

SCHEDULE 12

Regulation 2(1)

(Annex XIII to the Lifts Directive) FULL QUALITY ASSURANCE FOR LIFTS (module H)

1. Full quality assurance is the procedure whereby the installer of a lift who satisfies the obligations of Section 2 ensures and declares that lifts satisfy the requirements of the Directive that apply to them.

The installer of a lift must affix the CE marking on each lift 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 installer of a lift must operate an approved quality assurance system for design, manufacture, assembly, installation and final inspection of the lifts 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 installer of a lift must lodge an application for assessment of his quality assurance system with a notified body.

The application must include:

- all relevant information on the lifts, in particular information which makes for an understanding of the relationship between the design and operation of the lift and enables conformity with the requirements of the Directive to be assessed,
- the documentation on the quality assurance system.

(3.2) The quality assurance system must ensure conformity of the lifts with the requirements of the Directive that apply to them.

All the elements, requirements and provisions adopted by the lift installer 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 procedures such as programmes, plans, manuals and quality 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 lifts,
- the technical design specifications, including standards that will be applied and, where the standards referred to in Article 5 of the Directive will not be applied in full, the means that will be used to ensure that the requirements of the Directive that apply to the lifts will be met,
- the design control and design verification techniques, processes and systematic actions that will be used when designing the lifts,
- the examinations and tests that will be carried out on acceptance of the supplies of materials, components and sub-assemblies,
- the corresponding assembly, installation and quality control techniques, processes and systematic actions that will be used,
- the examinations and tests that will be carried out before (inspection of installation conditions: shaft, housing of machinery, etc.), during and after installation (including at the very least the tests laid down in Annex VI, Section 4 (b)),

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- 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 installation quality and the effective operation of the quality assurance system.

Design inspection

(3.3) When the design is not entirely in accordance with harmonized standards, the notified body must ascertain whether the design conforms to the provisions of the Directive and, if it does, issue an 'EC design examination certificate' to the installer, stating the limits of the certificate's validity and giving the details required for identification of the approved design.

Assessment of the quality assurance system

(3.4) 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 lift installer's premises and a visit to an installation site.

The decision must be notified to the lift installer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

(3.5) The lift installer 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 lift installer must keep the notified body that 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 lift installer. 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 installer of a lift duly fulfils the obligations arising out of the approved quality assurance system.

(4.2) The lift installer must allow the notified body access for inspection purposes to the design, manufacture, assembly, installation, 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 assurance system, such as results of analyses, calculations, tests, etc.,
- the quality records provided for in the part of the quality assurance system concerning acceptance of supplies and installation, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

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

(4.3) The notified body must periodically carry out audits to make sure that the installer of a lift maintains and applies the quality assurance system and must provide the installer with an audit report.

(4.4) Additionally, the notified body may pay unexpected visits to the premises of a lift installer or to the assembly site of a lift. 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 lift installer with a visit report and, if a test has been carried out, with a test report.

5. The installer of a lift must, for a period of 10 years after the lift has been placed on the market, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of the second paragraph of Section 3.1,
- the updating referred to in the second paragraph of Section 3.5,
- the decisions and reports from the notified body which are referred to in the final paragraph of Section 3.5 and in Sections 4.3 and 4.4.

Where the installer is not established in the Community, this obligation falls to the notified body.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality assurance systems 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.