

SCHEDULE 5

Regulation 55(4)

REQUIREMENTS RELATED TO NOTIFIED BODIES

1. A conformity assessment body must be established under the national law of an EEA state and have legal personality.

2. A conformity assessment body must be independent of the organisation or the measuring instrument it assess. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of measuring instruments 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 tasks must not be—

- (a) the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the measuring instruments they assess; or
- (b) the representative of any of the parties referred to in paragraph (a).

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

(3) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not—

- (a) be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the measuring instruments they assess;
- (b) represent the parties engaged in the activities referred to in paragraph (a); or
- (c) 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, in particular consultancy services.

(4) Paragraph (3) does not preclude the possibility of exchanges of technical information between the manufacturer and the body for the purposes of conformity assessment.

(5) Conformity assessment bodies must ensure that the activities of their subsidiaries or sub-contractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

4. Conformity assessment bodies and their personnel must—

- (a) carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field; and
- (b) be free from all pressures and inducements, particularly financial, which might influence—
 - (i) their judgement or
 - (ii) the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in those activities.

5.—(1) A conformity assessment body must be capable of carrying out all the conformity assessment tasks assigned to it by Schedule 1 and in relation to which it has been notified, whether those tasks are carried out by—

- (a) the conformity assessment body itself; or
- (b) on its behalf and under its responsibility.

Status: This is the original version (as it was originally made).

(2) At all times and for each conformity assessment procedure and each kind or category of measuring instruments 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 procedure in accordance with which conformity assessment is carried out, ensuring, the transparency and the ability of reproduction of those procedures;
- (c) appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities; and
- (d) procedure for the performance of activities which take due account of the size of and undertaking, the sector in which it operates, its structure, the degree of complexity of the measuring instrument technology in question and the mass or serial nature of the production process.

(3) A conformity assessment body must have—

- (a) the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner; and
- (b) access to all necessary equipment or facilities.

6. The personnel responsible for carrying out conformity assessment tasks 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—
 - (i) the essential requirements;
 - (ii) the applicable harmonised standards and normative documents; and
 - (iii) the relevant provisions of Union harmonisation legislation and of national legislation; and
- (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

7.—(1) The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks must be guaranteed.

(2) The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body must not depend on the number of assessments carried out or the results of those assessments.

8.—(1) Conformity assessment bodies must take out liability insurance.

(2) Sub-paragraph (1) does not apply to the Secretary of State or a body where liability for conformity assessment activities is assumed by the Crown.

9.—(1) The personnel of a conformity assessment body must observe professional secrecy with regard to all information obtained in the carrying out their tasks under these Regulations except in relation to competent authorities of the EEA states in which its activities are carried out.

(2) Proprietary rights must be protected.

10. Conformity assessment bodies must participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body co-ordination group established under the relevant Union harmonisation legislation and must apply as general guidance, the administrative decisions and documents produced as a result of the work of that group.