LEIA Quality and Technical Committee Publication
July 2021

TECHNICAL GUIDANCE NOTE

Guidance on routes to approval of lifts and safety components for lifts from 1 January 2022

1. *Introduction*

The Lifts Regulations along with many other regulations formerly linked to EU Directives have been amended by various EU Exit regulations.

These amendments allow lifts and safety components for lifts approved by EU Notified Bodies to continue to be placed onto the GB (UK excluding Northern Ireland) market until the end of 2021. From 1 January 2022, lifts placed onto the GB market (put into service and a declaration of conformity issued) and safety components for lifts must be UKCA-marked. **BEIS Guidance on the Lifts Regulations** includes: *"A fully manufactured good is 'placed on the market' when there is a written or verbal agreement (or offer of an agreement) to transfer ownership or possession or other rights in the product. This does not require physical transfer of the good"*.

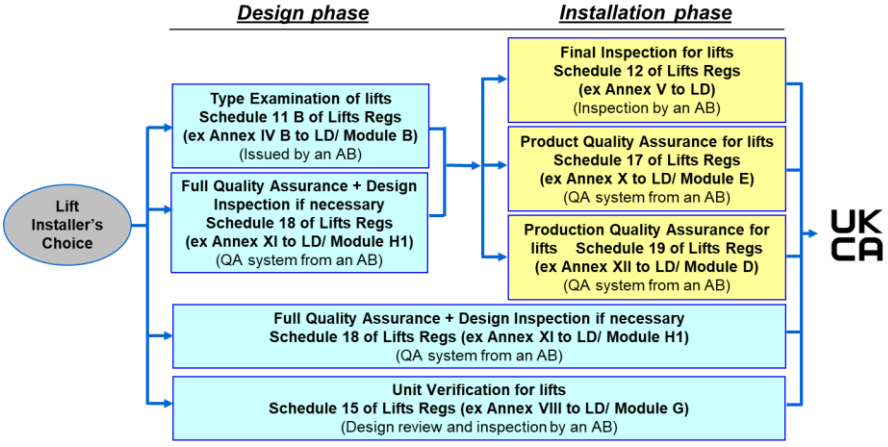
From 1 January 2021, most UK Notified Bodies for lifts became **UK Approved Bodies for lifts listed here**. Lifts and safety components for lifts placed on the GB market where conformity assessment procedures have used UK Approved Bodies must have the UKCA mark although, until 31 December 2022, it may be on accompanying documentation.

These changes allow until the end of 2021 for any conformity assessment procedure using EU Notified Bodies to be moved to UK Approved Bodies. This guidance looks at the options for UK companies wishing to place lifts and safety components for lifts onto the GB market from 1 January 2022 and build on the **guidance on the LEIA website**. It looks first at lifts and then at safety components for lifts.

LEIA alerted its members to these challenges, especially for safety components, in early February. LEIA recommended action by manufacturers of safety components to pursue approvals from UK Approved Bodies. This remains the recommended approach. Although the conformity assessment of lifts might be more easily addressed by LEIA members, safety components represent a very significant challenge.

This guidance has been agreed between the UK Approved Bodies for lifts and LEIA for use by both whilst working together to meet these challenges.

2. *Conformity assessment of lifts*



Conformity Assessment Procedures for Lifts

2.1 Lifts with conformity based on unit verification by a UK Approved Body and full quality assurance approved by a UK Approved Body

Lift installers using UK Approved Bodies for the following conformity assessment procedures for lifts should not need to take action for their conformity assessment procedures for lifts (but will need to take action on the conformity assessment procedures for safety components for lifts - see 3. below):

- Conformity based on unit verification for lifts using a UK Approved Body. This procedure is usually used only for small numbers of lifts so is not widely used.
- Conformity based on full quality assurance plus design inspection for lifts by a UK Approved Body. This is widely used by lift installers either following the designated standard BS EN 81-20 without deviation or where deviations are approved by their Approved Body by design inspection (also known as design examination).

Lift installers who are not following one of the above conformity assessment procedures and are buying-in a lift package will need to take action – see 2.2.

2.2 Lifts designed and manufactured according to full quality assurance system approved by an EU Notified Body and Model lifts designed and manufactured according to EU type examination issued by an EU Notified Body

This applies to lift installers who are installing a lift package which has been designed and manufactured according to one of the following:

- a quality assurance (QA) system approved under full quality assurance for lifts [Module H1] approved by an EU Notified Body;
- a model lift that has undergone an EU type examination for EU Notified Body.

In these cases, the lift may be placed onto the market (put into service and declaration of conformity issued) until the end of 2021. From 1 January 2022, a UK Approved Body must be used for these conformity assessment procedures (and for safety components for lifts). Lift installers should take action to ensure that they are compliant from 1 January 2022. The options available are:

- The lift designer/manufacturer obtains approval under "Full Quality Assurance plus Design Inspection" for lifts from a UK Approved Body OR the lift designer/manufacturer has a model lift approved by "Type Examination for lifts" by a UK Approved Body. Where this involves a lift which has been EU Type Examined then **UK Government guidance on issuing new certificates based on previous assessments** makes clear that it is for the UK Approved Body "*to assure themselves that products for which they are issuing certificates are compliant with the relevant requirements. However, it is not necessarily required to retest or fully re-assess a product or process before a UK body issues a new certificate*".
- The EU Notified Body which has approved the model lift gains approval as a UK Approved Body and then issues the lift designer/manufacturer with a type examination certificate under the Lifts Regulations. We understand that some EU Notified Bodies are looking at this option; they will need a UK establishment and there is no guarantee that they will gain approval by the end of 2021.

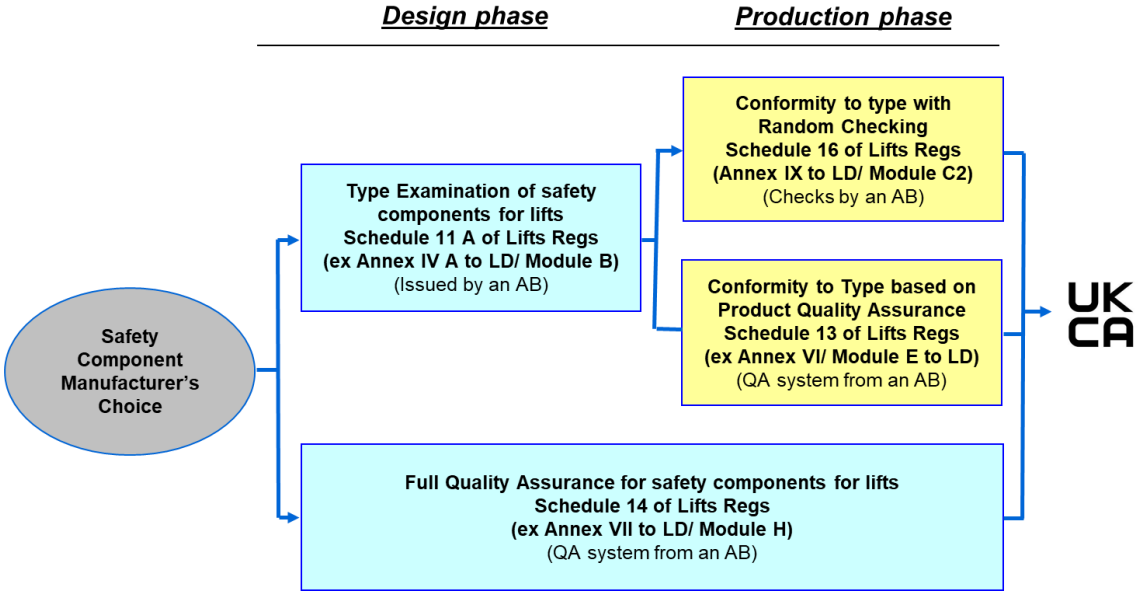
- The lift installer uses the procedure for unit verification by a UK Approved Body. This procedure is usually used only for small numbers of lifts so is not widely used.
- The lift installer uses the procedure for "Full Quality Assurance plus Design Inspection" for lifts by a UK Approved Body and follows the designated standard BS EN 81-20 without deviation or has deviations approved by their Approved Body by design inspection based on details available for the EU Type Examination.

A lift company installing lifts should agree a solution with their UK Approved Body.

In addition to the conformity assessment of the lift, action will be needed for the safety components for lifts (see 3 below).

3. *Conformity assessment for safety components for lifts*

Regardless of the conformity assessment procedure used for lifts, safety components for lifts (defined in Schedule 3 of the Lifts Regulations as: landing door locks, safety gears, devices to prevent uncontrolled movement, overspeed governors, energy accumulating buffers (except linear types), energy dissipating buffers and electric safety devices (PESSRAL)) need to follow one of the conformity assessment procedures below.



Conformity Assessment Procedures for Safety Components for Lifts

3.1 Safety components for lifts with type examination by a UK Approved Body or full quality assurance for safety components approved by a UK Approved Body

From 1 January 2022, any safety component for lifts placed onto the GB market must have followed one of the following conformity assessment procedures:

- "Type Examination of safety components for lifts" by a UK Approved Body with either random checking of the safety components or based on product quality assurance checked by the UK Approved Body;
- "Full Quality Assurance for safety components for lifts" (Module H) with quality assurance checks by the UK Approved Body.

Where a safety component follows one of these, it must be UKCA-marked although, until the end of 2022, this may be on accompanying documentation.

3.2 Safety components for lifts not with type examination by a UK Approved Body or full quality assurance for safety components approved by UK Approved Body

Where a safety component for lifts does not follow one of the conformity assessment procedures in 3.1 then it cannot be UKCA-marked and placed onto the GB market after 31 December 2021. The options available to place such a safety component onto the GB market from 1 January 2022 are as follows:

- The safety component manufacturer follows one of the conformity assessment procedures in 3.1 using a UK Approved Body. Where this involves a safety component which has been EU Type Examined then **UK Government guidance on issuing new certificates based on previous assessments** makes clear that it is for the UK Approved Body "*to assure themselves that products for which they are issuing certificates are compliant with the relevant requirements. However, it is not necessarily required to retest or fully re-assess a product or process before a UK body issues a new certificate*".
- The EU Notified Body which has approved the safety component gains approval as a UK Approved Body and then issues the safety component manufacturer with a (UKCA) type examination certificate under the Lifts Regulations. We understand that some EU Notified Bodies are looking at this option; they will need a UK establishment and there is no guarantee that they will gain approval by the end of 2021.
- The lift company takes on the responsibility as the safety component manufacturer and obtains approval under "Full Quality Assurance for safety components for lifts" from a UK Approved Body (Module H).

We encourage manufacturers to use one of the first two options. The last option presents an alternative which UK lift companies might want to use. The next section provides further guidance in support of this.

Note: Safety components for lifts placed on the GB market before the end of 2021 may bear a CE-mark and may later be incorporated into a lift. This means that a lift placed into service from 1 January 2022 (and for some time until stock is used up) with a UKCA mark may contain CE-marked safety components. Since the CE-marked safety components for lifts were placed on the market before the end of 2021, this is acceptable. See the Introduction above.

3.3 Full quality assurance for safety components approved by a UK Approved Body

Principles

This guidance is based on the following principles:

- There are no technical changes for the requirements for safety components for lifts; the Essential Requirements (ERs) of the UK Lifts Regulations remain identical to the EHSRs of the EU Lift Directive. The designated standards BS EN 81-20 and BS EN 81-50 are identical to the EU harmonised standards.
- The lift company has the scope of its quality systems (under ISO 9001) extended to include the sub-contracted manufacture of safety components and obtains approval under "Schedule 14" (Module H) of the Lifts Regulations.
- This conformity assessment procedure might not be appropriate for all lift companies and so its use should be discussed and agreed with the Approved Body.

- The company following this procedure has the following documents:
    - EU Type Examination Certificate;
    - Details of the EU Notified Body used for EU type examination (certificate, scope of approval)
    - EU Declaration of Conformity, including details of the EU Notified Body used for approval of the quality system used for the production phase
    - Commissioning instructions and final inspection (as required)
    - Proof of access to the technical file with any sub-contracted manufacturer.
- The company following this procedure either has access to the technical file either under its direct control (if they are the manufacturer) or it has an agreement in place with the sub-contracted manufacturer to provide the technical file if required by the UK market surveillance authorities. See below for further details.

Access to the technical file defined in Schedule 14

The technical file is available if ever called for by a market surveillance authority for the purpose of investigation following a specific need or event. Any required translation of documents would be performed at the time the file is called for.

This is in line with current EU processes today if a technical file were to be called for by a market surveillance body of a member state.

There is no requirement to review the technical file routinely as part of the annual audit.

There are 3 scenarios to consider for the UK company following this procedure:

1. The company following this procedure manufactures the safety component and can put together the technical file.
2. The company following this procedure is the certificate holder of the type examination with subcontracted manufacture of the safety component and so can put together the technical file.
3. The company following this procedure sub-contracts design and manufacture of the safety component and the technical file is held by the sub-contracted manufacturer. The sub-contracted manufacturer might request a licence agreement to allow the company to add its marking, under a contractual agreement for branding and Intellectual Property requirements.

   In the case of option 3, where the company requests the technical file from the sub-contracted manufacturer, giving evidence that the request for the technical file has been called for by a UK market surveillance authority, the sub-contracted manufacturer would send the required information directly to the UK market surveillance authority.

Lift company quality assurance

The following are suggestions for points to be considered as part of the company's quality management system under ISO 9001 and Schedule 14 of the Lifts Regulations.

Existing EU conformity assessment process documents are used by the company as evidence for the quality system:

- Use the existing EU type examination certificate as evidence:
    - of meeting the Essential Requirements (ERs) of the Lifts Regulations as long as these are identical to the EHSRs of the Lift Directive; and
    - of the details and scope of the component
- Use the EU Declaration of Conformity as evidence:
    - of conformity to the technical requirements of the Lifts Regulations as long as these are identical to those of the EU Lift Directive, BS EN 81-50 & supporting Designated Standards; and
    - details of the EU Notified Body used for approval of the quality system used for the production phase
- A UKCA Declaration of Conformity will be issued by the 'UK Manufacturer' (UK lift company), for the Safety Component for Lifts.

The UKCA Declaration of Conformity provides details of the safety component and reference the name, address and number of the UK Approved Body.

The company following this procedure would have someone responsible for the overall process ensuring the certificate remains in accordance with the quality system. This person would:

- work with their own factory and sub-contracted manufacturers to ensure all certification remains aligned;
- monitor the UK market to ensure there is no divergence of EU and UK legislation or designated/harmonised standards.

The company following this procedure would maintain a database or equivalent to keep an accurate record of the safety components placed on the GB market, and to provide evidence for the Approved Body, this might include;

- Volume of components place on the market
- Batch or serial numbers of components
- Part numbers of components
- Site (address) where the components are fitted
- Lift serial number where the components are fitted
- Record the date the annual audit last checked each component

For all safety components a library would be maintained identifying the latest:

- EU type examination certificate
- EU declaration of conformity for the component

The annual Schedule 14 audit would include:

- Review ISO 9001 Certificate
- Review the Notified Body being used for EU Type Examination
- Review the organisation's internal structure with responsibilities for safety components
- Review of components installed in the last year including the volumes
- Review any changes to components or new components
- Site visit to inspect the components (possible witness test if required)
- Commissioning instructions and final inspection (as required)
- Review random number of all listed safety components, for evidence of:
    - EU Type examination certificate
    - EU Declaration of Conformity
    - UK Declaration of Conformity

The EU Type Examination certificate and EU Declaration of Conformity would be used as the evidence to satisfy of the quality objectives in Schedule 14.