

## SCHEDULE 2

Regulations 2(1) and 8

### NOTIFIED BODIES

#### PART 1

##### NOTIFIED BODY CRITERIA

1. The body, its director and staff involved in conformity assessment tasks shall not be the designer, manufacturer, supplier, installer or user of the relevant instrument that they inspect, nor the authorised representative of any of them. In addition, they may not be directly involved in the design, manufacture, marketing or maintenance of the relevant instrument, nor represent the parties engaged in these activities. The preceding criterion does not, however, preclude in any way the possibility of exchanges of technical information between the manufacturer and the body for the purposes of conformity assessment.

2. The body, its director and staff involved in conformity assessment tasks shall be free from all pressures and inducements, in particular financial inducements, that might influence their judgement or the results of their conformity assessment, especially from persons or groups of persons with an interest in the results of the assessments.

3. The conformity assessment shall be carried out with the highest degree of professional integrity and requisite competence in the field of metrology. Should the body sub-contract specific tasks, it shall first ensure that the sub-contractor meets the requirements of these Regulations, and in particular of this Schedule. The body shall keep the relevant documents assessing the sub-contractor's qualifications and the work carried out by him under these Regulations at the disposal of GEMA (or NIAER, where that authority designates the body).

4. The body shall be capable of carrying out all the conformity assessment tasks for which it has been designated, whether those tasks are carried out by the body itself or on its behalf and under its responsibility. It shall have at its disposal the necessary staff and shall have access to the necessary facilities for carrying out in a proper manner the technical and administrative tasks entailed in conformity assessment.

5. The body's staff shall have—

- (a) sound technical and vocational training, covering all conformity assessment tasks for which the body was designated;
- (b) satisfactory knowledge of the rules governing the tasks which it carries out, and adequate experience of such tasks; and
- (c) the requisite ability to draw up the certificates, records and reports demonstrating that the tasks have been carried out.

6. The impartiality of the body, its director and staff shall be guaranteed. The remuneration of the body shall not depend on the results of the tasks it carries out. The remuneration of the body's director and staff shall not depend on the number of tasks carried out or on the results of such tasks.

7. The body shall satisfy GEMA (or NIAER, where that authority designates the body) that it has adequate civil liability insurance.

8. The body's director and staff shall be bound to observe professional secrecy with regard to all information obtained in the performance of their duties pursuant to these Regulations, except vis-à-vis the authority of GEMA (or NIAER, where that authority designates the body).

## PART 2

### FUNCTIONS

#### **Assessment of applications for certificates or notifications**

**9.—(1)** Subject to paragraph 10, a notified body shall assess an application made by a manufacturer for the issue of—

- (a) a certificate of conformity;
- (b) a design or type examination certificate; or
- (c) a notification of approval of the manufacturer's quality system,

in accordance with the Annex applicable to the relevant conformity assessment procedure in respect of a relevant instrument.

(2) In determining such an application, the notified body—

- (a) shall have regard to the actual or usual environment of the relevant instrument; and
- (b) may have regard to any other standard or other technical criteria appearing to it to be relevant.

(3) Where in the opinion of the notified body the relevant instrument to which an application relates is compliant with the essential requirements, it shall issue a certificate or notification in accordance with paragraph 12.

(4) Where, in the opinion of the notified body, the relevant instrument to which an application relates is not compliant with the essential requirements, it shall issue a notice to the applicant in accordance with paragraph 15.

(5) Where a certificate or notification under sub-paragraph (3) is issued by a United Kingdom notified body, it shall send a copy to GEMA (or to NIAER, where that authority has designated the body).

#### **Limitations on duties to exercise functions**

**10.—(1)** A notified body shall not accept an application for a certificate or notification in respect of a relevant instrument unless the application—

- (a) is in writing, in English or another language acceptable to that notified body;
- (b) is accompanied by all relevant documentation, in which all writing is in English or another language acceptable to that notified body; and
- (c) includes particulars of which applicable standards the manufacturer has applied or proposes to apply in respect of the instrument.

(2) A notified body shall not be required to determine an application for a certificate or notification where the manufacturer has not—

- (a) granted the notified body access to a relevant instrument to which the application relates or the production facilities for the instrument (including, where applicable, the production facilities envisaged in relation to a representative instrument) to the extent that the notified body reasonably requests; and
- (b) made available to the notified body such information as it may reasonably require to determine the application.

(3) A notified body shall not be required to carry out the functions referred to in regulation 7(4)  
(d) if—

- (a) the person making the application has not submitted with the application the amount of the fee which the notified body requires to be submitted with the application pursuant to regulation 11; or
- (b) the notified body reasonably believes that, having regard to the number of applications made to it pursuant to its designation which are outstanding, it will be unable to commence the required work within three months of receiving the application.

### **Contractors**

**11.**—(1) A notified body may, in exercising its functions—

- (a) arrange for some other person to carry out any test, assessment or inspection on its behalf; or
- (b) require the applicant to satisfy another person with respect to any matter at the applicant's expense.

(2) But nothing in sub-paragraph (1) authorises a notified body to rely on the opinion of another person with regard to whether a relevant instrument is compliant with any of the essential requirements.

(3) Nothing in these Regulations shall preclude a person referred to in paragraph (a) or (b) of sub-paragraph (1) from charging any fee in respect of any work undertaken by him in pursuance of those paragraphs.

### **Form of certificates and notifications**

**12.** A certificate or notification issued by a notified body shall be in writing and, in addition to the requirements provided for in the conformity assessment procedures shall—

- (a) be in English;
- (b) give the name and address—
  - (i) of the applicant;
  - (ii) where the applicant is not the manufacturer, of the manufacturer;
- (c) be signed by or on behalf of the notified body and give the identification number of the notified body;
- (d) bear—
  - (i) the date of issue; and
  - (ii) the number,of the certificate or notification;
- (e) give particulars of the relevant instrument (where applicable, in relation to each variant) to which it relates sufficient to identify it, and shall state whether the instrument to which it relates is a single item or a representative, or if it covers a number of variants of that instrument; and
- (f) certify that the instrument to which it relates is compliant with the essential requirements.

### **Conditions in certificates or notifications**

**13.**—(1) A certificate or notification may be unconditional or may be subject to such conditions as the notified body considers appropriate.

(2) Such conditions may include—

- (a) a limitation on the environment for which the relevant instrument is stated to be suitable; or

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(b) a requirement that the instrument is only to be installed at a specific site.

(3) The conditions imposed pursuant to sub-paragraph (1) may be varied in accordance with paragraph 15 by the notified body which issued the certificate or notification and such variation may include the imposition of new conditions or the removal of conditions.

#### **Withdrawal of certificates or notifications**

14. The notified body which issued the certificate or notification shall withdraw that certificate or notification in accordance with paragraph 15, if it appears that the relevant instrument to which it relates is not compliant with the essential requirements.

#### **Procedure where a notified body is minded to refuse to give, or to vary or withdraw a certificate or notification**

15.—(1) Where a notified body is minded to—

- (a) refuse to issue a certificate or notification;
- (b) vary a certificate or notification (other than at the request of the person to whom it was given); or
- (c) withdraw a certificate or notification,

it shall give the applicant, or the person to whom the certificate or notification was given, a notice in writing—

- (i) giving reasons for the refusal, variation or withdrawal;
- (ii) specifying the date on which the refusal, variation or withdrawal is to take effect; and
- (iii) giving the applicant or person the opportunity to make representations within 21 days from the date of the notice and stating that the notified body shall consider any representations made to it within that period by that applicant or person.

(2) Where a notified body, having considered representations made to it under sub-paragraph (1), remains of the opinion that—

- (a) an application for a certificate or notification should be refused; or
- (b) a certificate or notification should be varied or withdrawn,

it shall give notice in writing to the applicant or the person to whom the certificate or notification was given, and give that applicant or person information about the judicial remedies available to him.

(3) Where a notice is given under sub-paragraph (1) or (2) by a United Kingdom notified body, it shall send a copy to GEMA (or to NIAER, where that authority has designated the body).