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;

[[F1](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—

[[F2](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 [M1]; 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 [M2].

[[F3](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.**]**

[[F4](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;

[[F5](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.

[[F6]SCHEDULE 1A

Regulations 10 and 42

Conformity Assessment Procedures for Pressure Equipment and Assemblies

Textual Amendments

F6 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.**]**

[F7SCHEDULE 1B

Regulation 3

Conformity Assessment Tables

Textual Amendments

F7 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;

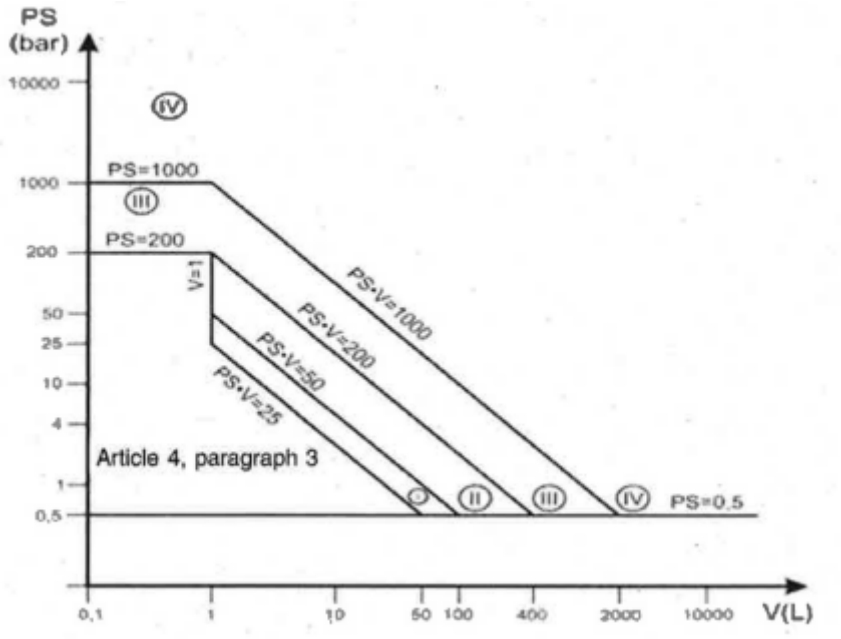
(c) the group of fluids for which they are intended.

(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.

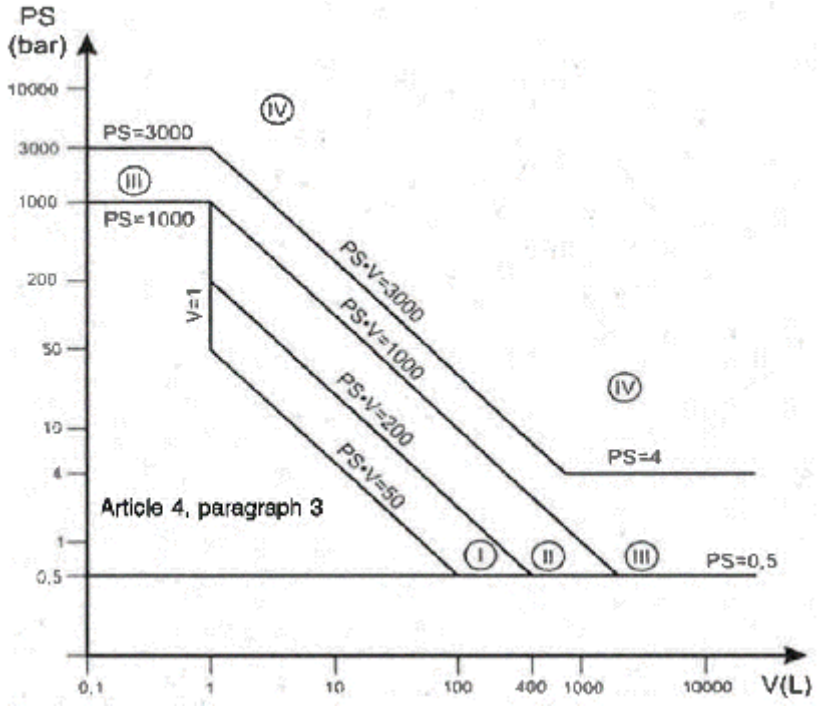
4.—(1) The demarcation lines in the following conformity assessment tables indicate the upper limit for each category.

(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



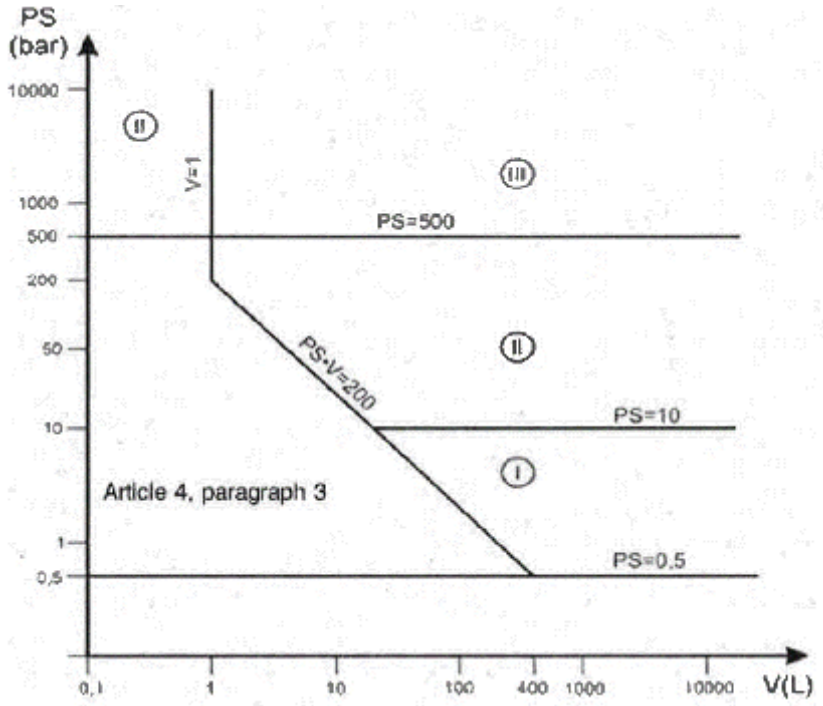
(ii) Exceptionally, vessels intended to contain an unstable gas and falling within categories I or II on the basis of table 1 shall be classified in category III.

(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

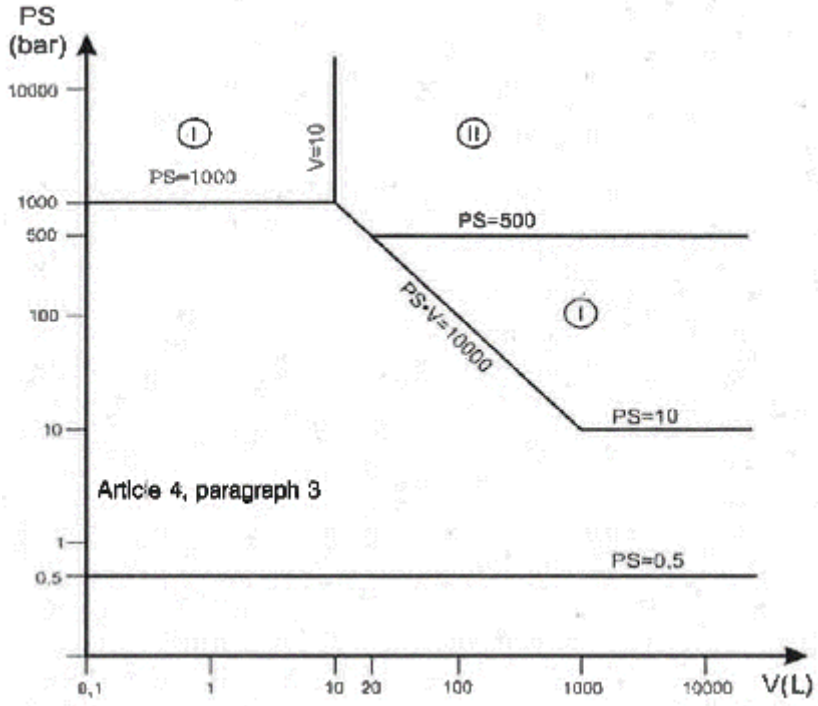


(ii) Exceptionally, portable extinguishers and bottles for breathing equipment shall be classified at least in category III.

(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



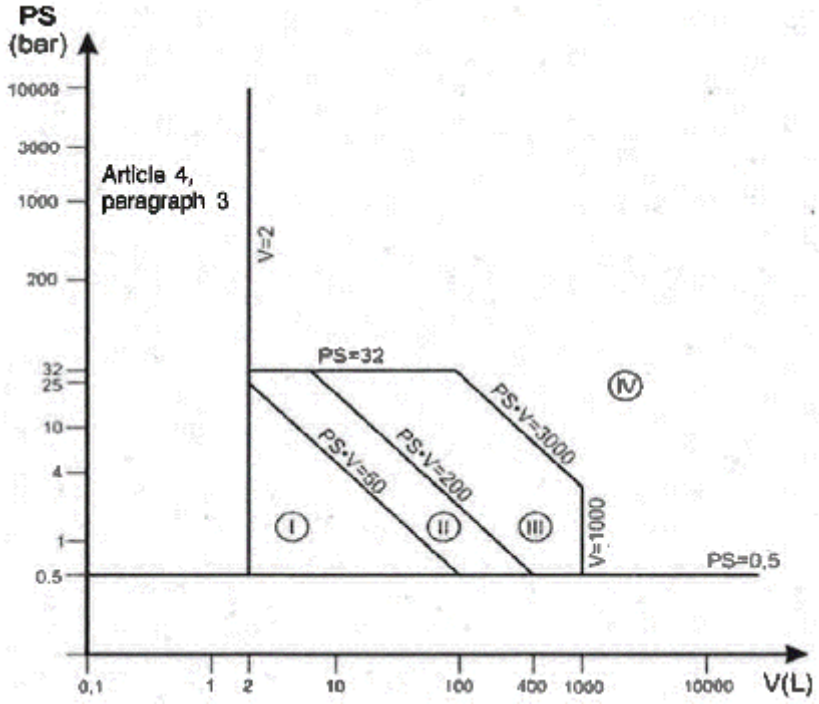
(d) (i) Table 4: Vessels for liquids having a vapour pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure (1013 mbar) and, for fluids in Group 2 with a pressure PS greater than 10 bar and a product of PS and V greater than 10000 bar.L, or with a pressure 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

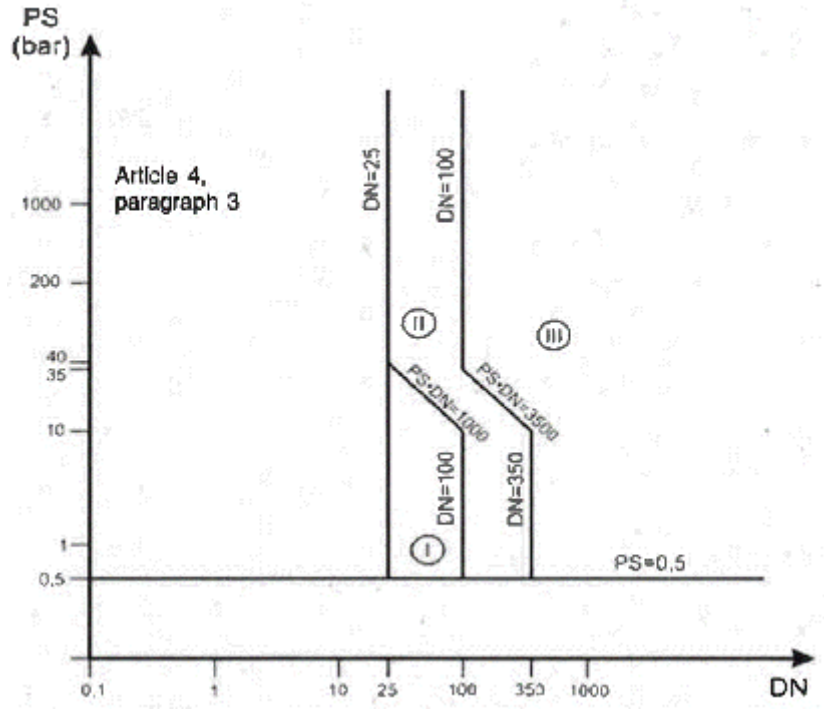
their conformity with the essential requirements referred to in paragraphs 14, 15, 16, 17 and 30 and subparagraphs 33(2)(a) and (d) of Schedule 2 to these Regulations, or to full quality assurance (Module H).

(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



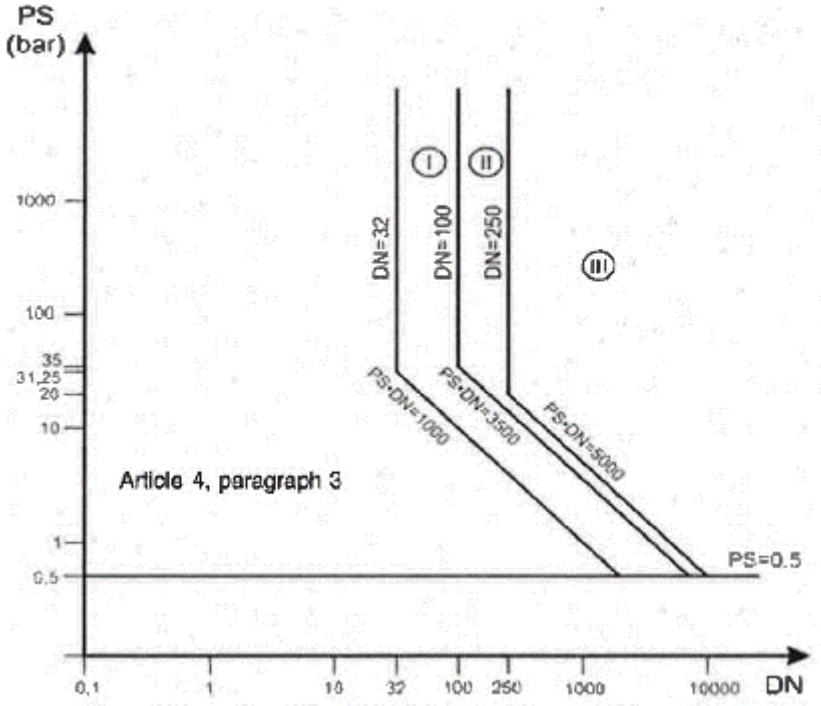
(ii) Exceptionally, the design of pressure-cookers shall be subject to a conformity assessment procedure equivalent to at least one of the category III modules.

(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



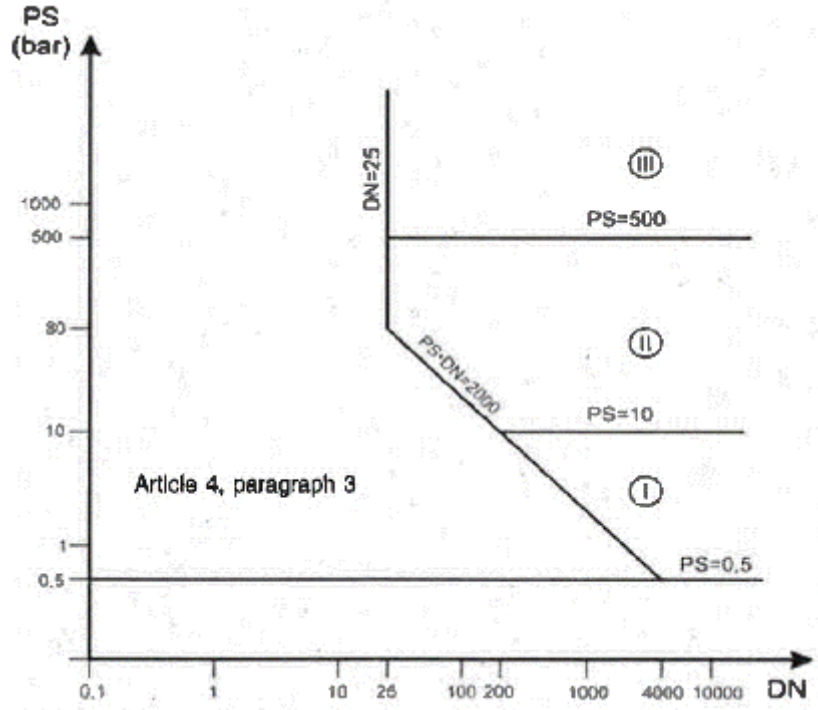
(ii) Exceptionally, piping intended for unstable gases and falling within categories I or II on the basis of Table 6 shall be classified in category III.

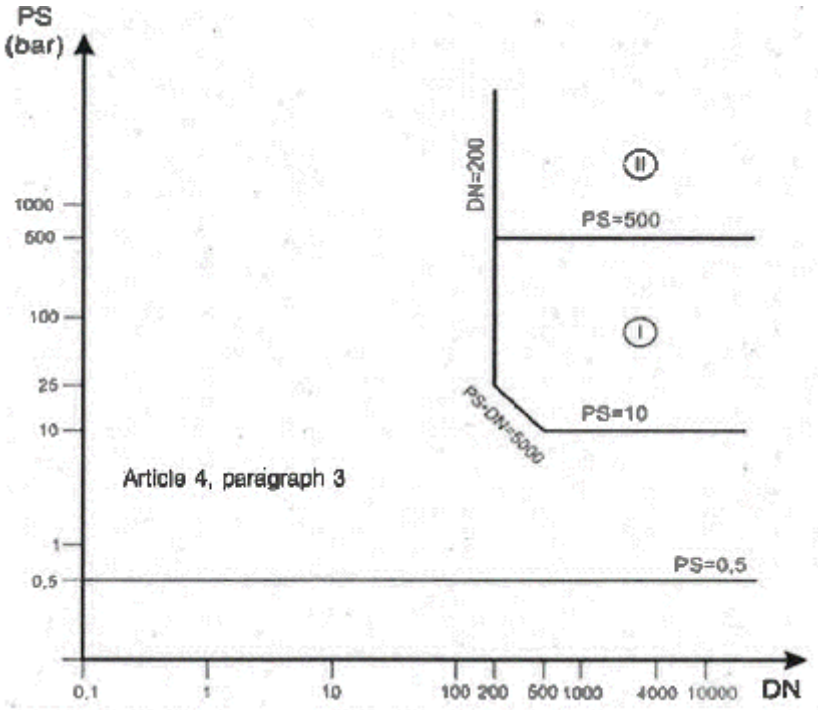
(g) (i) Table 7: Piping intended for gases, liquefied gases, gases dissolved under pressure, vapours and those liquids whose vapour pressure at the maximum allowable temperature is greater than 0.5 bar above normal atmospheric pressure (1013 mbar), and for fluids in Group 2 with a DN greater than 32 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 **[**[F8]approved**]** 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

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

Textual Amendments

F8 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

E32 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) **[**F9an 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 **[**F10designated**]** standards or equivalent examinations and tests or must have them performed.

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

Textual Amendments

F9 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)**

F10 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

E33 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 **[**[F11]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

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

Textual Amendments

F11 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

E34 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 **[**F12designated**]** standards;

F13(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 **[**F14approved**]** 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 **[**F15in 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 **[**[F16]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

[F17PART 1]

[F18Classification of pressure equipment][F18Classification of pressure equipment before IP completion day]

Textual Amendments

F17 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)

F18 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 [M3].

Marginal Citations

M3 OL L 353, 31.12.2008.

[F19PART 2

Classification of pressure equipment immediately on or after IP completion day

Textual Amendments

F19 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)

[[F20]Notified**][**[F20]Approved**]** body requirements

Textual Amendments

F20 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. [[F21]An 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 **[**F22approved**]** (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 **[**F21an 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 **[**F22approved**]**;

(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 **[**F23designated 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 **[**F22approved**]** body coordination group F24... 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 **[**F25designated**]** standards and F26... 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 **[**F27approved**]** body coordination group F28... 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 [F29notified][F29approved] bodies, recognised third party organisations and user inspectorates

Textual Amendments

F29 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. [F30An approved body], recognised third party organisation or user inspectorate must carry out conformity assessments in accordance with the relevant conformity assessment procedures.

2. [F30An 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. [F30An 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. [F30An 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 [F30an approved body], recognised third party organisation or user inspectorate finds that essential safety requirements or corresponding [F31designated] 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, [F30an 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 [F32approved] 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 [F32approved] body must restrict, suspend or withdraw any certificate of conformity or approval.

8. Paragraph 9 applies where [F30an 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 **[**F32approved**]** 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. [F30An 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. [F30An 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. [F30An approved body**]**, recognised third party organisation or user inspectorate must provide other **[**F33other 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. [F30An approved body**]**, recognised third party organisation or user inspectorate must participate in the work of any **[**F32approved**]** body coordination group **[**F34established 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;

[F35(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";

[F36(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";

F37(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;

[[F38](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;

[[F39](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";**]**

[[F40](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 ";

[[F41](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;

[F42(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;

[F43(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);

[F44(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;

[F45(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.

Textual Amendments

F35 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))

F36 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))

F37 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))

F38 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))

F39 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))

F40 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))

F41 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))

F42 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))

F43 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))

F44 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))

F45 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)

[F46EU] Declaration of Conformity

Textual Amendments

F46 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)

[F46]... Declaration of conformity (No xxxx) [M4] E+W+S

1. Pressure equipment or assembly (product, type, batch or serial number):

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

Marginal Citations

M4 It is optional for the manufacturer to assign a number to the declaration of conformity.

EU declaration of conformity (No xxxx) [F64] N.I.

1. Pressure equipment or assembly (product, type, batch or serial number):

Extent Information

E57 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F64 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 **[**[F47]statutory requirements**]**:

6. References to the relevant **[**[F48]designated**]** 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 **[**[F49]approved**]** 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, [F46]... 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 [M5] omit the entry "The Pressure Equipment Regulations 1999" and in the appropriate place insert " The Pressure Equipment (Safety) Regulations 2016 ".

Marginal Citations

M5 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 [M6] omit the entry "The Pressure Equipment Regulations 1999" and in the appropriate place insert " The Pressure Equipment (Safety) Regulations 2016 ".

Marginal Citations

M6 S.R. 1999/305.

Amendment of the Pressure Systems Safety Regulations 2000

3.—(1) The Pressure Systems Safety Regulations 2000 [M7] 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

M7 S.I. 2000/128.

Amendment of the Pressure Systems Safety Regulations (Northern Ireland) 2004

4.—(1) The Pressure Systems Safety Regulations (Northern Ireland) 2004 [M8] 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

M8 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 [M9] 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

M9 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 [M10] 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

M10 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 [M11] 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
M11 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 [M12] for "the Pressure Equipment Regulations 1999" substitute " the Pressure Equipment (Safety) Regulations 2016 ".

Marginal Citations
M12 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 [M13] for "the Pressure Equipment Regulations 1999" substitute " the Pressure Equipment (Safety) Regulations 2016 ".

Marginal Citations
M13 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 [M14]—

(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

M14 2015 c.15.

Changes to legislation:
There are currently no known outstanding effects for the The Pressure Equipment (Safety) Regulations 2016.