SCHEDULE 7

Regulation 10

(Annex IV of the ATEX Directive)
MODULE: PRODUCTION QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned are in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of the Directive which apply to them. The manufacturer, or his authorized representative established in the Community, shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for EC monitoring, as specified in Section 4.

2. The manufacturer shall operate an approved quality system for production, final equipment inspection and testing as specified in Section 3 and shall be subject to monitoring as specified in Section 4.

3. Quality system

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

The application shall include:

- all relevant information for the product category envisaged;
- the documentation concerning the quality system;
- technical documentation on the approved type and a copy of the EC-type-examination certificate.

(3.2) The quality system shall ensure compliance of the equipment with the type as described in the EC-type-examination certificate and with the requirements of the Directive which apply to them.

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 system documentation must permit a consistent interpretation of 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 equipment quality;
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions which will be used;
- the examinations and tests which 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, reports on the qualifications of the personnel concerned, etc.;
- the means to monitor the achievement of the required equipment quality and the effective operation of the quality system.

(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 with experience of evaluation in the equipment technology concerned. The evaluation procedure shall include an inspection 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 fulfil the obligations arising out of the quality system as approved and to uphold the system so that it remains adequate and efficient.

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 amended 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.

Surveillance under the responsibility of the notified body

4.—(4.1) The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

(4.2) The manufacturer shall, for inspection purposes, allow the notified body access to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular

— the quality system documentation

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

(4.3) The notified body shall periodically carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

(4.4) Furthermore, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may carry out tests, or arrange for tests to be carried out, to check that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.

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

— the documentation referred to in the second indent of Section 3.1;

— the updating referred to in the second paragraph of Section 3.4;

— the decisions and reports from the notified body which are referred to in Section 3.4, last paragraph, Section 4.3 and Section 4.4.

6. Each notified body shall apprise the other notified bodies of the relevant information concerning the quality system approvals issued and withdrawn.