SCHEDULE 4

Conformity assessment module H

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.