SCHEDULE 11

(ANNEX VIII to the Directive)

Full Quality Assurance

1. This Annex describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the equipment concerned satisfies the requirements of this Directive. The manufacturer, or his authorised representative established in the Community, must affix the CE marking supplemented by the information as required in Article 11 to each product and draw up the written EC declaration of conformity referred to in Article 8.

2. The manufacturer must operate an approved quality assurance system for design, manufacture and final product inspection and testing as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. *Quality assurance system*

3.1. The manufacturer must lodge an application for assessment of his quality assurance system with a notified body of his choice.

The application must include:

- all relevant information for the product category envisaged, including technical documentation of all equipment already in phase of design or production that must contain at least the following information:
  - name and address of the manufacturer or his authorised representative established in the Community
  - a description of the equipment
  - make
  - trade name
  - type, series and numbers
  - the technical data relevant for the identification of the equipment and the assessment of its noise emission, including, if appropriate, schematic drawings and any description and explanation necessary for their understanding.
  - the reference to this Directive
  - the technical report of noise measurements carried out in accordance with the provisions of this Directive
  - the technical instruments applied and the results of the evaluation of the uncertainties due to production variation and their relation to the guaranteed sound power level
  - a copy of the EC declaration of conformity.
- the documentation concerning the quality assurance system.

3.2. The quality assurance system must ensure compliance of the product with the requirements of the Directives that apply to it.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality assurance system documentation must permit a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

3.3. It must contain in particular an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality

— the technical documentation to be drawn up for each product, containing at least the information indicated in point 3.1 for the technical documentations mentioned there

— the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the equipment category covered

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used

— the examinations and test that will be carried out before, during and after manufacture, and the frequency with which they will be carried out

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned etc.

— the means to monitor the achievement of the required design and product quality and the effective operation of the quality assurance system.

The notified body must assess the quality assurance system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume conformity with these requirements in respect of quality assurance systems that implement EN ISO 9001.

The auditing team must have at least one member with experience as an assessor in the equipment technology concerned. The assessment procedure must include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusion of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality assurance system as approved and to maintain it in an adequate and efficient manner.

The manufacturer or his authorised representative established within the Community shall keep the notified body that has approved the quality assurance system informed of any intended updating of the quality assurance system.

The notified body must evaluate the modifications proposed and decide whether the modified quality assurance system will still satisfy the requirements referred to in point 3.2 or whether a reassessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. 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 assurance system.

4.2. The manufacturer must allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:

— the quality assurance system documentation

— the quality records as foreseen by the design part of the quality assurance system, such as results of analyses, calculations, tests, etc.

— the quality records as foreseen by the manufacturing part of the quality assurance system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned etc.

4.3. The notified body shall periodically carry out audits to make sure that the manufacturer maintains and applies the quality assurance system and must provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out, or cause to be carried out, tests to verify that the quality assurance system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period ending at least 10 years after the last equipment has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of point 3.1 of this Annex

— the updating referred to in the second paragraph of point 3.4

— the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.

6. Each notified body must give the other notified bodies the relevant information concerning the quality assurance system approvals issued and withdrawn.