

ANNEX IV

**CONFORMITY ASSESSMENT PROCEDURES FOR SUBSYSTEMS
AND SAFETY COMPONENTS: MODULE D: CONFORMITY TO TYPE
BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS**

4. Surveillance under the responsibility of [^{F1}the approved body]
- 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
- 4.2. The manufacturer shall, for assessment purposes, allow [^{F2}the approved body] access to the manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:
- (a) the quality system documentation;
- (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

Textual Amendments

- F2** Words in Annex 4 Point 4 substituted (31.12.2020) by [The Cableway Installations \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1347\)](#), regs. 1, **54(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

- 4.3. [^{F3}The approved body] shall carry out periodic audits of at least once every two years to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

Textual Amendments

- F3** Words in Annex 4 Point 4.3 substituted (31.12.2020) by [The Cableway Installations \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1347\)](#), regs. 1, **54(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

- 4.4. In addition, [^{F4}the approved body] may pay unexpected visits to the manufacturer. During such visits [^{F4}the approved body] may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. [^{F5}The approved body] shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Textual Amendments

- F4** Words in Annex 4 Point 4.4 substituted (31.12.2020) by [The Cableway Installations \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1347\)](#), regs. 1, **54(c)(iv)(aa)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Annex 4 Point 4.4 substituted (31.12.2020) by [The Cableway Installations \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1347\)](#), regs. 1, **54(c)(iv)(bb)**; 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2016/424 of the European Parliament and of the Council, Division 4.. (See end of Document for details)

Textual Amendments

- F1** Words in Annex 4 Point 4 heading substituted (31.12.2020) by [The Cableway Installations \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/1347\)](#), regs. 1, **54(c)(i)**; 2020 c. 1, **Sch. 5 para. 1(1)**

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There are currently no known outstanding effects for the Regulation (EU) 2016/424 of the European Parliament and of the Council, Division 4..