SCHEDULE 7 Regulation 2(1)

(Annex VIII to the Lifts Directive)
PRODUCT QUALITY ASSURANCE
(module E)

1. Product quality assurance is the procedure whereby the manufacturer of the safety component who satisfies Section 2 ensures and declares that the safety components are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the Directive that apply to them and ensures and declares that the safety component will enable a lift to which it is correctly fitted to satisfy the provisions of the Directive.

The manufacturer of the safety component or his authorized representative established in the Community must affix the CE marking to each safety component and draw up an EC declaration of conformity. The CE marking must be accompanied by the identification number of the notified body responsible for surveillance as specified in Section 4.

2. The manufacturer must apply an approved quality assurance system for final inspection of the safety component and testing as specified in Section 3, and must be subject to surveillance as specified in Section 4.

3 Quality assurance system

(3.1) The manufacturer of the safety component must lodge an application for assessment of his quality assurance system for the safety components concerned with a notified body of his choice.

The application must include:

- all relevant information for the safety components envisaged,
- the documentation on the quality assurance system,
- the technical documentation of the approved safety components and a copy of the EC type-examination certificates.

(3.2) Under the quality assurance system, each safety component must be examined and appropriate tests as set out in the relevant standards referred to in Article 5 or equivalent tests must be carried out in order to ensure its conformity to the relevant requirements of the Directive.

All the elements, requirements and provisions adopted by the manufacturer of the safety components must be documented in a systematic and orderly manner in the form of written measures, procedures and instructions. This quality assurance system documentation must ensure a common understanding of the quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

(a) the quality objectives;

(b) the organizational structure, responsibilities and powers of the management with regard to safety component quality;

(c) the examinations and tests that will be carried out after manufacture;

(d) the means to verify the effective operation of the quality assurance system;

(e) 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 must assess the quality assurance system to determine whether it satisfies the requirements referred to in Section 3.2. It must presume conformity with these requirements in respect of quality assurance systems that implement the relevant harmonized standard(**1**).

(**1**) This harmonised standard will be EN 29003, supplemented where necessary to take account of the specific features of safety components.

The auditing team must have at least one member with experience of assessment in the lift technology concerned. The assessment procedure must include a visit to the premises of the safety component manufacturer.

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

(3.4) The manufacturer of the safety components must undertake to discharge the obligations arising from the quality assurance system as approved and to ensure that it is maintained in an appropriate and efficient manner.

The manufacturer of the safety components or his authorized representative established in the Community must keep the notified body which has approved the quality assurance system informed of any intended updating of the quality assurance system.

The notified body must assess the modifications proposed and decide whether the modified quality assurance system still satisfies the requirements referred to in Section 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 of the safety component duly fulfils the obligations arising out of the approved quality assurance system.

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

— the quality assurance system documentation,

— the technical documentation,

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

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

(4.4) Additionally, the notified body may pay unexpected visits to the manufacturer of the safety component.

At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality assurance system where necessary; it must provide the manufacturer of the safety components with a visit report and, if a test has been carried out, with a test report.

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

— the documentation referred to in the third indent of the second paragraph 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 the final paragraph of Section 3.4 and in Sections 4.3 and 4.4.

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