[F1SCHEDULE 2

United Kingdom Conformity Assessment Procedures

Textual Amendments

F1 Schs. 2-5 inserted (31.12.2020) by The Merchant Shipping (Marine Equipment) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/470), reg. 1(1), **Sch. para. 27(2)** (with regs. 5, 6) (as amended by S.I. 2020/1000, regs. 1, 7(2)); 2020 c. 1, Sch. 5 para. 1(1)

PART 3

Conformity to type based on product quality assurance (Module E)

18. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 19 and 22 and it is the manufacturer's sole responsibility to ensure and declare that the marine equipment concerned is in conformity with the type described in the United Kingdom type-examination certificate and that it satisfies the applicable international standards that apply to it.

Manufacturing

19. A manufacturer must operate an approved quality system for final product inspection and testing of the products concerned as specified in paragraph 20, and must be subject to surveillance as specified in paragraph 21.

Quality system

20.—(1) A manufacturer must lodge an application for assessment of its quality system for the marine equipment concerned with an approved body of its choice.

(2) The application must include —

(a) the name and address of the manufacturer and if the application is lodged by the authorised representative, its 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 for the marine equipment category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the United Kingdom type-examination certificate.

(3) The quality system must ensure compliance of the products with the type described in the United Kingdom type-examination certificate and with the applicable international standards.

(4) The manufacturer must document in the form of written policies, procedures and instructions all the elements, requirements and provisions that it has adopted.

(5) The quality system documentation must enable a consistent interpretation of the programmes, plans, manuals and records and must include an adequate description of—

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

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

(c) the quality records, including inspection reports and test data, calibration data and qualification reports on the personnel concerned;

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

(6) The approved body must assess the quality system to determine whether it satisfies the requirements set out in sub-paragraphs (3), (4) and (5).

(7) The auditing team of the approved body must include members with experience in quality management systems and must include at least one member with—

(a) experience of evaluation in the relevant marine equipment field;

(b) experience of the marine equipment technology concerned;

(c) knowledge of the applicable international standards.

(8) The audit carried out by the approved body must include—

(a) an assessment visit to the manufacturer's premises, and

(b) a review of the technical documentation of the approved type in order to verify the manufacturer's ability to identify the applicable international standards and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

(9) The approved body must notify the manufacturer of its decision and that notification must contain the conclusions of the audit and the reasoned assessment decision.

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

(11) The manufacturer must keep the approved body that has approved the quality system informed of any intended change to the quality system.

(12) Where the manufacturer proposes changes to the quality system, the approved body must—

(a) evaluate any proposed changes;

(b) decide whether the modified quality system will continue to satisfy the requirements set out in sub-paragraphs (3), (4) and (5) or whether a re-assessment is necessary;

(c) notify the manufacturer of its decision and that notification must contain the conclusions of the examination and the reasoned assessment decision.

Surveillance under the responsibility of the approved body

21.—(1) The manufacturer must allow the approved body access to the manufacture, inspection, testing and storage sites, and must provide it with all necessary information, in particular—

(a) the quality system documentation;

(b) the quality records, including inspection reports and test data, calibration data and qualification reports on the personnel concerned.

(2) The approved body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system, and must provide the manufacturer with an audit report.

(3) The approved body may make unannounced visits to the manufacturer and, during such visits may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly.

(4) Where the approved body has made an unannounced visit to the manufacturer, the approved body must provide the manufacturer with a visit report and, if tests have been carried out during such a visit, with a test report.

United Kingdom conformity marking and declaration of conformity

22.—(1) The manufacturer must affix the United Kingdom conformity mark and the identification number of the approved body that has approved the quality system to each individual product that is in conformity with the type described in the United Kingdom type-examination certificate and that satisfies the applicable international standards.

(2) The manufacturer must draw up a written United Kingdom declaration of conformity for each product model and keep it at the disposal of the Secretary of State for a period of at least 10 years after the United Kingdom conformity mark has been affixed on the last product manufactured and in no case for a period shorter than the expected life of the marine equipment concerned.

(3) The United Kingdom declaration of conformity must identify the marine equipment model for which it has been drawn up and a copy of the United Kingdom declaration of conformity must be made available to the Secretary of State on request.

(4) The manufacturer must keep at the disposal of the Secretary of State for a period of at least 10 years after the United Kingdom conformity mark has been affixed on the last product manufactured and in no case for a period shorter than the expected life of the marine equipment concerned—

(a) the documentation referred to in paragraph 20(2);

(b) the change referred to in paragraph 20(12), as approved;

(c) the decisions and reports of the approved body referred to in paragraphs 20(12), 21(2) and 21(4).

(5) Each approved body must inform the Secretary of State of quality system approvals that it has issued or withdrawn and must, periodically or on request, make available to the Secretary of State the list of quality system approvals that it has refused, suspended or otherwise restricted.

(6) Each approved body must inform the other United Kingdom approved bodies of quality system approvals which it has refused, suspended or withdrawn, and, on request, of quality system approvals which it has issued.

Authorised representative

23. The manufacturer's obligations set out in paragraphs 20(1), (2), (10) and (11) and 22(1), (2), (3) and (4) may be fulfilled by its authorised representative, on its behalf and under its responsibility, 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 Merchant Shipping (Marine Equipment) Regulations 2016, PART 3.