KBA

Designation body

AMEVSC-03-13e
September 2010

Kraftfahrt-Bundesamt

Your central information service provider concerning vehicles and their users

Rules for designation/recognition of test laboratories

Issue: April 2010

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[1] Binding

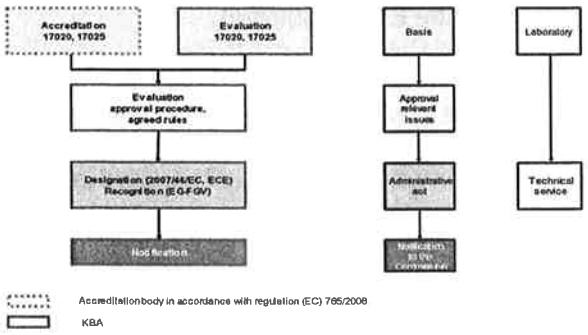
1 General

The designation body of the Kraftfahrt-Bundesamt (KBA) evaluates the competence of bodies for tests or supervision of tests of vehicles and vehicle parts in the context of the Decree on re-organisation of legislation for EC approval procedures (EG-FGV). As a result, these bodies are designated/recognised as technical services (TS) in the sense of the framework directive 2007/46/EC[2] and/or the ECE agreement of 1958 for test reports to be used in approval procedures. The scope of possible designation is described by the Catalogue of indexes for test procedures of the designation body[3].

The designation body acts also as recognition body in the content of the EG-FGV.

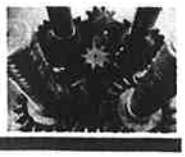
The designation will be performed according to a procedure developed by the designation body of the KBA on the basis of the ISO/IEC 17011, ISO/IEC 17025, ISO/IEC 17020 and approval relevant traffic legal and technical regulations. The Administrative Expenses- and the Administrative Procedure Act (Verwaltungskosten- und Verwaltungsverfahrensgesetz - VwVfG) are valid.

For designation, the fulfilment of above mentioned requirements of standards may be documented by a certificate of accreditation issued in accordance with regulation (EC) 765/2008.



2 As far as relevant and as long as it is not expressly different represented, under the framework directive 2007/46/EC also framework directives 2002/24/EC and 2003/37/EC are understood.

3 To be downloaded from the internet. All links to the internet refer to www.kba.de, **Motor vehicle technology – Designation of Technical services.**



Designation/recognition[4] of test laboratories is aimed at promoting confidence in the equivalence of test results of designated bodies within the European Union (EU), and to document the competence of these bodies for tests according to German and international legislation.

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

Preconditions for designation are[5]:

- Meeting of general criteria for the operation of test laboratories according to ISO/IEC 17020[6] and/or ISO/IEC 17025[7]
- Fulfilment of approval relevant requirements
- Acceptance of these Rules for designation/recognition of test laboratories[8]

A test 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 an EC directive, if and as far this is stated in the EC directive (regulation)
- Be designated for test procedures according to an ECE regulation, if and as far as this is stated in the ECE regulation.

2 Scope of the designation

The designation comprises the scope indicated in the designation certificate.

4 For better legibility, under the term „designation" and its derivatives apart from the actual designation according to 2007/46/EC, also the procedures of designation/recognition according to similar directives/regulations and the consequential notification are understood in the following, as long as it is not expressly differently represented.

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

6 ISO/IEC 17020 is used here in the sense of the framework directive 2007/46/EC for test laboratories. In accordance with EA IAF/ILAC-A4:2004:2004-5/1, tests must be carried out as given in ISO/IEC 17025:05.

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

8 In the following, the term **"designation rules" will be used.**

3 Responsibilities

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

The designated body 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.

Designation of multiple site organisations is carried out on the basis of DAR-3-EM-16 **"Accreditation of laboratories and inspection bodies with multiple sites".** [9]

Further information and forms are available on the internet.

Test laboratories are classified into categories relevant for the procedure depending on **the number of Subscopes (Prüfumfänge). Within the procedure "Designation on the basis of a certificate of accreditation", only Subscopes (Prüfumfänge) will be calculated** which are <u>not</u> included in the accreditation.[10]

Category	Subscopes (Prüfumfänge)
L 1	up to 3
L 2	**4 – 9**
L 3	**10 – 22**
L 4	**23 – 40**
L 5	more than 40

[9] If branch offices, subsidiaries etc. are operated, all locations must be subject to a consistent QM system, which is specified, realized and supervised by the headquarters. The headquarters must have the right to introduce corrective actions at a location if these are necessary.

[10] **If there are no additional subscopes (Prüfumfänge): category L 1**

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

In accordance with EC and ECE documents, the positively evaluated body will be designated and recognized according to EG-FGV as TS category A, B and/or D[11] for test procedures out of the Classification directory of the designation body.

It will be designated only if all requirements of the designation body are met and invoiced fees and costs are registered on the bank account of the designation body. It can be designated with reservations.

The designation is bound to positive surveillance results.

As a result, the designated TS will be notified to the European commission for test procedures according to EC documents. For test procedures according to ECE regulations it will be notified to the Secretariat of the UNECE. The designation and notification takes place for the status of the respective rules indicated in the certificate. In addition, the designation will be published on the internet.

Test reports of designated TS will be accepted in the TAP of the KBA if they

- Have been created in the designated scope with consideration of the current issue of directives/regulations from the point of view of designation
- Are signed by one of the authorized signatories
- Correspond to the requirements specified in the TAP
- Do not show deficiencies and tests were carried out correctly and in all conscience.

For the recognition in the TAP it is necessary that the designation body has not expressed restrictions for the respective scope.

The KBA can specify further criteria.

6 Extensions to the designation

Designated bodies have the option to extend the existing designation with a supplement. The application for the supplement is to be submitted in writing through a form.[12] The reason of the application must be described in detail. 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 designation body decides about possible deviations or simplifications.

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[11] On request, a TS to be designated for category A and/or B, is also designated as a TS category D for the same scope.

[12] To be downloaded from the internet.

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

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

In this case, the input reduces for the system evaluation of the second standard. The QM system is evaluated in principle according to ISO/IEC 17025. The evaluation includes specifics of the ISO/IEC 17020.

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

- **If a test procedure representative for the Scope (Prüfgebiet) is requested for** designation for category A, in general this will be witnessed.
- If also a designation for category B is requested, the surveillance of at least 1 representative test procedure under ISO/IEC 17020 is witnessed.

For further requirements see Annex 4.

On application, a TS designated in categories A and/or B will be designated in category D for the same scope.

In case of findings, complaints etc., which primarily lead to suspension, restriction, cancellation of the designation for one of the categories, also the effects (the loss of the level of trust) on the other designation for the other category are examined.

The extension of an existing designation with a category based on another standard[13] is generally connected with an on-site assessment as for surveillance/re-assessment.

[13] e.g. extension of a designation for test procedures categorized as B (ISO/IEC 17020) to new test procedures to be categorized as A (ISO/IEC 17025)

8 Designation on the basis of a certificate of accreditation

Basis for the designation on the 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.

In this case, the evaluation generally extends to the

- consideration in the QM system of
  - The designation rules
  - Specific KBA requirements as for example
    - Knowledge about TAP
    - Obligations regarding information policy
    - Analysis of quality of test reports (ISGQ)
    - Organisation of recalls
    - Usage of templates for test reports
    - Authorisation of persons to sign test reports (authorized signatories)
    - Usage of technical experts
    - Usage of data from other laboratories
  - Fulfillment of requirements concerning classification of TS[14]
    etc.
- Witnessing of test procedures.[15]

In all other respects the procedure is carried out as described in section 4.

The designation body is authorized to give on request information concerning the designation to the accreditation body.[16]

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

[14] See Annex 4
[15] See Footnote 33
[16] Obligations of the TS regarding information policy: see section 11.2

9 Restriction, suspension or cancellation of the designation

A restriction or suspension of the designation may take place

- Upon request of the designated body
- At the instigation of the designation body, 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
  - During surveillance assessments, major non-conformities were identified
  - Surveillance measures could not be realized within the designated period and the designated body is responsible for this
  - In surveillance measures, evidence was found that corrective actions had not been effective
  - **The designated body's methods cause qualified doubts in expertise, impartiality or creditableness.**

During the restriction or suspension, the designated body has the opportunity to re-establish the preconditions required for designation.

The suspension can be totally or partly and is limited to a maximum of one year. In general, the suspension will only be repealed if efficiency of the management system is demonstrated in an on-site assessment.

If in case of a multi-site based organization it is discovered in one of the sites that the joined management system is not effective and if the assessment of other sites shows that this is valid also for other sites, the designation will be restricted or suspended until an effective realization of the management system can be guaranteed.

The designation will be terminated totally or partly

- Upon request of the designated body
- After expiration of the limitation or suspension of the designation
- As soon as the TS or the organisation to which the TS belongs become manufacturer in the content of the framework directive 2007/46/EC and the designation of manufacturers is not expressly allowed by this framework directive or other relevant documents
- With revocation or abandonment by the designation body
- 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 of the change and the disagreement is not redressed
- If the change of legal requirements orders this.

The designation body can impose conditions in connection with the termination and supervise their fulfilment.

The designation body 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 persistently contravenes the requirements of the designation (breach of designation rules, of ISO/IEC 17025 and/or ISO/IEC 17020 or approval related requirements)
- Despite repeated deadlines, observed deficiencies have not been settled or sufficient evidence for settlement has not been submitted.

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

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 withdrawal are given via a notification. The bodies specified under section 5 are informed about the associated restriction, suspension or omission of the designation[17].

In case of offences against these designation rules, it can be demanded that authorisation for signing test reports is withdrawn from individual persons.

10 Appeal

Appeal against the decision of the designation body is permitted. It must be submitted within 1 month after announcement of the decision to the designation body:

Kraftfahrt-Bundesamt
Benennungsstelle
Postfach 12 01 53
01002 Dresden
Germany

in writing or for record.

The KBA as appeal authority with participation of an appeal committee decides about the appeal. The decision about the appeal will be communicated in writing as official notification and is accompanied by peremptory legal remedy instructions.

[17] With restrictions and suspensions only in exceptional cases after discretion of the designation body.

11 Rights and obligations of the designated body

11.1 Rights

The designated body has the right to

- Access to all services of the KBA designation body
- 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 designation body
- Confidentiality concerning internal documents and data, which the assessor received during the procedure
- Use the certificate and logo of the designation body in documents and promotional material for the declared scope[18]
- Designation and notification to the competent bodies (see section 5)
- Publication of the designation by the designation body
- Ask for information at the designation body in case of alterations of regulations which are relevant to maintain the designation, such as legislation, standards or guidelines, so that necessary steps can be taken in a timely manner if applicable
- Appeal against decisions of the designation body.

11.2 Obligations

The designated body is obligated to

- Fulfil the requirements of ISO/IEC 17025 and/or ISO/IEC 17020[19] and approval relevant requirements
- Accept and fulfil these designation rules[20]
- Fulfil the standards of the KBA concerning the type approval procedure[21]
- Carry out internal audits in appropriate intervals to check fulfillment of requirements related to the designation
- Use competent personnel (see Annex 3); authorized signatories and technical experts are to be designated according to a documented procedure

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

19 See also footnote 6.

20 This includes the obligation to fulfil all relevant requirements of the designation body. The TS will be informed according to section 12. Further information will be published on the internet.

21 Information by the department **"Technical matters" of the KBA**.

- Make sure that authorized signatories ensure that tests are carried out appropriately[22]
- Carry out regular measures to assure the quality of test results; all Scopes (Prüfgebiete) must be covered within an appropriate period; where applicable, the TS must enable and participate in interlaboratory tests
- Take part actively at any form of exchange of experience, training and workshops
- Identify together with the KBA causes of deficiencies and to reduce deficiencies (e.g. in ISGQ consultations)
- Only consider external test data and/or test reports for test reports which are to be used in the TAP, if these are handed over by a TS designated for the respective scope by the KBA and the measured data/(part of) test report was created in accordance with the applicable technical/approval-relevant legislation[23]
- Only test in test laboratories/at test areas, which conform to the relevant requirements of ISO/IEC 17025:05 and the applicable technical/approval-relevant legislation (including test locations at subcontractors)
- Use virtual testing methods only if
  - This is explicitly permitted for the respective scope by the designation body
  - The virtual test procedure is sufficiently validated
  - Data is received from a TS which is designated for virtual testing in the relevant scope and the receiving TS has assured that the virtual testing procedure is sufficiently validated
  - The authorized signatory has given evidence that he/she is able to judge data from virtual testing appropriately
- Offer all necessary co-operation to the designation body, 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)
- Enable the execution of witness assessments at all test locations (participation of the KBA in type approval testing)
- Communicate immediately and without being asked to the designation body 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 locations (including external test locations)
  - Designated scope (e. g. actualisation, extension, restriction, cancellation)
  - Basis accreditation, if relevant
  - Other affairs, which are related to the designation

[22] This includes that they ensure that tests are carried out by only qualified personell of the TS and that they can at any time be included on-site in the test process and can intervene. They should judge the test conditions themselves and monitor the test process appropriately.

[23] The receiving TS is responsible for the correctness of the received measuring data/(parts of) test reports.

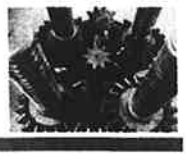
- Inform the designation body promptly, and wherever possible before the occurrence of an event, if conditions for the designation become void or restricted
- In case of a designation on the basis of a certificate of accreditation
  - Provide for the designation body without being asked results of assessments by the accreditation body
  - Not give the impression that the certificate of accreditation on which the designation is based refers to type approval issues in the content of designation
- Avoid any statements concerning their designation that can be understood by the designation body or anybody else as mistakable or unjustified
- Use the designation only in the scope for which it has been granted [24]
- Not give 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 designation body when making reference to its designation in communication media such as the internet, documents, brochures, advertising
- Use the logo of the designation body according to the rules for its usage[25] and only in connection with tests, which are enclosed expressly within the designation
- Not use the designation in a way harming to the reputation of the designation body
- Pay fees in accordance with the Scale of fees for measures in road traffic (GebOSt) in the latest amendment and the latest KBA chart of fees and to pay travelling expenses, daily allowance and other expenditure without any delay (see Annex 5).

12 Obligations of the designation body

The KBA designation body has to

- Fulfil the requirements of the ISO/IEC 17011 in the content of the EG-FGV and the designation rules
- Guarantee the rights of the designated body
- Inform the designated body sufficiently and promptly about changes in the procedure and changes of the designation rules
- Follow up on complaints about the designated body, if these are directly addressed to the designation body
- Publish the version of the directive/regulation, which must be designated so that the test can be considered in the TAP of the KBA[26], on the internet

[24] In particular the test laboratory may not offer services, in which it is confirmed that one of the accreditation standards (e. g. ISO/IEC 17025:05) is fulfilled.
[25] To be downloaded from the internet.
[26] The department in charge for approvals decides on exceptions.



13 Confidentiality, discretion, privacy policy

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

Information about process and results of the designation will only be provided with explicit consent of the body concerned or if this is required by these designation rules.

Personal data concerning contact persons and key personnel will digitally and in other form be stored at the designation body for organisational purpose in accordance with the Federal Data Protection Act. In addition, procedure-relevant data is stored digitally and in other form. Privacy and data security is 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 deleting the designation of the person.

The data contained in the certificate about designation is published in responsibility of the KBA according to section 5.

14 Change of the legal basis

Changes of the legal basis which are relevant to the designation are considered by the designation body only on special request. The designated body submits a request for actualization of the designation. Thereupon, the designation body informs the designated body about measures to be initiated and imposes conditions if applicable.

Changes of the legal basis can lead to suspension, limitation or revocation of the designation if conditions imposed are not met or if the basis of the designation has fully or partially been dropped or limited due to changes of the legal basis.

15 Fees

Liability to charges originates with the application and independently of the result of the procedure. The amount of fee depends on the Scale of fees for measures in road traffic (GebOSt) in the amendment valid at the time of service provision.

The sliding-scale fees of the GebOSt are specified in Annex 5. The fees indicated there can be adapted according to the trend of costs within given by the GebOSt limits according to the trend of costs.

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

Fees and travelling expenses (transport, hotel, daily allowance and other) as well as other disbursement will be raised by invoice. The given amount has to be transferred to the indicated bank account. Possible bank charges which are due (e. g. with transfers from abroad) are to be paid by the body which is being designated or monitored.

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 loose its 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 is to be valid which, so far legally possible, is as closely as possible to intended sense and purpose of these designation rules.

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

Annex 1

Terms and abbreviations

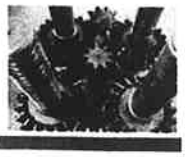
Accreditation	Formal confirmation by an accreditation body in accordance with regulation (EC) 765/2008 that the test laboratory, using a QM system according to ISO/IEC 17025 and/or 17020, is competent to carry out tests.
Assessment	On-site examination of a designated (to be designated) body for evaluation whether the designation criteria is fulfilled.
Authorized signatory	Staff of the designated TS[27], which fulfils the requirements according to Annex 3 and was designated by the TS in case of fulfilling the requirements according to Annex 3. The designation 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.
Designation (Recognition)	Authorization as Technical service category A, B and/or D in the content of the framework directive 2007/46/EC, chapter XVI and/or ECE agreement of 1958 procedures to carry out tests according to EC directives (regulations) or ECE regulations. Basis of designation (recognition) is passing a KBA evaluation procedure. In result, the TS is authorized to issue test reports to be used in the KBA TAP and/or to perform CoP product tests at the approval holder.
Evaluation	Examination by the KBA if the test laboratory, using a QM system according to ISO/IEC 17025 and/or 17020, is competent to perform tests and to meet approval relevant requirements. The evaluation can be based on a certificate of accreditation.
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, test reports • A recorded deficiency from the preceding assessment, which was not effectively corrected. A major non-conformity normally leads to a suspension procedure. It must be settled, before the designation is given.

[27] Person employed by the TS or having a contract with the TS; paragraph 5.2 of ISO/IEC 17025:05 or paragraph 8 of ISO/IEC 17020:98 respectively as well as these rules can be applied to this person.

Minor deficiency	Lack of fulfilment of demands of the designation bases; the confidence in an effective QM system and in correct test reports is not questioned; usually without direct effects on the designation.
Notification	Report to the European Commission for test procedures in accordance with EU directives/regulations and to the secretariat of the UNECE for test procedures according to ECE regulations.
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 (Ü-W): Assessment similar to the initial assessment considering experience gained during previous evaluations (in general every 6 years, **alternating with Ü-3)** Surveillance in the 3rd year (Ü-3): On-site assessment similar **to Ü-W but in general less comprehensive (in general every 6 years, alternating with Ü-W)** Continuing surveillance: Continuing evaluation of quality parameters and of fulfillment of obligations as given in these rules.
Suspension	Limited partial or complete de-recognition of the rights connected with the designation.
Technical Expert	Staff of the designated TS[28] with special qualification (e.g. authorization for testing of pressure devices), who was designated by the TS in case of fulfilling the requirements according to Annex 3. The designation 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 responsibility.
Withdrawal	Cancellation (totally or partly) of an illegal administrative act **with effect on the past and/or future (see § 48 VwVfG).**
Witness Assessment	Attendance at a test by the designation body or other KBA staff to evaluate the Implementation of test procedures – Implementation of other internal definitions resulting from the QM system of the (to be) designated body – Realization of requirements of these designation rules – Expertise of the engineer – Test conditions – Legal conditions (with external test locations).

[28] See footnote 27

CoP	Conformity of Production (with approved characteristics)
DAR	German Accreditation Council (Deutscher Akkreditierungsrat)
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)
EOQ	European Organization for Quality
EU	European Union
GebOSt	Scale of fees for measures in road traffic (Gebührenordnung für Maßnahmen im Straßenverkehr)
IAF	International Accreditation Forum
ILAC	International Laboratory Accreditation Cooperation
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-3	On-site surveillance assessment in the 3rd year
Ü-W	On-site assessment (re-assessment)
UNECE	United Nations Economic Commission for Europe
VwVfG	Administrative Procedure Act (Verwaltungsverfahrensgesetz)



Annex 2

Designation procedure

Application and contract	- Application - Consultation (optional) - Formal application for designation - Evaluation of the application for completeness - Confirmation of the application
Evaluation	- Technical evaluation of application documents - **Assessment on the applicant's premises:** • ISO/IEC 17025 and/or ISO/IEC 17020[29] • Approval relevant requirements • Meeting of special criteria of the designation body • Representative test procedures - Assessment report
Decision	- Evaluation of the assessment results and decision about designation/recognition - Certificate - Notification and publication at www.kba.de
Surveillance	- Analysis of information about activities of the designated body - On-site evaluation to which extent these designation rules, approval relevant requirements and agreed with the KBA measures are fulfilled (exchange of experiences, trainings, ISGQ consultations, workshops, attendance of the KBA at type approval tests, interlaboratory tests etc.) - Witnessing of test procedures - Document check (if necessary) - Additional witness assessments if external test locations are used

[29] Not applicable in case of designation on the basis of a certificate of accreditation (see section 8)

Comments

Application and contract

Applications must be submitted to:

Kraftfahrt-Bundesamt
Benennungsstelle
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 can be submitted by email or other.

The application must be signed by a representative of the body responsible for the organization to be designated, if such exists[30]. The documentation must be submitted in German or English.

The application documentation must be plausible. In the questionnaire, only the relevant for designation part (basis standard) is to be filled in. The statements must document the fulfilment of the requirements from the standard and/or other regulations[31].

In the case of acceptance of a certificate of accreditation, the latest assessment report of the basis accreditation must be submitted.

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

The contract between KBA and the body to be designated is achieved through a formal filing of an application, if the application was not rejected. It is generally unlimited. The designation rules are a part of the contract.

Contract alterations need to be put in writing.

The application can be rejected, because

- The test laboratory or the organisation to which the test laboratory belongs is manufacturer in the content of the framework directive 2007/46/EC and designation of manufacturers is not explicitly permitted by this framework directive or other legislation
- The designation body is not competent
- The demands of the body to be designated are not feasible by the designation body
- Of no agreement about the service to be generated and fees.

[30] Otherwise a representative of the body to be designated signs.
[31] **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.

The contract can be cancelled in written form from both sides for important reasons, in particular on change of the designation rules and offence against these rules. With the cancellation, the designation expires.

Evaluation

The lead assessor defines which documents and records must be submitted prior to the assessment for evaluation[32]. Unless otherwise agreed, this documentation must be available in the designation body 1 month prior to the assessment.

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

The assessor team and the assessment itself will be agreed between the designation body and the organization to be evaluated. Upon request, the applicant can get information about the employer of the assessors if they are not employees of the KBA.

The assessment is carried out according to EG-FGV in connection with the framework directive 2007/46/EC as well as the designation rules. It includes for all locations to be assessed

- The assessment, to what extent the demands of the standard on which the designation is based (ISO/IEC 17020 and/or 17025)[33], approval relevant requirements and these designation rules are implemented
- **The witnessing of a representative test procedure for each Scope (Prüfgebiet). The selection** of the test procedure takes place upon discretion of the designation body.[33]

At least the initial evaluation covers all locations, at which key activities[34] are carried out.

If testing in external test facilities is planned, upon request, the body to be designated informs about all tests planned there. The designation body decides about the sample check for witnessing of test procedures[35] in these facilities.

Competent personnel of the body to be designated have to give the assessors all required information, documentation and demonstrate procedures.

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

33 In general in case of designation on the basis of a certificate of accreditation, only one representative **test procedure out of each Scope (Prüfgebiet) not** covered by the accreditation will be witnessed.

34 See IAF/ILAC A5:04/2009 M.7.5.7.1 ii, e. g. definition of fundamental regulations, design and development, contract review, examination and decision for results of the audit.

35 If applicable, at least one test procedure in 6 years in non EU countries.

Findings are communicated to the organisation to be evaluated during the assessments. The evaluated organisation and the organisation to be designated 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, to which the organisation to be designated/the TS can comment on within 4 weeks.

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

If not otherwise agreed, submitted documentation after their evaluation will be filed in the designation body or destroyed.

Decision

A condition for the designation is that all requirements of the designation body are met. Granting or rejection are administrative acts in the sense of the Administrative proceedings law.

Precondition for the designation of a Subscope (Prüfumfang) from Scope (Prüfgebiet) 01 "Complete vehicle"[36] is, as far as this is relevant for the Subscope (Prüfumfang), the designation of

- At least one test procedure out of each Scope (Prüfgebiet) (except 04, 06, 07, 09, 13)
- At least one test procedure out of Subscope (Prüfumfang) 04-01
- At least one test procedure regarding break systems (Subscopes (Prüfumfänge) 04-02 to 04-09)
- At least one test procedure out of Subscopes (Prüfumfang) 09-03, 09-05, 09-10

The TS will be designated for virtual testing in specified scopes if

- This is explicitly permitted in the relevant legislation
- Owns expertise for the properties to be tested are verified
- The process of validation of the virtual test is determined.

After granting the designation, the applicant gets a certificate of designation as given by the type of procedure. Normally the version (amendment) of the applicable regulation relevant from the point of view of designation is listed in the annex of this certificate. All following amendments of the regulation are enclosed into the designation. If the designation body publishes new relevant versions in the documents "Current issue of EC directives from the point of view of designation" and/or "Current issue of ECE regulations from the point of view of designation" [37], these and all following are not included in the designation. The designated body can extent the designation to these versions by a supplement.

In the certificate, only test procedures according to the Classification directory are listed, i. e. no other regulations (e. g. standards) are listed, which are possibly quoted in the default documents as per directory.

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[36] See Classification directory; to be downloaded from the internet.
[37] To be downloaded from the internet.

Surveillance

The on-site surveillance regularly consists of

- An office assessment in every third year
- **Witnessing of one representative test procedure for each Scope (Prüfgebiet) during the office assessment**[38]
- If relevant, the assessment of a representative test procedure at an external location. Other locations will be randomly assessed[38, 39].

The on-site surveillance (Ü-3 or Ü-W) must generally be finished by the end of the surveillance period. In exceptional justified cases, the procedure might be finished at a maximum of 3 months later.

Furthermore, it will permanently monitored to which extent approval relevant requirements and actions agreed with the KBA (exchange of experiences, trainings, meetings for analysis of test report quality, workshops, KBA attendance in type approval testing, interlaboratory comparisions) are realized.

Further surveillance measures, in particular for evaluation if designation rules are met in external locations, can be specified, in order to ensure the necessary confidence into the designation or find whether the designated body introduced effective measures in result of changes in the basis of the designation.

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

[38] Not applicable in case of designation on the basis of a certificate of accreditation, if the scope **(Prüfgebiet) is covered by the basis accreditation.**

[39] Locations with key activities (see footnote 34) will be assessed at least once in 6 years.

Annex 3

Basic requirements for personnel

Personnel working for the designated body, including contractually bound external personnel, must meet the requirements of ISO/IEC 17025 and/or ISO/IEC17020.

The following special conditions must be fulfilled:

Head of the designated body and his deputies:

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

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 designation body.
- At the time of designation, at least 3 years experience, within the last 5 years, of routine testing or surveillance of testing in the respective Subscope (Prüfumfang)[40] must be proven.
- Additionally for authorized signatories in Scope (Prüfgebiet) 01 (complete vehicle)
  - valid authorisation as officially certified expert (aaS) or
  - Test experience in all Subscopes (Prüfumfängen) as required for designation of TS for Scope (Prüfgebiet) 01 (see Annex 2, section "Decision"). Test experience must be documented for 3 years within the last 5 years, in an appropriate ratio.
- After designation: routine testing and/or surveillance of testing in the designated scope and/or proof of other measures for the preservation of qualification[41]

Technical expert

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

In justified individual cases, the designation body can permit exceptions.

The current proofs for the fulfilment of the requirements are to be kept at the designated body.

[40] According to the Classification directory of the designation body.
[41] At least one test per year and scope should be realized.

Annex 4

Categorization of Technical services

In addition to the requirements of relevant EC and ECE 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
  - There are equipment and facilities bound by contract, and the exclusive access to and right of disposal of these facilities is guaranteed.
  - **The leasing agreement between lessor and lessee (TS) guarantees the lessee's exclusive** access to and right of disposal of leased equipment and facilities. A transfer of the right of use by the lessor to a third party or own use by the lessor are excluded.
  - The validity of the designation is bound to the duration of the leasing agreement.

A TS designated in category A is allowed to perform or supervise tests included in its scope of designation also in other facilities, e.g. in facilities of manufacturers.

A TS will be categorized in category A for scope (Prüfgebiet) 01 if it has category A at least for one of the procedures out of subscopes (Prüfumfänge) required for scope (Prüfgebiet) 01.[42]

Categories B and D

- 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.

Additional focus for assessment:

- Maintenance of an effective procedure to guarantee quality of tests and test reports in all test locations
- Maintenance of an effective procedure to guarantee qualification of authorized signatories as required by these designation rules
- Evaluation of test equipment and facilities by the TS prior to each testing if relevant requirements of ISO/IEC 17025 are met. This is valid also in case of several tests on the same location.

[42] **See Annex 2, section "Decision"**

Annex 5

Fees

The amount of fees depends on the number of subscopes (Prüfumfänge) at the time of the application.

		L 1	L 2	L 3	L 4	L 5
Designation (full procedure)	Initial assessment	€9,400	€13,140	€22,910	€35,900	€46,310
	Ü-3	€3,110	€4,340	€7,570	€11,850	€15,290
	Ü-W	€4,700	€6,300	€10,400	€16,000	€21,470
Designation on the basis of a certificate of accreditation[43]	Initial assessment	€7,200	€10,200	€15,100	€22,000	€30,750
	Ü-3	€2,050	€2,430	€2,980	€3,780	€6,110
	Ü-W	€3,600	€4,270	€5,240	€6,650	€10,700

Fees include the assessment of one test procedure per scope (Prüfgebiet). For assessment of further test procedures 2 hourly rates[44] will be charged.

The amount of fees for bodies with subsidiaries depends on the situation (e. g. structure of the organisation and the QM system) and will be calculated separately.

Witness assessments at external locations are calculated according to expenditure on the 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.

In procedures "Designation on the basis of a certificate of accreditation", any expenses exceeding the minimum[45] will be charged in hourly rates.

[43] See also section 8
[44] 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
[45] For assessments, 5 hours will be taken as minimum for preparation and post-processing respectively.

Supplements

Alteration of administrative data (e. g. name, address, logo)	€120
Alterations of the scope: • Basic fee • **Per scope (Prüfgebiet)**	 €50 €70

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

Up to 3 certificates A4 German/English, not laminated	free
1st page • A4 • A3	 €10.00 €15.00
Following pages, per page	€1.00
Additional lamination, per page	€0.80
Languages other then German/English • Non-recurring extra charge • Translation	 €5.00 according to costs

Travelling expenses

The real travelling time will be taken for calculation[46] as long as this time was spent during the working hour window of the KBA[47], but not more than the following:

Region Germany	6 hours per assessor/expert
Region Europe[48]	8 hours per assessor/expert
Region World[49]	12 hours per assessor/expert.

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

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46 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**

47 at present from 06:00 (a.m.) until 20:00 (p.m.)

48 Mainland and Great Britain, Ireland, Malta, Cyprus

49 All other countries

Other

The fee for the evaluation according to ISO/IEC 17025 includes the designation as Technical service category A and D, that according to ISO/IEC 17020 - as technical service category B and D.

Further activities are calculated according to expenditure on the basis of the hourly rate. Information meetings on the premises of the designation body are not charged for.

No value-added tax is charged on these fees.

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This document replaces the Rules for accreditation, evaluation, designation and recognition of certification bodies, revision 01 from January 2009.

The present copy is not subject to updating. An up-to date version is placed for download on the internet at www.kba.de, **Motor vehicle technology – Designation of Technical services – Information for testing laboratories.**

For non-dated references, the newest version of the document is valid and referred to as such.

Binding is only the German version.