

## SCHEDULE 4

Regulations 46(4) and 52(2)

### Notified bodies

## PART 1

### Notified Body Requirements

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

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

3.—(1) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the vessels that they assess, nor the representative of any of those parties.

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

4. 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 those vessels, or represent the parties engaged in those activities. They must not engage in any activity (including consultancy services) that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified.

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

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

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

8. A conformity assessment body must have at its disposal:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency of and the ability to reproduce those procedures, and have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities.
- (c) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the

degree of complexity of the product technology in question and the mass or serial nature of the production process.

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

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

- (a) sound technical and vocational training, covering all conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments which the conformity assessment body carries out, and adequate authority to carry out those assessments;
- (c) appropriate knowledge and understanding of the essential safety requirements, of the applicable harmonised standards and of the applicable provisions of the relevant Directives and of these Regulations; and
- (d) the ability to draw up certificates, records and reports demonstrating that the assessments have been carried out.

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

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

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

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

**15.** Paragraph 14 does not prevent the personnel from providing the information to the Secretary of State.

**16.** A conformity assessment body must participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of any notified body coordination group established under the Directive and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

## PART 2

### Operational obligations of notified bodies

**17.** A notified body must carry out conformity assessments in accordance with the conformity assessment procedures.

**18.** A notified body must carry out conformity assessments in a proportionate manner, avoiding unnecessary burdens on economic operators.

**19.** A notified body must perform its activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the vessel technology in question and the mass or serial nature of the production process.

**20.** A notified body must respect the degree of rigour and the level of protection required to ensure that the vessel is in conformity with the requirements of these Regulations.

**21.** Where a notified body finds that essential safety requirements or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it must require the manufacturer to take appropriate corrective measures and must not issue a certificate of conformity.

**22.** Where, in the course of the monitoring of conformity following the issue of a certificate of conformity, a notified body finds that a vessel is no longer in conformity with the essential safety requirements, it must require the manufacturer to take appropriate corrective measures and must, if necessary, suspend or withdraw the certificate of conformity.

**23.** Where the notified body has required a manufacturer to take corrective measures and the manufacturer has failed to take such measures, or those measures have not had the required effect, the notified body must restrict, suspend or withdraw any certificate of conformity.

**24.** Paragraph 25 applies where a notified body is minded to—

- (a) refuse to issue a certificate of conformity;
- (b) restrict, suspend or withdraw a certificate of conformity.

**25.** Where this paragraph applies, the notified body must—

- (a) give the person applying for the certificate of conformity, or the person to whom the certificate of conformity has been given, a notice in writing giving reasons and specifying the date on which the refusal, restriction, suspension or withdrawal is intended to take effect;
- (b) give the person referred to in sub-paragraph (a), an opportunity to make representations within a reasonable period from the date of the notice;
- (c) take account of any representations made within the period referred to in subparagraph (b) before taking its decision.

**26.** A notified body must inform the Secretary of State of—

- (a) any refusal, restriction, suspension or withdrawal of a certificate of conformity;
- (b) any circumstances affecting the scope of or conditions for notification under regulation 46 (notification);
- (c) any request for information which it has received from a market surveillance authority regarding conformity assessment activities;
- (d) on request, any conformity assessment activities performed within the scope of its notification under regulation 46 and any other activity performed, including cross-border activities and subcontracting.

**27.** A notified body must make provision in its contracts with its clients enabling such clients to appeal against a decision—

- (a) to refuse to issue a certificate of conformity or grant an approval;
- (b) to restrict, suspend or withdraw a certificate of conformity or approval.

**28.** A notified body must provide other bodies notified under these Regulations carrying out similar conformity assessment activities covering the same vessels with relevant information on issues relating to negative and, on request, positive conformity assessment results.

**29.** A notified body must participate in the work of any notified body coordination group established under the Directive, directly or by means of its designated representatives.