

1995-13 **Gibraltar Merchant Shipping (Safety, etc.)**

Subsidiary Legislation made under ss.59 and 118.

**Gibraltar Merchant Shipping (Marine Equipment)
Regulations 2016**

LN.2016/187

Commencement **18.9.2016**

Amending enactments	Relevant current provisions	Commencement date
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In exercise of the powers conferred on it by sections 59 and 118 of the Gibraltar Merchant Shipping (Safety, etc.) Act 1993 and all other enabling powers, the Government has made the following Regulations—

PART 1
Preliminary

Title and commencement.

1. These Regulations may be cited as the Gibraltar Merchant Shipping (Marine Equipment) Regulations 2016 and come into operation on 18 September 2016.

Interpretation.

2.(1) In these Regulations—

“accreditation” means an attestation by the accreditation body that a conformity assessment body meets the requirements set out in Schedule 3 to carry out conformity assessment activities;

“accreditation body” means the National Accreditation Body of the United Kingdom;

“accreditation certificate” means a certificate issued by the accreditation body, attesting that a conformity assessment body meets the approved body requirements set out in Schedule 3;

“applicable international standards” means the design, construction and performance requirements of the international instruments which the equipment must satisfy as set out in Annex 1 or 2 of MSN 1874 Amendment 3;

“applicable standards” means the requirements set out in Annex 3 of MSN 1874 Amendment 3 for equipment which is not subject to applicable international standards;

“approved body” means a conformity assessment body which—

- (a) has been approved by the GMA pursuant to the procedure set out in Schedule 4;
or
- (b) immediately before exit day was a notified body in respect of which the GMA 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 13;

“competent national authority” means the competent national authority in each member State of the European Union responsible for ensuring compliance with the requirements of the Directive;

“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, 8 and 9 and that is set out in Schedule 2;

“conformity mark” means the mark affixed to equipment by the manufacturer in accordance with regulation 12;

“declaration of conformity” means a statement issued by the manufacturer in accordance with regulation 11(2);

“Directive” means Directive 2014/90/EU of the European Parliament and of the Council of 23rd July 2014 on marine equipment and repealing Council Directive 96/98/EC;

“distributor” means any person in the supply chain, other than the manufacturer or the importer, who makes marine equipment available on the market;

“domestic passenger ship” means a passenger ship which has been issued a certificate -

- (a) to embark only on domestic voyages but not for international voyages; and
- (b) to carry more than 12 passengers;

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“domestic voyage” shall have the meaning assigned to it by regulation 2(1) of the Gibraltar Merchant Shipping (Survey, Certification and Safety) Regulations 2004;

“economic operator” means a manufacturer, authorised representative, importer or distributor;

“EU conformity approval” means approval issued by an EU notified body in accordance with the Directive;

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

“fishing vessel” means a vessel used to catch fish or other living resources of the sea with a registered length of 24 metres or more;

“Gibraltar market” includes a market for the purposes of these Regulations available in the United Kingdom (UK market market);

“Gibraltar ship” means a ship registered in Gibraltar under the Gibraltar Merchant Shipping (Registration) Act 1993;

“GMA” means the Gibraltar Maritime Administration;

“importer” means a person who-

- (a) is established in Gibraltar; and
- (b) places marine equipment from a country outside of the United Kingdom or Gibraltar on the 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-

- (a) have entered into force;
- (b) has been extended to Gibraltar; and
- (c) lays down specific requirements for the approval by the flag State of marine equipment to be placed on board ships-

- (i) the 1972 Convention on the International Regulations for Preventing Collisions at Sea (Colreg) as amended;
- (ii) the 1973 International Convention for the Prevention of Pollution from Ships (Marpol) as amended; and
- (iii) the 1974 International Convention for the Safety of Life at Sea (SOLAS) as amended;

“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;

“international voyage” means a voyage from a port in one country to a port in another country, either of the countries being a country to which the 1974 Convention for the Safety of Life at Sea applies;

“length” means the greater of the following distances-

- (a) the distance between the fore side of the stem and the axis of the rudder stock; or
- (b) 96 per cent of the distance between the fore side of the stem and the aft side of the stern,

the points and measurements being taken respectively at and along the waterline at 85 per cent of the least moulded depth of the ship; in the case of a ship with a rake of keel, the waterline must be parallel to the designated waterline;

“making available on the market” means any supply of marine equipment on the Gibraltar 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;

“market” means the Gibraltar market;

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“MSN 1874 (M+F) Amendment 3” means the Merchant Shipping Notice MSN 1874(M+F) Amendment 3 issued by the Secretary of State of the United Kingdom as amended from time to time;

“nominated body” means a person designated as a nominated body under regulation 4(2);

“notified body” means a body which the GMA 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;

“passenger” means every person on a ship other than-

- (a) the master and the members of the crew or other persons employed or engaged in any capacity on board a ship on the business of that ship;
- (b) a person on board the ship in pursuance of an obligation on the master to carry shipwrecked, distressed or other persons or by reason of any circumstance that neither the master nor the owner could have prevented; and
- (c) a child under one year of age;

“passenger ship” means a ship which carries more than 12 passengers;

“product” means an item of marine equipment;

“Regulation (EC) 765/2008” means the Regulation (EC) 765/2008 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 Gibraltar ship or purchased with the intention of being placed on a Gibraltar 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 procedures the GMA is satisfied, taking into account relevant international instruments, is equivalent to those of the United Kingdom or of Gibraltar;

“relevant period” means a period of at least 10 years from the date that the conformity mark was affixed to the equipment and not less than the expected life of the equipment;

“United Kingdom national accreditation body” means the body appointed by the Secretary of State of the United Kingdom in accordance with Article 4 of Regulation (EC) 765/2008;

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

(2) In the application of these Regulations to a hovercraft, a reference to the master of a ship includes a reference to the captain of that hovercraft.

(3) Where a ship is managed by a person other than the owner (whether on behalf of the owner, some other person or on his own behalf), a reference in these Regulations to the owner is construed as including a reference to that person.

(4) Any direction, prohibition or restriction given under these Regulations must be given in writing and must specify the date on which it takes effect and the conditions, if any, on which it is given.

Application of these Regulations.

3.(1) These Regulations apply to any Gibraltar ship wherever it may be.

(2) MSN 1874 (M+F) Amendment 3 shall apply to, and be treated as part of these Regulation in so far as any Annex to it has been specifically referred to in these Regulations.

Designation of approved and nominated bodies.

4.(1) The GMA may, with prior approval or consent of the Minister, designate any person as an approved body to carry out the procedures specified in Schedule 2, if the GMA is satisfied that the person meets the requirements specified in Schedule 3.

(2) The GMA may designate any person as a nominated body to carry out the procedures specified in paragraphs 12 and 13 of Schedule 1.

(3) A designation must be made in writing and it must set out-

- (a) the functions to be performed by the approved or nominated body;
- (b) the equipment to which the designation applies; and
- (c) any time limit or condition which applies to the designation.

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- (4) The GMA may withdraw a designation-
- (a) on request by the approved or nominated body;
 - (b) where the approved body ceases to comply with the requirements in Schedule 3;
or
 - (c) where the notified approved or nominated body fails to comply with any condition imposed under sub-regulation (3) above.
- (5) The GMA may vary a designation-
- (a) on request by the approved or nominated body; or
 - (b) where it appears necessary or expedient to do so.
- (6) The GMA may inspect an approved or nominated body to ensure if it has been performing its functions-
- (a) under regulation 9 or 15 and
 - (b) in accordance with the conditions of its designation.
- (7) The procedure for making a designation under sub-regulation (1) is specified in Schedule 4.
- (8) Where a person applies for designation under sub-regulation (1) or (2), the GMA must inform that person in writing of the reasons for-
- (a) refusing to designate that person as an approved or nominated body;
 - (b) imposing any condition more onerous than proposed by the applicant; or
 - (c) withdrawing or varying a designation.

PART 2
Requirements for equipment

Requirements for equipment.

5.(1) Subject to sub-regulation (2), where under international instruments equipment must be approved by the flag state administration, that equipment must comply with applicable international standards when it is placed on board a ship.

(2) When equipment is placed on board a domestic passenger ship or a fishing vessel and that equipment is listed in Annex 1 or 2 of MSN 1874 Amendment 3 it must comply with-

- (a) applicable international standards;
- (b) an alternative standard; or
- (c) (where there is no requirement to place that equipment on board a ship but it is placed on board voluntarily) the standard specified by the GMA.

(3) When equipment listed in Annex 3 of MSN 1874 Amendment 3 is placed on board a ship it must comply with applicable standards.

(4) Equipment listed in Annex 1 of 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 conformity under regulation 11; and
 - (ii) affixed with a conformity mark under regulation 12;
- (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 GMA may specify.

(5) Equipment listed in Annex 2 of MSN 1874 (M+F) Amendment 3 must be taken to comply with applicable international standards or an alternative standard where it is accompanied by a certificate under regulation 15.

(6) In this regulation-

“alternative standard” means a standard specified as an alternative to an applicable international standard in any instrument listed in Annex 4 of the MSN 1874 (M+F) Amendment 3.

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(7) For the purposes of this regulation and other relevant provisions of these Regulations, Schedule 1 shall have effect

Exemptions.

6.(1) The GMA may allow equipment that does not comply with applicable international standards to be placed on board a ship, if he 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 GMA may, on reasonable notice, alter or cancel any exemption granted under sub-regulation (1).

(3) An exemption granted under sub-regulation (1) and an alteration or cancellation under sub-regulation (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.

Transfer of a ship.

7.(1) Where a ship is transferred to the Gibraltar register, the GMA must inspect any relevant equipment to ensure-

- (a) its condition corresponds to the safety certificates for that equipment; and
- (b) the equipment complies with applicable international standards or is equivalent to equipment that complies with those standards.

(2) Where, following inspection of equipment under sub-regulation (1), the GMA is not satisfied that the equipment complies with the applicable international standards or is equivalent to equipment that complies with those standards, the GMA must direct the owner in writing to replace the equipment.

(3) Where, following inspection under sub-regulation (1), the GMA considers that the equipment does not comply with applicable international standards but is equivalent to equipment that complies with those standards, the GMA must issue a certificate for that equipment, which must-

- (a) confirm the GMA's approval of the equipment;
 - (b) specify any restrictions or conditions on the use of the equipment; and
 - (c) be carried with the equipment.
- (4) The GMA may withdraw a certificate where a restriction or condition on the use of equipment is breached.
- (5) In this regulation-
- “relevant equipment” means any equipment-
- (a) to which regulation 5(1) would have applied at the time the equipment was placed on board the ship if that ship had been a Gibraltar ship at that time; and
 - (b) that is specified in Annex 1 of MSN 1874 (M+F) Amendment 3.

PART 3

Conformity Assessment Procedures

Applications for grant of conformity approval.

8.(1) Subject to sub-regulation (2), for equipment listed in Annex 1 of MSN 1874 (M+F) Amendment 3, the manufacturer must apply to an approved body for conformity approval in accordance with the procedures set out in Schedule 2.

(2) A manufacturer must not apply under sub-regulation (1) where an application for a conformity assessment has been made (whether by that manufacturer or another), in respect of that type of equipment, under these Regulations, and that application has not been withdrawn.

(3) An application under sub-regulation (1) must be-

- (a) in writing; and
- (b) accompanied by the documentation required by Schedule 2.

Grant of conformity approval: obligations of an approved body.

9.(1) An approved body must-

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- (a) decide whether to grant or refuse 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 conformity approval, it must-
- (a) for the type approval of equipment under Part 2 (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 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 conformity approval no longer complies with applicable international standards; or
 - (b) a manufacturer has failed to comply with an obligation under regulation 17(1),
- 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 conformity approval, an approved body must comply with the provision of information requirements in Schedule 2 and must, in particular, inform the GMA 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.

Amendments to conformity approval.

10.(1) The manufacturer of equipment granted a 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 9(2)(b) of any intended changes to that system.

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

(4) Where an amendment to the 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.

Declaration of conformity.

11.(1) A manufacturer must provide a declaration of conformity with all equipment for which conformity approval has been granted.

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

(3) The manufacturer must provide a copy of the declaration of conformity, in English, with the equipment and send a copy of that declaration to the approved body which granted the conformity approval certificate.

(4) The owner and master of a ship must each ensure that the declaration of conformity is kept with the equipment on board the ship.

Affixing the conformity mark.

12.(1) The manufacturer must, at the end of the production stage, affix the conformity mark to-

- (a) each item of equipment for which a declaration of conformity is required; or
- (b) a data plate attached to that equipment, and

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where relevant, embed the conformity mark in the equipment’s software.

(2) Where it is not possible or warranted due to the nature of the item of equipment to affix the conformity mark in accordance with sub-regulation (1), it must be affixed to-

- (a) the package of the item of equipment;
- (b) a label on the item of equipment or its packaging; or
- (c) a document distributed with the item of equipment.

(3) The conformity mark must be-

- (a) in the form specified in Annex 5 of MSN 1874 (M+F) Amendment 3;
- (b) affixed so that it is visible, legible and indelible; and
- (c) followed by-
 - (i) the identification number of the notified body which approved the equipment, where that body is involved in the production control phase; and
 - (ii) the year in which the mark was affixed.

(4) Where the number of the notified body is to be affixed under sub-regulation (3)(c)(i), it must be affixed by-

- (a) the notified body itself; or
- (b) the manufacturer on instruction of the notified body.

(5) No person may affix a mark or inscription which is likely to mislead any person with regard to the meaning or the graphics of the mark.

(6) In this regulation—

“production control phase” means the phase of production during which the manufacturer ensures that each item of equipment complies with its conformity approval in accordance with modules D, E, F or G of Schedule 2.

Authorised representatives.

13.(1) Where a manufacturer is not located in Gibraltar, 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 17(1)(c) and 19(2).

PART 4

Other Conformity Assessment Procedures

Application for grant of conformity approval.

14.(1) For equipment listed in Annex 2 of MSN 1874 (M+F) Amendment 3, the manufacturer must apply to a nominated body for conformity approval in accordance with the procedures set out in paragraph 11 of Schedule 1.

(2) An application under sub-regulation (1) must be-

(a) in writing; and

(b) accompanied by the documentation required by paragraph 11 of Schedule 1.

Grant of conformity approval: obligations of nominated bodies.

15.(1) A nominated body must decide whether to grant or refuse conformity approval for equipment in accordance with the requirements of paragraph 12 of Schedule 1.

(2) Where a nominated body grants conformity approval for equipment, it must issue a certificate containing the information specified in paragraph 13 of Schedule 1.

(3) Where a nominated body refuses conformity approval, it must notify the manufacturer, giving detailed reasons for its decision in writing.

PART 5

Obligations of Economic Operators

Application of Part 5.

16. This Part applies only to equipment to which regulation 5(1) applies that is listed in Annex 1 of MSN 1874 (M+F) Amendment 3.

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Obligations of a manufacturer.

17.(1) A manufacturer must ensure that-

- (a) a conformity assessment is carried out in respect of all marine equipment using one of the procedures referred to in sub-regulation (2);
- (b) marine equipment is marked in accordance with regulation 12; and
- (c) keep the technical documentation specified in Schedule 2 and the declaration of conformity for the relevant period.

(2) The procedures mentioned in sub-regulation (1)(a) are-

- (a) where the 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); and
- (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) A manufacturer must undertake to fulfil any obligation arising from a quality system approved under regulation 9(2)(b) and must ensure that quality system is maintained.

(4) A manufacturer must ensure-

- (a) its name;
- (b) a type, batch or serial number or other element allowing identification of its product;
- (c) its registered trade name or trade mark; and

- (d) the address at which it can be contacted,

is on any equipment or, where that is not possible, on the packaging of that equipment or in a document accompanying that equipment or both, as appropriate.

- (5) A manufacturer must provide with any equipment-

- (a) clear instructions and all necessary information for that equipment to be installed and operated safely; and
- (b) any other documentation required by international instruments.

- (6) Where a manufacturer knows or has reason to believe that its equipment does not comply with applicable international standards, that manufacturer must-

- (a) take immediate corrective measures to ensure that the equipment complies with applicable international standards;
- (b) withdraw the equipment from the market; or
- (c) issue a recall of the equipment.

- (7) Where a manufacturer considers that equipment presents a risk, that manufacturer must immediately inform the GMA of the risk and provide details of any non-compliance with applicable international standards and any action taken in accordance with sub-regulation (6).

- (8) On request by the GMA, a manufacturer must provide to the GMA -

- (a) samples of equipment approved by a notified approved body at the manufacturer's own cost; or
- (b) access to such samples.

- (9) This regulation applies to an importer or a distributor as if that person were a manufacturer where the importer or distributor-

- (a) places equipment on the market or on board a ship under the importer or distributor's own name or trademark; or
- (b) modifies equipment already placed on the market or on board a ship in such a way that compliance with applicable international standards may be affected.

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(10) In this regulation-

“clear instructions” means instructions in a form and language which the user easily understands.

Obligations of an importer.

18. An importer which places on the market or on board a ship any equipment accompanied by a declaration of conformity under regulation 11 must ensure that-

- (a) its name;
- (b) registered trade name or trade mark; and
- (c) the address at which it can be contacted,

is on the equipment or, where that is not possible, on the packaging of the equipment or in a document accompanying the equipment or both, as appropriate.

Obligations of an economic operator.

19.(1) On receipt of a request from the GMA, an economic operator must identify any other economic operator-

- (a) who has supplied it with equipment; or
- (b) to whom it has supplied equipment, during the relevant period.

(2) On receipt of a written request from a competent national authority, which includes the reasons for making the request, an economic operator must-

- (a) provide the GMA with all information and documents necessary to show that the equipment meets applicable international standards; and
- (b) cooperate with the GMA in any action it takes to eliminate risks posed by that equipment.

(3) Information and documents provided to the GMA must be in a language easily understood by, or acceptable to, the GMA.

Restricting, suspending or withdrawing conformity approval.

20.(1) An approved body may by giving notice to the manufacturer restrict, suspend or withdraw EU conformity approval of equipment or a quality system where a manufacturer fails-

- (a) to take corrective measures required under regulation 9(5); or
 - (b) to comply with regulation 13 or 17(1) to (6).
- (2) Before issuing a notice under sub-regulation (1), a notified an approved body must give the manufacturer an opportunity to make written representations.
- (3) A notice under sub-regulation (1) must-
- (a) be in writing;
 - (b) specify the date on which it is to take effect; and
 - (c) specify the grounds for the decision.
- (4) The approved body must send a copy of any notice given under sub-regulation (1) to the GMA.

Sample checks.

21. Where equipment approved by an approved body under regulation 9 is placed on the market or supplied for use in Gibraltar but not yet placed on board a ship, the GMA may carry out sample checks of that equipment to ensure it complies with the applicable international standards.

Defective equipment.

- 22.(1) The GMA may-
- (a) direct an economic operator to withdraw or recall defective equipment from the market;
 - (b) prohibit or restrict the extent to which an economic operator may place defective equipment on the market; or
 - (c) prohibit or restrict the use of defective equipment on ships.

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(2) Before issuing a direction, prohibition or restriction, the GMA must notify any economic operator in writing and give the economic operator, not less than 10 days, to make written representations.

(3) The GMA may withdraw or vary a direction, prohibition or restriction.

(4) In this regulation-

“defective equipment” means equipment to which regulation 5(1) applies that is specified in Annex 1 of MSN 1874 (M+F) Amendment 3 and complies with applicable international standards, but which, in the opinion of the GMA -

- (a) may compromise the health and safety of the ship’s crew, passengers or other persons; or
- (b) adversely affect the marine environment.

Delegation of powers.

23. The Minister may, for administering the provisions of these Regulations, delegate by notice in the Gazette such of his powers to the Maritime Administrator as he may deem fit and proper.

Appeals.

24.(1) Where a person is aggrieved by a decision of a notified body or the Maritime Administrator who performs a function under a delegation referred to in regulation 34, that person may prefer an appeal to the Minister.

(2) The decision of the Minister given on an appeal referred to in sub-regulation (1) shall be final and conclusive.

Offences and penalties.

25.(1) The owner and master of a ship are each guilty of an offence, where-

- (a) equipment is placed on a ship otherwise than in compliance with regulation 5; or
- (b) any of the restrictions or conditions imposed by a certificate issued under regulation 7 are not complied with.

(2) It is an offence for a person-

- (a) to affix a conformity mark to equipment which has not been granted EU conformity approval;
 - (b) to fail to comply with regulation 11, 12, 17, 18 or 19;
 - (c) to forge, counterfeit or otherwise alter, deface or remove any conformity mark or identification number affixed to equipment under these Regulations; or
 - (d) to fail to comply with a direction, prohibition or restriction given under regulation 22.
- (3) A person guilty of an offence under this regulation is liable on summary conviction to a fine, and on conviction on indictment, to imprisonment for a term not exceeding two years or a fine, or both.
- (4) Where a body corporate is guilty of an offence under this regulation and that offence is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or a person who was purporting to act in any such capacity, that person as well as the body corporate is guilty of an offence.
- (5) Where the affairs of the body corporate are managed by its members, sub-regulation (4) applies in relation to the acts and defaults of a member in connection with that member's functions of management as if that member were a director of the body corporate.
- (6) In any proceedings for an offence under these Regulations, it is a defence for the person charged to show that all reasonable steps had been taken by that person to ensure compliance with the provision concerned.

Market Surveillance.

26.(1) The GMA must carry out market surveillance of equipment listed in Annex 1 of MSN 1874 (M+F) Amendment 3.

(2) In this regulation-

“market surveillance” means the measures required under the EU market surveillance framework set out in Chapter III of Regulation (EC) No 765/2008 to ensure equipment placed on the market in the United Kingdom or Gibraltar complies with applicable international standards.

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Review.

27.(1) The GMA may from time to time-

- (a) carry out a review of these Regulations;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) The report may in particular-

- (a) set out the objectives intended to be achieved by these Regulations;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(3) The first report under this regulation may be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(4) Reports under this regulation may afterwards be published at intervals not exceeding five years.

Defence to offences.

28. In any proceedings for an offence under these Regulations it must be a defence for the person charged to prove that he took all reasonable steps to avoid the commission of the offence.

Power to detain.

29. In any case where equipment on board a ship does not comply with the requirements of these Regulation, or the owner of a ship has not complied with a direction under regulation 7(2) to replace equipment on board the ship, the ship shall be liable to be detained and dealt with in accordance with the relevant provisions of the Gibraltar Merchant Shipping (Safety etc.,) Act, 1993.

Repeal

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Gibraltar Merchant Shipping (Marine Equipment) Regulations 2016 2016/187

30. The Gibraltar Merchant shipping (Marine Equipment) Regulations 2002 are repealed (the repealed Regulations).

Savings and transitional provision.

31. Notwithstanding the repeal under regulation 30, the requirements and testing standards for marine equipment applicable on 18 September 2016 under these Regulations in order to comply with the repealed Regulations shall continue to apply until the entry into force of the implementing acts referred to in Article 35(2) of the EU Directive.

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SCHEDULE 1

Regulations 4(2), 5 (7), 14 and 15.

Technical Information and Guidance

Chapter 1 Introduction

Objects of Schedule 1.

1.(1) Schedule 1 provides for-

- (a) technical information and guidance about the procedures for obtaining type approval in conformity with these Regulations; and
- (b) other pertinent information regarding Gibraltar's approach for enforcing the requirements of these Regulations, and other standards to be applied to equipment on board Gibraltar ships.

Scope of Schedule 1.

2.(1) This Schedule together with other provisions of these Regulations sets out performance and testing standards to be met by marine equipment placed or to be placed on board a Gibraltar ship in accordance with the conformity assessment procedures, as detailed in Chapter II of this Schedule.

(2) This Schedule sets out –

- (a) type approval procedures for equipment placed or to be placed on board Gibraltar ships which is outside the scope of the conformity assessment procedures for marine equipment, but requires conformity approval by various other legislative provisions and such type approvals are carried out by nominated bodies in accordance with the procedures in Chapter III of this Schedule;
- (b) the technical standards for equipment not requiring conformity assessment of type approval, before being placed on board a Gibraltar ship and for which the carriage requirement does not provide for a specific standard of equipment;
- (c) the equipment within the scope of the conformity assessment procedures for marine equipment and the associated technical requirements to which equipment must be approved by an approved body;

- (d) the requirements for equipment that falls outside the scope of the conformity assessment procedures for marine equipment but nonetheless requires type of the UK's Maritime & Coastguard Agency ("MCA") as the flag administration for Gibraltar ships under the international instruments, and equipment required to be approved in accordance with Gibraltar's other domestic maritime legislation; and
- (e) technical standards and arrangements for other equipment, where there is no specified standard for such equipment specified in existing Gibraltar legislation.

Chapter II

Equipment within the scope of the conformity assessment procedures for marine equipment

Scope of equipment approval according to the conformity assessment procedures for marine equipment.

3.(1) Equipment within the scope of this chapter is that –

- (a) which is required by the international instruments; and
- (b) must be approved by the flag state administration of the relevant ship, as provided for in regulation 5(1) of these Regulations.

(2) Equipment to which this chapter applies must be approved by one or more approved bodies.

(3) Manufacturers with existing approval certificates in accordance with the Directive (Directive 2014/90/EU on marine equipment) may continue to make their equipment available to the market and to be placed on board Gibraltar ships as provided for in regulation 5 of these Regulations.

Requirements for equipment to be placed on board a Gibraltar ship.

4.(1) Equipment placed on board a Gibraltar ship to which this chapter applies must meet the design, construction and performance requirements of the international instruments detailed in Annex 1 of MSN 1874(M+F) Amendment 3 applicable at the time when that equipment is placed on board in accordance with regulation 5(1) of these Regulations.

(2) Unless there is a change in the applicable standards specified in Annex 1 of MSN 1874(M+F) Amendment 3-

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- (a) for equipment already placed on board a Gibraltar ship, existing approval will continue to be accepted providing equipment continues to operate in accordance with its existing approval; and
- (b) if equipment is replaced, it must be replaced with equipment which complies with these Regulations.

Domestic passenger ships and large Fishing vessels.

5.(1) As required by regulation 5(2) of these Regulations, where equipment is specified in Annex 1 of MSN 1874(M+F) Amendment 3, a domestic passenger ship or fishing vessel must carry equipment that complies with applicable international standards, except where a carriage requirement provides for an alternative standard.

(2) The carriage requirements are listed in Annex 4 of MSN 1874(M+F) Amendment 3.

(3) Regulation 5(2)(c) of these Regulations provides an exception to regulation 5(2) detailed above, such that equipment voluntarily placed on board must meet the standard specified by the GMA.

(4) The objects of this paragraph-

- (a) is to allow flexibility while ensuring a minimum standard of safety; and
- (b) to provide for an opportunity that specified standards must be agreed by a ship's appointed surveyor from the GMA where it is proven that the equipment complying with applicable international standards does not offer a practicable solution for reasons of size of the equipment or integration with the ship or vessel etc.

Approved Bodies.

6.(1) The GMA must publish in its website a list of designated organisations as approved bodies for the purpose of carrying out approvals of equipment to undertake the examination, testing and certification of the equipment specified in Annex 1 of MSN 1874(M+F) Amendment 3.

(2) Approved bodies must meet the requirements of Schedule 3 of the Regulations and will be assessed at least once every 2 years to confirm compliance with those requirements.

Market Surveillance.

7.(1) The GMA is the market surveillance authority for equipment and is required to carry out market surveillance.

(2) Approved bodies, manufacturers and manufacturer's authorised representatives must cooperate with GMA market surveillance inspectors as indicated in this Schedule and in accordance with these Regulations.

(3) Market surveillance seeks to ensure the safety of products offered for supply to the market and Gibraltar ships and such market surveillance must take into consideration the conformity assessment procedures applicable to equipment and the responsibilities of the flag state administrations in the international instruments.

(4) Market surveillance may include the inspection of documents supplied with equipment to confirm its compliance as well as checks of equipment specified in regulation 5(1) of these Regulations whether or not it has been placed on board a Gibraltar ship.

(5) Where checks are carried out on equipment placed on board a Gibraltar ship, such checks must be limited to examinations that can be carried out while the equipment remains fully functional on board.

(6) When the GMA has received evidence to suggest equipment specified in this chapter may not be in compliance with the international instruments and poses a risk to the safety of persons on board Gibraltar ships or the marine environment it may seek further evidence by carrying out sample checks of such equipment.

(7) In the circumstances under sub-paragraph (6) above, the GMA may request the manufacturer to provide the necessary samples at the manufacturer's own cost, or give on-the-spot access to the samples at the manufacturer's premises.

(8) Where the GMA has sufficient reason to believe that equipment to which this chapter is applicable presents a risk to maritime safety, to health or to the environment, it may –

- (a) carry out an evaluation in relation to the equipment concerned covering all the requirements for such equipment and in such circumstances the relevant economic operators must cooperate as necessary with the GMA in accordance with these Regulations; and
- (b) inform the public on the potential risk via the publication of safety bulletins etc.

(9) Where the GMA finds that, subject to the evaluation under sub-paragraph (8), the equipment does not comply with the requirements in this chapter, the GMA may without delay

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require the relevant economic operator to take all appropriate corrective actions to bring the equipment into compliance with those requirements, using existing powers in the Gibraltar Merchant Shipping (Safety, etc.) Act, 1993 which must be commensurate with the nature and extent of the risk which the GMA considers is posed by the equipment, as it may prescribe, or any other corrective measure justified by the GMA and it must inform the relevant approved body accordingly.

(10) Where the economic operator does not carry out such corrective measures within the timeframe specified by the GMA under sub-paragraph (9), the GMA may initiate such appropriate measures as are necessary to prohibit or restrict non-compliant equipment from being supplied to the market or placed on board Gibraltar ships.

(11) Where it is considered that non-compliance may not be limited to the market, the GMA may inform other parties to the international instruments flag administrations and international organisations to include the nature of the non-compliance and the corrective actions which has been implemented.

Chapter III

Approved equipment outside the scope of the conformity assessment procedures but requiring approval under international instruments or other domestic legislation of Gibraltar.

Scope of approval.

8.(1) Equipment to which chapter III of this Schedule applies is that equipment outside the scope the conformity assessment procedures for marine equipment, but nonetheless requires approval by the GMA as a Gibraltar ship's flag administration under international instruments.

(2) Chapter II of this Schedule also applies to equipment that requires approval by other legislation of Gibraltar, but such equipment must-

(a) be specified in Annex 2 of MSN 1874(M+F) Amendment 3; and

(b) have type approval by the nominated bodies.

(3) Where equipment within the scope of this Chapter is of a novel nature or subject to significant design changes or the specifications or testing requirements of which are not considered to be sufficiently developed or experience of their usage is limited, the GMA must be contacted regarding the undertaking of the necessary approval procedure.

Requirements for equipment.

9.(1) Equipment which is placed on board a Gibraltar ship to which this chapter applies must hold a valid type approval certificate issued by a nominated body at the time when that equipment is placed on board.

(2) The performance and testing standards of equipment within the scope of this chapter are specified in Annex 2 of MSN 1874(M+F) Amendment 3.

(3) In consultation with the GMA, a nominated body may waive the requirements for any test specifically cited in a performance standard providing it is satisfied that the sample has met the criteria of a specification superior to that of the prescribed test.

(4) Existing type approval certificates for equipment within the scope of this chapter must remain valid before the certificate's expiry date, or until cancelled and upon the expiry date of the certificate, manufacturers must re-apply for renewal of their certificate to a Nominated Body.

(5) If requirements have not changed a new certificate must be issued and all certificates of type approval must remain valid for up to 5 years.

(6) Unless there is a change in the required standards specified in Annex 2 of MSN 1874(M+F) Amendment 3 applicable to equipment already placed on board a Gibraltar ship, existing approval must continue to be accepted providing the equipment operates satisfactorily and if it needs to be replaced, then it must be replaced with equipment for which a current type approval certificate is in force.

Domestic Passenger Ships and Large Fishing Vessels.

10.(1) As required by regulation 5(2) of these Regulations, where equipment is specified in Annex 2 of MSN 1874(M+F) Amendment 3, a domestic passenger ship or fishing vessel must carry equipment that has been approved by a nominated body, except where a carriage requirement provides for an alternative standard to be met and such carriage requirements are listed in Annex 4 of MSN 1874(M+F) Amendment 3.

(2) Regulation 5(2)(c) of these Regulations provides an exception to regulation 5(2) of these Regulations as referred to in sub-paragraph (1) above, such that equipment voluntarily placed on board must meet the standards specified by the GMA.

(3) The effect of sub-paragraph (2) above is to allow flexibility while ensuring a minimum standard of safety and such specified standards must be agreed by a ship's appointed GMA surveyor where it is proven that the equipment complying with applicable international standards does not offer a practicable solution for reasons of size of the equipment/ integration with the ship or vessel etc.

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Application for type approval

11.(1) A manufacturer or person wishing to obtain type approval of equipment specified in Annex 2 of MSN 1874(M+F) Amendment 3 must submit an application to a Nominated Body, in accordance with Part 4 of these Regulations.

- (2) An application referred to in sub-paragraph (1) above must include-
- (a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, their name and address;
 - (b) a written declaration that the same or a similar application has not been lodged with another nominated body;
 - (c) the technical documentation described in sub-paragraph (5) below; and
 - (d) the applicant must place at the disposal of the nominated body sufficient specimens representative of the production envisaged.
- (3) The nominated body may request further specimens if needed for carrying out the test programme.
- (4) The technical documentation must enable a nominated body to assess conformity of the product with the requirements and testing standards specified in Annex 2 of MSN 1874(M+F) Amendment 3 and it must cover the design, build standards, manufacture and functioning of the equipment, as far as relevant for conformity assessment.
- (5) The technical documentation must contain all relevant data or means used by the manufacturer to ensure that the equipment complies with the essential requirements relating to it and it must also enable understanding of the design, manufacture and operation of the product and assessment of conformity with the relevant requirements.
- (6) The documentation shall contain so far as is relevant for assessment-
- (a) a general description of the equipment;
 - (b) conceptual design and manufacturing drawings and schemes of components and relevant supporting drawings;
 - (c) descriptions and explanations necessary for the understanding of the drawings and schemes including operation of the equipment;

- (d) results of design calculations made, impartial examinations carried out etc;
 - (e) impartial test reports; and
 - (f) manuals for installation, use and maintenance.
- (7) Where appropriate, the design documentation must contain the following elements-
- (a) attestations relating to the equipment incorporated in the appliance;
 - (b) attestations and certificates relating to the methods of manufacture, inspections or monitoring of the appliance or all of them; and
 - (c) any other document making it possible for the nominated body to improve its assessment.

Assessment of type approval.

12.(1) On receipt of an application for type approval in accordance with paragraph 11 above, a nominated body must-

- (a) examine the technical documentation and verify that the equipment has been manufactured in conformity with the technical documentation;
 - (b) agree with the applicant the location where the examination and necessary tests are to be carried out; and
 - (c) perform or have performed the appropriate examination and necessary tests to check whether the relevant requirements specified in Annex 2 of MSN 1874(M+F) Amendment 3 are complied with.
- (2) Type approval tests must be conducted at a laboratory accredited for such tests by a laboratory recognised by the nominated body as offering suitable and satisfactory guarantee of technical and professional competence, quality procedures and autonomy with particular reference to the application of ISO/IEC 17025 (2017), as amended may be used.
- (3) Where the equipment meets the provisions of the relevant requirements specified in Annex 2 of MSN 1874(M+F) Amendment 3 and test and performance standards, the nominated body must issue a certificate of type approval to the applicant.

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(4) The certificate issued under sub-paragraph (3) above must contain the name and address of the manufacturer, details of the equipment, conclusions of the examination, conditions for its validity and the necessary data for identification of the approved type.

(5) A list of the relevant parts of the technical documentation including drawings and instructions must be annexed to the certificate and a copy kept by the nominated body.

(6) If the manufacturer is refused a certificate of type approval, the nominated body must provide detailed reasons for such refusal in writing, to the applicant for type approval.

(7) Where an application is rejected after completion of the type approval procedure, the manufacturer must modify the equipment to take account of the reasons for rejection before making a new submission to the nominated body. In the manufacturer's application to the nominated body they must include-

- (a) the original examination and test results;
- (b) the detailed reasons provided by the nominated body for the previous refusal; and
- (c) details of all modifications made to the equipment since the previous application.

(8) Upon receipt of the re-submission of the application for type approval, the nominated body must re-open the approval procedure.

(9) The applicant must inform the nominated body that holds the technical documentation concerning the certificate of type approval of all modifications to the approved product which must receive additional approval where such changes may affect the conformity with the requirements or the prescribed conditions for use of the equipment and such additional approval must be given in the form of an addition to the original certificate of type approval.

Issue of type approval.

13.(1) Where the nominated body is satisfied that the equipment complies in all respects with the requirements in Annex 2 of MSN 1874(M+F) Amendment 3 and any specifications laid down by the GMA and subject to the provisions below, the nominated body must issue a certificate of type approval stating the terms and conditions of approval and period of validity which must be up to 5 years.

(2) A certificate of type approval refers only to equipment identical to that assessed and it is also a condition of issue of the certificate that a manufacturer must consult with the nominated body prior to any alteration to the approved standard of the equipment, hardware, software or firmware.

(3) The nominated body may require further testing and assessment to be undertaken in the event of a modification, or series of modifications, being considered to constitute sufficient departure from the approved standard of the equipment hardware, software or firmware for which the certificate of type approval was originally issued.

(4) The certificates of type approval and their additions and annexes to the certificates, technical documentation, other documentary evidence used to type approve the equipment must be kept at the disposal of the GMA and other nominated bodies for a period of not less than 10 years after the last product has been manufactured.

(5) The manufacturer or his authorised representative shall keep the technical documentation copies of certificates of type approval and their additions for a period of at least 10 years after the last product has been manufactured.

Nominated bodies.

14.(1) Nominated bodies are those bodies which have been designated by the GMA to carry out type approval of equipment placed on board Gibraltar ships under regulation 4 of these Regulations.

(2) Each nominated body must provide upon request to the GMA and other nominated bodies the relevant information concerning the certificates of type approval and additions issued and withdrawn.

Chapter IV
Other equipment standards

Scope of equipment standards and requirements.

15. Equipment that falls within chapter IV is the equipment required by these Regulations and specified in Annex 3 of MSN 1874(M+F) Amendment 3, but where no standard for such equipment is specified to provide an acceptable level of safety to domestic ships outside the scope of the international conventions and such equipment may not be of an approved type and in all cases must comply with the relevant standard specified in Annex 3 of MSN 1874(M+F) Amendment 3.

Requirements for equipment.

16.(1) Equipment specified in Annex 3 of MSN 1874(M+F) Amendment 3 and placed on board a Gibraltar ship to which this chapter applies in accordance with regulation 5(3) of these Regulations must meet the design, construction and performance requirements of the standards

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in Annex 3 MSN 1874(M+F) Amendment 3 valid at the time when that equipment is placed on board.

(2) Annex 3 of MSN 1874(M+F) Amendment 3 also sets out the ship type to which each specified standard is applicable.

SCHEDULE 2

Regulations 8 and 9

Conformity Assessment Procedures

PART 1

Type-Examination (Module B)

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

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- (e) the supporting evidence for the adequacy of the technical solution; this supporting evidence must-
 - (i) mention any documents that have been used; and
 - (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;
 - (d) results of design calculations made and examinations carried out;
 - (e) 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 GMA, 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 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 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 Type certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

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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 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 type examination certificate.

9.(1) Each approved body must inform the GMA about all the 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 GMA 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 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 type-examination certificates and any additions to those certificates which it has issued.

(4) An approved body must keep a copy of 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 GMA may, on request, obtain-

- (a) a copy of a type examination certificate from an approved body that it has issued, refused, suspended or restricted; and
- (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 type examination certificate, its annexes and additions together with the technical documentation at the disposal of the GMA for a period of at least 10 years after the 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 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 type-examination certificate.

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(3) The quality system must ensure that the products are in conformity with the type described in the 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; and
 - (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; and
 - (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.

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(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.

Conformity marking and declaration of conformity.

16.(1) The manufacturer must affix the 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 type examination certificate and that satisfies the applicable international standards.

(2) The manufacturer must draw up a written declaration of conformity for each product model and keep it at the disposal of the GMA for a period of at least 10 years after the 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 declaration of conformity must identify the marine equipment model for which it has been drawn up and a copy of the declaration of conformity must be made available to the GMA on request.

(4) The manufacturer must keep at the disposal of the GMA for a period of at least 10 years after the 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 paragraphs 14(12)(c), 15(2) and 15(4).

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

(6) Each approved body must inform the other 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 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; and

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- (e) the technical documentation of the approved type and a copy of the type-examination certificate.
- (3) The quality system must ensure compliance of the products with the type described in the 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; and
 - (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; and
- (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.

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(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.

Conformity marking and declaration of conformity.

22.(1) The manufacturer must affix the 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 type-examination certificate and that satisfies the applicable international standards.

(2) The manufacturer must draw up a written declaration of conformity for each product model and keep it at the disposal of the GMA for a period of at least 10 years after the 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 declaration of conformity must identify the marine equipment model for which it has been drawn up and a copy of the declaration of conformity must be made available to the GMA on request.

(4) The manufacturer must keep at the disposal of the GMA for a period of at least 10 years after the 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; and
- (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 GMA of quality system approvals that it has issued or withdrawn and must, periodically or on request, make available to the GMA the list of quality system approvals that it has refused, suspended or otherwise restricted.

(6) Each approved body must inform the other 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 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 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 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 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.

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(3) The manufacturer must keep the certificates of conformity available for inspection by the GMA for a period of at least 10 years after the 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; and
- (c) the manufacturer must keep the certificate of conformity at the disposal of the GMA for a period of at least 10 years after the 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 GMA must take appropriate measures to prevent that lot being placed on the market and, in the event of the frequent rejection of lots, the approved body may suspend the statistical verification and take appropriate measures.

Conformity marking and declaration of conformity.

29.(1) The manufacturer must affix the 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 type-examination certificate and that satisfies applicable international standards.

(2) The manufacturer must draw up a written declaration of conformity for each product model and keep it at the disposal of the GMA for a period of at least 10 years after the 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 declaration of conformity must identify the marine equipment model for which it has been drawn up and a copy of the declaration of conformity must be made available to the GMA 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;

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- (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; and
 - (vi) test reports.

(3) A manufacturer must keep the technical documentation at the disposal of the GMA for a period of at least 10 years after the 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 GMA for a period of at least 10 years after the 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.

Conformity marking and declaration of conformity.

35.(1) The manufacturer must affix the 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 declaration of conformity and keep it at the disposal of the GMA for a period of at least 10 years after the 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 declaration of conformity must identify the product for which it has been drawn up.

(3) A copy of the declaration of conformity must be made available to the GMA 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.

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SCHEDULE 3

Regulations 2(1), 4(1) and 4(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 or in Gibraltar 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; and
 - (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

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- (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 GMA 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 GMA.
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(a).
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(7)

Designation Procedure

Application for designation.

1.(1) An application by a conformity assessment body to become an approved body must be made to the GMA 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; and
- (b) the marine equipment for which that body claims to be competent; and
- (c) either-
 - (i) an accreditation certificate; or
 - (ii) the documentary evidence necessary for the GMA to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

(2) The GMA 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.

2. The GMA 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 GMA must-

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

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- (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 11(2).

Declaration of Conformity

A 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 any additional information;
- (h) 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.