Kraftfahrt-
Bundesamt

Rules for designation/recognition of technical services

(Categories A, B, D)

18 January 2017

Type-approval

Contents

Annexes: [1]

[1] Binding

1 General

The Kraftfahrt-Bundesamt (KBA) evaluates the competence of organisations for tests or supervision of tests of vehicles and vehicle parts within the approval procedure according to the Decree on re-organisation of legislation for EC approval procedures (EG-FGV). As a result, these organisations are designated as technical services (TS) in the sense of the framework directive 2007/46/EC, the framework regulations (EU) 167/2013 and 168/2013[2, 3] and/or the UNECE agreement of 1958. The scope of possible designation is described by the Classification directory for designation[4].

The designation will be performed according to a procedure developed by the KBA on the basis of ISO/IEC 17011, ISO/IEC 17020, ISO/IEC 17025[5], and approval relevant regulations. The Federal Act on Fees (Bundesgebührengesetz–BGebG) and the Administrative Proceedings Act (Verwaltungsverfahrensgesetz-VwVfG) are valid.

Designation/recognition[6] of technical services[7] is aimed at documenting the competence of these bodies for tests according to German and international regulatory acts, and at promoting confidence in the equivalence of test results of these bodies. It is precondition for activities within the KBA type approval procedure (TAP).

All prospective customers have equal access to the procedures leading to the designation.

Preconditions for designation are[8]:

- Meeting of general criteria for the operation of testing laboratories according to ISO/IEC 17020[9] and/or ISO/IEC 17025[10]
- Fulfilment of approval relevant requirements
- Acceptance of these Rules for designation/recognition of TS[11] and the Sanctioned interpretations for test laboratories/inspection bodies published on the Internet.

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2 Or relevant replacing regulatory acts respectively

3 If relevant and as long as it is not expressly differently represented, in the following references to 2007/46/EC refer also to Regulations (EU) 167/2013 and 168/2013 as well as to the UNECE agreement of 1958

4 Download from the Internet is available

5 As long as it is not expressly differently represented, standards and regulatory acts are to be applied in their latest version.

6 For better legibility in the following, as long as it is not expressly differently represented, under the term „designation“ and its derivatives apart from the actual designation, also the consequential notification and the recognition according to EG-FGV (also applied to replacing EU regulatory acts) are understood.

7 Here and in the following, the term “technical service” refers also to applicants for designation.

8 Here and in all other listings, items are linked by AND relation, as long as it is not expressly differently represented.

9 ISO/IEC 17020 is used here in the sense of the framework directive 2007/46/EC for testing laboratories. Tests must be carried out as given in corresponding requirements of ISO/IEC 17025.

10 Here and in the following, the standard refers to the procedure applied for.

11 In the following, the term “designation rules” will be used.

A testing laboratory can only be designated as TS if it is located in the European Union or in a third country according to the framework directive 2007/46/EC article 41 paragraph 8.

Provided these conditions are fulfilled, a manufacturer's laboratory can only be designated

- For test procedures according to EU regulatory acts, if and as far this is stated in EU regulatory acts
- For test procedures according to an UN regulation, if and as far as this is stated in the UN regulation.

2 Scope of the designation

The designation comprises the scope indicated in the designation certificate. It is valid within the KBA TAP.

3 Responsibilities

The KBA is responsible for the execution of the procedure which leads to the designation, the designation as TS itself and the notification.

Decisions about initial designation in the Main scope (Prüfgebiet), suspension, withdrawal etc. are taken by the KBA Designation Council. The Designation Council acts also as Appeal Committee.

The TS is responsible for the fulfilment of requirements specified in these designation rules, in particular of the obligations specified in section 11.2.

Details are described in the following sections.

4 Designation procedure

The process of the designation procedure is represented in Annex 2

Further information and forms are available on the Internet.

5 Designation, notification, recognition, acceptance in the TAP of the KBA

In accordance with EU and UNECE regulatory acts, the positively evaluated organisation will be designated as TS category A, B and/or D[12] for test procedures listed in the Classification directory for designation[13] and recognized according to EG-FGV. In general, only complete regulatory acts or such parts of them can be designated which lead to separate approvals.[14, 15] Above the revision of the regulatory act as given in the certificate, the designation covers all following revisions as long as the designation body did not publish a new designation relevant status.[16]

Precondition for the designation of a Subscope (Prüfumfang) from Main scope (Prüfgebiet) 01 "Whole vehicle"[17] is, as far as this is relevant for the respective Subscope (Prüfumfang), the designation of

- At least one test procedure out of Engine/toxic emission (Subscopes (Prüfumfänge) 02-01 to 02-04)
- At least one test procedure out of Subscopes (Prüfumfänge) 03, 07, 08, 10 to 12 respectively
- At least one test procedure out of Subscope (Prüfumfang) 04-01
- At least one test procedure out of Braking systems (Subscopes (Prüfumfänge) 04-02 to 04-09)
- At least one test procedure out of Subscope (Prüfumfang) 05-03
- At least one test procedure out of Subscopes (Prüfumfang) 09-03, 09-05, 09-10 respectively

The designation for the Scope Whole vehicle (01) can be granted only in category A[18].

The TS will be designated for virtual testing[19] for specified test procedures if

- This is explicitly permitted by relevant regulatory acts
- The process of validation of the virtual test is determined by the quality system
- The TS is designated for practical (physical) testing in the relevant scope
- Persons authorized to sign test reports and other persons included in the procedure have proven that they are able to properly evaluate functioning of the procedure and data resulting from virtual testing.

12 For requirements see Annex 4. The TS can be designated in several categories at the same time.
13 Only test procedures listed in the Classification directory can be designated. If documents listed in the Classification directory refer to other regulatory acts, standards etc, those referred documents cannot be designated.
14 The KBA decides about exceptions.
15 If such part of a regulatory act is represented by several scope numbers, all relevant Subscopes (Prüfumfänge) can only be designated for the identical revision. These Subscopes (Prüfumfänge) must be designated as complete combination.
16 For explanation to "designation relevant status" see Annex 1.
17 See Classification directory; to be downloaded from the Internet.
18 Based on designation in category A, for Scope 01 the TS can also be designated in category D.
19 Regarding "calculation methods for testing" see Annex 1.

As a result, the designated TS will be notified to the European commission for test procedures according to EU regulatory acts. For test procedures according to UN regulations, it will be notified to the Secretariat of the UNECE. The designation and notification take place for the status of the respective regulatory acts indicated in the certificate. In addition, the designation will be published on the Internet.

The designation is bound to positive surveillance results.

Test reports[20] of designated TS will be accepted in the TAP of the KBA if

- The TS is designated for the relevant scope with consideration of the designation relevant status[21]
- They reflect the approval relevant status
- They are signed by this one authorized signatory who
  - Is authorized for the relevant scope
  - Bears the responsibility for the respective test as given in section 11.2
- They correspond to the requirements specified in the TAP
- They do not show deficiencies and tests were carried out in accordance with relevant regulatory acts and the state of the art.

The KBA can specify further criteria.

6 Extensions to the designation

TS can apply for an amendment to the existing designation. The reason for the amendment shall precisely be described. Necessary documents, e. g. evidence of competence, certified copies of extracts from the trade register, test instructions, lists of test equipment etc., are to be attached.

The procedure of supplements is analogue to that of the designation. The KBA decides about possible deviations or simplifications.

7 Combined procedure according to ISO/IEC 17020 and ISO/IEC 17025 (Combi-Procedure)

On application, a combined procedure for designation as TS category A, B and/or D can be carried out.

The QM system is evaluated in general according to ISO/IEC 17025. The evaluation includes specifics of the ISO/IEC 17020.

[20] (This footnote exists only in the German version, referring to different meanings of this term in German language.)

[21] Regulatory acts formally replaced by other regulatory acts will not be designated. If a regulatory act was replaced and the new regulatory act covers the previous requirements to competence of the TS, the old one is seen as designated as well.

The test procedures which are to be witnessed are selected under the following criteria:

- In general such test procedures will be witnessed where testing is carried out on own equipment
- If also a designation as TS supervising tests is requested, the supervising of at least 1 representative test procedure under ISO/IEC 17020 will be witnessed.

The extension of an existing designation to category A is generally connected with an on-site assessment.

8 Designation on basis of a certificate of accreditation

Basis for the designation on basis of a certificate of accreditation is that the existing certificate of accreditation

- Is granted on the basis of Regulation (EC) 765/2008
- Covers at least the required standard
- The accreditation body is officially registered in the European Economic Area
- Is valid.

In this case, the evaluation generally covers only the

- Consideration of the following aspects in the QM system
  - Designation rules
  - Other specific KBA requirements as for example
    - Knowledge about TAP, including relevant regulatory acts
    - Knowledge and application of KBA Information Sheets and Guidances as well as of the “Type-approval procedure information collection (IST)”
    - Knowledge and application of KBA requirements to usage of external data
    - Implementation of special requirements to virtual testing (if applied for)
    - Obligations regarding information policy
    - Analysis of quality of test reports (ISGQ)
    - Designation specific requirements to personnel
  - Fulfillment of requirements concerning classification of TS[22] regarding categories etc.
- Witnessing of test procedures if not all designated Subscopes (Prüfumfänge) are covered by the accreditation.[23, 24]

In all other respects the procedure is carried out as described in Annex 2.

A combination of accreditation of the QM system and of individual test procedures[25] on the one side and of designation of other test procedures (without accreditation) on the other side is possible.

[22] See Annex 4.
[23] If applicable, additional test procedures with special requirements.
[24] The Scope „Whole vehicle“ will always be evaluated by the KBA.
[25] 0 - 100 per cent of test procedures.

The KBA is authorized to give on request information concerning the designation to the accreditation body and to apply at the accreditation body for information possibly relevant for the designation.

The designation is bound to the validity of the laid down accreditation. In case of restriction or suspension of the accreditation, the KBA evaluates to which extent the designation is concerned.

9 Restriction, suspension or cancellation of the designation

In general, restriction or suspension will be carried out in 2 stages. After initiation of the procedure, the TS is requested to implement corrective actions. If evidence submitted in result is not sufficient, the designation will formally be restricted or suspended. During restriction or suspension, the designated body can reestablish the required for designation preconditions. If necessary by good reason, designation can be restricted or suspended without passing stage 1.

In particular, a procedure for restriction or suspension of the designation may take place

- Upon request of the designated body
- At the instigation of the KBA if
  - Preconditions of designation as described in the application documents and/or seen during the assessments are no longer given fully or partially
  - The designation rules (in particular the obligations in accordance with section 11.2) are breached
  - Major non-conformities were identified during surveillance, if minor-non-conformities were not closed in due time, or if the number of minor non-conformities indicates that the QM system has been collapsed
  - Found deficiencies were not verifiably eliminated within the agreed period
  - Surveillance measures could not be realized within the required time limit and the designated body is responsible for this
  - The designated body's operations cause qualified doubts in expertise, impartiality or trustworthiness
  - In case of designation on basis of a certificate of accreditation, evidence of continuing accreditation was not submitted in due time before the expiration of accreditation.

The designation can be totally or partly suspended. Suspension is limited to a maximum of one year. In general, the restriction or suspension will only be repealed if efficiency of the management system is demonstrated in an on-site assessment and, if relevant, the affected test procedures are released. Further on-site assessments or other measures can become necessary for verification of sustainability of initiated corrective actions.

Among others, the designation will be terminated totally or partly

- Upon request of the designated body
- After expiration of the restriction or suspension of the designation
- As soon as the TS or the organisation to which the TS belongs become manufacturer[26] and the designation of manufacturers is not expressly allowed by the relevant regulatory acts
- With revocation or abandonment by the KBA
- If the TS ceases its business in the designated scope
- On change of these rules, if the designated body disagrees with the change within 1 month after the change and the disagreement is not redressed
- If the change of legal requirements orders this.

Among others, the KBA can revoke a granted designation totally or partly if

- Preconditions of designation as described in the application documents are no longer given fully or partially and are not renewed within the given period
- The designated body continuously contravenes the requirements of the designation (breach of designation rules, of ISO/IEC 17025 and/or ISO/IEC 17020 or of other approval related requirements)
- Despite repeated deadlines, observed deficiencies have not been settled or sufficient evidence for settlement has not been submitted.

The KBA can abandon the designation totally or partly if it is detected that the designation took place on the basis of incorrect data.

The KBA can impose conditions in connection with the restriction, suspension or termination and supervise their fulfilment.

During restriction and suspension as well as after termination, the designation may not be referred to within the area concerned. Respective documents may not be used and must be withdrawn if applicable.

Restriction, suspension, revocation or abandonment are given via a notification. The bodies specified under section 5 are correspondingly informed[27].

In case of offences against these designation rules, the KBA can require that authorisation for signing test reports is withdrawn from individual persons.

[26] The term “manufacturer” is used as synonym for “approval holder” (see 2007/46/EC Article 3 No. 27 and similar regulatory acts).

[27] With restrictions and suspensions only in exceptional cases after discretion of the KBA.

10 Appeal

Appeal against the decision of the KBA is permitted. It must be submitted in writing or for record within 1 month after announcement of the decision to:

Kraftfahrt-Bundesamt
Dienstsitz Dresden
Postfach 12 01 53
01002 Dresden
Germany

The Appeal Committee decides if no agreement can be reached. The decision about the appeal will be communicated in writing as official notification and is accompanied by peremptory legal remedy instructions. In general, appeal has suspensory effect.

11 Rights and obligations of the technical service

11.1 Rights

The TS has the right to

- Access to all services of the KBA in connection with designation and TAP
- Get impartial, objective and competent information about the procedure
- Equal treatment with other applicants
- Well trained proficient assessors and contact persons
- Reject assessors designated by the KBA
- Confidentiality concerning internal documents and data, which the assessor received during the procedure
- Designation and notification to the competent bodies (see section 5)
- Publication of the designation by the KBA
- Use the certificate and logo for designation in documents and promotional material for the declared scope[28]
- Appeal against decisions of the KBA.

[28] The following text can be used in an adequate form: "Technical service category A (B, D), designated by the Kraftfahrt-Bundesamt, Federal Republic of Germany, Registration-number: KBA-P XXXXX-XX".

11.2 Obligations

The TS is obligated to

- Fulfil the requirements of ISO/IEC 17025 and/or ISO/IEC 17020[29] and approval relevant requirements
- Accept and fulfil these designation rules[30]
- Fulfil the standards of the KBA concerning the type approval procedure[31]
- Unsolicited update internal procedures so that they permanently reflect applicable automotive legislation, designation rules and other published KBA requirements
- Use competent personnel (see Annex 3)
- Employ or have bound by contract at least one authorized signatory for each regulatory act covered by the designation
- Make sure that persons signing test reports
  - Are authorized to sign for the scope, which is relevant for the test report
  - Perform the test themselves or supervise the test in an appropriate way and ensure that tests are properly carried out.[32]
- Based on internal evaluation and risk analysis to carry out regular measures to assure the quality of test results; all Main scopes (Prüfgebiete) must be covered within an appropriate period[33]; where applicable, the TS must enable and participate in interlaboratory tests
- Take part actively in any form of exchange of experience, training and workshops
- Identify together with the KBA causes of deficiencies and to eliminate them
- Test only in testing laboratories/at test areas, which conform to the relevant requirements of ISO/IEC 17025 and the applicable technical/approval-relevant regulatory acts (this is analogously valid also for subcontracting)
- Only in exceptional cases use subcontracting as described in ISO/IEC 17025[34] and external data in accordance with Annex 5
- Use “virtual testing methods” only if the TS is explicitly designated for virtual testing in the relevant scope; use “calculation methods for testing” only if this was notified to the designation body before the first application
- Offer all necessary co-operation to the KBA, in particular to give assessors access to all business facilities and information as far as this is relevant to the designation (including documents and records giving information about the level of independence from related bodies, the impartiality and performance of the TS)

29 See also footnote 9.

30 This includes the obligation to fulfil all relevant requirements of the KBA. The TS will be informed according to section 12. Further information will be published on the Internet.

31 Information by the KBA’s technical departments on the Internet or through other channels.

32 Sufficiently competent personnel can assist the test if the person signing the test report can at any time be included on-site in the test process and can intervene.

33 Max. within 3 years.

34 Prior acceptance on case-by-case basis by the KBA required.

- Enable the execution of witness assessments at all test locations; this includes that “external test sites” will be obligated to enable the attendance of a witness-assessor
- Communicate immediately and without being asked to the KBA planned changes in relation to the documents relevant for the designation e. g.
  - Legal, financial, organisational and ownership status
  - Contact details
  - Organisation, top and key management
  - Basic regulations
  - Resources and autonomous branches[35]
  - Designated scope (e. g. actualisation, extension, restriction, cancellation)
  - Other affairs, which are related to the designation
- Inform the KBA promptly, and wherever possible before the occurrence of an event, if conditions for the designation become void or restricted
- In case of a designation on basis of a certificate of accreditation
  - To inform the KBA about changes and other important aspects in connection with the basis accreditation (e.g. change of scope, validity)
  - To provide assessment results of the accreditation body on request
  - Not to give the impression that the accreditation relates to specifics of TAP in the content of the designation
- Avoid any statements concerning their designation that can be understood as mistakable or unjustified
- Use the designation only in the scope for which it has been granted [36]
- Avoid the impression that non-designated areas (e. g. scope, test through personnel who were active in a function outside of the designation) are enclosed into the designation
- Fulfil any requirements of the KBA when making reference to its designation in communication media such as the Internet, documents, brochures, advertising
- Use the assigned logo according to the Rules for its usage[37] and only in connection with tests, which are expressly enclosed in the designation
- Avoid using the designation in a way harming to the reputation of the KBA
- Pay fees in accordance with section 15.

Fulfillment of these obligations as well as quality of testing in the approval relevant scope must be evaluated at least once within 12 months. Internal audits must be carried out for this purpose in appropriate intervals.

[35] For definition see Annex 1.
[36] In particular, the testing laboratory must not offer any service confirming the fulfillment of one of the accreditation standards (e. g. ISO/IEC 17025) as long as it acts as designated technical service.
[37] To be downloaded from the Internet.

12 Obligations of the KBA

The KBA has to

- Carry out a designation procedure in the content of these designation rules
- Guarantee the rights of the testing laboratory
- Inform the testing laboratory sufficiently and promptly about changes in the procedure and changes of the designation rules[38]
- Follow up on complaints about the TS if these are directly addressed to the KBA
- Publish the version of the regulatory act on the Internet which must be designated so that the test can be considered in the KBA TAP

13 Confidentiality, discretion, privacy policy

Personnel of the KBA as well as external assessors deal confidentially with all information obtained in connection with the designation of the concerned TS and analyse it only for the agreed purpose. Documentation or information provided by the TS will not be forwarded to third parties without explicit consent of the TS, except where the law, ISO/IEC 17011 or these designation rules require disclosure without explicit consent.

The following data will be published in context with notification, and publication of the designation on www.kba.de, as well as on request:

- Name and address of the TS
- Contact data of the TS
- Scope of designation.

In case of justified request, other data can be provided to relevant bodies of EU, UNECE, and the Ministry in charge of the KBA.

Personal data concerning contact persons and key personnel will digitally and in other form be stored at the KBA for organisational purpose in accordance with the Federal Data Protection Act (Bundesdatenschutzgesetz). In addition, procedure-relevant data is stored digitally and in other form. Data security and privacy are guaranteed. The data is deleted and/or destroyed at the latest 5 years after termination of the designation. Personal data is deleted and/or destroyed at the latest 5 years after information that the person left the position.

[38] Such information can be given in exchanges of experiences, on the Internet (www.kba.de) or by other means.

14 Changes to the designation

The designation will be altered on request of the TS. Thereupon, the KBA informs the TS about measures to be initiated and imposes conditions if applicable.

15 Fees

Liability to charges originates with the application and independently of the result of the procedure. The amount of fee depends on the Federal Act on Fees (BGebG) and related decrees in the amendment valid at the time of service provision.

Sliding-scale fees are specified in Annex 6. The fees indicated there can be adapted within the given limits according to the trend of costs.

Fees to be expected can also be raised as an advance payment.

Fees and travelling expenses (travel, hotel, daily allowance and other) as well as other disbursement will be raised by invoice. Possible bank charges which are due (e. g. with transfers from abroad) are to be paid by the TS.

16 Other

Special agreements are to be documented in writing.

The transfer of the designation to another legal entity is not allowed.

If regulations of the designation rules should not be totally or partly legally effective or not feasible or lose their legal force or feasibility at a later date, then the validity of the remaining regulations is not affected. In place of the ineffective or infeasible regulations or for filling out a possible gap, an appropriate regulation shall be valid which, so far legally possible, is as close as possible to intended sense and purpose of these designation rules.

Claim for compensation in relation to the KBA is impossible, except in cases of intent, with rough negligence or with breach of substantial obligations as given in these designation rules. The TS has to indemnify the Federal Republic of Germany and federal states from all claims of third parties because of damage which is caused by activities in connection with the designation.

Annex 1

Terms and abbreviations

Abandonment	Cancellation (totally or partly) of an illegal administrative act with effect on the past and/or future (see § 48 VwVfG).
Accreditation	Formal confirmation by an accreditation body in accordance with Regulation (EC) 765/2008 that the testing laboratory/the inspection body, using a QM system according to ISO/IEC 17025 and/or ISO/IEC 17020, is competent to carry out tests/inspections.
Appeal Committee	The Appeal Committee decides in case of appeal and complaints if no agreement can be reached between designation body and TS. There is no need to involve the Appeal committee in case of ordinary complaints
Assessment	On-site examination of a testing laboratory for evaluation whether the designation criteria are fulfilled.
Authorized signatory	Staff of the designated TS[39], who was authorised by the TS in case of fulfilling the requirements according to Annex 3. The authorisation must be documented. The authorized signatory bears the full responsibility for proper execution of the test and correctness of the data in the test report (see also section 11.2).
Branch, autonomous	Organisation (however called), independently carrying out key activities[40] or parts of them, and acting under the single QM system of the laboratory.

[39] Person employed by the TS or having a contract with the TS; paragraph 5.2 of ISO/IEC 17025 or paragraph 6.1 of ISO/IEC 17020 respectively as well as these rules can be applied to this person.

[40] E. g. definition of fundamental regulations, design and development, contract review, testing, examination and decision (e.g. about test results).

Calculation methods for testing	Computer simulations and other calculation allowed by relevant regulatory acts for the TAP but not listed in EU regulatory acts as virtual procedures. Calculation schemes, specified in regulatory acts, are not seen as calculation methods as defined here. Calculation schemes, specified in regulatory acts, are not seen as calculation methods as defined here. There is no explicit designation for calculation methods. Nevertheless, the use of calculation methods must be notified to the designation body. Requirements to virtual testing are analogously valid with the following exceptions: - Validation can take place in any appropriate form (however, particularly in case of complex methods and in such methods which go beyond simple physical principles, in general the result must be compared with the result of physical testing) - There is no approval of the validation report by the KBA.
Designation (Recognition)	Authorization as TS to carry out or to supervise tests in the designated scope. In result, the TS is authorized to issue test reports to be used in the KBA.
Designation Council	The Designation Council decide about essential elements of designation procedures (see also Appeal Committee)
Designation procedure	Initial evaluation and evaluation as surveillance Full procedure Fulfilment of requirements of the ISO standard as well as of designation relevant requirements will be completely evaluated by the KBA. Procedure on basis of a certificate of accreditation The KBA evaluates the fulfilment of all requirements, not covered by the accreditation, and the certificate of accreditation itself.
Designation relevant status of a regulatory act	Initial version or amendment with essentially other requirements to competence and/or equipment of the TS. All following amendments of the regulatory act are enclosed into the designation until the KBA has published a new designation relevant status in the Classification directory.[41] Note: In general, tests for approvals must follow the latest amendment of the regulatory act (approval relevant status can differ from designation relevant status).

[41] To be downloaded from the Internet.

Headquarters	Part of the TS, which is responsible for realization of rights and obligations resulting from designation as well as for the QM system's central functions of the TS.
Major non-conformity	Non-conformity, which concerns at least one of the following points: • Missing or insufficient implementation of requirements of the designation basis • Substantial impairment of confidence in an effective QM system as required by the designation rules • Substantial doubts about the quality of tests, decisions about test results or test reports • A major or minor non-conformity from the preceding assessment, which has not been effectively corrected. A major non-conformity normally leads to a suspension procedure or blocks the designation.
Minor non-conformity	Lack of fulfilment of demands of the designation bases; the confidence in an effective QM system and in correct test reports is not questioned. Minor non-conformities block the initial designation. They lead to a suspension procedure if they are not settled in due time or if in case of a number of minor non-conformities the conclusion about malfunction of the QM system must be drawn.
Notification	Report to the European Commission for test procedures in accordance with EU regulatory acts and to the Secretary of the UNECE for test procedures according to UN regulatory acts
Restriction	Temporary or permanent reduction of the scope of designation (see section 9)
Revocation	Invalidation (totally or partly) of a legal decision with effect on the future (see § 49 VwVfG).

Surveillance	Verification of the initial evaluation in terms of 2007/46/EC, Article 42 • Surveillance with re-assessment (ÜW): On-site assessment similar to the initial assessment considering experience gained during previous evaluations (in general every 5 years, alternating with Ü) Surveillance after 2.5 years (Ü): On-site assessment similar to ÜW but in general less comprehensive (in general every 5 years, alternating with ÜW) In addition, an regular on-site assessment takes place one year after the Main scope (Prüfgebiet) 01 (Whole vehicle) was added to the scope. Further on-site assessments will be initiated in case of ongoing non-observance of designation relevant requirements. • Continuing surveillance: Continuing evaluation of fulfillment of obligations resulting from designation and of other information about the TS' activities. Additional actions will be initiated at the discretion of the KBA.
Suspension	Temporary partial or complete de-recognition of the rights connected with the designation.
Technical expert	Staff of the TS[42] with special qualification (e.g. authorization for testing of pressure devices) and fulfilling the requirements according to Annex 3, who was authorised by the TS. The authorisation must be documented. The technical expert signs in test records for the proper execution and the correctness of the data in the part of the test which is in his/her responsibility. His/her signature does not replace the signature of the person authorised to sign test reports.
Termination	Definite complete de-recognition of rights as given by designation (see section 9)
Test location	Place, where tests are carried out or supervised[43]
Virtual testing	Computer simulation or calculation, explicitly marked as virtual testing in EU regulatory acts and which is subject to special requirements

[42] See footnote 39
[43] can be identical with a branch

Witness Assessment

Attendance at a test by KBA staff or their delegates to evaluate the Performance of test procedures

- Expertise of testing staff
- Test conditions
- Implementation of other internal requirements resulting from the QM system of the TS
- Implementation of requirements of these designation rules
- Legal conditions (in case of external test locations).

BGebG	Federal Act on Fees (Bundesgebührengesetz)
CoP	Conformity of Production (with approved characteristics)
EC	European Community
EG-FGV	Decree on re-organisation of legislation for EC type approval procedures (Verordnung über die EG-Genehmigung für Kraftfahrzeuge und ihre Anhänger sowie für Systeme, Bauteile und selbstständige technische Einheiten für diese Fahrzeuge)
EU	European Union
GebOSt	Scale of fees for measures in road traffic (Gebührenordnung für Maßnahmen im Straßenverkehr)
ISGQ	Information system for quality of test reports Informationssystem Gutachten- (Prüfbericht-) Qualität
KBA	Kraftfahrt-Bundesamt
QM	Quality management
TAP	Type approval procedure
TS	Technical service
Ü	On-site surveillance assessment after 2.5 years
ÜW	On-site assessment (re-assessment)
UNECE	United Nations Economic Commission for Europe
VwVfG	Administrative Proceedings Act (Verwaltungsverfahrensgesetz)

Annex 2

Designation procedure

Application

Applications for designation must be submitted in writing to:

Kraftfahrt-Bundesamt
Dienstsitz Dresden
Postfach 12 01 53
01002 Dresden
GERMANY

They can also be submitted by fax +49 351 47385-36. Additional documents according to the annex of the application form can be submitted by email or other.

The application must be signed by a representative of the body responsible for the TS to be designated, if such exists[44]. The documentation must be submitted in German or English.

The application documentation must be plausible. For the “full procedure”, only the relevant for designation part (basis standard) of the questionnaire, is to be filled in. The statements must document the fulfilment of the requirements from the standards and/or other regulatory acts[45, 46].

Well prepared application documents and active support of the KBA in all stages guarantee a rapid progress of the procedure.

These designation rules become binding with submission of the application.

The application will be rejected if

- The applicant cannot be designated as TS[47]
- The KBA is not responsible
- The demands of the applicant are not feasible by the KBA
- No agreement about the service to be generated or fees can be reached.

[44] Otherwise a representative of the TS to be designated signs.
[45] The edited version of the standard’s requirements in the questionnaire is possibly not sufficient to be understood comprehensively. As such it is recommended to check the original text of the standard.
[46] For designation on basis of a certificate of accreditation, a separate questionnaire must be used.
[47] See section 1.

Evaluation

Testing laboratories are classified into categories relevant for the procedure depending on the number of Subscopes (Prüfumfänge). In case of designation on basis of a certificate of accreditation, only Subscopes (Prüfumfänge) will be calculated which are not included in the accreditation.[48]

Category	Subscopes (Prüfumfänge)
L1	up to 3
L2	4 – 9
L3	10 – 22
L4	23 – 40
L5	more than 40

The Lead assessor defines which documents and records must be submitted prior to the assessment for evaluation[49]. Unless otherwise agreed, this documentation must be available in the KBA 1 month prior to the assessment.

Prior to the assessment, the assessors evaluate all applicable documents and records of the TS as well as, so far applicable, records from earlier measures in the context of the designation. The TS to be evaluated will be informed about non-conformities found during the document review. The assessment can depend on the settlement of these non-conformities.

The assessor team and the assessment itself will be agreed between the KBA and the TS to be evaluated[50]. Upon request, the TS can get information about the employer of the assessors and experts if they are not employees of the KBA.

The assessment is carried out according to relevant regulatory acts as well as the designation rules. It includes for the headquarters and for all autonomous branches at least

- The evaluation, to what extent the demands of the standard on which the designation is based (ISO/IEC 17020 and/or 17025)[51], these designation rules and other applicable approval relevant requirements are implemented
- The witnessing of one representative test procedure for each designated Main scope (Prüfgebiet)[52]. The selection of the test procedure takes place upon discretion of the KBA.
- The assessment of the procedure for virtual testing or use of calculation methods (if relevant).

48 If there are no additional Subscopes (Prüfumfänge): category L1

49 In case of initial evaluation, generally documentation according to the application form.

50 The lead assessor decides about content and procedure of the assessment.

51 Generally not in case of designation on basis of a certificate of accreditation covering the scope of designation

52 In general, in case of designation on basis of a certificate of accreditation not applicable for Main Scopes (Prüfgebiete), where all Subscopes (Prüfumfänge)are already covered by the basis accreditation. Basically, in case of designation on basis of a certificate of accreditation, only Subscopes (Prüfumfänge) not covered by the accreditation will be witnessed. Increased sampling if several locations shall be covered by the designation.

If testing or supervising of tests in external test facilities is planned, upon request, the TS to be designated informs about all test locations. The KBA decides about the sample check for witnessing of test procedures in these facilities.

Competent personnel of the TS have to give the assessors all required information, documentation and demonstrate procedures. In particular, effective co-operation of all parties involved is expected during preparation and execution of witness-assessments.

Findings are communicated to the TS during the assessments. The TS to be evaluated and the body responsible for the TS get the opportunity to ask questions concerning findings and to comment on the assessment. The result of the assessment is summarized in an assessment report. If no objections have been submitted within 2 weeks after receiving, the report is deemed to be approved.

For non-conformities, a root cause analysis as well as corrections, corrective actions are to be communicated, and the agreed evidence for settlement are to be submitted by the defined deadline. If necessary, a follow-up on-site assessment will be carried out.

If not otherwise agreed, submitted documentation after their evaluation will be filed in the KBA or destroyed in case that it is not needed any more at the KBA.

Decision

Precondition for the designation is that requirements resulting from the designation procedure are met (no open non-conformities, invoices are settled).

After granting the designation, the applicant gets a certificate of designation. Test procedures according to EU and UN regulatory acts are explicitly listed in the annex to this certificate.

If testing competence is proved for a Subscope (Prüfumfang), on request competence for testing according to national regulations and for new technologies and concepts can be included in the certificate, as long as these regulations are approval relevant. This scope will not be specified in detail.

Surveillance

The on-site surveillance regularly consists of

- An office assessment for system evaluation after each 2.5 years respectively
- If relevant, the assessment of fulfilment of approval relevant requirements at other autonomous branches
- Witnessing of testing or supervising tests in the headquarters and other locations[53, 54, 55]
- For TS with designation for Main scope (Prüfgebiet) 01, an additional assessment 1 year after this scope has been included in the designation. This assessment is limited to Main scope (Prüfgebiet) 01 and related to this Main scope (Prüfgebiet) other scopes[56].

The on-site surveillance (Ü and ÜW) must generally be finished by the end of the surveillance period (2.5 years). In exceptional justified cases with agreement of the designation body, the procedure might be finished at a maximum of 3 months later.

Furthermore, it will permanently be monitored to which extent approval relevant requirements and actions agreed with the KBA (ISGQ, exchange of experiences, trainings, workshops, KBA attendance in type approval testing, interlaboratory comparisons etc.) are realized.

Further surveillance measures, in particular for evaluation if designation rules are met in external locations, for evaluation of supervising, and due to special events can be applied, in order to ensure the necessary confidence into the designation or to find whether the TS introduced effective processes in result of alterations in the basis of the designation or after non-conformities.

As a result of the surveillance, a decision about the continuance of the designation will be taken.

53 If applicable, at least one assessment within 5 years in non-EU countries.
54 See footnote 52.
55 Sampling as in case of initial assessment.
56 See section 5.

Annex 3

Basic requirements for personnel

1 General

Personnel working for the TS, including contractually bound external staff, shall meet the requirements of ISO/IEC 17025 and/or ISO/IEC17020 and at least the following approval relevant requirements.

The process of authorization, maintenance and evaluation of qualification for Authorized signatories for separate test procedures and for qualification of other personnel involved in designation related activities[57] is, considering the requirements given in these Rules, to be defined by the TS and documented. As a minimum, there must be defined regarding knowledge, capabilities and skills:

- Required competence
- Competence criteria
- Ways to obtain and maintain required competence
- Kind of initial evaluation of competence and of evaluation of continuing competence
- Documentation of evidence.

Documentation of meeting the criteria and of realized activities shall be retained for at least 5 years.

In justified individual cases, the KBA can permit deviations.

2 Criteria for authorization

2.1 Head of the TS and his/her deputies

- Graduation from a university (college of higher education or similar),
- General knowledge of approval relevant requirements

2.2 Authorized signatories

- Relevant to the scope of testing graduation from a university (college of higher education or similar)
- Up-to-date knowledge of approval relevant requirements and the TAP of the KBA, proven by the successful completion of a relevant KBA training or of a training program accepted by the KBA. This training must not be older than 36 months.[58]

[57] E.g. management, personnel involved in testing, administrative staff.

[58] Additional training is not required for authorized signatories, which already act or acted within the last 36 months for a TS designated by the KBA.

- Authorized signatories in the Main scope (Prüfgebiet) 01 (whole vehicle) must prove knowledge, capabilities and skills in accordance with the “Framework curriculum for authorized signatories for testing/inspection of a whole vehicle” (A-3.3) as amended.[59]

- Authorized signatories in other Main scopes (Prüfgebieten) must be trained in accordance with a curriculum created by the TS. They must prove knowledge, capabilities and skills related to requirements of ISO/IEC 17025 and ISO/IEC 17020, to the relevant Subscope (Prüfumfang) and to the specifics in the TS with following focus:
  - QM system of the TS
  - Requirements to the technical proceeding of tests and assuring quality, in particular
    - Handling of test items
    - Requirements to test procedures and test environment, selection of appropriate measuring and test equipment
    - Consideration of uncertainty of measurement
    - Metrological traceability
    - Testing (including possible problems)
    - Inspection of external test sites and supervision of tests (if relevant)
    - Test records, test reports.

  Knowledge, capabilities and skills regarding the above listed aspects must be proven in a test and confirmed by the head of the TS. If there are no specific requirements, results of previous tests can be taken into consideration.[60]

- Except in Main scope (Prüfgebiet) 01, experience in testing or surveillance of testing in the relevant Subscope (Prüfumfang)[61] at least for a period as given by the requirement category[62] for the respective test procedure is expected. This experience must not be older than 5 years.

Requirement category	Characteristic of the test procedure	Risk exposure/ Environmental relevance	Minimum test experience
1	Very simple test procedures	not significant	6 months
2	Between category 1 and 3	small	1.5 to 2 years
3	Sophisticated test procedures	high	3 years
4	Analogue to category 3, but additional specific expertise/authorization required		

[59] Download from the Internet is available (only in German language).
[60] E.g. prove of ability for appropriate generation of test reports.
[61] See Classification directory of the KBA (www.kba.de).
[62] The requirement category is given in the Classification directory. It refers to testing of parts/systems. In general, for testing of mounting/installation, the next lower requirement category is relevant. In justified individual cases, the head of the TS can permit deviations. Justification must be documented.

Proven test experience can be taken into consideration for other test procedures out of the same Subscope (Prüfumfang).[63]

- Authorized signatories must be entirely competent to evaluate the real test process and the test result.[64] This includes also obligations regarding safety of the test (e.g. safeguarding of the test area, cancellation of testing if necessary etc.). It is valid for own testing as well as for supervision of tests.

2.3 Technical expert

- Completion of a relevant for the scope training
- If normal for the scope: national or other official authorization

3 Additional criteria of competence after authorisation

Head of the TS and his/her deputies	Regular involvement in designation relevant procedures
Authorized signatory	Regular testing or supervision of testing in the authorized scope or proof of other measures for the preservation of qualification[65]

[63] Example 1: If there is sufficient test experience in 02-01-02, scope 02-01-03 can be awarded. Example 2: If there is sufficient test experience in 09-02-03, only 1-1.5 years of additional test experience is required for 09-02-05.

[64] So for example, it is required for tests including driving that the Authorized person holds a valid driving license for the relevant vehicle type and has sufficient driving experience for this type of vehicle.

[65] At least one test per year and field of competency (at least Main scope (Prüfgebiet)) should be realized.

Annex 4

Categorization of technical services

In addition to the requirements of relevant EU and UNECE documents, TS are categorized according to following criteria:

Category A

- The TS owns the essential test equipment and has the exclusive access to and right of disposal of this test equipment and related facilities or
- The TS does not own the essential test equipment but
  - Equipment and facilities are bound by a contract for at least one surveillance period.
  - The contract guarantees the TS' exclusive access to and right of disposal of leased equipment and facilities. The lessor is not allowed to admit the right of use to third parties or to use them himself.

Categorisation as "A" for a procedure out of Main scope (Prüfgebiet) 01 can apply if at least one of the procedures out of Subscopes (Prüfumfänge) required for Main scope (Prüfgebiet) 01 has category A.[66]

Categories B and D

The same as in category A, but own test equipment is not required

- Contracts to bound equipment and facilities are not required. Exclusive access and right of disposal are not required.
- In procedures of designation and surveillance, a representative sample check will be assessed. This sample check will in general be increased in case of frequently alternating test locations.

[66] See section 5.

Annex 5

Use of external data

In general, external data[67] can only be used for test reports to be used in the approval procedure if they are handed over by a TS designated for the respective scope by the KBA and data were collected in accordance with the applicable technical regulatory acts. Possible ownership of third parties must be respected.

The receiving TS must be designated by the KBA for the relevant test scope.They are responsible for the correctness of the received data. In case of indirect hand-over (e.g. by the manufacturer), the explicite confirmation of data correctness must be asked at the TS which originally created the data.

Data from TS not designated by the KBA can be used if this data was verifiably used by an EU approval authority for a type approval or if the granting of such a type approval can be assumed.[68]

If data from other sources of information is used, the correctness is principally to be questioned, and everything must be done to create sufficient confidence in this data. In general it is to be taken into consideration:

- Only reliable data taken from sources which are to a large extent neutral is used (e.g. databases from EU type approval authorities or from industrial associations)
- Plausibility of data must be proven in any case

In case that external data created in virtual test procedures[69] will be used, additionally the following must be taken into consideration:

- The issuing TS must be designated for virtual procedures in the relevant scope
- The issuing TS states clearly that this data comes from virtual testing. The issuing TS provides sufficient information for the receiving TS, so that this one is able to evaluate limits of the mathematical model and usability of data.
- There is no requirement that the receiving TS must be designated for virtual testing. Nevertheless, the TS must be able to evaluate the received data (take responsibility).
- If data will be taken from manufacturer's virtual test procedures, appropriate precaution must be taken to guarantee integrity if data.

If regulatory acts have different requirements, the requirements of these regulatory acts have to be applied.[70]

67 External data means also parts of or complete test reports etc.
68 In particular, in case of approvals with only national validity it must be checked if procedures, limits etc. correspond with requirements for the intended use.
69 Analogous requirements are to be applied for data from "calculation methods".
70 E.g. for individual approvals.

Annex 6

Fees

The amount of fees depends on the number of Subscopes (Prüfumfänge) at the time of service provision.

		L 1	L 2	L 3	L 4	L 5
Designation (full procedure)	Initial assessment	€9,870	€13,800	€24,060	€37,700	€48,630
	Ü	€2,730	€3,800	€6,630	€10,370	€13,380
	ÜW	€4,120	€5,520	€9,100	€14,000	€18,790
Designation on basis of a certificate of accreditation	Initial assessment	€7,560	€10,710	€15,860	€23,100	€32,290
	Ü	€1,800	€2,130	€2,610	€3,310	€5,350
	ÜW	€3,150	€3,740	€4,590	€5,820	€9,370

Fees include the assessment of one test procedure per Main scope (Prüfgebiet). For assessment of further test procedures 2 hourly rates[71] will be charged.

Assessments in autonomous branches, at external test sites etc. are calculated according to expenditure[72] (including breaks) on basis of the hourly rate. Additionally to the time on the client's premises, in general 5 hours for preparation and post-processing respectively of the witness assessment are calculated.

Any expenditure exceeding the minimum[73] will be charged in hourly rates.

Procedures for limitation, suspension or termination of the designation

Independently of the outcome, for limitation, suspension or termination of the designation initiated by the KBA, there will be raised a fee of at least 5 hourly rates. Additional expenses and assessments will separately be invoiced.

[71] According to the Scale of fees for measures in road traffic (GebOSt) in the amendment valid at the time of service provision; at the moment of publication of these rules: €97.10.

[72] Rounded up to full hours.

[73] For assessments, 5 hours will be taken as minimum for preparation and post-processing respectively.

Supplements

- Basic fee for extension €50.00
- In addition
  - Per altered Main scope (Prüfgebiet) €70.00
  - Alteration of administrative data €70.00
    (e. g. name, address, logo, registration number of accreditation)

If an additional assessment is necessary for the supplement, the fee is calculated on the basis of hourly rates. In addition to the on-site time, in general 5 hours for preparation and post-processing of the assessment respectively will be calculated.

Certificates

1 certificate A4 German	Free
1 certificate A4 English (only on request)	Free
Further 1st pages • A4, each • A3, each	 €10.00 €15.00
Following pages, per page	€1.00
Languages other than German/English • Non-recurring extra charge • Translation	 €5.00 according to costs

Travelling expenses

The real travelling time, but not more than the following, will be taken for calculation[74]:

Region Germany	5 hours per assessor/expert and direction
Region Europe[75]	8 hours per assessor/expert and direction

For other destinations, no upper limits will be applied.

Travelling expenses and reimbursements will be charged according to the effective outlays as given by the Federal law about travelling expenses.

[74] According to the Scale of fees for measures in road traffic (GebOSt) in the amendment valid at the time of service provision; at the moment of publication of these rules: €61.40.

[75] Mainland and Great Britain, Ireland, Malta, Cyprus.

Other

The fee for designation includes all relevant categories and the corresponding notification.

Fees and costs for the annual exchange of experiences between KBA and TS are also included[76].

Further activities and additional expenditures[77] are calculated according to expenditure on the basis of the hourly rate. Information meetings on the premises of the KBA are not charged for.

No value-added tax is charged on these fees.

[76] Except travelling expenses and lunch.

[77] e.g. for assessment of external locations, designation for virtual testing and other special procedures, assessments in a foreign language etc.

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