SCHEDULE 10

(Annex VII of the ATEX Directive)
MODULE: PRODUCT QUALITY ASSURANCE

Quality system

3.—(3.1) The manufacturer shall lodge an application for assessment of his quality system for the equipment and protective systems, with a notified body of his choice.

The application shall include:

— all relevant information for the product category envisaged;

— documentation on the quality system;

— technical documentation on the approved type and a copy of the EC-type-examination certificate.

(3.2) Under the quality system, each piece of equipment shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the Directive. 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 instruments. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of:

— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality;

— the examinations and tests which will be carried out after manufacture;

— the means to monitor the effective operation of the quality system;

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

(3.3) The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in Section 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonized standard.

The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The assessment procedure shall include an assessment visit to the manufacturer's premises.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

(3.4) The manufacturer shall undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorized representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in Section 3.2 or whether a re-assessment is required.

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