SCHEDULE 8 Regulation 2(1)

(Annex IX to the Lifts Directive)
FULL QUALITY ASSURANCE
(module H)

1. Full quality assurance is the procedure whereby the manufacturer of the safety component who satisfies the obligations of Section 2 ensures and declares that the safety components satisfy the requirements of the Directive that apply to them and that the safety component will enable a lift to which it is correctly fitted to satisfy the requirements of the Directive.

The manufacturer 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 the surveillance as specified in Section 4.

2. The manufacturer must operate an approved quality assurance system for design, manufacture and final inspection of the safety components 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 must lodge an application for assessment of his quality assurance system with a notified body. The application must include:

— all relevant information on safety components,

— the documentation on the quality assurance system.

(3.2) The quality assurance system must ensure compliance of the safety components with the requirements of the Directive that apply to them and enable lifts to which they have been correctly fitted to satisfy those requirements.

All the elements, requirements and provisions adopted by the manufacturer 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 policies and procedures such as quality programmes, plans, manuals and records.

It must contain in particular an adequate description of:

— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to the design and quality of the safety components,

— the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 5 will not be applied in full, the means that will be used to ensure that the essential requirements of the Directive that apply to the safety components will be met,

— the design control and design verification techniques, processes and systematic actions that will be used when designing the safety components,

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

— the examinations and tests 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, reports on the qualifications of the personnel concerned, etc.,

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

(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 compliance with these requirements in respect of quality assurance systems that implement the relevant harmonized standard(**1**).

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 manufacturer's premises.

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 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 will still satisfy 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 components duly fulfils the obligations arising out of the approved quality assurance system.

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

— the quality assurance system documentation,

— the quality records provided for in the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— the quality records provided for in the manufacturing part of the quality assurance system, 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 make sure 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 components. 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 of the safety components or his authorized representative must, for a period of 10 years after the last safety component has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of the second paragraph of Section 3.1,

(**1**) This harmonised standard will be EN 29001, supplemented where necessary to take account of the specific features of safety components.

— 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.

Where neither the manufacturer of the safety components nor his authorized representative is established in the Community, the obligation to keep the technical documentation available falls to the person who places the safety component on the Community market.

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

7. The dossiers and correspondence relating to the full quality assurance procedures must be drawn up in one of the official languages of the Member State where the notified body is established or in a language acceptable to it.