SCHEDULE 9

Regulation 53

Operational obligations of notified bodies

1. A notified body must carry out conformity assessments in accordance with the relevant conformity assessment procedures in Schedule 3 (conformity assessment concerning EU-type examination) or Schedule 4 (conformity assessment concerning quality system approval).

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

3. A conformity assessment 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 radio equipment technology in question and the mass or serial nature of the production process.

4. A conformity assessment body must respect the degree of rigour and the level of protection required to ensure that the radio equipment is in conformity with the requirements of these Regulations.

5. Where a notified body finds that the essential requirements or the corresponding harmonised standards have not been met by the manufacturer, that body must require that manufacturer to take appropriate corrective measures and must not issue an EU-type examination certificate or quality system approval until the appropriate corrective measures have been taken.

6. Where, in the course of the monitoring of conformity following the issue of an EU-type examination certificate or a quality system approval, a notified body finds that the radio equipment is no longer in conformity with the essential requirements, it must require the manufacturer to take appropriate corrective measures and must suspend or withdraw the EU-type examination certificate or quality system approval (if necessary).

7. 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 EU-type examination certificates or quality system approvals as appropriate.

8. Paragraph 9 applies where a notified body is minded to—

(a) refuse to issue an EU-type examination certificate,

(b) refuse to grant a quality system approval, or

(c) restrict, suspend or withdraw an EU-type examination certificate or quality system approval.

9. Where this paragraph applies, the notified body must—

(a) give the person applying for the EU-type examination certificate or quality system approval, or the person to whom the EU-type examination certificate or quality system approval was given—

(i) a notice in writing giving reasons and specifying the date on which the refusal, restriction, suspension or withdrawal is intended to take effect, and

(ii) an opportunity to make representations within a reasonable period from the date of the notice, and

(b) take account of any representations made under sub-paragraph (a)(ii) before taking its decision.

10. A notified body must inform the Secretary of State of—

(a) any refusal, restriction, suspension or withdrawal of an EU-type examination certificate or quality system approval in accordance with the requirements of Schedule 3 or Schedule 4 as appropriate,

(b) any circumstances affecting the scope of, or conditions for, notification under regulation 47 (notification),

(c) any request for information which it has received from an enforcing authority or a competent national authority of another Member State regarding conformity assessment activities, and

(d) on request, conformity assessment activities performed within the scope of its notification under regulation 47 and any other activity performed, including cross-border activities and subcontracting.

11. 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 an EU-type examination certificate or quality system approval decision, or

(b) to restrict, suspend or withdraw an EU-type examination certificate or quality system approval decision.

12. A notified body must, in accordance with the requirements in Schedule 3 and Schedule 4, provide other bodies notified under the Directive carrying out similar conformity assessment activities covering the same type of radio equipment with relevant information on issues relating to negative and, on request, positive conformity assessment results.

13. 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.

14. A notified body must fulfil any information obligations under Schedules 3 and 4.