

Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (Text with EEA relevance)

## CHAPTER XII

### DESIGNATION AND NOTIFICATION OF TECHNICAL SERVICES

#### *Article 45*

#### **Requirements relating to technical services**

1 A technical service shall be designated by an approval authority in accordance with Article 47 and shall fulfil the requirements laid down in paragraphs 2 to 9 of this Article.

2 A technical service shall be established under the national law of a Member State and have legal personality.

3 The technical service shall be a third-party body independent of the process of design, manufacture, supply or maintenance of the engines it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacture, provision, assembly, installation, use or maintenance of the engines it assesses, tests or inspects may, provided that it demonstrates its independence and the absence of any conflict of interest, be considered to fulfil the requirements of the first subparagraph.

4 The technical service, including its top-level management and the personnel responsible for carrying out the categories of activities for which the technical service is designated in accordance with Article 47(1), shall not be the designer, manufacturer, supplier, installer or maintainer of the engines which it assesses, and shall not represent parties engaged in those activities. This restriction shall not preclude the use of assessed engines referred to in paragraph 3 of this Article that are necessary for the operation of the technical service, or the use of such engines for personal purposes.

The technical service shall ensure that the activities of its subsidiaries or subcontractors do not affect its confidentiality, objectivity or impartiality in relation to the categories of activities for which it has been designated.

5 The technical service shall carry out the categories of activities for which it has been designated with the highest degree of professional integrity and the requisite technical competence in the specific field, and its personnel shall be free from any pressure or inducements, particularly financial, which might influence its judgment or the results of its assessment activities, especially such pressure or inducements emanating from persons or groups of persons with an interest in the results of those activities.

6 The technical service shall demonstrate to its designating approval authority that it is capable of carrying out all the categories of activities for which it is seeking to be designated in accordance with Article 47(1), by ensuring that it has:

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- a personnel with appropriate skills and specific technical knowledge and vocational training as well as sufficient and appropriate experience to perform the task;
- b descriptions of the procedures relevant to the categories of activities for which it is seeking to be designated, thereby ensuring the transparency and reproducibility of those procedures;
- c procedures for the performance of the categories of activities for which it is seeking to be designated, which take due account of the degree of complexity of the technology of the engine in question and of whether the engine is manufactured pursuant to a mass or serial production process; and
- d the means necessary to perform in an appropriate manner the tasks connected with the categories of activities for which it is seeking to be designated and that it has access to all the necessary equipment or facilities.

7 The technical service, including its top-level management and the assessment personnel, shall be impartial and shall not engage in any activity that could conflict with their independence of judgment or integrity in relation to the categories of activities for which the technical service is designated.

8 The technical service shall take out liability insurance covering its activities, unless liability is assumed by the Member State in accordance with national law or the Member State is itself directly responsible for the assessment.

9 The personnel of a technical service shall be bound by professional secrecy with regard to all information obtained in carrying out their tasks under this Regulation or any provision of national law giving effect to it.

The personnel of a technical service shall not be bound by the obligation referred to in the first subparagraph in respect of the sharing of information with the designating approval authority, or where such sharing is required by Union or national law.

Proprietary rights shall be protected.

#### *Article 46*

### **Subsidiaries of and subcontracting by technical services**

1 The technical service may, only with the agreement of their designating approval authority, subcontract specific tasks connected with the categories of activities for which it has been designated in accordance with Article 47(1), or have those activities carried out by a subsidiary.

In such cases, the technical service shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 45 and shall inform the designating approval authority accordingly.

2 The technical service shall take full responsibility for the tasks performed by any of its subcontractors or subsidiaries, irrespective of their place of establishment.

3 The technical service shall keep at the disposal of the designating approval authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the tasks performed by them.

## Article 47

### Designation of technical services

1 Approval authorities shall designate technical services for one or more of the following categories of activities, in accordance with their fields of competence:

- (a) category A : carrying out the tests referred to in this Regulation in the facilities belonging to the technical service in question;
- (b) category B : supervising the tests referred to in this Regulation, where such tests are performed in the facilities of a manufacturer or of a third party;
- (c) category C : assessing and monitoring on a regular basis the manufacturer's procedures for ensuring the conformity of production;
- (d) category D : supervising or performing tests or inspections for ensuring the conformity of production.

2 An approval authority may act as a technical service for one or more of the categories of activities referred to in paragraph 1.

3 Technical services of a third country, other than those designated in accordance with this Article, may be the subject of a notification pursuant to Article 50 where such a recognition of technical services is provided for by a bilateral agreement concluded between the Union and the third country concerned.

However, a technical service established in accordance with Article 45(2) may establish subsidiaries in third countries, provided that the subsidiaries are directly managed and controlled by that technical service.

## Article 48

### Procedures for performance standards and assessment of technical services

The Commission is empowered to adopt delegated acts in accordance with Article 55 supplementing this Regulation by laying down:

- (a) the standards with which the technical services have to comply; and
- (b) the procedure for the assessment of the technical services, including the corresponding report, in accordance with Article 49.

## Article 49

### Assessment of the skills of technical services

1 The designating approval authority shall draw up an assessment report demonstrating that the candidate technical service has been assessed for its compliance with this Regulation and the delegated acts adopted pursuant to it. The assessment report may include a certificate of accreditation issued by a national accreditation body attesting that the technical service fulfils the requirements of this Regulation.

The assessment on which the assessment report is based shall be conducted in accordance with the provisions laid down in a delegated act referred to in Article 48.

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2 The designating approval authority shall review the assessment report at least once every three years.

3 The designating approval authority shall communicate the assessment report to the Commission upon the latter's request. In such cases, where the assessment is not based on an accreditation certificate issued by a national accreditation body, the designating approval authority shall provide the Commission with documentary evidence which attests to the following:

- a the technical service's competence;
- b the arrangements in place to ensure that the technical service is monitored regularly by the designating approval authority; and
- c that the technical service fulfils the requirements of this Regulation and of the delegated acts adopted pursuant to it.

4 An approval authority that intends to act as a technical service in accordance with Article 47(2) shall document compliance by means of an assessment conducted by auditors independent of the activity being assessed. Such auditors may be from the same organisation, provided that they are managed separately from the personnel undertaking the assessed activity.

#### *Article 50*

### **Procedures for notification**

1 In respect of each technical service that they have designated, Member States shall notify the Commission of the following:

- a the name of the technical service;
- b the address, including electronic address;
- c the responsible persons;
- d the category of activities; and
- e any modifications relating to the designation referred to in Article 47.

2 A technical service may only conduct the activities referred to in Article 47(1) on behalf of the designating approval authority if that technical service has been notified beforehand to the Commission in accordance with paragraph 1 of this Article.

3 The same technical service may be designated by several designating approval authorities and notified by the Member States of those designating approval authorities irrespective of the category or categories of activities it is to conduct in accordance with Article 47(1).

4 Where a specific organisation or competent body carrying out an activity not included in Article 47(1) needs to be designated in application of a delegated act, the Member States concerned shall notify the Commission in accordance with this Article.

5 The Commission shall publish on its website a list and details of the technical services which have been the subject to a notification in accordance with this Article.

## Article 51

### Changes to designations

1 Where a designating approval authority has ascertained or has been informed that a technical service designated by it either no longer fulfils the requirements laid down in this Regulation or is failing to meet its obligations, it shall restrict, suspend or revoke the designation, as appropriate, depending on the seriousness of the failure to fulfil those requirements or meet those obligations.

The Member State that has provided the Commission with notification of that technical service in accordance with Article 50(1) shall immediately inform the Commission of any such restriction, suspension or revocation.

The Commission shall modify the published information referred to in Article 50(5) accordingly.

2 In the event of the restriction, suspension or revocation of the designation referred to in paragraph 1, or where the technical service has ceased its activity, the designating approval authority shall take appropriate steps to ensure that the files of that technical service are either processed by another technical service or kept available for the designating approval authority or for the market surveillance authorities at their request.

## Article 52

### Challenge to the competence of technical services

1 The Commission shall investigate all cases where it has doubts, or where doubts are brought to its attention, as to the competence of a technical service or the continued fulfilment by a technical service of the requirements and responsibilities to which it is subject.

2 The Member State of the designating approval authority shall, upon request, provide the Commission with all information relating to the basis for the designation or the maintenance of the designation of the technical service concerned.

3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 Where the Commission ascertains that a technical service does not fulfil or no longer fulfils the requirements for its designation, it shall inform the Member State of the designating approval authority accordingly with a view to establishing, in cooperation with that Member State, the corrective measures necessary and shall request that that Member State take those corrective measures, including the revocation of the designation if necessary.

## Article 53

### Operational obligations of technical services

1 Technical services shall carry out the categories of activities for which they have been designated on behalf of the designating approval authority and in accordance with the assessment and test procedures provided for in this Regulation and its delegated and implementing acts.

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Technical services shall supervise or shall themselves carry out the tests required for EU type-approval or inspections as set out in this Regulation or in one of its delegated or implementing acts, unless alternative procedures are permitted.

Technical services shall not conduct tests, assessments or inspections for which they have not been designated.

- 2 Technical services shall at all times:
  - a allow the designating approval authority to observe them conducting their assessments, if deemed appropriate by that authority; and
  - b without prejudice to Article 45(9) and Article 54, provide the designating approval authority with such information as may be requested on the categories of activities which they carry out and which fall within the scope of this Regulation.

- 3 Where a technical service finds that the requirements laid down in this Regulation have not been fulfilled by a manufacturer, it shall report that fact to the designating approval authority, which shall, in turn, require the manufacturer to take appropriate corrective measures.

The designating approval authority shall not issue an EU type-approval certificate until the manufacturer has taken the appropriate corrective measures to the satisfaction of that approval authority.

- 4 Where, in the course of monitoring conformity of production following the issue of an EU type-approval certificate, a technical service acting on behalf of the designating approval authority finds that an engine type or engine family no longer complies with this Regulation, it shall report that fact to the designating approval authority.

The approval authority shall take the appropriate measures as provided for in Article 26.

#### *Article 54*

#### **Information obligations of technical services**

- 1 Technical services shall inform their designating approval authority of any:
  - a non-conformity which might require a refusal, restriction, suspension or withdrawal of an EU type-approval;
  - b circumstances affecting the scope of, or conditions for, their designation;
  - c request for information from market surveillance authorities regarding their activities.
- 2 Upon request from their designating approval authority, technical services shall provide information on the activities within the scope of their designation and on any other activity performed, including cross-border activities and subcontracting.

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