SCHEDULE 8

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

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.

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

(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.