

ANNEX III

**PROCEDURES TO BE FOLLOWED WITH
RESPECT TO [F1GB] TYPE-APPROVAL****Textual Amendments**

- F1** Word in Annex 3 heading substituted (31.12.2022 at 11.00 p.m.) by [The Road Vehicles and Non-Road Mobile Machinery \(Type-Approval\) \(Amendment and Transitional Provisions\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1273\)](#), regs. 1(2), **42(2)**

1. Objectives and scope
 - 1.1. This Annex establishes the procedures for the proper conduct of the vehicle type-approval in accordance with Articles 26, 27 and 28.
 - 1.2. It also includes:
 - (a) the list of international standards which are of relevance for the designation of the technical services in accordance with Articles 68 and 70;
 - (b) the description of the procedure to be followed for the assessment of the skills of technical services in accordance with Article 73;
 - (c) the general requirements for the drafting of test reports by technical services.
2. Type-approval procedure

When receiving an application for vehicle type-approval, the approval authority shall:

- (a) verify that all [F2GB] type-approval certificates issued pursuant to the regulatory acts as listed in Annex II which are applicable for vehicle type-approval cover the type of vehicle and correspond to the prescribed requirements;
- (b) make sure that the vehicle specifications and data are included in the data in the information packages and in the [F3GB] type-approval certificates issued in accordance with the relevant regulatory acts;
- (c) when an item number is not included in the information package as provided for in any of the regulatory acts, confirm that the relevant part or characteristic conforms to the particulars in the information folder;
- (d) on a selected sample of vehicles from the type to be approved carry out or arrange to be carried out inspections of vehicle parts and systems to verify that the vehicle or vehicles are built in accordance with the relevant data contained in the authenticated information package in respect of the relevant [F4GB] type-approval certificates;
- (e) carry out or arrange to be carried out relevant installation checks in respect of separate technical units, where applicable;
- (f) carry out or arrange to be carried out necessary checks in respect of the presence of the devices provided for in explanatory notes 1 and 2 of Part I of Annex II, where applicable;
- (g) carry out or arrange to be carried out necessary checks in order to ensure that the requirements set out in explanatory note 5 of Part I of Annex II are fulfilled.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2018/858 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)

Textual Amendments

- F2** Word in Annex 3 point 2(a) substituted (31.12.2022 at 11.00 p.m.) by [The Road Vehicles and Non-Road Mobile Machinery \(Type-Approval\) \(Amendment and Transitional Provisions\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1273\)](#), regs. 1(2), **42(3)**
- F3** Word in Annex 3 point 2(b) substituted (31.12.2022 at 11.00 p.m.) by [The Road Vehicles and Non-Road Mobile Machinery \(Type-Approval\) \(Amendment and Transitional Provisions\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1273\)](#), regs. 1(2), **42(3)**
- F4** Word in Annex 3 point 2(d) substituted (31.12.2022 at 11.00 p.m.) by [The Road Vehicles and Non-Road Mobile Machinery \(Type-Approval\) \(Amendment and Transitional Provisions\) \(EU Exit\) Regulations 2022 \(S.I. 2022/1273\)](#), regs. 1(2), **42(3)**

3. Combination of technical specifications

The number of vehicles to be submitted shall be sufficient to permit the proper check of the various combinations to be type-approved according to the following criteria:

Technical specifications	Vehicle category									
	M ₁	M ₂	M ₃	N ₁	N ₂	N ₃	O ₁	O ₂	O ₃	O ₄
Engine	X	X	X	X	X	X	—	—	—	—
Gear box	X	X	X	X	X	X	—	—	—	—
Number of axles	—	X	X	X	X	X	X	X	X	X
Powered axles (number, position and interconnection)	X	X	X	X	X	X	—	—	—	—
Steered axles (number and position)	X	X	X	X	X	X	X	X	X	X
Body styles	X	X	X	X	X	X	X	X	X	X
Number of doors	X	X	X	X	X	X	X	X	X	X
Hand of drive	X	X	X	X	X	X	—	—	—	—
Number of seats	X	X	X	X	X	X	—	—	—	—

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2018/858 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)

Level of equipment	X	X	X	X	X	X	—	—	—	—
--------------------	---	---	---	---	---	---	---	---	---	---

4. Specific provisions

Where no approval certificates as provided for in the relevant regulatory acts are available, the approval authority shall:

- (a) arrange for the necessary tests and checks as required by each of the relevant regulatory acts;
- (b) verify that the vehicle conforms to the particulars in the information folder and that it meets the technical requirements of each of the relevant regulatory acts;
- (c) carry out or arrange to be carried out relevant installation checks in respect of separate technical units, where applicable;
- (d) carry out or arrange to be carried out necessary checks in respect of the presence of the devices provided for in explanatory notes 1 and 2 of Part I of Annex II where applicable;
- (e) carry out or arrange to be carried out necessary checks in order to ensure that the requirements set out in explanatory note 5 of Part I of Annex II are fulfilled.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2018/858 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)

Appendix 1

Standards with which the technical services referred to in Article 68 have to comply

1. Activities related to testing for type-approval to be carried out in accordance with the regulatory acts listed in Annex II:
 - 1.1. Category A (tests performed in own facilities):

Standard EN ISO/IEC 17025:2005 on the general requirements for the competence of testing and calibration laboratories.

A technical service designated for category A activities may also carry out the tests provided for in the regulatory acts for which it has been designated, in the facilities of a manufacturer or of a third party. In either case, the personnel responsible for using professional judgement for determination of conformity with the regulatory acts for which the technical service has been designated shall comply with the Standard EN ISO/IEC 17020:2012.
 - 1.2. Category B (supervision of tests, which includes test preparation, where such tests are performed at the manufacturer's facilities or at the facilities of a third party):

Standard EN ISO/IEC 17020:2012 on the general criteria for the operation of various types of bodies performing inspection.

Before performing or supervising any test in the manufacturer's facilities or in the facilities of a third party, the technical service shall verify that the tests facilities and measurement devices comply with the appropriate requirements of Standard EN ISO/IEC 17025:2005.
2. Activities related to conformity of production
 - 2.1. Category C (procedure for the initial assessment and surveillance audits of the manufacturer's quality management system):

Standard EN ISO/IEC 17021:2011 on the requirements for bodies providing audit and certification of management systems.
 - 2.2. Category D (inspection or testing of production samples or supervision thereof):

Standard EN ISO/IEC 17020:2012 on the general criteria for the operation of various types of bodies performing inspection.

Appendix 2

Procedure for the assessment of the technical services

1. Objective and scope
 - 1.1. This Appendix establishes the conditions in accordance with which the assessment procedure of the technical services shall be conducted by the authority, competent under Article 73 ('competent authority').
 - 1.2. Those requirements shall apply to all technical services, irrespective of their legal status (independent organisation, manufacturer or approval authority acting as technical service).

2. Assessments

The carrying out of an assessment shall be governed by the following:

- (a) principle of independence, which is the basis for the impartiality and objectivity of the conclusions; and
- (b) an evidence-based approach, which guarantees reliable and reproducible conclusions.

Auditors shall show trust and integrity. They shall respect confidentiality and discretion.

They shall report truthfully and accurately about findings and conclusions.

3. Skills requirements for auditors
 - 3.1. The assessments may only be conducted by auditors having the technical and administrative knowledge necessary for such purposes.
 - 3.2. The auditors shall have been trained specifically for assessment activities. In addition, they shall have the specific knowledge of the technical area in which the technical service will exercise its activities.
 - 3.3. Without prejudice to points 3.1 and 3.2, the assessment referred to in Article 73 shall be conducted by auditors independent of the activities for which the assessment is conducted.
4. Application for designation
 - 4.1. A duly authorised representative of the applicant technical service shall submit a formal application to the competent authority that includes the following information:
 - (a) general features of the technical service, including corporate entity, name, addresses, legal status and technical resources;
 - (b) a detailed description, including curriculum vitae, of the personnel in charge of testing and of the managerial staff, setting out their educational qualifications and professional skills;
 - (c) technical services which use virtual testing methods shall provide evidence of their ability to work in a Computer-Aided-x environment;
 - (d) general information concerning the technical service, including its activities, its relationship in a larger corporate entity, if any, and addresses of all its physical location(s) to be covered by the scope of designation;

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2018/858 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)

- (e) an agreement to fulfil the requirements for designation and the other obligations of the technical service as provided for in the relevant regulatory acts for which it is designated;
- (f) a description of the conformity assessment services that the technical service undertakes in the framework of the relevant regulatory acts and a list of the regulatory acts for which the technical service applies for designation, including limits of capability, where applicable;
- (g) a copy of the quality assurance manual of the technical service.

4.2. The competent authority shall review the adequacy of the information provided by the technical service.

4.3. The technical service shall notify to the competent authority any modifications to the information provided in accordance with point 4.1.

5. Resource review

The competent authority shall review its ability to carry out the assessment of the technical service, in terms of its own policy, its competence and the availability of suitable auditors and experts.

6. Subcontracting the assessment

6.1. The competent authority may subcontract parts of the assessment to another competent authority or ask for support from technical experts provided by other competent authorities. The subcontractors and experts have to be accepted by the applicant technical service.

6.2. The competent authority shall take into account accreditation certificates with adequate scope in order to complete its global assessment of the technical service.

7. Preparation for assessment

7.1. The competent authority shall formally appoint a joint assessment team. The competent authority shall ensure that the expertise brought to each joint assessment team is appropriate. In particular, the joint assessment team as a whole shall have both:

- (a) appropriate knowledge of the specific scope for which designation is sought; and
- (b) sufficient understanding to reliably assess the competence of the technical service to operate within its scope of designation.

7.2. The competent authority shall clearly define the assignment given to the joint assessment team. The task of the joint assessment team is to review the documents collected from the applicant technical service and to conduct the on-site assessment.

7.3. The competent authority shall agree, together with the technical service and the assigned assessment team, to the date and timetable for the assessment. However, it remains the responsibility of the competent authority to pursue a date that is in accordance with the surveillance and reassessment plan.

7.4. The competent authority shall ensure that the joint assessment team is provided with the appropriate criteria documents, previous assessment records, and the relevant documents and records of the technical service.

8. On-site assessment

The joint assessment team shall conduct the assessment of the technical service at the premises of the technical service from which one or more key activities are performed and, where relevant, shall perform eyewitness assessment at other selected locations where the technical service operates.

9. Analysis of findings and assessment report
 - 9.1. The joint assessment team shall analyse all relevant information and evidence gathered during the document and record review and the on-site assessment. That analysis shall be sufficient to allow the team to determine the extent of competence and conformity of the technical service with the requirements for designation.
 - 9.2. The competent authority's reporting procedures shall ensure that the following requirements are fulfilled.
 - 9.2.1. A meeting shall take place between the joint assessment team and the technical service prior to leaving the site. At that meeting, the joint assessment team shall provide a written and/or oral report on its findings obtained from the analysis. An opportunity shall be provided for the technical service to ask questions about the findings, including non-compliance, if any, and its basis.
 - 9.2.2. A written report on the outcome of the assessment shall be promptly brought to the attention of the technical service. That assessment report shall contain comments on competence and compliance, and shall identify non-compliance, if any, to be resolved in order to conform to all of the requirements for designation.
 - 9.2.3. The technical service shall be invited to respond to the assessment report and to describe the specific actions taken or planned to be taken, within a specific period of time, to resolve any identified non-compliance.
 - 9.3. The competent authority shall ensure that the responses of the technical service are sufficient and effective to resolve non-compliance. If the technical service responses are found to be insufficient, further information shall be requested. Additionally, evidence of effective implementation of actions taken may be requested, or a follow-up assessment may be carried out, to verify effective implementation of corrective actions.
 - 9.4. The assessment report shall include at least the following:
 - (a) unique identification of the technical service;
 - (b) date(s) of the on-site assessment;
 - (c) name(s) of the auditor(s) and/or expert(s) involved in the assessment;
 - (d) unique identification of all premises assessed;
 - (e) proposed scope of designation that was assessed;
 - (f) a statement on the adequacy of the internal organisation and procedures adopted by the technical service supporting its competence, as determined through its fulfilment of the requirements for designation;
 - (g) information on resolving all non-compliance;
 - (h) a recommendation of whether the applicant should be designated or confirmed as technical service and, if so, the scope of designation.

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2018/858 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)

10. Granting, confirming or extending a designation
 - 10.1. The competent authority shall, without undue delay, make the decision on whether to grant, confirm or extend a designation on the basis of the assessment report(s) and any other relevant information.
 - 10.2. The competent authority shall provide a certificate to the technical service. That certificate shall identify the following:
 - (a) the identity and logo of the competent- authority;
 - (b) the unique identity of the designated technical service;
 - (c) the effective date of designation and the expiry date;
 - (d) a brief indication of or a reference to the scope of designation (relevant regulatory acts or part of them);
 - (e) a statement of conformity and a reference to this Regulation.

11. Reassessment and surveillance

- 11.1. Reassessment is similar to an initial assessment except that experience gained during previous assessments shall be taken into account. Surveillance on-site assessments are less comprehensive than reassessments.
- 11.2. The competent authority shall design its plan for reassessment and surveillance of each designated technical service so that representative samples of the scope of designation are assessed on a regular basis.

The interval between on-site assessments, whether reassessment or surveillance, depends on the proven stability that the technical service has reached.

- 11.3. Where, during surveillance or reassessments, non-compliance is identified, the competent authority shall define strict time limits for corrective actions to be taken.
- 11.4. Where the corrective or improvement actions have not been taken within the agreed time limit or are not deemed to be sufficient, the competent authority shall adopt appropriate measures, such as conducting a further assessment, or suspending or withdrawing the designation for one or more of the activities for which the technical service has been designated.
- 11.5. Where the competent authority decides to suspend or withdraw the designation of a technical service, it shall inform the technical service of its decision by registered mail. In any case, the competent authority shall adopt all the necessary measures to ensure the continuity of the activities already undertaken by the technical service.

12. Records on designated technical services

- 12.1. The competent authority shall maintain records on technical services to demonstrate that the requirements for designation, including competence, have been effectively fulfilled.
- 12.2. The competent authority shall keep the records on technical services secure to ensure confidentiality.
- 12.3. Records on technical services shall include at least the following:

Changes to legislation: There are currently no known outstanding effects for the Regulation (EU) 2018/858 of the European Parliament and of the Council, ANNEX III. (See end of Document for details)

- (a) relevant correspondence;
- (b) assessment records and reports;
- (c) copies of designation certificates.

Changes to legislation:

There are currently no known outstanding effects for the Regulation (EU) 2018/858 of the European Parliament and of the Council, ANNEX III.