

Before achieving the type approval certificates (EU or UNECE) the Manufacturer owner of type approval shall achieve a Conformity of Production (CoP) clearance by the Authority that will issue the required Type approval.

Each European Authority have its own guideline and procedures in this regard; you could find below those relating to the EU Authority to which CETOC TS have been designated:

1. STA (E5 – Sweden).
2. SNCH (E13 – Luxembourg);
3. NSAI (E24 – Ireland);
4. CYPRUS (E49 - Cyprus);

E5 STA (Sweden):

Manufacturer has a valid Initial Assessment by another EU Type Approval Authority

If the Manufacturer owned a valid Initial Assessment certificate released by another EU Type Approval Authority and it is related to the same EU/UNECE regulations subject of type approval request, so the Technical Service will have just to review the documentation for validate it.

Manufacturer has a QMS certification

For COP Initial Assessment, an ISO 9001 certificate or an IATF16949 certificate, relevant to the product sector, is accepted, only if it is referring to the Manufacturer production facilities where Vehicles / systems / Components subject of type approval are assembled.

Unless the type Approval required is referring to Whole Vehicle or the EU/UNECE regulation will requires for manufacturer to test a product at certain time interval or production volume to ensure conformity of production (see ECE R16 for example), the Technical Service will have to schedule a Web meeting with Manufacturer for reviewing the documentation related to CoP process and validate the manufacturer knowledge about CoP and the Quality Management System on the basis of the CETOC TS procedures, however the Authority may decide, on a case-by-case basis, to carry out a verification audit anyway.

If a Whole Vehicle type approval is required or an EU/UNECE regulation subject of type approval required will requires for manufacturer to test a product at certain time interval or production volume to ensure conformity of production (see ECE R16 for example) an on site audit shall be planned.

After the release of CoP clearance, within its expired date we should plan a CoP surveillance audit in according to the CETOC TS procedures

Manufacturer does not have a QMS certification

If the Manufacturer does not have one of these QMS certificates, an audit at the production site(s) will be necessary to verify all the processes that ensure production conformity on the basis of the CETOC TS procedures.

After the release of CoP clearance, within its expired date we should plan a CoP surveillance audit in according to the CETOC TS procedures.

The above applies also if the manufacturer has alternative assembly plants i.e. if assembly plant is not part of the certified QMS, on site audits are required.

E13 SNCH (Luxembourg):

For COP Initial Assessment and audit surveillance, CETOC TS will follow specific SNCH procedure - D1-13 Initial Assessment (CoP-Q)_Conformity of Production (CoP-P) Process. You could find below the risk assessment guide line to identify the process for Initial Assessment:

Production of products covered by an e13/E13 type-approval has not started

CoP clearance issued by SNCH if the manufacturer is also a customer of another technical service or by another Type-Approval Authority may be accepted if the scope is sufficiently identical (same manufacturer, same plants, same regulations...) or the scopes have been audited.

If a Quality Management System certificate issued by an IAF accredited certification body is available, a remote documentary review might be sufficient. However, if the production of equivalent products but not covered by an e13/E13 type-approval has started, an on-site audit is requested.

Production of products covered by an e13/E13 type-approval has started

an on-site audit by the Category C technical service is requested.

E24 NSAI (Ireland):

Manufacturer has certified QMS

For COP Initial Assessment, an ISO 9001 certificate or an IATF16949 certificate, relevant to the product sector, is accepted only if it is referring to the Manufacturer production facilities where Vehicles / systems / Components subject of type approval are assembled; the manufacturer must maintain the validity of this certification throughout the lifespan of the approval issued to them. In this case the procedure will be carried out by documentary means on the basis of the CETOC TS procedures.

NSAI shall have recorded the expiry date of the QMS documentation submitted. CETOC TS and NSAI will monitor the validity and the scope of the QMS certificate.

Manufacturer does not have certified QMS

If the Manufacturer does not have a QMS certificate, an audit at the production site(s) will be necessary to verify all the processes that ensure production conformity in accordance with the CETOC TS procedures using the NSAI forms.

After the release of CoP Clearance, NSAI would also require that CETOC TS would carry out an annual surveillance audit on the same manufacturer in accordance with the CETOC TS procedures using the NSAI forms.

The above applies also if the manufacturer has alternative assembly plants i.e. if an assembly plant is not part of the certified QMS, on-site audits are required.



**EU AUTHORITY GUIDELINE FOR RISK
ASSESSMENT OF PRODUCTION (CoP) INITIAL
ASSESSMENT PROCESS**

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E49 CYPRUS:

Manufacturer has certified QMS

For COP Initial Assessment, an ISO 9001 certificate or an IATF16949 certificate, relevant to the product sector, is accepted, only if it is referring to the Manufacturer production facilities where Vehicles / systems / Components, subject of type approval, are assembled, the manufacturer must maintain the validity of this certification throughout the lifespan of the approval issued to them. In this case the procedure will be carried out by documentary means on the basis of the CETOC TS procedures.

After the release of CoP clearance, within its expired date we should plan a CoP surveillance audit in accordance to the CETOC TS procedures.

Manufacturer does not have certified QMS

If the Manufacturer does not have a QMS certificates, an audit at the production site(s) will be necessary to verify all the processes that ensure production conformity in accordance to the CETOC TS procedures using the NSAI forms.

After the release of CoP clearance, within its expired date we should plan a CoP surveillance audit in accordance to the CETOC TS procedures

The above applies also if the manufacturer has alternative assembly plants i.e. if assembly plant is not part of the certified QMS, on site audits are required.