[F1SCHEDULE 1A

Regulations 10 and 42

Conformity Assessment Procedures for Pressure Equipment and Assemblies

Textual Amendments

F1 Sch. 1A inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 24 para. 44** (with Sch. 24 para. 41) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

PART 1

Module A: Internal Production Control

General

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3 and 4 and ensures and declares on their sole responsibility that the pressure equipment concerned satisfy the requirements of these Regulations.

Technical documentation

2.—(1) The manufacturer shall establish the technical documentation.

(2) The technical documentation shall—

(a) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(b) include an adequate analysis and assessment of the risk;

(c) specify the applicable requirements and contain, where applicable—

(i) a general description;

(ii) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(iv) a list of the designated standards;

(v) results of design calculations made, examinations carried out and the results of any other relevant calculation or examination;

(vi) test reports;

(vii) manufacture; and

(viii) operation,

of the pressure equipment or assembly.

(3) The technical documentation must be kept at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Manufacturing

3. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured pressure equipment with the technical documentation referred to in paragraph 2 and the requirements of these Regulations.

UK marking and declaration of conformity

4. The manufacturer shall—

(a) affix the UK marking to each individual piece of pressure equipment, or assembly, that satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request; and

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Authorised representative

5. The manufacturer's obligations set out in paragraph 4 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 2

Module A2: Internal production control plus supervised pressure equipment checks at random

General

6. Internal production control plus supervised pressure equipment checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3 ,4 and 5, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned satisfies the requirements of these Regulations.

Technical documentation

7.—(1) The manufacturer shall establish the technical documentation.

(2) The technical documentation shall—

(a) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(b) include an adequate analysis and assessment of the risk;

(c) specify the applicable requirements and contain, where applicable—

(i) a general description;

(ii) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(iv) a list of the designated standards;

(v) results of design calculations made, examinations carried out, and the results of any other relevant calculation or examination;

(vi) test reports;

(vii) manufacture; and

(viii) operation

of the pressure equipment or assembly.

(4) The technical documentation must be kept at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Manufacturing

8. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured pressure equipment with the technical documentation referred to in paragraph 7 and the requirements of these Regulations.

Final assessment and pressure equipment, assembly, checks

9.—(1) The manufacturer shall perform a final assessment of the pressure equipment, or assembly, monitored by means of unexpected visits by an approved body chosen by the manufacturer.

(2) The approved body shall carry out, or have carried out for them, product checks which shall—

(a) be carried out at random intervals determined by the approved body;

(b) verify the quality of the internal checks of the pressure equipment, or assembly (taking into account the technological complexity of the equipment, or assembly, and the quantity of production);

(c) establish that the manufacturer performs final assessment in accordance with paragraphs 25 to 28 of Schedule 2 to these Regulations;

(d) take samples of pressure equipment and assemblies at the manufacturing or storage premises in order to conduct checks (the approved body assesses the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment of the samples).

(3) The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pressure equipment, or assembly, performs within acceptable limits, with a view to ensuring conformity of the pressure equipment, or assembly.

(4) The approved body shall take appropriate measures where an item of pressure equipment or assembly does not conform.

(5) The manufacturer shall, under the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.

UK marking and declaration of conformity

10. The manufacturer shall—

(a) affix the UK marking to each individual pressure equipment, or assembly, that satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request; and

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Authorised representative

11. The manufacturer's obligations set out in paragraph 10 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 3

Module B: Type examination

Type examination–production type

12. Type examination–production type is the part of a conformity assessment procedure in which an approved body examines the technical design of the pressure equipment, or assembly, and verifies and attests that the technical design of the pressure equipment meets the requirements of these Regulations.

13. Type examination–production type shall consist of an assessment of the adequacy of the technical design of the pressure equipment, or assembly, through examination of the technical documentation and supporting evidence referred to in paragraph 14, plus examination of a specimen, representative of the production envisaged, of the complete pressure equipment or assembly.

14. The manufacturer shall lodge an application with a single approved body of their choice. The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application had not been lodged with any other approved body;

(c) the technical documentation which shall—

(i) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(ii) include an adequate analysis and assessment of the risk;

(iii) specify the applicable requirements and contain, where applicable—

(aa) a general description;

(bb) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, and all other relevant parts, to component level;

(cc) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(dd) a list of the designated standards;

(ee) results of design calculations made, examinations carried out, and the results of any other relevant calculation or examination;

(ff) test reports;

(gg) information concerning the tests provided for in manufacture;

(hh) information concerning the qualifications and approvals required under paragraphs 21 and 22 of Schedule 2 (essential safety requirements);

(ii) manufacture; and

(jj) operation;

(d) specimens representative of the product envisaged which—

(i) may cover several versions of the pressure equipment or assembly (provided that the differences between the versions do not affect the level of safety);

(ii) the approved body may request further of, if needed for carrying out the test programme;

(e) supporting evidence for the adequacy of the technical design solution which shall—

(i) mention any documents that have been used, in particular where the relevant designated standards have not been applied in full; and

(ii) include, where necessary, the results of tests carried out—

(aa) by the appropriate laboratory of the manufacturer applying other relevant technical specifications; or

(bb) by any other testing laboratory on their behalf and under their responsibility.

15. The approved body shall—

(a) examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the pressure equipment, or assembly, and the manufacturing procedures;

(b) where the materials are not in conformity with the relevant designated standards, assess the materials and check the certificate issued by the material manufacturer in accordance with subparagraphs 31(5) to (8) of Schedule 2 to these Regulations;

(c) approve the procedures for the permanent joining of pressure equipment, or assembly, parts, or check that they have been previously approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(d) verify that the personal undertaking in the permanent joining of pressure equipment, or assembly, parts and the non-destructive tests are qualified or approved in accordance with paragraphs 21 or 22 of Schedule 2 to these Regulations;

(e) verify that the specimens have been manufactured in conformity with the technical documents and identify the elements which have been designed in accordance with the applicable provisions of the relevant designated standards as well as the elements which have been designed using other relevant technical specifications without applying the relevant provisions of those standards;

(f) carry out appropriate examinations and necessary tests to check whether—

(i) when the manufacturer has chosen to apply the solutions in the relevant designated standards, these have been applied correctly;

(ii) where the solutions in the relevant designated standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of these Regulations;

(g) agree, with the manufacturer, on a location where the examinations and tests will be carried out;

(h) draw up an evaluation report—

(i) recording the activities undertaken, in accordance with this paragraph, and their outcomes; and

(ii) only release the content, in full or in part, with the agreement of the manufacturer.

16. Where the type meets the requirements of these Regulations, the approved body shall issue a Type examination–production type certificate to the manufacturer.

17. The Type examination-production type certificate shall—

(a) include—

(i) the name and address of the manufacturer;

(ii) the conclusions of the examination;

(iii) any conditions for the certificate's validity; and

(iv) necessary data for identification of the approved type;

(b) include an annex listing the relevant parts of the technical documentation, a copy of which shall be kept by the approved body;

(c) contain all relevant information to allow the conformity of manufactured equipment pressure equipment, or assemblies, with the examined type to be evaluated and to allow for in-service control;

(d) be valid for 10 years, without prejudice to paragraphs 20 and 21, and be renewable.

18. Where the type does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a Type examination-production type certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

19. Provision shall be made for an appeals procedure.

20. The approved body shall keep itself appraised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly.

21. The manufacturer shall inform the approved body that holds the technical documentation relating to the Type examination-production type certificate of all modifications to the approved type that may affect the conformity of the pressure equipment, or assembly, with the essential safety requirements of these Regulations or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original Type examination-production type certificate.

22. Each approved body shall inform the Secretary of State concerning Type examination-production type certificates and any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the enforcing authorities the list of certificates and any additions thereto refused, suspended or otherwise restricted.

23. Each approved body shall inform the other approved bodies concerning the Type examination-production type certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted and, upon request, concerning the certificates and additions thereto that it has issued.

24. Other approved bodies may, on request, obtain a copy of the Type examination-production type certificate and additions thereto.

25. The approved body shall keep a copy of the Type examination-production type certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

26. The manufacturer shall keep a copy of the Type examination-production type certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

27. The manufacturer's authorised representative may lodge the application referred to in paragraph 14 and fulfil the obligations set out in paragraphs 21 and 26, provided that they are specified in the mandate.

Type examination–design type

28. Type examination-design type is the part of a conformity assessment procedure in which an approved body examines the technical design of the pressure equipment, or assembly, and verifies and attests that the technical design of the pressure equipment, or assembly, meets the requirements of these Regulations.

29. Type examination-design type shall consist of an assessment of the adequacy of the technical design of the pressure equipment through examination of the technical documentation and supporting evidence referred to in paragraph 31, without examination of a specimen.

30. The experimental design method provided for at paragraph 6 of Schedule 2 to these Regulations shall not be used in the context of this module.

31. The manufacturer shall lodge an application with a single approved body of their choice. The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application had not been lodged with any other approved body;

(c) the technical documentation which shall—

(i) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(ii) include an adequate analysis and assessment of the risk;

(iii) specify the applicable requirements and contain, where applicable—

(aa) a general description;

(bb) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits and all other relevant parts, to component level;

(cc) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(dd) a list of the designated standards;

(ee) information concerning the qualifications and approvals required under paragraphs 21 and 22 of Schedule 2;

(d) supporting evidence for the adequacy of the technical design solution which shall—

(i) mention any documents that have been used, in particular where the relevant designated standards have not been applied in full; and

(ii) include, where necessary, the results of tests carried out—

(aa) by the appropriate laboratory of the manufacturer applying other relevant technical specifications; or

(bb) by any other testing laboratory on their behalf and under their responsibility.

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

33. The approved body shall—

(a) examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product;

(b) assess the materials where they are not in conformity with the relevant designated standards;

(c) approve the procedures for the permanent joining of pressure equipment, or assembly, parts or check that they have been previously approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(d) carry out appropriate examinations and necessary tests to check whether—

(i) when the manufacturer has chosen to apply the solutions in the relevant designated standards, these have been applied correctly;

(ii) where the solutions in the relevant designated standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of these Regulations;

(e) draw up an evaluation report—

(i) recording the activities undertaken, in accordance with this paragraph, and their outcomes;

(ii) only release the content, in full or in part, with the agreement of the manufacturer.

34. Where the design meets the requirements of these Regulations, the approved body shall issue a Type examination–design type certificate to the manufacturer.

35. The Type examination-design certificate type shall—

(a) include—

(i) the name and address of the manufacturer;

(ii) the conclusions of the examination;

(iii) any conditions for the certificate's validity; and

(iv) necessary data for identification of the approved type;

(b) include an annex listing the relevant parts of the technical documentation, a copy of which shall be kept by the approved body;

(c) contain all relevant information to allow the conformity of manufactured pressure equipment, or assemblies, with the examined design to be evaluated and to allow for in-service control;

(d) be valid for 10 years, without prejudice to paragraphs 36 and 37, and be renewable.

36. Where the design does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a Type examination-design type certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

37. The approved body shall keep itself appraised of any changes in the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of these Regulations and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly.

38. The manufacturer shall inform the approved body that holds the technical documentation relating to the Type examination-design type certificate of all modifications to the approved type

that may affect the conformity of the pressure equipment, or assembly, with the essential safety requirements of these Regulations or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original Type examination-design type certificate.

39. Each approved body shall inform its approved authority concerning Type examination-design type certificates and any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its approved authorities the list of certificates and any additions thereto refused, suspended or otherwise restricted.

40. Each approved body shall inform the other approved bodies concerning the Type examination-design type certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted and, upon request, concerning the certificates and additions thereto that it has issued.

41. Other approved bodies may, on request, obtain a copy of the Type examination-design type certificate and additions thereto.

42. The approved body shall keep a copy of the Type examination-design type certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

43. The manufacturer shall keep a copy of the Type examination-design type certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

44. The manufacturer's authorised representative may lodge the application referred to in paragraph 31 and fulfil the obligations set out in paragraphs 37 and 42, provided that they are specified in the mandate.

PART 4

Module C2: Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals

General

45. Conformity to type based on internal production control plus supervised pressure equipment checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 46, 47 and 48, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned is in conformity with the type described in the Type examination certificate and satisfies the requirements of these Regulations that apply to it.

Manufacturing

46. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pressure equipment, or assembly, with the type described in the Type examination certificate and with the requirements of these Regulations.

Final assessment and pressure equipment check

47.—(1) The manufacturer shall choose an approved body to carry out checks, or have them carried out, at random intervals determined by that body.

(2) Checks carried out by the approved body shall—

(a) verify the quality of the final assessment;

(b) verify the quality of the internal checks,

taking into account the technological complexity of the pressure equipment, or assembly, and the quantity of production.

(3) The approved body shall establish that the manufacturer actually performs the final assessment in accordance with paragraphs 25 to 28 of Schedule 2 to these Regulations.

(4) An adequate sample of the final pressure equipment, or assembly, taken on-site by the approved body before placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the designated standards, or equivalent test applying other technical specifications, shall be carried out to check the conformity of the pressure equipment, or assembly, with the relevant requirements of these Regulations.

(5) The approved body shall assess the number of items of equipment to sample and whether it is necessary to perform, or have performed, all or part of the final assessment on pressure equipment, or assembly, samples.

(6) Where a sample does not conform to the acceptable quality level, the approving body shall take appropriate measures.

(7) The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the pressure equipment performs within acceptable limits, with a view to ensuring conformity of the pressure equipment or assembly.

(8) Where the tests are carried out by an approved body, the manufacturer shall, under the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.

UK marking and declaration of conformity

48. The manufacturer shall—

(a) affix the UK marking to each individual pressure equipment, or assembly, that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request; and

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Authorised representative

49. The manufacturer's obligations set out in paragraph 47 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 5

Module D: Conformity to type based on quality assurance in the production process

General

50. Conformity to type based on quality assurance in the production process is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 51 and 54 and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned is in conformity with the type described in the Type examination certificate and satisfies the requirements of these Regulations that apply to it.

Manufacturing

51. The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pressure equipment, or assembly, concerned as specified in paragraph 52 and shall be subject to surveillance as specified in paragraph 53.

Quality system

52.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) all relevant information on the pressure equipment, or assembly, type envisaged;

(d) the documentation concerning the quality; and

(e) the technical documentation of the approved type and a copy of the Type examination certificate.

(3) The quality system shall ensure that the pressure equipment is in conformity with the type described in the Type examination certificate and comply with the requirements of these Regulations.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment or assembly;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(e) the means of monitoring the achievement of the required quality and the effective operation of the quality system.

(5) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems;

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with experience in the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises;

(iii) reviews the technical documentation referred to in paragraph 52, to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(6) The decision shall—

(a) be notified to the manufacturer;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(7) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(8) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system informed of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

53.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned;

(d) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, will be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

UK marking and declaration of conformity

54.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 51(1), the latter's identification number, to each individual piece of pressure equipment, or assembly, that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) for a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation referred to in paragraph 52(1);

(ii) any change referred to in paragraph 52(8)(a), as approved; and

(iii) the decisions and reports of the approved body referred to in paragraphs 52(6) and (8) and 53(2) to (4),

(2) Each approved body shall inform the Secretary of State of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(3) Each approved body shall inform the other approved bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

55. The manufacturer's obligations set out in paragraph 52(1) and (8) and paragraph 54 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 6

Module D1: Quality assurance of the production process

General

56. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 57, 58 and 61, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned satisfies the requirements of these Regulations.

Technical documentation

57.—(1) The manufacturer shall establish the technical documentation.

(2) The technical documentation shall—

(a) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(b) include an adequate analysis and assessment of the risk;

(c) specify the applicable requirements and contain, where applicable—

(i) a general description of the individual piece of equipment or the assembly;

(ii) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(iv) a list of the designated standards;

(v) results of design calculations made, examinations carried out the results of any other relevant calculation or examination; and

(vi) test reports.

(3) The technical documentation must be kept at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Manufacturing

58. The manufacturer shall operate an approved quality system for production, final product inspection and testing of the pressure equipment, or assembly, concerned as specified in paragraph 59 and shall be subject to surveillance as specified in paragraph 60.

Quality system

59.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) all relevant information on the pressure equipment, or assembly, type envisaged;

(d) the documentation concerning the quality system; and

(e) the technical documentation referred to in paragraph 57.

(3) The quality system shall ensure compliance of the pressure equipment, or assembly, with the requirements of these Regulations that apply to it.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment or assembly;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(e) the means of monitoring the achievement of the required quality and the effective operation of the quality system.

(5) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems; and

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with experience in the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises; and

(iii) reviews the technical documentation referred to in paragraph 56, to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(6) The decision shall—

(a) be notified to the manufacturer;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(7) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(8) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system informed of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

60.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the technical documentation referred to in paragraph 57;

(d) provide the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

(e) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, should be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits, the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

UK marking and declaration of conformity

61.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 58(1), the latter's identification number, to each individual piece of pressure equipment, or assembly, that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) For a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation referred to in paragraphs 59(1) and (2);

(ii) the change referred to in paragraph 59(8); and

(iii) the decisions and reports of the approved body referred to in paragraphs 58(8) and 60(2) to (4),

(2) Each approved body shall inform the Secretary of State of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(3) Each approved body shall inform the other approved bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

62. The manufacturer's obligations set out in paragraphs 59(1), (2) and (8) and paragraph 61 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 7

Module E: Conformity to type based on pressure equipment quality assurance

General

63. Conformity to type based on pressure equipment quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 64 and 67, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned is in conformity with the type described in the Type examination certificate and satisfies the requirements of these Regulations.

Manufacturing

64. The manufacturer shall operate an approved quality system for the final product inspection and testing of the pressure equipment, or assembly, concerned as specified in paragraph 65 and shall be subject to surveillance as specified in paragraph 66.

Quality system

65.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) all relevant information on the pressure equipment, or assembly, type envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the Type examination certificate.

(3) The quality system shall ensure compliance of the products with the type described in the Type examination certificate and with the applicable requirements of these Regulations.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment or assembly;

(b) the examinations and tests that will be carried out after manufacture;

(c) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(d) the means of monitoring the effective operation of the quality system.

(5) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems;

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with experience in the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises;

(iii) reviews the technical documentation referred to in paragraph 65(2)(e), to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(6) The decision shall—

(a) be notified to the manufacturer;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(7) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(8) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system informed of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

66.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the technical documentation;

(d) provide the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

(e) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, should be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits, the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

UK marking and declaration of conformity

67.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 65(1), the latter's identification number, to each individual piece of pressure equipment, or assembly, that is conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) for a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation referred to in paragraphs 65(1) and (2);

(ii) the change referred to in paragraph 65(8); and

(iii) the decisions and reports of the approved body referred to in paragraphs 65(5) and (8) and 66(2) and (3).

(2) Each approved body shall inform the Secretary of State of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(3) Each approved body shall inform the other approved bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

68. The manufacturer's obligations set out in paragraphs 65(1), (2) and (8) and paragraph 67 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate agreed between the manufacturer and representative.

PART 8

Module E1: Quality assurance of final pressure equipment inspection and testing

General

69. Quality assurance of final pressure equipment inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 70 (technical documentation), 71 (manufacturing) and 74 (UK marking and declaration of conformity), and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned satisfies the requirements of these Regulations that apply to it.

Technical documentation

70.—(1) The manufacturer shall establish the technical documentation. The technical documentation shall—

(a) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(b) include an adequate analysis and assessment of any risk;

(c) specify the applicable requirements and contain, where applicable—

(i) a general description;

(ii) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits, and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(iv) a list of the designated standards;

(v) results of design calculations made, examinations carried out and the results of any other relevant calculation or examination; and

(vi) test reports.

(2) The technical documentation must be kept at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Manufacturing

71. The manufacturer shall operate an approved quality system for the final product inspection and testing of the pressure equipment, or assembly, concerned as specified in paragraph 72 and shall be subject to surveillance as specified in paragraph 73.

Quality system

72.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) all relevant information on the pressure equipment, or assembly, type envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation referred to in paragraph 70.

(3) The quality system shall ensure compliance of the pressure equipment, or assembly, with the requirements of these Regulations that apply to it.

(4) Under the quality system, each item of pressure equipment, or assembly, shall be examined and appropriate tests as set out in the designated standards and particularly final assessments as set out in paragraphs 25 to 28 of Schedule 2 shall be carried out in order to ensure its conformity with the requirements of these Regulations.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment or assembly;

(b) the procedures used for the permanent joining of parts as approved with paragraph 21 of Schedule 2 to these Regulations;

(c) the examinations and tests that will be carried out after manufacture;

(d) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(e) the means of monitoring the achievement of the required quality and the effective operation of the quality system.

(6) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems;

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with experience in the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises;

(iii) reviews the technical documentation referred to in paragraph 70, to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(7) The decision shall—

(a) be notified to the manufacturer;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(8) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(9) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system informed of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

73.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the technical documentation referred to in paragraph 70;

(d) provide the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

(e) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, should be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

UK marking and declaration of conformity

74.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 72(1), the latter's identification number, to each individual piece of pressure equipment, or assembly, that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) for a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation referred to in paragraphs 70(1) and (2);

(ii) the change referred to in paragraph 72(9); and

(iii) the decisions and reports of the approved body referred to in paragraphs 72(9) and 73(2) to (4).

(2) Each approved body shall inform the Secretary of State of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(3) Each approved body shall inform the other approved bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

75. The manufacturer's obligations set out in paragraphs 72(1), (2) and (9) and paragraphs 70 and 74 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 9

Module F: Conformity to type based on pressure equipment verification

General

76. Conformity to type based on pressure equipment verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 77 and 80, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned, which has been subject to the provisions of paragraph 78, is in conformity with the type described in the Type examination certificate and satisfies the requirements of these Regulations which apply to it.

Manufacturing

77. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the Type examination certificate and with the requirements of these Regulations which apply to them.

Verification

78.—(1) An approved body chosen by the manufacturer shall carry out the appropriate examinations and tests in order to check the conformity of the pressure equipment, or assembly, with the approved type described in the Type examination certificate and with the appropriate requirements of these Regulations.

(2) The examinations and tests to check the conformity of the pressure equipment with the appropriate requirements shall be carried out by examination and testing of every product as specified in paragraph 79.

Verification of conformity by examination and testing of every item of pressure equipment or assembly

79.—(1) All pressure equipment, or assemblies, shall be individually examined and appropriate tests set out in the relevant designated standards or equivalent tests shall be carried out in order to verify conformity with the approved type and described in the Type examination certificate and with the appropriate requirements of these Regulations.

(2) In the absence of such a designated standard, the approved body concerned shall decide on the appropriate tests to be carried out.

(3) The approved body shall—

(a) verify that the personnel undertaking the permanent joining of parts and the non-destructive tests are qualified or approved in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations;

(b) verify the certificate issued by the materials manufacturer in accordance with paragraphs 31(6) to (8) of Schedule 2 to these Regulations; and

(c) carry out or have carried out the final inspection and proof test referred to in paragraphs 25 to 28 to Schedule 2 of these Regulations.

(4) The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number or have it affixed under its responsibility to each approved item of pressure equipment or assembly.

(5) The manufacturer shall keep certificates of conformity available for inspection by the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

UK marking and declaration of conformity

80. The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 78(1), the latter's identification number, to each individual item of pressure equipment, or assembly, that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for each pressure equipment model, or assembly, which identifies the pressure equipment model, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market; and

(e) if the approved body referred to in paragraph 78(1) agrees and under its responsibility, the manufacturer may also affix the approved body's identification number to the pressure equipment, or assembly, during the manufacturing process.

Authorised representative

81. The manufacturer's obligations may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligation set out in paragraph 77.

PART 10

Module G: Conformity based on unit verification

General

82. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 83, 84 and 85, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned, which has been

subject to the provisions of paragraph 85, is in conformity with the requirements of these Regulations that apply to it.

Technical documentation

83.—(1) The manufacturer shall establish the technical documentation and make it available to the approved body referred to in paragraph 85.

(2) The technical documentation shall—

(a) make it possible to assess the conformity of the pressure equipment, or the assembly, to the relevant requirements;

(b) include an adequate analysis and assessment of the risk;

(c) specify the applicable requirements and contain, where applicable—

(i) a general description;

(ii) the conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for an understanding of those drawings and diagrams and the operation of the pressure equipment;

(iv) a list of the designated standards;

(v) results of design calculations made, examinations carried out the results of any other relevant calculation or examination;

(vi) test reports; and

(vii) appropriate details relating to the approval of the manufacturing and test procedures and of the qualifications or approvals of the personnel concerned in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations.

(3) The technical documentation must be kept at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Manufacturing

84. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured pressure equipment, or assembly, with the applicable requirements of these Regulations.

Verification

85.—(1) An approved body chosen by the manufacturer shall carry out the appropriate examinations and tests, set out in the relevant designated standards or equivalent tests, to check the conformity of the pressure equipment, or assembly, with the appropriate requirements of these Regulations, or have them carried out.

(2) In the absence of such a designated standard the approved body concerned shall decide on the appropriate tests to be carried out applying other technical specifications.

(3) The approved body shall—

(a) examine the technical documentation with respect to the design and manufacturing process;

(b) assess the materials used where these are not in conformity with the relevant designated standards and check the certificate issued by the materials manufacturer in accordance with paragraphs 31(6) to (8) of Schedule 2 to these Regulations;

(c) approve the procedures for the permanent joining of parts and check that they have been previously approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(d) verify the qualifications and approvals required under paragraphs 21 and 22 of Schedule 2 of these Regulations;

(e) carry out the final inspection referred to in paragraphs 25 to 28 of Schedule 2 of these Regulations and perform or have performed the proof test, referred to in the same paragraphs, and examine safety devices, if applicable.

(4) The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number or have it affixed under its responsibility to each approved item of pressure equipment or assembly.

(5) The manufacturer shall keep certificates of conformity available for inspection by the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

UK marking and declaration of conformity

86. The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 85, the latter's identification number, to each individual item of pressure equipment, or assembly, that satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity which identifies the pressure equipment model, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request; and

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Authorised representative

87. The manufacturer's obligations set out in paragraphs 83 and 85 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that the responsibilities are specified in the mandate set out between the manufacturer and representative.

PART 11

Module H: Conformity based on full quality assurance

General

88. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 89 and 92, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned satisfies the requirements of these Regulations that apply to them.

Manufacturing

89. The manufacturer shall operate an approved quality system for; the final design, manufacture, final product inspection and testing of the pressure equipment, or assembly concerned; as specified in paragraph 90 and shall be subject to surveillance as specified in paragraph 91.

Quality system

90.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) the technical documentation for one model of each type of pressure equipment, or assembly, intended to be manufactured which shall, wherever applicable, contain—

(i) a general description of the pressure equipment or assembly;

(ii) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits and all other relevant parts, to component level;

(iii) descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment or assembly;

(iv) a list of the designated standards, applied in part or in full, and descriptions of the solutions adopted to meet the essential safety requirements of these Regulations where those designated standards have not been applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out and the results of any other relevant calculation or examination;

(vi) test reports;

(c) a written declaration that the same application has not been lodged with any other approved body; and

(d) the documentation concerning the quality system.

(3) The quality system shall ensure compliance of the pressure equipment, or assembly, with the requirements of these Regulations that apply to it.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to the quality of the pressure equipment or assembly;

(b) the technical design specifications, including standards, that will be applied and, where the relevant designated standards will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations that apply to the pressure equipment or assembly will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment, or assembly, pertaining to the product type covered, particularly with regard to materials in accordance with Part 4 of Schedule 2 to these Regulations;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures used for the permanent joining of parts as approved in accordance with paragraph 21 of Schedule 2 to these Regulations;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(g) the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.

(5) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems;

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with knowledge of the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises;

(iii) reviews the technical documentation referred to in paragraph 90(2)(b), to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(6) The decision shall—

(a) be notified to the manufacturer, or his authorised representative;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(7) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(8) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system informed of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in sub-paragraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

91.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the quality records provided for by the design part of the quality system, such as results of analyses, calculations, tests and any other relevant quality records;

(d) provide the quality records provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, and any other relevant quality records; and

(e) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, should be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

UK marking and declaration of conformity

92.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 90(1), the latter's identification number, to each individual item of pressure equipment, or assembly, that satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment model, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) for a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation referred to in paragraph 90(2);

(ii) the documentation concerning the quality system referred to in paragraph 90(4);

(iii) the change referred to in paragraph 90(8); and

(iv) the decisions and reports of the approved body referred to in paragraphs 90(8) and 91(2) to (4);

(2) Each approved body shall inform the Secretary of State of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(3) Each approved body shall inform the other approved bodies of the quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

93. The manufacturer's obligations set out in paragraphs 90(1), (2) and (8) and paragraph 92 may be fulfilled by their authorised representative, on their behalf and under their responsibility, provided that they are specified in the mandate.

PART 12

Module H1: Conformity based on full quality assurance plus design examination

General

94. Conformity based on full quality assurance plus design examination and special surveillance of the final assessment is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 95 and 99, and ensures and declares on their sole responsibility that the pressure equipment, or assembly, concerned satisfies the requirements of these Regulations that apply to it.

Manufacturing

95. The manufacturer shall operate an approved quality system for design, manufacture, final product inspection and testing of the products concerned as specified in paragraph 96 and shall be subject to surveillance as specified in paragraph 98. The adequacy of the technical design of the pressure equipment, or assembly, shall have been examined in accordance with paragraph 97.

Quality system

96.—(1) The manufacturer shall lodge an application for assessment of their quality system with the approved body of their choice for the pressure equipment, or assembly, concerned.

(2) The application shall include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, their name and address as well;

(b) the technical documentation for one model of each type of pressure equipment, or assembly, intended to be manufactured which shall, wherever applicable, contain—

(i) a general description of the pressure equipment or assembly;

(ii) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits and any other relevant parts, to component level;

(iii) descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment or assembly;

(iv) a list of the designated standards, applied in part or in full, and descriptions of the solutions adopted to meet the essential safety requirements of these Regulations where those designated standards have not been applied. In the event of partly applied designated standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out and the results of any other relevant calculation or examination;

(vi) test reports;

(c) a written declaration that the same application has not been lodged with any other approved body; and

(d) the documentation concerning the quality system.

(3) The quality system shall ensure compliance of the pressure equipment, or assembly, with the requirements of these Regulations that apply to it.

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

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant designated standards will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations that apply to the pressure equipment or assembly will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the pressure equipment, or assembly, pertaining to the product type covered, particularly with regard to materials in accordance with Part 4 of Schedule 2 to these Regulations;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used, particularly the procedures used for the permanent joining of parts as approved with paragraph 21 of Schedule 2 to these Regulations;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications and approvals of the personnel concerned, particularly of those of the personnel undertaking the permanent joining of parts and the non-destructive test in accordance with paragraphs 21 and 22 of Schedule 2 to these Regulations; and

(g) the means of monitoring the achievement of the required design and pressure equipment quality and the effective operation of the quality system.

(5) The approved body shall—

(a) assess the quality system to determine whether it satisfies the requirements referred to in sub-paragraphs (3) and (4);

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard;

(c) provide a team with experience in quality management systems;

(d) ensure that the audit—

(i) is carried out by a team containing at least one member with knowledge of the relevant pressure equipment, or assembly, field and pressure equipment and assembly technology concerned, and knowledge of the applicable requirements of these Regulations;

(ii) includes an inspection visit to the manufacturer's premises;

(iii) reviews the technical documentation referred to in sub-paragraph (2)(b), to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(6) The decision shall—

(a) be notified to the manufacturer, or his authorised representative;

(b) contain the conclusions of the audit; and

(c) contain a reasoned assessment decision.

(7) The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(8) Where the manufacturer intends to change the quality system—

(a) the manufacturer shall inform the approved body that has approved the quality system of the intended change to the quality system;

(b) the approved body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in subparagraph (5) or whether a reassessment is necessary;

(c) the approved body shall notify the manufacturer of its decision; and

(d) the notification shall contain the conclusions of the examination and the reasoned assessment decision.

Design examination

97.—(1) The manufacturer shall lodge an application for the examination of the design of each item of pressure equipment, or assembly, not covered by a previous design examination with the approved body referred to in paragraph 96(1).

(2) The application shall make it possible to understand the design, manufacture and operation of the pressure equipment, or assembly, and to assess the conformity with the requirements of these Regulations that apply to it.

(3) The application shall include—

(a) the name and address of the manufacturer;

(b) the technical documentation for one model of each type of pressure equipment, or assembly, intended to be manufactured which shall, wherever applicable, contain—

(i) a general description of the pressure equipment or assembly;

(ii) conceptual design and manufacturing drawings and diagrams of components, sub-assemblies, circuits all other relevant parts, to component level;

(iii) descriptions and explanations necessary for the understanding of those drawings and diagrams and the operation of the pressure equipment or assembly;

(iv) a list of the designated standards, applied in part or in full, and descriptions of the solutions adopted to meet the essential safety requirements of these Regulations where those designated standards have not been applied. In the event of partly

applied designated standards, the technical documentation shall specify the parts which have been applied;

(v) results of design calculations made, examinations carried out and the results of any other relevant calculation or examination;

(vi) test reports;

(c) a written declaration that the same application has not been lodged with any other approved body; and

(d) the supporting evidence for the adequacy of the technical design. The supporting evidence shall mention any documents that have been used, in particular where the relevant designated standards have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on their behalf and under their responsibility.

(4) Where the design meets the requirements of these Regulations the approved body shall issue a design examination certificate.

(5) The design examination certificate—

(a) must include—

(i) the name and address of the manufacturer;

(ii) the conclusions of the examination;

(iii) the conditions (if any) for the validity of the certificate; and

(iv) data necessary for identification of the approved design;

(b) may have one or more annexes attached;

(c) shall contain all relevant information to allow the conformity of manufactured products with the examined design to be evaluated, and to allow for in-service control, where applicable.

(6) Where the design does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving details for its refusal.

(7) The approved body shall keep itself appraised of any changes in the generally acknowledged state of the art which indicates that the approved design may no longer comply with the applicable requirements of these Regulations, and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly.

(8) The manufacturer shall inform the approved body that issued the design examination certificate of all modifications to the approved design that may affect the conformity of the pressure equipment, or assembly, with the essential safety requirements of these Regulations or the conditions for validity of the certificate. Such modifications shall require additional approval, from the approved body that issued the design examination certificate, in the form of an addition to the original design examination certificate.

(9) Each approved body shall inform the Secretary of State of the design examination certificates and any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of certificates and any additions thereto refused, suspended or otherwise restricted.

(10) Each approved body shall inform the other approved bodies concerning the design examination certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted and, upon request, concerning the certificates and additions thereto that it has issued.

(11) Other approved bodies may, on request, obtain a copy of the design examination certificate and additions thereto.

(12) The approved body shall keep a copy of the design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

(13) The manufacturer shall keep a copy of the design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market.

Surveillance under the responsibility of the approved body

98.—(1) The manufacturer shall—

(a) allow the approved body access to the manufacture, inspection, testing and storage sites for assessment;

(b) provide the quality system documentation;

(c) provide the quality records provided for by the design part of the quality system, such as results of analyses, calculations, tests and any other relevant quality records;

(d) provide the quality records provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, and any other relevant quality records; and

(e) provide any other information deemed necessary by the approved body.

(2) The approved body shall—

(a) carry our periodic audits to make sure that the manufacturer maintains and applies the quality system;

(b) provide the manufacturer with an audit report;

(c) ensure that the frequency of the periodic audits is such that a full reassessment is carried out every three years.

(3) The approved body may pay unexpected visits to the manufacturer. The need for such additional visits, and their frequency, will be determined on the basis of a visit control system operated by the approved body. The following factors shall be considered in the visit control system—

(a) the category of the pressure equipment or assembly;

(b) the results of previous surveillance visits;

(c) the need to follow up corrective actions;

(d) special conditions linked to the approval of the system, where applicable; and

(e) significant changes in manufacturing organisation, policies or techniques.

(4) During unexpected visits, the approved body—

(a) may carry out product tests or have them carried out, where necessary, in order to verify that the quality system is functioning correctly;

(b) shall provide the manufacturer with a visit report; and

(c) shall, where tests have been carried out, provide the manufacturer with a test report.

(5) Final assessment as referred to in paragraphs 25 to 28 of Schedule 2 to these Regulations is subject to increased surveillance in the form of unexpected visits by the approved body. In the course of such visits, the approved body shall conduct examinations on the pressure equipment, or assembly, and provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking and declaration of conformity

99.—(1) The manufacturer shall—

(a) affix the UK marking and, under the responsibility of the approved body referred to in paragraph 96(1), the latter's identification number, to each individual items of pressure equipment, or assembly, that satisfies the applicable requirements of these Regulations;

(b) draw up a written declaration of conformity for the pressure equipment model, or assembly, which identifies the pressure equipment, or assembly, for which it has been drawn up;

(c) make a copy of the declaration of conformity available, to the relevant authorities, on request;

(d) keep a copy of the declaration of conformity at the disposal of the national authorities for 10 years after the pressure equipment, or assembly, has been placed on the market;

(e) for a period ending 10 years after the pressure equipment, or assembly, has been placed on the market, keep at the disposal of the national authorities—

(i) the documentation concerning the quality system referred to in paragraph 96(2);

(ii) the change referred to in paragraph 96(8); and

(iii) the decisions and reports of the approved body referred to in paragraphs 96(8) and 98(2) and (3),

Authorised representative

100. The manufacturer's authorised representative may lodge the application referred to in paragraphs 96(1) and (2) and fulfil the obligations set out in paragraphs 95(1), (2) and (8), 96(8) and (13) and paragraph 98, on the manufacturer's behalf and under his responsibility, provided that they are specified in the mandate set out between the manufacturer and his representative.**]**

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Pressure Equipment (Safety) Regulations 2016. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:
Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

– Sch. 2 para. 21(3)(3A) substituted for Sch. 2 para. 21(3) by S.I. 2024/490 reg. 2(4)(a)