SCHEDULE 2 Regulations 40 and 41

Conformity Assessment Procedures

PART 1

EU-Type Examination (Module B)

1. EU-type examination (Module B) is a conformity assessment procedure in which a notified body examines the technical design of a vessel and verifies and attests that the technical design of the vessel meets the applicable requirements of these Regulations that apply to it.

2.—(1) A manufacturer must lodge an application for EU-type examination (Module B) with a single notified body of the manufacturer's choice.

(2) The application must include—

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

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

(c) the technical documentation;

(d) where applicable, the prototype vessels (and any further prototype vessels requested by the notified body if needed for carrying out the test programme) representative of the production envisaged;

(e) the supporting evidence for the adequacy of the technical design solution; this supporting evidence must—

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

(ii) include, where necessary, the results of tests carried out in accordance with other technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under his responsibility.

3.—(1) The technical documentation referred to in paragraph 2(2)(c) must—

(a) make it possible to assess the vessel's conformity with the applicable requirements of these Regulations and must include an adequate analysis and assessment of any risks;

(b) specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the vessel;

(c) contain, wherever applicable, at least the following elements—

(i) a general description of the vessel;

(ii) conceptual design and manufacturing drawings and schemes of components;

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the vessel;

(iv) a list of the harmonised standards applied in full or in part (where applicable specifying the parts which have been applied), the references to which have been published in the Official Journal;

(v) where harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements, including a list of other relevant technical specifications applied;

(vi) results of design calculations made and examinations carried out;

(vii) test reports;

(viii) the instructions and safety information;

(ix) A document describing—

(aa) the materials selected;

(bb) the welding processes selected;

(cc) the checks selected; and

(dd) any pertinent details as to the vessel design.

(2) Where a prototype vessel is examined, the technical documentation must also include—

(a) the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators;

(b) the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel;

(c) a report on the examination and tests performed or a description of the proposed checks.

4.—(1) The notified body must examine the technical documentation and supporting evidence in respect of a vessel and, if provided, the prototype representative of the production of the vessel, to assess the adequacy of the technical design of the vessel.

(2) Where a prototype vessel is examined, the notified body must—

(a) verify that a prototype vessel—

(i) has been manufactured in conformity with the technical documentation;

(ii) may safely be used under its intended working conditions;

(iii) identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

(b) carry out, or arrange the carrying out, of appropriate examinations and tests to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;

(c) carry out, or arrange the carrying out, of appropriate examinations and tests to check whether, where the solutions in the relevant harmonised 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; and

(d) agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body must draw up an evaluation report that records the activities undertaken in accordance with paragraph 4 and their outcomes and, without prejudice to the notified body's obligations vis-à-vis the Secretary of State, the notified body may disclose the content of that report, in full or in part, only with the agreement of the manufacturer.

6.—(1) Where the type meets the requirements of these Regulations, the notified body must issue an EU-type examination certificate to the manufacturer, which must contain—

(a) the name and address of the manufacturer;

(b) the conclusions of the examination;

(c) the conditions (if any) for its validity;

(d) all relevant information to allow the conformity of manufactured vessels with the examined type to be evaluated and to allow for in-service control; and

(e) the necessary data for the identification of the approved type.

(2) The EU-type examination certificate referred to in sub-paragraph (1)—

(a) may have one or more annexes attached;

(b) must be accompanied by the descriptions and drawings necessary for identification of the approved type.

(3) Where the type does not satisfy the applicable requirements of these Regulations, the notified body must refuse to issue an EU-type certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

7.—(1) A notified body must keep itself appraised of any changes to 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 must determine whether such changes require further investigation and, if so, the notified body must inform the manufacturer accordingly.

(2) A manufacturer must inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the vessel with the essential safety requirements or the conditions for validity of the certificate; such modifications require additional approval in the form of an addition to the original EU-type examination certificate.

8.—(1) Each notified body must inform the Secretary of State of all the EU-type examination certificates and any additions thereto which it has issued or withdrawn and must, periodically or upon request, make available to the Secretary of State the list of such certificates and any additions thereto refused, suspended, or otherwise restricted.

(2) Each notified body must inform the other notified bodies concerning the EU-type examination certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted and, upon request, concerning such certificates and additions thereto which it has issued.

(3) A notified body must, on request, provide the Commission, the member States and the other notified bodies, with a copy of the EU-type examination certificates and additions thereto which it has issued.

(4) A notified body must, on request, provide the Commission and the member States with a copy of the technical documentation and the results of the examinations carried out by the notified body.

(5) A notified body must keep a copy of the EU-type 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 that certificate.

9. A manufacturer must keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the enforcing authorities for a period of 10 years beginning on the day on which the vessel is placed on the market.

PART 2

Conformity to type based on internal production control plus supervised vessel testing (Module C1)

10. Conformity to type based on internal production control plus supervised vessel testing is a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 11 to 13 and it is the manufacturer's sole responsibility to ensure and declare that the

vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the applicable requirements of these Regulations.

Manufacturing

11.—(1) A manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the applicable requirements of these Regulations.

(2) Before commencing manufacture, a manufacturer must provide a notified body of the manufacturer's choice with all necessary information, and in particular—

(a) the technical documentation referred to in paragraph 2(2)(c), together with —

(i) the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators;

(ii) the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel; and

(iii) a report on the examination and tests performed;

(b) the inspection document, describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed; and

(c) the EU-type examination certificate.

Vessel checks

12.—(1) For each individual type of vessel manufactured, the notified body must carry out the appropriate examinations and tests in order to verify the conformity of the vessel with the type described in the EU-type examination certificate and with the corresponding requirements of these Regulations.

(2) The manufacturer must present the vessels in the form of uniform batches and must take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

(3) When a batch is examined, the notified body must ensure that the vessels have been manufactured and checked in accordance with the technical documentation, and must perform a hydrostatic test or a pneumatic test of equivalent effect on each vessel in the batch at a pressure Ph equal to 1.5 times the vessel's design pressure in order to check its strength; the pneumatic test must be subject to acceptance of the test safety procedures by the Member State in which the test is performed.

(4) In order to examine the weld quality, the notified body must carry out tests on test-pieces taken from, at the choice of the manufacturer, either a production test-piece or from a vessel. The tests must be carried out on longitudinal welds; however, where differing weld techniques are used for longitudinal and circumferential welds, the tests must be repeated on the circumferential welds.

(5) For the vessels subject to the experimental methods referred to in paragraph 17 (experimental method) of Schedule 1, these tests on test-pieces must be replaced by a hydrostatic test on five vessels taken at random from each batch in order to check that they conform to the essential safety requirements set out in that paragraph.

(6) In the case of accepted batches, the notified body must affix its identification number, or cause that number to be affixed, to each vessel and must draw up a written certificate of conformity relating to the tests carried out. All vessels in the batch may be placed on the market except for those which have not successfully undergone a hydrostatic test or a pneumatic test.

(7) If a batch is rejected, the notified body must take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches, the notified body may suspend the statistical verification.

(8) The manufacturer must be able to supply on request by the relevant authorities the notified body's certificates of conformity referred to in sub-paragraph (6).

(9) The notified body must supply the Secretary of State and, on request, other notified bodies, other Member States and the Commission, with a copy of the inspection report issued by it.

(10) The manufacturer must, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

(11) In this paragraph, a "batch" of vessels must consist of no more than 3,000 vessels of the model of the same type.

CE marking and EU declaration of conformity

13.—(1) The manufacturer must affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of these Regulations.

(2) The manufacturer must draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the enforcing authority for a period of 10 years beginning on the day on which the vessel was placed on the market. The EU declaration of conformity must identify the vessel model for which it has been drawn up.

(3) A copy of the EU declaration of conformity must be made available to the enforcing authority upon request.

PART 3

Conformity to type based on internal production control plus supervised vessel checks at random intervals (Module C2)

14. Conformity to type based on internal production control plus supervised vessel checks at random intervals is a conformity assessment procedure whereby the manufacturer fulfills the obligations laid down in paragraphs 15 to 17, and it is the manufacturer's sole responsibility to ensure and declare that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the applicable requirements of these Regulations.

Manufacturing

15.—(1) The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the type described in the EU-type examination certificate and with the applicable requirements of these Regulations.

(2) Before commencing manufacture, the manufacturer must provide a notified body of his choice with all necessary information, and in particular—

(a) the technical documentation referred to in paragraph 2(2)(c), together with —

(i) the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators;

(ii) the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel; and

(iii) a report on the examination and tests performed;

(b) the EU-type examination certificate;

(c) a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels with the type described in the EU-type examination certificate, which document must include—

(i) a description of the means of manufacture and checking appropriate to the construction of the vessels;

(ii) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;

(iii) an undertaking to carry out the examinations and tests in accordance with the inspection document and to ensure that a hydrostatic test or, subject to the agreement of the relevant authorities, a pneumatic test is carried out on each vessel manufactured at a test pressure equal to 1.5 times the design pressure; and

(iv) the addresses of the places of manufacture and storage and the date on which manufacture is to commence.

(3) The examinations and tests referred to in paragraph 15(2)(c)(iii) must be—

(i) carried out under the responsibility of qualified staff who are independent of production personnel; and

(ii) the subject of a report.

(4) The notified body must, before the date on which any manufacture begins, examine the documents referred to in paragraphs 15(2)(a) and (c) in order to certify their conformity with the EU-type examination certificate.

Vessel checks

16.—(1) The notified body must carry out vessel checks, or ensure that vessel checks are carried out, on random samples at random intervals determined by the body, in order to verify the quality of the internal checks on the vessel, taking into account, inter alia, the technological complexity of the vessels and the quantity of production.

(2) An adequate sample of the final vessels, taken on site by the notified body before their placing on the market, must be examined and appropriate tests as identified by the relevant parts of the harmonised standards, or equivalent tests set out in other relevant technical specifications, must be carried out to check the conformity of the vessel with the type described in the EU-type examination certificate and with the relevant requirements of these Regulations.

(3) The notified body must also ensure that the manufacturer checks series-produced vessels in accordance with paragraph 15(2)(c)(iii).

(4) Where a sample does not conform to the acceptable quality level, the notified body must take appropriate measures.

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

(6) The notified body must supply the Secretary of State and, on request, other notified bodies, other Member States and the Commission, with a copy of the inspection report issued by it.

(7) The manufacturer must, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

CE marking and EU declaration of conformity

17.—(1) The manufacturer must affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of these Regulations.

(2) The manufacturer must draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the enforcing authority for a period of 10 years beginning on the day on which the vessel has been placed on the market. The EU declaration of conformity must identify the vessel model for which it has been drawn up.

(3) A copy of the EU declaration of conformity must be made available to the enforcing authority upon request.

PART 4

Conformity to type based on internal production control (Module C)

18. Conformity to type based on internal production control is a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 19 and 20, and ensures and declares that the vessels concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

Manufacturing

19.—(1) The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured vessels with the approved type described in the EU-type examination certificate and with the requirements of these Regulations that apply to them.

(2) Before commencing manufacture, the manufacturer must provide the notified body which issued the EU-type examination certificate with all necessary information, and in particular—

(a) the certificates relating to the suitable qualification of the welding operations and of the welders or welding operators;

(b) the inspection slip for the materials used in the manufacture of parts and components contributing to the strength of the vessel;

(c) a report on the examinations and tests performed;

(d) a document describing the manufacturing processes and all of the predetermined systematic measures taken to ensure conformity of the vessels with the type described in the EU-type examination certificate. That document must include—

(i) a description of the means of manufacture and checking appropriate to the construction of the vessels;

(ii) an inspection document describing the appropriate examinations and tests to be carried out during manufacture, together with the procedures in respect thereof and the frequency with which they are to be performed;

(iii) an undertaking to carry out the examinations and tests in accordance with the inspection document and to have a hydrostatic test or, subject to the agreement of the relevant authorities, a pneumatic test carried out on each vessel manufactured at a test pressure equal to 1,5 times the design pressure;

(iv) the addresses of the places of manufacture and storage and the date on which manufacture is to commence.

(3) The examinations and tests referred to in paragraph 19(2)(d)(iii) must be—

(a) carried out under the responsibility of qualified staff who are independent from production personnel; and

(b) the subject of a report.

(4) The notified body must, before the date on which any manufacture begins, examine the documents referred to in paragraph 19(2) in order to certify their conformity with the EU-type examination certificate.

CE marking and EU declaration of conformity

20.—(1) The manufacturer must affix the CE marking to each individual vessel that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of these Regulations.

(2) The manufacturer must draw up a written EU declaration of conformity for each vessel model and keep it at the disposal of the enforcing authority for a period of 10 years beginning on the day on which the vessel has been placed on the market. The EU declaration of conformity must identify the vessel model for which it has been drawn up.

(3) A copy of the EU declaration of conformity must be made available to the enforcing authority upon request.

PART 5

Interpretation

21. In this Schedule—

(a) "design pressure" means the gauge pressure in Bar chosen by the manufacturer and used to determine the thickness of the vessel's pressurised parts;

(b) "inspection slip" means the document by which the producer of the materials certifies that the products delivered meet the requirements of the order and in which the producer sets out the results of the routine in-plant inspection test, in particular chemical composition and mechanical characteristics, performed on products made by the same production process as the supply, but not necessarily on the products delivered.

(c) "P_h" means hydrostatic or pneumatic test pressure in Bar.