# SCHEDULE 4

Regulation 41(4)(c)

## Conformity assessment module H

### Conformity based on full quality assurance

**1.** Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 and 5 and ensures and declares the manufacturer's sole responsibility that the radio equipment concerned satisfies the requirements of these Regulations that apply to it.

### Manufacturing

**2.** The manufacturer must operate an approved quality system for design, manufacture, final radio equipment inspection and testing of the radio equipment concerned as specified in paragraph 3 and must be subject to surveillance as specified in paragraph 4.

### Quality system

**3.**—(1) The manufacturer must lodge an application for assessment of the manufacturer's quality system with the notified body of the manufacturer's choice, for the radio equipment concerned. The application must include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the representative's name and address as well,

(b) the technical documentation for each radio equipment type intended to be manufactured. The technical documentation must contain, wherever applicable, the elements set out in Schedule 5 (contents of technical documentation),

(c) the documentation concerning the quality system, and

(d) a written declaration that the same application has not been lodged with any other notified body.

(2) The quality system must ensure compliance of the radio equipment with the requirements of these Regulations that apply to it. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records. It must, in particular, contain an adequate description of—

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations that apply to the radio equipment will be met;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing radio equipment pertaining to the radio equipment type covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

(3) The notified body must—

(a) assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3(2), and

(b) presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

(4) In addition to experience in quality management systems, the auditing team must—

(a) have at least one member experienced as an assessor in the relevant radio equipment field and radio equipment technology concerned, and knowledge of the applicable requirements of these Regulations, and

(b) review the technical documentation referred to in paragraph 3(1)(b) to verify the manufacturer's ability to identify the applicable requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the radio equipment with those requirements.

(5) The audit must include an assessment visit to the manufacturer's premises.

(6) The manufacturer or the manufacturer's authorised representative must be notified of the decision.

(7) The notification must contain the conclusions of the audit and the reasoned assessment decision.

(8) The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

(9) The manufacturer must keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body must evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in paragraph 3(2) or whether a reassessment is necessary. The notified body must notify the manufacturer of its decision. The notification must contain the conclusions of the examination and the reasoned assessment decision.

**Surveillance under the responsibility of the notified body**

**4.**—(1) The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

(2) The manufacturer must, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and must provide it with all necessary information, in particular—

(a) the quality system documentation;

(b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc;

(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, reports concerning the qualifications of the personnel, etc.

(3) The notified body must carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and must provide the manufacturer with an audit report.

(4) In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out radio equipment tests, or have them carried out, in order to check the proper functioning of the quality system. It must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

**CE marking and EU declaration of conformity**

**5.**—(1) The manufacturer must affix the CE marking in accordance with regulations 39 (prohibition on improper use of CE marking) and 44 (CE marking) and, under the responsibility of the notified body referred to in paragraph 3(1), the latter's identification number to each item of radio equipment that satisfies the requirements of these Regulations.

(2) The manufacturer must draw up a written EU declaration of conformity for each radio equipment type and keep it at the disposal of the national authorities for 10 years after the radio equipment has been placed on the market. The EU declaration of conformity must identify the radio equipment type for which it has been drawn up. A copy of the EU declaration of conformity must be made available to the relevant authorities upon request.

**6.** The manufacturer must, for a period ending 10 years after the radio equipment has been placed on the market, keep at the disposal of the national authorities—

(a) the technical documentation referred to in paragraph 3(1);

(b) the documentation concerning the quality system referred to in paragraph 3(1);

(c) the change referred to in paragraph 3(9), as approved;

(d) the decisions and reports of the notified body referred to in paragraphs 3(9), 4(3) and 4(4).

**7.**—(1) Each notified body must inform its notifying authority of quality system approvals which it has issued or withdrawn, and must, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

(2) Each notified body must inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

**Authorised representative**

**8.** The manufacturer's obligations set out in paragraphs 3(1) and (9), 5 and 6 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

**Status:**
Point in time view as at 26/12/2017.

**Changes to legislation:**
There are currently no known outstanding effects for the The Radio Equipment Regulations 2017, SCHEDULE 4.