SCHEDULE 24 Regulation 27

Amendment of the Pressure Equipment (Safety) Regulations 2016

Introduction

1. The Pressure Equipment (Safety) Regulations 2016 are amended in accordance with paragraphs 2 to 50.

Amendment to regulation 2

2.—(1) Regulation 2 (interpretation) is amended as follows.

(2) In paragraph (1)—

(a) omit the definition of "accreditation";

(b) omit the definition of "accreditation certificate";

(c) for the definition of "authorised representative" substitute—

""authorised representative" means—

(a) a person who—

(i) immediately before exit day was established in the United Kingdom or an EEA state and was appointed by a manufacturer by written mandate to perform specified tasks for that manufacturer, in accordance with regulation 19, as it had effect immediately before exit day; and

(ii) on or after exit day continues to be so established and appointed by the manufacturer to perform those tasks; or

(b) a person who, on or after exit day, is established in the United Kingdom and appointed in accordance with regulation 19;";

(d) omit the definition of "Commission";

(e) for the definition of "conformity assessment procedure" substitute—

""conformity assessment procedure" means a procedure for conformity assessment set out in Schedule 1A;";

(f) after the definition of "conformity assessment procedure" insert—

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

"designated standard" has the meaning given to it in regulation 2A;";

(g) in the definition of "the Directive", at the end insert "(as it has effect immediately before exit day)";

(h) omit the definition of "EU declaration of conformity";

(i) omit the definition of "European approval for materials";

(j) omit the definition of "harmonised standard";

(k) for the definition of "importer" substitute—

""importer" means a person who—

(a) is established in the United Kingdom; and

(b) places pressure equipment of an assembly from a country outside of the United Kingdom on the market;";

(l) in the definition of "make available on the market" for "EU" substitute "United Kingdom";

(m) omit the definition of "national accreditation body";

(n) omit the definition of "Official Journal";

(o) in the definition of "place on the market", for "EU" substitute "United Kingdom";

(p) after the definition of "technical specification" insert—

""UK marking" means the marking in the form published in accordance with Article 30(1) of RAMS;".

(3) Omit paragraphs (5) and (7).

Insertion of paragraph 2A

3. After regulation 2 (interpretation) insert—

"**Designated standard**

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

(a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and

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

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

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

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

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

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

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

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

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

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

(d) the British Standards Institution (BSI).

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

(5) Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other standardisation organisations.

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

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

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

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

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

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

Amendment to regulation 8

4. In regulation 8 (requirement for pressure equipment and assemblies to comply with sound engineering practice)—

(a) in paragraph (2)(a) for "the sound engineering practice of a Member State" substitute "sound engineering practice"; and

(b) for paragraph (3) substitute—

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

Insertion of Regulation 8A

5. After regulation 8 insert—

"**Power to reclassify pressure equipment and assemblies**

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

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

(3) Regulations made under paragraph (1)—

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

(b) include power—

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

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

Amendment to regulation 10

6. In regulation 10 (technical documentation and conformity assessment)—

(a) in paragraph (2) for "Annex III to the Directive (as amended from time to time)", substitute "Schedule 1A to these regulations"; and

(b) for "EU-type" in each place where it occurs, substitute "Type".

Amendment to regulation 11

7. In regulation 11 (EU declaration of conformity and CE marking)—

(a) in the heading—

(i) for "EU declaration", substitute "Declaration"; and

(ii) for "CE" substitute "UK";

(b) in paragraph (1)(a), omit "EU";

(c) in paragraph (1)(b), for "CE" substitute "UK";

(d) in paragraph (3), omit "EU";

(e) for paragraph (4), substitute—

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

Amendment to regulation 12

8. In regulation 12 (duty to keep technical documentation and EU declaration of conformity) and in the heading omit "EU".

Amendment to regulation 13

9. In regulation 13 (labelling of pressure equipment and assemblies), for paragraph (3) substitute—

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

Amendment to regulation 14

10. In regulation 14 (instructions and safety information)—

(a) in paragraphs (1) and (3), for "in a language which can be easily understood by consumers and other users" substitute "that are clear, legible and in easily understandable English";

(b) omit paragraphs (4) and (5).

Amendment to regulation 15

11. In regulation 15 (compliance procedures for series production), in paragraph (2)(b)—

(a) for "harmonised" substitute "designated"; and

(b) omit "EU".

Amendment to regulation 17

12. In regulation 17 (duty to take action in respect of pressure equipment or assemblies placed on the market which are considered not to be in conformity), in paragraph (2), omit ",and the competent national authorities of any other member State in which the manufacturer made the pressure equipment or assembly available on the market,".

Amendment to regulation 19

13. In regulation 19 (manufacturer's authorised representatives), in paragraph (2)(a), omit "EU".

Amendment to regulation 21

14. In regulation 21 (requirements which must be satisfied before an importer places pressure equipment or assemblies on the market), in paragraph (1)(c)(i), for "CE" substitute "UK".

Amendment to regulation 23

15. In regulation 23 (information identifying importer)—

(a) in paragraph (2), omit from "in the member State" to the end of the paragraph; and

(b) for paragraph (3) substitute—

"(3) Paragraph (1) does not apply where—

(a) either—

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

(ii) the importer has imported the pressure equipment from an EEA state and places it on the market within the period of eighteen months beginning with exit day, and

(b) before placing the pressure equipment on the market, the importer sets out the information referred to in paragraph (1) in a document accompanying the pressure equipment.".

Amendment to regulation 24

16. In regulation 24 (instructions and safety information)—

(a) in paragraphs (1) and (3), for "in a language which can be easily understood by consumers and other users", substitute "that are clear, legible and in easily understandable English"; and

(b) omit paragraph (4).

Amendment to regulation 27

17. In regulation 27 (duty to take action in respect of pressure equipment or assemblies placed on the market considered not to be in conformity), in paragraph (2), omit "of any other member State in which the importer made the pressure equipment or assembly available on the market".

Amendment to regulation 28

18. In regulation 28 (retention of technical documentation and EU declaration of conformity), in the heading and in paragraph (a), omit "EU".

Amendment to regulation 29

19. In regulation 29 (provision of information and cooperation), in paragraph (3)(b), for "must be in a language which can be easily understood by the enforcing authority", substitute "must be clear, legible and in easily understandable English".

Amendment to regulation 31

20. In regulation 31 (requirements which must be satisfied before a distributor makes pressure equipment or assemblies available on the market)—

(a) in paragraphs (1)(a)(i) and (2)(d) for "CE", substitute "UK";

(b) for paragraph (1)(a)(iii), substitute "is accompanied by instructions and safety information that are clear, legible and in easily understandable English";

(c) omit paragraph (3).

Amendment to regulation 34

21. In regulation 34 (duty to take action in respect of pressure equipment made available on the market which are not in conformity), in paragraph (2), omit "of the member States in which the distributor has made the pressure equipment or assembly available on the market".

Amendment to regulation 35

22. In regulation 35 (provision of information and cooperation), in paragraph (2)(b), for "must be in a language which can clearly be understood by the enforcing authority", substitute "must be clear, legible and in easily understandable English".

Amendment to regulation 37

23. In regulation 37 (translation of EU declaration of conformity)—

(a) in the heading to that regulation, and in paragraph (1), omit "EU";

(b) in paragraph (1), for "prepared in, or translated into, the language required by the member State in which it is to be made available on the market" substitute "in English"; and

(c) omit paragraph (2).

Amendment to regulation 39

24. In regulation 39 (prohibition on improper use of CE marking), and in its heading, for "CE" substitute "UK" in every place in which it occurs.

Insertion of regulations 39A and 39B

25. After regulation 39 (prohibition on improper use of CE marking), insert—

"**Obligations which are met by complying with the obligations in the Directive**

39A.—(1) In this regulation—

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

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

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

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

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

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

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

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

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

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

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

(3) Where this paragraph applies—

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

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

(c) Part 3 does not apply;

(d) regulation 74 does not apply.

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

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

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

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

(5) Where this paragraph applies—

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

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

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

(7) Where this paragraph applies—

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

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

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

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

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

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

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

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

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

38B.—(1) In this regulation any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive.

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

(3) Where this paragraph applies—

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

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

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

Amendment to regulation 40

26. In regulation 40 (presumption of conformity)—

(a) in paragraph (1)—

(i) for "harmonised", substitute "designated"; and

(ii) omit "the reference to which has been published in the Official Journal";

(b) omit paragraph (2);

(c) for paragraph (3) substitute—

"(3) The presumption in paragraph (1) is rebuttable.".

Amendment to regulation 42

27. In regulation 42 (conformity assessment procedures), in paragraph (1) for "Annex III to the Directive (as amended from time to time)", substitute "Schedule 1A to these Regulations".

Insertion of regulation 42A

28. After regulation 42 insert—

"**Power to amend applicable module**

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

(2) Regulations made under paragraph (1)—

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

(b) include power—

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

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

Amendment to regulation 43

29. In regulation 43, in paragraph (4), for "Annex III to the Directive (as amended from time to time)", substitute "Schedule 1A to these Regulations".

Amendment to regulation 45

30. In regulation 45 (conformity assessment procedures), in paragraph (a), for "CE", substitute "UK".

Amendment to regulation 47

31. For regulation 47 (conformity assessment procedures), substitute—

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

Amendment to regulation 48

32. In regulation 48 (EU declaration of conformity)—

(a) in the heading and in the opening words of the regulation, omit "EU"; and

(b) in paragraph (b), for "Annex III to the Directive (as amended from time to time)", substitute "Schedule 1A to these Regulations".

Amendment to regulation 49

33. In regulation 49 (CE marking)—

(a) in the heading and in each place in which it occurs, for "CE" substitute "UK";

(b) in each place in which it occurs for "notified" substitute "approved".

Omission of regulation 50

34. Omit regulation 50 (European approval for materials).

Substitution of Part 4

35. For Part 4 substitute—

"PART 4

Approval of Conformity Assessment Bodies

Approved bodies

51.—(1) An approved body is a conformity assessment body which—

(a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 54 (approval of conformity assessment bodies); or

(b) immediately before exit day was a notified body in respect of which the Secretary of State has taken no action under regulation 62(1) or (2) as they had effect immediately before exit day to suspend or withdraw the body's status as a notified body.

(2) Paragraph (1) has effect subject to regulation 60 (restriction, suspension or withdrawal of approval).

(3) In this Part—

"notified body" means a body—

(a) which the Secretary of State had before exit day notified to the European Commission and the member States of the European Union as a notified body, in accordance with Article 20 of the Directive; and

(b) in respect of which no objections had been raised, as referred to in regulation 51(1)(b), as it had effect immediately before exit day;

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

"product" means pressure equipment or assemblies;

"accreditation certificate" means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.

Recognised third party organisations

52.—(1) A recognised third party organisation is a conformity assessment body which—

(a) has been approved by the Secretary of State to be a recognised third party organisation, under regulation 54 (approval of conformity assessment bodies); or

(b) immediately before exit day—

(i) was a conformity assessment body which the Secretary of State had before exit day notified to the European Commission and the member States of the European Union as a recognised third party organisation, in accordance with Article 20 of the Directive;

(ii) in respect of which no objections had been raised, as referred to in regulation 52(1)(b), as it had effect immediately before exit day; and

(iii) in respect of which the Secretary of State had taken no action under regulation 62(1) or (2), as they had effect immediately before exit day to suspend or withdraw the body's status as a recognised third party organisation.

(2) Paragraph (1) has effect subject to regulation 60 (restriction, suspension or withdrawal of approval).

User inspectorates

53.—(1) A user inspectorate is a conformity assessment body which—

(a) has been approved as a user inspectorate by the Secretary of State under regulation 54 (approval of conformity assessment bodies); or

(b) immediately before exit day—

(i) was a conformity assessment body which the Secretary of State had before exit day notified to the European Commission and the member States of the European Union as a user inspectorate, in accordance with Article 20 of the Directive;

(ii) in respect of which no objections had been raised, as referred to in regulation 53(1)(b), as it had effect immediately before exit day; and

(iii) in respect of which the Secretary of State had taken no action under regulation 62(1) or (2), as they had effect immediately before exit day, to suspend or withdraw the body's status as a recognised third party organisation.

(2) Paragraph (1) has effect subject to regulation 61 (restriction, suspension or withdrawal of approval (user inspectorates)).

Approval of conformity assessment bodies

54.—(1) The Secretary of State may approve only those conformity assessment bodies which—

(a) qualify for approval as an approved body in accordance with regulation 55;

(b) qualify for approval as a recognised third party organisation in accordance with regulation 56; or

(c) qualify for approval as a user inspectorate in accordance with regulation 57.

(2) When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may—

(a) have regard to any other matter which appears to the Secretary of State to be relevant; and

(b) set conditions that the conformity assessment body must meet.

Approval of approved bodies

55.—(1) A conformity assessment body qualifies for approval as an approved body if the first and second conditions below are met.

(2) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

(iii) the category of products in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate, or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

(3) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(4) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

Approval of recognised third party organisations

56.—(1) A conformity assessment body qualifies for approval as a recognised third party organisation if the conditions in paragraphs (2), (3) and (4) are met.

(2) The first condition is that the conformity assessment body has applied to the Secretary of State to become a recognised third party organisation and that application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

(iii) the category of products in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate, or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

(3) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(4) The third condition is that the conformity assessment body must carry out approvals of only those activities referred to in paragraphs 21 and 22 of Schedule 2 (permanent joining and non-destructive tests).

(5) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

Approval of user inspectorates

57.—(1) A conformity assessment body qualifies for approval as a user inspectorate if the conditions in paragraphs (2) to (7) are met.

(2) The conformity assessment body must apply to the Secretary of State to become a user inspectorate and that application must be accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

(iii) the category of products in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate, or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the user inspectorate requirements.

(3) The Secretary of State must be satisfied that the conformity assessment body meets the user inspectorate requirements.

(4) The conformity assessment procedures which a user inspectorate may carry out are modules A2, C2, F and G, set out in Part 2, Part 4, Part 9 and Part 10 of Schedule 1A respectively.

(5) The group of which the user inspectorate is part must apply a common safety policy as regards the technical specifications for the design, manufacture, inspection, maintenance and use of products.

(6) The user inspectorate must act exclusively for the group of which it is part.

(7) Where the conformity of a product has been assessed by a user inspectorate, that product may only be used in establishments operated by the group of which the user inspectorate is part.

(8) For the purposes of paragraph (3), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (2)(b), as sufficient evidence that the conformity assessment body meets the user inspectorate requirements.

Presumption of conformity of conformity assessment bodies

58.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements or the user inspectorate requirements (as the case may be) covered by that standard (or part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

Monitoring

59. The Secretary of State must monitor each approved body, recognised third party organisation and user inspectorate with a view to verifying that the body—

(a) continues to meet the approved body requirements or user inspectorate requirements, as applicable;

(b) meets any conditions set—

(i) in accordance with regulation 54(2)(b), or

(ii) in the case of—

(aa) an approved body which was a notified body immediately before exit day;

(bb) a recognised third party organisation falling within regulation 52(1)(b); or

(cc) a user inspectorate falling within regulations 53(1)(b);

in accordance with regulation 55(2)(b) as it applied immediately before exit day; and

(c) carries out its functions in accordance with these Regulations.

Restriction, suspension or withdrawal of approval (approved bodies and recognised third party organisations)

60.—(1) Where the Secretary of State determines that an approved body or a recognised third party organisation—

(a) no longer meets an approved body requirement, or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 54(2)(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body or a recognised third party organisation under regulation 51 or 52 (as the case may be).

(2) Where the Secretary of State determines that an approved body or a recognised third party organisation no longer meets a condition referred to in regulation 54(2)(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body or a recognised third party organisation under regulation 51 or 52 (as the case may be).

(3) In deciding what action is required under paragraph (1) or (2) the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2) the Secretary of State must—

(a) give notice in writing to the approved body or recognised third party organisation of the proposed action and the reasons for it;

(b) give the approved body or recognised third party organisation an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and

(c) consider any such representations made by the approved body or recognised third party organisation.

(5) Where the Secretary of State has taken action in respect of an approved body or recognised third party organisation under paragraph (1) or (2), or where an approved body or recognised third party organisation has ceased its activity, the approved body or recognised third party organisation must, at the request of the Secretary of State—

(a) transfer its files relating to the activities it has undertaken as an approved body or recognised third party organisation to another approved body or recognised third party organisation or to the Secretary of State, or

(b) keep its files relating to the activities it has undertaken as an approved body or recognised third party organisation available for the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.

(6) The activities undertaken by an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.

Restriction, suspension or withdrawal of approval (user inspectorates)

61.—(1) Where the Secretary of State determines that a user inspectorate—

(a) no longer meets a user inspectorate requirement, or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 54(2)(b),

the Secretary of State must restrict, suspend or withdraw the body's status as a user inspectorate under regulation 53.

(2) Where the Secretary of State determines that a user inspectorate no longer meets a condition referred to in regulation 54(2)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a user inspectorate under regulation 53.

(3) In deciding what action is required under paragraph (1) or (2) the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2) the Secretary of State must—

(a) give notice in writing to the user inspectorate of the proposed action and the reasons for it;

(b) give the user inspectorate an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and

(c) consider any such representations made by the user inspectorate.

(5) Where the Secretary of State has taken action in respect of a user inspectorate under paragraph (1) or (2), or where a user inspectorate has ceased its activity, the user inspectorate must at the request of the Secretary of State—

(a) transfer its files relating to the activities it has undertaken as a user inspectorate to an approved body, a recognised third party organisation or to the Secretary of State, or

(b) keep its files relating to the activities it has undertaken as a user inspectorate available for the Secretary of State and market surveillance authorities for a period of 10 years from the date they were created.

Operational matters in relation to approved bodies, recognised third party organisations and user inspectorates

62.—(1) Subject to the terms of its appointment and to paragraph (3), an approved body, recognised third party organisation or user inspectorate must carry out the conformity assessment activities and procedures—

(a) in respect of which the body's approval was given under regulation 51, 52 or 53 (as the case may be); or

(b) in respect of which the body's notification was made as referred to in 51(3) (approved bodies), 52(1)(b) (recognised third party organisations) or 53(1)(b) (user inspectorates).

(2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 6.

(3) An approved conformity assessment body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body—

(a) to issue a Type examination certificate referred to in Schedule 1A, or

(b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 49 (UK marking), where applicable.

Subsidiaries and contractors

63.—(1) An approved body, recognised third party organisation or user inspectorate may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

(a) the body, organisation or inspectorate is satisfied that the subcontractor or subsidiary meets the approved body requirements or user inspectorate requirements, as applicable;

(b) the body, organisation or inspectorate has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meet those requirements; and

(c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

(2) The approved body, recognised third party organisation or user inspectorate which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

(3) Where an approved body, recognised third party organisation or user inspectorate subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the body, organisation or inspectorate must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documents concerning—

(a) the assessment of the qualifications of the subcontractor or the subsidiary; and

(b) the conformity assessment activity carried out by the subcontractor or subsidiary.

(4) In this regulation "subsidiary" has the meaning given to it in section 1159 of the Companies Act 2006(**1**).

Register of approved bodies

64.—(1) The Secretary of State must—

(a) assign—

(i) an approved body identification number to each approved body;

(ii) a recognised third party organisation identification number to each third party organisation;

(iii) a user inspectorate identification number to each user inspectorate; and

(b) compile and maintain a register of—

(i) approved bodies, recognised third party organisations and user inspectorates;

(ii) their identification numbers;

(iii) the activities for which they have been approved; and

(iv) any restrictions on those activities.

(2) The register referred to in paragraph (1) must be made publicly available.

United Kingdom Accreditation Service

65. The Secretary of State may authorise the United Kingdom Accreditation Service to carry out the following activities on behalf of the Secretary of State—

(**1**) 2006 c.46.

(a) assessing whether a conformity assessment body meets the approved body requirements or user inspectorate requirements (as applicable);

(b) monitoring approved bodies, recognised third party organisations and user inspectorates in accordance with regulation 59; and

(c) compiling and maintaining the register of approved bodies, recognised third party organisations and user inspectorates, in accordance with regulation 64.".

Amendment to regulation 69

36. In regulation 69 (exercise of enforcement powers) omit paragraph (c).

Amendment to regulation 71

37. In regulation 71 (enforcement action in respect of pressure equipment or assemblies which are not in conformity and which present risk)—

(a) in paragraph (2), for "notified", substitute "approved";

(b) omit paragraphs (3), (4) and (7);

(c) in paragraph (8), for "notices in paragraphs (6) and (7)", substitute "notice in paragraph (6)"; and

(d) in paragraph (8)(f)(ii) for "harmonised" substitute "designated".

Omission of regulation 72

38. Omit regulation 72 (EU safeguard procedure).

Amendment to regulation 73

39. In regulation 73 (pressure equipment or assemblies which are in conformity, but present a risk)—

(a) omit paragraph (3); and

(b) in paragraph (4), for "notices referred to in paragraphs (2) and (3)", substitute "notice referred to in paragraph (2)".

Amendment to regulation 74

40. In regulation 74 (enforcement action in cases of formal non-compliance)—

(a) in paragraphs (1)(a) and (1)(c)(ii) for "CE" substitute "UK" in each place in which it occurs;

(b) in paragraph (1)(c) omit "EU" in each place in which it occurs; and

(c) in paragraph (4) omit ", 72 (EU safeguard procedure)".

Insertion of regulation 88A

41. After regulation 88 (transitional provisions) insert—

"**Transitional provision in relation to EU Exit**

88A.—(1) In this regulation—

"pre-exit period" means the period beginning with the commencement date and ending immediately before exit day;

"product" means a vessel to which these Regulations apply on or after exit day.

(2) Subject to paragraph (3), where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 24 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019(**2**), any obligation to which a person was subject under these Regulations as they had effect immediately before exit day, continues to have effect as it did immediately before exit day, in relation to that product.

(3) Paragraph (2) does not apply to—

(a) any obligation of any enforcing authority to inform the European Commission or the member States of any matter; or

(b) any obligation to take action outside of the United Kingdom in respect of that product.

(4) Where during the pre-exit period—

(a) a product has not been placed on the market; and

(b) a manufacturer has taken any action under regulation 42 as it had effect immediately before exit day in relation to that product

that action has effect as if it had been done under regulation 42 as it had effect on and after exit day.".

Amendment to regulation 90

42. In regulation 90 (revocations, amendments and savings)—

(a) in paragraph (1) after "paragraph (2)" insert "and (2A)";

(b) for paragraph (2), substitute—

"(2) Subject to the modifications made in paragraph (2A), the Regulations referred to in paragraph (1) continue to apply, as if they had not been revoked, to pressure equipment or assemblies placed on the market before the commencement date.

(2A) The modifications referred to in paragraph (2) are that in the 1999 Regulations—

(a) references to "the Community" shall be read as including the United Kingdom;

(b) references to a "member State" shall be read as including the United Kingdom; and

(c) in Schedule 8 (enforcement), in paragraph 6, omit "with a view to this information being passed by him to the Commission"."

Amendment to Schedule 1

43. Schedule 1 (excluded pressure equipment and assemblies) is amended as follows—

(a) for sub-paragraphs (c) to (f) of paragraph 1, substitute—

"(c) simple pressure vessels to which the Simple Pressure Vessel (Safety) Regulations 2016(**3**) apply;

(d) aerosol dispensers to which the Aerosol Dispensers Regulations 2009(**4**) apply;

(e) equipment intended for the functioning of vehicles as defined in—

(i) the Road Vehicles (Approvals) Regulations 2009(**5**);

(**2**) S.I. 2019/XXXX.
(**3**) S.I. 2016/1092 as amended by S.I. 2017/1206 and S.I. 2018/966.
(**4**) S.I. 2009/2824 as amended by S.I. 2014/1130 and S.I. 2018/29.
(**5**) S.I. 2009/717 as amended by S.I. 2011/1946, S.I. 2013/602, S.I. 2018/235, S.I. 2018/236, S.I. 2018/673 and S.I. 2018/984.

(ii) the Motor Vehicles (Type and Approval and Approval Marks) (Fees) Regulations 1999(**6**);

(iii) Regulation 167/2013 of the European Parliament and of the Council of February 2013 on the approval and market surveillance of agricultural and forestry vehicles;

(iv) Regulation 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;

(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(**7**);

(ii) the Lift Regulations 2016(**8**);

(iii) the Electrical Equipment (Safety) Regulations 2016(**9**);

(iv) the Medical Devices Regulations 2002(**10**);

(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(**11**).";

(b) for paragraph 1(g) substitute—

"(g) products connected with the production of trade in arms, munitions and war material;";

(c) for paragraph 1(s) substitute—

"(s) equipment covered by—

(i) the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009(**12**); and

(ii) equipment covered by the International Maritime Dangerous Goods Code(**13**) and the Convention on International Civil Aviation(**14**).".

Insertion of Schedule 1A and 1B

44. After Schedule 1 insert—

(**6**) S.I. 1999/2149 as amended by S.I. 2003/2258, S.I. 2004/2106, S.I. 2006/1638 and S.I. 2009/719.
(**7**) S.I. 2008/1597 as amended by S.I. 2011/1043, S.I. 2014/469, S.I. 2015/1682, S.I. 2014/3248, S.I. 2015/1630, S.I. 2016/1105 and S.I. 2016/427.
(**8**) S.I. 2016/1093 as amended by S.I. 2016/1186 and S.I. 2018/389.
(**9**) S.I. 2016/1101 as amended by S.I. 2017/1206 and S.I. 2018/966.
(**10**) S.I. 2002/618 as amended by S.I. 2003/1400, S.I. 2003/1697, S.I. 2005/2759, S.I. 2005/2909, S.I. 2007/400, S.I. 2007/610, S.I. 2007/803, S.I. 2008/530, S.I. 2008/2936, S.I. 2009/383, S.I. 2010/557, S.I. 2012/1426, S.I. 2013/525, S.I. 2013/2327 and S.I. 2017/207.
(**11**) S.I. 2016/1107.
(**12**) S.I. 2009/1348 as amended by S.I. 2011/1885, S.I. 2013/235, S.I. 2014/469, S.I. 2014/1638, S.I. 2013/119, S.I. 2015/1682, S.I. 2016/721 and S.I. 2017/1075.
(**13**) As published by the International Maritime Organisation (a specialised agency of the United Nations).
(**14**) As published by the International Civil Aviation Organisation (a specialised agency of the United Nations).

"SCHEDULE 1A Regulations 10 and 42

Conformity Assessment Procedures for Pressure Equipment and Assemblies

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, etc.;

(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, etc.,

(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, etc.;

(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, etc.,

(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, etc.;

(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, etc.,

(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;

(b) 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 its approving authority 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, etc.;

(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 45, 46 and 47, 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 paragraphs 52(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, etc.;

(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, etc.;

(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, etc.; 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, etc.;

(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, etc.; 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, etc.;

(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, etc.,

(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 to Schedule 2 of 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, etc.;

(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, etc.,

(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;

(e) 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, etc.;

(e) 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, etc.; and

(f) 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, etc.;

(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, etc.,

(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, etc.;

(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, etc.,

(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, etc.;

(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, etc.; 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.

SCHEDULE 1B

Regulation 3

Conformity Assessment Tables

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;

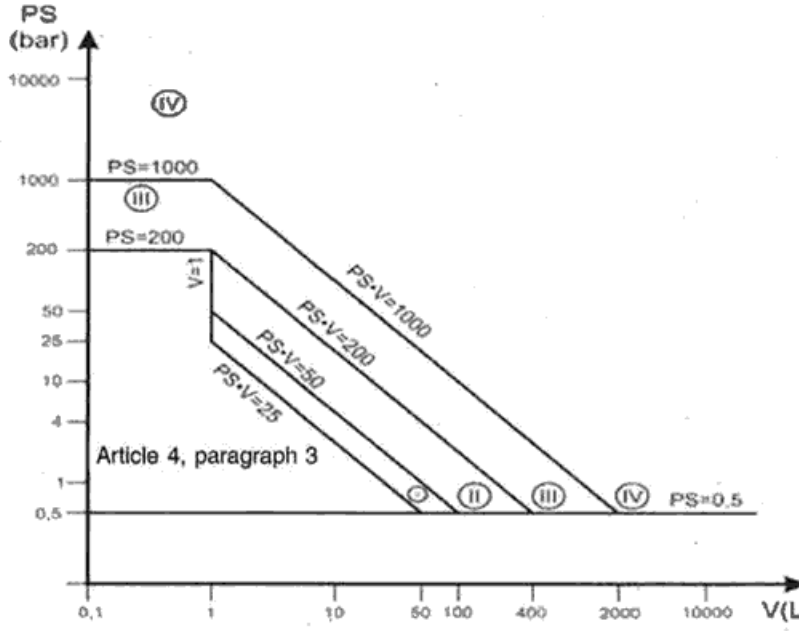
(c) the group of fluids for which they are intended.

(2) The appropriate table for vessels or piping is to be used to determine the conformity assessment category.

(2) 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.

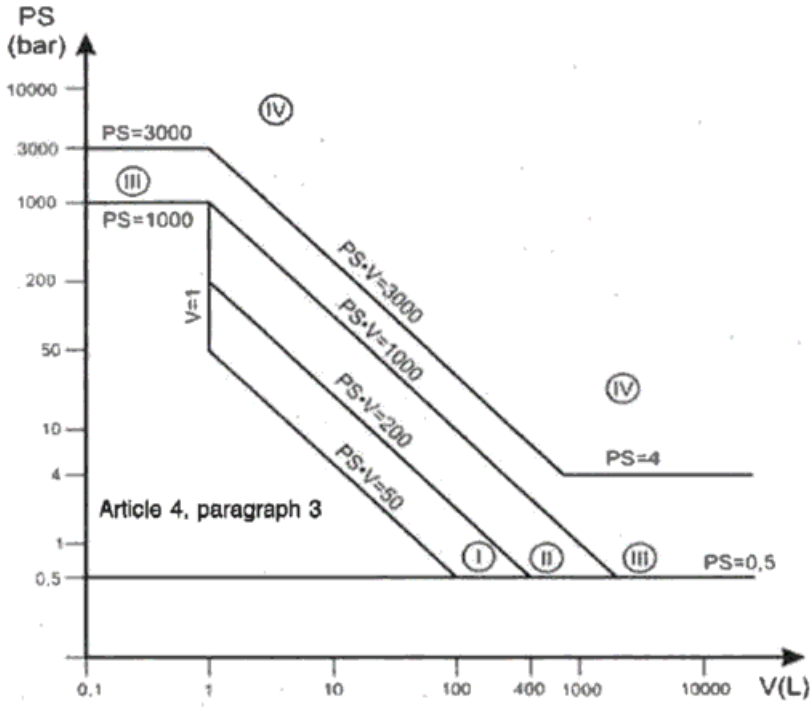
4.—(1) The demarcation lines in the following conformity assessment tables indicate the upper limit for each category.

(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



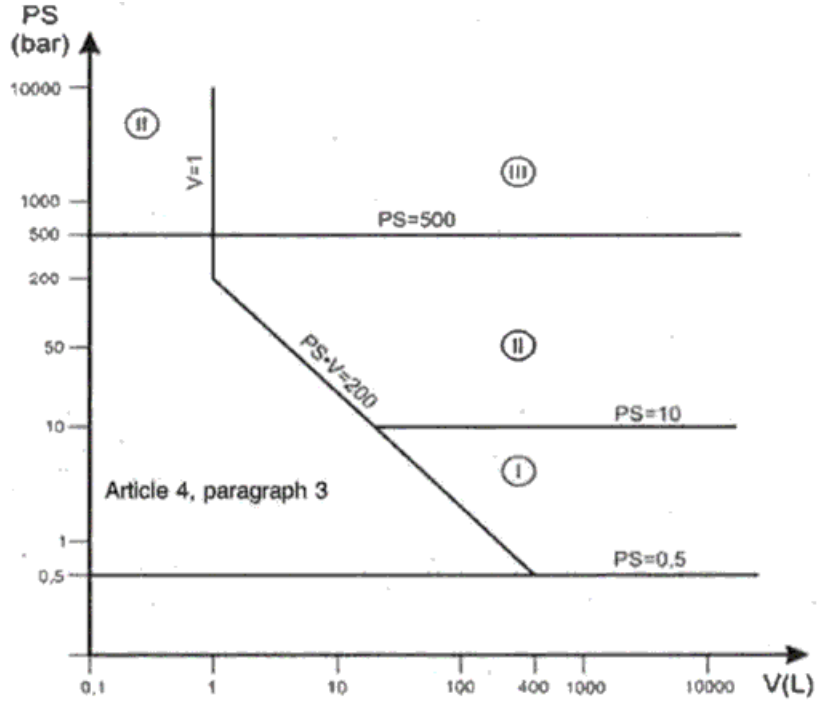
(ii) Exceptionally, vessels intended to contain an unstable gas and falling within categories I or II on the basis of table 1 shall be classified in category III.

(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

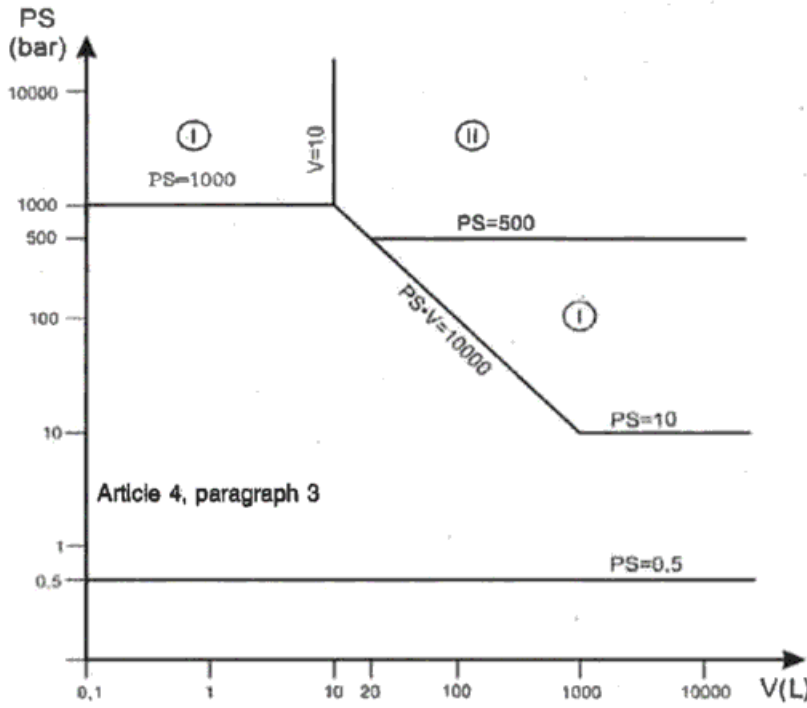


(ii) Exceptionally, portable extinguishers and bottles for breathing equipment shall be classified at least in category III.

(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

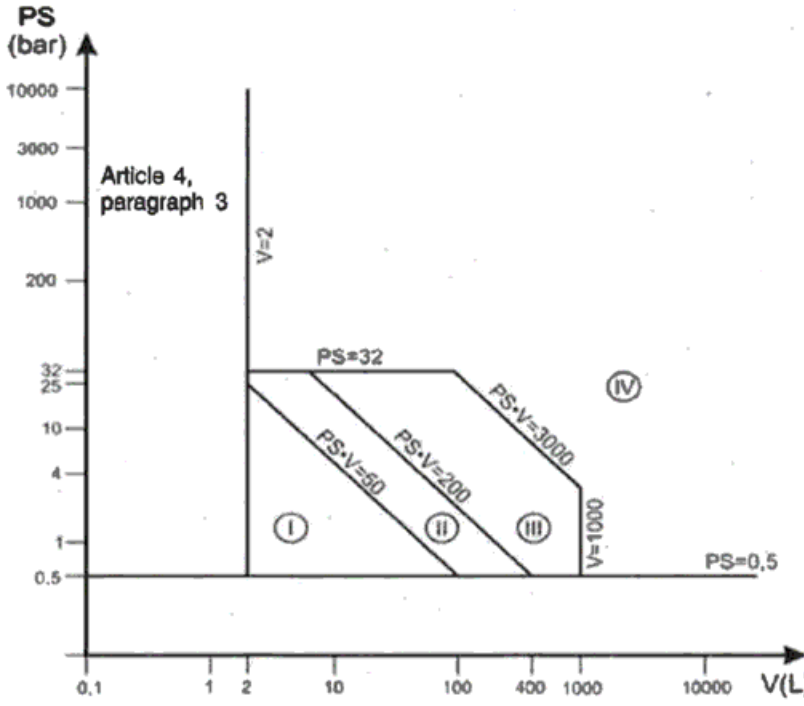


(d) (i) Table 4: Vessels for liquids having a vapour pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure (1013 mbar) and, for fluids in Group 2 with a pressure PS greater than 10 bar and a product of PS and V greater than 10000 bar.L, or with a pressure PS greater than 1000 bar



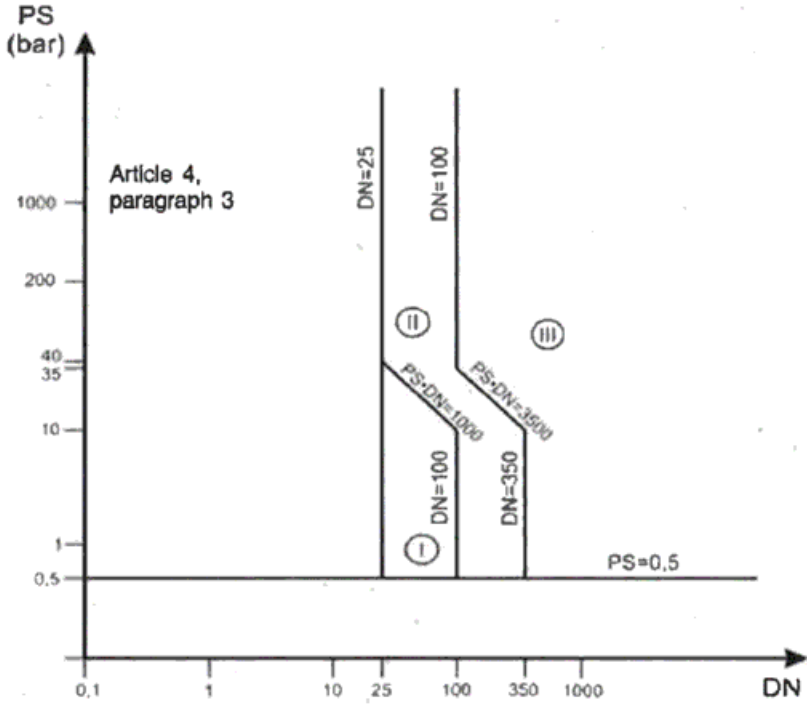
(ii) Exceptionally, assemblies intended for generating warm water at temperatures not greater than 110°C which are manually fed with solid fuels and have a PS.V, shall be subject either to a Type examination (Module B — design type) with respect to their conformity with the essential requirements referred 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



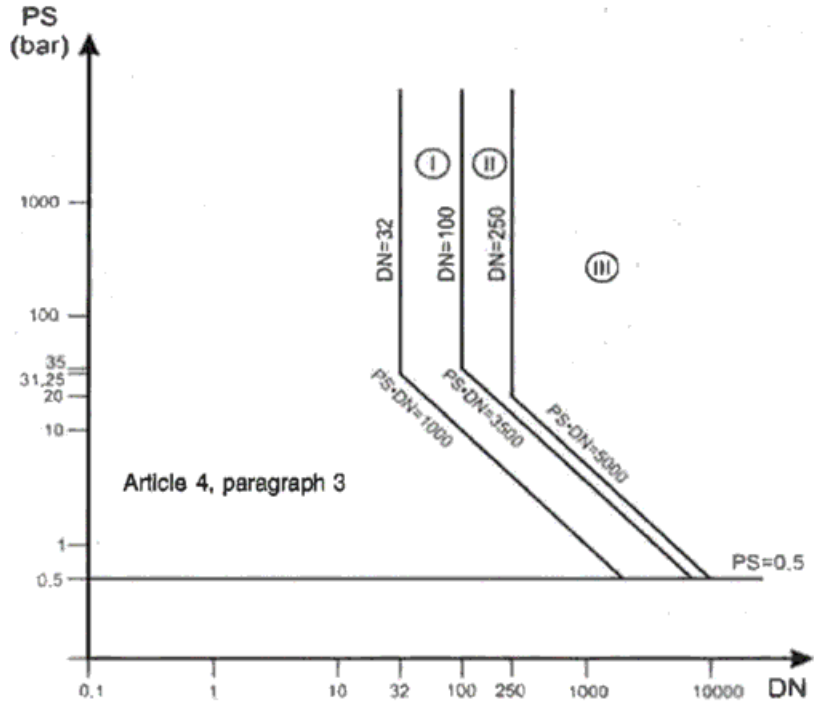
(ii) Exceptionally, the design of pressure-cookers shall be subject to a conformity assessment procedure equivalent to at least one of the category III modules.

(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



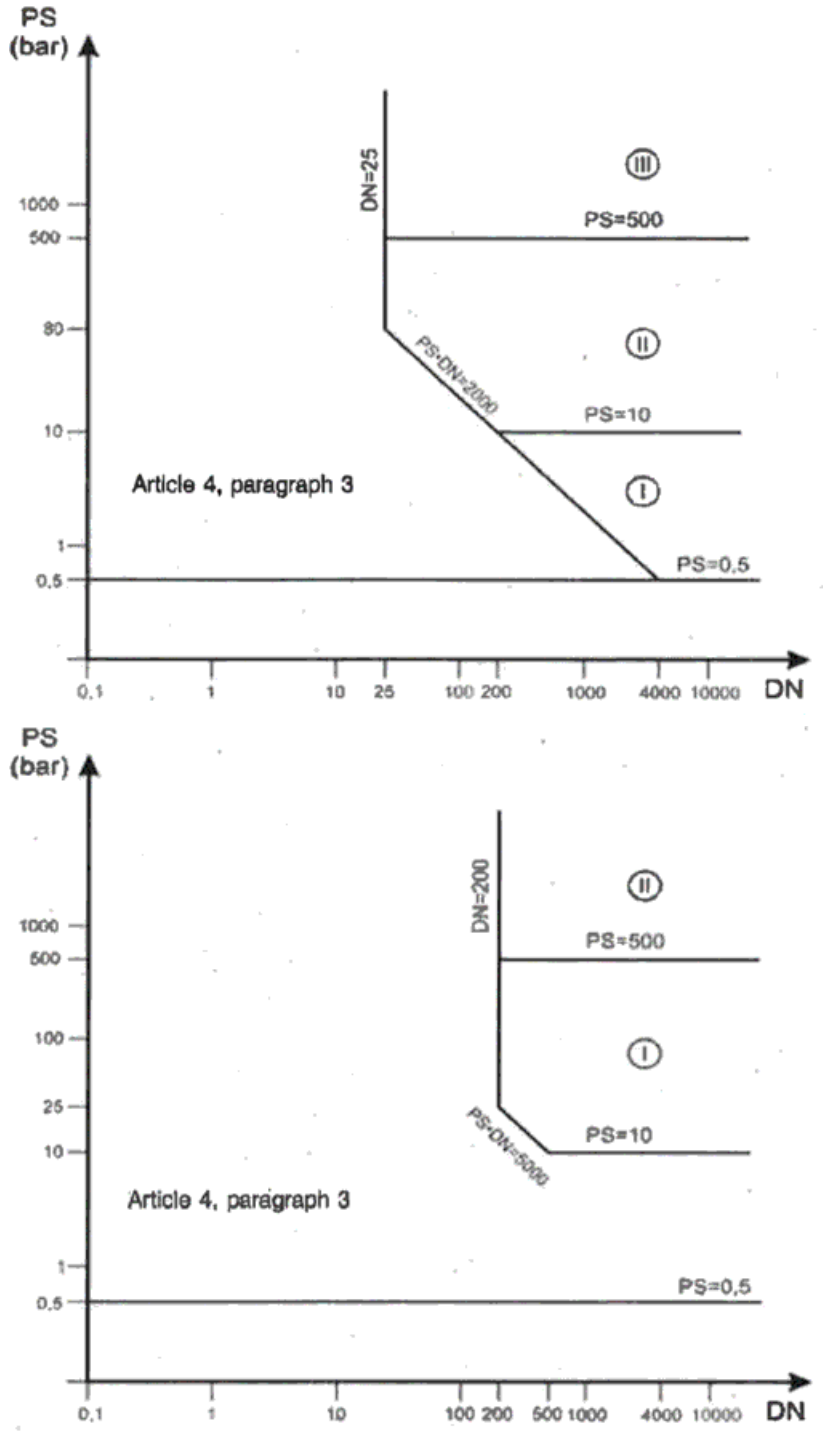
(ii) Exceptionally, piping intended for unstable gases and falling within categories I or II on the basis of Table 6 shall be classified in category III.

(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."

Amendment to Schedule 2

45. Schedule 2 (essential safety requirements) is amended as follows—

(a) in paragraph 21(4), 31 (4)(b)(i) and 35 (1) for "harmonised" substitute "designated";

(b) in paragraph 29 (1) for "CE" substitute "UK"; and

(c) omit paragraphs 31(4)(b)(ii) and (8).

Amendment to Schedule 3

46. Schedule 3 (classification of pressure equipment) is amended as follows—

(a) Beneath the heading to "Schedule 3" insert the Part heading "Part 1";

(b) For the heading "classification of pressure equipment" substitute "classification of pressure equipment before exit day";

(c) after paragraph 4 insert—

"PART 2

Classification of pressure equipment immediately on or after exit day

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.".

Amendment to Schedule 4

47. Schedule 4 (notified body requirements) is amended as follows—

(a) in the heading and in every place in which it occurs, for "notified", substitute "approved";

(b) for "a notified body" substitute "an approved body" in every place in which it occurs;

(c) in paragraph 12(c) for "harmonised standards and of the Directive and" substitute "designated standards";

(d) in paragraph 18 omit "established under the Directive".

Amendment to Schedule 5

48. Schedule 5 (user inspectorate requirements) is amended as follows—

(a) in paragraph 10(c)—

(i) for "harmonised" substitute "designated";

(ii) omit "of the Directive and";

(b) in paragraph 16—

(i) for "notified", substitute "approved"; and

(ii) omit "established under the Directive".

Amendment to Schedule 6

49. Schedule 6 (operational obligations of notified bodies, recognised third party organisations and user inspectorates) is amended as follows—

(a) in the heading and in every place in which it occurs, for "notified", substitute "approved";

(b) in every place in which it occurs, for "a notified body", substitute "an approved body";

(c) in paragraph 5, for "harmonised", substitute "designated";

(d) in paragraph 12, for "bodies notified under the Directive", substitute "other approved bodies"; and

(e) in paragraph 13, for "established under the Directive", substitute "established by the Secretary of State".

Amendment to Schedule 11

50. Schedule 11 (EU Declaration of Conformity) is amended as follows—

(a) omit "EU" in each place in which it occurs;

(b) in paragraph 5, for "Union harmonisation legislation", substitute "statutory requirements";

(c) in paragraph 6, for "harmonised", substitute "designated"; and

(d) in paragraph 7, for "notified", substitute "approved".