[F1SCHEDULE 1] U.K.

Regulation 31

Amendment of Regulations

Textual Amendments

F1 Sch. renumbered as Sch. 1 (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(1)** (with regs. 5, 6) (as amended by S.I. 2020/1000, regs. 1, **7(2)**); 2020 c. 1, **Sch. 5 para. 1(1)**

The Merchant Shipping (Prevention of Oil Pollution) Regulations 1996 U.K.

F2**1.** . . . . . .

Textual Amendments

F2 Sch. para. 1 revoked (1.3.2019) by The Merchant Shipping (Prevention of Oil Pollution) Regulations 2019 (S.I. 2019/42), reg. 1(1), **Sch. Pt. 2** (with regs. 2, 5)

The Merchant Shipping (Crew Accommodation) Regulations 1997 U.K.

2. In regulation 36 of the Merchant Shipping (Crew Accommodation) Regulations 1997 (equipment to be of an approved type) M1, for paragraph (2), substitute—

"(2) In this regulation—

"approved" means, in relation to an item of equipment, approved under the Merchant Shipping (Marine Equipment) Regulations 2016.".

Marginal Citations

M1 S.I. 1997/1508.

The Merchant Shipping (Fire Protection: Small Ships) Regulations 1998 U.K.

3. In regulation 1 of the Merchant Shipping (Fire Protection: Small Ships) Regulations 1998 (Interpretation) M2, for the definition of "approved", substitute—

""approved" means, in relation to any equipment or arrangement, approved under the Merchant Shipping (Marine Equipment) Regulations 2016;".

Marginal Citations

M2 S.I. 1998/1011. The definition of "approved" was substituted by S.I. 1999/1957, regulation 3, **Schedule 1**, paragraph 3.

The Merchant Shipping (Fire Protection: Large Ships) Regulations 1998 U.K.

F3**4.** . . . . . .

Textual Amendments

F3 Sch. 1 para. 4 omitted (15.6.2023) by virtue of The Merchant Shipping (Fire Protection) Regulations 2023 (S.I. 2023/568), reg. 1(1), **Sch. 1 para. 15** (with reg. 5)

The Merchant Shipping (Radio Installations) Regulations 1998 U.K.

5. In regulation 6(4) of the Merchant Shipping (Radio Installations) Regulation 1998 (performance standards) [M3], for "the Merchant Shipping (Marine Equipment) Regulations 1999" substitute " the Merchant Shipping (Marine Equipment) Regulations 2016 ".

Marginal Citations

M3 S.I. 1998/2070. Regulation 6(4) was inserted by S.I. 1999/1957, regulation 3, **Schedule 1**, paragraph 1.

The Merchant Shipping (Life-Saving Appliances for Passenger Ships other than Ships of Classes III to VI(A)) Regulations 1999 U.K.

[F4]**6.** . . . . . .

Textual Amendments

F4 Sch. 1 para. 6 omitted (9.6.2020) by virtue of The Merchant Shipping (Life-Saving Appliances and Arrangements) Regulations 2020 (S.I. 2020/501), reg. 1, **Sch. 1 para. 17** (with reg. 4)

The Merchant Shipping (Life-Saving Appliances for Passenger Ships of Classes III to VI(A)) Regulations 1999 U.K.

7. In regulation 10 of the Merchant Shipping (Life-Saving Appliances for Passenger Ships of Classes III to VI(A)) Regulations 1999 (approval and replacement of appliances and arrangements) [M4], for paragraph (1), substitute—

> "(1) Life-saving appliances and arrangements required by these Regulations shall be of a type which has been approved under the Merchant Shipping (Marine Equipment) Regulations 2016.".

Marginal Citations

M4 S.I. 1999/2723.

The Fishing Vessels (EC Directive on Harmonised Safety Regime) Regulations 1999 U.K.

8. In Schedule 4 to the Fishing Vessels (EC Directive on Harmonised Safety Regime) Regulations 1999 [M5]—

(a) in paragraph 39, for "the Merchant Shipping (Marine Equipment) Regulations 1999" substitute " the Merchant Shipping (Marine Equipment) Regulations 2016 "; and

(b) in paragraph 59, for "Council Directive 96/98/EC on marine equipment, as amended by Commission Directives 98/35/EC, 2001/53/EC and 2002/75/EC", substitute " Directive

2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC[M6] ".

Marginal Citations

M5 S.I. 1999/2998.

M6 O.J. L 257, 28.8.2014, p.146.

The Merchant Shipping (Radio) (Fishing Vessels) Regulations 1999 U.K.

9. In regulation 7(1) of the Merchant Shipping (Radio) (Fishing Vessels) Regulations 1999 (performance standards) [M7], for paragraph (c), substitute—

"(c) in either case, be of a type approved under the Merchant Shipping (Marine Equipment) Regulations 2016;".

Marginal Citations

M7 S.I. 1999/3210.

The Merchant Shipping (Fire Protection) Regulations 2003 U.K.

[F5]**10.** . . . . . .

Textual Amendments

F5 Sch. 1 para. 10 omitted (15.6.2023) by virtue of The Merchant Shipping (Fire Protection) Regulations 2023 (S.I. 2023/568), reg. 1(1), **Sch. 1 para. 15** (with reg. 5)

The Merchant Shipping (High Speed Craft) Regulations 2004 U.K.

[F6]**11.** . . . . . .

Textual Amendments

F6 Sch. 1 para. 11 revoked (19.12.2022) by The Merchant Shipping (High Speed Craft) Regulations 2022 (S.I. 2022/1219), reg. 1(1), **Sch. Pt. 2** (with reg. 4(2)-(4))

The Merchant Shipping (Fees) Regulations 2006 U.K.

12. In the Table in Schedule 1 to the Merchant Shipping (Fees) Regulations 2006 (fees under the Merchant Shipping Act 1995) [M8], for the entry relating to the Merchant Shipping (Marine Equipment) Regulations 1999, substitute—

(a) in column 1, "the Merchant Shipping (Marine Equipment) Regulations 2016"; and

(b) in column 2, "S.I. 2016/1025".

Marginal Citations

M8 S.I. 2006/2055. There are amendments to these Regulations, but none is relevant.

The Merchant Shipping and Fishing Vessels (Provision and Use of Work Equipment) Regulations 2006 U.K.

13. In the Table in Schedule 1 of the Merchant Shipping and Fishing Vessels (Provision and Use of Work Equipment) Regulations 2006 (instruments which give effect to Community Directives concerning the safety of products) [M9], omit the entry for the Merchant Shipping (Marine Equipment) Regulations 1999 and, in the appropriate place, add—

(a) in column 1, "The Merchant Shipping (Marine Equipment) Regulations 2016", and

(b) in column 2, "S.I. 2016/1025".

Marginal Citations

M9 S.I. 2006/2183.

The Legislation and Regulatory Reform (Regulatory Functions) Order 2007 U.K.

14. In Part 2 of the Schedule to the Legislation and Regulatory Reform (Regulatory Functions) Order 2007 (regulatory functions) [M10], under the heading "Marine Transport", omit "Merchant Shipping (Marine Equipment) Regulations 1999 and, in the appropriate place, add " Merchant Shipping (Marine Equipment) Regulations 2016 ".

Marginal Citations

M10 S.I. 2007/3544. There are amendments to his Order, but none is relevant.

The Merchant Shipping (Prevention of Pollution by Sewage and Garbage from Ships) Regulations 2008 U.K.

15. In regulation 21(1)(a) of the Merchant Shipping (Prevention of Pollution by Sewage and Garbage from Ships) Regulations 2008 (sewage systems) [M11], for "the Merchant Shipping (Marine Equipment) Regulations 1999" substitute " the Merchant Shipping (Marine Equipment) Regulations 2016 ".

Marginal Citations

M11 S.I. 2008/3257.

The Merchant Shipping (Prevention of Air Pollution from Ships) Regulations 2008 U.K.

16.—(1) The Merchant Shipping (Prevention of Air Pollution from Ships) Regulations 2008 [M12] are amended as follows.

(2) In regulation 21(7) (nitrogen oxides), for "Merchant Shipping Notice 1734(M + F) or Merchant Shipping Notice 1735 (M + F) as appropriate", substitute " the Merchant Shipping (Marine Equipment) Regulations 2016 ".

(3) In regulation 24 (shipboard incineration), for "Merchant Shipping Notice 1734 (M + F)", wherever occurring, substitute " the Merchant Shipping (Marine Equipment) Regulations 2016 ".

Marginal Citations
M12 S.I. 2008/2924.

[F7SCHEDULE 2 U.K.

Regulation 4

United Kingdom Conformity Assessment Procedures

Textual Amendments
F7 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 1 U.K.

United Kingdom Type-Examination (Module B) U.K.

1. United Kingdom type-examination is the part of a conformity assessment procedure in which an approved body examines the technical design of marine equipment and verifies and attests that the technical design of the marine equipment meets the applicable requirements of these Regulations.

2. United Kingdom type-examination may be carried out in either of the following ways—

(a) examination of a specimen, representative of the production envisaged, of the complete product (production type);

(b) assessment of the adequacy of the technical design of the marine equipment through examination of the technical documentation and supporting evidence referred to in paragraph 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type).

3.—(1) The manufacturer must lodge an application for United Kingdom-type examination with a single 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) the technical documentation;

(e) the specimens representative of the production envisaged. The approved body may request further specimens if needed for carrying out the test programme;

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

(i) mention any documents that have been used;

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

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

(a) make it possible to assess the conformity of the marine equipment with the applicable international standards and must include an adequate analysis and assessment of the risks;

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

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

(i) a general description of the marine equipment;

(ii) conceptual design and manufacturing drawings and schemes of components , sub-assemblies and circuits;

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

(iv) a list of the requirements and testing standards which are applicable to the marine equipment concerned in accordance with these Regulations, together with a description of the solutions adopted to meet those requirements;

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

(vi) test reports.

5.—(1) The approved body must examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the marine equipment.

(2) When examining a specimen, the approved body must—

(a) verify that the specimen has been manufactured in conformity with the technical documentation;

(b) identify the elements which have been designed in accordance with the relevant applicable requirements of these Regulations and testing standards, as well as the elements which have been designed without applying the relevant provisions of those standards;

(c) carry out appropriate examinations and tests, or have them carried out in accordance with these Regulations;

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

6. The approved body must draw up an evaluation report that records the activities taken in accordance with paragraph 5 and their outcomes and, without prejudice to its obligations in relation to the Secretary of State, the approved body may disclose the content of that report, in full or in part, only with the agreement of the manufacturer.

7.—(1) Where the type meets the requirements of the applicable international standards that apply to the marine equipment concerned, the approved body must issue a United Kingdom 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 products with the examined type to be evaluated and to allow for in-service control; and

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

(2) The United Kingdom-type examination certificate referred to in sub-paragraph (1) may have one or more annexes attached.

(3) Where the type does not satisfy the applicable requirements of the applicable international standards, the approved body must refuse to issue a United Kingdom-type certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

8.—(1) Where the approved type no longer complies with the applicable requirements, the approved body must determine whether further testing or a new conformity assessment procedure is necessary.

(2) A manufacturer must inform the approved body that holds the technical documentation relating to the United Kingdom-type examination certificate of all modifications to the approved type that may affect the conformity of the marine equipment with the requirements of the applicable international standards or the conditions for validity of the certificate; such modifications require additional approval in the form of an addition to the original United Kingdom-type examination certificate.

9.—(1) Each approved body must inform the Secretary of State about all the United Kingdom type-examination certificates and any additions to those certificates which it has issued or withdrawn, and must, periodically or on request, make available to the Secretary of State the list of such certificates and any additions to those certificates which it has refused, suspended or otherwise restricted.

(2) Each approved body must inform the other approved bodies about all the United Kingdom-type examination certificates and any additions to those certificates which it has refused, withdrawn, suspended or otherwise restricted.

(3) An approved body must, on request, provide the other approved bodies with a copy of the United Kingdom type-examination certificates and any additions to those certificates which it has issued.

(4) An approved body must keep a copy of United Kingdom-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.

(5) The Secretary of State may, on request, obtain—

(a) a copy of a United Kingdom-type examination certificate from an approved body that it has issued, refused, suspended or restricted;

(b) a copy of the technical documentation and the results of the examinations carried out by approved bodies.

10. A manufacturer must keep a copy of the United Kingdom type-examination certificate, its annexes and additions together with the technical documentation 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.

11. The manufacturer's authorised representative may lodge the application referred to in paragraph 3 and fulfil the obligations set out in paragraphs 8(2) and 10, provided that they are specified in the mandate.

PART 2 U.K.

Conformity to type based on quality assurance of the production process (Module D) U.K.

12. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 13 and 16 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 requirements of the applicable international standards that apply to it.

Manufacturing U.K.

13. A manufacturer must operate an approved quality system for production, final product inspection and testing of the products concerned as specified in paragraph 14, and be subject to surveillance as specified in paragraph 15.

Quality system U.K.

14.—(1) A manufacturer that seeks to obtain approval for its quality system for manufacture must lodge an application for assessment 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 that the products are in conformity with the type described in the United Kingdom type-examination certificate and that they comply with the applicable international standards that apply to them.

(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 corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(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, including inspection reports and test data, calibration data and qualification reports on the personnel concerned; and

(e) the means of monitoring the achievement of the required product quality and 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 and must include at least one member with —

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

(b) experience of the marine technology concerned;

(c) knowledge of the applicable requirements 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 maintain the quality system 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 changes 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 U.K.

15.—(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 U.K.

16.—(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 marking 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 14(2);

(b) any change referred to in paragraph 14(11), which has been approved;

(c) the decisions and reports of the approved body referred to in paragraph 14(12)(c), 15(2) and 15(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 upon 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, withdrawn or otherwise restricted and, on request, of quality system approvals which it has issued.

Authorised representative U.K.

17. The manufacturer's obligations set out in paragraphs 14(1), (2), (11) and (12) and 16(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.

PART 3 U.K.

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

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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 U.K.

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.

PART 4 U.K.

Conformity to type based on product verification (Module F) U.K.

24. Conformity to type based on product verification is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 25, 28(1) and 29 and it is the manufacturer's sole responsibility to ensure and declare that the products concerned, which have been subject to the verification provisions set out in paragraph 26, are in conformity with the type described in the United Kingdom-type examination certificate and that they satisfy the applicable international standards.

Manufacturing U.K.

25. A manufacturer must take all measures necessary so that the manufacturing procedure and its monitoring ensure conformity of the manufactured products with the type described in the United Kingdom type-examination certificate and with applicable international standards.

Verification U.K.

26.—(1) An approved body of the manufacturer's choice must carry out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the United Kingdom-type examination certificate and with applicable international standards.

(2) The examinations and tests to check conformity of the products with the applicable international standards must be carried out, at the manufacturer's choice, either by examination and testing of every product as specified in paragraph 27 or by examination and testing of the products on a statistical basis as specified in paragraph 28.

Verification of conformity by examination and testing of every product U.K.

27.—(1) Where verification is to be by examination and testing of every product, all products must be individually examined and tested in accordance with these Regulations, in order to verify conformity with the approved type described in the United Kingdom-type examination certificate and with applicable international standards.

(2) An approved body must issue a certificate of conformity in respect of the examinations and tests carried out and must affix its identification number to each approved product or have it affixed under its responsibility.

(3) The manufacturer must keep the certificates of conformity available for inspection by 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.

Statistical verification of conformity U.K.

28.—(1) Where verification is to be by examination and testing of the products on a statistical basis, the manufacturer must take all measures necessary so that the manufacturing process and

its monitoring ensure the homogeneity of each lot produced, and must present its products for verification in the form of homogeneous lots.

(2) A random sample must be taken from each lot and all products in a sample must be individually examined and tested in accordance with these Regulations, in order to ensure their conformity with applicable international standards and to determine whether the lot is accepted or rejected.

(3) If a lot is accepted—

(a) all products of the lot must be considered approved, except for those products from the sample that have been found not to satisfy the tests;

(b) the approved body must issue a certificate of conformity in respect of the examinations and tests carried out, and must affix its identification number to each approved product or have it affixed under its responsibility;

(c) the manufacturer must keep the certificate of conformity 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.

(4) If a lot is rejected, the approved body or the Secretary of State must take appropriate measures to prevent that lot being placed on the United Kingdom market and, in the event of the frequent rejection of lots, the approved body may suspend the statistical verification and take appropriate measures.

United Kingdom conformity marking and declaration of conformity U.K.

29.—(1) The manufacturer must affix the United Kingdom conformity mark and, under the responsibility of the approved body referred to in paragraph 26, the latter's identification number to each individual product that is in conformity with the approved type described in the United Kingdom type-examination certificate and that satisfies 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 upon request.

(4) If the approved body agrees, under its responsibility, the manufacturer may affix the approved body's identification number to the products during the manufacturing process.

Authorised representative U.K.

30. The manufacturer's obligations under this Part may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate but an authorised representative may not fulfil the manufacturer's obligations set out in paragraphs 25 and 28(1).

PART 5 U.K.

Conformity based on unit verification (Module G) U.K.

31. Conformity based on unit verification is a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 32, 33 and 35 and it is the manufacturer's sole responsibility to ensure and declare that the product concerned, which has been subject to the verification provisions set out in paragraph 34, is in conformity with the applicable international standards.

Technical documentation U.K.

32.—(1) A manufacturer must draw up the technical documentation and make it available to the approved body referred to in paragraph 34.

(2) The technical documentation referred to in sub-paragraph (1) must—

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

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

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

(i) a general description of the product;

(ii) conceptual design and manufacturing drawings and schemes of component, sub-assemblies and circuits;

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

(iv) a list of the requirements and testing standards which are applicable to the marine equipment concerned in accordance with these Regulations and descriptions of the solutions adopted to meet those requirements;

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

(vi) test reports.

(3) A manufacturer must keep the technical documentation 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.

Manufacturing U.K.

33. A manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with applicable international standards.

Verification U.K.

34.—(1) An approved body of the manufacturer's choice must carry out appropriate examinations and tests in accordance with these Regulations in order to check the conformity of the product with applicable international standards.

(2) The approved body must issue a certificate of conformity in respect of the examinations and tests carried out and must affix its identification number to the approved product or have it affixed under its responsibility.

(3) The manufacturer must keep the certificates of conformity 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.

United Kingdom conformity marking and declaration of conformity U.K.

35.—(1) The manufacturer must affix the United Kingdom conformity mark, under the responsibility of the approved body referred to in paragraph 34, the latter's identification number, to each product that satisfies the applicable international standards.

(2) The manufacturer must draw up a written declaration of United Kingdom declaration of conformity 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. The United Kingdom declaration of conformity must identify the product for which it has been drawn up.

(3) A copy of the United Kingdom declaration of conformity must be made available to the Secretary of State on request.

Authorised representative U.K.

36. The manufacturer's obligations set out in paragraphs 32 and 35 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.**]**

[F7SCHEDULE 3 U.K.

Regulation 4

Requirements to be met by Conformity Assessment Bodies in order to become Approved Bodies

1. In order to be designated as an approved body, a conformity assessment body must meet the requirements set out in paragraphs 2 to 19.

[F8 2.—(1) A conformity assessment body must have legal personality and must be established in—

(a) the United Kingdom; or

(b) the territory of a party to the CPTPP.

(2) In sub-paragraph (1) "the CPTPP" has the meaning set out in section 1 of the Trade (Comprehensive and Progressive Agreement for Trans-Pacific Partnership) Act 2024.**]**

Textual Amendments

F8 Sch. 3 para. 2 substituted (coming into force in accordance with reg. 1(2) of the amending S.I.) by The Treatment of Conformity Assessment Bodies (Comprehensive and Progressive Agreement for Trans-Pacific Partnership) Regulations 2024 (S.I. 2024/504), **reg. 6**

3. A conformity assessment body must be a third party body independent of the organisation or the marine equipment which it assesses. A body belonging to a business association or professional federation representing businesses involved in the design, manufacturing, provision, assembly, use or maintenance of marine equipment which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered a conformity assessment body.

4.—(1) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be the designer, manufacturer, or an authorised representative of a manufacturer, supplier, installer, purchaser, owner, user or maintainer of the marine equipment which is assessed.

(2) Sub-paragraph (1) does not preclude the use of products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

5. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of that marine equipment, or represent the parties engaged in those activities. They must not engage in any activity (including consultancy services) that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are designated.

6. A conformity assessment body must ensure that the activities of its subsidiaries or sub-contractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.

7. A conformity assessment body and its personnel must carry out conformity assessment activities with the highest degree of professional integrity and the requisite competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, particularly with regard to persons or groups of persons who have an interest in the results of those activities.

8. A conformity assessment body must be capable of carrying out all of the conformity assessment activities for which it has been designated, whether that assessment is carried out by the body itself or on its behalf and under its responsibility.

9. A conformity assessment body must have at its disposal—

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency of and the ability to reproduce those procedures, and have appropriate policies and procedures in place that distinguish between tasks it carries out as an approved body and other activities;

(c) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the marine equipment technology in question and the mass or serial nature of the production process.

10. A conformity assessment body must have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to the necessary equipment and facilities.

11. The personnel responsible for carrying out conformity assessment must have—

(a) sound technical and vocational training, covering all conformity assessment activities in relation to which the conformity assessment body has been designated;

(b) satisfactory knowledge of the requirements of the assessments which the conformity assessment body carries out, and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the applicable requirements and testing standards and of the applicable provisions of these Regulations; and

(d) the ability to draw up certificates, records and reports demonstrating that the assessments have been carried out.

12. A conformity assessment body must be able to demonstrate the impartiality of its top level management and the personnel responsible for carrying out the conformity assessment activities.

13. The remuneration of the top level management and the personnel responsible for carrying out the conformity assessment activities must not depend on the number of assessments carried out or on the results of those assessments.

14. A conformity assessment body must have, and must satisfy the Secretary of State that it has, adequate civil liability insurance in respect of its activities.

15. A conformity assessment body must ensure that its personnel observe professional secrecy with regard to all information obtained in carrying out their tasks in accordance with these Regulations, and that proprietary rights are protected.

16. Paragraph 15 does not prevent the personnel from providing the information to the Secretary of State.

17. A conformity assessment body must participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities, are informed of the relevant standardisation activities and the activities of any approved body co-ordination group that may be established and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

18. A conformity assessment body must meet the requirements of standard EN ISO/IEC 17065:2012.

19. A conformity assessment body must ensure that testing laboratories used for conformity assessment purposes meet the requirements of standard EN ISO/IEC 17025:2017.**]**

[F7SCHEDULE 4 U.K.

Regulation 4

Designation Procedure

Application for designation U.K.

1.—(1) An application by a conformity assessment body to become an approved body must be made to the Secretary of State and be accompanied by—

(a) a description of—

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

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

(iii) the marine equipment for which that body claims to be competent; and

(iv) either—

(aa) an accreditation certificate; or

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

(2) The Secretary of State must be satisfied that that the conformity assessment body meets the approved body requirements and may accept an accreditation certificate, provided in accordance with paragraph 1(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

Designation procedure U.K.

2. The Secretary of State may designate as approved bodies only those conformity assessment bodies which have satisfied the requirements set out in Schedule 3.

Identification numbers and lists of approved bodies U.K.

3. The Secretary of State must—

(a) assign an identification number to each approved body;

(b) make and maintain an up-to-date public list of approved bodies, which will include the identification numbers that have been allocated to them and the conformity assessment activities that they carry out.**]**

[F7SCHEDULE 5 U.K.

Regulation 14

United Kingdom Declaration of Conformity

1. A United Kingdom declaration of conformity must provide—

(a) the unique identification number of the marine equipment in respect of which the declaration of conformity is issued;

(b) the name and address of the manufacturer;

(c) a statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;

(d) the object of the declaration (identification of marine equipment allowing traceability; it may, where necessary for the identification of the marine equipment, include an image);

(e) that the object of the declaration described in sub-paragraph (d) is in conformity with the applicable international standards;

(f) references to the applicable international standards used or references to the specifications in relation to which conformity is declared;

(g) details of the approved body (name, number) which performed the intervention (details of the intervention) and issued the certificate

(h) any additional information;

(i) a statement that the declaration of conformity has been signed for, and on behalf of the approved body in question, together with the name of the place it was signed and the date of its issue, and the name, function and signature of the person making the statement.**]**

Changes to legislation:
There are currently no known outstanding effects for the The Merchant Shipping (Marine Equipment) Regulations 2016.