

(Category C)

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#### 1 Introduction

These designation rules lay out the requirements and the procedure for the designation of organisations as technical services in category C by the KBA (Kraftfahrt-Bundesamt).

The requirements for technical services are defined uniformly for all legal frameworks, unless stated otherwise in these rules.

All statements in this document, including the footnotes, annexes and associated documents/information, are binding, unless explicitly stated otherwise.

If a version is not explicitly cited, the versions valid at the time the service is provided or the evaluation is conducted apply.

The AND operation applies in all listings, unless otherwise stated.

The designation rules, their associated documents and additional information regarding the designation are published on the website of the Kraftfahrt-Bundesamt www.kba.de.

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

## 2 General

The Kraftfahrt-Bundesamt (KBA) carries out the evaluations, designation, notification and surveillance of technical services. Existing accreditations and designations from other member states are taken into consideration.

The designation is mainly conducted on the basis of the following legal provisions:

- Regulation on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles Regulation (EU) 2018/858
- Regulation on the approval and market surveillance of agricultural and forestry vehicles Regulation (EU) 167/2013
- Regulation on the approval and market surveillance of two- or three-wheel vehicles and quadricycles
   Regulation (EU) 168/2013
- UNECE convention from 1958
- National regulatory acts

and relevant successor regulatory acts.

Among others the German Administrative Proceedings Act (VwVfG, Verwaltungsverfahrensgesetz), the EU General Data Protection Regulation (GDPR), the German Federal Data Protection Act (BDSG, Bundesdatenschutzgesetz), the German Federal Fees Act (BGebG, Bundesgebührengesetz) and other relevant regulatory acts apply.

A proceeding to evaluate and designate a technical service by the KBA is conditional on:

- Legal registration in the European Union or in a third state in the sense of Regulation (EU) 2018/858 Article 68 (5)
- Proof of the legal identity of the technical service or of the superordinate body except for technical services of the approval authority
- Proof of liability insurance for the activities to be conducted
- Recognition of these designation rules, including the associated documents and information.

The designation of technical services serves to prove the competence of these bodies for the evaluation of QM systems according to German and international regulatory acts and to increase confidence in the audit results of these bodies. This is certified by a notification in form of a designation certificate. Such designation is a precondition for activities in the procedures for approval and market surveillance of the KBA.

Decisions on initial and re-designation, confirmation, suspension and withdrawal of the designation, as well as on the designation proceedings, are taken by the KBA Designation Council.

#### 3 Definitions

The definitions pursuant to Regulation (EU) 2018/858 and, where reference is made to EN ISO/IEC 17021-1, requirements of this standard apply for these designation rules, including the annexes and associated documents/information; if applicable they are specified below. References in Regulation (EU) 2018/858 are always to be understood in relation to the currently valid version of EN ISO/IEC 17021-1.

In addition, the following terms are used:

**Accreditation:** Confirmation by an accreditation body pursuant to Regulation (EC) 765/2008 that the certification body is competent to evaluate other organisations' fulfilment of a certain standard, using a quality management system in accordance with EN ISO/IEC 17021-1.

**Approval-relevant requirements (ARR):** The KBA requirements for manufacturers and technical services in the German type approval procedure.

**ARR auditor:** Persons at the technical service who fulfil the requirements of Annex 1 and who were appointed by the head of the technical service to audit the approval-relevant requirements of the KBA.

**BGebG:** German Federal Fees Act

**Branch:** Site of a technical service that works in accordance with the unified QM system of the technical service. At least one auditor is organisationally assigned to the branch. The branch is listed on the designation certificate and is included in the surveillance.

**CoP:** Conformity of Production

**Designation:** The issuing of the authorisation to carry out, as a technical service, evaluations of management systems that can be recognised in the KBA type approval and market surveillance procedures. The term "recognition" used in this context in the EC-VAO (EC Vehicle Approval Ordinance, EG-FGV) has the same meaning.

**Designation Council:** Body of the KBA that decides on significant aspects of the designation procedure.

**Designation procedure:** Procedure for designation through initial evaluation, monitoring and re-evaluation of technical services by the KBA.<sup>1</sup>

Procedure	Accredited (EN ISO/IEC 17021-1 regarding QM)	Evaluation by the KBA
Designation based on a full accreditation (BVA)	Full	ARR
Designation without accreditation (BOA)	No	Full

For a designation based on a full accreditation it does not matter for which branches the accreditation was granted. Several accreditations may be considered.

Designation by another EU member state can be considered equivalent to accreditation.

**Evaluation:** Inspection of technical services through on-site assessment or other measures and analysis of the results of this inspection.

**Exchange of experiences, internal of the technical service:** Face-to-face event that aims to ensure a high quality and a consistent application of the process to evaluate the approval-relevant requirements at the manufacturer.

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The designation procedure based on a partial accreditation (BTA) is not relevant for technical services category C.

**Finding:** Result of the evaluation of the collected evidence related to requirements. It indicates whether the requirements were fulfilled. In addition to the description of the fulfilment of a requirement, a distinction is made between major non-conformity, minor non-conformity, opportunity for improvement and positive finding:

**Major non-conformity**: Non-conformity regarding at least one of the following items:

- Lacking or insufficient implementation of requirements of the basic documents for designation
- Substantial impairment of confidence in an effective QM system that corresponds to the designation rules
- Substantial doubts about the quality of audits and certification decisions
- A non-conformity regarding the effectiveness of corrective measures from the previous
   5 years that has been repeatedly found.

A major non-conformity results in a suspension procedure if it is not addressed in a timely manner, or it prevents (re-)designation. In general, settlement will be checked by an on-site assessment.

**Minor non-conformity:** Shortcomings in the fulfilment of requirements of the basic documents for designation that do not fundamentally undermine confidence in the existence of an effective quality management system and in proper evaluation of approval-relevant requirements. Opportunity for improvement that has not been evaluated results in a minor non-conformity in relation to the improvement process. Minor non-conformities prevent initial designation. They lead to a suspension procedure if they are not settled in a timely manner. If the number of minor deviations indicates that the quality management system has failed, the consequences are the same as for a major deviation.

**Opportunity for improvement:** Requirements are in general fulfilled but there is room for improvement.

**Positive Finding:** Fulfilment of the requirements beyond what is expected.

**Headquarters:** Location of the technical service from which the implementation of the rights and obligations of the technical service resulting from the designation are organised and monitored.

IAF: International Accreditation Forum

Joint team: Assessor team pursuant to Regulation (EU) 2018/858 Article 73 para. 4

**Manufacturer:** Type approval holder or applicant for a type approval (see definition in Regulation (EU) 2018/858). In the context of these designation rules, manufacturers are equivalent to other customers of the technical service for whom the fulfilment of the approval-relevant requirements is to be certified.

**Notification:** Reporting of the designation of the technical service to the European Commission and to the Secretariat of UNECE.

**On-site assessment:** Inspection in the premises of the technical service (headquarters and/or branch of the technical service)

**QM:** Quality management

**Restriction:** temporary or permanent reduction of the scope of designation by the KBA or at request of the technical service.

**Scope:** All sets of management systems and branches which are included in the designation of the technical service or for which the technical service can request a designation.

**Surveillance**: Verification of the initial evaluation pursuant to Regulation (EU) 2018/858, Article 76. In addition to the continuous evaluation of the obligations resulting from the designation and the other information about the activity of the technical service, it includes onsite evaluations. The intervals in which on-site evaluations are carried out depend on the demonstrated stability that the technical service has achieved. They occur at the latest **after 30 months (Ü)**, less comprehensive than initial or re-evaluation, and after another 30 months as **Re-evaluation (ÜW)** based on the initial evaluation and taking into account the findings of previous evaluations for designation renewal. Additional measures may be defined by the KBA.

**Suspension:** temporary partial or full revocation of the rights associated with the designation by the KBA.

**TAP:** Type approval procedure

**Technical service (TS)**: Organisation or body that was designated by the approval authority to conduct evaluations of management systems that can be recognised in the KBA type approval and market surveillance procedures. Here and below, the term "technical service" also applies to applicants in the designation process.

**Termination of the designation:** permanent and full revocation of the rights associated with the designation by withdrawal or revocation by the KBA (§§ 48 and 49 VwVfG) or termination at request of the technical service.

**UNECE:** United Nations Economics Commission for Europe

**VwVfG:** German Administrative Procedures Act (Verwaltungsverfahrensgesetz)

**Witness assessment:** Participation in an audit by employees of the KBA, with the aim of assessing the following:

- Proper auditing of approval-relevant requirements
- Expertise of auditors
- Realization of other requirements of these designation rules and
- Implementation of the technical service's internal processes during the audit.

# 4 Evaluation, designation, renewal of designation and surveillance of technical services

The procedure for the designation of technical services by the KBA is described in **Fehler! Verweisquelle konnte nicht gefunden werden.** 

The applicant applies for designation as technical service and the following monitoring over 5 years.

On the basis of the submitted application documents and under consideration of existing accreditations and designations by other type approval authorities, a decision is made on whether an evaluation by a joint evaluation team pursuant to Regulation (EU) 2018/858 Article 73 or an evaluation only by assessors of the KBA should be conducted, and on the scope of the assessment.

Following a positive evaluation of the certification body and its branches, a decision is made on the designation as a technical service for the conducting of evaluations of management systems which can be recognised in the KBA type approval procedure.

The designation is only granted when all the KBA's requirements are fulfilled. It may be granted conditionally pending a successful witness assessment.

The designated technical service receives an information in form of a designation certificate and is notified

Technical services are continuously monitored to ensure that the requirements in the designation rules are observed. If the designation is based in full or in part on an accreditation or other designation, the technical service must submit the corresponding certificate and, if requested, the assessment reports of the respective body, in German or in English.

The KBA conducts an on-site surveillance at the latest every 30 months to ensure that the technical service continues to adhere to the requirements.

The validity of the designation is restricted to five years. If an accreditation or another designation was taken into consideration, the validity of the designation is bound to the continuance of the accreditation/designation in the relevant area.

At the end of its validity, the designation as a technical service is on request only renewed after the KBA has determined that the technical service continues to fulfil the designation rules of the KBA. For re-evaluation, the findings of previous evaluations are considered.

#### 5 Notification

The designated technical service is notified to the European Commission and to the UNECE Secretariat. In addition, the designation is published on the internet.

## 6 Amendments to designation

Technical services may apply to amend an existing designation. For this purpose, they must use the form "Application for designation for technical services (C)". Changes may be restrictions or extensions to the designation. The KBA decides on the scope of the assessment.

Changes are notified.

#### 7 Restriction, suspension, termination of designation

The technical service may, at any time, by application, request the complete or partial suspension or termination of the designation with immediate effect.

If the KBA finds that a technical service no longer fulfils some or all of the requirements of the designation rules, it may restrict, suspend or terminate the designation depending on the extent of the failure to fulfil these requirements.

During the period of the restriction or suspension, the designated body has the opportunity to restore the necessary conditions for the designation.

A restriction or suspension procedure is initiated in particular if:

- The designation rules, in particular the obligations pursuant to chapter 9.2, were violated
- A non-conformity was not satisfactorily settled on time
- The number of minor non-conformities leads to the conclusion that the quality management system has failed
- The conditions for the designation determined in the application documentation and/or in the assessment are no longer present in part or in full
- Surveillance measures could not be carried out in the planned time frame, and the designated body is responsible for this situation
- The methods of the designated body or of individual employees at this body raise doubts about their competence, independence, integrity or reliability
- There are justified reasons to assume that fraudulent behaviour takes place in the scope of designation or in the approval procedure or that the technical service purposefully provided false information or withheld information
- The technical service requests this.

A suspension is limited to at most one year. The KBA may define conditions in connection with a restriction or suspension of a designation and monitor their fulfilment. Generally, a restriction or suspension is lifted only after an on-site assessment has confirmed the effectiveness of the management system. Additional on-site assessments or other surveillance measures may be required to verify the sustainability of undertaken corrective measures.

While a restriction or suspension is in force, the designation may not be referred to in the relevant area. Corresponding documents may no longer be used and may have to be withdrawn. Restrictions and suspensions are communicated by official notification.

The termination of the designation or of a part of it may be caused, amongst others, to the following reasons:

- After the end of the suspension of a designation, if the conditions necessary for the designation have not been restored
- Upon revocation or abandonment by the KBA. Revocation occurs when the conditions for the designation determined in the application documentation are no longer present in part or in full and were not restored within the specified period
- Following an amendment to these rules, if the designated body has appealed the changes within one month but the appeal could not be satisfied
- As soon as the technical service or the organisation to which it belongs becomes a manufacturer and the designation of a manufacturer is not explicitly permitted by the relevant regulatory acts
- If the technical service ceases operations in the designated scope
- If changes to legislation require this
- Upon the request of the technical service.

The Designation Council is always involved, except in cases where the technical service itself has requested the suspension or termination of the designation or parts thereof, or has ceased operations in the relevant scope in part or in full.

The KBA notifies the European Commission and the UNECE Secretariat of every restriction, suspension and termination of a designation.

In the event of suspensions and of terminations resulting from suspensions, the KBA submits to the EU Commission a report with the findings on the failure to observe the requirements within two months. If required for the safety of vehicles, systems, components or independent technical units that are already in circulation, the KBA will in its report ask the affected approval authorities to take any required measures.

# 8 Appeal

Decisions of the KBA may be appealed. Appeals shall be submitted within a month of notification of the decision to the following address in writing or for record:

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

# 9 Rights and obligations of the technical service

#### 9.1 Rights of the technical service

The technical service has the right

- Access all services of the KBA related to the designation and type approval procedure of the KBA
- Unbiased, factual and competent information on the procedure
- Equal treatment with other applicants
- Well-trained, competent assessors and contact persons
- Reject the assessors proposed by the KBA
- Confidentiality and discretion regarding company documents and information that are disclosed, transmitted or submitted to the assessor as part of the procedure
- Designation and notification to the appropriate bodies
- Publishing of the designation by the KBA
- Use the certificate and the logo for the designation in documents and advertising material for the stated area of applicability
- Appeal decisions of the KBA.

#### 9.2 Obligations of the technical service

The technical service is obligated to

- Acknowledge these designation rules and to fulfil their requirements. In particular proof of
  its observance of the norm EN ISO/IEC 17021-1 and of the approval-relevant requirements
  shall be provided. Additional conditions of the KBA regarding the type approval and market
  surveillance procedures must be fulfilled.
- Carry out the activities for which it is designated independently and with the highest degree of professional integrity and to continuously maintain the requisite competence
- Use only competent staff with the requisite training and a sufficient level of experience. The
  minimum requirements for staff listed in Fehler! Verweisquelle konnte nicht gefunden w
  erden, must be observed.
- Bear full responsibility for the works that are carried out in its designated branches, regardless of where they are located
- Subcontract for approval-relevant requirements only in exceptional cases and only after the prior agreement of the KBA on a case-by-case basis
- Use information for evaluation of the fulfilment of approval-relevant requirements by the manufacturer only from technical services that were also designated by the KBA at the time of the certification
- Independently update internal procedures for conducting its activities in line with the state of
  the art and the designation rules and with any other requirements of the KBA, and to
  provide evidence of the transparency and repeatability of the procedures

- Regularly evaluate the quality of conducted audits and other surveillance measures and to include the IS-CoP results in this process
- Determine causes for deficiencies together with the KBA and to remedy these
- Actively participate in the various forms of exchange of experiences, trainings and joint workshops
- Inform the KBA pursuant to Annex 4
- Provide the KBA with the requisite collaboration, and in particular to grant to the assessors and other representatives of relevant approval authorities access to all business premises and information, insofar as this is required for the designation or the approval to be issued
- Enable the conducting of witness assessments by the KBA. This includes obligating manufacturers to enable the participation of the witness assessor
- Not publicly create any false impressions about the awarded designation and to observe the rules governing the use of the designation logo. Designated and not designated services must be clearly distinguished.
- Not use the designation in a manner that harms the reputation of the KBA
- Regularly carry out measures to ensure the quality of audits, based on internal evaluations and risk assessments
- Conduct internal audits of the QM system and of the activity of the auditors at appropriate intervals
- Review by the management the fulfilment of the obligations of technical services, the observance of the approval-relevant requirements and the quality of tests at least once every twelve months
- Pay fees pursuant to chapter 12 without undue delay.

The KBA may define additional obligations, in particular upon request by other approval authorities that use the designation.

# 10 Obligations of the KBA

The KBA is obligated to

- Conduct the designation procedure according to these designation rules
- Guarantee the rights of the technical service
- Inform the technical service sufficiently and in a timely manner about changes to the
  procedure, changes to the designation rules, about sanctioned interpretations of regulatory
  acts, and about other relevant issues as part of exchange of experience, online at
  www.kba.de or in another manner
- Accept Reports on CoP from the technical services designated by the KBA that fulfil the requirements (Annex 2) in the type approval procedure
- Address complaints about the technical service if these are directly sent to the KBA.

# 11 Confidentiality, discretion, data protection

The employees of the KBA and external persons acting on its behalf deal confidentially with all information obtained in connection with the designation of the concerned technical service and analyse it only for the agreed purpose.

Unless otherwise agreed, submitted documents are saved (stored) at the KBA and destroyed once they are no longer needed there.

Documentation and information provided by the technical service, as well as any other information arising from the designation procedure, are not disclosed to third parties if the affected party has not explicitly consented to this, unless legal provisions or these designation rules require disclosure without explicit consent.

The required personal data collected to fulfil the task of designating the technical service are stored digitally and in other forms in accordance with the German Federal Data Protection Act and the EU General Data Protection Regulation. Procedure-related data are also stored digitally and in other forms. Data safety and data protection are ensured.

By signing the application for designation and the associated acknowledgement of these rules, the technical service consents to the storage, processing and disclosure of these data in the scope described here. Explicit consent is requested for any use of the data that goes beyond this.

As part of the process of notification and publishing of the designation under www.kba.de and upon request, the following data are disclosed.

- Name and address of the technical service
- Contact information (e-mail address, responsible persons of the technical service and their position)
- Scope of designation.

The relevant bodies of the EU and UNECE, the Ministry responsible for the KBA and other bodies may, upon instruction by the supervisor in charge of the organisational unit responsible for the designation or by the Ministry, be provided with additional information if there is a legal justification to do so.

In accordance with the provisions of the KBA data protection concept the data are deleted or destroyed.

#### 12 Fees

An obligation to pay fees arises upon submission of the application and regardless of the result of the procedure. The amount of fee is defined by the German Federal Fees Act (BGebG) and associated regulations in the amendment valid at the time of service provision.

Sliding-scale fees are defined in Annex 5. The fees stated there may be adjusted within the defined sliding scale depending on the actual costs.

Expected fees may also be requested in advance.

Fees and travel expenses (transport, accommodation, daily allowance etc.) and other disbursements will be raised by invoice. Any due bank charges (e.g. for transfers from abroad) are to be paid by the technical service.

#### 13 Other

Side-agreements must be documented in writing.

The designation may not be transferred to another legal entity.

Except in cases of wilful intent or of gross negligence, the designated body must hold harmless the Federal Republic of Germany against all claims of third parties for damages that arise from the execution of activities associated with the designation.

#### Associated documents:

- Application for designation for technical services (C)
- Requirements catalogue Assessment of technical services (C)
- Questionnaire on surveillance of designated bodies
- Questionnaire on preparation of witness audits
- Template for reporting operations regarding approval relevant requirements
- Rules on the use of the designation logo
- Application E-Typ (designation)
- Quick Guide E-Typ (designation)
- User manual E-Typ (designation)
- Retention periods for approvals and relevant quality records
- KBA Privacy Declaration
- Stipulations at www.kba.de, in particular
  - Technical portal of the Type Approval Department including
    - Sanctioned interpretations for certification bodies
    - Material for exchange of experiences with technical services
    - Tips for auditing approval relevant requirements
  - Market surveillance Department

Annex 1

## Designation procedure for technical services

#### 1 Application for designation

Applications for a designation or for changes to or termination of a designation must be submitted in the form " Application for designation for technical services (C)" in writing to:

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

All documents must be submitted in German. They may also be submitted in English following the agreement of the KBA.

The forms provided by the KBA for applications are available at www.kba.de.

The additional documents requested in the application, as well as applications to change the designation, may, unless explicitly required otherwise, be submitted by e-mail or in another manner.

The application must be signed by a properly authorised representative of the legal entity that is of relevance to the technical service.

The application documents must be plausible. The information must in any case document the fulfilment of the requirements in norms or other relevant regulatory acts. By submitting the application, these designation rules and the KBA's privacy declaration are acknowledged.

The application is rejected if the conditions for the procedure for evaluation and designation pursuant to chapter 2 are not fulfilled or

- The KBA is not the responsible body or
- The demands of the applicant cannot be fulfilled by the KBA or
- No agreement on the services to be provided or the fees can be reached.

#### 2 Preparation of the evaluation

The submitted application and the associated documents are verified and evaluated by the KBA. The submitted accreditation certificates, designation certificates from other type approval authorities as well as the respective evaluation reports are considered. Consequently, the extent of further measures required for the evaluation is determined.

The fulfilment of the approval-relevant requirements is always be evaluated by the KBA in an on-site assessment. This does not preclude an evaluation pursuant to Regulation (EU) 2018/858 Article 73 paragraph 3.

For procedures without accreditation (BOA) the evaluation is conducted by a joint evaluation team that is appointed by the KBA in accordance with Regulation (EU) 2018/858 Article 73. The KBA will request that the European Commission assign team members. If the technical service that is to be designated is not headquartered in Germany, the EU Commission is asked to consider this in the team building process

The technical service will, upon request, be informed of the current position of the assessors if these are not employees of the KBA.

The KBA, in coordination with the technical service and evaluation team, should one have been formed, sets a date and a schedule for the evaluation; this schedule is also in harmony with the surveillance and re-evaluation programme.

The technical service must provide the KBA with the documentation requested for the assessment at the latest one month before the date of the assessment. The documents are made available to the evaluation team. Non-conformities determined in the documents are reported to the technical service to be evaluated. The execution of the evaluation may be conditioned on the remedy of these non-conformities.

#### 3 Evaluation

For initial and re-designation, the evaluation of the technical service always includes an on-site assessment by the KBA and a joint team to be formed if necessary.

As part of this assessment, the fulfilment of the designation requirements is evaluated based on the criteria in the Requirements catalogue - Assessment of technical services (C).

Issues that have already been accredited or designated are generally only evaluated as part of a document review.

In general, the evaluation includes the following:

- The evaluation of approval-relevant requirements and requirements of standards on which the designation is based
- The evaluation of the branches. The extent of the evaluation of the branches is determined at the discretion of the KBA.
- The witnessing of an audit in the scope "Approval-relevant requirements", which is selected at the KBA's discretion.
  - Witnessing may take place within one year after the provisional decision on initial designation. The provisional initial designation guarantees the full ability to act as a technical service, but is conditional and can be revoked with retroactive and future effect if a major non-conformity is found during witnessing and the subsequent suspension process does not yield a positive result.

The assessors will be provided all requested information and documents and shown all requested processes by competent employees of the technical service.

The technical service is informed of determinations during the on-site assessment. The on-site assessment concludes with a meeting of the evaluation team and the technical service. The evaluated technical service has the opportunity to ask questions regarding the findings and to comment on the assessment.

Following the assessment, the technical service will get a comprehensive written evaluation report. This report contains information on the competence and on the observance of the requirements as well as significant findings. If no desired changes have been enforced within two weeks from the report's reception, the report is deemed accepted.

In the presence of non-conformities, a root cause analysis and the corrections and corrective measures must be reported within the given time, and the agreed evidence of execution must be submitted. If necessary, a follow-up on-site assessment will be carried out.

The evaluation in the re-procedure must generally be concluded by the end of the validity of the designation. In justified exceptions, the procedure may be concluded up to 3 months later if the designating body agrees.

#### 4 Decision

If the framework regulatory acts foresee this, after the evaluation report has been accepted by the technical service and the Reports of findings are completed, a summary report as required by the respective regulatory acts is submitted to the respective bodies. Upon request, it is also submitted to the type approval authorities of other member states. The KBA will answer the open questions and concerns and will send, if applicable, any additional information within four weeks.

Based on these submitted documents, within four weeks the EU Commission and/or the other type approval authorities may submit a recommendation regarding the designation of the technical service. After this deadline, the KBA decides on the designation of the technical service. The KBA takes into account any recommendation that was possibly received. Within a period of two weeks an explanation is provided to the EU Commission or to the member state if a recommendation was not followed.

The KBA's Designation Council decides on the designation based on the evaluation report and all other relevant information

- In the initial procedure
- In re-procedures, if any recommendations that were received are not to be followed.

The technical service receives notification of the granted designation in form of a designation certificate. This certificate is valid for five years from the date of designation.

In cases where the evaluation for re-designation is finished after the end of the validity of the designation, the validity of the new designation certificate is limited to the time remaining from the date of expiry of the previous designation.

#### 5 Surveillance

Information on the activity of the technical service is evaluated continuously and through on-site surveillance by the KBA.

In such on-site surveillance, the KBA evaluates whether the technical service continues to fulfil the designation requirements.

On-site evaluations for surveillance purposes are generally less comprehensive than those prior to designation or associated with re-designation.

On-site surveillance of the headquarters must generally be finished by the end of the surveillance period of 30 months. Additional branches are assessed on-site at least once during the validity of the designation.

Among others, surveillance also includes

- The check of submitted Reports on CoP
- At least once every 5 years an on-site evaluation of the internal exchange of experiences of the technical service
- The evaluation of decision-making processes regarding the fulfilment of approval-relevant requirements
- The evaluation of participation in activities recommended by the KBA
- The review of other information about the technical service.

The technical service is assigned to a category based on the number of certificates and similar procedures related to the type approval procedure. Sub-certificates are considered as own procedures in this context. Witness assessments are conducted at the following frequencies:

Category	Procedures	Witness assessments in 5 years
Z1	bis 20	2
Z2	21 - 50	3
Z3	51 - 100	4
Z4	above 100	5

During initial designation, the technical service is preliminarily assigned to category Z1. The classification is confirmed with future effect if it is appropriately based on the number of designation-relevant processes.

If the designation includes other branches in addition to the headquarters, further witness assessments of audits that are organised by these sites may be required.

The choice of audit is at the KBA's discretion. If possible, audits are selected for witnessing based on the following criteria:

- Changing and significant specifics regarding approval-relevant requirements
- Evaluation of various, possibly also new auditors
- Requirements for auditors (requirements for planning and execution of the audit, foreign language (if relevant, at least once in 5 years)
- Suitability for demonstrating the effectiveness of corrective actions after prior nonconformities.

For the preparation of witness audits, the requested documents must be submitted to the KBA on time.

Additional surveillance activities may take place in order to ensure the necessary confidence in the designation or in order to determine whether the technical service has introduced effective processes as a result of the changes to the designation basis or after non-conformities.

In result of surveillance, a decision is made on the continuance of the designation.

At the latest two months after the conclusion of an on-site assessment for surveillance after 30 months (except witness), the KBA will report to anybody foreseen by a respective framework regulatory act.

Annex 2

# Requirements for the process of evaluation of the fulfilment of approval-relevant requirements by the manufacturer in the procedure "Report on CoP"

#### 1 Information of the manufacturer by the technical service

- 1.1 The manufacturer must be informed of the rights and obligations of the approval owner and the approval authority. It must be explained to the manufacturer that these rights and obligations apply regardless of a successful certification.
- 1.2 The manufacturer must be informed that the KBA has the right, at any time to request audit reports, quality records and other documents relevant to the type approval.

# 2 On-site audit of the QM system

- 2.1 When contacting manufacturers and in advance of each audit, it must be clarified the type approvals of the manufacturer (especially with the KBA) or whether the manufacturer intends to apply for type approvals in the foreseeable future.
- 2.2 Generally at least 10 % of the time pursuant to IAF MD5, but no less than 4 hours, shall be planned for each branch to be audited for the on-site auditing of approval-relevant requirements pursuant to the "Report on CoP". The calculated time can be reduced to 16 hours for initial and re-audits and to 8 hours for surveillance audits.
- 2.3 At least one person from the audit team<sup>2</sup> must be authorised as an auditor for approvalrelevant requirements. At the same time, he or she must have demonstrated the requisite technical competence for the company to be audited.

This person must be involved in the audit phases that are most important to the approval procedure.

The lead auditor is responsible for ensuring that all other auditors have a general overview of the KBA requirements for the company's management system and consider these in their auditing. The lead auditor uses the auditor for approval-relevant requirements to inform the audit team.

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Not necessarily the lead auditor.

2.4 All approval-relevant requirements must be audited on-site. The selection of the approval objects to be audited should be done in accordance with the explanations in the example for the CoP report and must be planned, in case of a certification or other procedures with regular audits, at least for an entire certification period or for the duration of the other procedures.

The programme must be documented. It is possible to cluster approval objects whose nature is closely related. The objective shall be to audit all types of approval objects during one certification period if possible, and to audit all approval objects over a longer period of time.

Following a risk analysis regarding

- Critical or approval-relevant product and system characteristics,
- Process parameters,
- Fulfilment of specific requirements from regulatory act, approval, type approval procedure,

the audit must be planned and executed in a process-oriented and company and approval object-specific manner.

- 2.5 Additionally to general requirements of automotive legislation, the auditor with authorization according to these designation rules must know further approval relevant requirements and must on-site check their implementation in the client's organization.
- 2.6 Additionally to the systematic evaluation of the QM system, the audit on the client's premises must at least for the chosen samples also cover the check if approval data (not only such data which relates directly to the product) is up-to-date. It must also include the assessment if applicable legislative documents are up-to-date and available.
- 2.7 If a company produces at several sites, it is not required that approval relevant requirements are annually assessed at all relevant sites. It is sufficient to audit this topic only in those locations, where, according to the audit program (site sampling), the ISO-audit is carried out. However, in general it must be ensured that all approval-relevant sites are audited at least once in 3 years.
- 2.8 If the approval owner (A) manufacturers products that are to be approved/that are approved, or substantial parts thereof, in other, legally independent companies (B), it must be evaluated to what extent the approval owner fulfils its obligations arising from its approval regarding the production at B. It is generally sufficient for the type approval procedure of the KBA to evaluate the interface to B. An auditing of B is generally not necessary.
- 2.9 A "Report on CoP" is created after each on-site QM-audit.

If some approval-relevant processes could not be evaluated due to objective circumstances, "ne" (not evaluated) is to be entered in the respective fields together with a comment.

#### 3 Evaluation of the determinations reached

3.1 The classification of the results takes place in accordance with the requirements of ISO/IEC 17021-1.

In addition, a major non-conformity is defined as follows:

- There is a risk that
  - An unapproved product is brought into market with an approval sign or that the impression is created that it is approved, or
  - A non-conform product can be brought into market, or
  - Malfunctioning products cannot be recalled.
- The approval holder does not comply with the stipulations given in the approval and does not immediately implement adequate corrections and corrective actions.
- Other serious violations of approval-relevant requirements.
- 3.2 An ARR auditor of the team checks the settlement of approval relevant requirements related non-conformities. If this cannot be realised in an appropriate timeframe, the check can be realised by another ARR auditor together with the team leader.

# 4 Decision on the fulfilment of the approval-relevant requirements

4.1 The result of the evaluation is documented in the CoP report.

In procedures in which the technical service monitors the fulfilment of the requirements itself for a defined time period, it can additionally issue an attestation for the fulfilment of the approval-relevant requirements. Open major non-conformities prevent the issuance of such attestation. The validity of the attestation must be limited to the period of the surveillance by the technical service. This attestation must contain the following or analogous information:

- "The (quality) management system fulfils the approval-relevant requirements."
- Sufficient general description of the approval objects
- Registration number of the KBA designation and/or designation logo.

In case that the fulfillment of all approval relevant requirements to a manufacturer cannot be completely evaluated, but a separate attestation shall be issued for that organization, exclusions must be clearly described.<sup>3</sup>

This attestation may generally only list the types of approval objects for which at least one product was audited for fulfilment of the system requirements. Exceptions (e.g. for a large number of various types of approval objects) must be agreed with the KBA.

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E.g. "The quality management system fulfils the approval-relevant requirements for a production site without type approval."

If the evaluation was carried out as part of a certification process, it must be bound to the ISO 9001 certificate or similar standards, such as e.g. VDA 6.1, IATF 16949, of the own certification body. It may only relate to matters to which the main certificate pertains.

4.2 The persons who make the decision on the procedure should not have taken part in the audit, if possible.

#### 5 Other

Additional requirements or clarifications can be found in the Requirements catalogue - Assessment of technical services (C) of the designation body.

Annex 3

## **Basic requirements for personnel**

#### 1 General information

The technical service must employ competent personnel with appropriate training and experience. This includes the contractually bound external auditors.

In addition to the personnel requirements of EN ISO/IEC 17021-1, at least the approval-relevant requirements listed below must be fulfilled:

- The process of authorization, maintenance and surveillance for/of the scope "Approval relevant requirements" as well as of technical expertise is to be defined and documented by the technical service according to the requirements in these rules. At least the following must be determined regarding the knowledge, capabilities and skills for the personnel participating in the scope of designation (leading, auditing, administrative personnel, decision-makers/veto-persons):
  - Required competence
  - Competence criteria
  - Methods to achieve and maintain the necessary competence
  - Type of the initial evaluation and of the evaluation of the maintenance of competence
  - Records of the evidence.
- The Head of the technical service appoints the auditors, and the veto-persons, if any, in writing. If the KBA has not defined any specific requirements, the Head defines the requirements.
- Evidence for the fulfilment of the criteria and for implemented measures must be stored at least for the current and the subsequent certification period of any of the auditor's clients.

The fulfilment of the requirements for the authorisation criteria (chapter 2 of this annex) and for the maintenance of the competence (chapter 3 of this annex) is monitored under the responsibility of the Head of the technical service.

The KBA may set further requirements for the approval and the continuous monitoring of the competence. In justified individual cases, the KBA may permit deviations.

If these designation rules are not observed, the KBA may require that individual persons have their authorisation as auditors for approval-relevant requirements withdrawn.

#### 2 Eligibility criteria

- 2.1 Head of the technical service and his/her deputy
  - Completion of a higher education degree at a university, applied university or equivalent institute of higher education.
  - Basic knowledge of approval-relevant requirements
  - Basic knowledge of the evaluation of management systems.

#### 2.2 Auditors

- Completion of a higher education degree of relevance to the audited processes at a university, applied university or equivalent institute of higher education
- Demonstrated competence as a QM auditor
- Evidence of the requisite technical expertise
- Evidence of current knowledge of the approval-relevant requirements through completed training at the KBA or at a training provider confirmed by the KBA. The training should not have been completed more than 36 months before the authorisation.
- Completed monitoring of an audit to evaluate the fulfilment of approval-relevant requirements.
  - This authorisation monitoring for auditors may take place during the first 3 audits if the (temporary) authorisation is preceded by a sufficient practical test of competence (including skills and abilities).

#### 2.3 Persons authorised for monitoring, veto-persons

- Authorisation as lead auditor to evaluate the fulfilment of approval-relevant requirements
- At least 3 audits to evaluate the fulfilment of approval-relevant requirements.

#### 3 Additional competence criteria after appointment

- 3.1 Head of the technical service and his/her deputy
  - Dealing with at least one procedure in the context of the KBA designation within
     12 months
  - Should the Head not fulfil these requirements, a veto holder must absolutely be included in the decision process for appointing auditors and the decision process for certification procedures. Their decisions may not be changed in a way that is favourable to the applicant.

#### 3.2 Auditors

- Conducting at least one audit within 12 months
   The interval between 2 audits under KBA designation may be at most 24 months if the auditor's competence in the approval-relevant requirements is demonstrably confirmed before or during the audit.
- Annual, active participation in internal exchange of experiences/internal training
- Evidence of current knowledge of the approval-relevant requirements through completed training at the KBA or at a training provider confirmed by the KBA that is not older than 60 months after completion of the transition phase.

#### 3.3 Persons authorised for monitoring, veto-persons

As for auditors, but acts as lead auditor.

#### 4 Monitoring of competence

The technical service is obligated to make sure that every ARR-auditor regularly undergoes a monitoring procedure. The technical service must be able to justify that the interval is appropriate.

The monitoring must include also preparation and follow-up activities of the audit. In addition to the general requirements for auditor qualification, the following in particular must be evaluated:

- Knowledge of the type approval and market surveillance procedures of the KBA
- Knowledge of the basic approval procedures (in particular regarding requirements for CoP), knowledge of the approval object (including approval-relevant risks in the production process)
- Process-oriented and company-specific auditing of approval-relevant requirements, in particular regarding
  - Ensuring approval-conform production
  - Planning, execution and evaluation of tests of approval-relevant product characteristics
  - Requirements for production at external production sites
  - Possibility of recall of non-conforming products
  - Information flow regarding approval-relevant aspects.

In justified exceptions, a monitoring in non-ARR audits in acceptable for QM auditors if knowledge, capabilities and skills in approval-relevant requirements are additionally demonstrated in a close to practice examination.

Monitoring by the co-auditor is permissible. In this case, at least those audit parts, which are essential for evaluation of approval relevant requirements, but not less than 50 % of the overall audit time, must be monitored.

The on-site monitoring must be completed by a check of a sufficiently large sample of the audit documentation. Initial, surveillance and re-audits must be considered.

At least every 3 years, the technical service must evaluate the auditors' knowledge of approvalrelevant requirements and audit focus points. Knowledge of staff in other key functions must be evaluated at least once in 3 years as part of internal audits or similar measures.

The monitoring and its results must be recorded.

#### 5 Internal exchange of experiences

Every year, the technical service conducts at least one exchange of experiences as a face-to-face event of at least 2 hours with the following thematic focus:

- Discussion of the application of approval-relevant requirements by the technical service
- Teaching/refreshing of knowledge on the current approval-relevant requirements
- Teaching/refreshing of knowledge on approval objects and on production processes for their manufacture.

All the technical service's auditors are obligated to participate in the exchange of experiences annually.<sup>4</sup>

If the management of the technical service is not also an auditor, he or she is at least expected to have some knowledge of the contents of the respective exchange of experiences. It is recommended to include also other personnel of the technical service in the exchange of experiences.

The KBA reserves the right to assign subjects.

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In case of activities for several technical services, participation at each technical service is required at least once every 3 years. In the remaining years, the auditor is obliged to inform himself/herself about the content of the exchange of experiences of the other technical services relevant to him/her.

Annex 4

# Information obligations of the technical service

#### 1 Provision of information

The technical service is obligated to

- Immediately inform the KBA, regardless of the information obligation of the approval holder, in the following situations, amongst others:
  - Major non-conformities regarding approval-relevant requirements in the audited organisation, if the organisation does not immediately and effectively engage appropriate corrections and corrective measures
  - Final refusal to certify the fulfilment of the ARR
  - Invalidation, restriction or suspension of the certification for approval-relevant requirements, and open procedures in this regard.
- Inform the KBA of all circumstances that could be of significance to its designation in a timely manner, if possible before the event occurs. The KBA shall in particular be informed about
  - Changes and important events with regard to the accreditation or designation by other approval authorities and shall be provided, upon request, with assessment results of the respective body in German or in English
  - Initiated administrative or criminal proceedings
- Inform the KBA unrequested about designations and inquiries by approval bodies of relevance to the KBA designation as well as about inquiries from market surveillance authorities. Copies of the replies to the inquiries shall be sent to the KBA.
- Inform the KBA upon request on activities within the scope of designation, including crossborder activities
- Inform the KBA of initiated contravention or criminal proceedings in connection to the designation
- Compare the portfolio of proceedings under KBA designation with the KBA at least by 30 June and 30 December of each year.

All assessed companies which are monitored and certified by the technical service for the fulfilment of the approval relevant requirements for a defined period of time shall be reported.

The notification shall include:

- Registration number of the branch of the technical service
- Date of the notification
- Name, place and country of the evaluated company
- Type of procedure (see template for reporting operations regarding approval relevant requirements)
- Time of validity of the certification.

The notification shall be made using the template for reporting operations regarding approval relevant requirements.

For every reported procedure, the completely filled-in Report on CoP (for certifications according to the certification program, otherwise at least once during the time of validity) shall be sent by the technical service immediately after the audit to the KBA in Dresden, using the E-type channel.

#### 2 Use of information

Regardless of the existence of information obligations of third parties, the technical service shall make appropriate use of all accessible sources of information and shall use this information in the scope of the designation (pull principle, unless otherwise stated).

In particular, this applies to

- Information on the surveillance of the fulfilment of approval-relevant requirements by its own clients
- Information that is provided by the KBA, such as e.g.
  - Additional determinations and interpretations regarding the designation procedure
  - Information on the type approval procedure
  - Information on guaranteeing conformity of production
  - Information on market surveillance.

Annex 5

#### **Fees**

	Procedure	All categories
Designation based	Initial evaluation	€ 7,560
on a full accreditation (BVA)	Ü	€ 1,800
	ÜW	€ 3,150
Designation without	Initial evaluation	€ 9,870
accreditation	Ü	€ 2,730
(BOA)	ÜW	€ 4,120

The basic fee is invoiced together with the evaluation of the headquarters.

The basic fee includes, amongst others:

- Fixed designation costs
- The evaluation of one site (headquarters) (without travel expenses)
- One A4 certificate each, German and English (initial procedures, re-procedures)
- Notification and publishing on the KBA website
- Annual exchange of experiences between the KBA and the technical services (travel expenses and meals are not included).

Additional costs are invoiced based on hourly rates, e.g. for

- Evaluation at additional sites
- Witness assessment
- Additional measures (e.g. surveillance of exchange of experience, surveillance of anomalies etc.)
- Preparation and follow-up of additional evaluations cited here
- Any expenses that go beyond the norm for measures covered by the basic fee (e.g. assessments in a foreign language)
- Training measures
- Meetings outside the KBA premises.

Break times are included in additional expenses, and started hours are rounded up.

#### Procedure for the restriction, suspension, or termination of the designation

In the event of proceedings initiated by the KBA regarding restriction, suspension or termination of the designation, a processing fee in the amount of at least five hourly rates is charged regardless of the outcome of the proceedings. Additional costs and evaluations are also invoiced.

#### **Amendments**

Changes to the certificate are charged € 120.

If the amendment requires an additional assessment, the fee is calculated based on the hourly rate. In addition to the on-site time, generally five hours each are calculated for the preparation and follow-up of the evaluation.

#### Certificates

1 certificate A4, German
 1 certificate A4, English (only on request)
 Additional certificates A4, German or English

(without annex), each € 10.00

#### **Travel expenses**

The actual travel time, but no more than the following hourly rates, is invoiced:

Region Germany: 5 hours per assessor and direction Region Europe<sup>5</sup>: 8 hours per assessor and direction

For other destinations, no upper limits apply.

Travel expenses and disbursements are invoiced pursuant to the German Federal Travel Expenses Act (Bundesreisekostengesetz).

#### Other

Additional costs incurred by the KBA for the work of joint teams are invoiced to the technical service.

The fees are free of value-added tax (VAT).

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Mainland, United Kingdom, Ireland, Malta, Cyprus

# Legal notice

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