

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 371/2010

of 16 April 2010

replacing Annexes V, X, XV and XVI to Directive 2007/46/EC of the European Parliament and of the Council establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) ⁽¹⁾, and in particular Articles 41(6), 11(5) and 39(2) thereof,

Whereas:

- (1) Directive 2007/46/EC establishes a harmonised framework containing the administrative provisions and general technical requirements for all new vehicles, systems, components and separate technical units. In particular it includes a description of the procedures to be followed with respect to type-approval including the practical measures to be taken in order to ensure that vehicles are produced in accordance with their type-approval documentation as well provisions concerning how tests must be conducted in order to be granted type-approval.
- (2) When examining the major policy areas which impact the competitiveness of the European automotive industry the CARS 21 High Level Group, set up by the Commission in 2005 to chart the way towards sustainable development of a competitive European automotive industry, agreed on a number of recommendations aiming at enhancing the industry's global competitiveness and employment while sustaining further progress in safety and environmental

performance. In the area of simplification the Group recommended the introduction of the possibility for a manufacturer to conduct himself tests required for approval, which implies his designation as technical service (hereinafter 'self-testing'). It also recommended the possibility to use computer simulations instead of conducting physical tests (hereinafter 'virtual testing').

- (3) One of the main features of the type-approval system lies in the high level of confidence which must exist between the approval authority and the technical services it has appointed. It is therefore important that the documents exchanged between technical services and approval authority ensure transparency and clarity. For this reason, the format of the test reports as well the information which needs to be included therein should be clearly specified in Annex V to Directive 2007/46/EC related to the procedures to be followed with respect to type-approval.
- (4) The verification of the conformity of the vehicles, components or separate technical units throughout the whole production process is an essential mechanism of the type-approval system. One of the ways of verifying conformity of production consists in conducting physical tests on vehicles, components or separate technical units taken from the production in order to ensure that they continue to meet the technical requirements. Even when virtual test methods have been used for the purposes of type-approval it should be clarified that only physical tests may be performed when the authority selects samples at random.
- (5) Tests required with a view to granting type-approval are conducted by technical services duly notified by the approval authorities of the Member States after their skills and competence have been assessed under relevant international standards. Those standards

⁽¹⁾ OJ L 263, 9.10.2007, p. 1.

contain the necessary requirements to allow a manufacturer or a subcontractor acting on his behalf to be designated as technical service by the approval authority in the meaning of Directive 2007/46/EC. It is however important to specify what the responsibilities of the manufacturers are in order to prevent potential conflict of interests in particular when tests are subcontracted.

- (6) A list of the regulatory acts for which a manufacturer may be designated as technical service is included in Annex XV to Directive 2007/46/EC. To conform to the recommendations of the CARS 21 High Level Group it is necessary to amend that list.
- (7) Computer-aided techniques, in particular Computer-Aided-Design, are used widely throughout the engineering process from conceptual design and layout of components and equipments, through strength and dynamic analysis of assemblies to definition of manufacturing methods. Available software makes possible the use of virtual testing methods based on those techniques, the introduction of which was identified by the CARS 21 High Level Group as a means of reducing costs for manufacturers by removing the obligation of building prototypes for the purposes of type-approval. To conform to the recommendations of the Group, it is necessary to establish a list of the regulatory acts for which virtual testing is permitted.
- (8) A virtual testing method should provide for the same level of confidence in the results as a physical test. Therefore, it is appropriate to lay down relevant conditions to ensure that proper validation of the mathematical models is conducted.
- (9) It is appropriate with a view to ensuring the proper operation of the type-approval system to update the Annexes to Directive 2007/46/EC in order to adapt them to the development of scientific and technical

knowledge. Since the provisions of those Annexes are sufficiently detailed and need not further transposition measures by Member States, it is therefore appropriate to replace them by means of a Regulation in accordance with Article 39(8) of Directive 2007/46/EC.

- (10) Annexes V, X, XV and XVI to Directive 2007/46/EC should be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Technical Committee — Motor Vehicles,

HAS ADOPTED THIS REGULATION:

Article 1

Directive 2007/46/EC shall be amended as follows:

1. Annex V is replaced by the text set out in Annex I to this Regulation.
2. Annex X is replaced by the text set out in Annex II to this Regulation.
3. Annex XV is replaced by the text set out in Annex III to this Regulation.
4. Annex XVI is replaced by the text set out in Annex IV to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 29 April 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 April 2010.

For the Commission
The President

José Manuel BARROSO

ANNEX I

ANNEX V

PROCEDURES TO BE FOLLOWED WITH RESPECT TO EC TYPE-APPROVAL**0. Objectives and scope**

0.1. This Annex establishes the procedures for the proper operation of the vehicle type-approval in accordance with the provisions of Article 9.

0.2. It also includes:

- (a) the list of international standards which are of relevance for the designation of the technical services in accordance with Article 41;
- (b) the description of the procedure to be followed for the assessment of the skills of technical services in accordance with Article 42;
- (c) the general requirements for the drafting of test reports by technical services.

1. Type-approval process

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

- (a) verify that all EC type-approval certificates issued pursuant to the regulatory acts which are applicable for vehicle type-approval cover the vehicle type and correspond to the prescribed requirements;
- (b) by reference to the documentation make sure that the vehicle specifications and data contained in Part I of the vehicle information document are included in the data in the information packages and in the EC type-approval certificates in respect of the relevant regulatory acts;
- (c) when an item number in Part I of the information document is not included in the information package of 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(s) is/are built in accordance with the relevant data contained in the authenticated information package in respect of the relevant EC 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 footnotes (1) and (2) of Part I of Annex IV where applicable;
- (g) carry out or arrange to be carried out necessary checks in order to ensure that the requirements provided for in footnote (5) of Part I of Annex IV are fulfilled.

2. 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	—	—	—	—
Level of equipment	X	X	X	X	X	X	—	—	—	—

3. Specific provisions

Where no approval certificates for any of 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 vehicle 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 footnotes (1) and (2) of Part I of Annex IV where applicable;
- (e) carry out or arrange to be carried out necessary checks in order to ensure that the requirements provided for in footnote (5) of Part I of Annex IV are fulfilled.

*Appendix 1***Standards with which the entities referred to in Article 41 have to comply**

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

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 carry out or supervise 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.
 - 1.2. Category B (supervising of tests performed in the manufacturer's facilities or in the facilities of a third party):

EN ISO/IEC 17020:2004 on the general criteria for the operation of various types of bodies performing inspection.

Before performing or supervising any test in the facilities of a manufacturer or of a third party, the technical service shall check that the tests facilities and measurement devices comply with the appropriate requirements of the standard referred to in point 1.1.
 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):

EN ISO/IEC 17021:2006 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):

EN ISO/IEC 17020:2004 on the general criteria for the operation of various types of bodies performing inspection.
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*Appendix 2***Procedure for the assessment of the technical services****1. Purpose of this Appendix**

- 1.1. This Appendix establishes the conditions according to which the assessment procedure of the technical services shall be conducted by the competent authority referred to in Article 42.
- 1.2. These requirements shall apply *mutatis mutandis* to all technical services, irrespective of their legal status (independent organisation, manufacturer or approval authority acting as technical service).

2. Principles of assessing

Assessing shall be characterised by reliance on a number of principles:

- independence which is the basis for the impartiality and objectivity of the conclusions,
- 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 findings and conclusions.

3. Skills required of the 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 of this Appendix, the assessment referred to in Article 42 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 make a formal application to the competent authority that includes the following:
 - (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 as evidenced by the skills both educational and professional;
 - (c) in addition to the above, 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 such as 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;
 - (e) an agreement to fulfil the requirements for designation and the other obligations of the technical service as applicable in the relevant Directives;
 - (f) a description of the conformity assessment services that the technical service undertakes in the framework of the applicable 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 manual of the technical service.

4.2. The competent authority shall review for adequacy the information supplied by the technical service.

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 designation 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 an assessment team. The former shall ensure that the expertise brought to each assignment is appropriate. In particular, the team as a whole:

(a) shall have appropriate knowledge of the specific scope for which designation is sought; and

(b) shall have understanding sufficient to make a reliable assessment of 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 assessment team. The task of the 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 schedule 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 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 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 witnessing at other selected locations where the technical service operates.

9. **Analysis of findings and assessment report**

9.1. The assessment team shall analyse all relevant information and evidence gathered during the document and record review and the on-site assessment. This 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 assessment team and the technical service prior to leaving the site. At this meeting, the 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-conformities, if any, and their basis.

9.2.2. A written report on the outcome of the assessment shall be promptly brought to the attention of the technical service. This assessment report shall contain comments on competence and conformity, and shall identify non-conformities, 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 defined time, to resolve any identified non-conformities.

- 9.3. The competent authority shall ensure that the responses of the technical service to resolve non-conformities are reviewed to see if the actions appear to be sufficient and effective. If the technical service responses are found not to be sufficient, 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, as a minimum the following:
- (a) unique identification of the technical service;
 - (b) date(s) of the on-site assessment;
 - (c) name(s) of the auditors(s) and/or experts 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 to give confidence in its competence, as determined through its fulfilment of the requirements for designation;
 - (g) information on the resolution of all non-conformities;
 - (h) a recommendation of whether the applicant should be designated or confirmed as technical service and, if so, the scope of designation.

10. **Granting/confirming a designation**

- 10.1. The approval authority shall, without undue delay, make the decision on whether to grant, confirm or extend designation on the basis of the report(s) and any other relevant information.
- 10.2. The approval authority shall provide a certificate to the technical service. This certificate shall identify the following:
- (a) the identity and logo of the approval authority;
 - (b) the unique identity of the designated technical service;
 - (c) the effective date of granting of designation and the expiry date;
 - (d) a brief indication of or a reference to the scope of designation (applicable directives, regulations or part of them);
 - (e) a statement of conformity and a reference to the present Directive.

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. When, during surveillance or reassessments, non-conformities are identified, the competent authority shall define strict time limits for corrective actions to be implemented.

11.4. When the corrective or improvement actions have not been taken within the agreed timeframe or are not deemed to be sufficient, the competent authority shall adopt appropriate measures, such as conducting a further assessment or suspending/withdrawing the designation for one or more of the activities for which the technical service has been designated.

11.5. When the competent authority decides to suspend or withdraw the designation of a technical service, it shall inform the latter 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 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:

- (a) relevant correspondence;
 - (b) assessment records and reports;
 - (c) copies of designation certificates.
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*Appendix 3***General requirements concerning the format of the test reports**

1. For each of the regulatory acts listed in Part I of Annex IV, the test report shall comply with the provisions of Standard EN ISO/IEC 17025:2005. In particular it shall include the information mentioned in point 5.10.2, including footnote (1) of that Standard.
2. The template of the test reports shall be laid down by the approval authority in accordance with its rules of good practice.
3. The test report shall be drafted in the official language of the Community determined by the approval authority.
4. Moreover it shall include at least the following information:
 - (a) the identification of the vehicle, component or separate technical unit tested;
 - (b) a detailed description of the vehicle, component or separate technical unit characteristics in connection with the regulatory act;
 - (c) the results of the measurements specified in the relevant regulatory acts and, when required, the limits or thresholds which are to be met;
 - (d) in regard to each measurement mentioned in point 4(c) the relevant decision: passed or failed;
 - (e) a detailed statement of compliance with the various provisions which are to be met, i.e. such provisions for which it is not required to make measurements.

Example from Section 3.2.2 of Annex I to Council Directive 76/114/EEC (1):

“Check that the vehicle identification number is placed in such a way that it cannot be obliterated or deteriorate”;

the report shall include a statement such as: “the place of stamping the vehicle identification number fulfils the requirements of Section 3.2.2 of Annex I”;

- (f) when test methods other than those prescribed in the regulatory acts are permitted the report shall include a description of the test method used for performing the test.

The same applies when alternative provisions in the regulatory acts may be used;

- (g) pictures taken during testing, the number of which shall be decided by the approval authority.

In the case of virtual testing, screen prints or other suitable evidence may replace pictures;

- (h) conclusions drawn up;
 - (i) when opinions and interpretations have been made, they shall be documented properly and marked as such in the test report.
5. When the tests are conducted on a vehicle, component or technical unit that combines a number of most unfavourable features with regard to the required level of performance to be achieved (i.e. the worst-case), the test report shall include a reference stating how the selection has been made by the manufacturer in agreement with the approval authority.

(1) OJ L 24, 30.1.1976, p. 1.

ANNEX II

‘ANNEX X

CONFORMITY OF PRODUCTION PROCEDURES**0. Objectives**

- 0.1. The conformity of production procedure aims to ensure that each produced vehicle, system, component and technical separate unit is in conformity with the approved type.
- 0.2. Procedures include inseparably the assessment of quality management systems, referred to below as “initial assessment” and verification of the approval subject and product-related controls, referred to as “product conformity arrangements”.

1. Initial assessment

- 1.1. The approval authority of a Member State shall verify the existence of satisfactory arrangements and procedures for ensuring effective control so that components, systems, separate technical units or vehicles when in production conform to the approved type.
- 1.2. Guidance for conducting assessments may be found in Standard EN ISO 19011:2002 — Guidelines for quality and/or environmental management systems auditing.
- 1.3. The requirements referred to in point 1.1 shall be verified to the satisfaction of the authority granting type-approval.

That authority shall be satisfied with the initial assessment and the product conformity arrangements at section 2 below, taking account as necessary of one of the arrangements described in points 1.3.1 to 1.3.3, or a combination of those arrangements in full or in part as appropriate.

- 1.3.1. The actual initial assessment and/or verification of product conformity arrangements shall be carried out by the approval authority granting the approval or an appointed body acting on behalf of the approval authority.
 - 1.3.1.1. When considering the extent of the initial assessment to be carried out, the approval authority may take account of available information relating to:
 - (a) the manufacturer's certification described in point 1.3.3 below, which has not been qualified or recognised under that point;
 - (b) in the case of component or separate technical unit type-approval, quality system assessments performed in the component or separate technical unit manufacturer's premises by vehicle manufacturer(s), according to one or more of the industry sector specifications satisfying the requirements in harmonised standard EN ISO 9001:2008.
 - 1.3.2. The actual initial assessment and/or verification of product conformity arrangements may also be carried out by the approval authority of another Member State or the appointed body designated for this purpose by the approval authority.
 - 1.3.2.1. In such a case, the approval authority of the other Member State shall prepare a statement of compliance outlining the areas and production facilities it has covered as relevant to the product(s) to be type-approved and to the regulatory acts according to which these products are to be type-approved.
 - 1.3.2.2. On receiving an application for a compliance statement from the approval authority of a Member State granting type-approval, the approval authority of another Member State shall send forthwith the statement of compliance or advise that it is not in a position to provide such a statement.

1.3.2.3. The statement of compliance shall include at least the following:

- (a) Group or company (e.g. XYZ Automotive)
- (b) Particular organisation (e.g. European Division)
- (c) Plants/Sites (e.g. Engine Plant 1 (United Kingdom) — Vehicle Plant 2 (Germany))
- (d) Vehicle/Component range (e.g. All Category M₁ models)
- (e) Areas assessed (e.g. Engine assembly, body pressing and assembly, vehicle assembly)
- (f) Documents examined (e.g. Company and site quality manual and procedures)
- (g) Date of the assessment (e.g. Audit conducted from 18 to 30.5.2009)
- (h) Planned monitoring visit (e.g. October 2010)

1.3.3. The approval authority shall also accept the manufacturer's suitable certification to harmonised standard EN ISO 9001:2008 or an equivalent harmonised standard as satisfying the initial assessment requirements of point 1.3. The manufacturer shall provide details of the certification and undertake to inform the approval authority of any revisions to its validity or scope.

1.4. For the purpose of vehicle type-approval, the initial assessments carried out for granting approvals for systems, components and technical units of the vehicle need not be repeated but shall be completed by an assessment covering the locations and activities relating to the assembly of the whole vehicle not covered by the former assessments.

2. **Product conformity arrangements**

2.1. Every vehicle, system, component or separate technical unit approved pursuant to this Directive or a separate Directive or Regulation shall be so manufactured as to conform to the type approved by meeting the requirements of this Directive or the applicable regulatory acts listed in Annex IV.

2.2. The approval authority of a Member State shall verify the existence of adequate arrangements and documented control plans, to be agreed with the manufacturer for each approval, to carry out at specified intervals those tests or associated checks necessary to verify continued conformity with the approved type including specifically physical tests specified in the regulatory acts.

2.3. The holder of the type-approval shall, in particular:

2.3.1. ensure the existence and application of procedures for effective control of the conformity of products (vehicles, systems, components or separate technical units) to the approved type;

2.3.2. have access to the testing or other appropriate equipment necessary for checking the conformity to each approved type;

2.3.3. ensure that test or check results data are recorded and that annexed documents remain available for a period to be determined in agreement with the approval authority. This period shall not exceed 10 years;

2.3.4. analyse the results of each type of test or check, in order to verify and ensure the stability of the product characteristics, making allowance for variation of an industrial production;

2.3.5. ensure that for each type of product, at least the checks prescribed in this Directive and the tests prescribed in the applicable regulatory acts listed in Annex IV are carried out;

2.3.6. ensure that any set of samples or test pieces, giving evidence of non-conformity in the type of test or check in question gives rise to a further sampling and test or check. All the necessary steps shall be taken to restore conformity of the corresponding production;

2.3.7. in the case of vehicle type-approval, the checks referred to in point 2.3.5 shall at least consist in verifying the correct built specifications in relation to the approval and the information required for certificates of conformity given in Annex IX.

3. Continued verification arrangements

- 3.1. The authority which has granted type-approval may at any time verify the conformity control methods applied in each production facility.
 - 3.1.1. The normal arrangements shall be to monitor the continued effectiveness of the procedures laid down in Sections 1 and 2 (initial assessment and product conformity arrangements) of this Annex.
 - 3.1.1.1. Surveillance activities carried out by the technical services (qualified or recognised as required in point 1.3.3) shall be accepted as satisfying the requirements of point 3.1.1 with regard to the procedures established at initial assessment.
 - 3.1.1.2. The normal frequency of verifications by the approval authority (other than those referred to in point 3.1.1.1) shall be such as to ensure that the relevant controls applied in accordance with Sections 1 and 2 are reviewed over a period consistent with the climate of trust established by the approval authority.
 - 3.2. At every review, records of tests or checks and records of production shall be made available to the inspector; in particular, records of those tests or checks documented as required in point 2.2.
 - 3.3. The inspector may select samples at random to be tested in the manufacturer's laboratory or in the facilities of the technical service. In such a case only physical test shall be carried out. The minimum number of samples may be determined according to the results of the manufacturer's own verification.
 - 3.4. Where the level of control appears unsatisfactory, or when it seems necessary to verify the validity of the tests carried out in accordance with point 3.2, the inspector shall select samples to be sent to a technical service to perform physical tests.
 - 3.5. Where unsatisfactory results are found during an inspection or a monitoring review, the approval authority shall ensure that all necessary steps are taken to restore conformity of production as rapidly as possible.
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ANNEX III

ANNEX XV

REGULATORY ACTS FOR WHICH A MANUFACTURER MAY BE DESIGNATED AS TECHNICAL SERVICE**0. Objectives and scope**

- 0.1. This Annex lays down the list of the regulatory acts for which a manufacturer may be designated as technical service in accordance with Article 41(6).
- 0.2. It also includes appropriate provisions concerning the designation of a manufacturer as technical service, to be applied in the framework of the type-approval of vehicles, components and separate technical units concerned by Part I of Annex IV.
- 0.3. However it does not apply to manufacturers which apply for small series approval in accordance with Article 22.

1. Appointment of a manufacturer as technical service

- 1.1. A manufacturer appointed as technical service is a manufacturer who has been designated by the approval authority as a testing laboratory to carry out approval tests on its behalf in the meaning of point 31 of Article 3.

In accordance with Article 41(6), a manufacturer may only be designated as technical service for category A activities.

- 1.2. The expression "to carry out test" is not restricted to the measurement of performances but covers also the registration of test results and the submission of a report to the approval authority including the relevant conclusions.

It covers the checking of compliance with those provisions which do not necessarily require measurement. This is the case for the assessment of the design against legislative requirements.

For example, "check compliance of the location of the fuel tank in a vehicle with the provisions of point 5.10 of Annex I to Directive 70/221/EEC" has to be understood as part of "to carry out test".

2. List of regulatory acts and restrictions

	Regulatory act reference	Subject
4.	Directive 70/222/EEC	Rear registration plate space
7.	Directive 70/388/EEC	Audible warning
18.	Directive 76/114/EEC	Plates (statutory)
20.	Directive 76/756/EEC	Installation of lighting and light signalling devices
27.	Directive 77/389/EEC	Towing hooks
33.	Directive 78/316/EEC	Identification of controls, tell-tales and indicators
34.	Directive 78/317/EEC	Defrost/demist
35.	Directive 78/318/EEC	Wash/wipe
36.	Directive 2001/56/EC	Heating systems Except the provisions in Annex VIII relating to installation requirements of LPG heating systems in vehicle.
37.	Directive 78/549/EEC	Wheel guards
44.	Directive 92/21/EEC	Masses and dimensions (cars)

	Regulatory act reference	Subject
45.	Directive 92/22/EEC	Safety glazing Restricted to the provisions included in Annex 21 to UNECE Regulation 43.
46.	Directive 92/23/EEC	Tyres
48.	Directive 97/27/EC	Masses and dimensions (other than vehicles referred to in item 44)
49.	Directive 92/114/EEC	External projections of cabs
50.	Directive 94/20/EC	Couplings Restricted to the provisions included in Annexes V (up to and including Section 8) and VII.
61.	Directive 2006/40/EC	Air-conditioning system

*Appendix***Designation of a manufacturer as technical service****1. General**

- 1.1. The designation and notification of a manufacturer as technical service shall be made in accordance with the provisions of Articles 41, 42 and 43 as well with the practical measures included in this Appendix.
- 1.2. The manufacturer shall be accredited under Standard EN ISO/IEC 17025:2005 — General requirements for the competence of testing and calibration laboratories.

2. Subcontracting

- 2.1. In accordance with the provisions of Article 41(6) first subparagraph, a manufacturer may nominate a subcontractor for performing tests on his behalf.

By subcontractor it shall be understood:

- a) either a subsidiary which is entrusted with testing activities by the manufacturer inside its own organisation; or
- b) a third party under contract with the manufacturer to perform test activities.

- 2.2. Turning to the services of a subcontractor does not remove the obligation for the manufacturer to comply with the provisions of Article 41 in particular those concerning the skills of the technical services and compliance with Standard EN ISO/IEC 17025:2005.

- 2.3. Section 1 of Annex XV shall apply to the subcontractor.

3. Test report

Test reports shall be drafted in accordance with the general requirements set out in Appendix 3 of Annex V to Directive 2007/46/EC.

ANNEX IV

ANNEX XVI

SPECIFIC CONDITIONS REQUIRED FROM VIRTUAL TESTING METHODS AND REGULATORY ACTS FOR WHICH VIRTUAL TESTING METHODS MAY BE USED BY A MANUFACTURER OR A TECHNICAL SERVICE**0. Objectives and scope**

This Annex lays down appropriate provisions concerning virtual testing in accordance with Article 11(3).

It shall not apply to the second subparagraph of Article 11(2).

1. List of regulatory acts

No	Regulatory act reference	Subject
3.	Directive 70/221/EEC	Fuel tanks/rear protective devices
6.	Directive 70/387/EEC	Door latches and hinges
8.	Directive 2003/97/EC	Indirect vision devices
12.	Directive 74/60/EEC	Interior fittings
16.	Directive 74/483/EEC	Exterior projections
20.	Directive 76/756/EEC	Installation of lighting and light signalling devices
27.	Directive 77/389/EEC	Towing hooks
32.	Directive 77/649/EEC	Forward vision
35.	Directive 78/318/EEC	Wash/wipe
37.	Directive 78/549/EEC	Wheel guards
42.	Directive 89/297/EEC	Lateral protection
49.	Directive 92/114/EEC	External projections of cabs
50.	Directive 94/20/EC	Couplings
52.	Directive 2001/85/EC	Buses and coaches
57.	Directive 2000/40/EC	Front underrun protection

*Appendix 1***General conditions required from virtual testing methods****1. Virtual test pattern**

The following scheme shall be used as basis structure for describing and conducting virtual testing:

- (a) purpose;
- (b) structure model;
- (c) boundary conditions;
- (d) load assumptions;
- (e) calculation;
- (f) assessment;
- (g) documentation.

2. Fundamentals of computer simulation and calculation**2.1. Mathematical model**

The mathematical model shall be supplied by the manufacturer. It shall reflect the complexity of the structure of the vehicle, system and components to be tested in relation to the requirements of the regulatory act and its boundary conditions.

The same provisions shall apply *mutatis mutandis* for testing components or technical units independently from the vehicle.

2.2. Validation process of the mathematical model

The mathematical model shall be validated in comparison with the actual test conditions.

To that effect a physical test shall be conducted for the purposes of comparing the results obtained when using the mathematical model with the results of a physical test. Comparability of the test results shall be proven. A validation report shall be drafted by the manufacturer or by the technical service and submitted to the approval authority.

Any change made to the mathematical model or to the software likely to invalidate the validation report shall be brought to the attention of the approval authority which may require that a new validation process is conducted.

The flow chart of the validation process is shown in Appendix 3.

2.3. Documentation

The data and auxiliary tools used for the simulation and calculation shall be made available by the manufacturer and be documented in a suitable way.

3. Tools and support

At the request of the technical service, the manufacturer shall supply or provide access to the necessary tools including appropriate software.

In addition he shall provide appropriate support to the technical service.

Providing access and support to a technical service does not remove any obligation of the technical service regarding the skills of its personnel, the payment of licence rights and respect of confidentiality.

Appendix 2

Specific conditions concerning virtual testing methods

1. List of regulatory acts

	Regulatory act reference	Annex and paragraph	Specific conditions
3.	Directive 70/221/EEC	Annex II (Rear underrun protection) Point 5.4.5.	
6.	Directive 70/387/EEC	Annex II Point 4.3.	
8.	Directive 2003/97/EC	Annex III All provisions in Sections 3, 4 and 5.	Prescribed fields of vision of rear-view mirrors.
12.	Directive 74/60/EEC	Annex I All provisions in Section 5 (Specifications).	Measurement of all radii of curvature and of all projections except for those requirements where a force has to be applied in order to check compliance with the provisions.
		Annex II	Determination of the head-impact zone.
16.	Directive 74/483/EEC	Annex I All provisions in Section 5 (General specifications) and Section 6 (Particular specifications).	Measurement of all radii of curvature and of all projections except for those requirements where a force has to be applied in order to check compliance with the provisions.
20.	Directive 76/756/EEC	Section 6 (Individual specifications) of UNECE Regulation No 48.	The test drive provided for in Point 6.2.2.9.2.2 shall be performed on a real vehicle.
		Provisions of Annexes 4, 5 and 6 to UNECE Regulation No 48.	
27.	Directive 77/389/EEC	Annex II, Section 2	
32.	Directive 77/649/EEC	Section 5 (Specifications) of Annex I.	
35.	Directive 78/318/EEC	Annex I	Point 5.1.2. Measurement of the swept area only.
37.	Directive 78/549/EEC	Section 2 (Special requirements) of Annex I	
42.	Directive 89/297/EEC	Annex I Point 2.8.	Resistance under a horizontal force and deflection measurement.
49.	Directive 92/114/EEC	Annex I All provisions in Section 4 (Specific requirements). Regarding N_1 vehicles, the provisions referred to in item 16 of this Appendix shall apply.	Measurement of all radii of curvature and of all projections except for those requirements where a force has to be applied in order to check compliance with the provisions.

	Regulatory act reference	Annex and paragraph	Specific conditions
50.	Directive 94/20/EC	Annex V "Requirements for mechanical coupling Devices"	All provisions of Sections 1 to 8 included.
		Annex VI Point 1.1.	Strength tests on mechanicals couplings of simple design may be replaced by virtual tests.
		Section 4 of Annex VI "Testing of mechanical coupling devices"	Points 4.5.1. (Strength test), 4.5.2. (Resistance to buckling) and 4.5.3. (Resistance to bending moment) only.
52.	Directive 2001/85/EC	Annex I	Point 7.4.5. Stability test under the conditions specified in the Appendix to Annex I.
		Annex IV Strength of superstructure	Appendix 4 — Verification of strength of the superstructure by calculation.
57.	Directive 2000/40/EC	Section 3 of Annex 5 to UNECE Regulation 93.	Resistance under a horizontal force and deflection measurement.

Appendix 3

Validation process

