SCHEDULE Regulation 2

Amendment of the 2016 Regulations

Amendment of paragraph (1) of regulation 2 (interpretation)

1.—(1) Paragraph (1) of regulation 2 (interpretation) of the 2016 Regulations is amended as follows.

(2) Before the definition of "the Act" insert—

""accreditation" means an attestation by the United Kingdom national accreditation body that a conformity assessment body meets the requirements set out in Schedule 3 to carry out conformity assessment activities;

"accreditation certificate" means a certificate issued by the United Kingdom national accreditation body, attesting that a conformity assessment body meets the approved body requirements set out in Schedule 3;".

(3) In the definition of "applicable international standards", after "MSN 1874" insert "Amendment 3".

(4) In the definition of "applicable UK" standards, after "MSN 1874" insert "Amendment 3".

(5) After the definition of "applicable UK standards" insert—

""approved body" means a conformity assessment body which—

(a) has been approved by the Secretary of State pursuant to the procedure set out in Schedule 4; or

(b) immediately before exit day was a notified body in respect of which the Secretary of State had taken no action to suspend or withdraw the body's status as a notified body.

"approved body requirements" means the requirements set out in Schedule 3; "authorised representative" means a person who—

(a) immediately before exit day was established in an EEA state and appointed in accordance with article 13 of the Directive; or

(b) after exit day is appointed in accordance with regulation 16 (authorised representatives);".

(6) After the definition of "competent national authority", insert—

""conformity assessment" means the process demonstrating whether marine equipment complies with the requirements set out in these Regulations;

"conformity assessment activities" means any activities connected with conformity assessment, including calibration, testing, certification and inspection;

"conformity assessment body" means a body that performs conformity assessment activities;

"conformity assessment procedure" means a procedure referred to in regulations 4 (designation of approved and nominated bodies), 11 (applications for grant of United Kingdom conformity approval) and 12 (grant of United Kingdom conformity approval: obligations of an approved body) and Schedule 2 (United Kingdom conformity assessment procedures);".

(7) After the definition of "the Directive" insert—

""distributor" means any person in the supply chain, other than the manufacturer or the importer, who makes marine equipment available on the United Kingdom market;".

(8) For the definition of "EU Conformity Approval" substitute—

""EU conformity approval" means approval issued by an EU notified body in accordance with the Directive;".

(9) After the definition of "EU conformity approval" insert—

""EU notified body" means a body designated by the competent national authority of an EU Member State in accordance with the Directive;".

(10) After the definition of "fishing vessel" insert—

""importer" means a person who—

(a) is established in the United Kingdom; and

(b) who places marine equipment from a country outside of the United Kingdom on the United Kingdom market;

"international conventions" means the following conventions, together with their protocols and codes of mandatory application, adopted under the auspices of the International Maritime Organisation ("IMO"), which have entered into force and which lay down specific requirements for the approval by the flag State of marine equipment to be placed on board ships—

(a) the 1972 Convention on the International Regulations for Preventing Collisions at Sea (Colreg);

(b) the 1973 International Convention for the Prevention of Pollution from Ships (Marpol);

(c) the 1974 International Convention for the Safety of Life at Sea (Solas);

"international instruments" means the international conventions, together with the resolutions and circulars of the IMO giving effect to those conventions as amended from time to time, and the testing standards;".

(11) After the definition of "length" insert—

""making available on the market" means any supply of marine equipment on the United Kingdom market in the course of a commercial activity, whether in return for payment or free of charge;

"manufacturer" means any person who—

(a) manufactures marine equipment or has marine equipment designed or manufactured; and

(b) markets that equipment under that person's name or trademark;

"marine equipment" means equipment falling within the scope of these Regulations;".

(12) Omit the definition of "market surveillance authority".

(13) For the definition of "notified body" substitute—

""notified body" means a body which the Secretary of State had before exit day notified to the European Commission and the member States of the European Union in accordance with Article 17 of the Directive;".

(14) After the definition of "passenger ship" insert—

""product" means an item of marine equipment;

"RAMS" means Regulation (EC) 765/2008(**1**) of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93;

"recall" means any measure aimed at achieving the return of marine equipment that has already been placed on board a United Kingdom ship or purchased with the intention of being placed on a United Kingdom ship;

"recognised third country" means a country, that is not part of the United Kingdom or the European Union, whose marine equipment accreditation and conformity assessment

(**1**) OJ No. L 218, 13.8.2008, p. 30.

procedures the Secretary of State is satisfied, taking into account relevant international instruments, is equivalent to those of the United Kingdom;".

(15) In the definition of "relevant period", before "conformity mark" insert "United Kingdom".

(16) After the definition of "relevant period" insert—

""United Kingdom conformity mark" means the mark affixed to equipment by the manufacturer in accordance with regulation 15;

"United Kingdom declaration of conformity" means a statement issued by the manufacturer in accordance with regulation 14(2);

"United Kingdom national accreditation body" means "the body appointed by the Secretary of State in accordance with Article 4 of RAMS;".

(17) After the definition of "United Kingdom ship" insert—

""withdrawal", in relation to marine equipment, means any measure aimed at preventing marine equipment in the supply chain from being made available on the United Kingdom market".

Further amendment of regulation 2 (interpretation)

2. In regulation 2 of the 2016 Regulations (interpretation), omit paragraphs (2) and (4).

Amendment of regulation 4 (designation of notified and nominated bodies)

3.—(1) Regulation 4 of the 2016 Regulations (designation of notified and nominated bodies) is amended as follows.

(2) In the heading to regulation 4, for "notified" substitute "approved".

(3) For paragraph (1) substitute—

"(1) The Secretary of State may designate any person as an approved body to carry out the procedures specified in Schedule 2 (which makes provision about United Kingdom Conformity Assessment Procedures), provided that the Secretary of State is satisfied that person meets the requirements specified in Schedule 3 (which makes provision about requirements to be met by conformity assessment bodies in order to become approved bodies).".

(4) In paragraph (2) for the words after "Part II of" to the end substitute "Merchant Shipping Notice MSN 1874 Amendment 3".

(5) In sub-paragraph (a) of paragraph (3) for "notified" substitute "approved".

(6) In paragraph (4)—

(a) in sub-paragraph (a) for "notified" substitute "approved";

(b) in sub-paragraph (b)—

(i) for "notified" substitute "approved";

(ii) for "Annex III of the Directive" substitute "Schedule 3";

(c) in sub-paragraph (c), for "notified" substitute "approved body".

(7) In sub-paragraph (a) of paragraph (5) for "the notified" substitute "an approved".

(8) In paragraph (6) substitute "a notified" with "an approved".

(9) After paragraph (6) insert—

"(6A) The procedure for making a designation under paragraph (1) is specified in Schedule 4 (designation procedure).".

(10) In sub-paragraph (a) of paragraph (7) for "a notified" substitute "an approved".

Amendment of regulation 5 of the 2016 Regulations (requirements for equipment)

4.—(1) Regulation 5 of the 2016 Regulations (requirements for equipment) is amended as follows.

(2) In paragraph (2) after "MSN 1874", insert "Amendment 3".

(3) In paragraph (3), after "MSN 1874", insert "Amendment 3".

(4) For paragraph (4) substitute—

"(4) Equipment listed in Annex 1 of Merchant Shipping Notice MSN 1874 Amendment 3 must be taken to comply with applicable international standards where it is—

(a) approved by an approved body, accompanied by—

(i) a declaration of United Kingdom conformity under regulation 14; and

(ii) affixed with a conformity mark under regulation 15;

(b) approved by an EU notified body, accompanied by an EU declaration of conformity and affixed with an EU conformity mark; or

(c) approved by a recognised third country and accompanied by such declarations and marks of conformity (if any) as the Secretary of State may specify.".

(5) In paragraph (5), for "Annex 2 of Merchant Shipping Notice MSN 1874" substitute "Annex 2 of Merchant Shipping Notice MSN 1874 Amendment 3".

(6) In the definition of "alternative standard" in paragraph (6), for "in Annex 4" until the end, substitute "in Annex 4 of Merchant Shipping Notice MSN 1874 Amendment 3".

Amendment of regulation 6 of the 2016 Regulations (application of exemptions)

5. For regulation 6 of the 2016 Regulations (application of exemptions) substitute—

"**Exemptions**

6.—(1) The Secretary of State may allow equipment that does not comply with applicable international standards to be placed on board a ship, provided that the Secretary of State is satisfied, by whatever means, that—

(a) compliance with applicable international standards is either impracticable or unreasonable in that case or cases; and

(b) the exemption is subject to such conditions and limitations as will provide a level of safety which is at least equivalent to that provided by applicable international standards.

(2) The Secretary of State may, on reasonable notice, alter or cancel any exemption granted under paragraph (1).

(3) An exemption granted under paragraph (1) and an alteration or cancellation under paragraph (2) must be given in writing and must specify the date on which it takes effect and the terms (if any) on which it is given.".

Omission of regulations 7 (exemptions for technical innovation), 8 (exemptions for testing or evaluation) and 9 (exemptions in exceptional circumstances) of the 2016 Regulations

6. Omit—

(a) regulation 7 (exemptions for technical innovation);

(b) regulation 8 (exemptions for testing or evaluation); and

(c) regulation 9 (exemptions in exceptional circumstances),

of the 2016 Regulations.

Amendment of regulation 10 of the 2016 Regulations (transfer of a ship)

7.—(1) Regulation 10 of the 2016 Regulations (transfer of a ship) is amended as follows.

(2) In paragraph (5), in paragraph (b) of the definition of "relevant equipment", after "MSN 1874" insert "Amendment 3".

Amendment of the sub-heading of Part 3 of the 2016 Regulations

8. For the sub-heading to Part 3 of the 2016 Regulations, substitute "United Kingdom Conformity Assessment Procedures".

Amendment of regulation 11 of the 2016 Regulations (applications for grant of EU conformity approval)

9.—(1) Regulation 11 of the 2016 Regulations (applications for grant of EU conformity approval) is amended as follows.

(2) In the heading for "EU" substitute "United Kingdom".

(3) For paragraph (1), substitute—

"(1) Subject to paragraph (2), for equipment listed in Annex 1 of Merchant Shipping Notice MSN 1874 Amendment 3, the manufacturer must apply to an approved body for United Kingdom conformity approval in accordance with the procedures set out in Schedule 2.".

(4) In paragraph (2)—

(a) for "an EU" substitute "a United Kingdom";

(b) omit "or in another member State".

(5) In paragraph (3), in sub-paragraph (b), for "Annex II of the Directive" substitute "Schedule 2".

Substitution of regulation 12 of the 2016 Regulations (grant of EU conformity approval: obligations of a notified body)

10. For regulation 12 of the 2016 Regulations (grant of EU conformity approval: obligations of a notified body) substitute—

"**Grant of United Kingdom conformity approval: obligations of an approved body**

12.—(1) An approved body must—

(a) decide whether to grant or refuse United Kingdom conformity approval in accordance with the provisions of Schedule 2; and

(b) where an application is made under Part 1 of Schedule 2 (Module B), produce an evaluation report recording the activities undertaken in accordance with paragraph 5 of that Schedule and their outcomes.

(2) Where an approved body grants United Kingdom conformity approval, it must—

(a) for the type approval of equipment under Part 1 (Module B) of Schedule 2, issue a certificate containing the information specified in paragraph 7 of that module;

(b) for approval of a quality system under Part 2 (Module D) or Part 3 (Module E) of Schedule 2, notify the manufacturer of its decision in writing, including the conclusions of the audit of the quality system and the reasons for its decision; or

(c) where verifying a product under Part 4 (Module F) or Part 5 (Module) G of Schedule 2, issue a certificate of conformity for that product.

(3) Where an approved body refuses United Kingdom conformity approval, it must notify the manufacturer, giving detailed reasons for its decision.

(4) An approved body must—

(a) periodically audit a quality system that it has approved; and

(b) provide the manufacturer with a report containing the results of the audit.

(5) Where an approved body knows or has reason to believe that—

(a) equipment to which it has granted United Kingdom conformity approval no longer complies with applicable international standards; or

(b) a manufacturer has failed to comply with an obligation under regulation 20(1) to (6) (obligations of a manufacturer),

it must require the manufacturer to take immediate corrective measures to ensure that the equipment complies with applicable international standards, and where necessary, suspend or withdraw its approval for that equipment.

(6) Following the grant of United Kingdom conformity approval, an approved body must comply with the provision of information requirements in Schedule 2 and must, in particular, inform the Secretary of State about any refusal, restriction, suspension or withdrawal of a conformity certificate and, on request, information about the conformity assessment activities performed within the scope of that approved body's designation, and any other activity performed.".

Substitution of regulation 13 of the 2016 Regulations (amendments to EU conformity approval)

11. For regulation 13 of the 2016 Regulations (amendments to EU conformity approval), including the heading, substitute—

"**Amendments to United Kingdom conformity approval**

13.—(1) The manufacturer of equipment granted a United Kingdom type approval certificate by an approved body must notify that body of any changes that may affect the conformity of the equipment with applicable international standards or the conditions for validity of the certificate.

(2) The manufacturer must notify the approved body that approved a quality system under regulation 12(2)(b) of any intended changes to that system.

(3) Following receipt of a notification under paragraph (1) or (2), the approved body must determine whether an amendment to the United Kingdom conformity approval certificate or to the approval of the quality system is required and notify the manufacturer accordingly.

(4) Where an amendment to the United Kingdom conformity approval certificate or to the approval of the quality system is required, the manufacturer must apply in writing for the approval to be amended and provide such documents as requested by the approved body.".

Amendment of regulation 14 of the 2016 Regulations (declarations of conformity)

12.—(1) Regulation 14 of the 2016 Regulations (declarations conformity) is amended as follows.

(2) In the heading to regulation 14, after "Declarations of" insert "United Kingdom".

(3) In paragraph (1) for "EU" substitute "United Kingdom".

(4) For paragraph (2) substitute—

"(2) The declaration of conformity must provide the information specified in Schedule 5.".

(5) In paragraph (3)—

(a) after "the declaration of" insert "United Kingdom";

(b) for ", in one or more languages required by the flag state administration of a member State," substitute "in English";

(c) for "notified" substitute "approved".

(6) In paragraph (4), "after the declaration of" insert "United Kingdom".

Amendment of regulation 15 of the 2016 Regulations (affixing the conformity mark)

13.—(1) Regulation 15 of the 2016 Regulations (affixing the conformity mark) is amended as follows.

(2) In the heading after "Affixing the" insert "United Kingdom".

(3) For each time that "notified" occurs substitute "approved".

(4) In paragraph (1)—

(a) after "affix the" insert "United Kingdom";

(b) in sub-paragraph (a) after "declaration of" insert "United Kingdom";

(c) in the text following sub-paragraph (b) after "embed the" insert "United Kingdom".

(5) in paragraph (2), after "affix the" insert "United Kingdom".

(6) in paragraph (3)—

(a) after "The" insert "United Kingdom"

(b) in sub-paragraph (a) for "Annex I of the Directive" substitute "Annex 5 of MSN 1874 Amendment 3".

(7) in paragraph (6), in the definition of "production control phase"—

(a) for "EU" substitute "United Kingdom";

(b) for "Annex II of the Directive" substitute "Schedule 2".

Substitution of regulation 16 of the 2016 Regulations (authorised representatives)

14. For regulation 16 of the 2016 Regulations (authorised representatives) substitute—

"**16.**—(1) Where a manufacturer is not located in the United Kingdom, that manufacturer may, by a written mandate, appoint an authorised representative with the mandate to include the name and contact address of the authorised representative.

(2) Where a manufacturer appoints an authorised representative, that representative must carry out the manufacturer's obligations under regulation 20(1)(c) and 22(2).".

Substitution of regulation 17 of the 2016 Regulations (application for grant of conformity approval)

15. For regulation 17 of the 2016 Regulations (application for grant of conformity approval) substitute—

"**17.**—(1) For equipment listed in Annex 2 of Merchant Shipping Notice MSN 1874 Amendment 3, the manufacturer must apply to a nominated body for conformity approval in accordance with the procedures set out in paragraph 10 of Merchant Shipping Notice MSN 1874 Amendment 3.

(2) An application under paragraph (1) must be—

(a) in writing; and

(b) accompanied by the documentation required by paragraph 10 of Merchant Shipping Notice MSN 1874 Amendment 3.".

Amendment of regulation 18 of the 2016 Regulations (grant of conformity approval: obligations of nominated bodies)

16.—(1) Regulation 18 of the 2016 Regulations (grant of conformity approval: obligations of nominated bodies) is amended as follows.

(2) In paragraph (1), for "paragraph 11" to the end substitute "paragraph 11 of Merchant Shipping Notice MSN 1874 Amendment 3".

(3) In paragraph (2), for "paragraph 12" to the end substitute "paragraph 12 of Merchant Shipping Notice MSN 1874 Amendment 3".

Amendment of regulation 19 of the 2016 Regulations (application of Part 5)

17.—(1) Regulation 19 of the 2016 Regulations (application of Part 5) is amended as follows.

(2) For "Annex" until the end substitute "Annex 1 of Merchant Shipping Notice MSN 1874 Amendment 3".

Amendment of regulation 20 of the 2016 Regulations (obligations of a manufacturer)

18.—(1) Regulation 20 of the 2016 Regulations (obligations of a manufacturer) is amended as follows.

(2) For paragraph (1) substitute—

"(1) A manufacturer must ensure that—

(a) a United Kingdom conformity assessment is carried out in respect of all marine equipment using one of the procedures referred to in paragraph (1A);

(b) marine equipment is marked in accordance with regulation 15 (affixing the United Kingdom conformity mark); and

(c) keep the technical documentation specified in Schedule 2 and the United Kingdom declaration of conformity for the relevant period.

(1A) The procedures mentioned in paragraph (1)(a) are—

(a) where the United Kingdom type-examination as outlined in Part 1 of Schedule 2 (module B) is to be used, before being placed on the market, all marine equipment must be subject to—

(i) production-quality assurance as outlined in Part 2 of Schedule 2 (module D);

(ii) product-quality assurance as outlined in Part 3 of Schedule 2 (module E); or

(iii) product verification as outlined in Part 4 of Schedule 2 (module F);

(b) where sets of marine equipment are produced individually or in small quantities and not in series or in mass, the conformity assessment procedure may be the unit verification as set out in Part 5 of Schedule 2 (module G).".

(3) In paragraph (5), in sub-paragraph (b), after "from the" insert "United Kingdom".

(4) In paragraph (6) for "competent national authority" substitute "Secretary of State".

(5) In paragraph (7)—

(a) for "a competent national authority" substitute "the Secretary of State";

(b) for "that competent national authority" substitute "to the Secretary of State";

(c) in sub-paragraph (a) for "a notified" substitute "an approved".

(6) In paragraph (8)—

(a) in sub-paragraph (a) after "on the" insert "United Kingdom";

(b) in sub-paragraph (b) after "on the" insert "United Kingdom".

Amendment of regulation 21 of the 2016 Regulations (obligations of an importer)

19.—(1) Regulation 21 of the 2016 Regulations (obligations of an importer) is amended as follows.

(2) After—

(a) "on the" insert "United Kingdom"; and

(b) "accompanied by a" insert "United Kingdom".

Amendment of regulation 22 of the 2016 Regulations (obligations of an economic operator)

20.—(1) Regulation 22 of the 2016 Regulations (obligations of an economic operator) is amended as follows.

(2) In paragraph (1), for "a market surveillance authority" substitute "the Secretary of State".

(3) In paragraph (2)—

(a) for "a competent national authority" substitute "the Secretary of State";

(b) in sub-paragraph (a) for "that authority" substitute "the Secretary of State";

(c) in sub-paragraph (b) for "that authority" substitute "the Secretary of State".

(4) In paragraph (3) for—

(a) "a competent national authority" substitute the "Secretary of State"; and

(b) "that authority" substitute "the Secretary of State".

Amendment of regulation 23 of the 2016 Regulations (restricting, suspending or withdrawing EU conformity approval)

21.—(1) Regulation 23 of the 2016 Regulations (restricting, suspending or withdrawing EU conformity approval) is amended as follows.

(2) In the heading, for "EU" substitute "United Kingdom".

(3) In paragraph (1), for "A notified" substitute "An approved".

(4) In paragraph (2) for "a notified", substitute "an approved".

(5) In paragraph (4) for "The notified" substitute "The approved".

Amendment of regulation 24 of the 2016 Regulations (sample checks)

22.—(1) Regulation 24 of the 2016 Regulations (sample checks) is amended as follows.

(2) For "a notified" substitute "an approved".

(3) After "placed on the" insert "United Kingdom".

Amendment of regulation 25 of the 2016 Regulations (defective equipment)

23.—(1) Regulation 25 of the 2016 Regulations (defective equipment) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (a), after "from the" insert "United Kingdom"; and

(b) in sub-paragraph (b), after "equipment on the" insert "United Kingdom".

(3) In paragraph (4), in the definition of "defective equipment" after "MSN 1874" insert "Amendment 3".

Amendment of regulation 26 of the 2016 Regulations (offences and penalties)

24.—(1) Regulation 26 of the 2016 Regulations (offences and penalties) is amended as follows.

(2) In paragraph (1)(b), for "regulations 7(3), 8(3) or 10(3) are not complied with" substitute "regulation 10 are not complied with".

Amendment of regulation 29 of the 2016 Regulations (market surveillance)

25.—(1) Regulation 29 of the 2016 Regulations (market surveillance) is amended as follows.

(2) In paragraph (1), for "Annex I" to the end, substitute "Annex 1 of Merchant Shipping Notice MSN 1874 Amendment 3".

Amendment of regulation 30 (review)

26.—(1) Regulation 30 (review) is amended as follows.

(2) In paragraph (3)(a), after "to be achieved by" omit "the Directive and by".

New Schedules

27.—(1) The Schedule to the 2016 Regulations (amendment of regulations) is renumbered "Schedule 1".

(2) After Schedule 1 insert—

"SCHEDULE 2 Regulation 4

United Kingdom Conformity Assessment Procedures

PART 1

United Kingdom Type-Examination (Module B)

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

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

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

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

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

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

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

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

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.

PART 4

Conformity to type based on product verification (Module F)

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

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

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

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

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

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

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

Conformity based on unit verification (Module G)

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

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

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

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

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

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.

SCHEDULE 3

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.

2. A conformity assessment body must be established in the United Kingdom and have legal personality.

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(**2**).

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.

SCHEDULE 4

Regulation 4

Designation Procedure

Application for designation

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

(**2**) This standard and EN ISO/IEC 17025:2017 is accessible, upon payment, at https://www.iso.org/standard/39883.html.

with paragraph 1(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

Designation procedure

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

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.

SCHEDULE 5

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.”.