

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 (Text with EEA relevance)

CHAPTER 4

**CONFORMITY ASSESSMENT AND NOTIFICATION
OF CONFORMITY ASSESSMENT BODIES**

Article 15

Conformity assessment procedures

- 1 The conformity assessment procedures shall be as set out in Annex II.
- 2 Member States shall ensure that the manufacturer or the manufacturer's authorised representative has the conformity assessment carried out, 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), from among one of the following procedures:
 - a where the EC type-examination (module B) is to be used, before being placed on the market, all marine equipment shall be subject to:
 - production-quality assurance (module D); or
 - product-quality assurance (module E); or
 - product verification (module F);
 - b where sets of marine equipment are produced individually or in small quantities and not in series or in mass, the conformity assessment procedure may be the EC unit verification (module G).
- 3 The Commission shall, by means of the information system made available for that purpose, keep an up to date list of approved marine equipment and applications withdrawn or refused and shall make that list available to interested parties.

Article 16

EU declaration of conformity

- 1 The EU declaration of conformity shall state that the fulfilment of the requirements laid down in accordance with Article 4 has been demonstrated.
- 2 The EU declaration of conformity shall follow the model structure set out in Annex III to Decision No 768/2008/EC. It shall contain the elements specified in the relevant modules set out in Annex II to this Directive and shall be kept up to date.
- 3 By drawing up the EU declaration of conformity, the manufacturer shall assume the responsibility and the obligations referred to in Article 12(1).
- 4 When marine equipment is placed on board an EU ship, a copy of the EU declaration of conformity covering the equipment concerned shall be provided to the ship, and shall be kept on board until the said equipment is removed from the ship. It shall be translated by the

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manufacturer into the language or languages required by the flag Member State, including at least a language commonly used in the maritime transport sector.

5 A copy of the EU declaration of conformity shall be provided to the notified body or to the bodies which carried out the relevant conformity assessment procedures.

Article 17

Notification of conformity assessment bodies

1 Member States shall, by means of the information system made available by the Commission for that purpose, notify the Commission and the other Member States of bodies authorised to carry out conformity assessment tasks under this Directive.

2 Notified bodies shall comply with the requirements laid down in Annex III.

Article 18

Notifying authorities

1 Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 20.

2 Notified bodies shall be monitored at least every two years. The Commission may choose to participate as an observer in the monitoring exercise.

3 Member States may decide that the assessment and monitoring referred to in paragraph 1 are to be carried out by a national accreditation body.

4 Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Annex V. In addition, it shall have in place arrangements to cover liability arising out of its activities.

5 The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 4.

6 The notifying authority shall comply with the requirements laid down in Annex V.

Article 19

Information obligation on notifying authorities

1 Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of such bodies, and of any changes thereto.

2 The Commission shall, by means of the information system made available for that purpose, make that information publicly available.

Article 20

Subsidiaries of, and subcontracting by, notified bodies

1 Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Annex III and shall inform the notifying authority accordingly.

2 Notified bodies shall 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 shall 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 this Directive.

Article 21

Changes to notifications

1 Where a notifying authority has ascertained, or has been informed, that a notified body no longer meets the requirements laid down in Annex III, or that it is failing to fulfil its obligations under this Directive, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall, by means of the information system made available by the Commission for that purpose, immediately inform the Commission and the other Member States accordingly.

2 In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall 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.

Article 22

Challenges to the competence of notified bodies

1 The Commission shall investigate all cases where it doubts, based on the information available to it or brought to its attention, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2 The notifying Member State shall 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.

3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for its notification, it shall without delay inform the notifying Member

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State accordingly and request it to take the necessary corrective measures without delay, including de-notification if necessary.

Article 23

Operational obligations of notified bodies

- 1 Notified bodies shall carry out conformity assessments or have them carried out in accordance with the procedures provided for in Article 15.
- 2 Where a notified body finds that the obligations laid down in Article 12 have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures without delay and shall 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 shall require the manufacturer to take appropriate corrective measures without delay and shall suspend or withdraw the certificate if necessary. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw the certificate, as appropriate.

Article 24

Obligation of notified bodies to provide information

- 1 Notified bodies shall 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;
 - 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 Notified bodies shall provide the Commission and the Member States, on request, with relevant information concerning issues relating to negative and positive conformity assessment results. Notified bodies shall 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.