GIBRALTAR MERCHANT SHIPPING (MARINE EQUIPMENT) REGULATIONS 2016

Subsidiary Legislation made under s.59 and 118.

GIBRALTAR MERCHANT SHIPPING (MARINE EQUIPMENT) REGULATIONS 2016

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Commencement **18.9.2016**

Amending enactments	Relevant current provisions	Commencement date

Transposing:
Directive 2014/90/EU

ARRANGEMENT OF REGULATIONS.

Regulation

Subsidiary 2016/187

GIBRALTAR MERCHANT SHIPPING (MARINE EQUIPMENT) REGULATIONS 2016

This version is out of date

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, and for the purpose of transposing into the law of Gibraltar Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC, 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. In these Regulations, unless the context otherwise requires–

"'accreditation" means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

"Administration" means the Gibraltar Maritime Administration;

"authorised representative" means any natural or legal person established within the European Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks;

"conformity assessment" means the process carried out by the notified bodies, in accordance with regulation 14, demonstrating whether marine equipment complies with the requirements laid down in these Regulations;

"conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

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

"economic operators" means the manufacturer, the authorised representative, the importer and the distributor;

"EU declaration of conformity" means a statement issued by the manufacturer in accordance with regulation 15;

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

"EU ship" means a ship flying the flag of a Member State and falling within the scope of the international conventions;

"Gibraltar ship" means a ship which is registered in Gibraltar under the provisions of the Gibraltar Merchant Shipping (Registration) Act 1993;

"Gibraltar register" means the register kept under section 6(1) of the Gibraltar Merchant Shipping (Registration) Act 1993 for the purposes of Gibraltar ships;

"importer" means any natural or legal person established within the European Union who places marine equipment from a third country on the European Union market;

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

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

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

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

"international instruments" means the international conventions, together with the resolutions and circulars of the IMO giving effect to those conventions in their up-to-date version, and the testing standards;

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

"manufacturer" means any natural or legal person who manufactures marine equipment or has marine equipment designed or manufactured, and markets that equipment under its name or trademark;

"marine equipment" means equipment falling within the scope of these Regulations in accordance with regulation 3(2) and (3);

"notified body" means an organisation designated by the competent national administration of a Member State in accordance with regulation 18;

"national accreditation body" means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

"placing on the market" means the first making available of marine equipment on the European Union market;

"product" means an item of marine equipment.

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

"testing standards" means the testing standards for marine equipment set by–

(a) the International Maritime Organization (IMO);

(b) the International Organization for Standardization (ISO);

(c) the International Electrotechnical Commission (IEC);

(d) the European Committee for Standardization (CEN);

(e) the European Committee for Electrotechnical Standardization (Cenelec);

(f) the International Telecommunication European Union (ITU);

(g) the European Telecommunications Standards Institute (ETSI);

(h) the Commission, in accordance with Article 8 and Article 27(6) of the EU Directive;

(i) the regulatory authorities recognised in the mutual recognition agreements to which the European Union is a party;

"wheel mark" means the symbol referred to in regulation 8 and set out in Schedule 1 or, as appropriate, the electronic tag referred to in regulation 10;

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

The purposes and application of these Regulations.

3.(1) These Regulations seek to–

(a) enhance safety at sea and to prevent marine pollution through the uniform application of the relevant international instruments relating to marine equipment to be placed on board EU ships; and

(b) ensure the free movement of such equipment within the European Union.

(2) These Regulations must apply to equipment placed or to be placed on board an EU ship and for which the approval of the flag State administration is required by the international instruments, regardless of whether the ship is situated in the European Union at the time when it is fitted with the equipment.

(3) Notwithstanding the fact that the equipment referred to in sub-regulation (2) may also fall within the scope of instruments of European Union law other than the EU Directive being transposed by these Regulations, that equipment must, for the purpose set out in sub-regulation (1), be subject only to these Regulations.

(4) These Regulations apply to a state party to the European Economic Area and any reference to a Member State shall be deemed to include an EEA State.

PART 2
GENERAL PROVISIONS FOR MARINE EQUIPMENT

Requirements for marine equipment.

4.(1) Marine equipment that is placed on board an EU ship on or after 18 September 2016 must meet the design, construction and performance requirements of the international instruments as applicable at the time when that equipment is placed on board.

(2) Compliance of marine equipment with the requirements referred to in sub-regulation (1) must be demonstrated solely in accordance with the testing standards and by means of the conformity assessment procedures referred to in regulation 14.

(3) The international instruments must apply, without prejudice to the conformity checking procedure set out in Article 5 of Regulation (EC) No 2099/2002 of the European Parliament and of the Council.

Marine equipment to comply with these Regulations and international instruments.

5.(1) Where the Administration issues, endorses or renews the certificates of a Gibraltar ship as required by the international conventions, it must ensure that the marine equipment on board that ships complies with the requirements of these Regulations.

(2) The Administration must take the necessary measures to ensure that marine equipment on board a Gibraltar ship complies with the requirements in the international instruments which are applicable to equipment already placed on board.

Functioning of the internal market

6.(1) The Government must not prohibit the placing on the market or the placing on board an EU ship of marine equipment which complies with these Regulations.

(2) The Administration must not refuse to issue the certificates relating marine equipment referred to in sub-regulation (1) to any EU ship, or to renew such certificates.

Transfer of a ship to the flag of a Member State.

7.(1) Where a non-EU ship is required to be transferred to the Gibraltar register, that ship must, during transfer, be subject to inspection by the Administration to verify that the actual condition of its marine equipment corresponds to its safety certificates and either complies with these Regulations and bears the wheel mark or is equivalent, to the satisfaction of

the Administration, to marine equipment certified in accordance with these Regulations as of 18 September 2016.

(2) In cases where the date of installation on board of marine equipment cannot be established, the Administration may determine satisfactory requirements of equivalence, taking into account relevant international instruments.

(3) Unless the equipment either bears the wheel mark or the Administration considers it to be equivalent, the Administration must direct the owner of the ship to replace that equipment immediately.

(4) Marine equipment which is considered equivalent under this regulation must be issued with a certificate by the Administration which must at all times be carried with the equipment.

(5) A certificate issued under sub-regulation (4) constitutes the Administration's permission for the equipment to be retained on board subject to any restrictions or any provisions relating to the use of the equipment, which the Administration may impose.

PART 3
THE WHEEL MARK

The wheel mark.

8.(1) Marine equipment the compliance of which with the requirements laid down in these Regulations has been demonstrated in accordance with the relevant conformity assessment procedures must have the wheel mark affixed to it.

(2) The wheel mark must not be affixed to any other product.

(3) The form of the wheel mark to be used must be as set out in Schedule 1.

(4) Use of the wheel mark must be subject to the general principles set out in paragraphs 1 and 3 to 6 of Article 30 of Regulation (EC) No 765/2008, where any reference to the CE marking must be construed as a reference to the wheel mark.

Rules and conditions for affixing the wheel mark.

9.(1) The wheel mark must be affixed visibly, legibly and indelibly to the product or to its data plate and, where relevant, embedded in its software.

(2) Where the wheel mark is–

(a) not possible to be affixed or embedded in accordance with sub-regulation (1); or

(b) not warranted on account of the nature of the product,

it must be affixed to the packaging and to the accompanying documents.

(3) The wheel mark must be–

(a) affixed at the end of the production phase; and

(b) followed by the identification number of the notified body, where that body is involved in the production control phase, and by the year in which the mark is affixed.

(4) The identification number of the notified body must be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.

Electronic tag.

10.(1) In order to facilitate market surveillance and prevent the counterfeiting of specific items of marine equipment referred to in paragraph 3 of Article 11 of the EU Directive, manufacturers may use an appropriate and reliable form of electronic tag instead of, or in addition to, the wheel mark.

(2) Where the manufacturers use an electronic tag referred to in sub-regulation (1), the provisions of regulations 8 and 9 shall apply, as appropriate, mutatis mutandis.

(3) For marine equipment identified in accordance with Article 11(3) of the EU Directive, the wheel mark may, within 3 days after the date of adoption of the appropriate technical criteria referred to in Article 11(4) of the EU Directive, be supplemented by an appropriate and reliable form of electronic tag.

(4) For marine equipment identified in accordance with Article 11(3) of the EU Directive, the wheel mark may be replaced, 5 years after the date of the adoption of the appropriate technical criteria referred to in Article 11(4) of the EU Directive, by an appropriate and reliable form of electronic tag.

PART 4
OBLIGATIONS OF ECONOMIC OPERATORS

Obligation of manufacturer.

11.(1) By affixing the wheel mark, the manufacturers must–

(a) take on responsibility for guaranteeing that the marine equipment to which the mark is affixed has been designed and manufactured in accordance with the technical specifications and standards implemented in accordance with Article 35(2) of the EU Directive; and

(b) assume the obligations laid down in sub-regulations (2) to (10).

(2) Manufacturers must draw up the required technical documentation and have the applicable conformity assessment procedures carried out.

(3) Where the compliance of marine equipment with the applicable requirements has been demonstrated by the conformity assessment procedure, manufacturers must draw up an EU declaration of conformity in accordance with regulation 15 and affix the wheel mark in accordance with regulations 8 and 9.

(4) Manufacturers must keep the technical documentation and the EU declaration of conformity referred to in regulation 15 for at least 10 years after the wheel mark has been affixed and in no case for a period shorter than the expected life of the marine equipment concerned.

(5) Manufacturers must ensure that–

(a) procedures are in place for series production to remain in conformity and changes in marine equipment design or characteristics and changes in the requirements in the international instruments as referred to in regulation 4, on the basis of which conformity of marine equipment is declared, are taken into account; and

(b) when necessary in accordance with Schedule 2, manufacturers must have a new conformity assessment carried out.

(6) Manufacturers must ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information

is provided on the packaging or in a document accompanying the product or both, as appropriate.

(7) Manufacturers must indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product or both, as appropriate and the address must indicate a single point at which the manufacturer can be contacted.

(8) Manufacturers must ensure that the product is accompanied by instructions and all necessary information for safe installation on board and safe use of the product, including limitations of use, if any, that can be easily understood by the users, together with any other documentation required by the international instruments or testing standards.

(9) Manufacturers who consider or have reason to believe that a product to which they have affixed the wheel mark is not in conformity with the applicable design, construction and performance requirements and with the testing standards implemented in accordance with Article 35(2) and (3) of the EU Directive, must immediately take the necessary corrective measures to bring that product into conformity, to withdraw it or to recall it, if appropriate.

(10) Where the product presents a risk, manufacturers must immediately inform the Administration, giving details, in particular, of the non-compliance and of any corrective measures taken.

(11) Manufacturers must, further to a reasoned request from the Administration, promptly provide it with all the information and documentation necessary to demonstrate the conformity of the product, in English, and grant the Administration access to their premises for market surveillance purposes in accordance with Article 19 of Regulation (EC) No 765/2008 and provide samples or access to samples in accordance with Article 25(4) of the EU Directive.

(12) Manufacturers must cooperate with the Administration on any action taken to eliminate the risks posed by products which they have placed on the market.

Authorised representatives.

12.(1) Any manufacturer who is not located in the territory of at least one Member State must, by a written mandate, appoint an authorised representative for the European Union and must indicate in the mandate the

name of the authorised representative and the address at which it can be contacted.

(2) Fulfilment of the obligations laid down in regulation 11(1) and the drawing-up of technical documentation must not form part of the authorised representative's mandate.

(3) An authorised representative must perform the tasks specified in the mandate received from the manufacturer.

(4) The mandate must allow the authorised representative to do at least the following–

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national surveillance authority for at least 10 years after the wheel mark has been affixed and in no case for a period shorter than the expected life of the marine equipment concerned;

(b) further to a reasoned request from the Administration, provide the Administration with all the information and documentation necessary to demonstrate the conformity of a product; and

(c) co-operate with the Administration, at it's request, on any action taken to eliminate the risks posed by products covered by its mandate.

Other economic operators.

13.(1) Every importer must indicate to the Administration his name, registered trade name or registered trade mark and the address at which he can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product or both, as appropriate.

(2) Every importer and distributor must, further to a reasoned request from the Administration, provide it with all the information and documentation necessary to demonstrate the conformity of a product in English and they must cooperate with the Administration, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

(3) An importer or distributor must be considered a manufacturer for the purposes of these Regulations and must be subject to the obligations of the manufacturer under regulation 11, where it places marine equipment on the

market or on board an EU ship under its name or trademark or modifies marine equipment already placed on the market in such a way that compliance with the applicable requirements may be affected.

(4) For a period of at least 10 years after the wheel mark has been affixed and in no case for a period shorter than the expected life of the marine equipment concerned, economic operators must, on request, identify the following to the market surveillance authorities-

(a) any economic operator who has supplied them with a product; and

(b) any economic operator to whom they have supplied a product.

PART 5
CONFORMITY ASSESSMENT AND NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Conformity assessment procedures.

14.(1) The conformity assessment must be done in accordance with the procedures as set out in Schedule 2.

(2) The Administration must ensure that the manufacturer or the manufacturer's authorised representative has carried out the conformity assessment, through a notified body, for a specific item of marine equipment, by using one of the options provided by means of implementing acts adopted by the Commission in accordance with the examination procedure referred to in Article 38(2) of the EU Directive, from among one of the following procedures–

(a) where the EU type-examination (module B) is to be used, before being placed on the market, all marine equipment must be subject to-

(i) production-quality assurance (module D);

(ii) product-quality assurance (module E); or

(iii) product verification (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 EU unit verification (module G).

EU declaration of conformity.

15.(1) The EU declaration of conformity must state that the fulfilment of the requirements under regulation 4 has been demonstrated.

(2) The EU declaration of conformity must–

(a) follow the model structure set out in Annex III to Decision No 768/2008/EC;

(b) contain the elements specified in the relevant modules set out in Schedule 3; and

(c) be kept up to date.

(3) By drawing up the EU declaration of conformity, the manufacturer must assume the responsibility and the obligations referred to in regulation 11(1).

(4) When marine equipment is placed on board an EU ship, a copy of the EU declaration of conformity covering the equipment concerned must be–

(a) provided to the ship;

(b) kept on board until the said equipment is removed from the ship; and

(c) provided to the notified body or to the bodies which carried out the relevant conformity assessment procedures.

(5) The copy of the EU Declaration referred to in sub-regulation (4) must be translated by the manufacturer into English.

Notification of conformity assessment bodies.

16.(1) The Administration must, by means of the information system made available by the Commission for that purpose, notify the Commission and Member States of bodies authorised to carry out conformity assessment tasks under these Regulations.

(2) Notified bodies must comply with the requirements laid down in Schedule 2.

Notifying authorities.

17.(1) The Minister must designate a notifying authority that must be responsible for–

(a) setting up and carrying out the necessary procedures for the assessment;

(b) notification of conformity assessment bodies in accordance with Schedule 4; and

(c) the monitoring of notified bodies, including compliance with regulation 18.

(2) Notified bodies must be monitored at least every two years and in such monitoring the Commission may choose to participate as an observer in the monitoring exercise.

(3) The Administration may decide that the assessment and monitoring referred to in sub-regulation (1) are to be carried out by an accreditation body recognised by the Administration.

(4) Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in sub-regulation (1) to a body which is not a governmental entity, that body must be a legal entity and must comply *mutatis mutandis* with the requirements laid down in Schedule 5 and in addition, it must have in place arrangements to cover liability arising out of its activities.

(5) The notifying authority must take full responsibility for the tasks performed by the body referred to in sub-regulation (4).

(6) The notifying authority must comply with the requirements laid down in Schedule 5.

Information obligation on notifying authorities.

18. The Minister must ensure that the Commission is informed of the procedures followed in Gibraltar for the assessment and notification of conformity assessment bodies and the monitoring of such bodies, and of any changes thereto.

Subsidiaries of, and subcontracting by, notified bodies.

19.(1) Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it must–

(a) ensure that the subcontractor or the subsidiary meets the requirements set out in Schedule 3; and

(b) inform the notifying authority accordingly.

(2) Notified bodies must take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

(3) Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

(4) Notified bodies must keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by such subcontractor or subsidiary under these Regulations.

Changes to notifications.

20.(1) Where a notifying authority has ascertained, or has been informed, that a notified body no longer meets the requirements laid down in Schedule 3, or that it is failing to fulfil its obligations under these Regulations, the notifying authority must restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

(2) The Administration must, by means of the information system made available by the Commission for that purpose, immediately inform the Commission and Member States accordingly.

(3) In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the Administration must take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Challenges to the competence of notified bodies.

21. The Administration must provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned in order to take action under regulation 22.

Operational obligations of notified bodies.

22.(1) Notified bodies must carry out conformity assessments or have them carried out in accordance with the procedures provided for in regulation 14.

(2) Where a notified body finds that the obligations laid down in regulation 11 have not been met by a manufacturer, it must require that manufacturer to take appropriate corrective measures without delay and must not issue a conformity certificate.

(3) Where, in the course of monitoring conformity following the issue of a conformity certificate, a notified body finds that a product no longer complies, it must require the manufacturer to take appropriate corrective measures without delay and must suspend or withdraw the certificate if necessary.

(4) Where corrective measures are not taken or do not have the required effect as required by sub-regulation (3), the notified body must restrict, suspend or withdraw the certificate, as appropriate.

Obligation of notified bodies to provide information.

23.(1) Notified bodies must inform the notifying authority of the following-

(a) any refusal, restriction, suspension or withdrawal of a conformity certificate;

(b) any circumstances affecting the scope of, and the conditions for, notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities; and

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

(2) Every notified body must provide the Commission and the Administration, on request, with relevant information concerning issues relating to negative and positive conformity assessment results.

(3) Every notified body must provide the other notified bodies carrying out conformity assessment activities covering the same products with information concerning negative and, on request, positive conformity assessment results.

PART 6
EUROPEAN UNION MARKET SURVEILLANCE, CONTROL OF PRODUCTS, SAFEGUARD PROVISIONS

EU market surveillance framework.

24.(1) As regards marine equipment, the Administration must undertake market surveillance in accordance with the EU market surveillance framework laid down in Chapter III of Regulation (EC) No 765/2008, subject to sub-regulations (2) and (3).

(2) National market surveillance infrastructures and programmes must take into account the specific features of the marine equipment sector, including the various procedures carried out as part of the conformity assessment, and in particular the responsibilities placed on the Administration by the international conventions.

(3) Market surveillance may include documentary checks as well as checks of marine equipment which bears the wheel mark, whether or not it has been placed on board ships.

(4) Checks of marine equipment already placed on board must be limited to such examination as can be carried out while the equipment concerned remains fully functional on board.

(5) Where the market surveillance authority, as defined in Regulation (EC) No 765/2008, intend to carry out sample checks, it may, when it is reasonable and practicable to do so, request the manufacturer to make the necessary samples available or to give on-the-spot access to the samples at the manufacturer's own cost.

Procedure for dealing with marine equipment presenting a risk.

25.(1) Where the market surveillance authority has sufficient reason to believe that marine equipment covered by these Regulations presents a risk to maritime safety, to health or to the environment, it must carry out an evaluation in relation to the marine equipment concerned covering all the requirements laid down in these Regulations and the relevant economic operators must cooperate as necessary with the market surveillance authority.

(2) Where, in the course of evaluation under sub-regulation (1), the market surveillance authority finds that the marine equipment does not comply with the requirements laid down in these Regulations, it must, without delay, require the relevant economic operator to–

(a) take all appropriate corrective actions to bring the marine equipment into compliance with those requirements;

(b) withdraw the marine equipment from the market; or

(c) recall it within such reasonable period, commensurate with the nature of the risk, as they may prescribe,

and the market surveillance authority must inform the relevant notified body accordingly.

(3) Article 21 of Regulation (EC) No 765/2008 must apply to the measures referred to in sub-regulation (2).

(4) Where the market surveillance authority considers that non-compliance is not restricted to Gibraltar or to Gibraltar ships, it must inform the Commission and Member States, by means of the information system made available by the Commission for market surveillance purposes, of the results of the evaluation carried out under sub-regulation (1) and of the actions which it has required the economic operator to take.

(5) The economic operator must ensure that all appropriate corrective action is taken in respect of all the products concerned that it has made available on the market throughout the European Union or, placed or delivered to be placed on board EU ships.

(6) Where the relevant economic operator does not take adequate corrective action within the period prescribed by the market surveillance authority in accordance with the sub-regulation (2), or otherwise fails to meet its obligations under these Regulations, the market surveillance authority must take all appropriate provisional measures to–

(a) prohibit or restrict the marine equipment being made available on the Gibraltar market or placed on board Gibraltar ships;

(b) withdraw the product from that market; or

(c) recall it,

and the market surveillance authority must inform the Commission and Member States, without delay, of those measures.

(7) The information on the measures taken by the market surveillance authority referred to in sub-regulation (6) must include all available details, in particular–

(a) the data necessary for the identification of the non-compliant marine equipment;

(b) the origin of the product;

(c) the nature of the alleged non-compliance and the risk involved;

(d) the nature and duration of the national measures taken; and

(e) the arguments put forward by the economic operator concerned.

(8) The market surveillance authority must indicate whether the non-compliance is due to -

(a) failure of the marine equipment to comply with the applicable design, construction and performance requirements under regulation 4;

(b) non-compliance with the testing standards referred to in regulation 4 during the conformity assessment procedure; or

(c) shortcomings in those testing standards.

(9) Where the Administration has not initiated the procedure it must, without delay, inform the Commission and Member States of any measures adopted and of any additional information at it's disposal relating to the non-compliance of the marine equipment concerned, and, in the event of disagreement with the notified national measure, of their objections.

(10) Where, within four months of receipt of the information concerning the measures taken by the market surveillance authority, as referred to in sub-regulation (6), no objection has been raised by a Member State or by the Commission in respect of a provisional measure taken by the market surveillance authority, that measure must be deemed justified.

(11) The Administration must ensure that appropriate restrictive measures in respect of the marine equipment concerned, such as withdrawal of the product from the market, are taken without delay.

EU safeguard procedure.

26. Where a measure referred to in Article 27(1) of the EU Directive is considered–

(a) justified by the Commission, the Administration must ensure that that the non-compliant marine equipment is withdrawn from the Gibraltar market and if necessary, recalled; and

(b) unjustified by the Commission, the Administration must withdraw the non-compliant marine equipment from the Gibraltar market.

Compliant products which present a risk to maritime safety, to health or to the environment.

27.(1) Where, having performed an evaluation under regulation 25(1), the Administration finds that marine equipment which is in compliance with these Regulations nevertheless presents a risk to maritime safety, to health or to the environment, it must require the economic operator concerned to take all appropriate measures to ensure that the marine equipment concerned, when placed on the market, no longer presents that risk, to withdraw the marine equipment from the market or to recall it within such reasonable period, commensurate with the nature of the risk, as it may prescribe.

(2) The economic operator must ensure that corrective action is taken in respect of all the products concerned that it has made available on the market throughout the European Union or placed on board EU ships.

(3) The Administration must immediately provide the information specified in sub-regulation (4) to the Commission and Member States.

(4) The information provided under sub-regulation (3) must include all available details, in particular the data necessary for the identification of the marine equipment concerned, the origin and the supply chain of the marine equipment, the nature of the risk involved and the nature and duration of the measures taken in Gibraltar.

Formal non-compliance.

28.(1) Without prejudice to regulation 25, where the Administration makes one of the following findings, it must require the relevant economic operator to put an end to the non-compliance concerned–

(a) the wheel mark has been affixed in violation of regulation 8 or 9;

(b) the wheel mark has not been affixed;

(c) the EU declaration of conformity has not been drawn up;

(d) the EU declaration of conformity has not been drawn up correctly;

(e) technical documentation is either not available or not complete; or

(f) the EU declaration of conformity has not been sent to the ship.

(2) Where the non-compliance referred to in sub-regulation (1) persists, the Administration must take all appropriate measures to restrict or to prohibit the marine equipment being made available on the market or to ensure that it is recalled or withdrawn from the market.

Exemptions based on technical innovation.

29.(1) In exceptional circumstances of technical innovation, the Administration may permit marine equipment which does not comply with the conformity assessment procedures to be placed on board an EU ship if it is established by trial or otherwise to the satisfaction of the Administration that such equipment meets the objectives of these Regulations.

(2) The trial procedures must in no way discriminate between marine equipment produced in Gibraltar and marine equipment produced in Member States.

(3) Marine equipment covered by this regulation must be given a certificate by the Administration which must at all times be carried with the equipment and which gives the Administration's permission for the equipment to be placed on board the ship and imposes any restrictions or lays down any provisions relating to the use of the equipment.

(4) Where the Administration allows marine equipment covered by this regulation to be placed on board an EU ship, it must forthwith communicate the particulars thereof together with the reports of all relevant trials, assessments and conformity assessment procedures to the Commission and to Member States.

(5) Where a ship with marine equipment on board which is covered by sub-regulation (1) is transferred to Gibraltar registry, the Administration may take the necessary measures, which may include tests and practical demonstrations, to ensure that the equipment is at least as effective as equipment which does comply with the conformity assessment procedures.

Exemptions for testing or evaluation.

30. The Administration may permit marine equipment which does not comply with the conformity assessment procedures or which is not covered by regulation 29 to be placed on board an EU ship for reasons of testing or evaluation, if the following cumulative conditions are complied with–

(a) the marine equipment must be given a certificate by the Administration which must at all times be carried with the equipment, state the Administration's permission for the equipment to be placed on board the EU ship, impose all necessary restrictions and lay down any other appropriate provisions as regards the use of the equipment concerned;

(b) the permission must be limited to the period considered by the Administration as being necessary to complete the testing, which should be as short as possible; and

(c) the marine equipment must not be relied on in place of equipment which meets the requirements of these Regulations and must not replace such equipment, which must remain on board the EU ship in working order and ready for immediate use.

Exemptions in exceptional circumstances.

31.(1) In exceptional circumstances, which must be duly justified to the Administration, when marine equipment needs to be replaced in a port outside the European Union where it is not practicable in terms of reasonable time, delay and cost to place on board equipment which bears the wheel mark, other marine equipment may be placed on board subject to sub-regulations (2) to (4).

(2) The marine equipment placed on board must be accompanied by documentation issued by a Member State of the IMO which is a party to the relevant conventions, certifying compliance with the relevant IMO requirements.

(3) The Administration must be informed at once of the nature and characteristics of such other marine equipment.

(4) The Administration must, at the earliest opportunity, ensure that the marine equipment referred to in sub-regulation (1), along with its testing documentation, complies with the relevant requirements of the international instruments and of these Regulations.

(5) Where it has been demonstrated that specific marine equipment bearing the wheel mark is not available on the market, the Administration may authorise other marine equipment to be placed on board, subject to sub-regulations (6) to (8).

(6) The authorised marine equipment must comply, as much as possible, with the requirements and testing standards referred to in regulation 4(2).

(7) The marine equipment placed on board must be accompanied by an interim certificate of approval issued by the Administration or Member State, stating the following-

(a) the equipment bearing the wheel mark which the certified equipment is due to replace;

(b) the exact circumstances under which the certificate of approval has been issued, and in particular the unavailability in the market of equipment bearing the wheel mark;

(c) the exact design, construction and performance requirements against which the equipment has been approved by the certifying Member State; and

(d) the testing standards applied, if any, in the relevant approval procedures.

(8) Where the Administration issues an interim certificate of approval it must inform the Commission forthwith.

(9) When the Commission considers that the conditions in sub-regulations (6) and (7) have not been met, the Administration must revoke the interim certificate or take such other measures as the Commission requires under Article 32(8) of the Directive.

Coordination of notified bodies.

32. Where an appropriate coordination and cooperation between notified bodies are put in place by the Commission under Article 34 of the EU Directive and properly operated in the form of a sectoral group of notified bodies, the Administration must ensure that the bodies notified by it participate in the work of the sectoral group, directly or by means of designated representatives.

PART 7
ENFORCEMENT

Unauthorised use of mark of conformity.

33.(1) Subject to sub-regulation (2), any person who, in respect of any item of equipment–

(a) affixes a mark of conformity in contravention of regulation 8;

(b) forges or counterfeits or in any other manner alters or defaces any mark of conformity or identification number or symbol affixed in accordance with these Regulations;

(c) removes any mark of conformity or identification number or symbol affixed in accordance with these Regulations; or

(d) makes any alteration to the equipment after a mark of conformity or identification number or symbol has been affixed to it in accordance with these Regulations so that the equipment no longer complies with the applicable international standards,

Is guilty of an offence.

(2) A person is not guilty of an offence under sub-regulation (1) by reason solely of alteration, defacement or removal of a mark of conformity or identification symbol or number in the course of the adjustment or repair of any item of equipment by, or by the duly authorised agent of, a person who is a manufacturer of such equipment or is regularly engaged in the business of the repair of such equipment.

(3) Any person who places on the market, supplies, or exposes or offers for supply, an item of equipment which to his knowledge–

(a) bears a mark of conformity or identification number or symbol which is a forgery or counterfeit, or which has been transferred from another item of equipment, or which has been altered or

defaced otherwise than in accordance with these Regulations; or

(b) does not comply with the applicable international standards by reason of any alteration made to it after any mark of conformity or identification number or symbol was affixed to it in accordance with these Regulations.

shall be guilty of an offence.

(4) Any equipment in respect of which an offence under this regulation has been committed must be liable to be forfeited.

Delegation of powers.

34. 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.

35.(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.

36.(1) If any piece of equipment is carried on a ship otherwise than in compliance with regulation 4 or 5, the owner and master of the ship shall each be guilty of an offence punishable on summary conviction by a fine not exceeding level 5 on the standard scale.

(2) A manufacturer who fails to comply with regulation 11, shall be punishable on summary conviction by a fine not exceeding level 4 on the standard scale.

(3) Any person guilty of an offence under regulation 33, shall be punishable on summary conviction by a fine not exceeding level 5 on the standard scale.

Defence to offences.

37. 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.

38. 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(3) 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

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

Savings and transitional provision.

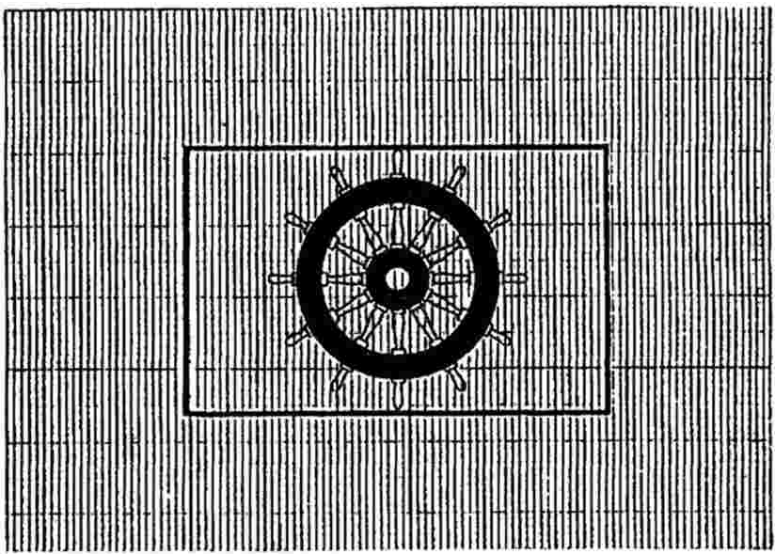
40. Notwithstanding the repeal under regulation 39, the requirements and testing standards for marine equipment applicable on 18 September 2016 under these Regulations in order to comply with the repealed Regulations shall continue to apply until the entry into force of the implementing acts referred to in Article 35(2) of the EU Directive.

SCHEDULE 1

Regulation 2(1) and 8

WHEEL MARK

The mark of conformity must take the following form:



If the wheel mark is reduced or enlarged the proportions given in the graduated drawing must be respected.

The various components of the wheel mark must have substantially the same vertical dimension, which may not be less than 5 mm.

That minimum dimension may be waived for small devices.

SCHEDULE 2

Regulations 11(5)), 14(1) and 16(2)

CONFORMITY ASSESSMENT PROCEDURES

I. MODULE B: EU TYPE-EXAMINATION

1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of marine equipment and verifies and attests that the technical design of the marine equipment meets the relevant requirements.

2. EU type-examination may be carried out in either of the following manners:

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

(b) assessment of the adequacy of the technical design of the marine equipment through examination of the technical documentation and supporting evidence referred to in point 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. The manufacturer must lodge an application for EU type-examination with a single notified body of its choice.

The application must include:

the name and address of the manufacturer and, if the application is lodged by the authorised representative, its name and address as well;

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

(c) the technical documentation. The technical documentation must make it possible to assess the conformity of the marine equipment with the applicable requirements of the international instruments as referred to in regulation 4, and must include an adequate analysis and assessment of the risk(s). The technical documentation must specify the applicable requirements and must cover, as far as relevant for the assessment, the design, manufacture and operation of the marine equipment. The

technical documentation must 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, circuits, etc.;

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

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

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

(vi) test reports;

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

(c) the supporting evidence for the adequacy of the technical design solution. This supporting evidence must mention any documents that have been used. The supporting evidence must 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 its responsibility.

4. The notified body must:

For the marine equipment:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the marine equipment;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant requirements and testing standards, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3. carry out appropriate examinations and tests, or have them carried out, in accordance with these Regulations;

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

5. The notified body must draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body must release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of the specific international instruments that apply to the marine equipment concerned, the notified body must issue an EU type-examination certificate to the manufacturer. The certificate must contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes must contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of the international instruments, the notified body must refuse to issue an EU type-examination certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

7. If the approved type no longer complies with the applicable requirements, the notified body must determine whether further testing or a new conformity assessment procedure is necessary.

The manufacturer must inform the notified body that holds the technical documentation relating to the EU type-examination certificate of all modifications to the approved type that may affect the conformity of the marine equipment with the requirements of the relevant international instruments or the conditions for validity of the certificate. Such

modifications must require additional approval in the form of an addition to the original EU type-examination certificate.

8. Each notified body must inform its notifying authorities concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and must, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

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

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type-examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body must keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer must keep a copy of the EU type-examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for at least 10 years after the wheel 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.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

II. MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. 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 points 2 and 5, and ensures and declares on its sole responsibility that the marine equipment concerned is in conformity with the type described in the EU type-examination certificate and that it satisfies the requirements of the international instruments that apply to it.

2. Manufacturing

The manufacturer must operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 3, and must be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer must lodge an application for assessment of its quality system with the notified body of its choice, for the marine equipment concerned.

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 notified body;

(c) all relevant information for the marine equipment category envisaged;

(d) the documentation concerning the quality system;

the technical documentation of the approved type and a copy of the EU type-examination certificate.

3.2. The quality system must ensure that the products are in conformity with the type described in the EU type-examination certificate and that they comply with the requirements of the international instruments that apply to them.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must, in particular, contain 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, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.; and

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

In addition to experience in quality management systems, the auditing team must have at least one member with experience of evaluation in the relevant marine equipment field and marine equipment technology concerned, and knowledge of the applicable requirements of the international instruments. The audit must include an assessment visit to the manufacturer's premises. The auditing team must review the technical documentation referred to in the fifth indent of point 3.1 in order to verify the manufacturer's ability to identify the relevant requirements of the international instruments and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the audit and the reasoned assessment decision.

3.4. 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.

3.5. The manufacturer must keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body.

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and must provide it with all necessary information, in particular:

(a) the quality system documentation;

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

4.3. The notified 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.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer, except where, under national law, and for defence or security reasons, certain restrictions apply to such visits. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Conformity marking and declaration of conformity.

5.1. The manufacturer must affix the wheel mark referred to in regulation 8, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EU type-examination certificate and that satisfies the applicable requirements of the international instruments.

5.2. The manufacturer must draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for

at least 10 years after the wheel 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 marine equipment model for which it has been drawn up.

A copy of the declaration of conformity must be made available to the relevant authorities upon request.

6. The manufacturer must keep at the disposal of the competent authorities, for at least 10 years after the wheel 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 point 3.1;

(b) the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body must inform its notifying authorities of quality system approvals issued or withdrawn, and must, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body must inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

8. Authorised representative.

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.

III.MODULE E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE.

1. 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 points 2 and 5, and ensures and declares on its sole responsibility that the marine equipment concerned is in conformity with the type described in the EU type-examination certificate and that it satisfies the requirements of the international instruments that apply to it.

2. Manufacturing.

The manufacturer must operate an approved quality system for final product inspection and testing of the products concerned as specified in point 3, and must be subject to surveillance as specified in point 4.

3. Quality system

3.1 The manufacturer must lodge an application for assessment of its quality system with the notified body of its choice, for the marine equipment concerned.

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 notified body;

(c) all relevant information for the marine equipment category envisaged;

(d) the documentation concerning the quality system; and

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

3.2 The quality system must ensure compliance of the products with the type described in the EU type-examination certificate and with the applicable requirements of the international instruments.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It must, in particular, contain 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, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;

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

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

In addition to experience in quality management systems, the auditing team must have at least one member with experience of evaluation in the relevant marine equipment field and marine equipment technology concerned, and knowledge of the applicable requirements of the international instruments. The audit must include an assessment visit to the manufacturer's premises. The auditing team must review the technical documentation referred to in the fifth indent of point 3.1, in order to verify the manufacturer's ability to identify the relevant requirements of the international instruments and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the audit and the reasoned assessment decision.

3.4. 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.
3.5. The manufacturer must keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a re-assessment is necessary.

It must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body.

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites, and must provide it with all necessary information, in particular:

(a) the quality system documentation;

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

4.3. The notified 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.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer, except where, under national law, and for defence or security reasons, certain restrictions apply to such visits. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Conformity marking and declaration of conformity.

5.1. The manufacturer must affix the wheel mark referred to in Article 9, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EU type-examination certificate and that satisfies the applicable requirements of the international instruments.

5.2. The manufacturer must draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for at least 10 years after the wheel 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 marine equipment model for which it has been drawn up.

A copy of the declaration of conformity must be made available to the relevant authorities upon request.

6. The manufacturer must keep at the disposal of the competent authorities, for at least 10 years after the wheel 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 point 3.1;

(b) the change referred to in point 3.5, as approved;

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body must inform its notifying authorities of quality system approvals issued or withdrawn, and must, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body must inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.

IV. MODULE F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on its sole responsibility that the products concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EU type-examination certificate and that they satisfy the requirements of the international instruments that apply to them.

2. Manufacturing.

The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EU type-examination certificate and with the requirements of the international instruments that apply to them.

3. Verification.

A notified body chosen by the manufacturer must carry out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the EU type-examination certificate and with the appropriate requirements of the international instruments.
The examinations and tests to check the conformity of the products with the appropriate requirements must be carried out, at the choice of the manufacturer, either by examination and testing of every product as specified in point 4 or by examination and testing of the products on a statistical basis as specified in point 5.

4. Verification of conformity by examination and testing of every product.

4.1. 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 EU type-examination certificate and with the appropriate requirements of the international instruments.

4.2. The notified 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.

The manufacturer must keep the certificates of conformity available for inspection by the national authorities for at least 10 years after the wheel 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.

5. Statistical verification of conformity.

5.1. 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.

5.2. A random sample must be taken from each lot. All products in a sample must be individually examined and tested in accordance with these Regulations, in order to ensure their conformity with the applicable requirements of the international instruments and to determine whether the lot is accepted or rejected.

5.3. If a lot is accepted, 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.

The notified 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.

The manufacturer must keep the certificates of conformity at the disposal of the national authorities for at least 10 years after the wheel 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.

5.4. If a lot is rejected, the notified body or the competent authority must take appropriate measures to prevent that lot being placed on the market. In the event of the frequent rejection of lots, the notified body may suspend the statistical verification and take appropriate measures.

6. Conformity marking and declaration of conformity.

6.1. The manufacturer must affix the wheel mark referred to in Article 9, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual product that is in conformity with the approved type described in the EU type-examination certificate and that satisfies the applicable requirements of the international instruments.

6.2. The manufacturer must draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for at least 10 years after the wheel 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 marine equipment model for which it has been drawn up.

A copy of the declaration of conformity must be made available to the relevant authorities upon request.

7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the products during the manufacturing process.

8. Authorised representative.

The manufacturer's obligations may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

V. MODULE G: CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5 and ensures and declares on its sole responsibility that the product concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of the international instruments that apply to it.

2. Technical documentation.

The manufacturer must draw up the technical documentation and make it available to the notified body referred to in point 4. The documentation must make it possible to assess the product's conformity with the relevant requirements, and must include an adequate analysis and assessment of the risk(s). The technical documentation must specify the applicable requirements and must cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation must, wherever applicable, contain at least the following elements:

(a) a general description of the product;

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

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

(d) 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;

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

(f) test reports.

The manufacturer must keep the technical documentation at the disposal of the relevant national authorities for at least 10 years after the wheel 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. Manufacturing

The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of the international instruments.

4. Verification

A notified body chosen by the manufacturer must carry out appropriate examinations and tests in accordance with these Regulations, in order to check the conformity of the product with the applicable requirements of the international instruments.

The notified 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.

The manufacturer must keep the certificates of conformity at the disposal of the national authorities for at least 10 years after the wheel 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.

5. Conformity marking and declaration of conformity.

5.1. The manufacturer must affix the wheel mark referred to in regulation 8 and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each product that satisfies the applicable requirements of the international instruments.

5.2. The manufacturer must draw up a written declaration of conformity and keep it at the disposal of the national authorities for at least 10 years after the wheel 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.
A copy of the declaration of conformity must be made available to the relevant authorities upon request.

3. Authorised representative

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.

Subsidiary 2016/187

GIBRALTAR MERCHANT SHIPPING (MARINE EQUIPMENT) REGULATIONS 2016

This version is out of date

SCHEDULE 3

Regulations 15(2)(b) and 19(1)(a)

REQUIREMENTS TO BE MET BY CONFORMITY ASSESSMENT BODIES IN ORDER TO BECOME NOTIFIED BODIES

1. For the purposes of notification, a conformity assessment body must meet the requirements laid down in points 2 to 11.

2. A conformity assessment body must be established under the law of Gibraltar and which must 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.

4. A body belonging to a business association or professional federation representing undertakings 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.

5. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the marine equipment which is assessed, nor the authorised representative of any of those parties. This must not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

6. 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 that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This must apply, in particular, to consultancy services.

7. Conformity assessment bodies must ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

8. Conformity assessment bodies and their personnel must carry out the conformity assessment activities with the highest degree of professional

integrity and the requisite technical competence in the specific field and must be free from all pressures and inducements, particularly of a financial nature, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

9. A conformity assessment body must be capable of carrying out all the conformity assessment tasks assigned to it under these Regulations and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

10. At all times and for each conformity assessment procedure and each kind, category or sub-category of marine equipment in relation to which it has been notified, a conformity assessment body must have at its disposal the necessary:

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

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency of those procedures and the possibility of reproducing them. It must have in place appropriate policies and procedures that distinguish between tasks that it carries out as a notified body and other activities;

(c) procedures for the performance of 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.

11. 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 all necessary equipment and facilities.

12. The personnel responsible for carrying out conformity assessment activities must have the following:

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

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the applicable requirements and testing standards and of the relevant provisions of European Union legislation on harmonisation and of the regulations implementing that legislation;

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

13. The impartiality of the conformity assessment bodies, of their top-level management and of the assessment personnel must be guaranteed.

14. The remuneration of the top-level management and of the assessment personnel of a conformity assessment body must not depend on the number of assessments carried out or on the results of those assessments.

15. Conformity assessment bodies must take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

16. The personnel of a conformity assessment body must observe professional secrecy with regard to all information obtained in carrying out their tasks under these Regulations or pursuant to any provision of Gibraltar law giving effect to it, except in relation to the competent authority if it carries out its activities in Gibraltar. Proprietary rights must be protected.

17. Conformity assessment bodies must participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under these Regulations, and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

18. Conformity assessment bodies must meet the requirements of standard EN ISO/IEC 17065:2012.

19. Conformity assessment bodies must ensure that testing laboratories used for conformity assessment purposes meet the requirements of standard EN ISO/IEC 17025:2005.

SCHEDULE 4

Regulation 17 (1).

NOTIFICATION PROCEDURE

1.Application for notification

1.1. A conformity assessment body must submit an application for notification to the notifying authority.

1.2. That application must be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the marine equipment for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Schedule 3.

1.3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it must provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Schedule 3.

2.Notification procedure

2.1. Notifying authority may notify only conformity assessment bodies which have satisfied the requirements laid down in Schedule 3.

2.2. It must notify the Commission and Member States using the electronic notification tool developed and managed by the Commission.

2.3. The notification must include full details of the conformity assessment activities, the conformity assessment module or modules and marine equipment concerned and the relevant attestation of competence.

2.4. Where a notification is not based on an accreditation certificate as referred to in section 1, the notifying authority must provide the Commission and Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Schedule 3.

2.5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or Member States within

two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

2.6. Only a body referred to in point 2.5 must be considered a notified body for the purposes of these Regulations.

2.7. The Commission and Member States must be notified of any subsequent relevant changes to the notification.

3. Identification numbers and lists of notified bodies

3.1. The Commission shall assign an identification number to a notified body

3.2 It shall assign a single such number even where the notified body is recognised as notified under several legislative acts of the Union.

3.3 The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

3.4 The Commission shall ensure that that list is kept up to date.

SCHEDULE 5

Regulation 17 (4) & (6)

REQUIREMENTS TO BE MET BY NOTIFYING AUTHORITIES

1. A notifying authority designated under regulation 17 must have been established in such a way that no conflict of interest with conformity assessment bodies occurs.

2. A notifying authority must be organised and operated in such a way as to safeguard the objectivity and impartiality of its activities.

3. A notifying authority must be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. A notifying authority must not offer or provide, on a commercial or competitive basis, any activities that conformity assessment bodies perform or any consultancy services.

5. A notifying authority must safeguard the confidentiality of the information it obtains.

6. A notifying authority must have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.