of assemblies referred to in regulation 7, the manufacturer must apply a global conformity assessment procedure comprising—

(a) the assessment (the procedure for which is to be determined by the category of each item) of each item of pressure equipment making up the assembly and referred to in regulation 6 which has not been previously subjected to a conformity assessment procedure and to a separate **[**[F82]UK**]** marking;

(b) the assessment of the integration of the components of the assembly as referred to in paragraphs 7, 12 and 13 of Schedule 2 which must be determined by the highest category applicable to the equipment concerned other than that applicable to any safety accessories; and

(c) the assessment of the protection of an assembly against exceeding the permissible operating limits as referred to in paragraph 14 and 28 of Schedule 2 which must be conducted against the highest category applicable to individual items of equipment included in the assembly.

Extent Information

E25 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F82 Word in reg. 45(a) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 30** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

N.I.

45. For the assessment of conformity of assemblies referred to in regulation 7, the manufacturer must apply a global conformity assessment procedure comprising—

(a) the assessment (the procedure for which is to be determined by the category of each item) of each item of pressure equipment making up the assembly and referred to in regulation 6 which has not been previously subjected to a conformity assessment procedure and to a separate CE marking;

(b) the assessment of the integration of the components of the assembly as referred to in paragraphs 7, 12 and 13 of Schedule 2 which must be determined by the highest category applicable to the equipment concerned other than that applicable to any safety accessories; and

(c) the assessment of the protection of an assembly against exceeding the permissible operating limits as referred to in paragraph 14 and 28 of Schedule 2 which must be conducted against the highest category applicable to individual items of equipment included in the assembly.

Extent Information

E91 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

46. Regulations 41 to 45 do not apply to pressure equipment items and assemblies which are made available on the market or put into service solely in the interests of experimentation.

E+W+S

[F83 47. The records and correspondence relating to conformity assessment must be clear, legible and in easily understandable English.**]**

Extent Information

E26 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F83 Reg. 47 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 31** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

N.I.

47. The records and correspondence relating to conformity assessment must be in an official language of the **[**[F218]relevant state**]** where the body responsible for carrying out such conformity assessment procedures is established, or in a language accepted by that body.

Extent Information

E92 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F218 Words in reg. 47 substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 4(1)**

[F84]... Declaration of conformity E+W+S

48. The [F85]... declaration of conformity in respect of pressure equipment or an assembly must—

(a) state that the fulfilment of the essential safety requirements has been demonstrated in respect of pressure equipment;

(b) contain the elements specified in **[**[F86]Schedule 1A to these Regulations**]** for the relevant conformity assessment procedure followed in respect of the pressure equipment or assembly; and

(c) have the model structure set out in Schedule 11.

Extent Information

E27 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F84 Word in reg. 48 heading omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 32(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F85 Word in reg. 48 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 32(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F86 Words in reg. 48(b) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 32(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

EU declaration of conformity N.I.

48. The EU declaration of conformity in respect of pressure equipment or an assembly must—

(a) state that the fulfilment of the essential safety requirements has been demonstrated in respect of pressure equipment;

(b) contain the elements specified in Annex III to the Directive (as amended from time to time) for the relevant conformity assessment procedure followed in respect of the pressure equipment or assembly; and

(c) have the model structure set out in Schedule 11.

Extent Information

E93 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F87UK] marking E+W+S

49.—(1) Before placing on the market, the **[**F88UK**]** marking must be affixed visibly, legibly and indelibly to the following:

(a) any item of pressure equipment referred to in regulation 6 or its dataplate; and

(b) any assembly referred to in regulation 7 or its **[**F89data plate; or**]**

[F90(c) where paragraph (1A) applies—

(i) a label affixed to the pressure equipment or assembly; or

(ii) to a document accompanying the pressure equipment or assembly.**]**

[F91(1A) For a period of **[**F92seven years**]** beginning with IP completion day, the UK marking may be affixed to—

(a) a label affixed to the pressure equipment or assembly; or

(b) to a document accompanying the pressure equipment or assembly.**]**

(2) The requirement in paragraph (1) does not apply in cases where—

(a) the conformity assessment procedure followed in accordance with regulation 42 is either module A2, C2, F or G; and

(b) the conformity assessment procedure has been carried out by a user inspectorate.

(3) Where **[**F93paragraph (1A) does not apply and**]** it is not possible or warranted, on account of the nature of the equipment or assembly, to affix the **[**F88UK**]** marking in accordance with paragraph (1), the **[**F88UK**]** marking must be affixed to—

(a) the packaging; and

(b) the accompanying documents.

(4) At the time the **[**F88UK**]** marking is affixed, the item or assembly referred to in subparagraph (1)(a) or (b) must be—

(a) complete; or

(b) in a state permitting final assessment as described in paragraph 25 (Final assessment) of Schedule 2.

(5) Individual items of pressure equipment already bearing the **[**F88UK**]** marking when incorporated into an assembly must continue to bear that marking, but the **[**F88UK**]** marking need not be affixed to each additional item of pressure equipment making up an assembly.

(6) The **[**F88UK**]** marking must be followed by the identification number of the **[**F94approved**]** body which carried out the relevant conformity assessment procedure for the pressure equipment or assembly, where that body is involved in the production control phase.

(7) The identification number of the **[**F94approved**]** body must be affixed—

(a) by the **[**F94approved**]** body itself; or

(b) under the instructions of the **[**F94approved**]** body, by the manufacturer or his authorised representative.

(8) The **[**F88UK**]** marking and, where applicable, the identification number of the **[**F94approved**]** body may be followed by any other mark indicating a special risk or use.

Extent Information

E28 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F87 Word in reg. 49 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 33(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F88 Word in reg. 49 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 33(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F89 Words in reg. 49(1)(b) substituted (E.W.S.) by S.I. 2019/696, Sch. 24 para. 33(c) (as inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 16(4)**)

F90 Reg. 49(1)(c) inserted (E.W.S.) by S.I. 2019/696, Sch. 24 para. 33(d) (as inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 16(4)**)

F91 Reg. 49(1A) inserted (E.W.S.) by S.I. 2019/696, Sch. 24 para. 33(e) (as inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 16(4)**)

F92 Words in reg. 49(1A) substituted (E.W.S.) (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), 3, **Sch. 2** para. (m)

F93 Words in reg. 49(3) inserted (E.W.S.) by S.I. 2019/696, Sch. 24 para. 33(f) (as inserted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(4), **Sch. 3 para. 16(4)**)

F94 Word in reg. 49 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 33(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

CE marking N.I.

49.—(1) Before placing on the market, the CE marking must be affixed visibly, legibly and indelibly to the following:

(a) any item of pressure equipment referred to in regulation 6 or its dataplate; and

(b) any assembly referred to in regulation 7 or its dataplate.

(2) The requirement in paragraph (1) does not apply in cases where—

(a) the conformity assessment procedure followed in accordance with regulation 42 is either module A2, C2, F or G; and

(b) the conformity assessment procedure has been carried out by a user inspectorate.

(3) Where it is not possible or warranted, on account of the nature of the equipment or assembly, to affix the CE marking in accordance with paragraph (1), the CE marking must be affixed to—

(a) the packaging; and

(b) the accompanying documents.

(4) At the time the CE marking is affixed, the item or assembly referred to in subparagraph (1)(a) or (b) must be—

(a) complete; or

(b) in a state permitting final assessment as described in paragraph 25 (Final assessment) of Schedule 2.

(5) Individual items of pressure equipment already bearing the CE marking when incorporated into an assembly must continue to bear that marking, but the CE marking need not be affixed to each additional item of pressure equipment making up an assembly.

(6) The CE marking must be followed by the identification number of the notified body which carried out the relevant conformity assessment procedure for the pressure equipment or assembly, where that body is involved in the production control phase.

(7) The identification number of the notified body must be affixed—

(a) by the notified body itself; or

(b) under the instructions of the notified body, by the manufacturer or his authorised representative.

(8) The CE marking and, where applicable, the identification number of the notified body may be followed by any other mark indicating a special risk or use.

Extent Information

E94 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F95UK(NI) indication

49A.—(1) Where the CE marking is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the pressure equipment or assembly, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

(a) visibly, legibly and indelibly; and

(b) before pressure equipment or an assembly is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 49.

(4) The UK(NI) indication must be affixed by—

(a) the manufacturer; or

(b) the manufacturer's authorised representative.

(5) When placing pressure equipment or an assembly on the market in Northern Ireland, an importer must ensure that the manufacturer has complied with their obligations under this regulation.

F95 Regs. 49A, 49B inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), **Sch. 2 para. 10(3)**

Register of notified bodies established in the United Kingdom

49B.—(1) The Secretary of State must ensure that—

(a) each notified body established in the United Kingdom is assigned an identification number; and

(b) there is a register of—

(i) notified bodies established in the United Kingdom;

(ii) their notified body identification number;

(iii) the activities for which they have been notified;

(iv) any restrictions on those activities.

(2) The Secretary of State must ensure that the register referred to in paragraph (1) is maintained and made publicly available.

(3) The Secretary of State may authorise the United Kingdom Accreditation Service to compile and maintain the register in accordance with paragraph (1)(b).**]**

F95 Regs. 49A, 49B inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), **Sch. 2 para. 10(3)**

[F96European approval for materials

50.—(1) For the purpose of this regulation, an issuing body is a body which has been notified under regulation 55 (notification) specifically in relation to the activity of issuing European approval for materials.

(2) European approval for materials must be issued, at the request of one or more manufacturers of materials or equipment, by an issuing body.

(3) The issuing body must 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.

(4) In the case of materials recognised as being safe to use before 29 November 1999, the issuing body must take account of the existing data when certifying such conformity.

(5) Prior to issuing a European approval for materials, the issuing body must inform the other **[**F97relevant states**]** and the Commission by sending them the appropriate information.

(6) Where, within three months of being informed by the issuing body, a **[**F98relevant state**]** or the Commission provides comments with reasons, the issuing body must take those comments into account before issuing the European approval for materials.

(7) A copy of the European approval for materials must be sent to the **[**F99relevant states**]**, the bodies notified under regulation 55 and the Commission.

(8) The issuing body must withdraw its approval if it finds that it should not have been issued or that the type of materials is covered by a harmonised standard.

(9) If an issuing body withdraws approval for materials under paragraph 8, it must immediately inform the other **[**F100relevant states**]** and the bodies notified under regulation 55 of that withdrawal.**]**

F96 Reg. 50 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 34** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F97 Words in reg. 50(5) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 4(2)**

F98 Words in reg. 50(6) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 4(3)**

F99 Words in reg. 50(7) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 4(2)**

F100 Words in reg. 50(9) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 4(2)**

PART 4

[F101Notification of conformity assessment bodies]

[F101Approval of Conformity Assessment Bodies]

F101 Pt. 4 substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 35** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/852, reg. 1, **Sch. 1 para. 1(m)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F101Approved bodies E+W+S

51.—(1) An approved body is a conformity assessment body which—

(a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 54 (approval of conformity assessment bodies); or

(b) immediately before IP completion day was a notified body in respect of which the Secretary of State has taken no action under regulation 62(1) or (2) as they had effect immediately before IP completion day to suspend or withdraw the body's status as a notified body.

(2) Paragraph (1) has effect subject to regulation 60 (restriction, suspension or withdrawal of approval).

(3) In this Part—

"notified body" means a body—

(a) which the Secretary of State had before IP completion day notified to the European Commission and the member States of the European Union as a notified body, in accordance with Article 20 of the Directive; and

(b) in respect of which no objections had been raised, as referred to in regulation 51(1)(b), as it had effect immediately before IP completion day;

"approved body requirements" means the requirements set out in Schedule 4;

"product" means pressure equipment or assemblies;

"accreditation certificate" means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.]

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Notified bodies N.I.

51.—(1) For the purposes of these Regulations, a notified body is a conformity assessment body—

(a) which has been notified by the Secretary of State to the Commission and to other **[**[F219]relevant states**]** as a notified body—

(i) under regulation 55 (notification); or

(ii) before the date these Regulations come into force, in accordance with Article 21 of the Directive; and

(b) in respect of which no objection **[**[F220]other than an immaterial objection,**]** has been raised by the Commission or other **[**[F221]relevant states**]**—

(i) within two weeks of the date of notification, where the notification is accompanied by an accreditation certificate; or

(ii) within two months of the notification, where the notification is not accompanied by an accreditation certificate.

[[F222](c) in sub-paragraph (b), an "immaterial objection" is an objection on the grounds that—

(i) the conformity assessment body is established in the United Kingdom; or

(ii) the accreditation certificate was issued by the United Kingdom Accreditation Service.**]**

(2) Paragraph (1) has effect subject to regulation 62 (changes to notifications).

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F219 Words in reg. 51(1)(a) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 5(1)**

F220 Words in reg. 51(1)(b) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), Sch. 12 para. 1(2)**(4)**

F221 Words in reg. 51(1)(b) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 5(1)**

F222 Reg. 51(1)(c) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), Sch. 12 para. 1(2)**(5)**

[[F101]Recognised third party organisations E+W+S

52.—(1) A recognised third party organisation is a conformity assessment body which—

(a) has been approved by the Secretary of State to be a recognised third party organisation, under regulation 54 (approval of conformity assessment bodies); or

(b) immediately before IP completion day—

(i) was a conformity assessment body which the Secretary of State had before IP completion day notified to the European Commission and the member States of the European Union as a recognised third party organisation, in accordance with Article 20 of the Directive;

(ii) in respect of which no objections had been raised, as referred to in regulation 52(1)(b), as it had effect immediately before IP completion day; and

(iii) in respect of which the Secretary of State had taken no action under regulation 62(1) or (2), as they had effect immediately before IP completion day to suspend or withdraw the body's status as a recognised third party organisation.

(2) Paragraph (1) has effect subject to regulation 60 (restriction, suspension or withdrawal of approval).**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Recognised third party organisations N.I.

52.—(1) For the purposes of these Regulations, a recognised third party organisation is a conformity assessment body—

(a) which has been notified to the Commission and the other **[**F223relevant states**]** by the Secretary of State as a recognised third party organisation—

(i) under regulation 55 (notification); or

(ii) before the date these Regulations come into force, in accordance with Article 21 of the Directive; and

(b) in respect of which no objection **[**F224other than an immaterial objection,**]** has been raised by the Commission or other **[**F225relevant states**]**—

(i) within two weeks of a notification, where the notification is accompanied by an accreditation certificate; or

(ii) within two months of a notification, where the notification is not accompanied by an accreditation certificate.

[F226(c) in sub-paragraph (b), an "immaterial objection" is an objection on the grounds that—

(i) the conformity assessment body is established in the United Kingdom; or

(ii) the accreditation certificate was issued by the United Kingdom Accreditation Service.**]**

(2) Paragraph (1) has effect subject to regulation 62 (changes to notifications).

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F223 Words in reg. 52(1)(a) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 5(1)**

F224 Words in reg. 52(1)(b) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), Sch. 12 para. 1(2)**(4)**

F225 Words in reg. 52(1)(b) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 5(1)**

F226 Reg. 52(1)(c) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), Sch. 12 para. 1(2)**(5)**

[F101User inspectorates E+W+S

53.—(1) A user inspectorate is a conformity assessment body which—

(a) has been approved as a user inspectorate by the Secretary of State under regulation 54 (approval of conformity assessment bodies); or

(b) immediately before IP completion day—

(i) was a conformity assessment body which the Secretary of State had before IP completion day notified to the European Commission and the member States of the European Union as a user inspectorate, in accordance with Article 20 of the Directive;

(ii) in respect of which no objections had been raised, as referred to in regulation 53(1)(b), as it had effect immediately before IP completion day; and

(iii) in respect of which the Secretary of State had taken no action under regulation 62(1) or (2), as they had effect immediately before IP completion day, to suspend or withdraw the body's status as a recognised third party organisation.

(2) Paragraph (1) has effect subject to regulation 61 (restriction, suspension or withdrawal of approval (user inspectorates)).]

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

User inspectorates N.I.

53.—(1) For the purposes of these regulations, a user inspectorate is a conformity assessment body—

(a) which has been notified by the Secretary of State to the Commission and the other [F227relevant states] as a user inspectorate—

(i) under regulation 55 (notification); or

(ii) before the date these Regulations come into force, in accordance with Article 21 of the Directive (as amended from time to time); and

(b) in respect of which no objection [F228other than an immaterial objection,] has been raised by the European Commission or other [F229relevant states]—

(i) within two weeks of a notification, where the notification is accompanied by an accreditation certificate; or

(ii) within two months of a notification, where the notification is not accompanied by an accreditation certificate.

[F230(c) in sub-paragraph (b), an "immaterial objection" is an objection on the grounds that—

(i) the conformity assessment body is established in the United Kingdom; or

(ii) the accreditation certificate was issued by the United Kingdom Accreditation Service.]

(2) Paragraph (1) has effect subject to regulation 62 (changes to notifications).

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F227 Words in reg. 53(1)(a) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 5(1)**

F228 Words in reg. 53(1)(b) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), Sch. 12 para. 1(2)**(4)**

F229 Words in reg. 53(1)(b) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 5(1)**

F230 Reg. 53(1)(c) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/1112), reg. 1(b), Sch. 12 para. 1(2)**(5)**

[F101Approval of conformity assessment bodies E+W+S

54.—(1) The Secretary of State may approve only those conformity assessment bodies which—

(a) qualify for approval as an approved body in accordance with regulation 55;

(b) qualify for approval as a recognised third party organisation in accordance with regulation 56; or

(c) qualify for approval as a user inspectorate in accordance with regulation 57.

(2) When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may—

(a) have regard to any other matter which appears to the Secretary of State to be relevant; and

(b) set conditions that the conformity assessment body must meet.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Presumption of conformity of conformity assessment bodies N.I.

54.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a harmonised standard (or part of such a standard), the reference of which has been published in the Official Journal, the Secretary of State is to presume that the conformity assessment body meets the notified body requirements or user inspectorate requirements (as the case may be) covered by that standard (or part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F101Approval of approved bodies E+W+S

55.—(1) A conformity assessment body qualifies for approval as an approved body if the first and second conditions below are met.

(2) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

(iii) the category of products in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate, or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

(3) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(4) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Notification N.I.

55.—(1) The Secretary of State may notify to the European Commission and the other **[**F231relevant states**]** only those conformity assessment bodies which—

(a) qualify for notification as a notified body in accordance with regulation 56;

(b) qualify for notification as a recognised third party organisation in accordance with regulation 57; or

(c) qualify for notification as a user inspectorate in accordance with regulation 58.

(2) When deciding whether to notify a conformity assessment body to the European Commission and the other **[**F232relevant states**]**, the Secretary of State may—

(a) have regard to any other matter which appears to the Secretary of State to be relevant; and

(b) set conditions that the conformity assessment body must meet.

(3) The Secretary of State must inform the European Commission of the United Kingdom's procedures for the assessment and notification of conformity assessment bodies, and any changes to those procedures.

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F231 Words in reg. 55(1) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 5(2)**

F232 Words in reg. 55(2) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 5(2)**

[F101Approval of recognised third party organisations E+W+S

56.—(1) A conformity assessment body qualifies for approval as a recognised third party organisation if the conditions in paragraphs (2), (3) and (4) are met.

(2) The first condition is that the conformity assessment body has applied to the Secretary of State to become a recognised third party organisation and that application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

(iii) the category of products in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate, or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

(3) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(4) The third condition is that the conformity assessment body must carry out approvals of only those activities referred to in paragraphs 21 and 22 of Schedule 2 (permanent joining and non-destructive tests).

(5) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

N.I.

56.—(1) A conformity assessment body qualifies for notification as a notified body if the conditions in paragraphs (2) and (3) below are met.

(2) The first condition is the conformity assessment body has made an application to the Secretary of State for notification as a notified body and the application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment modules for which the conformity assessment body claims to be competent; and

(iii) the pressure equipment or assemblies for which the conformity assessment body claims to be competent; and either—

(b) an accreditation certificate; or

(c) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the notified body requirements.

(3) The second condition is the Secretary of State is satisfied that the conformity assessment body meets the notified body requirements.

(4) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the notified body requirements.

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F101Approval of user inspectorates E+W+S

57.—(1) A conformity assessment body qualifies for approval as a user inspectorate if the conditions in paragraphs (2) to (7) are met.

(2) The conformity assessment body must apply to the Secretary of State to become a user inspectorate and that application must be accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

(iii) the category of products in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate, or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the user inspectorate requirements.

(3) The Secretary of State must be satisfied that the conformity assessment body meets the user inspectorate requirements.

(4) The conformity assessment procedures which a user inspectorate may carry out are modules A2, C2, F and G, set out in Part 2, Part 4, Part 9 and Part 10 of Schedule 1A respectively.

(5) The group of which the user inspectorate is part must apply a common safety policy as regards the technical specifications for the design, manufacture, inspection, maintenance and use of products.

(6) The user inspectorate must act exclusively for the group of which it is part.

(7) Where the conformity of a product has been assessed by a user inspectorate, that product may only be used in establishments operated by the group of which the user inspectorate is part.

(8) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the user inspectorate requirements.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

N.I.

57.—(1) A conformity assessment body qualifies for notification as a recognised third party organisation if the conditions in paragraphs (2), (3) and (4) below are met.

(2) The first condition is that the conformity assessment body has made an application to the Secretary of State for notification as a recognised third party organisation and that application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment modules for which the conformity assessment body claims to be competent; and

(iii) the pressure equipment or assemblies for which the conformity assessment body claims to be competent; and either—

(b) an accreditation certificate; or

(c) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the notified body requirements.

(3) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the notified body requirements.

(4) The third condition is that the conformity assessment body must carry out approvals of only those activities referred to in paragraphs 21 and 22 of Schedule 2 (permanent jointing and non-destructive tests);

(5) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the notified body requirements.

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F101Presumption of conformity of conformity assessment bodies E+W+S

58.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements or the user inspectorate requirements (as the case may be) covered by that standard (or part of that standard).

(2) The presumption in paragraph (1) is rebuttable.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

N.I.

58.—(1) A conformity assessment body qualifies for notification as a user inspectorate if the conditions in paragraphs (2) to (7) below are met.

(2) The conformity assessment body must make an application to the Secretary of State for notification as a user inspectorate and that application must be accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment modules for which the conformity assessment body claims to be competent; and

(iii) the pressure equipment or assemblies for which the conformity assessment body claims to be competent;

(iv) a list of the establishments satisfying the requirement in paragraph (7); and either—

(b) an accreditation certificate; or

(c) documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the user inspectorate requirements.

(3) The Secretary of State must be satisfied that the conformity assessment body meets the user inspectorate requirements.

(4) The conformity assessment procedures which a user inspectorate may carry out are modules A2, C2, F and G referred to in Annex III to the Directive (as amended from time to time).

(5) The group of which the user inspectorate is part must apply a common safety policy as regards the technical specifications for the design, manufacture, inspection, maintenance and use of pressure equipment and assemblies.

(6) The user inspectorate must act exclusively for the group of which it is part.

(7) Pressure equipment or assemblies, the conformity of which has been assessed by a user inspectorate, may be used only in establishments operated by the group of which the user inspectorate is part.

(8) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the user inspectorate requirements.

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F101Monitoring E+W+S

59. The Secretary of State must monitor each approved body, recognised third party organisation and user inspectorate with a view to verifying that the body—

(a) continues to meet the approved body requirements or user inspectorate requirements, as applicable;

(b) meets any conditions set—

(i) in accordance with regulation 54(2)(b), or

(ii) in the case of—

(aa) an approved body which was a notified body immediately before IP completion day;

(bb) a recognised third party organisation falling within regulation 52(1)(b); or

(cc) a user inspectorate falling within regulations 53(1)(b);

in accordance with regulation 55(2)(b) as it applied immediately before IP completion day; and

(c) carries out its functions in accordance with these Regulations.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Contents of notification N.I.

59. A notification under regulation 55 must include—

(a) details of—

(i) the conformity assessment activities in respect of which the conformity assessment body has made its application for notification;

(ii) the conformity assessment modules in respect of which the conformity assessment body has made its application for notification;

(iii) the pressure equipment in respect of which the conformity assessment body has made its application for notification; and

(iv) where the notification relates to a user inspectorate, a list of the establishments satisfying the requirement in regulation 58(7) in relation to that user inspectorate; and either—

(b) an accreditation certificate; or

(c) documentary evidence which attests to—

(i) the conformity assessment body's competence; and

(ii) the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to meet the notified body requirements or the user inspectorate requirements, as the case may be.

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F101Restriction, suspension or withdrawal of approval (approved bodies and recognised third party organisations) E+W+S

60.—(1) Where the Secretary of State determines that an approved body or a recognised third party organisation—

(a) no longer meets an approved body requirement, or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 59(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body or a recognised third party organisation under regulation 51 or 52 (as the case may be).

(2) Where the Secretary of State determines that an approved body or a recognised third party organisation no longer meets a condition referred to in regulation 59(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body or a recognised third party organisation under regulation 51 or 52 (as the case may be).

(3) In deciding what action is required under paragraph (1) or (2) the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2) the Secretary of State must—

(a) give notice in writing to the approved body or recognised third party organisation of the proposed action and the reasons for it;

(b) give the approved body or recognised third party organisation an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and

(c) consider any such representations made by the approved body or recognised third party organisation.

(5) Where the Secretary of State has taken action in respect of an approved body or recognised third party organisation under paragraph (1) or (2), or where an approved body or recognised third party organisation has ceased its activity, the approved body or recognised third party organisation must, at the request of the Secretary of State—

(a) transfer its files relating to the activities it has undertaken as an approved body or recognised third party organisation to another approved body or recognised third party organisation or to the Secretary of State, or

(b) keep its files relating to the activities it has undertaken as an approved body or recognised third party organisation available for the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.

(6) The activities undertaken by an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Monitoring N.I.

60.—(1) The Secretary of State must monitor each notified body, recognised third party organisation and user inspectorate with a view to verifying that the notified body, recognised third party organisation or user inspectorate—

(a) continues to meet the notified body requirements or user inspectorate requirements, as applicable;

(b) meets any conditions set in accordance with regulation 55(2)(b); and

(c) carries out its functions in accordance with these Regulations.

(2) The Secretary of state must inform the European Commission of the United Kingdom's procedures for the monitoring of notified bodies, recognised third party organisations and user inspectorates, and any changes to those procedures.

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F101Restriction, suspension or withdrawal of approval (user inspectorates) E+W+S

61.—(1) Where the Secretary of State determines that a user inspectorate—

(a) no longer meets a user inspectorate requirement, or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 59(b),

the Secretary of State must restrict, suspend or withdraw the body's status as a user inspectorate under regulation 53.

(2) Where the Secretary of State determines that a user inspectorate no longer meets a condition referred to in regulation 59(b), the Secretary of State may restrict, suspend or withdraw the body's status as a user inspectorate under regulation 53.

(3) In deciding what action is required under paragraph (1) or (2) the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2) the Secretary of State must—

(a) give notice in writing to the user inspectorate of the proposed action and the reasons for it;

(b) give the user inspectorate an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and

(c) consider any such representations made by the user inspectorate.

(5) Where the Secretary of State has taken action in respect of a user inspectorate under paragraph (1) or (2), or where a user inspectorate has ceased its activity, the user inspectorate must at the request of the Secretary of State—

(a) transfer its files relating to the activities it has undertaken as a user inspectorate to an approved body, a recognised third party organisation or to the Secretary of State, or

(b) keep its files relating to the activities it has undertaken as a user inspectorate available for the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

United Kingdom Accreditation Service N.I.

61. The Secretary of State may authorise the United Kingdom Accreditation Service (a company limited by guarantee incorporated in England and Wales under number 03076190) to carry out the following activities on behalf of the Secretary of State—

(a) assessing whether a conformity assessment body meets the notified body requirements or the user inspectorate requirements, as applicable; and

(b) monitoring notified bodies, recognised third party organisations and user inspectorates in accordance with regulation 60 (monitoring).

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F101Operational matters in relation to approved bodies, recognised third party organisations and user inspectorates E+W+S

62.—(1) Subject to the terms of its appointment, an approved body, recognised third party organisation or user inspectorate must carry out the conformity assessment activities and procedures—

(a) in respect of which the body's approval was given under regulation 55, 56 or 57 (as the case may be); or

(b) in respect of which the body's notification to the European Commission was made as a notified body, a recognised third party organisation or a user inspectorate (as the case may be).

(2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 6.

(3) An approved conformity assessment body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body—

(a) to issue a Type examination certificate referred to in Schedule 1A, or

(b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 49 (UK marking), where applicable.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Changes to notifications N.I.

62.—(1) Where the Secretary of State determines that a notified body or recognised third party organisation—

(a) no longer meets a notified body requirement, or

(b) is failing to fulfil any of its obligations under these Regulations other than conditions set in accordance with regulation 55(2)(b),

the Secretary of State must restrict, suspend or withdraw that body's status as a notified body or recognised third party organisation under regulation 51 or 52, as the case may be.

(2) With the consent of the notified body or recognised third party organisation, or where the Secretary of State determines that a notified body or recognised third party organisation no longer meets a condition set in accordance with regulation 55(2)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a notified body or recognised third party organisation under regulation 51 or 52, as the case may be.

(3) In deciding what action is required under paragraph (1), the Secretary of State must have regard to the seriousness of the failure.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

(a) give notice in writing that the Secretary of State intends to take such action and the reasons for taking such action; and

(b) give the notified body or recognised third party organisation an opportunity to make representations within a reasonable period from the date of that notice and consider any such representations.

(5) Where the Secretary of State takes action under paragraph (1) or (2), the Secretary of State must immediately inform the Commission and the other **[**[F233]relevant states**]**.

(6) Where the Secretary of State has taken action in respect of a notified body or recognised third party organisation under paragraph (1) or (2), or where a notified body or recognised third party organisation has ceased its activity, the body must—

(a) on the request of the Secretary of State, transfer its files relating to the activities it has undertaken as a notified body or recognised third party organisation to another notified body or recognised third party organisation or to the Secretary of State; or

(b) in the absence of a request under sub-paragraph (a), ensure that its files relating to the activities it has undertaken as a notified body or recognised third party organisation are kept available for inspection by the Secretary of State and enforcing authorities for a period of 10 years from the date they were created.

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F233 Words in reg. 62(5) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 5(2)**

[[F101]Subsidiaries and contractors E+W+S

63.—(1) An approved body, recognised third party organisation or user inspectorate may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

(a) the body, organisation or inspectorate is satisfied that the subcontractor or subsidiary meets the approved body requirements or user inspectorate requirements, as applicable;

(b) the body, organisation or inspectorate has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meet those requirements; and

(c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

(2) The approved body, recognised third party organisation or user inspectorate which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

(3) Where an approved body, recognised third party organisation or user inspectorate subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the body, organisation or inspectorate must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documents concerning—

(a) the assessment of the qualifications of the subcontractor or the subsidiary; and

(b) the conformity assessment activity carried out by the subcontractor or subsidiary.

(4) In this regulation "subsidiary" has the meaning given to it in section 1159 of the Companies Act 2006.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

N.I.

63.—(1) Where the Secretary of State determines that a user inspectorate no longer meets the user inspectorate requirements, or that it is failing to fulfil its obligations under these Regulations, the Secretary of State must restrict, suspend or withdraw that body's status as a user inspectorate under regulation 53.

(2) Where the Secretary of State determines that a user inspectorate no longer meets any conditions set in accordance with regulation 55(2)(b), the Secretary of State may restrict, suspend or withdraw that body's status as a user inspectorate under regulation 53.

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the failure.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

(a) give notice in writing that the Secretary of State intends to take such action and the reasons for taking such action; and

(b) give the user inspectorate an opportunity to make representations within a reasonable period from the date of that notice and consider any such representations.

(5) Where the Secretary of State takes action under paragraph (1) or (2), the Secretary of State must immediately inform the Commission and the other **[**[F234]relevant states**]**.

(6) Where the Secretary of State has taken action under paragraph (1) or (2), or where the user inspectorate has ceased its activity, the body must—

(a) on the request of the Secretary of State, transfer its files relating to the activities it has undertaken as a user inspectorate to another notified body or recognised third party organisation or to the Secretary of State; or

(b) in the absence of a request under sub-paragraph (a), ensure that its files relating to the activities it has undertaken as a user inspectorate are kept available for the Secretary of State and enforcing authorities for a period of 10 years from the date they were created.

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F234 Words in reg. 63(5) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 5(2)**

[F101Register of approved bodies E+W+S

64.—(1) The Secretary of State must—

(a) assign—

(i) an approved body identification number to each approved body;

(ii) a recognised third party organisation identification number to each third party organisation;

(iii) a user inspectorate identification number to each user inspectorate; and

(b) compile and maintain a register of—

(i) approved bodies, recognised third party organisations and user inspectorates;

(ii) their identification numbers;

(iii) the activities for which they have been approved; and

(iv) any restrictions on those activities.

(2) The register referred to in paragraph (1) must be made publicly available.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Operational matters in relation to notified bodies, recognised third party organisations and user inspectorates N.I.

64.—(1) When a conformity assessment body carries out a relevant conformity assessment procedure, it must do so in accordance with Schedule 6 (operational obligations of notified bodies, recognised third parties and user inspectorates).

(2) A notified body must make provision for a manufacturer to be able to appeal against a refusal by the body—

(a) to issue an EU-type examination certificate in relation to a conformity assessment procedure; or

(b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 49 (CE marking).

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F101United Kingdom Accreditation Service E+W+S

65. The Secretary of State may authorise the United Kingdom Accreditation Service to carry out the following activities on behalf of the Secretary of State—

(a) assessing whether a conformity assessment body meets the approved body requirements or user inspectorate requirements (as applicable);

(b) monitoring approved bodies, recognised third party organisations and user inspectorates in accordance with regulation 59; and

(c) compiling and maintaining the register of approved bodies, recognised third party organisations and user inspectorates, in accordance with regulation 64.**]**

Extent Information

E29 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Subsidiaries and contractors N.I.

65.—(1) Where a notified body, recognised third party organisation or user inspectorate subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the activities are only to be treated as having been carried out by a notified body, recognised third party organisation or user inspectorate for the purposes of regulation 41 (conformity assessment procedures) where the conditions in paragraphs (2) and (3) are met.

(2) The notified body, recognised third party organisation or user inspectorate must—

(a) ensure that the subcontractor or subsidiary meets the notified body requirements or user inspectorate requirements, as applicable; and

(b) inform the Secretary of State accordingly.

(3) The notified body, recognised third party organisation or user inspectorate must have obtained the agreement of the client to the use of a subcontractor or subsidiary.

(4) Where a notified body, recognised third party organisation or user inspectorate subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the notified body, recognised third party organisation or user inspectorate must for a period of 10 years beginning on the day on which the activities are carried out, keep available for inspection by the Secretary of State the documentation concerning—

(a) the assessment of the qualifications of the subcontractor or the subsidiary; and

(b) the conformity assessment activities carried out by the subcontractor or subsidiary.

(5) When monitoring a notified body, recognised third party organisation or user inspectorate in accordance with regulation 60, the Secretary of State must treat the notified body, recognised third party organisation or user inspectorate as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.

Extent Information

E95 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

PART 5

Market surveillance and enforcement

Designation of market surveillance authority

66.—(1) The market surveillance authority is—

(a) in the case of pressure equipment and assemblies for use in the workplace—

(i) subject to paragraph (2), in Great Britain, the Health and Safety Executive [M12]; and

(ii) in Northern Ireland, the Health and Safety Executive for Northern Ireland [M13];

(b) in the case of pressure equipment and assemblies for private use or consumption—

(i) in Great Britain, within its area, a weights and measures authority; and

(ii) in Northern Ireland, within its area, a district council.

(2) In so far as these Regulations apply to pressure equipment or assemblies intended exclusively or primarily for use on relevant nuclear sites, the market surveillance authority is the Office for Nuclear Regulation.

(3) In paragraph (2), "relevant nuclear site" means a site which is—

(a) a GB nuclear site (within the meaning given in section 68 of the Energy Act 2013 [M14]);

(b) an authorised defence site (within the meaning given in regulation 2(1) of the Health and Safety (Enforcing Authority) Regulations 1998 [M15]); or

(c) a new nuclear build site (within the meaning given in regulation 2A of those Regulations).

Marginal Citations

M12 Established under section 10 of the Health and Safety at Work etc Act 1974.

M13 Established under Article 12 of the Health and Safety at Work (Northern Ireland) Order 1978.

M14 2013 c.32.

M15 S.I. 1998/494, amended by S.I. 2014/469; there are other amending instruments but none is relevant.

Enforcement

67.—(1) Subject to paragraph (2), these Regulations and RAMS (in its application to pressure equipment or assemblies) must be enforced by the market surveillance authority.

(2) The Secretary of State, or a person appointed by the Secretary of State to act on behalf of the Secretary of State, may enforce these Regulations and RAMS (in its application to pressure equipment or assemblies).

(3) Before taking enforcement action under paragraph (2), an enforcing authority which is not the market surveillance authority must notify the market surveillance authority of the proposed action.

(4) In Scotland, only the Lord Advocate may commence proceedings for an offence under these Regulations.

Enforcement powers

68.—(1) Schedule 7 (enforcement powers of weights and measures authorities, district councils and the Secretary of State under the 1987 Act) has effect where the enforcing authority is—

(a) a weights and measures authority;

(b) a district council; or

(c) the Secretary of State.

(2) Schedule 8 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act) has effect where the enforcing authority is the Health and Safety Executive or the Office for Nuclear Regulation.

(3) Schedule 9 (Enforcement Powers of the Health and Safety Executive for Northern Ireland under the 1978 Order) has effect where the enforcing authority is the Health and Safety Executive for Northern Ireland.

(4) In addition to the powers available to an enforcement authority by virtue of, as appropriate, paragraph (1), (2) or (3), the authority may use the powers in Schedule 10 (compliance, withdrawal and recall notices) [M16].

(5) This regulation does not prevent an enforcing authority from taking action in respect of pressure equipment or assemblies under the General Product Safety Regulations 2005 [M17].

Marginal Citations

M16 For the investigatory powers available to an enforcing authority for the purposes of the duty imposed by regulation 67, see Schedule 5 to the Consumer Rights Act 2015 (c.15).

M17 S.I. 2005/1083.

Exercise of enforcement powers

69. When enforcing these Regulations or RAMS (in its application to pressure equipment or assemblies) the enforcing authority must exercise its powers in a manner which is consistent with—

(a) regulation 70 (evaluation of pressure equipment or assemblies presenting a risk);

(b) regulation 71 (enforcement action in respect of pressure equipment or assemblies which are not in conformity and which present a risk);

(c) **[**[F102]regulation 72 (EU safeguard procedure);**]**

(d) regulation 73 (pressure equipment or assemblies which are in conformity, but present a risk);

(e) regulation 74 (enforcement action in cases of formal non-compliance);

(f) regulation 75 (restrictive measures).

F102 Reg. 69(c) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 36** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Evaluation of pressure equipment or assemblies presenting a risk

70.—(1) Where the market surveillance authority has sufficient reason to believe that pressure equipment or an assembly presents a risk, the market surveillance authority must carry out an

evaluation to determine whether that pressure equipment or assembly is in conformity with the requirements of Part 2 applying in respect of that equipment or assembly.

(2) Where an enforcing authority other than the market surveillance authority has sufficient reason to believe that pressure equipment or an assembly presents a risk, that enforcing authority may carry out an evaluation to determine whether that pressure equipment or assembly is in conformity with the requirements of Part 2 applying in respect of that equipment or assembly.

Enforcement action in respect of pressure equipment or assemblies which are not in conformity and which present a risk E+W+S

71.—(1) Where, in the course of an evaluation referred to in regulation 70, an enforcing authority finds that pressure equipment or an assembly is not in conformity with Part 2, it must, without delay, require a relevant economic operator to—

(a) take all appropriate corrective action to bring the pressure equipment or assembly into conformity with those requirements within a prescribed period;

(b) withdraw the pressure equipment or assembly within a prescribed period; or

(c) recall the pressure equipment or assembly within a prescribed period.

(2) The enforcing authority must inform the **[**F103approved**]** body which carried out the conformity assessment procedure in respect of the pressure equipment or assembly of—

(a) the respect in which the pressure equipment or assembly is not in conformity with Part 2; and

(b) the action which the enforcing authority has required the relevant economic operator to take.

F104(3) . . . . . .

F104(4) . . . . . .

(5) Where the relevant economic operator does not take adequate corrective action within the prescribed period referred to in paragraph (1), the enforcing authority must take all appropriate measures to—

(a) prohibit or restrict the pressure equipment or assembly being made available on the market in the United Kingdom;

(b) withdraw the pressure equipment or assembly from the United Kingdom market; or

(c) recall the pressure equipment or assembly.

(6) Where the enforcing authority is not the Secretary of State and it takes measures under paragraph (5), it must notify the Secretary of State of those measures without delay.

F105(7) . . . . . .

(8) The **[**F106notice in paragraph (6)**]** must include all available details about the pressure equipment or assembly and, in particular—

(a) the data necessary for the identification of the pressure equipment or assembly;

(b) the origin of the pressure equipment or assembly;

(c) the nature of the lack of conformity alleged and the risk involved;

(d) the nature and duration of the measures taken;

(e) the arguments put forward by the relevant economic operator; and

(f) whether the lack of conformity is due to either of the following—

(i) failure of the pressure equipment or assembly to meet relevant requirements relating to a risk;

(ii) shortcomings in a **[**[F107]designated**]** standard referred to in regulation 40 conferring a presumption of conformity.

(9) In this regulation, "prescribed period" means a period which is—

(a) prescribed by the enforcing authority; and

(b) reasonable and commensurate with the nature of the risk presented by the pressure equipment or assembly.

Extent Information

E30 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F103 Word in reg. 71(2) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 37(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F104 Reg. 71(3)(4) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 37(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F105 Reg. 71(7) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 37(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F106 Words in reg. 71(8) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 37(c)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F107 Word in reg. 71(8)(f)(ii) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 37(d)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Enforcement action in respect of pressure equipment or assemblies which are not in conformity and which present a risk N.I.

71.—(1) Where, in the course of an evaluation referred to in regulation 70, an enforcing authority finds that pressure equipment or an assembly is not in conformity with Part 2, it must, without delay, require a relevant economic operator to—

(a) take all appropriate corrective action to bring the pressure equipment or assembly into conformity with those requirements within a prescribed period;

(b) withdraw the pressure equipment or assembly within a prescribed period; or

(c) recall the pressure equipment or assembly within a prescribed period.

(2) The enforcing authority must inform the notified body which carried out the conformity assessment procedure in respect of the pressure equipment or assembly of—

(a) the respect in which the pressure equipment or assembly is not in conformity with Part 2; and

(b) the action which the enforcing authority has required the relevant economic operator to take.

(3) Where the enforcing authority is not the Secretary of State and it considers that the lack of conformity referred to in paragraph (1) is not restricted to **[**[F235]Northern Ireland**]**, it must notify the Secretary of State of—

(a) the results of the evaluation; and

(b) the actions which it has required the economic operator to take.

(4) **[**[F236]Subject to paragraph 4(A),**]** where the Secretary of State receives a notice under paragraph (3) or otherwise considers that the lack of conformity referred to in paragraph (1) is not restricted to **[**[F237]Northern Ireland**]**, the Secretary of State must inform the European Commission and the other **[**[F238]relevant states**]** of—

(a) the results of the evaluation; and

(b) the action which the enforcing authority has required the economic operator to take.

[[F239](4A) Paragraph (4) does not require the Secretary of State to inform the Commission or other relevant states where the lack of conformity extends only to any of England or Wales or Scotland.**]**

(5) Where the relevant economic operator does not take adequate corrective action within the prescribed period referred to in paragraph (1), the enforcing authority must take all appropriate measures to—

(a) prohibit or restrict the pressure equipment or assembly being made available on the market in **[**[F240]Northern Ireland**]**;

(b) withdraw the pressure equipment or assembly from the **[**[F241]market in Northern Ireland**]**; or

(c) recall the pressure equipment or assembly.

(6) Where the enforcing authority is not the Secretary of State and it takes measures under paragraph (5), it must notify the Secretary of State of those measures without delay.

(7) Where the Secretary of State receives a notice under paragraph (6), or takes measures under paragraph (5), the Secretary of State must notify the European Commission and the other **[**[F242]relevant states**]** of those measures without delay.

(8) The notices in paragraphs (6) and (7) must include all available details about the pressure equipment or assembly and, in particular—

(a) the data necessary for the identification of the pressure equipment or assembly;

(b) the origin of the pressure equipment or assembly;

(c) the nature of the lack of conformity alleged and the risk involved;

(d) the nature and duration of the measures taken;

(e) the arguments put forward by the relevant economic operator; and

(f) whether the lack of conformity is due to either of the following—

(i) failure of the pressure equipment or assembly to meet relevant requirements relating to a risk;

(ii) shortcomings in a harmonised standard referred to in regulation 40 conferring a presumption of conformity.

(9) In this regulation, "prescribed period" means a period which is—

(a) prescribed by the enforcing authority; and

(b) reasonable and commensurate with the nature of the risk presented by the pressure equipment or assembly.

Extent Information

E96 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F235 Words in reg. 71(3) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(1)(a)**

F236 Words in reg. 71(4) inserted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(1)(c)**

F237 Words in reg. 71(4) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(1)(a)**

F238 Words in reg. 71(4) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(1)(b)**

F239 Reg. 71(4A) inserted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(1)(d)**

F240 Words in reg. 71(5)(a) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(1)(e)(i)**

F241 Words in reg. 71(5)(b) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(1)(e)(ii)**

F242 Words in reg. 71(7) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(1)(b)**

EU safeguard procedure

72.—**[**F108(1) Where another **[**F109relevant state**]** has initiated the procedure under Article 40 of the Directive (as amended from time to time), each enforcing authority (other than the Secretary of State) must, without delay, inform the Secretary of State of—

(a) any measures taken by the enforcing authority in respect of the pressure equipment or assembly which is the subject of the procedure;

(b) any additional information which the enforcing authority has at its disposal relating to the lack of conformity of the pressure equipment or assembly.

(2) Where another **[**F110relevant state**]** has initiated the procedure under Article 40 of the Directive (as amended from time to time), the Secretary of State must, without delay, inform the European Commission and the other **[**F111relevant states**]** of—

(a) any measures taken **[**F112in Northern Ireland**]** by an enforcing authority in respect of the pressure equipment or assembly which is the subject of the procedure;

(b) any additional information which an enforcing authority has at its disposal relating to the lack of conformity of the pressure equipment or assembly; F113...

F113(c) . . . . . .

(3) Where a measure taken by another **[**F114relevant state**]** in respect of pressure equipment or an assembly is considered justified by the European Commission under Article 40(7) of the Directive (as amended from time to time), the market surveillance authority must ensure that appropriate measures, such as withdrawal, are taken **[**F115in Northern Ireland**]** in respect of the pressure equipment or assembly without delay.

(4) Where a measure taken by another **[**F116relevant state**]** in respect of pressure equipment or an assembly is considered justified by the European Commission under Article 41(1) of the Directive (as amended from time to time), the market surveillance authority must take the necessary measures to ensure that the pressure equipment or assembly is withdrawn from the **[**F117market in Northern Ireland**]**.

(5) Where the market surveillance authority has taken action under paragraph (3) or (4), it must notify the Secretary of State.

(6) Where the Secretary of State receives a notice under paragraph (5), the Secretary of State must inform the European Commission of the action taken **[**F118in respect of Northern Ireland**]**.

(7) If a measure taken by an enforcing authority pursuant to regulation 71 is considered unjustified by the European Commission under Article 41(1) of the Directive (as amended from time to time), the enforcing authority must withdraw that measure **[**F119in respect of Northern Ireland**]**.**]**

F108 Reg. 72 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 38** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)
F109 Words in reg. 72(1) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(a)**
F110 Words in reg. 72(2) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(b)(i)**
F111 Words in reg. 72(2) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(b)(ii)**
F112 Words in reg. 72(2)(a) inserted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(b)(iii)**
F113 Reg. 72(2)(c) and word omitted (N.I.) (31.12.2020) by virtue of The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(b)(iv)**
F114 Words in reg. 72(3) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(a)**
F115 Words in reg. 72(3) inserted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(c)**
F116 Words in reg. 72(4) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(a)**
F117 Words in reg. 72(4) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(d)**
F118 Words in reg. 72(6) inserted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(e)**
F119 Words in reg. 72(7) inserted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(2)(e)**

Pressure equipment or assemblies which are in conformity, but present a risk E+W+S

73.—(1) Where, having carried out an evaluation under regulation 70, an enforcing authority finds that although pressure equipment is in conformity with Part 2, it presents a risk, the enforcing authority must require a relevant economic operator to take all appropriate measures to—

(a) ensure that the pressure equipment or assembly, when placed on the market, no longer presents a risk;

(b) withdraw the pressure equipment or assembly within a prescribed period;

(c) recall the pressure equipment or assembly within a prescribed period.

(2) Where an enforcing authority is not the Secretary of State and it takes measures under paragraph (1), it must notify the Secretary of State immediately.

F120(3) . . . . . .

(4) The **[**F121notice referred to in paragraph (2)**]** must include all available details about the pressure equipment or assembly and, in particular—

(a) the data necessary for the identification of the pressure equipment or assembly;

(b) the origin and the supply chain of the pressure equipment or assembly;

(c) the nature of the risk involved; and

(d) the nature and duration of the measures taken by the enforcing authority.

(5) In this regulation, "prescribed period" means a period which is—

(a) prescribed by the enforcing authority; and

(b) reasonable and commensurate with the nature of the risk presented by the pressure equipment or assembly.

Extent Information

E31 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F120 Reg. 73(3) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 39(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F121 Words in reg. 73(4) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 39(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Pressure equipment or assemblies which are in conformity, but present a risk N.I.

73.—(1) Where, having carried out an evaluation under regulation 70, an enforcing authority finds that although pressure equipment is in conformity with Part 2, it presents a risk, the enforcing authority must require a relevant economic operator to take all appropriate measures to—

(a) ensure that the pressure equipment or assembly, when placed on the market, no longer presents a risk;

(b) withdraw the pressure equipment or assembly within a prescribed period;

(c) recall the pressure equipment or assembly within a prescribed period.

(2) Where an enforcing authority is not the Secretary of State and it takes measures under paragraph (1), it must notify the Secretary of State immediately.

(3) **[**F243Subject to paragraph (3A),**]** where the Secretary of State receives a notice under paragraph (2) or takes measures under paragraph (1), the Secretary of State must notify the European Commission and the other **[**F244relevant states**]** immediately.

[F245(3A) Paragraph (3) only applies to measures taken in Northern Ireland.**]**

(4) The notices referred to in paragraphs (2) and (3) must include all available details about the pressure equipment or assembly and, in particular—

(a) the data necessary for the identification of the pressure equipment or assembly;

(b) the origin and the supply chain of the pressure equipment or assembly;

(c) the nature of the risk involved; and

(d) the nature and duration of the measures taken by the enforcing authority.

(5) In this regulation, "prescribed period" means a period which is—

(a) prescribed by the enforcing authority; and

(b) reasonable and commensurate with the nature of the risk presented by the pressure equipment or assembly.

Extent Information

E97 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F243 Words in reg. 73(3) inserted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(3)(a)(i)**

F244 Words in reg. 73(3) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(3)(a)(ii)**

F245 Reg. 73(3A) inserted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 6(3)(b)**

Enforcement action in cases of formal non-compliance E+W+S

74.—(1) Where an enforcing authority makes one of the following findings in relation to pressure equipment or an assembly, it must require a relevant economic operator to remedy the non-compliance within a specified period—

(a) the **[**F122UK**]** marking—

(i) has not been affixed; or

(ii) has been affixed otherwise than in accordance with regulations 39 (Prohibition on improper use of **[**F122UK**]** marking) and 49 (**[**F122UK**]** marking);

(b) where **[**F123an approved**]** body is involved in the production control phase for the pressure equipment or assembly, the identification number of **[**F124the approved**]** body—

(i) has not been affixed; or

(ii) has been affixed otherwise than in accordance with regulation 49;

(c) the F125... declaration of conformity—

(i) has not been drawn up;

(ii) has been drawn up otherwise than in accordance with regulations 11 (F125... declaration of conformity and **[**F126UK**]** marking) and 48 (F125... declaration of conformity);

(d) the technical documentation is either not available or not complete;

(e) the following information is absent, false or incomplete—

(i) the information specified in regulation 13 (labelling of pressure equipment and assemblies); or

(ii) the information specified in regulation 14 (instructions and safety information);

(f) any other administrative requirement imposed on the manufacturer or importer under Part 2 has not been fulfilled.

(2) Until the specified period has elapsed, the enforcing authority must not commence proceedings under these Regulations, or take any other enforcement action under these Regulations, against the relevant economic operator in respect of the non-compliance concerned.

(3) Where the non-compliance referred to in paragraph (1) persists, the enforcing authority must take appropriate measures to—

(a) restrict or prohibit the pressure equipment or assembly being made available on the market;

(b) ensure that the pressure equipment or assembly is withdrawn; or

(c) ensure that the pressure equipment or assembly is recalled.

(4) Nothing in this regulation is to prevent an enforcing authority from taking action under regulation 71 (enforcement action in respect of pressure equipment or assemblies which are not in conformity and which present a risk)F127... or 73 (pressure equipment or assemblies which are in conformity but present a risk).

Extent Information

E32 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F122 Word in reg. 74(1)(a) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 40(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F123 Words in reg. 74(1)(b) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 24 para. 40(aa)(i) (as inserted by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(3), **14(b)**; 2020 c. 1, Sch. 5 para. 1(1))

F124 Words in reg. 74(1)(b) substituted (E.W.S.) (31.12.2020) by S.I. 2019/696, Sch. 24 para. 40(aa)(ii) (as inserted by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(3), **14(b)**; 2020 c. 1, Sch. 5 para. 1(1))

F125 Word in reg. 74(1)(c) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 40(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F126 Word in reg. 74(1)(c)(ii) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 40(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F127 Words in reg. 74(4) omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 40(c)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Enforcement action in cases of formal non-compliance N.I.

74.—(1) Where an enforcing authority makes one of the following findings in relation to pressure equipment or an assembly, it must require a relevant economic operator to remedy the non-compliance within a specified period—

(a) the CE marking—

(i) has not been affixed; or

(ii) has been affixed otherwise than in accordance with regulations 39 (Prohibition on improper use of CE marking) and 49 (CE marking);

[[F246](aa) the UK(NI) indication—

(i) has not been affixed, in contravention of regulation 49A; or

(ii) has been affixed other than in accordance with regulation 49A;**]**

(b) where a notified body is involved in the production control phase for the pressure equipment or assembly, the identification number of the notified body—

(i) has not been affixed; or

(ii) has been affixed otherwise than in accordance with regulation 49;

(c) the EU declaration of conformity—

(i) has not been drawn up;

(ii) has been drawn up otherwise than in accordance with regulations 11 (EU declaration of conformity and CE marking) and 48 (EU declaration of conformity);

(d) the technical documentation is either not available or not complete;

(e) the following information is absent, false or incomplete—

(i) the information specified in regulation 13 (labelling of pressure equipment and assemblies); or

(ii) the information specified in regulation 14 (instructions and safety information);

(f) any other administrative requirement imposed on the manufacturer or importer under Part 2 has not been fulfilled.

(2) Until the specified period has elapsed, the enforcing authority must not commence proceedings under these Regulations, or take any other enforcement action under these Regulations, against the relevant economic operator in respect of the non-compliance concerned.

(3) Where the non-compliance referred to in paragraph (1) persists, the enforcing authority must take appropriate measures to—

(a) restrict or prohibit the pressure equipment or assembly being made available on the market;

(b) ensure that the pressure equipment or assembly is withdrawn; or

(c) ensure that the pressure equipment or assembly is recalled.

(4) Nothing in this regulation is to prevent an enforcing authority from taking action under regulation 71 (enforcement action in respect of pressure equipment or assemblies which are not in conformity and which present a risk), 72 (EU safeguard procedure) or 73 (pressure equipment or assemblies which are in conformity but present a risk).

Extent Information

E98 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F246 Reg. 74(1)(aa) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), **Sch. 2 para. 10(4)**

Restrictive measures

75. When enforcing these Regulations, an enforcing authority must comply with the requirements of Article 21 of RAMS (as amended from time to time) in relation to any measure to—

(a) prohibit or restrict pressure equipment or an assembly being made available on the market;

(b) withdraw pressure equipment or an assembly; or

(c) recall pressure equipment or an assembly.

Offences

76.—(1) It is an offence for a person to contravene or fail to comply with any requirement of regulations 9 to 17, 18(4), 20 to 28, 29(4), 30 to 34, 35(3), 38 or 39.

(2) It is an offence for any person to contravene or fail to comply with any requirement of a withdrawal or recall notice served on that person by an enforcing authority under these Regulations.

Penalties E+W+S

77.—(1) A person guilty of an offence under regulation 76 (other than an offence arising from a contravention of or failure to comply with a requirement of regulation 12 or regulation 28) is liable—

(a) on summary conviction—

(i) in England and Wales, to a fine or imprisonment for a term not exceeding three months, or to both;

(ii) in Scotland, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding three months, or to both;

(iii) in Northern Ireland, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding three months, or to both;

(b) on conviction on indictment, to a fine or imprisonment for a term not exceeding two years or to both.

(2) A person guilty of an offence arising from a contravention of or failure to comply with a requirement of regulation 12 or regulation 28 is liable on summary conviction—

(a) in England and Wales, to a fine or imprisonment for a term not exceeding three months, or to both;

(b) in Scotland and Northern Ireland, to a fine not exceeding level 5 on the standard scale or imprisonment for a term not exceeding three months, or to both.

Extent Information

E33 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Penalties **N.I.**

77.—(1) A person guilty of an offence under regulation 76 (other than an offence **[**F247referred to in paragraphs (2) or (3)**]**) is liable—

(a) on summary conviction—

(i) in England and Wales, to a fine or imprisonment for a term not exceeding three months, or to both;

(ii) in Scotland, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding three months, or to both;

(iii) in Northern Ireland, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding three months, or to both;

(b) on conviction on indictment, to a fine or imprisonment for a term not exceeding two years or to both.

(2) A person guilty of an offence arising from a contravention of or failure to comply with a requirement of regulation 12 or regulation 28 is liable on summary conviction—

(a) in England and Wales, to a fine or imprisonment for a term not exceeding three months, or to both;

(b) in Scotland and Northern Ireland, to a fine not exceeding level 5 on the standard scale or imprisonment for a term not exceeding three months, or to both.

[F248(3) A person guilty of an offence under regulation 76(2) insofar as the requirement relates to a UK(NI) indication is liable on summary conviction to a fine not exceeding level 5 on the standard scale.**]**

Extent Information

E99 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F247 Words in reg. 77(1) substituted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), **Sch. 2 para. 10(5)(a)**

F248 Reg. 77(3) inserted (N.I.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (UK(NI) Indication) (EU Exit) Regulations 2020 (S.I. 2020/1460), reg. 1(2), **Sch. 2 para. 10(5)(b)**

Defence of due diligence

78.—(1) In proceedings for an offence under regulation 76, it is a defence for a person ("P") to show that P took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) P may not rely on a defence under paragraph (1) which involves a third party allegation unless P has—

(a) served a notice in accordance with paragraph (3); or

(b) obtained the leave of the court.

(3) The notice must—

(a) give any information in P's possession which identifies or assists in identifying the person who—

(i) committed the act or default; or

(ii) supplied the information on which P relied.

(b) be served on the person bringing the proceedings not less than seven clear days before—

(i) in England, Wales and Northern Ireland, the hearing of the proceedings;

(ii) in Scotland, the trial diet.

(4) P may not rely on a defence under paragraph (1) which involves an allegation that the commission of the offence was due to reliance on information supplied by another person unless it was reasonable for P to have relied upon the information, having regard in particular—

(a) to the steps that P took, and those which might reasonably have been taken, for the purpose of verifying the information; and

(b) to whether P had any reason to disbelieve the information.

(5) In this regulation, "third party allegation" means an allegation that the commission of the offence was due—

(a) to the act or default of another person; or

(b) to reliance on information supplied by another person.

Liability of persons other than principal offender

79.—(1) Where the commission of an offence under regulation 76 (offences) is due to anything which another person did or failed to do in the course of business, that other person is guilty of the offence and may be proceeded against and punished, whether or not proceedings are taken against the first person.

(2) Where a body corporate commits an offence, a relevant person is also guilty of the offence where the offence was committed by the body corporate—

(a) with the consent or connivance of the relevant person; or

(b) as a result of the negligence of the relevant person.

(3) In paragraph (2), "relevant person" means—

(a) a director, manager, secretary or other similar officer of the body corporate;

(b) in relation to a body corporate managed by its members, a member of that body corporate performing managerial functions;

(c) in relation to a Scottish partnership, a partner; or

(d) a person purporting to act as a person described in sub-paragraphs (a), (b) or (c).

Time limit for prosecution of offences

80.—(1) In England and Wales an information relating to an offence under regulation 76 that is triable by a magistrates' court may be so tried if it is laid within 12 months after the date on which evidence sufficient in the opinion of the prosecutor to justify the proceedings comes to the knowledge of the prosecutor.

(2) In Scotland—

(a) summary proceedings for an offence under regulation 76 may be commenced before the end of 12 months after the date on which evidence sufficient in the Lord Advocate's opinion to justify the proceedings came to the Lord Advocate's knowledge; and

(b) section 136(3) of the Criminal Procedure (Scotland) Act 1995 [M18] (time limit for certain offences) applies for the purpose of this paragraph as it applies for the purpose of that section.

(3) In Northern Ireland, summary proceedings for an offence under regulation 76 may be instituted within 12 months after the date on which evidence sufficient in the opinion of the prosecutor to justify proceedings comes to the knowledge of the prosecutor.

(4) No proceedings may be brought more than three years after the commission of the offence.

(5) For the purposes of this regulation a certificate of the prosecutor (or in Scotland, the Lord Advocate) as to the date on which the evidence referred to paragraph (1), (2) or (3) came to light, is conclusive evidence.

(6) This regulation has effect subject to paragraph (1)(n) of Schedule 8 and paragraph (1)(n) of Schedule 9.

Marginal Citations

M18 1995 c.46.

Service of documents

81.—(1) Any document required or authorised by these Regulations to be served on a person may be served by—

(a) delivering it to that person in person;

(b) leaving it at that person's proper address; or

(c) sending it by post or electronic means to that person's proper address.

(2) In the case of a body corporate, a document may be served on a director of that body.

(3) In the case of a partnership, a document may be served on a partner or a person having control or management of the partnership business.

(4) For the purposes of this regulation, “proper address” means—

(a) in the case of a body corporate or its director—

(i) the registered or principal office of that body; or

(ii) the email address of the secretary or clerk of that body;

(b) in the case of a partnership, a partner or person having control or management of the partnership business—

(i) the principal office of the partnership; or

(ii) the email address of a partner or person having that control or management;

(c) in any other case, a person's last known address, which may be an email address.

(5) If a person to be served with a document has specified an address in the United Kingdom (other than that person's proper address) at which that person or someone on that person's behalf will accept service, that address must also be treated as that person's proper address.

(6) In this regulation, "partnership" includes a Scottish partnership.

Recovery of expenses of enforcement

82.—(1) This regulation applies where a person commits an offence under regulation 76.

(2) The court may (in addition to any other order it may make as to costs or expenses) order the person to reimburse the enforcing authority for any expenditure which the enforcing authority has incurred in investigating the offence.

Action by enforcing authority

83.—(1) An enforcing authority may itself take action which an economic operator could have been required to take by a notice served under regulation 68 (enforcement powers) where the conditions for serving such a notice are met and either—

(a) the enforcing authority has been unable to identify any economic operator on whom to serve such a notice; or

(b) the economic operator on whom such a notice has been served has failed to comply with it.

(2) If the enforcing authority has taken action under paragraph (1) following the failure of an economic operator to comply with a notice, the authority may recover from that person as a civil debt any costs or expenses reasonably incurred by the enforcing authority in taking the action.

(3) A civil debt recoverable under paragraph (2) may be recovered summarily—

(a) in England and Wales by way of a complaint pursuant to section 58 of the Magistrates' Courts Act 1980 [M19];

(b) in Northern Ireland in proceedings under article 62 of the Magistrates' Courts (Northern Ireland) Order 1981 [M20].

Marginal Citations

M19 1980 c.43; section 58 was amended by the Crime and Courts Act 2013 (c.22), Schedule 10 paragraph 40.

M20 S.I. 1981/1675 (N.I. 26).

Appeals against notices

84.—(1) An application for an order to vary or set aside the terms of a notice served under regulation 68 may be made—

(a) by the economic operator on whom the notice has been served; and

(b) in the case of a notice other than a recall notice, by a person having an interest in the pressure equipment or assembly in respect of which the notice has been served.

(2) An application must be made before the end of the period of 21 days beginning with the day on which the notice was served.

(3) The appropriate court may only make an order setting aside a notice served under regulation 68 (enforcement powers) if satisfied—

(a) that the pressure equipment or assembly to which the notice relates is in conformity with Part 2; or

(b) that the enforcing authority failed to comply with regulation 69 (exercise of enforcement powers) when serving the notice.

(4) On an application to vary the terms of a notice served under regulation 68, the appropriate court may vary the terms of the notice as it considers appropriate.

(5) In this regulation—

(a) the "appropriate court" is to be determined in accordance with regulation 85 (appropriate court for appeals against notices); and

(b) "notice" means any of the following—

(i) a prohibition notice served in accordance with Schedule 7;

(ii) a notice to warn served in accordance with Schedule 7;

(iii) a suspension notice served in accordance with Schedule 7;

(iv) a compliance notice served in accordance with Schedule 10;

(v) a withdrawal notice served in accordance with Schedule 10; or

(vi) a recall notice served in accordance with Schedule 10.

Appropriate court for appeals against notices

85.—(1) In England and Wales or Northern Ireland, the appropriate court for the purposes of regulation 84 is—

(a) the court in which proceedings have been brought in relation to the pressure equipment or assembly for an offence under regulation 76 (offences);

(b) an employment tribunal seized of appeal proceedings against a notice which relates to pressure equipment and which has been served under or by virtue of paragraph 1 of Schedule 8 (enforcement powers of the Health and Safety Executive under the 1974 Act); or

(c) an industrial tribunal seized of appeal proceedings against a notice which relates to pressure equipment and which has been served under or by virtue of paragraph 1 of Schedule 9 (enforcement powers of the Health and Safety Executive for Northern Ireland under the 1978 Order); or

(d) in any other case, a magistrates' court.

(2) In Scotland, the appropriate court for the purposes of regulation 84 is—

(a) the sheriff court within whose sheriffdom the appellant resides or, as the case may be, has a registered or principal office; or

(b) an employment tribunal seized of appeal proceedings against a notice which relates to pressure equipment and which has been served under or by virtue of paragraph 1 of Schedule 8.

(3) A person aggrieved by an order made by a magistrates' court in England and Wales or Northern Ireland pursuant to an application under regulation 84, or by a decision of such a 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.

Compensation

86.—(1) When an enforcing authority other than the Health and Safety Executive, the Health and Safety Executive for Northern Ireland or the Office for Nuclear Regulation serves a relevant notice in respect of pressure equipment or an assembly, that authority is liable to pay compensation to a person having an interest in the equipment or assembly for any loss or damage suffered by reason of the notice if both of the conditions in paragraph (2) are met.

(2) The conditions are that—

(a) the pressure equipment or assembly in respect of which the relevant notice was served neither—

(i) presents a risk; nor

(ii) contravenes any requirement of these Regulations; and

(b) the relevant notice was not served because of neglect or default by a relevant economic operator.

(3) In this regulation, "relevant notice" means a suspension, withdrawal or recall notice as referred to in regulation 84(5)(b).

PART 6

Miscellaneous

Review E+W+S

87.—(1) The Secretary of State must from time to time—

(a) carry out a review of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other member States.

(3) The report must, in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved by a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five years beginning on the commencement date.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Extent Information

E34 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Review N.I.

87.—(1) The Secretary of State must from time to time—

(a) carry out a review of these Regulations;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the Directive is implemented in other **[**F249relevant states**]**.

(3) The report must, in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved by a system that imposes less regulation.

(4) The first report under this regulation must be published before the end of the period of five years beginning on the commencement date.

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

Extent Information

E100 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F249 Words in reg. 87(2) substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 7(1)**

Transitional provisions

88.—(1) Nothing in these Regulations prevents the making available on the market or putting into service of pressure equipment or assemblies which—

(a) were placed on the market before the commencement date; and

(b) are in conformity with the 1999 Regulations.

(2) Nothing in these Regulations prevents the putting into service of pressure equipment and assemblies which—

(a) were placed on the market before 30th May 2002; and

(b) comply with any provisions with which they would have been required to comply in order for them to be placed on the market in the United Kingdom on 28th November 1999.

[F128**Transitional provision in relation to EU Exit**

88A.—(1) In this regulation—

"pre-exit period" means the period beginning with the commencement date and ending immediately before IP completion day;

"product" means **[**F129pressure equipment or an assembly required, under regulation 6 or 7, to satisfy the essential safety requirements set out in Schedule 2**]** to which these Regulations apply on or after IP completion day.

(2) Subject to paragraph (3), where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 24 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, any obligation to which a person was subject under these Regulations as they had effect immediately before IP completion day, continues to have effect as it did immediately before IP completion day, in relation to that product.

(3) Paragraph (2) does not apply to—

(a) any obligation of any enforcing authority to inform the European Commission or the member States of any matter; or

(b) any obligation to take action outside of the United Kingdom in respect of that product.

(4) Where during the pre-exit period—

(a) a product has not been placed on the market; and

(b) a manufacturer has taken any action under regulation 42 as it had effect immediately before IP completion day in relation to that product

that action has effect as if it had been done under regulation 42 as it had effect on and after IP completion day.

[

F130(5) Subject to paragraph (6), where before 11pm on 31st December 2024—

(a) a product has not been placed on the market or put into service; and

(b) a manufacturer has taken any action under the conformity assessment procedure that applies to that product in accordance with Article 14 of the Directive

that action has effect as if it had been done under the applicable conformity assessment procedure referred to in regulation 41 or 42.

(6) Paragraph (5) does not apply—

(a) after the expiry of the validity of any certificate issued pursuant to the applicable conformity assessment procedure; and

(b) in any event, after 31st December 2027.**]]**

F128 Reg. 88A inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 41** (as amended by S.I. 2020/676, regs. 1(1), **2** and by S.I. 2020/852, reg. 4(2), **Sch. 1 para. 1(m)(viii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F129 Words in reg. 88A(1) substituted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), **15(2)(a)**

F130 Reg. 88A(5)(6) inserted (31.12.2022) by The Product Safety and Metrology (Amendment and Transitional Provisions) Regulations 2022 (S.I. 2022/1393), regs. 1(1), **15(2)(b)**

E+W+S

89. For the purposes of these Regulations, a certificate issued, or approval granted, by a notified body, recognised third party organisation or user inspectorate under the 1999 Regulations, or any enactment of another member State which implemented Directive 97/23/EC[M21], is to be treated as a certificate issued or approval granted under Annex II to the Directive (as amended from time to time).

Extent Information

E35 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Marginal Citations

M21 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, OJ No L181, 9.7.1997, p.1.

N.I.

89. For the purposes of these Regulations, a certificate issued, or approval granted, by a notified body, recognised third party organisation or user inspectorate under the 1999 Regulations, or any enactment of another **[**F250relevant state**]** which implemented Directive 97/23/ECF251, is to be treated as a certificate issued or approval granted under Annex II to the Directive (as amended from time to time).

Extent Information

E101 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F250 Words in reg. 89 substituted (N.I.) (31.12.2020) by The Pressure Vessels (Amendment) (Northern Ireland) (EU Exit) Regulations 2020 (S.I. 2020/678), reg. 1(b), **Sch. 2 para. 7(2)**

F251 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, OJ No L181, 9.7.1997, p.1.

Revocations, amendments and savings E+W+S

90. —

(1) Subject to paragraph (2) **[**F131and (2A)**]**, the 1999 Regulations are revoked.

[F132(2) Subject to the modifications made in paragraph (2A), the Regulations referred to in paragraph (1) continue to apply, as if they had not been revoked, to pressure equipment or assemblies placed on the market before the commencement date.

(2A) The modifications referred to in paragraph (2) are that in the 1999 Regulations—

(a) references to "the Community" shall be read as including the United Kingdom;

(b) references to a "member State" shall be read as including the United Kingdom; and

(c) in Schedule 8 (enforcement), in paragraph 6, omit "with a view to this information being passed by him to the Commission".**]**

(3) Accordingly, despite its repeal by paragraph 12(a) of Schedule 12, the entry in paragraph 10 of Schedule 5 to the Consumer Rights Act 2015 relating to the 1999 Regulations is to continue to have effect in relation to pressure equipment or assemblies placed on the market before the commencement date.

Extent Information

E36 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F131 Words in reg. 90(1) inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 42(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F132 Reg. 90(2)(2A) substituted for reg. 90(2) (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 42(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Revocations, amendments and savings N.I.

90. —

(1) Subject to paragraph (2), the 1999 Regulations are revoked.

(2) The Regulations referred to in paragraph (1) continue to apply, as if they had not been revoked, to pressure equipment or assemblies placed on the market before the commencement date.

(3) Accordingly, despite its repeal by paragraph 12(a) of Schedule 12, the entry in paragraph 10 of Schedule 5 to the Consumer Rights Act 2015 relating to the 1999 Regulations is to continue to have effect in relation to pressure equipment or assemblies placed on the market before the commencement date.

Extent Information

E102 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

91. Schedule 12 (Consequential amendments and revocations) has effect.

Margot James
Parliamentary Under Secretary of State Minister for Small Business, Consumers and Corporate Responsibility

Department for Business, Energy and Industrial Strategy

SCHEDULE 1

Regulation 4

Excluded Pressure Equipment and Assemblies

1. These Regulations do not apply to—

(a) 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 and including all the annexed equipment designed specifically for pipelines, except where this constitutes standard pressure equipment such as may be found in pressure reduction stations or compression stations;

(b) 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;

[F133(c) simple pressure vessels to which the Simple Pressure Vessel (Safety) Regulations 2016 apply;

(d) aerosol dispensers to which the Aerosol Dispensers Regulations 2009 apply;**]**

(e) equipment intended for the functioning of vehicles defined by the following—

[F134(i) Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles;**]**

(ii) Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles M22; and

(iii) Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two-or three-wheel vehicles and quadricycles M23.

[F135(f) for equipment classified as no higher than category I in accordance with Schedule 1B to these Regulations and, to which, one of the following applies—

(i) the Supply of Machinery (Safety) Regulations 2008;

(ii) the Lift Regulations 2016;

(iii) the Electrical Equipment (Safety) Regulations 2016;

(iv) the Medical Devices Regulations 2002;

(v) Regulation 2016/426 of the European Parliament and of the Council of 9 March on appliances burning gaseous fuels;

(vi) the Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016.**]**

[F136(g) products connected with the production of trade in arms, munitions and war material;**]**

(h) items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;

(i) well-control equipment used in the petroleum, gas or geothermal exploration and extraction industry and in underground storage which is intended to contain and/or control well pressure; this shall comprise the wellhead (Christmas tree), the blow out preventers (BOP), the piping manifolds and all their equipment upstream;

(j) 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, which may include:

(i) engines including turbines and internal combustion engines;

(ii) steam engines, gas/steam turbines, turbo-generators, compressors, pumps and actuating devices;

(k) 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, remelting, de-gassing and casting of steel, iron and non-ferrous metals;

(l) enclosures for high-voltage electrical equipment such as switchgear, control gear, transformers, and rotating machines;

(m) pressurised pipes for the containment of transmission systems, e.g. for electrical power and telephone cables;

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

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

(p) exhaust and inlet silencers;

(q) bottles or cans for carbonated drinks for final consumption;

(r) 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;

[[F137](s) equipment covered by—

(i) the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009; and

(ii) equipment covered by the International Maritime Dangerous Goods Code and the Convention on International Civil Aviation.**]**

(t) radiators and pipes in warm water heating systems; and

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

[[F138]SCHEDULE 1A

Regulations 10 and 42

Conformity Assessment Procedures for Pressure Equipment and Assemblies

F138 Sch. 1A inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 44** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

PART 1

Module A: Internal Production Control

General

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3 and 4 and ensures and declares on their sole responsibility that the pressure equipment concerned satisfy the requirements of these Regulations.

Technical documentation

2.—(1) The manufacturer shall establish the technical documentation.

(2) The technical documentation shall—

(a) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(b) include an adequate analysis and assessment of the risk;

(c) specify the applicable requirements and contain, where applicable—

(i) a general description;

(ii) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(iv) a list of the designated standards;

(v) results of design calculations made, examinations carried out and the results of any other relevant calculation or examination;

(vi) test reports;

(vii) manufacture; and

(viii) operation,

of the pressure equipment or assembly.

(3) The technical documentation must be kept at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Manufacturing

3. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured pressure equipment with the technical documentation referred to in paragraph 2 and the requirements of these Regulations.

UK marking and declaration of conformity

4. The manufacturer shall—

(a) affix the UK marking to each individual piece of pressure equipment, or assembly, that satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request; and

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Authorised representative

5. The manufacturer's obligations set out in paragraph 4 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 2

Module A2: Internal production control plus supervised pressure equipment checks at random

General

6. Internal production control plus supervised pressure equipment checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3 ,4 and 5, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned satisfies the requirements of these Regulations.

Technical documentation

7.—(1) The manufacturer shall establish the technical documentation.

(2) The technical documentation shall—

(a) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(b) include an adequate analysis and assessment of the risk;

(c) specify the applicable requirements and contain, where applicable—

(i) a general description;

(ii) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(iv) a list of the designated standards;

(v) results of design calculations made, examinations carried out, and the results of any other relevant calculation or examination;

(vi) test reports;

(vii) manufacture; and

(viii) operation

of the pressure equipment or assembly.

(4) The technical documentation must be kept at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Manufacturing

8. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured pressure equipment with the technical documentation referred to in paragraph 7 and the requirements of these Regulations.

Final assessment and pressure equipment, assembly, checks

9.—(1) The manufacturer shall perform a final assessment of the pressure equipment, or assembly, monitored by means of unexpected visits by an approved body chosen by the manufacturer.

(2) The approved body shall carry out, or have carried out for them, product checks which shall—

(a) be carried out at random intervals determined by the approved body;

(b) verify the quality of the internal checks of the pressure equipment, or assembly (taking into account the technological complexity of the equipment, or assembly, and the quantity of production);

(c) establish that the manufacturer performs final assessment in accordance with paragraphs 25 to 28 of Schedule 2 to these Regulations;

(d) take samples of pressure equipment and assemblies at the manufacturing or storage premises in order to conduct checks (the approved 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 samples).

(3) The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pressure equipment, or assembly, performs within acceptable limits, with a view to ensuring conformity of the pressure equipment, or assembly.

(4) The approved body shall take appropriate measures where an item of pressure equipment or assembly does not conform.

(5) The manufacturer shall, under the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.

UK marking and declaration of conformity

10. The manufacturer shall—

(a) affix the UK marking to each individual pressure equipment, or assembly, that satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request; and

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Authorised representative

11. The manufacturer's obligations set out in paragraph 10 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 3

Module B: Type examination

Type examination–production type

12. Type examination–production type is the part of a conformity assessment procedure in which an approved body examines the technical design of the pressure equipment, or assembly, and verifies and attests that the technical design of the pressure equipment meets the requirements of these Regulations.

13. Type examination–production type shall consist of an assessment of the adequacy of the technical design of the pressure equipment, or assembly, through examination of the technical documentation and supporting evidence referred to in paragraph 14, plus examination of a specimen, representative of the production envisaged, of the complete pressure equipment or assembly.

14. The manufacturer shall lodge an application with a single approved body of their choice. The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application had not been lodged with any other approved body;

(c) the technical documentation which shall—

(i) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(ii) include an adequate analysis and assessment of the risk;

(iii) specify the applicable requirements and contain, where applicable—

(aa) a general description;

(bb) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, and all other relevant parts, to component level;

(cc) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(dd) a list of the designated standards;

(ee) results of design calculations made, examinations carried out, and the results of any other relevant calculation or examination;

(ff) test reports;

(gg) information concerning the tests provided for in manufacture;

(hh) information concerning the qualifications and approvals required under paragraphs 21 and 22 of Schedule 2 (essential safety requirements);

(ii) manufacture; and

(jj) operation;

(d) specimens representative of the product envisaged which—

(i) may cover several versions of the pressure equipment or assembly (provided that the differences between the versions do not affect the level of safety);

(ii) the approved body may request further of, if needed for carrying out the test programme;

(e) supporting evidence for the adequacy of the technical design solution which shall—

(i) mention any documents that have been used, in particular where the relevant designated standards have not been applied in full; and

(ii) include, where necessary, the results of tests carried out—

(aa) by the appropriate laboratory of the manufacturer applying other relevant technical specifications; or

(bb) by any other testing laboratory on their behalf and under their responsibility.

15. The approved body shall—

(a) examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the pressure equipment, or assembly, and the manufacturing procedures;

(b) where the materials are not in conformity with the relevant designated standards, assess the materials and check the certificate issued by the material manufacturer in accordance with subparagraphs 31(5) to (8) of Schedule 2 to these Regulations;

(c) approve the procedures for the permanent joining of pressure equipment, or assembly, parts, or check that they have been previously approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(d) verify that the personal undertaking in the permanent joining of pressure equipment, or assembly, parts and the non-destructive tests are qualified or approved in accordance with paragraphs 21 or 22 of Schedule 2 to these Regulations;

(e) verify that the specimens have been manufactured in conformity with the technical documents and identify the elements which have been designed in accordance with the applicable provisions of the relevant designated standards as well as the elements which have been designed using other relevant technical specifications without applying the relevant provisions of those standards;

(f) carry out appropriate examinations and necessary tests to check whether—

(i) when the manufacturer has chosen to apply the solutions in the relevant designated standards, these have been applied correctly;

(ii) where the solutions in the relevant designated standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of these Regulations;

(g) agree, with the manufacturer, on a location where the examinations and tests will be carried out;

(h) draw up an evaluation report—

(i) recording the activities undertaken, in accordance with this paragraph, and their outcomes; and

(ii) only release the content, in full or in part, with the agreement of the manufacturer.

16. Where the type meets the requirements of these Regulations, the approved body shall issue a Type examination–production type certificate to the manufacturer.

17. The Type examination-production type certificate shall—

(a) include—

(i) the name and address of the manufacturer;

(ii) the conclusions of the examination;

(iii) any conditions for the certificate's validity; and

(iv) necessary data for identification of the approved type;

(b) include an annex listing the relevant parts of the technical documentation, a copy of which shall be kept by the approved body;

(c) contain all relevant information to allow the conformity of manufactured equipment pressure equipment, or assemblies, with the examined type to be evaluated and to allow for in-service control;

(d) be valid for 10 years, without prejudice to paragraphs 20 and 21, and be renewable.

18. Where the type does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a Type examination-production type certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

19. Provision shall be made for an appeals procedure.

20. The approved body shall keep itself appraised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly.

21. The manufacturer shall inform the approved body that holds the technical documentation relating to the Type examination-production type certificate of all modifications to the approved type that may affect the conformity of the pressure equipment, or assembly, with the essential safety requirements of these Regulations or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original Type examination-production type certificate.

22. Each approved body shall inform the Secretary of State concerning Type examination-production type certificates and any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the enforcing authorities the list of certificates and any additions thereto refused, suspended or otherwise restricted.

23. Each approved body shall inform the other approved bodies concerning the Type examination-production type certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted and, upon request, concerning the certificates and additions thereto that it has issued.

24. Other approved bodies may, on request, obtain a copy of the Type examination-production type certificate and additions thereto.

25. The approved body shall keep a copy of the Type examination-production type certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

26. The manufacturer shall keep a copy of the Type examination-production type certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

27. The manufacturer's authorised representative may lodge the application referred to in paragraph 14 and fulfil the obligations set out in paragraphs 21 and 26, provided that they are specified in the mandate.

Type examination–design type

28. Type examination-design type is the part of a conformity assessment procedure in which an approved body examines the technical design of the pressure equipment, or assembly, and verifies

and attests that the technical design of the pressure equipment, or assembly, meets the requirements of these Regulations.

29. Type examination-design type shall consist of an assessment of the adequacy of the technical design of the pressure equipment through examination of the technical documentation and supporting evidence referred to in paragraph 31, without examination of a specimen.

30. The experimental design method provided for at paragraph 6 of Schedule 2 to these Regulations shall not be used in the context of this module.

31. The manufacturer shall lodge an application with a single approved body of their choice. The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application had not been lodged with any other approved body;

(c) the technical documentation which shall—

(i) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(ii) include an adequate analysis and assessment of the risk;

(iii) specify the applicable requirements and contain, where applicable—

(aa) a general description;

(bb) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits and all other relevant parts, to component level;

(cc) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(dd) a list of the designated standards;

(ee) information concerning the qualifications and approvals required under paragraphs 21 and 22 of Schedule 2;

(d) supporting evidence for the adequacy of the technical design solution which shall—

(i) mention any documents that have been used, in particular where the relevant designated standards have not been applied in full; and

(ii) include, where necessary, the results of tests carried out—

(aa) by the appropriate laboratory of the manufacturer applying other relevant technical specifications; or

(bb) by any other testing laboratory on their behalf and under their responsibility.

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

33. The approved body shall—

(a) examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product;

(b) assess the materials where they are not in conformity with the relevant designated standards;

(c) approve the procedures for the permanent joining of pressure equipment, or assembly, parts or check that they have been previously approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(d) carry out appropriate examinations and necessary tests to check whether—

(i) when the manufacturer has chosen to apply the solutions in the relevant designated standards, these have been applied correctly;

(ii) where the solutions in the relevant designated standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of these Regulations;

(e) draw up an evaluation report—

(i) recording the activities undertaken, in accordance with this paragraph, and their outcomes;

(ii) only release the content, in full or in part, with the agreement of the manufacturer.

34. Where the design meets the requirements of these Regulations, the approved body shall issue a Type examination–design type certificate to the manufacturer.

35. The Type examination-design certificate type shall—

(a) include—

(i) the name and address of the manufacturer;

(ii) the conclusions of the examination;

(iii) any conditions for the certificate's validity; and

(iv) necessary data for identification of the approved type;

(b) include an annex listing the relevant parts of the technical documentation, a copy of which shall be kept by the approved body;

(c) contain all relevant information to allow the conformity of manufactured pressure equipment, or assemblies, with the examined design to be evaluated and to allow for in-service control;

(d) be valid for 10 years, without prejudice to paragraphs 36 and 37, and be renewable.

36. Where the design does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a Type examination-design type certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

37. The approved body shall keep itself appraised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of these Regulations and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly.

38. The manufacturer shall inform the approved body that holds the technical documentation relating to the Type examination-design type certificate of all modifications to the approved type that may affect the conformity of the pressure equipment, or assembly, with the essential safety requirements of these Regulations or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original Type examination-design type certificate.

39. Each approved body shall inform its approved authority concerning Type examination-design type certificates and any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its approved authorities the list of certificates and any additions thereto refused, suspended or otherwise restricted.

40. Each approved body shall inform the other approved bodies concerning the Type examination-design type certificates and any additions thereto which it has refused, withdrawn,

suspended or otherwise restricted and, upon request, concerning the certificates and additions thereto that it has issued.

41. Other approved bodies may, on request, obtain a copy of the Type examination-design type certificate and additions thereto.

42. The approved body shall keep a copy of the Type examination-design type certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

43. The manufacturer shall keep a copy of the Type examination-design type certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

44. The manufacturer's authorised representative may lodge the application referred to in paragraph 31 and fulfil the obligations set out in paragraphs 37 and 42, provided that they are specified in the mandate.

PART 4

Module C2: Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals

General

45. Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 46, 47 and 48, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned is in conformity with the type described in the Type examination certificate and satisfies the requirements of these Regulations that apply to it.

Manufacturing

46. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pressure equipment, or assembly, with the type described in the Type examination certificate and with the requirements of these Regulations.

Final assessment and pressure equipment check

47.—(1) The manufacturer shall choose an approved body to carry out checks, or have them carried out, at random intervals determined by that body.

(2) Checks carried out by the approved body shall—

(a) verify the quality of the final assessment;

(b) verify the quality of the internal checks,

taking into account the technological complexity of the pressure equipment, or assembly, and the quantity of production.

(3) The approved body shall establish that the manufacturer actually performs the final assessment in accordance with paragraphs 25 to 28 of Schedule 2 to these Regulations.

(4) An adequate sample of the final pressure equipment, or assembly, taken on-site by the approved body before placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the designated standards, or equivalent test applying other technical

specifications, shall be carried out to check the conformity of the pressure equipment, or assembly, with the relevant requirements of these Regulations.

(5) The approved body shall assess 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 on pressure equipment, or assembly, samples.

(6) Where a sample does not conform to the acceptable quality level, the approving body shall take appropriate measures.

(7) The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pressure equipment performs within acceptable limits, with a view to ensuring conformity of the pressure equipment or assembly.

(8) Where the tests are carried out by an approved body, the manufacturer shall, under the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.

UK marking and declaration of conformity

48. The manufacturer shall—

(a) affix the UK marking to each individual pressure equipment, or assembly, that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request; and

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Authorised representative

49. The manufacturer's obligations set out in paragraph 47 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 5

Module D: Conformity to type based on quality assurance in the production process

General

50. Conformity to type based on quality assurance in the production process is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 51 and 54 and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned is in conformity with the type described in the Type examination certificate and satisfies the requirements of these Regulations that apply to it.

Manufacturing

51. The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pressure equipment, or assembly, concerned as specified in paragraph 52 and shall be subject to surveillance as specified in paragraph 53.

Quality system

52.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) all relevant information on the pressure equipment, or assembly, type envisaged;

(d) the documentation concerning the quality; and

(e) the technical documentation of the approved type and a copy of the Type examination certificate.

(3) The quality system shall ensure that the pressure equipment is in conformity with the type described in the Type examination certificate and comply with the requirements of these Regulations.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment or assembly;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(e) the means of monitoring the achievement of the required quality and the effective operation of the quality system.

(5) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems;

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with experience in the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises;

(iii) reviews the technical documentation referred to in paragraph 52, to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(6) The decision shall—

(a) be notified to the manufacturer;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(7) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(8) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system informed of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

53.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned;

(d) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, will be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

UK marking and declaration of conformity

54.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 51(1), the latter's identification number, to each individual piece of pressure equipment, or assembly, that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) for a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation referred to in paragraph 52(1);

(ii) any change referred to in paragraph 52(8)(a), as approved; and

(iii) the decisions and reports of the approved body referred to in paragraphs 52(6) and (8) and 53(2) to (4),

(2) Each approved body shall inform the Secretary of State of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(3) Each approved body shall inform the other approved bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

55. The manufacturer's obligations set out in paragraph 52(1) and (8) and paragraph 54 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 6

Module D1: Quality assurance of the production process

General

56. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 57, 58 and 61, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned satisfies the requirements of these Regulations.

Technical documentation

57.—(1) The manufacturer shall establish the technical documentation.

(2) The technical documentation shall—

(a) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(b) include an adequate analysis and assessment of the risk;

(c) specify the applicable requirements and contain, where applicable—

(i) a general description of the individual piece of equipment or the assembly;

(ii) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(iv) a list of the designated standards;

(v) results of design calculations made, examinations carried out the results of any other relevant calculation or examination; and

(vi) test reports.

(3) The technical documentation must be kept at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Manufacturing

58. The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pressure equipment, or assembly, concerned as specified in paragraph 59 and shall be subject to surveillance as specified in paragraph 60.

Quality system

59.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) all relevant information on the pressure equipment, or assembly, type envisaged;

(d) the documentation concerning the quality system; and

(e) the technical documentation referred to in paragraph 57.

(3) The quality system shall ensure compliance of the pressure equipment, or assembly, with the requirements of these Regulations that apply to it.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment or assembly;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(e) the means of monitoring the achievement of the required quality and the effective operation of the quality system.

(5) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems; and

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with experience in the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises; and

(iii) reviews the technical documentation referred to in paragraph 56, to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(6) The decision shall—

(a) be notified to the manufacturer;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(7) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(8) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system informed of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

60.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the technical documentation referred to in paragraph 57;

(d) provide the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

(e) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, should be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits, the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

UK marking and declaration of conformity

61.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 58(1), the latter's identification number, to each individual piece of pressure equipment, or assembly, that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) For a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation referred to in paragraphs 59(1) and (2);

(ii) the change referred to in paragraph 59(8); and

(iii) the decisions and reports of the approved body referred to in paragraphs 58(8) and 60(2) to (4),

(2) Each approved body shall inform the Secretary of State of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(3) Each approved body shall inform the other approved bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

62. The manufacturer's obligations set out in paragraphs 59(1), (2) and (8) and paragraph 61 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 7

Module E: Conformity to type based on pressure equipment quality assurance

General

63. Conformity to type based on pressure equipment quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 64 and 67, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned is in conformity with the type described in the Type examination certificate and satisfies the requirements of these Regulations.

Manufacturing

64. The manufacturer shall operate an approved quality system for the final product inspection and testing of the pressure equipment, or assembly, concerned as specified in paragraph 65 and shall be subject to surveillance as specified in paragraph 66.

Quality system

65.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) all relevant information on the pressure equipment, or assembly, type envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the Type examination certificate.

(3) The quality system shall ensure compliance of the products with the type described in the Type examination certificate and with the applicable requirements of these Regulations.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment or assembly;

(b) the examinations and tests that will be carried out after manufacture;

(c) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(d) the means of monitoring the effective operation of the quality system.

(5) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems;

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with experience in the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises;

(iii) reviews the technical documentation referred to in paragraph 65(2)(e), to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(6) The decision shall—

(a) be notified to the manufacturer;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(7) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(8) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system informed of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

66.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the technical documentation;

(d) provide the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

(e) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, should be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits, the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

UK marking and declaration of conformity

67.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 65(1), the latter's identification number, to each individual piece of pressure equipment, or assembly, that is conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) for a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation referred to in paragraphs 65(1) and (2);

(ii) the change referred to in paragraph 65(8); and

(iii) the decisions and reports of the approved body referred to in paragraphs 65(5) and (8) and 66(2) and (3).

(2) Each approved body shall inform the Secretary of State of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(3) Each approved body shall inform the other approved bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

68. The manufacturer's obligations set out in paragraphs 65(1), (2) and (8) and paragraph 67 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate agreed between the manufacturer and representative.

PART 8

Module E1: Quality assurance of final pressure equipment inspection and testing

General

69. Quality assurance of final pressure equipment inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 70 (technical documentation), 71 (manufacturing) and 74 (UK marking and declaration of conformity), and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned satisfies the requirements of these Regulations that apply to it.

Technical documentation

70.—(1) The manufacturer shall establish the technical documentation. The technical documentation shall—

(a) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(b) include an adequate analysis and assessment of any risk;

(c) specify the applicable requirements and contain, where applicable—

(i) a general description;

(ii) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(iv) a list of the designated standards;

(v) results of design calculations made, examinations carried out and the results of any other relevant calculation or examination; and

(vi) test reports.

(2) The technical documentation must be kept at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Manufacturing

71. The manufacturer shall operate an approved quality system for the final product inspection and testing of the pressure equipment, or assembly, concerned as specified in paragraph 72 and shall be subject to surveillance as specified in paragraph 73.

Quality system

72.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) all relevant information on the pressure equipment, or assembly, type envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation referred to in paragraph 70.

(3) The quality system shall ensure compliance of the pressure equipment, or assembly, with the requirements of these Regulations that apply to it.

(4) Under the quality system, each item of pressure equipment, or assembly, shall be examined and appropriate tests as set out in the designated standards and particularly final assessments as set out in paragraphs 25 to 28 of Schedule 2 shall be carried out in order to ensure its conformity with the requirements of these Regulations.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment or assembly;

(b) the procedures used for the permanent joining of parts as approved with paragraph 21 of Schedule 2 to these Regulations;

(c) the examinations and tests that will be carried out after manufacture;

(d) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(e) the means of monitoring the achievement of the required quality and the effective operation of the quality system.

(6) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems;

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with experience in the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises;

(iii) reviews the technical documentation referred to in paragraph 70, to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(7) The decision shall—

(a) be notified to the manufacturer;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(8) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(9) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system informed of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

73.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the technical documentation referred to in paragraph 70;

(d) provide the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

(e) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, should be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

UK marking and declaration of conformity

74.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 72(1), the latter's identification number, to each individual piece of pressure equipment, or assembly, that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) for a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation referred to in paragraphs 70(1) and (2);

(ii) the change referred to in paragraph 72(9); and

(iii) the decisions and reports of the approved body referred to in paragraphs 72(9) and 73(2) to (4).

(2) Each approved body shall inform the Secretary of State of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(3) Each approved body shall inform the other approved bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

75. The manufacturer's obligations set out in paragraphs 72(1), (2) and (9) and paragraphs 70 and 74 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 9

Module F: Conformity to type based on pressure equipment verification

General

76. Conformity to type based on pressure equipment verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 77 and 80, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned, which has been subject to the provisions of paragraph 78, is in conformity with the type described in the Type examination certificate and satisfies the requirements of these Regulations which apply to it.

Manufacturing

77. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the Type examination certificate and with the requirements of these Regulations which apply to them.

Verification

78.—(1) An approved body chosen by the manufacturer shall carry out the appropriate examinations and tests in order to check the conformity of the pressure equipment, or assembly, with the approved type described in the Type examination certificate and with the appropriate requirements of these Regulations.

(2) The examinations and tests to check the conformity of the pressure equipment with the appropriate requirements shall be carried out by examination and testing of every product as specified in paragraph 79.

Verification of conformity by examination and testing of every item of pressure equipment or assembly

79.—(1) All pressure equipment, or assemblies, shall be individually examined and appropriate tests set out in the relevant designated standards or equivalent tests shall be carried out in order to verify conformity with the approved type and described in the Type examination certificate and with the appropriate requirements of these Regulations.

(2) In the absence of such a designated standard, the approved body concerned shall decide on the appropriate tests to be carried out.

(3) The approved body shall—

(a) verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations;

(b) verify the certificate issued by the materials manufacturer in accordance with paragraphs 31(6) to (8) of Schedule 2 to these Regulations; and

(c) carry out or have carried out the final inspection and proof test referred to in paragraphs 25 to 28 to Schedule 2 of these Regulations.

(4) The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number or have it affixed under its responsibility to each approved item of pressure equipment or assembly.

(5) The manufacturer shall keep certificates of conformity available for inspection by the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

UK marking and declaration of conformity

80. The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 78(1), the latter's identification number, to each individual item of pressure equipment, or assembly, that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for each pressure equipment model, or assembly, which identifies the pressure equipment model, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market; and

(e) if the approved body referred to in paragraph 78(1) agrees and under its responsibility, the manufacturer may also affix the approved body's identification number to the pressure equipment, or assembly, during the manufacturing process.

Authorised representative

81. The manufacturer's obligations may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligation set out in paragraph 77.

PART 10

Module G: Conformity based on unit verification

General

82. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 83, 84 and 85, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned, which has been subject to the provisions of paragraph 85, is in conformity with the requirements of these Regulations that apply to it.

Technical documentation

83.—(1) The manufacturer shall establish the technical documentation and make it available to the approved body referred to in paragraph 85.

(2) The technical documentation shall—

(a) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(b) include an adequate analysis and assessment of the risk;

(c) specify the applicable requirements and contain, where applicable—

(i) a general description;

(ii) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(iv) a list of the designated standards;

(v) results of design calculations made, examinations carried out the results of any other relevant calculation or examination;

(vi) test reports; and

(vii) 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 paragraphs 21 and 22 of Schedule 2 to these Regulations.

(3) The technical documentation must be kept at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Manufacturing

84. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pressure equipment, or assembly, with the applicable requirements of these Regulations.

Verification

85.—(1) An approved body chosen by the manufacturer shall carry out the appropriate examinations and tests, set out in the relevant designated standards or equivalent tests, to check the conformity of the pressure equipment, or assembly, with the appropriate requirements of these Regulations, or have them carried out.

(2) In the absence of such a designated standard the approved body concerned shall decide on the appropriate tests to be carried out applying other technical specifications.

(3) The approved body shall—

(a) examine the technical documentation with respect to the design and manufacturing process;

(b) assess the materials used where these are not in conformity with the relevant designated standards and check the certificate issued by the materials manufacturer in accordance with paragraphs 31(6) to (8) of Schedule 2 to these Regulations;

(c) approve the procedures for the permanent joining of parts and check that they have been previously approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(d) verify the qualifications and approvals required under paragraphs 21 and 22 of Schedule 2 of these Regulations;

(e) carry out the final inspection referred to in paragraphs 25 to 28 of Schedule 2 of these Regulations and perform or have performed the proof test, referred to in the same paragraphs, and examine safety devices, if applicable.

(4) The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number or have it affixed under its responsibility to each approved item of pressure equipment or assembly.

(5) The manufacturer shall keep certificates of conformity available for inspection by the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

UK marking and declaration of conformity

86. The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 85, the latter's identification number, to each individual item of pressure equipment, or assembly, that satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity which identifies the pressure equipment model, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request; and

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Authorised representative

87. The manufacturer's obligations set out in paragraphs 83 and 85 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that the responsibilities are specified in the mandate set out between the manufacturer and representative.

PART 11

Module H: Conformity based on full quality assurance

General

88. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 89 and 92, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned satisfies the requirements of these Regulations that apply to them.

Manufacturing

89. The manufacturer shall operate an approved quality system for; the final design, manufacture, final product inspection and testing of the pressure equipment, or assembly concerned; as specified in paragraph 90 and shall be subject to surveillance as specified in paragraph 91.

Quality system

90.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) the technical documentation for one model of each type of pressure equipment, or assembly, intended to be manufactured which shall, wherever applicable, contain—

(i) a general description of the pressure equipment or assembly;

(ii) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment or assembly;

(iv) a list of the designated standards, applied in part or in full, and descriptions of the solutions adopted to meet the essential safety requirements of these Regulations where those designated standards have not been applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out and the results of any other relevant calculation or examination;

(vi) test reports;

(c) a written declaration that the same application has not been lodged with any other approved body; and

(d) the documentation concerning the quality system.

(3) The quality system shall ensure compliance of the pressure equipment, or assembly, with the requirements of these Regulations that apply to it.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment or assembly;

(b) the technical design specifications, including standards, that will be applied and, where the relevant designated standards will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations that apply to the pressure equipment or assembly will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment, or assembly, pertaining to the product type covered, particularly with regard to materials in accordance with Part 4 of Schedule 2 to these Regulations;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(g) the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.

(5) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems;

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with knowledge of the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises;

(iii) reviews the technical documentation referred to in paragraph 90(2)(b), to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(6) The decision shall—

(a) be notified to the manufacturer, or his authorised representative;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(7) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(8) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system informed of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

91.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the quality records provided for by the design part of the quality system, such as results of analyses, calculations, tests and any other relevant quality records;

(d) provide the quality records provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, and any other relevant quality records; and

(e) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, should be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

UK marking and declaration of conformity

92.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 90(1), the latter's identification number, to each individual item of pressure equipment, or assembly, that satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment model, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) for a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation referred to in paragraph 90(2);

(ii) the documentation concerning the quality system referred to in paragraph 90(4);

(iii) the change referred to in paragraph 90(8); and

(iv) the decisions and reports of the approved body referred to in paragraphs 90(8) and 91(2) to (4);

(2) Each approved body shall inform the Secretary of State of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(3) Each approved body shall inform the other approved bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

93. The manufacturer's obligations set out in paragraphs 90(1), (2) and (8) and paragraph 92 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 12

Module H1: Conformity based on full quality assurance plus design examination

General

94. Conformity based on full quality assurance plus design examination and special surveillance of the final assessment is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 95 and 99, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned satisfies the requirements of these Regulations that apply to it.

Manufacturing

95. The manufacturer shall operate an approved quality system for design, manufacture, final product inspection and testing of the products concerned as specified in paragraph 96 and shall be subject to surveillance as specified in paragraph 98. The adequacy of the technical design of the pressure equipment, or assembly, shall have been examined in accordance with paragraph 97.

Quality system

96.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) the technical documentation for one model of each type of pressure equipment, or assembly, intended to be manufactured which shall, wherever applicable, contain—

(i) a general description of the pressure equipment or assembly;

(ii) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits and any other relevant parts, to component level;

(iii) descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment or assembly;

(iv) a list of the designated standards, applied in part or in full, and descriptions of the solutions adopted to meet the essential safety requirements of these Regulations where those designated standards have not been applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out and the results of any other relevant calculation or examination;

(vi) test reports;

(c) a written declaration that the same application has not been lodged with any other approved body; and

(d) the documentation concerning the quality system.

(3) The quality system shall ensure compliance of the pressure equipment, or assembly, with the requirements of these Regulations that apply to it.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant designated standards will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations that apply to the pressure equipment or assembly will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment, or assembly, pertaining to the product type covered, particularly with regard to materials in accordance with Part 4 of Schedule 2 to these Regulations;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures used for the permanent joining of parts as approved with paragraph 21 of Schedule 2 to these Regulations;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(g) the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.

(5) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems;

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with knowledge of the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises;

(iii) reviews the technical documentation referred to in sub-paragraph (2)(b), to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(6) The decision shall—

(a) be notified to the manufacturer, or his authorised representative;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(7) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(8) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in subparagraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Design examination

97.—(1) The manufacturer shall lodge an application for the examination of the design of each item of pressure equipment, or assembly, not covered by a previous design examination with the approved body referred to in paragraph 96(1).

(2) The application shall make it possible to understand the design, manufacture and operation of the pressure equipment, or assembly, and to assess the conformity with the requirements of these Regulations that apply to it.

(3) The application shall include—

(a) the name and address of the manufacturer;

(b) the technical documentation for one model of each type of pressure equipment, or assembly, intended to be manufactured which shall, wherever applicable, contain—

(i) a general description of the pressure equipment or assembly;

(ii) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits all other relevant parts, to component level;

(iii) descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment or assembly;

(iv) a list of the designated standards, applied in part or in full, and descriptions of the solutions adopted to meet the essential safety requirements of these Regulations where those designated standards have not been applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out and the results of any other relevant calculation or examination;

(vi) test reports;

(c) a written declaration that the same application has not been lodged with any other approved body; and

(d) the supporting evidence for the adequacy of the technical design. The supporting evidence shall mention any documents that have been used, in particular where the relevant designated standards have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on their behalf and under their responsibility.

(4) Where the design meets the requirements of these Regulations the approved body shall issue a design examination certificate.

(5) The design examination certificate—

(a) must include—

(i) the name and address of the manufacturer;

(ii) the conclusions of the examination;

(iii) the conditions (if any) for the validity of the certificate; and

(iv) data necessary for identification of the approved design;

(b) may have one or more annexes attached;

(c) shall contain all relevant information to allow the conformity of manufactured products with the examined design to be evaluated, and to allow for in-service control, where applicable.

(6) Where the design does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving details for its refusal.

(7) The approved body shall keep itself appraised of any changes in the generally acknowledged state of the art which indicates that the approved design may no longer comply with the applicable requirements of these Regulations, and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly.

(8) The manufacturer shall inform the approved body that issued the design examination certificate of all modifications to the approved design that may affect the conformity of the pressure equipment, or assembly, with the essential safety requirements of these Regulations or the conditions for validity of the certificate. Such modifications shall require additional approval, from the approved body that issued the design examination certificate, in the form of an addition to the original design examination certificate.

(9) Each approved body shall inform the Secretary of State of the design examination certificates and any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of certificates and any additions thereto refused, suspended or otherwise restricted.

(10) Each approved body shall inform the other approved bodies concerning the design examination certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted and, upon request, concerning the certificates and additions thereto that it has issued.

(11) Other approved bodies may, on request, obtain a copy of the design examination certificate and additions thereto.

(12) The approved body shall keep a copy of the design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

(13) The manufacturer shall keep a copy of the design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Surveillance under the responsibility of the approved body

98.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the quality records provided for by the design part of the quality system, such as results of analyses, calculations, tests and any other relevant quality records;

(d) provide the quality records provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, and any other relevant quality records; and

(e) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, will be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits, the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

(5) Final assessment as referred to in paragraphs 25 to 28 of Schedule 2 to these Regulations is subject to increased surveillance in the form of unexpected visits by the approved body. In the course of such visits, the approved body shall conduct examinations on the pressure equipment, or assembly, and provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking and declaration of conformity

99.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 96(1), the latter's identification number, to each individual items of pressure equipment, or assembly, that satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment model, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) for a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation concerning the quality system referred to in paragraph 96(2);

(ii) the change referred to in paragraph 96(8); and

(iii) the decisions and reports of the approved body referred to in paragraphs 96(8) and 98(2) and (3),

Authorised representative

100. The manufacturer's authorised representative may lodge the application referred to in paragraphs 96(1) and (2) and fulfil the obligations set out in paragraphs 95(1), (2) and (8), 96(8) and (13) and paragraph 98, on the manufacturer's behalf and under his responsibility, provided that they are specified in the mandate set out between the manufacturer and his representative.**]**

[F139SCHEDULE 1B

Regulation 3

Conformity Assessment Tables

F139 Sch. 1B inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 44** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

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

I	=	Module A
II	=	Modules A2, D1, E1
III	=	Modules B (design type) + D, B (design type) + F, B (production type) + E, B (production type) + C2, H
IV	=	Modules B (production type) + D, B (production type) + F, G, H1

1A.—(1) Where in order to mitigate the effects of very serious safety concerns the Secretary of State considers that an item or family of pressure equipment are to be subject to different categories of modules, the Secretary of State may by regulations make such provision.

(2) Regulations made under paragraph (1)—

(a) are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament; and

(b) include power—

(i) to make different provision for different cases; and

(ii) to make such supplemental, consequential and transitional provision as the Secretary of State considers appropriate.

2. The safety accessories defined in paragraph 5, 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.—(1) The pressure accessories defined in paragraph 6, are classified on the basis of:

(a) their maximum allowable pressure PS;

(b) their volume V or their nominal size DN, as appropriate;

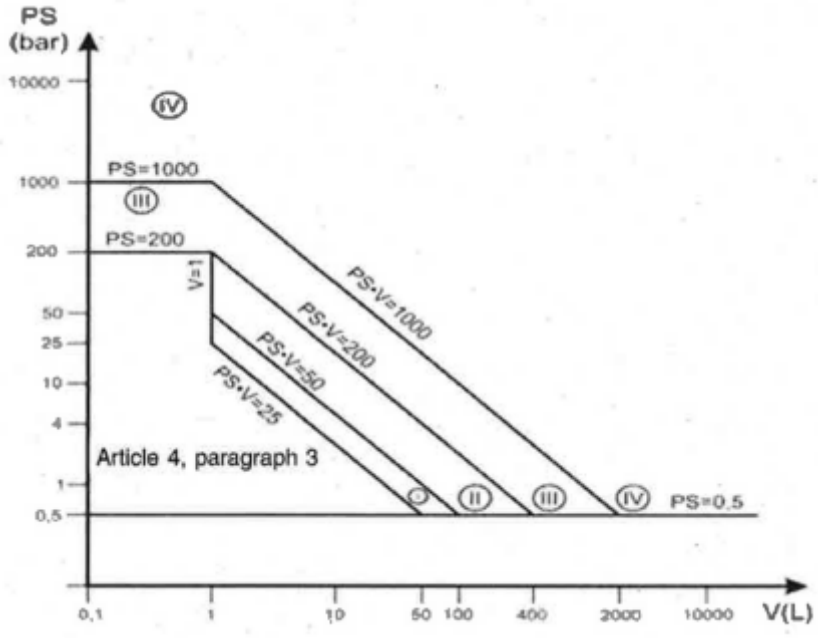
(c) the group of fluids for which they are intended.

(2) The appropriate table for vessels or piping is to be used to determine the conformity assessment category.

(3) Where both the volume and the nominal size are considered appropriate in subparagraph (1)(b), the pressure accessory shall be classified in the highest category.

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

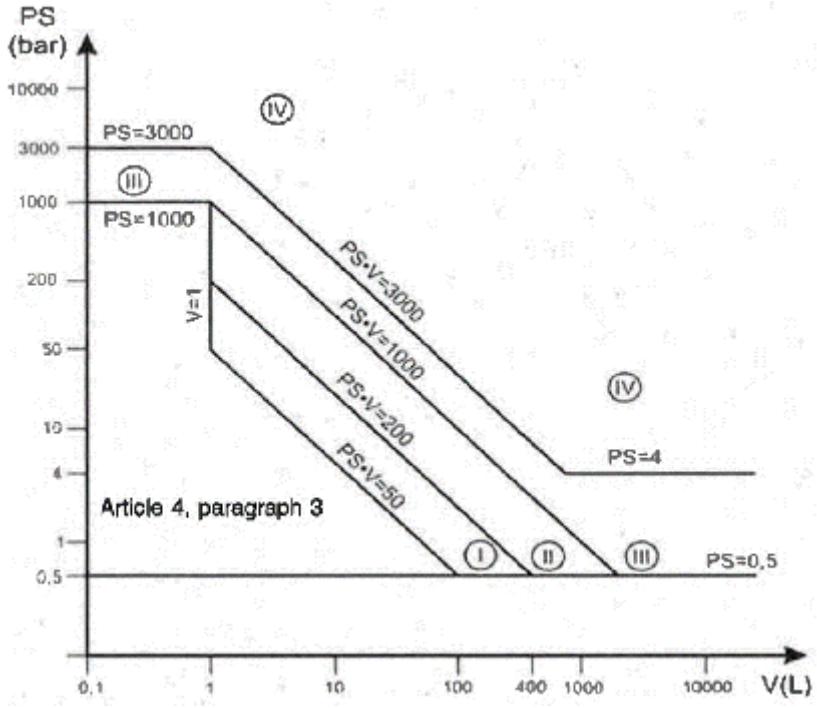
(a) (i) Table 1: Vessels for gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure is greater than 0.5 bar above normal atmospheric pressure (1013 mbar) and, for fluids in Group 1 with a volume greater than 1L and a product PS and V greater than 25 bar.L, or with a pressure PS greater than 200 bar



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

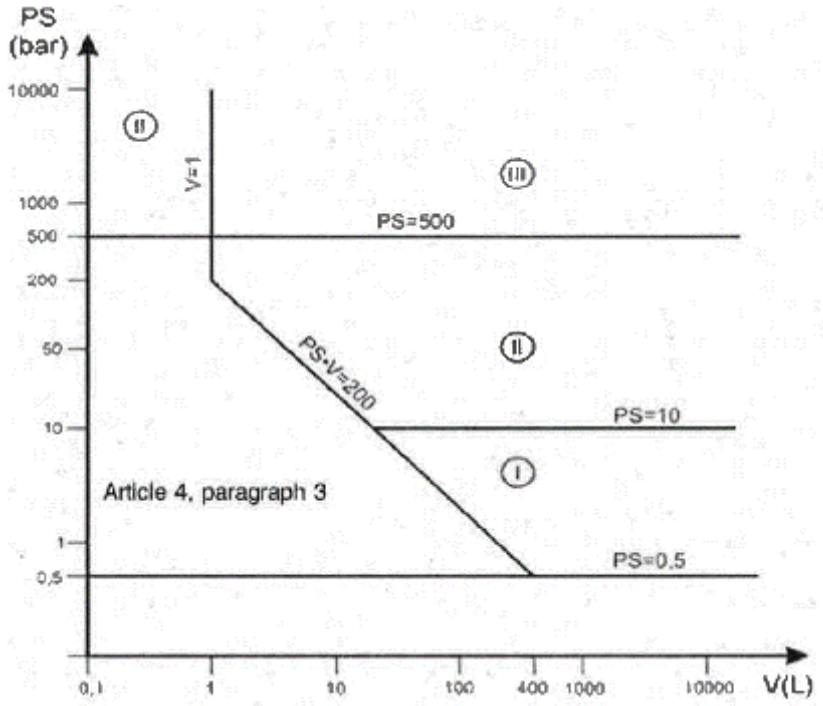
(b) (i) Table 2: Vessels for gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure is greater than 0.5 bar above normal atmospheric pressure (1013 mbar) and, for fluids in Group 2, with a volume greater

than 1L and a product of PS and V is greater than 50 bar.L, or a pressure PS greater than 1000bar

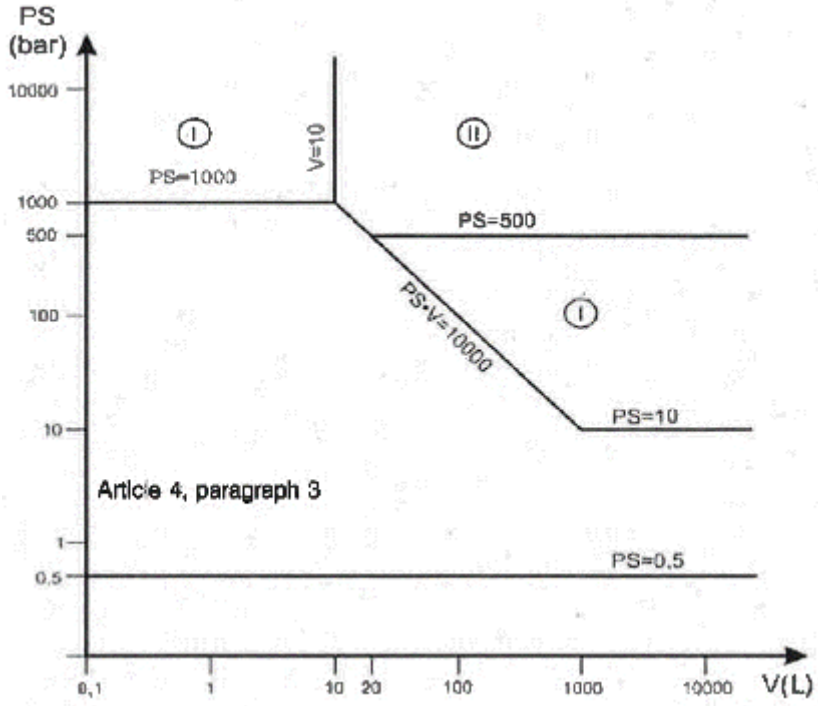


(ii) Exceptionally, portable extinguishers and bottles for breathing equipment shall be classified at least in category III.

(c) Table 3: Vessels for liquids having a vapour pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure (1013 mbar) and, for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 200 bar.L, or with a pressure PS greater than 500 bar



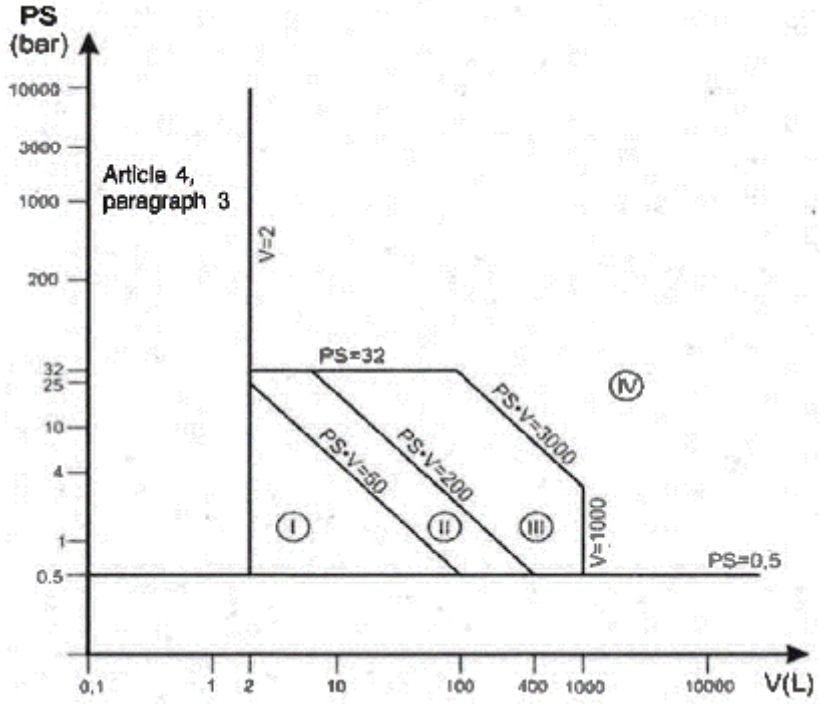
(d) (i) Table 4: Vessels for liquids having a vapour pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure (1013 mbar) and, for fluids in Group 2 with a pressure PS greater than 10 bar and a product of PS and V greater than 10000 bar.L, or with a pressure PS greater than 1000 bar



(ii) Exceptionally, assemblies intended for generating warm water at temperatures not greater than 110°C which are manually fed with solid fuels and have a PS.V, shall be subject either to a Type examination (Module B — design type) with respect to

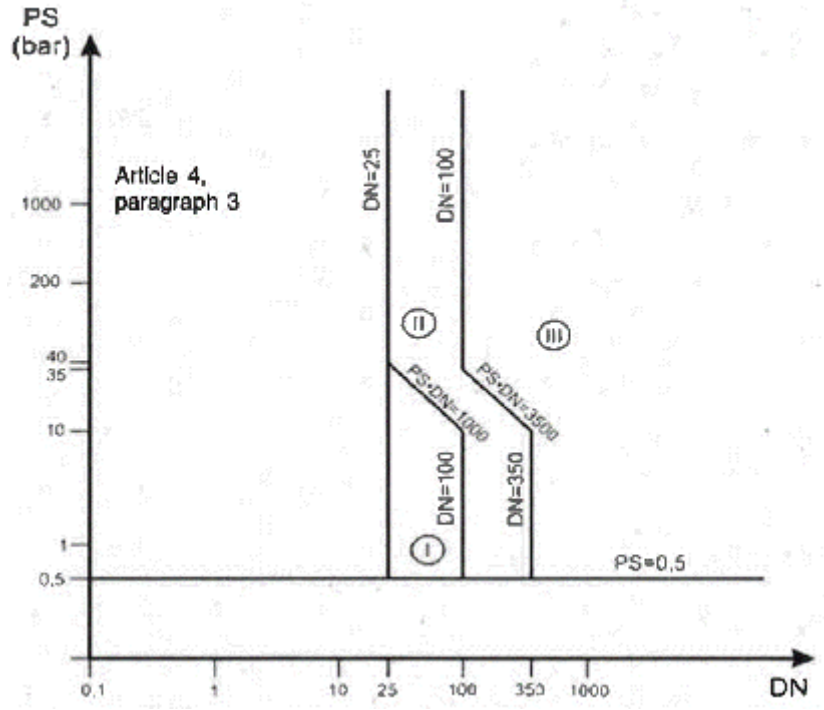
their conformity with the essential requirements referred to in paragraphs 14, 15, 16, 17 and 30 and subparagraphs 33(2)(a) and (d) of Schedule 2 to these Regulations, or to full quality assurance (Module H).

(e) (i) Table 5: Vessels fired or otherwise heated pressure equipment with the risk of overheating intended for generation of steam or superheated water at temperatures higher than 110°C having a volume greater than 2 L



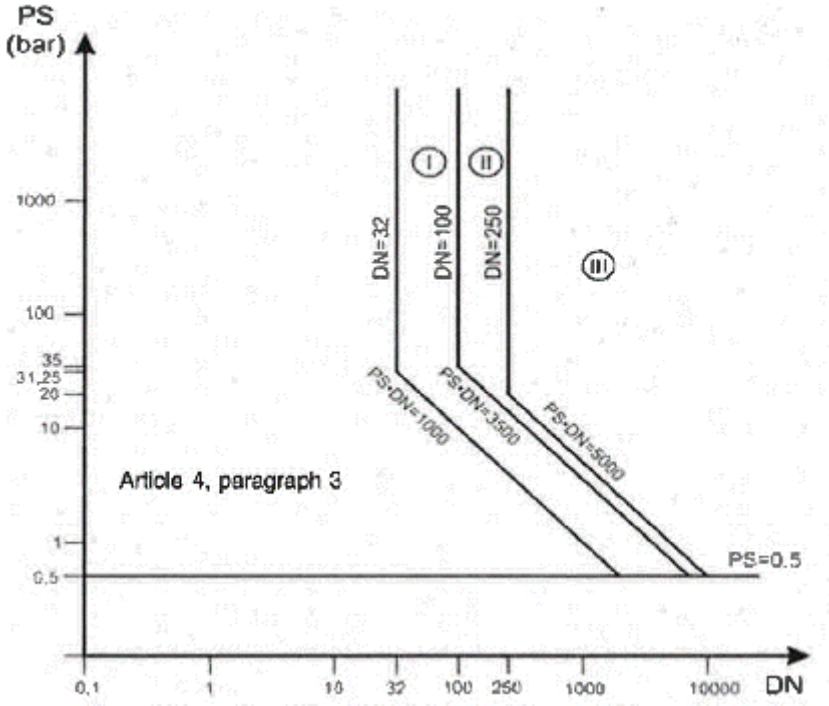
(ii) Exceptionally, the design of pressure-cookers shall be subject to a conformity assessment procedure equivalent to at least one of the category III modules.

(f) (i) Table 6: Piping intended for 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 (1013 mbar) and, for fluids in Group 1 with a DN greater than 25



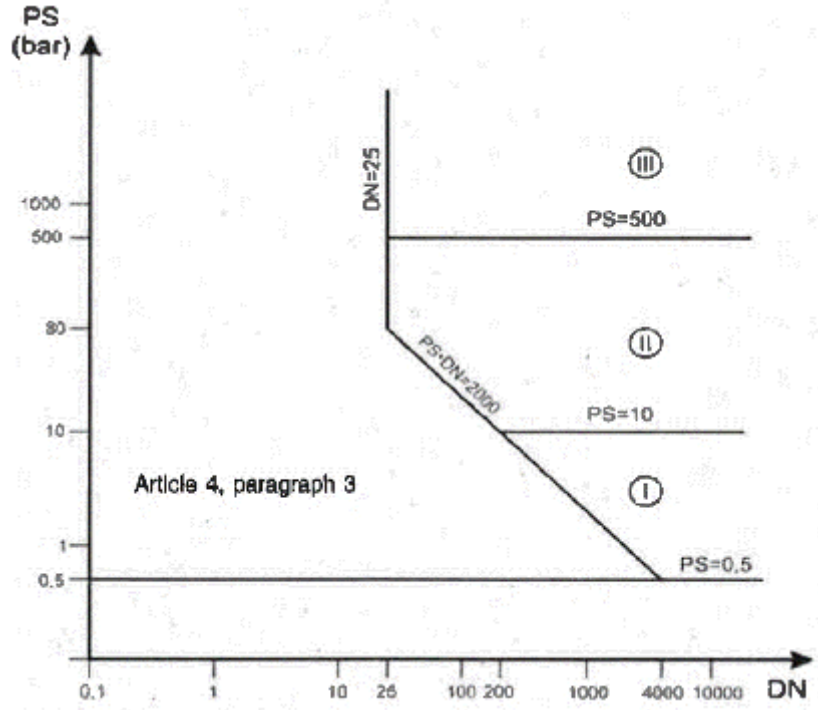
(ii) Exceptionally, piping intended for unstable gases and falling within categories I or II on the basis of Table 6 shall be classified in category III.

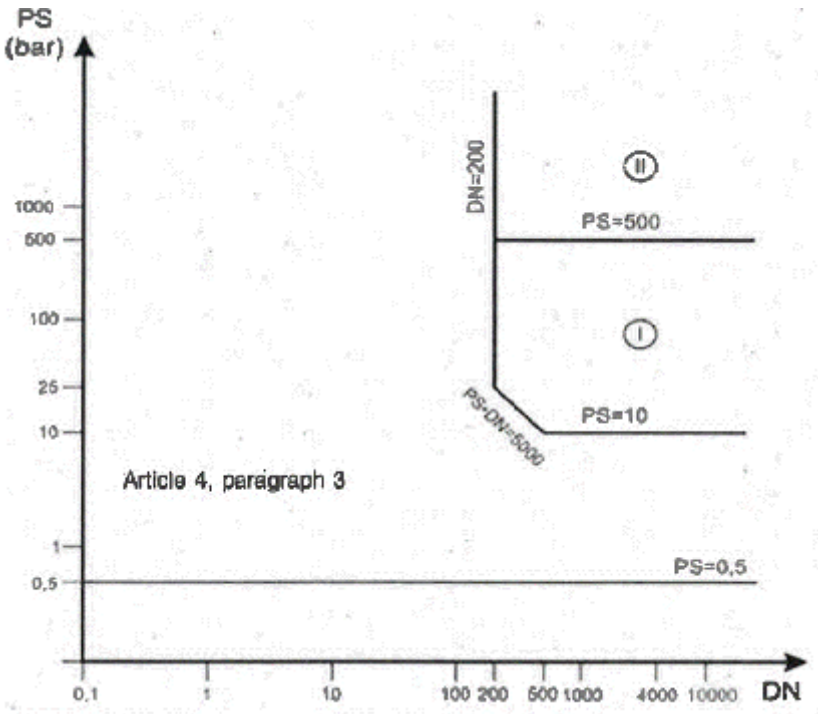
(g) (i) Table 7: Piping intended for gases, liquefied gases, gases dissolved under pressure, vapours and those liquids whose vapour pressure at the maximum allowable temperature is greater than 0.5 bar above normal atmospheric pressure (1013 mbar), and for fluids in Group 2 with a DN greater than 32 and a product of PS and DN greater than 1000 bar



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

(h) Table 8: Piping intended for liquids having a vapour pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure (1013 mbar) and, for fluids in Group 1 with a DN greater than 25 and a product of PS and DN greater than 2000 bar





(i) Table 9: Piping intended for liquids having a vapour pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure (1013 mbar) and, 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 5000 bar

5. In this Schedule "safety accessories" are defined as follows—

(a) devices designed to protect pressure equipment against the allowable limits being exceeded, including devices for direct pressure limitation, such as safety valves, bursting disc safety devices, buckling rods, controlled safety pressure relief systems (CSPRS), and limiting devices, which either activate the means for correction or provide for shutdown or a shutdown and lockout, such as pressure switched or temperature switches or fluid level switches and safety related measurement control and regulation (SRMCR) devices; and

(b) devices intended for equipment covered in the tables in paragraph 6 including where such equipment is incorporated into an assembly.

6. In this Schedule "pressure accessories" are defined as follows—

(a) devices with an operational function and having pressure-bearing housings; and

(b) devices intended for equipment covered in the tables in paragraph 6 including where such equipment is incorporated into an assembly.**]**

SCHEDULE 2 Regulations 2(1), 6, 7(1) and (2)

Essential Safety Requirements

PART 1

GENERAL

1.—(1) The obligations arising from the essential safety requirements listed in this Schedule for pressure equipment also apply to assemblies where the corresponding hazard exists.

(2) The obligations arising from the essential safety requirements apply only if the corresponding hazard exists for the pressure equipment when it is used under conditions which are reasonably foreseeable by the manufacturer.

(3) The manufacturer must analyse the hazards and risks in order to identify those which apply to the equipment on account of pressure, and must then design and construct it taking account of that analysis.

(4) The essential safety requirements are to be interpreted and applied in such a way as to take account of—

(a) the state of the art and current practice at the time of design and manufacture; and

(b) technical and economic considerations which are consistent with a high degree of health and safety protection.

2.—(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.

(2) In choosing the most appropriate solutions, the manufacturer must apply the principles set out below in the following order—

(a) eliminate or reduce hazards as far as is reasonably practicable;

(b) apply appropriate protection measures against hazards which cannot be eliminated;

(c) 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.

(3) Where the potential for misuse is known or can be clearly foreseen, the pressure equipment must be designed to prevent risks from such misuse or, if that is not possible, adequate warning given that the pressure equipment must not be used in that way.

PART 2

DESIGN

General

3.—(1) 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.

(2) The design of pressure equipment 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.

Design for adequate strength

4.—(1) Pressure equipment must be designed for loadings appropriate to its intended use and must take account of other reasonably foreseeable operating conditions, including, in particular, the following factors—

(a) internal/external pressure;

(b) ambient and operational temperatures;

(c) static pressure and mass of contents in operating and test conditions;

(d) traffic, wind, earthquake loading;

(e) reaction forces and moments which result from the supports, attachments, piping etc.;

(f) corrosion and erosion, fatigue, etc.;

(g) decomposition of unstable fluids.

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

(3) Design for adequate strength must be based on either of the following—

(a) as a general rule, a calculation method, as described in paragraph 5, and supplemented if necessary by an experimental design method as described in paragraph 6;

(b) an experimental design method without calculation, as described in paragraph 5, 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.

Calculation method

5.—(1) As regards pressure containment and other loading aspects—

(a) the allowable stresses for pressure equipment must be limited having regard to reasonably foreseeable failure modes under operating conditions, for which purpose safety factors must be applied to eliminate fully any uncertainty arising out of manufacture, actual

operational conditions, stresses, calculation models and the properties and behaviour of the material; and

(b) the calculation methods used must provide sufficient safety margins consistent, where applicable, with the requirements of Part 6.

(2) 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—

(a) design by formula;

(b) design by analysis; or

(c) design by fracture mechanics.

(3) As regards resistance—

(a) appropriate design calculations must be used to establish the resistance of the pressure equipment concerned; and in particular—

(i) 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;

(ii) 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;

(iii) the calculation temperatures must allow for appropriate safety margins;

(iv) 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;

(v) the maximum stresses and peak stress concentrations must be kept within safe limits;

(vi) 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 Part 4 together with appropriate safety factors; material characteristics to be considered, where applicable, include—

(aa) yield strength, 0.2 % or 1.0 % proof strength as appropriate at calculation temperature;

(bb) tensile strength;

(cc) time-dependent strength, i.e. creep strength;

(dd) fatigue data;

(ee) Young's modulus (modulus of elasticity);

(ff) appropriate amount of plastic strain;

(gg) bending rupture energy;

(hh) fracture toughness.

(vii) 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;

(viii) the design must take appropriate account of all reasonably foreseeable degradation mechanisms (for example corrosion, creep and fatigue) commensurate with the intended use of the equipment and attention must be drawn, in the instructions referred to in paragraph 30, to particular features of the design which are relevant to the life of the equipment, for example—

(aa) for creep: design hours of operation at specified temperatures;

(bb) for fatigue: design number of cycles at specified stress levels;

(cc) for corrosion: design corrosion allowance.

(4) As regards 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.

Experimental design methods E+W+S

6.—(1) 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.

(2) The test programme must be clearly defined prior to testing and accepted by the **[**F140approved**]** body responsible for the design conformity assessment module, where it exists.

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

(4) 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.

(5) The test programme must include—

(a) a pressure strength test, 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, for which the test pressure must—

(i) 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;

(ii) 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 example hold time at specified temperatures, number of cycles at specified stress-levels;

(c) where necessary, additional tests concerning other factors referred to in paragraph 4 such as corrosion and external damage.

Extent Information

E38 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F140 Word in Sch. 2 para. 6(2) substituted (E.W.S.) (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **10(a)(i)**

Experimental design methods N.I.

6.—(1) 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.

(2) 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.

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

(4) 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.

(5) The test programme must include—

(a) a pressure strength test, 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, for which the test pressure must—

(i) 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;

(ii) 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 example hold time at specified temperatures, number of cycles at specified stress-levels;

(c) where necessary, additional tests concerning other factors referred to in paragraph 4 such as corrosion and external damage.

Extent Information

E104 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Provisions to ensure safe handling and operation

7.—(1) The method of operation specified for pressure equipment must be such as to preclude any reasonably foreseeable risk in operation of the equipment, and particular attention must be paid, where appropriate, to—

(a) closures and openings;

(b) dangerous discharge of pressure relief blow-off;

(c) devices to prevent physical access whilst pressure or a vacuum exists;

(d) surface temperature taking into consideration the intended use;

(e) decomposition of unstable fluids.

(2) 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 risk, and 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 risk.

Means of examination

8.—(1) Pressure equipment must be designed and constructed so that all necessary examinations to ensure safety can be carried out.

(2) Where it is necessary to ensure the continued safety of the equipment, means of determining the internal condition of the equipment must be available (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.

(3) Other means of ensuring the safe condition of the pressure equipment may be applied in any of the following situations—

(a) where the pressure equipment is too small for physical internal access;

(b) where opening the pressure equipment would adversely affect the inside; or

(c) 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.

Means of draining and venting

9. Adequate means must be provided for the draining and venting of pressure equipment at all stages of operation and testing (and in particular pressure testing) where necessary—

(a) to avoid harmful effects such as water hammer, vacuum collapse, corrosion and uncontrolled chemical reactions;

(b) to permit cleaning, inspection and maintenance in a safe manner.

Corrosion or other chemical attack

10. 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.

Wear

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

(a) minimise that effect by appropriate design, for example additional material thickness, or by the use of liners or cladding materials;

(b) permit replacement of parts which are most affected; and

(c) draw attention, in the instructions referred to in paragraph 30, to measures necessary for continued safe use.

Assemblies

12. Assemblies must be so designed that—

(a) the components to be assembled together are suitable and reliable for their duty; and

(b) all the components are properly integrated and assembled in an appropriate manner.

Provisions for filling and discharge

13. 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 risks such as—

(a) on filling—

(i) overfilling or overpressurisation having regard in particular to the filling ratio and to vapour pressure at the reference temperature;

(ii) instability of the pressure equipment;

(b) on discharge, the uncontrolled release of the pressurised fluid;

(c) on filling or discharge, unsafe connection and disconnection.

Protection against exceeding the allowable limits of pressure equipment

14.—(1) 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.

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

(3) Suitable protective devices and combinations thereof comprise—

(a) safety accessories as defined in regulation 2(1);

(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.

Safety accessories

15.—(1) Safety accessories must—

(a) 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;

(b) be independent of other functions, unless their safety function cannot be affected by such other functions;

(c) comply with appropriate design principles in order to obtain suitable and reliable protection, including, in particular, fail-safe modes, redundancy, diversity and self-diagnosis.

Pressure limiting devices

16. Pressure limiting devices must be so designed that the pressure will not permanently exceed the maximum allowable pressure PS; provided that a short duration pressure surge in keeping with the specifications laid down in paragraph 39 is allowable, where appropriate.

Temperature monitoring devices

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

External fire

18. 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.

PART 3

MANUFACTURING

Manufacturing procedures

19. 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 in this Part.

Preparation of the component parts

20. Preparation of the component parts (for example 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.

Permanent joining E+W+S

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

(2) 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.

(3) 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 and 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) **[**F141an approved**]** body; or

(b) a recognised third-party organisation.

(4) In order to carry out the approvals referred to above, the third party must perform examinations and tests as set out in the appropriate **[**F142designated**]** standards or equivalent examinations and tests or must have them performed.

Extent Information

E39 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F141 Words in Sch. 2 para. 21(3)(a) substituted (E.W.S.) (9.12.2021) by The Product Safety and Metrology etc. (Amendment) Regulations 2021 (S.I. 2021/1273), regs. 1, **10(b)**

F142 Word in Sch. 2 para. 21(4) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 45(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Permanent joining N.I.

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

(2) 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.

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

(a) a notified body; or

(b) a recognised third-party organisation.

(4) In order to carry out the approvals referred to above, 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.

Extent Information

E105 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Non-destructive tests

22. For pressure equipment, non-destructive tests of permanent joints must be carried out by suitable qualified personnel provided that for pressure equipment in categories III and IV, the personnel must be approved by a recognised third-party organisation.

Heat treatment

23. 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.

Traceability

24. 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.

Final assessment

25. Pressure equipment must be subjected to final assessment in accordance with paragraphs 26 to 28.

Final inspection

26.—(1) Pressure equipment must undergo a final inspection to assess visually and by examination of the accompanying documents compliance with the requirements of these Regulations, for which purpose tests carried out during manufacture may be taken into account.

(2) So 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 (for example where examination during the final inspection is no longer possible).

Proof test

27.—(1) 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 paragraph 40.

(2) For category I series-produced pressure equipment, the test referred to above may be performed on a statistical basis.

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

Inspection of safety devices

28. 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 paragraph 14.

Marking and labelling E+W+S

29.—(1) In addition to the **[**[F143]UK**]** marking referred to in regulation 49 and the information to be provided in accordance with regulations 13(1)(b) and 23(1), the following information must be provided—

(a) for all pressure equipment—

(i) the year of manufacture;

(ii) identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number;

(iii) essential maximum/minimum allowable limits.

(b) depending on the type of pressure equipment, further information necessary for the safe installation, operation or use and, where applicable, maintenance and periodic inspection of the pressure equipment such as:

(i) the volume V of the pressure equipment in L;

(ii) the nominal size for piping DN;

(iii) the test pressure PT applied in bar and date;

(iv) safety device set pressure in bar;

(v) output of the pressure equipment in kW;

(vi) supply voltage in V (volts);

(vii) intended use;

(viii) filling ratio kg/L;

(ix) maximum filling mass in kg;

(x) tare mass in kg;

(xi) the fluid group;

(c) where necessary, warnings fixed to the pressure equipment drawing attention to misuse which experience has shown might occur.

(2) The information referred to in sub-paragraph (1) must be given on the pressure equipment or on a dataplate firmly attached to it, with the following exceptions—

(a) where applicable, appropriate documentation may be used to avoid repetitive marking of individual parts such as piping components, intended for the same assembly;

(b) where the pressure equipment is too small, for example in the case of accessories, this information may be given on a label attached to that pressure equipment;

(c) labelling or other adequate means may be used for the mass to be filled and the warnings referred to in sub-paragraph (1)(c), provided it remains legible for the appropriate period of time.

Extent Information

E40 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

F143 Word in Sch. 2 para. 29(1) substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 45(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

Marking and labelling N.I.

29.—(1) In addition to the CE marking referred to in regulation 49 and the information to be provided in accordance with regulations 13(1)(b) and 23(1), the following information must be provided—

(a) for all pressure equipment—

(i) the year of manufacture;

(ii) identification of the pressure equipment according to its nature, such as type, series or batch identification and serial number;

(iii) essential maximum/minimum allowable limits.

(b) depending on the type of pressure equipment, further information necessary for the safe installation, operation or use and, where applicable, maintenance and periodic inspection of the pressure equipment such as:

(i) the volume V of the pressure equipment in L;

(ii) the nominal size for piping DN;

(iii) the test pressure PT applied in bar and date;

(iv) safety device set pressure in bar;

(v) output of the pressure equipment in kW;

(vi) supply voltage in V (volts);

(vii) intended use;

(viii) filling ratio kg/L;

(ix) maximum filling mass in kg;

(x) tare mass in kg;

(xi) the fluid group;

(c) where necessary, warnings fixed to the pressure equipment drawing attention to misuse which experience has shown might occur.

(2) The information referred to in sub-paragraph (1) must be given on the pressure equipment or on a dataplate firmly attached to it, with the following exceptions—

(a) where applicable, appropriate documentation may be used to avoid repetitive marking of individual parts such as piping components, intended for the same assembly;

(b) where the pressure equipment is too small, for example in the case of accessories, this information may be given on a label attached to that pressure equipment;

(c) labelling or other adequate means may be used for the mass to be filled and the warnings referred to in sub-paragraph (1)(c), provided it remains legible for the appropriate period of time.

Extent Information

E106 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Operating instructions

30.—(1) When pressure equipment is made available on the market, it must be accompanied, as far as relevant, with instructions for the user, containing all the necessary safety information relating to—

(a) mounting including assembling of different pieces of pressure equipment;

(b) putting into service;

(c) use;

(d) maintenance including checks by the user.

(2) Instructions must include information affixed to the pressure equipment in accordance with paragraph 29, 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.

(3) If appropriate, these instructions must also refer to risks arising from misuse in accordance with paragraph 2(3) and particular features of the design in accordance with paragraph 5.

PART 4

MATERIALS

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

(2) Welding consumables and other joining materials need only comply with the relevant requirements of subparagraphs (3), (4)(a) and (5), in an appropriate way, both individually and in a joined structure.

(3) 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—

(i) they must be sufficiently ductile and tough;

(ii) where appropriate, the characteristics of the materials must comply with the requirements of paragraph 41;

(iii) due care must be exercised in particular in selecting materials in order to prevent brittle-type fracture where necessary;

(iv) 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, and in particular the chemical and physical properties necessary for operational safety must not be significantly affected within the scheduled lifetime of the equipment;

(c) not be significantly affected by ageing;

(d) be suitable for the intended processing procedures;

(e) be selected in order to avoid significant undesirable effects when the various materials are put together.

(4) The pressure equipment manufacturer must—

(a) define in an appropriate manner the values necessary for the design calculations referred to in paragraph 5 and the essential characteristics of the materials and their treatment referred to in subparagraph (3);

(b) provide in the technical documentation elements relating to compliance with the materials specifications relating to materials contained in these Regulations in one of the following forms—

(i) by using materials which comply with **[**F144designated**]** standards;

F145(ii) . . . . . .

(iii) by a particular material appraisal.

(5) For pressure equipment in categories III and IV, a specific assessment of the particular material appraisal must be performed by the **[**F146approved**]** body in charge of conformity assessment procedures for the pressure equipment.

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

(7) For the main pressure-bearing parts of equipment in categories II, III and IV, the documentation referred to in sub-paragraph (6) must take the form of a certificate of specific product control.

(8) Where a material manufacturer has an appropriate quality-assurance system, certified by a competent body established **[**F147in the United Kingdom**]** and having undergone a specific assessment for materials, certificates issued by the manufacturer are presumed to certify conformity with the relevant requirements of this paragraph.

PART 5

SPECIFIC PRESSURE EQUIPMENT REQUIREMENTS

32. In addition to the applicable requirements of Parts 1 to 4, the requirements in this Part apply to the pressure equipment covered by paragraphs 33 and 34.

Fired or otherwise heated pressure equipment with a risk of overheating as referred to in regulation 6

33.—(1) The requirements in sub-paragraph (2) apply to fired or otherwise heated pressure equipment with a risk of overheating as referred to in regulation 6, including—

(a) steam and hot-water generators as referred to in regulation 6(b), 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;

(b) process-heating equipment for other than steam and hot water generation falling under regulation 6(a), such as heaters for chemical and other similar processes and pressurised food-processing equipment.

(2) Pressure equipment of the type referred to in sub-paragraph (1) must be calculated, designed and constructed so as to avoid or 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.

Piping as referred to in regulation 6(c)

34. The design and construction of piping referred to in regulation 6(c) must ensure that—

(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 paragraph 11 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 recorded in the technical documentation to facilitate safe maintenance, inspection or repair.

PART 6

SPECIFIC QUANTITATIVE REQUIREMENTS FOR CERTAIN PRESSURE EQUIPMENT

35.—(1) The following provisions apply as a general rule, but where they are not applied, including in cases where materials are not specifically referred to and no **[**[F148]designated**]** standards are applied, the manufacturer must demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.

(2) The provisions laid down in this Part supplement the essential safety requirements of Parts 1 to 5 in relation to the pressure equipment to which they apply.

Allowable stresses

36.—(1) In paragraph 37, the following symbols have the following meanings—

(a) $R_{e/t}$, yield limit, indicates the value at the calculation temperature of—

(i) the upper flow limit for a material presenting upper and lower flow limits,

(ii) the 1.0 % proof strength of austenitic steel and non-alloyed aluminium,

(iii) the 0.2 % proof strength in other cases.

(b) $R_{m/20}$ indicates the minimum value of the ultimate tensile strength at 20°C.

(c) $R_{m/t}$ designates the ultimate tensile strength at the calculation temperature.

37. 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—

(a) in the case of ferritic 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 $R_{m/20}$,

(b) in the case of austenitic steel—

(i) if its elongation after rupture exceeds 30%, $^{2}/_{3}$ of $R_{e/t}$

(ii) or, alternatively, and if its elongation after rupture exceeds 35%, $^{5}/_{6}$ of $R_{e/t}$ and $^{1}/_{3}$ of $R_{m/t}$,

(c) in the case of non-alloy or low-alloy cast steel, $^{10}/_{19}$ of $R_{e/t}$ and $^{1}/_{3}$ of $R_{m/20}$,

(d) in the case of aluminium, $^{2}/_{3}$ of $R_{e/t}$,

(e) in the case of aluminium alloys excluding precipitation hardening alloys $^{2}/_{3}$ of $R_{e/t}$ and $^{5}/_{12}$ of $R_{m/20}$.

Joint coefficients

38.—(1) For welded joints, the joint coefficient must not exceed the following values—

(a) for equipment subject to destructive and non-destructive tests which confirm that the whole series of joints show no significant defects: 1;

(b) for equipment subject to random non-destructive testing: 0.85;

(c) for equipment not subject to non-destructive testing other than visual inspection: 0.7.

(2) If necessary, in addition to the factors referred to in sub-paragraph (1), the type of stress and the mechanical and technological properties of the joint must also be taken into account.

Pressure limiting devices, particularly for pressure vessels

39. The momentary pressure surge referred to in paragraph 16 must be kept to 10% of the maximum allowable pressure.

Hydrostatic test pressure

40. For pressure vessels, the hydrostatic test pressure referred to in paragraph 27 must be no less than whichever is greater of the following—

(a) that corresponding to the maximum loading to which the pressure equipment may be subject in service taking into account its maximum allowable pressure and its maximum allowable temperature, multiplied by the coefficient 1.25;

(b) the maximum allowable pressure multiplied by the coefficient 1.43.

Material characteristics

41. 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 paragraph 31(3)(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 V test-piece is no less than 27 J, at a temperature not greater than 20°C but not higher than the lowest scheduled operating temperature.

SCHEDULE 3 Regulation 10

[F149PART 1]

[F150Classification of pressure equipment][F150Classification of pressure equipment before IP completion day]

F149 Sch. 3 renumbered as Sch. 3 Pt. 1 (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 46(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F150 Sch. 3 Pt. 1 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 46(b)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/852, reg. 4(2), **Sch. 1 para. 1(m)(ix)**); 2020 c. 1, **Sch. 5 para. 1(1)**

1. Pressure equipment referred to in regulation 6 must be classified by category in accordance with Annex II to the Directive (as amended from time to time) according to an ascending level of hazard.

2.—(1) In order to determine the appropriate category for classification of pressure equipment coming within regulation 6(a) to (c), the manufacturer must refer to the following tables within Annex II to the Directive, as amended from time to time—

(a) for pressure equipment coming within—

(i) regulation 6(a)(i)(aa), table 1;

(ii) regulation 6(a)(i)(bb), table 2;

(iii) regulation 6(a)(ii)(aa), table 3;

(iv) regulation 6(a)(ii)(bb), table 4;

(v) regulation 6(b), table 5;

(vi) regulation 6(c)(i)(aa), table 6;

(vii) regulation 6(c)(i)(bb), table 7;

(viii) regulation 6(c)(ii)(aa), table 8;

(ix) regulation 6(c)(ii)(bb), table 9;

(b) for pressure equipment coming within regulation 6(d), the category must be determined in accordance with paragraphs (2) and (3) of Annex II.

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

3. For the purposes of the classification referred to in paragraph (1), fluids shall be divided into the following two groups—

(1) a fluid in Group 1 means—

(a) a substance or mixture—

(i) as defined in Article 2(7) and (8) respectively of the CLP Regulation; and

(ii) that is classified as hazardous in accordance with the following physical or health hazard classes laid down in Parts 2 and 3 of Annex I to the CLP Regulation—

(aa) unstable explosives or explosives of Divisions 1.1, 1.2, 1.3, 1.4 and 1.5;

(bb) flammable gases, categories 1 and 2;

(cc) oxidising gases, category 1;

(dd) flammable liquids, categories 1 and 2;

(ee) flammable liquids, category 3 where the maximum allowable temperature is above the flashpoint;

(ff) flammable solids, categories 1 and 2;

(gg) self-reactive substances and mixtures, types A to F;

(hh) pyrophoric liquids category 1;

(ii) pyrophoric solids, category 1;

(jj) substances and mixtures which in contact with water emit flammable gases, categories 1, 2 and 3;

(kk) oxidising liquids, categories 1, 2 and 3;

(ll) oxidising solids, categories 1, 2 and 3;

(mm) organic peroxides, types A to F;

(nn) acute oral toxicity, categories 1 and 2;

(oo) acute dermal toxicity, categories 1 and 2;

(pp) acute inhalation toxicity, categories 1, 2 and 3;

(qq) specific target organ toxicity – single exposure, category 1; or

(b) a substance or mixture contained in pressure equipment with a maximum allowable temperature TS which exceeds the flashpoint of the fluid;

(2) a fluid in Group 2 means any substance or mixture which is not a substance or mixture within the definition of a fluid in group 1.

4. In this Schedule, "the CLP Regulation" means Regulation (EC) No 1272/2008 of the European Parliament and the Council on classification, labelling and packaging of substances and mixtures [M24].

Marginal Citations

M24 OL L 353, 31.12.2008.

[F151PART 2

Classification of pressure equipment immediately on or after IP completion day

F151 Sch. 3 Pt. 2 inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 46(c)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), **2** and S.I. 2020/852, reg. 4(2), **Sch. 1 para. 1(m)(x)**); 2020 c. 1, **Sch. 5 para. 1(1)**

5. Pressure equipment referred to in regulation 6 (pressure equipment and assemblies subject to essential safety requirements) must be classified by category in accordance with Schedule 1B (conformity assessment tables) to these Regulations according to an ascending level of hazard.

6.—(1) In order to determine the appropriate category for classification of pressure equipment coming within regulations 6(a) to (c), the manufacturer must refer to the following tables within Schedule 1B to these Regulations—

(a) for pressure equipment coming within—

(i) regulation 6(a)(i)(aa), table 1;

(ii) regulation 6(a)(i) (bb), table 2;

(iii) regulation 6(a)(ii)(aa), table 3;

(iv) regulation 6(a)(ii)(bb), table 4;

(v) regulation 6(b), table 5;

(vi) regulation 6(c)(i)(aa), table 6;

(vii) regulation 6(c)(i)(bb), table 7;

(viii) regulation 6(c)(ii)(aa), table 8;

(ix) regulation 6(c)(ii)(bb), table 9;

(b) for pressure equipment coming within regulation 6(d), the category must be determined in accordance with paragraphs 2 and 3 of Schedule 1B to these Regulations.

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

7. For the purposes of the classification referred to in paragraph (5), fluids shall be divided up into the following groups—

(a) group 1 consisting of substances and mixtures, as defined in points 7 and 8 of Article 2 of Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EEC, and amending Regulation (EC) No 1907/2006, that are classified as hazardous in accordance with the following physical or health hazard classes laid down in Parts 2 and 3 of Annex 1 to that Regulation—

(i) unstable explosives or explosives of Divisions 1.1. 1.2. 1.3, 1.4 and 1.5;

(ii) flammable gases, category 1 and 2;

(iii) oxidising gases, category 1;

(iv) flammable liquids, categories 1 and 2;

(v) flammable liquids, category 3 where the maximum allowable temperature is above the flashpoint;

(vi) flammable solids, category 1 and 2;

(vii) self-reactive substances and mixtures, type A to F;

(viii) pyrophoric liquids, category 1;

(ix) pyrophoric solids, category 1;

(x) oxidising liquids, category 1, 2 and 3;

(xi) substances and mixtures which in contact with water emit flammable gases, category 1, 2 and 3;

(xii) oxidising liquids, category 1, 2 and 3;

(xiii) oxidising solids, category 1, 2 and 3;

(xiv) organic peroxides types A to F;

(xv) acute oral toxicity, category 1 and 2;

(xvi) acute dermal toxicity, category 1, 2 and 3;

(xvii) acute inhalation toxicity, category 1, 2 and 3;

(xviii) specific target organ toxicity – single exposure, category 1;

Group 1 also comprises substances and mixtures contained in pressure equipment with a maximum allowable temperature TS which exceeds the flashpoint of the fluid;

(b) group 2 consisting of substances and mixtures not referred to in point (a).

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

SCHEDULE 4

Regulation 2(1), 56(3)

[F152Notified**][**F152Approved**]** body requirements

F152 Word in Sch. 4 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 47(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. [F153An approved body**]** or recognised third party organisation must meet the requirements for conformity assessment bodies set out in this Schedule.

2. A conformity assessment body must be established in the United Kingdom and have legal personality.

3. A conformity assessment body must be a third party body independent of the organisation or the pressure equipment it assesses.

4.—(1) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of pressure equipment or assemblies, nor the representative of any of those parties.

(2) Subparagraph (1) does not preclude the use of pressure equipment or assemblies that are necessary for the operations of the conformity assessment body or the use of pressure equipment for personal purposes.

5. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of pressure equipment or assemblies, or represent the parties engaged in those activities.

6. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not engage in activity that may conflict with their independence of judgment or integrity in relation to conformity assessment activities for which they are **[**F154approved**]** (including consultancy services).

7. A conformity assessment body must ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

8. A conformity assessment body and its personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in those activities.

9. A conformity assessment body must be capable of carrying out all of the conformity assessment activities for which it has been authorised, whether those activities are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

10. A conformity assessment body must have at its disposal—

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures, and have appropriate policies and procedures in place that distinguish between tasks it carries out as **[**F153an approved body**]** and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the process.

11. A conformity assessment body must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to the necessary equipment or facilities.

12. The personnel responsible for carrying out conformity assessment activities must have—

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been **[**F154approved**]**;

(b) satisfactory knowledge of the requirements of the assessments which the personnel carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential safety requirements, of the applicable **[**F155designated standards**]** of these Regulations; and

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

13. A conformity assessment body must be able to demonstrate the impartiality of its top level management and the personnel responsible for carrying out the conformity assessment activities.

14. The remuneration of the top level management and the personnel responsible for carrying out the conformity assessment activities must not depend on the number of assessments carried out or on the results of those assessments.

15. A conformity assessment body must have, and must satisfy the Secretary of State that it has, adequate civil liability insurance in respect of its activities.

16. A conformity assessment body must ensure that its personnel observe professional secrecy with regard to all information obtained in carrying out their tasks in accordance with these Regulations and that proprietary rights are protected.

17. Paragraph 16 does not prevent the personnel from providing information to the Secretary of State or an enforcing authority.

18. A conformity assessment body must participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of any **[**F154approved**]** body coordination group F156... and

must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

SCHEDULE 5

Regulation 2(1), 58(3)

User inspectorate requirements

1. A user inspectorate must be established in the United Kingdom and have legal personality.

2. A user inspectorate must be organisationally identifiable and have reporting methods within the group of which it is part which can demonstrate its impartiality.

3.—(1) A user inspectorate, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the pressure equipment or assembly which they assess, nor the authorised representative of any of those parties.

(2) Subparagraph (1) does not preclude the use of pressure equipment or assemblies that are necessary for the operations of the user inspectorate or the use of pressure equipment for personal purposes.

4. A user inspectorate, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that pressure equipment or assembly, or represent the parties engaged in those activities.

5. A user inspectorate, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not engage in activity that may conflict with their independence of judgment or integrity in relation to conformity assessment activities for which they are notified (including consultancy services).

6. A user inspectorate and its personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

7. A user inspectorate must be capable of carrying out all of the conformity assessment tasks in respect of which it has been notified, whether those tasks are carried out by the user inspectorate itself or on its behalf and under its responsibility.

8. A user inspectorate must have at its disposal at all times and for each conformity assessment procedure and each kind or category of pressure equipment in relation to which it has been notified—

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures, and have appropriate policies and procedures in place that distinguish between tasks it carries out as a user inspectorate and other activities; and

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

9. A user inspectorate must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to all necessary equipment or facilities.

10. The personnel responsible for carrying out conformity assessment tasks must have—

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments which the personnel carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential safety requirements, of the applicable **[**F157designated**]** standards and F158... of these Regulations; and

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

11. A user inspectorate must be able to demonstrate the impartiality of its top level management and the personnel responsible for carrying out the conformity assessment activities. User inspectorates must not engage in any activities that might conflict with their independence of judgment and integrity in relation to their inspection activities.

12. The remuneration of the top level management and the personnel responsible for carrying out the conformity assessment tasks must not depend on the number of assessments carried out or on the results of those assessments.

13. Unless liability is assumed by the group of which it is part, a user inspectorate must have, and must satisfy the Secretary of State that it has, adequate civil liability insurance in respect of its activities. If liability is assumed by the group of which the user inspectorate is part, the user inspectorate must satisfy the Secretary of State that that group has adequate civil liability insurance in respect of those activities.

14. A user inspectorate must ensure that its personnel observe professional secrecy with regard to all information obtained in carrying out their tasks in accordance with these Regulations and that proprietary rights are protected.

15. Paragraph 14 does not prevent the personnel from providing information to the Secretary of State.

16. A user inspectorate must participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of any **[**F159approved**]** body coordination group F160... and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

SCHEDULE 6

Regulation 64(1)

Operational obligations of **[**F161notified**]****[**F161approved**]** bodies, recognised third party organisations and user inspectorates

F161 Words in Sch. 6 heading substituted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 49(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

1. **[**[F162]An approved body**]**, recognised third party organisation or user inspectorate must carry out conformity assessments in accordance with the relevant conformity assessment procedures.

2. **[**[F162]An approved body**]**, recognised third party organisation or user inspectorate must carry out conformity assessments in a proportionate manner, avoiding unnecessary burdens on economic operators.

3. **[**[F162]An approved body**]**, recognised third party organisation or user inspectorate must perform its activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

4. **[**[F162]An approved body**]**, recognised third party organisation or user inspectorate must respect the degree of rigour and the level of protection required to ensure that the pressure equipment is in conformity with the requirements of these Regulations.

5. Where **[**[F162]an approved body**]**, recognised third party organisation or user inspectorate finds that essential safety requirements or corresponding **[**[F163]designated**]** standards or other technical specifications have not been met by a manufacturer, it must require the manufacturer to take appropriate corrective measures and must not issue a certificate of conformity or grant an approval.

6. Where, in the course of the monitoring of conformity following the issue of a certificate or grant of an approval, **[**[F162]an approved body**]**, recognised third party organisation or user inspectorate finds that pressure equipment or an assembly is no longer in conformity with the essential safety requirements, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the certificate of conformity or approval if necessary.

7. Where the **[**[F164]approved**]** body, recognised third party organisation or user inspectorate has required a manufacturer to take corrective measures and the manufacturer has failed to take such measures, or those measures have not had the required effect, the **[**[F164]approved**]** body must restrict, suspend or withdraw any certificate of conformity or approval.

8. Paragraph 9 applies where **[**[F162]an approved body**]**, recognised third party organisation or user inspectorate is minded to—

(a) refuse to issue a certificate of conformity or grant an approval; or

(b) restrict, suspend or withdraw a certificate of conformity or approval.

9. Where this paragraph applies, the **[**[F164]approved**]** body, recognised third party organisation or user inspectorate must—

(a) give the person applying for the certificate or approval, or the person to whom the certificate or approval was given, a notice in writing giving reasons and specifying the date on which the refusal, restriction, suspension or withdrawal is intended to take effect;

(b) give the person applying for the certificate or approval, or the person to whom the certificate or approval was given, an opportunity to make representations within a reasonable period from the date of the notice; and

(c) take account of any such representations before taking its decision.

10. **[**[F162]An approved body**]**, recognised third party organisation or user inspectorate must inform the Secretary of State of—

(a) any refusal, restriction, suspension or withdrawal of a certificate of conformity or approval;

(b) any circumstances affecting the scope of, or conditions for, notification under regulation 55 (notification);

(c) any request for information which it has received from an enforcing authority regarding conformity assessment activities; and

(d) on request, conformity assessment activities performed within the scope of its notification under regulation 55 and any other activity performed, including cross-border activities and subcontracting.

11. **[**[F162]An approved body**]**, recognised third party organisation or user inspectorate must make provision in its contracts with its clients enabling such clients to appeal against a decision—

(a) to refuse to issue a certificate of conformity or grant an approval; or

(b) to restrict, suspend or withdraw a certificate of conformity or approval.

12. **[**[F162]An approved body**]**, recognised third party organisation or user inspectorate must provide other **[**[F165]other approved bodies**]** carrying out similar conformity assessment activities covering the same pressure equipment and assemblies with relevant information on issues relating to negative and, on request, positive conformity assessment results.

13. **[**[F162]An approved body**]**, recognised third party organisation or user inspectorate must participate in the work of any **[**[F164]approved**]** body coordination group **[**[F166]established by the Secretary of State**]**, directly or by means of its designated representatives.

SCHEDULE 7

Regulation 68(1)

Enforcement powers of weights and measures authorities, district councils and the Secretary of State under the 1987 Act

Enforcement powers under the 1987 Act

1. For the purposes of enforcing these Regulations, the following sections of the 1987 Act apply subject to the modifications in paragraph 2—

(a) section 13 (prohibition notices and notices to warn);

(b) section 14 (suspension notices);

(c) section 16 (forfeiture: England and Wales and Northern Ireland);

(d) section 17 (forfeiture: Scotland);

(e) section 18 (power to obtain information);

(f) section 19 (interpretation of Part II);

(g) section 29 (powers of search etc);

(h) section 30 (provisions supplemental to s 29);

(i) section 31 (powers of customs officer to detain goods);

(j) section 33 (appeals against detention of goods);

(k) section 34 (compensation for seizure and detention);

(l) section 35 (recovery of expenses of enforcement);

(m) section 37 (power of Commissioners for Revenue and Customs to disclose information);

(n) section 45 (interpretation);

(o) section 46(1) (meaning of "supply");

(p) Schedule 2 (prohibition notices and notices to warn).

Modifications to the 1987 Act

2. The sections of the 1987 Act referred to in paragraph 1 are to apply as if—

(a) in section 13—

(i) in subsection (1), for "unsafe" on each occasion that it appears, there were substituted " non-compliant ";

(ii) in subsection (1), "relevant" were omitted on each occasion that it appears;

(iii) in subsection (2), the words from "; and the Secretary of State may" to the end were omitted;

(iv) subsections (4) to (7) were omitted;

(b) in section 14—

(i) in subsection (1), after "any safety provision has been contravened in relation to any goods", there were inserted " or that such goods present a risk ";

(ii) in subsection (2(b), after "safety provision has been contravened in relation to the goods", there were inserted " or that such goods present a risk ";

(iii) in subsection (2)(c), "under section 15 below" were omitted;

(iv) subsections (6) to (8) were omitted;

(c) in section 16—

(i) in subsection (1), after "a contravention in relation to the goods of a safety provision" there were inserted " or that such goods present a risk ";

(ii) for subsection (2)(b) there were substituted—

(iii) "(b) where an application with respect to some or all of the goods has been made to a magistrates' court under regulation 84 (appeals against notices) of the 2016 Regulations, or section 33, to that court; and";

(iv) in subsection (3), after "a contravention in relation to the goods of a safety provision" there were inserted " or that such goods present a risk ";

(v) after subsection (4), there were inserted—

"(4A) A court may infer for the purposes of this section that any goods present a risk, if it is satisfied that such a risk is presented by goods which are representative of those goods (whether by reason of being of the same design or part of the same consignment or batch or otherwise).";

(vi) in subsection (6), the words "Subject to subsection (7) below," were omitted; and

(vii) subsection (7) were omitted;

(d) in section 17—

(i) in subsection (1), after "a contravention of a safety provision", there were inserted " or where the goods present a risk ";

(ii) in subsection (6), after "a contravention in relation to those goods of a safety provision" there were inserted " or that those goods present a risk ";

(iii) after subsection (7), there were inserted—

"(7A) (The Sheriff may infer for the purposes of this section that any goods present a risk, if satisfied that such a risk is presented by goods which are representative of those goods (whether by reason of being of the same design or part of the same consignment or batch or otherwise).";

(e) in section 18, subsections (3) and (4) were omitted;

(f) in section 29—

(i) in subsection (4)(a), after "any contravention of any safety provision in relation to the goods" there were inserted " or whether the goods present a risk ";

(ii) in subsection (4)(b), after "any such contravention" there were inserted " or whether the goods present a risk ";

(g) in section 30—

(i) at the end of subsection (2)(a)(ii), for "and" there were substituted " or ";

(ii) after subsection (2)(a)(ii), there were inserted—

"(iii) that any goods which any officer has power to inspect under section 29 are on any premises and their inspection is likely to demonstrate that they present a risk; and"; and

(iii) subsections (5), (7) and (8) were omitted;

(h) in section 31(1), for "Part II of this Act", there were substituted " the 2016 Regulations ";

(i) in section 34—

(i) the word "and" at the end of subsection (1)(a) were omitted; and

(ii) after that subsection, there were inserted—

"(aa) the goods do not present a risk; and";

(j) in section 37(1), for "Part II of this Act", there were substituted " the 2016 Regulations ";

(k) in section 45(1)—

(i) the definitions of "conditional sale agreement", "gas", "motor vehicle", "personal injury", "subordinate legislation" and "substance" were omitted;

(ii) before the definition of "aircraft", there were inserted—

""the 2016 Regulations" means the Pressure Equipment (Safety) Regulations 2016";

(iii) for the definition of "enforcement authority" there were substituted—

""enforcement authority" means an enforcing authority as defined in regulation 2(1) of the 2016 Regulations;";

(iv) for the definition of "goods" there were substituted—

""goods" means pressure equipment and assemblies within the scope of the 2016 Regulations;";

(v) after the definition of "modifications" there were inserted—

""non-compliant" in relation to any goods means that—

(a) a safety provision has been contravened in relation to the goods; or

(b) the goods present a risk;";

(vi) after the definition of "premises", there were inserted—

""present a risk" means present a risk within the meaning set out in regulation 2(4) of the 2016 Regulations;";

(vii) for the definition of "safety provision" there were substituted—

""safety provision" means any provision of the 2016 Regulations"; and

(viii) for the definition of "safety regulations" there were inserted—

""safety regulations" means the 2016 Regulations;";

(l) in section 46(1), the words "and, in relation to gas or water, those references shall be construed as including references to providing the service by which the gas or water is made available for use" were omitted; and

(m) in Schedule 2—

(i) for "unsafe", on each occasion that it appears, there were substituted " non-compliant "; and

(ii) for "safe", on each occasion that it appears, there were substituted " not non-compliant ".

SCHEDULE 8

Regulation 68(2)

Enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act

Enforcement powers under the 1974 Act

1. For the purposes of enforcing these Regulations and RAMS (in its application to pressure equipment and assemblies), the following sections of the 1974 Act apply subject to the modifications in paragraph 2—

(a) section 19 (appointment of inspectors);

(b) section 20 (powers of inspectors);

(c) section 21 (improvement notices);

(d) section 22 (prohibition notices);

(e) section 23 (provisions supplementary to sections 21 and 22);

(f) section 24 (appeal against improvement or prohibition notice);

(g) section 25 (power to deal with cause of imminent danger);

(h) section 25A (power of customs officer to detain articles and substances);

(i) section 26 (power of enforcing authorities to indemnify their inspectors);

(j) section 27 (obtaining of information by the Commission, the Executive, enforcing authorities etc);

(k) section 27A (information communicated by Commissioners for Revenue and Customs);

(l) section 28 (restrictions on disclosure of information);

(m) section 33 (offences);

(n) section 34 (extension of time for bringing summary proceedings);

(o) section 35 (venue);

(p) section 39 (prosecutions by inspectors);

(q) section 41 (evidence); and

(r) section 42 (power of court to order cause of offence to be remedied or, in certain cases, forfeiture).

Modifications to the 1974 Act

2. The sections of the 1974 Act referred to in paragraph 1 apply as if—

(a) references to "the relevant statutory provisions" were references to—

(i) the provisions of the 1974 Act set out in paragraph 1, as modified by this paragraph; and

(ii) these Regulations;

(b) references to "risk" were references to "risk" within the meaning of regulation 2(4) of these Regulations;

(c) in regulation 19—

(i) in subsection (1)—

(aa) for "Every enforcing authority" there were substituted " The Health and Safety Executive and the Office for Nuclear Regulation ";

(bb) for references to "it" there were substituted " they ";

(cc) for "thinks" there were substituted " think "

(dd) "within its field of responsibility" were omitted;

(ii) in subsection (2), paragraph (b) were omitted;

(iii) in subsection (3), for "enforcing authority which appointed him" there were substituted " Health and Safety Executive or the Office for Nuclear Regulation as the case may be ";

(d) in section 20—

(i) in subsection (1), "within the field of responsibility of the enforcing authority which appointed him" were omitted;

(ii) in subsection (2)(c)(i), for "his (the inspector's) enforcing authority" there were substituted " the Health and Safety Executive or the Office for Nuclear Regulation as the case may be ";

(iii) in subsection (2)(h), for "him to have caused or to be likely to cause danger to health and safety", there were substituted " contravene the relevant statutory provisions or present a risk "; and

(iv) subsection (3) were omitted;

(e) in section 21–

(i) before paragraph (a), there were inserted—

"(za) is making available on the market pressure equipment or an assembly which presents a risk;";

(ii) after "specifying the", there were inserted " risk, or "; and

(iii) after "requiring that person to", there were inserted " address the risk or ";

(f) for section 22(2) there were substituted—

"(2) An inspector may serve a notice (in this Part referred to as "a prohibition notice") on a person if, as regards any activities to which this section applies, the inspector is of the opinion that, as carried on or likely to be carried on by or under the control of the person in question, the activities involve or, as the case may be, will involve—

(a) a risk; or

(b) a contravention of a relevant statutory provision.";

(g) in section 23, subsections (3), (4) and (6) were omitted;

(h) for section 25A(1) there were substituted—

"(1) A customs officer may, for the purposes of facilitating the exercise or performance by the Health and Safety Executive, the Office for Nuclear Regulation or an inspector (as the case may be), of any of their powers and duties under any of the relevant statutory provisions, seize any imported article or imported substance and retain it for not more than two working days."

(i) for the heading to section 26, there were substituted " Power to indemnify inspectors ";

(j) in section 26, for each of the following references there were substituted " the body "

(i) "the enforcing authority";

(ii) "that authority"; and

(iii) "the authority";

(k) in section 27—

(i) for "Executive", on each occasion that it appears, there were substituted " Health and Safety Executive or the Office for Nuclear Regulation as the case may be ";

(ii) in subsection (1), paragraph (b) were omitted; and

(iii) in subsection (1), "or, as the case may be, to the enforcing authority in question" were omitted;

(l) for section 27A(2) there were substituted—

"(2) This subsection applies to the Health and Safety Executive, the Office for Nuclear Regulation and to an inspector.";

(m) in section 28—

(i) for "Executive", on each occasion that it appears, there were substituted " Health and Safety Executive ";

(ii) in subsection (1)(a), ", other than the Office for Nuclear Regulation (or an inspector appointed by it," and ", by virtue of section 43A(6) below" were omitted;

(iii) in subsection (3)(a), "or any enforcing authority" were omitted;

(iv) in subsection (4), "or an enforcing authority" and "or authority (including, in the case of an enforcing authority, any inspector appointed by it)" were omitted; and

(v) in subsection (5)(a), "or the purposes of the enforcing authority in question in connection with the relevant statutory provisions" were omitted; and

(vi) in subsection (7), "14(4)(a) or" were omitted;

(vii) for subsection (7)(b), there were substituted—

"(b) for the purposes of any legal proceedings or for the purposes of a report of any such proceedings;"; and

(viii) subsection (9B) were omitted.

(n) in section 33—

(i) in subsection (1), paragraphs (a) to (i) and (k) to (m) were omitted;

(ii) for subsection (2), there were substituted—

"(2) A person guilty of an offence under this section is liable—

(a) on summary conviction–

(i) in England and Wales, to a fine or imprisonment for a term not exceeding three months, or to both;

(ii) in Scotland, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding three months, or to both;

(b) on conviction on indictment to a fine or imprisonment for a term not exceeding two years, or to both."; and

(o) section 33(3) were omitted.

(p) in section 34—

(i) in subsection (1), paragraphs (a) and (b) were omitted; and

(ii) in subsection (1), for the words from "and it appears" to the end, there were substituted " and it appears from the investigation or, in a case falling within paragraph (d), from the proceedings at the inquiry, that any of the relevant statutory provisions was contravened at a time which is material in relation to the subject-matter of the investigation or inquiry, summary proceedings against any person liable to be proceeded against in respect of the contravention may be commenced at any time within three months of the conclusion of the investigation or inquiry. "; and

(iii) subsections (3) to (6) were omitted;

(q) in section 35, for "any enforcing authority", there were substituted " the Health and Safety Executive or the Office for Nuclear Regulation as the case may be ";

(r) in section 39(1), for "enforcing authority" there were substituted " Health and Safety Executive or the Office for Nuclear Regulation as the case may be "; and

(s) in section 42, subsections (3A), (4) and (5) were omitted.

SCHEDULE 9

Regulation 68(3)

Enforcement powers of the Health and Safety Executive for Northern Ireland under the 1978 Order

Enforcement powers under the 1978 Order

1. For the purposes of enforcing these Regulations and RAMS (in its application to pressure equipment or assemblies), the following Articles of the 1978 Order apply subject to the modifications in paragraph 2—

(a) Article 21 (appointment of inspectors);

(b) Article 22 (powers of inspectors);

(c) Article 23 (improvement notices);

(d) Article 24 (prohibition notices);

(e) Article 25 (provisions supplementary to Articles 23 and 24);

(f) Article 26 (appeal against improvement or prohibition notice);

(g) Article 27 (power to deal with cause of imminent danger);

(h) Article 27A (power of customs officer to detain articles and substances);

(i) Article 28 (power of enforcing authorities to indemnify inspectors);

(j) Article 29 (obtaining of information by the Executive, enforcing authorities etc);

(k) Article 29A (information communicated by Commissioners for Revenue and Customs);

(l) Article 30 (restrictions on disclosure of information);

(m) Article 31 (offences);

(n) Article 32 (extension of time for bringing summary proceedings);

(o) Article 33 (venue);

(p) Article 36 (prosecution by inspectors);

(q) Article 38 (evidence); and

(r) Article 39 (power of court to order cause of offence to be remedied and, in certain cases, forfeiture).

Modifications to the 1978 Order

2. The Articles of the 1978 Order referred to in paragraph 1 apply as if—

(a) references to "the relevant statutory provisions" were references to—

(i) the provisions of the 1978 Order set out in paragraph 1, as modified by this paragraph; and

(ii) these Regulations;

[F167(aa) references to "risk" were references to "risk" within the meaning of regulation 2(4) of these Regulations;**]**

(b) for the following references, there were substituted " the Health and Safety Executive for Northern Ireland "

(i) in Article 21(1), "Every enforcing authority";

[F168(ii) in Article 36, "the enforcing authority";**]**

(iii) in Article 22(2)(c)(i), "his (the inspector's) enforcing authority";

(iv) in Articles 27A(1), "any enforcing authority" and 29A(2), "an enforcing authority";

F169(v) . . . . . .

(vi) in Articles 29 and 30, "the Executive";

(c) in Article 21—

(i) in paragraph (1), "within its field of responsibility" were omitted;

(ii) in paragraph (2), sub-paragraph (b) were omitted;

(iii) in paragraph (3), for "enforcing authority which appointed him" there were substituted " Health and Safety Executive for Northern Ireland ";

(d) in Article 22(1), "within the field of responsibility of the enforcing authority which appointed him" were omitted;

[F170(da) in Article 22(2)(h), for "him to have caused or to be likely to cause danger to health or safety" there were substituted "contravene the relevant statutory provisions or present a risk";**]**

(e) Article 22(3) were omitted;

[F171(ea) in Article 23—

(i) before paragraph (a), there were inserted—

"(za) is making available on the market pressure equipment or an assembly which presents a risk";

(ii) in sub-paragraph (ii), after "specifying the", there were inserted "risk, or"; and

(iii) in sub-paragraph (iv), after "requiring that person to", there were inserted "address the risk or";**]**

[F172(f) for Article 24(2) and (3) there were substituted—

"(2) An inspector may serve a notice (in this Part referred to as a "prohibition notice") on a person if, as regards any activities to which this paragraph applies, the inspector is of the opinion that, as carried on or likely to be carried on by or under the control of the person in question, the activities involve or, as the case may be, will involve—

(a) a risk; or

(b) the contravention of a relevant statutory provision.

(3) A prohibition notice must—

(a) state that the inspector is of the said opinion;

(b) specify the matters which in his opinion give or, as the case may be, will give rise to the said risk;

(c) where in his opinion any of those matters involves or, as the case may be, will involve a contravention of any of the relevant statutory provisions, state that he is of the opinion, specify the provision or provisions as to which he is of that opinion, and give particulars of the reasons why he is of that opinion; and

(d) direct that the activities to which the notice relates must not be carried on by or under the control of the person on whom the notice is served unless the matters specified in the notice in pursuance of sub-paragraph (b) and any associated contraventions of provisions so specified in pursuance of sub-paragraph (c) have been remedied."**]**

(g) in Article 25, paragraphs (3), (4) and (5) were omitted;

(h) in Article 28, for "the enforcing authority which appointed him", "that authority" and "the authority", there were, in each case, substituted " the Health and Safety Executive for Northern Ireland ";

[F173(i) in Article 29—

(i) for paragraph 1(b) there were substituted—

"(b) any information which the Health and Safety Executive for Northern Ireland needs for the discharge of its functions;";

(ii) "the Department concerned, or" and "or as the case may be, to the enforcing authority in question" were omitted;**]**

(j) in Article 30—

(i) in paragraph (3), "or any enforcing authority" were omitted;

[F174(ii) in paragraph (4), "or an enforcing authority" and "or authority (including, in the case of an enforcing authority, any inspector appointed by it)" were omitted;**]**

(iii) in paragraph (5), "or the purposes of the enforcing authority in question" were omitted;

[F175(iv) in paragraph (6), "16(4)(a) or" were omitted;

(v) for paragraph (6)(b), there were substituted—

"(b) for the purposes of any legal proceedings or for the purposes of a report of any such proceedings;"**]**

(k) in Article 31(1), the following subparagraphs were omitted—

(i) sub-paragraphs (a) to (i); and

(ii) sub-paragraphs (k) to (m);

[F176(l) for Article 31(2), there were substituted—

"(2) A person guilty of an offence under this Article is liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum or imprisonment for a term not exceeding three months, or to both;

(b) on conviction on indictment, to a fine or imprisonment for a term not exceeding two years, or to both;"**]**

(n) Article 31(3) were omitted;

(o) In Article 32—

(i) in paragraph (1), sub-paragraphs (a) and (b) were omitted;

(ii) paragraphs (3) and (4) were omitted;

[[F177](p) in Article 33, for "any enforcing authority", there were substituted "the Health and Safety Executive for Northern Ireland"; and**]**

(q) in Article 39, paragraphs (3A), (4) and (5) were omitted.

F167 Sch. 9 para. 2(aa) inserted (1.10.2018) by The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), regs. 1(1), **4(2)(a)** (with reg. 1(2)-(4))

F168 Sch. 9 para. 2(b)(ii) substituted (1.10.2018) by The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), regs. 1(1), **4(2)(b)(i)** (with reg. 1(2)-(4))

F169 Sch. 9 para. 2(b)(v) omitted (1.10.2018) by virtue of The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), regs. 1(1), **4(2)(b)(ii)** (with reg. 1(2)-(4))

F170 Sch. 9 para. 2(da) inserted (1.10.2018) by The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), regs. 1(1), **4(2)(c)** (with reg. 1(2)-(4))

F171 Sch. 9 para. 2(ea) inserted (1.10.2018) by The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), regs. 1(1), **4(2)(d)** (with reg. 1(2)-(4))

F172 Sch. 9 para. 2(f) substituted (1.10.2018) by The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), regs. 1(1), **4(2)(e)** (with reg. 1(2)-(4))

F173 Sch. 9 para. 2(i) substituted (1.10.2018) by The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), regs. 1(1), **4(2)(f)** (with reg. 1(2)-(4))

F174 Sch. 9 para. 2(j)(ii) substituted (1.10.2018) by The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), regs. 1(1), **4(2)(g)(i)** (with reg. 1(2)-(4))

F175 Sch. 9 para. 2(j)(iv)(v) inserted (1.10.2018) by The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), regs. 1(1), **4(2)(g)(ii)** (with reg. 1(2)-(4))

F176 Sch. 9 para. 2(l) substituted for Sch. 9 para. 2(l)(m) (1.10.2018) by The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), **regs. 1(1)**, 4(2)(h) (with reg. 1(2)-(4))

F177 Sch. 9 para. 2(p) substituted (1.10.2018) by The Simple Pressure Vessels, Electrical Equipment and Pressure Equipment (Miscellaneous Amendments) (Northern Ireland) Regulations 2018 (S.I. 2018/966), regs. 1(1), **4(2)(i)** (with reg. 1(2)-(4))

SCHEDULE 10

Regulation 68(4)

Compliance, withdrawal and recall notices

Compliance notice

1.—(1) An enforcing authority may serve a compliance notice on a relevant economic operator in respect of pressure equipment or an assembly if the authority has reasonable grounds for believing that there is non-compliance with the requirements of these Regulations.

(2) A compliance notice must—

(a) require the relevant economic operator on which it is served to—

(i) end the non-compliance within such period as may be specified in the notice;

(ii) provide evidence, within such period as may be specified in the notice, demonstrating to the satisfaction of the enforcing authority that the non-compliance has not in fact occurred;

(b) warn the economic operator that, if the non-compliance persists or if satisfactory evidence has not been produced under sub-paragraph (a) within the period specified in the notice, further action may be taken in respect of the pressure equipment or assembly or any pressure equipment or assembly of the same type made available on the market by that relevant economic operator.

(3) A compliance notice may include directions as to the measures to be taken by the economic operator to secure compliance, including different ways of securing compliance.

(4) Subject to sub-paragraph (5), an enforcing authority may revoke or vary a compliance notice by serving a notification on the economic operator.

(5) An enforcing authority may not vary a compliance notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Withdrawal notice

2.—(1) An enforcing authority may serve a withdrawal notice on a relevant economic operator in respect of pressure equipment or an assembly if the authority has reasonable grounds for believing that—

(a) the pressure equipment or assembly has been made available on the market; and

(b) either of the following conditions are met—

(i) the pressure equipment or assembly presents a risk; or

(ii) the pressure equipment or assembly is not in conformity with the requirements of these Regulations or RAMS (in its application to pressure equipment or assemblies).

(2) A withdrawal notice must prohibit the relevant economic operator from making the pressure equipment or assembly available on the market without the consent of the enforcing authority.

(3) A withdrawal notice may require the relevant economic operator to take action to alert end-users to any risk presented by the pressure equipment or assembly.

(4) A withdrawal notice may require the relevant economic operator to keep the enforcing authority informed of the whereabouts of any pressure equipment or assembly referred to in the notice.

(5) A consent given by the enforcing authority pursuant to a withdrawal notice may impose such conditions on the making available on the market as the enforcing authority considers appropriate.

(6) Subject to paragraph (7), an enforcing authority may revoke or vary a compliance notice by serving a notification on the economic operator.

(7) An enforcing authority may not vary a compliance notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Recall notice

3.—(1) The enforcing authority may serve a recall notice on a relevant economic operator in respect of pressure equipment or an assembly if the authority has reasonable grounds for believing that—

(a) the pressure equipment or assembly has been made available to end-users; and

(b) either of the following conditions are met—

(i) the pressure equipment or assembly presents a risk;

(ii) the pressure equipment or assembly is not in conformity with the requirements of these Regulations or RAMS (in its application to pressure equipment or assemblies).

(2) A recall notice must require the relevant economic operator to use reasonable endeavours to organise the return of the pressure equipment or assembly from end-users to the relevant economic operator or another person specified in the notice.

(3) A recall notice may—

(a) require the recall to be effected in accordance with a code of practice;

(b) require the relevant economic operator to—

(i) contact end-users in order to inform them of the recall, to the extent that it is practicable to do so;

(ii) publish a notice in such form and manner as is likely to bring to the attention of end-users any risk the pressure equipment or assembly poses and the fact of the recall;

(iii) make arrangements for the collection or return of the pressure equipment or assembly from end-users or its disposal;

(c) impose such additional requirements on the relevant economic operator as are reasonable and practicable with a view to achieving the return of the pressure equipment or assembly.

(4) In determining what requirements to include in a recall notice, the enforcing authority must take into consideration the need to encourage distributors and end-users to contribute to its implementation.

(5) A recall notice may only be issued by the enforcing authority where—

(a) other action which it may require under these Regulations would not suffice to address the non-compliance;

(b) the action being undertaken by the relevant economic operator in fulfilment of the requirements of these Regulations is unsatisfactory or insufficient to address the non-compliance;

(c) the enforcing authority has given not less than ten days' notice to the relevant economic operator of its intention to serve such a notice; and

(d) the enforcing authority has taken account of any advice obtained under sub-paragraph (6).

(6) A relevant economic operator which has received notice from the enforcing authority of an intention to serve a recall notice may at any time prior to the service of the recall notice require the authority to seek the advice of such person as the Institute determines on the questions of—

(a) whether there is non-compliance; and

(b) whether the issue of a recall notice would be proportionate.

(7) Sub-paragraphs (5)(b), (c) and (d) do not apply in the case of pressure equipment or assemblies presenting a serious risk requiring, in the view of the enforcing authority, urgent action.

(8) Where a relevant economic operator requires the enforcing authority to seek advice under subparagraph (6), that relevant economic operator is to be responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute to advise the enforcing authority.

(9) In this regulation, "Institute" means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

(10) A recall notice served by the enforcing authority may require the relevant economic operator to keep the authority informed of the whereabouts of the pressure equipment or assembly to which the recall notice relates, so far as the relevant economic operator is able to do so.

(11) Subject to paragraph (12), an enforcing authority may revoke or vary a compliance notice by serving a notification on the economic operator.

(12) An enforcing authority may not vary a compliance notice so as to make it more restrictive for the economic operator or more onerous for the economic operator to comply.

Interpretation

4. In this Schedule, "non-compliance" means that pressure equipment—

(a) presents a risk; or

(b) is not in conformity with the requirements of these Regulations or RAMS (in its application to pressure equipment or assemblies).

SCHEDULE 11

Regulation 48(c)

[F178EU] Declaration of Conformity

F178 Word in Sch. 11 omitted (E.W.S.) (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 50(a)** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

F178... Declaration of conformity (No xxxx) M25 E+W+S

1. Pressure equipment or assembly (product, type, batch or serial number):

Extent Information

E63 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Marginal Citations

M25 It is optional for the manufacturer to assign a number to the declaration of conformity.

EU declaration of conformity (No xxxx) F266 N.I.

1. Pressure equipment or assembly (product, type, batch or serial number):

Extent Information

E129 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

F266 It is optional for the manufacturer to assign a number to the declaration of conformity.

2. Name and address of the manufacturer and, where applicable, his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (identification of pressure equipment or assembly allowing traceability; it may, where necessary for the identification of the pressure equipment or assembly, include an image):

(a) Description of the pressure equipment or assembly;

(b) Conformity assessment procedure followed;

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

5. The object of the declaration described above is in conformity with the relevant **[**F179statutory requirements**]**:

6. References to the relevant **[**F180designated**]** standards used or references to the other technical specifications in relation to which conformity is declared:

7. Where appropriate, the name, address and number of the **[**F181approved**]** body which carried out the conformity assessment and the number of the certificate issued, and a reference to the EU-type examination certificate – production type, EU-type examination certificate – design type, F178... design examination certificate or certificate of conformity.

8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

(where appropriate, particulars of the signatory authorised to sign the legally binding declaration for the manufacturer or his authorised representative):

SCHEDULE 12

Regulation 91

Consequential amendments and revocations

Amendment of the Provision and Use of Work Equipment Regulations 1998

1. In Schedule 1 to the Provision and Use of Work Equipment Regulations 1998 M26 omit the entry "The Pressure Equipment Regulations 1999" and in the appropriate place insert " The Pressure Equipment (Safety) Regulations 2016 ".

Marginal Citations

M26 S.I. 1998/2306.

Amendment of the Provision and Use of Equipment at Work Regulations (Northern Ireland) 1999

2. In Schedule 1 to the Provision and Use of Equipment at Work Regulations (Northern Ireland) 1999 [M27] omit the entry "The Pressure Equipment Regulations 1999" and in the appropriate place insert " The Pressure Equipment (Safety) Regulations 2016 ".

Marginal Citations
M27 S.R. 1999/305.

Amendment of the Pressure Systems Safety Regulations 2000

3.—(1) The Pressure Systems Safety Regulations 2000 [M28] are amended as follows.

(2) For regulation 14(1)(c) substitute the following—

"(c) instructions specified in paragraph 30 of Schedule 2 to the Pressure Equipment (Safety) Regulations 2016, and provided pursuant to regulation 14 or 24 of those Regulations."

(3) In Schedule 1, for subparagraph (1)(b) substitute—

"(b) pressure equipment or assemblies within the meaning of the Pressure Equipment (Safety) Regulations 2016 to which regulation 6, 7 or 8 of those Regulations applies."

Marginal Citations
M28 S.I. 2000/128.

Amendment of the Pressure Systems Safety Regulations (Northern Ireland) 2004

4.—(1) The Pressure Systems Safety Regulations (Northern Ireland) 2004 [M29] are amended as follows.

(2) For regulation 14(1)(c) substitute the following—

"(c) instructions specified in paragraph 30 of Schedule 2 to the Pressure Equipment (Safety) Regulations 2016 and provided pursuant to regulation 14 or 24 of those Regulations."

(3) In Schedule 1, Part II, for sub-paragraph 1(b) substitute " pressure equipment or assemblies within the meaning of the Pressure Equipment (Safety) Regulations 2016 to which regulation 6, 7 or 8 of those Regulations applies. "

Marginal Citations
M29 S.R. 2004/222.

Amendment of the Enterprise Act 2002 (Part 9 Restrictions on Disclosure of Information) (Specification) Order 2004

5.—(1) The Enterprise Act 2002 (Part 9 Restrictions on Disclosure of Information)(Specification) Order 2004 [M30] is amended as follows.

(2) In Schedule 1, omit the entry "Pressure Equipment Regulations 1999" and in the appropriate place insert " The Pressure Equipment (Safety) Regulations 2016 ".

(3) In Schedule 2, omit the entry in respect of Pressure Equipment Regulations 1999.

Marginal Citations

M30 S.I. 2004/693.

Amendment of the Legislative and Regulatory Reform (Regulatory Functions) Order 2007

6.—(1) The Legislative and Regulatory Reform (Regulatory Functions) Order 2007 [M31] is amended as follows.

(2) In Part 3 of the Schedule, under the heading "Public Health and Safety", omit the entry "The Pressure Equipment Regulations 1999" and in the appropriate place insert " The Pressure Equipment (Safety) Regulations 2016 ";

(3) In Part 8 of the Schedule, omit the entry "The Pressure Equipment Regulations 1999" and in the appropriate place insert " The Pressure Equipment (Safety) Regulations 2016 "; and

(4) In Part 13 of the Schedule, omit the entry "The Pressure Equipment Regulations 1999" and in the appropriate place insert " The Pressure Equipment (Safety) Regulations 2016 ".

Marginal Citations

M31 S.I. 2007/3544.

Amendment of the Legislative Reform (Health and Safety Executive) Order 2008

7. In Schedule 3 to the Legislative Reform (Health and Safety Executive) Order 2008, omit the entry referring to the Pressure Equipment Regulations 1999.

Amendment of the Supply of Machinery (Safety) Regulations 2008

8. In Schedule 7 to the Supply of Machinery (Safety) Regulations 2008, omit the entry at paragraph 3 referring to the Pressure Equipment Regulations 1999.

Amendment of the Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order 2009

9.—(1) The Co-ordination of Regulatory Enforcement (Regulatory Functions in Scotland and Northern Ireland) Order 2009 [M32] is amended as follows.

(2) In Part 4 of Schedule 1, omit the entry "The Pressure Equipment Regulations 1999" and after the last entry insert " The Pressure Equipment (Safety) Regulations 2016 ";

(3) In Part 2 of Schedule 2, omit the entry "The Pressure Equipment Regulations 1999" and after the last entry insert " The Pressure Equipment (Safety) Regulations 2016 ".

Marginal Citations

M32 S.I. 2009/669.

Amendment of the Fluorinated Greenhouse Gases Regulations 2015

10. In regulation 25(11)(c)(iii) of the Fluorinated Greenhouse Gases Regulations 2015 [M33] for "the Pressure Equipment Regulations 1999" substitute " the Pressure Equipment (Safety) Regulations 2016 ".

Marginal Citations
M33 S.I. 2015/310.

Amendment of the Fluorinated Greenhouse Gases Regulations (Northern Ireland) 2015

11. In regulation 23(11)(c)(iii) of the Fluorinated Greenhouse Gases Regulations (Northern Ireland) 2015 [M34] for "the Pressure Equipment Regulations 1999" substitute " the Pressure Equipment (Safety) Regulations 2016 ".

Marginal Citations
M34 S.R. 2015/425.

Amendment of the Consumer Rights Act 2015

12. Subject to regulation 90(3), in paragraph 10 of Schedule 5 to the Consumer Rights Act 2015 [M35]—

(a) omit the entry "paragraph 2(a) or 3(3)(a) of Schedule 8 to the Pressure Equipment Regulations 1999 (SI 1999/2001);", and

(b) at the appropriate place insert—

"regulation 67(1) or (2) of the Pressure Equipment (Safety) Regulations 2016 (S.I. 2016/1105);".

Marginal Citations
M35 2015 c.15.

EXPLANATORY NOTE

(This note is not part of these Regulations)
These Regulations transpose Directive 2014/68/EU of the European Parliament and of the Council of 15thMay 2014 on the harmonisation of the laws of member States relating to the making available on the market of pressure equipment (recast) (OJ No L 189, 27.6.2014 p164) ("the Directive").
The Directive repeals and replaces Directive 1997/23/EC of the European Parliament and of the Council of 29thMay 1997 relating to pressure equipment (OJ L 181, 9.7.1997, p.1) which

was implemented in the United Kingdom by the Pressure Equipment Regulations 1999 (S.I. 1999/2001) (as amended). These Regulations revoke and replace S.I. 1999/2001.
Article 13 of the Directive (classification of pressure equipment) was required to be implemented by 28th February 2015 and was transposed by S.I. 2015/399 which amended S.I. 1999/2001. That amendment has been incorporated into these Regulations.
Regulation 3 sets out the application of the Regulations to pressure equipment and assemblies as defined in Regulation 2. Regulation 4 introduces Schedule 1 which sets out exceptions to the application of the Regulations for certain types of equipment and for equipment covered by certain other EU legislation. Regulation 5 sets out an exception for the showing of pressure equipment at trade fairs, exhibitions and demonstrations. Regulations 6 and 7 detail the types of pressure equipment and assemblies of pressure equipment which must comply with the essential safety requirements of the Directive, and regulation 8 details the pressure equipment and assemblies, generally for lower temperatures or pressures, which must comply with sound engineering practice.
Part 2 sets out the obligations of economic operators. Regulations 9 to 19 set out the obligations that are specific to manufacturers. Manufacturers must ensure that pressure equipment or assemblies coming within regulation 6 or 7 comply with the essential safety requirements of the Directive set out in Schedule 2, and must classify the equipment and carry out the relevant conformity assessment procedure before the vessel is placed on the market, affixing the CE marking, labelling the equipment and ensuring it is accompanied by instructions and safety information. More limited obligations apply to pressure equipment and assemblies coming within regulation 8. Manufacturers must also take monitor pressure equipment and assemblies and take corrective action if it is found not to be in conformity with the requirements of these Regulations. Regulation 19 refers to authorised representatives who may be appointed by manufacturers to perform certain tasks on their behalf.
Regulations 20 to 29 set out the obligations that are specific to importers. These obligations include ensuring that they are not placing on the market pressure equipment or assemblies which are not in conformity with the essential safety requirements, checking that the manufacturer has carried out a relevant conformity assessment procedure and labelled the equipment correctly and indicating on the equipment the name and address of the importer.
Regulations 30 to 36 set out the obligations that are specific to distributors. These obligations include acting with due care to ensure that pressure equipment and assemblies are in conformity with Part 2 and checking that the equipment bears the CE marking and are labelled correctly. They also include an obligation to ensure that, while it is the distributor's responsibility, the storage and transport of pressure equipment does not jeopardise its conformity with the essential safety requirements.
Regulations 37 to 39 set out obligations which apply to all economic operators. These obligations include making sure, before making pressure equipment or assemblies available on the market, that the EU declaration of conformity is in English. They also include an obligation to identify other economic operators in the supply chain, and a prohibition on the improper use of the CE marking.
Part 3 sets out provisions concerning the conformity assessment procedure, declaration of conformity and CE marking for pressure equipment and assemblies coming within Regulation 6 or 7. It also sets out provisions for the issuing of European approval for materials.
Part 4 sets out provisions concerning notification and monitoring of the bodies which carry out conformity assessment procedures under the Regulations.
Part 5 sets out provisions for market surveillance and enforcement of these Regulations. Regulation 66 identifies the market surveillance authority which has an obligation to enforce the Regulations. Regulation 68 and Schedules 7 to 9 provide for the enforcement powers which the enforcing authorities are to have. Regulation 76 provides for the contravention of certain provisions of these Regulations to be an offence. Regulation 77 sets out the penalties that are to apply for offences under these Regulations. Regulation 84 sets out provision for appeals against notices served under these Regulations.

Part 6 sets out a review provision, transitional provisions, revocations and savings and introduces Schedule 12 (consequential amendments).
A transposition note and full impact assessment of the impact that these Regulations will have on the costs of business, the voluntary sector and the public sector are available from the Single Market Product Safety Team, Department for Business, Energy and Industrial Strategy, 1 Victoria Street, London SW1H 0ET and are also published with the Explanatory Memorandum alongside these Regulations on www.legislation.gov.uk.

Changes to legislation:
There are currently no known outstanding effects for the The Pressure Equipment (Safety) Regulations 2016.