TÜVNORD

Description of the procedure for Initial assessment and ongoing CoP-Q Audits

(CoP-Q Assessment conducted under TN CERT Technical Service C)

CONTENT

1. PURPOSE

This document, A04F302e, describes the service description linked to the "initial assessment and ongoing CoP-Q assessment" procedure, hereafter referred to as the "CoP Audit." The CoP Audit is conducted to ensure compliance with production quality standards and regulatory requirements. Through initial assessments and ongoing evaluations, the procedure aims to identify areas for improvement, maintain high-quality standards, and ensure adherence to regulations.

2. SCOPE OF APPLICATION

This document applies to TÜV NORD CERT GmbH (TN CERT) as well as to all international proceedings which make use of TN CERT accreditations, approvals, notifications etc. and/or when delivering TN CERT services in the scope of a designated Technical Service category C in accordance with the definition of Regulation (EU) 2018/858 and equivalent EU and UN frame regulations

3. DEFINITIONS

Abbreviations and definitions	
TAH	Approval Holder / Type Approval Holder
Approval Relevant Requirements (ARR):	Requirements set out by legal acts or SNCH regarding Approval Holder and technical services within the type-approval procedure
ARR-Auditor:	Person within the technical service who meets the requirements as defined by TN CERT and has been appointed by the head of the technical service to audit ARR for related TAA.
Assessment:	Review of technical services through on-site assessment or other measures including a review of the results.
CoP:	Conformity of Production

Abbreviations and definitions	
CoP clearance:	Certificate issued by TAA (e.g. SNCH) after the positive assessment of an assembly plant. The validity of the clearance is related to the regulations covered and to the outcome of the assessment. The validity starts at the date of the onsite (if relevant) audit. A separate clearance is issued for each combination AH/assembly plant, depending on the specific TAA process.
CoP-Q:	Process related to the assessment and monitoring on a regular basis of the procedures of the manufacturer for controlling the conformity of production.
CoP Audit:	initial assessment and ongoing CoP-Q assessment
Designation:	Granting an authorization to a technical service to carry out assessments of management systems which can be recognized in TAA specific requirements procedures.
External Production (SNCH specific definition):	Each production site with a difference in the company's name or address is considered as external. No difference is made whether the production site is active or not. If the approval holder decides to keep an inactive production site within an approval, the production site will be considered within the sample size. If there are any doubts if a production site has to be included in the audit program, SNCH has the final decision as well as the veto on the decision of the technical service.
IAF:	International Accreditation Forum
KBA	Kraftfahrt-Bundesamt (German TAA)
List of approval:	A list of all approvals of one approval holder which can be requested at TAA and needs to be confirmed by the approval holder during the process of a CoP-Q assessment.
NSAI	National Standards Authority of Ireland (Ireland TAA)
Relevant Location:	Locations which take over responsibilities within the processes relevant for ARR and the type-approval process (e.g. offices for research and design, homologation departments, testing areas, production, after sales, quality management and assurance departments, shipment/logistics/ storage, external production sites).
SNCH	Société Nationale de Certification et d'Homologation (Luxembourg TAA)

Abbreviations and definitions	
STA	Swedish Transport Agency (Sweden TAA)
TAA	Type Approval Authority
TN CERT	TÜV NORD CERT

4. RESPONSIBILITY AND PHASES OF PROVIDED SERVICES

TÜV NORD CERT is responsible to assured that provided services are inline with defined procedure (described below as phases).
The auditors responsible for conducting the CoP Audit are appointed by the TÜV NORD CERT certification body under the Technical C scope. They are selected based on their industry-specific code, standards, and associated regulation specific competences.

4.1. Offer and Contract:

- Initiate the process by presenting an offer to the organization, outlining the scope, objectives, and terms of the CoP-Audit.
- Upon acceptance, formalize the agreement through a contract, specifying the responsibilities and expectations of both parties.

4.2. Audit/Assessment Preparation:

- Prepare for the audit by gathering necessary documentation and information related to the production processes and quality management systems.
- Coordinate with the organization to schedule the audit and ensure the availability of key personnel and resources.

4.3. Execution of Audits (On-site Assessment):

- Conduct on-site assessments at the premises of the Type Approval Holder or applicant.
- Evaluate the type approval holder (or applicant) and production facilities (depend on TAA requirement), processes, and quality control measures to ensure conformity with established standards.

4.4. Preparation of and documentation of CoP Information for the Type Approval Authority (TAA):

- Compile relevant information from the audit to prepare documentation for submission to the TAA, such as the Kraftfahrt-Bundesamt (KBA) or other TAA (SNCH, NSAI, STA), based on TAA specific requirements.
- Each on-site assessment results are documented in a "CoP-audit report," which serves as a formal record of the audit, including findings and recommendations (if applicable).
- In case that nonconformities are identified during the audit, a structured follow-up process is initiated to address and rectify these issues.
- Ensure the accuracy and completeness of the information provided.

4.5. Submission of the CoP- Audit Report to the TAA:

- Create a comprehensive CoP- audit report detailing the results of the on-site assessment.
- Submit the report to the TAA for review and approval.

5. PROCESS DESCRIPTION

Process Description is defined under TN CERT procedure for “CoP Audit”.

5.1. Audit preparation

The audit preparation process is designed to evaluate the feasibility and necessity of conducting an initial or routine assessment for the client. This involves several key steps:

- Assessment of Client's Needs:
  - Determine whether an initial assessment is warranted by reviewing the client's current situation and objectives.
  - Clarify which approvals the client already possesses or plans to apply to the TAA, such as Kraftfahrt-Bundesamt (KBA), SNCH, NSAI or STA.
- Regulatory and Guideline Review:

  - Auditors familiarize themselves with the current valid regulations, guidelines, and informational leaflets, such as the "MAB" leaflet related to the initial assessment by the KBA or similar documents defined by the applicable TAA.
  - Ensure a comprehensive understanding of the requirements and standards applicable to the client's industry and situation.
- Audit plan and audit program development:
  - Develop an audit plan and program based on the information gathered during the preparation phase.
  - Coordinate the audit plan with the client to ensure alignment with their needs and expectations.
- Listing of Approval Objects/Groups:
  - Include in the audit plan a detailed list of approval objects or groups that will be assessed during the audit. Including request for related information from TAA, such as for KBA.

This preparation process ensures that the audit is conducted efficiently and effectively, with a clear understanding of the client's requirements and the regulatory framework.

5.2. On-site audit – (initial) assessment

Assessment of Management System and Compliance Control:
The on-site assessment evaluates the extent to which the management system effectively controls the compliance of manufactured permit objects with the approved type.

This assessment includes:

- Incorporation of road traffic law requirements or UN R requirements:
  - Ensure that additional requirements from road traffic law or UN R requirements are integrated into the assessment process. This involves comparing the Conformity of Production Product (CoP-P) tests conducted within the company with the requirements outlined in regulations such as VO, UN R, and StVZO.
- Documentation of Results:
  - Document the results using the "Information to Ensure the Conformity of Production" (CoP report), applying the most current version available.

  - Ensure that every CoP audit auditor has access to the relevant regulations to facilitate accurate assessment.

- Evaluation of Quality Management System:
  - On-site, the auditor evaluates the extent to which the Quality Management (QM) system ensures effective control over the manufactured parts/objects.
- Consideration of Third-party Production:
  - If parts are produced by third parties for which type approval is sought from the TAA (KBA, SNCH, NSAI or STA), this fact must be appropriately included in the CoP audit. Assessment at the third-party location, different from the type approval holder might be required, depend on the TAA requirement, such as for SNCH.
- Documentation of On-site assessment:
  - The on-site assessment is documented in the CoP report and, if necessary, in the "Deviation Report." (depend on the specific TAA requirement, such as for KBA, deviation report is required as applicable)
  - Ensure that the assessment is sufficiently documented with examples, details, and special features to provide a comprehensive overview of compliance and control measures.
  - This process ensures thorough evaluation and documentation of the management system's effectiveness in controlling compliance with approved types, incorporating all relevant legal and regulatory requirements.

5.3. Issuance of the certificate/confirmation

A certificate / confirmation is not issued. With the positive review of the procedure and related document by the head of the certification body, his deputy or designated persons, the CoP report and required documents are forwarded to the TAA.
The CoP report can only be completed and forwarded when all non-conformities have been resolved, i.e. when the corrective measures that have been defined (and implemented, if required) and accepted or verified by the audit team.

6. SURVEILLANCE / ROUTINE COP-AUDIT REQUESTED BY TYPE APPROVAL OWNERS

Type approval holders may request routine Conformity of Production Quality (CoP-Q) audits for surveillance purposes. In such cases, the procedure outlined in Chapter 5 and subsequent sections will be applied.
This ensures consistency and adherence to established protocols, providing a comprehensive framework for ongoing compliance and quality assurance.

7. MANAGEMENT OF NON-CONFORMITIES

The results are classified in accordance with the requirements of ISO/IEC 17021-1. This corresponds to the specifications of the "ISO 9001" certification procedure.
A major deviation is also defined as follows:

- there is a risk that an unapproved product with the approval mark will be placed on the market or that it will be given the impression that it is approved
- a product that does not comply with the authorization can enter the market
- defective products cannot be recalled
- the TAH deviates from the provisions of the ARR and does not immediately take adequate corrections and corrective measures
- other serious violations of permit-related requirements.

The examination of the settlement of deviations from approval-relevant requirements is carried out by a member of the appointed audit team. The customer will be informed of the result of the inspection.

8. RIGHTS AND OBLIGATIONS OF THE CUSTOMER AND THE TECHNICAL SERVICE C (TÜV NORD CERT)

- Customer (AH/TAH including applicant):
  - Enable the TAA to carry out witness assessments. This includes obliging manufacturers to facilitate the participation of the witness assessor.

- To grant the TAA the right to request audit reports, quality records and other documents relevant to type approval and market surveillance.
- The transfer of information and documents (e.g. CoP information) to the TAA.
- Obligation to provide information about new permits or the intention to apply for permits (for each initial evaluation).
- Allow the Technical Service C to request audit-relevant information (e.g. enquiry about the manufacturer's approvals) from the TAA.
- Obligation to provide the Technical Service C with all information relevant to the assessment as a whole.

■ Technical Service C:

- The manufacturer (and assembly plant as applicable) must be informed of the rights and obligations of the TAH and the approval authority (TAA). It must be explained to TAH that these rights and obligations are valid regardless of any certification (e.g. ISO9001, IATF16949).
- Before conducting each initial or ongoing assessment, a verification process is undertaken to determine:
  - Which approvals the entity already holds (List of approval), particularly those issued by KBA and SNCH.
  - -Whether the entity intends to apply for any approvals in the foreseeable future.
  - -This verification ensures that the assessment is aligned with the entity's current and anticipated regulatory requirements.

9. CONTACT (TÜV NORD CERT)

If you should require any further information, then please do not hesitate to contact us. We will be please to help you.

Please contact us via mail to info.tncert@tuev-nord.de or by telephone 0800 245 74 57 (Free phone from within Germany) or +49 511 9986-1222 from abroad.

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