[F1SCHEDULE 1A

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 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.**]**

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
There are currently no known outstanding effects for the The Pressure Equipment (Safety) Regulations 2016, PART 3.