RDW

INFORMATION for MANUFACTURERS regarding:

Surveillance and CoP clearance

EC Directives and ECE Regulations

Vehicle Category L, M, N, O, T, separate technical units, systems and components.

RDW

Inhoud

1 Introduction

Manufacturers of motor vehicles and their trailers, and or systems, components and separate technical units intended for such vehicles intending to place their products on the market in the European Union (EU) and/ or the countries that have signed the agreement of the Economic Commission for Europe of the United Nations (UNECE) shall meet the requirements stated in EC directives and (UN)ECE regulations.

Those requirements are:

- The manufacturer must have a type-approval for each product before the products can be placed on the market
- The manufacturer must comply with the provisions laid down in the legislation (e.g. method of application for type approvals, ensure the Conformity of Production (CoP), issuing certificate of conformity (when applicable), packaging and delivery of products, report changes in organization)

An approval authority will issue type approval certificates to the manufacturer if

- motor vehicles and their trailers, and or systems, components and separate technical units intended for such vehicles fulfill the technical requirements,
- the manufacturer fulfills the Initial Assessment, Conformity of Production (CoP) requirements and other administrative provisions.

Type approvals issued by an approval authority must be accepted by the other EU member states and UNECE contracting parties.

The Netherlands is EU member state and UNECE contracting party and signed many of the published ECE regulations.

RDW is the approval authority for the Netherlands and designated by the Dutch Ministry of Transport. RDW issues EC and ECE type approval certificates (e4 and E4) and is obliged to verify the Conformity of Production of the manufacturers whose type approvals have been granted according to the provisions.
Conformity of Production means all arrangements made by the manufacturer to ensure that produced vehicles, systems, components or separate technical units conform to the approved type.

The manufacturer is fully responsible for all aspects of the type approval and for ensuring the Conformity of Production.

1.1 General

The provisions concerning Conformity of Production and its verification by the approval authority are stated in:

- Appendix 2 of the Revision 2 of the Agreement of Geneva of 20 march 1958 (components and systems),
- Annex X of the EC Directive 2007/46/EC (vehicle category M, N, O: passenger cars, commercial vehicles and trailers),
- Annex VI of the EC Directive 2002/24/EC (vehicle category L: mopeds and motorcycles),
- Annex IV of the EC Directive 2003/37/EC (vehicle category T: agricultural and forestry tractors),
- Annex I of the EC Directive 97/68/EC (non road mobile machinery),
- specific requirements as laid down by the EC separate Directives and/or ECE Regulations.

Legislation tends to be updated regularly. It is the responsibility of the manufacturer to be up-to-date and to apply the changes into the products, production and organisation when applicable.

1.2 Legislation information

Relevant publications can be obtained as follows:

- EU website (EC Directives and Regulations): http://ec.europa.eu/enterprise/sectors/automotive/documents/directives/index_en.htm
- Eurlex website (EU legislation) http://eur-lex.europa.eu/en/index.htm
- UNECE website (ECE Regulations): http://www.unece.org/trans/main/welcwp29
- RDW website: http://www.rdw.nl/sites/tgk/englishversion

1.3 COP verification

The approval authority must verify – before granting a type approval (Initial Assessment) and during the manufacturing (Conformity of Production) - the existence and implementation of satisfactory arrangements and procedures by the manufacturer for ensuring effective control so that motor vehicles and their trailers, and or systems, components and separate technical units when in production conform to the approved type. It will also be verified if other administrative provisions, mentioned in the legislation, are covered.

The CoP verification comprises:

- The assessment of quality management systems, referred to as “Initial Assessment”
- The verification of the approval subject and product-related controls, referred to as “product conformity arrangements” (Conformity of Production)
- Continued verification arrangements

Figure 1 shows schematically the overview of the CoP procedures as listed above.

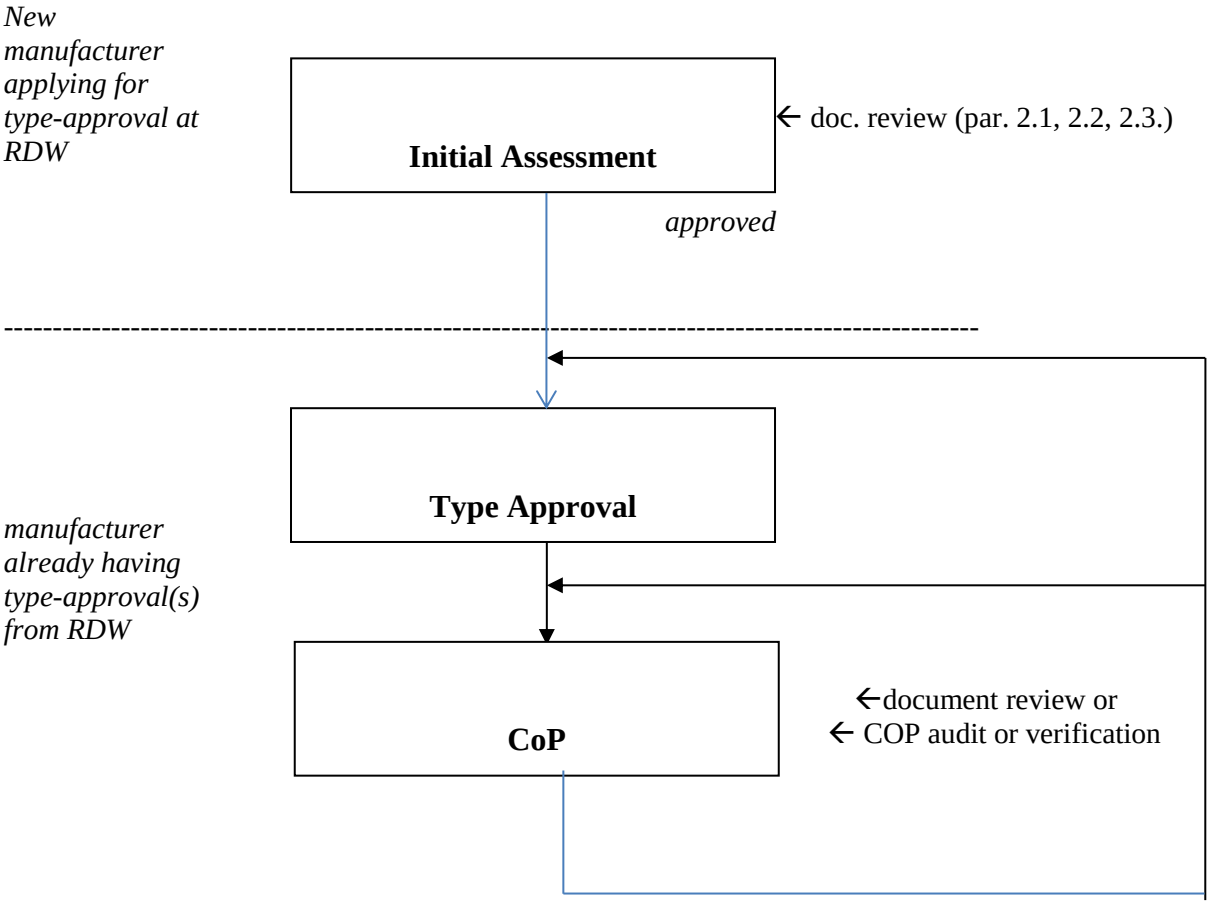

Figure 1: Schematic overview of the CoP procedure

2 Initial Assessment (IA)

2.1 Initial Assessment document review

- All new manufacturers to RDW must apply for Initial Assessment with the form 'Form surveillance and COP clearance'. Documents must be attached as stated in annex I and II of this form.
- Documents must be in Dutch, English or German language.
- The information to be submitted by the manufacturer depends on the fact if the manufacturer maintains an ISO9001 or TS16949 certification or not.
- If the manufacturer does not have a certified quality system an assessment audit has to be conducted, based on ISO 9001 including COP procedures (see point 2.2 and 2.3)
- RDW will review the documents to verify if all the information is sufficient, if it covers all the subjects of the type approval and can assure the future Conformity of Production.

- RDW will review the documents generally within 2 weeks after the application date
- In any case additional information is required; the RDW will contact the manufacturer (through the technical service when applicable).
- If the result of the Initial Assessment is satisfactory an 'Communication concerning Initial Assessment' will be issued. Validity is one year.
- RDW can decide to perform an Initial Assessment audit in addition to the document review even if the manufacturer has a certified quality system.

2.2 Initial Assessment audit

- In case of vehicle manufacturers, manufacturers without a certified quality system or when decided by RDW during the document review, an Initial Assessment audit will be performed.
- In case of a known manufacturer, applying for a new production location which is going to be holder of own type approvals, with proven company quality performance and sufficient CoP implementation, a practical approach can be decided by the RDW inspector (e.g. by issuing an 'Communication concerning Initial Assessment' based on the document review and a CoP audit scheduled soon after the type approval has been issued and after start of production.
- During an Initial Assessment audit the required procedures, instructions and control plans will be reviewed. The implementation of the procedures, instructions and plans is normally not possible or applicable yet hence the mass production of the specific type has not been started.
- If the result of the Initial Assessment audit is satisfactory ', a Compliance Statement will be issued. Validity will be maximum three years.
- When non conformities or observations are found during the Initial Assessment audit the manufacturer shall reply by sending corrective and preventive actions within a certain period (agreed during the audit). If all requirements are fulfilled a Compliance Statement will be issued. Validity will be maximum two years.

2.3 Factory Inspection

In case the manufacturer does not have a certified quality system and has production within the organization, an assessment will be conducted by RDW or a Technical Service notified by RDW. This assessment, called Factory Inspection, will be based on both EN ISO 9001:2008 and CoP procedures and covers the following aspects:

- Quality management system,
  - management Responsibility,
  - document Control,
  - purchase and Incoming goods inspection / Supplier Verification,
  - manufacturing procedures,
  - handling of non-conforming products,
  - calibration of test and measurement equipment,
  - measurements, analysis and improvements.
- CoP aspects:
  - CoP check and test frequency,
  - sample method and sample size,
  - CoP procedure,
  - filling the CoP check and test results in reports,
  - analyses of the CoP check and test results.
- When the assessment has been proven satisfactory, a Factory Inspection Report (FIR) is submitted to the manufacturer by the Technical Service and needs to be send to the RDW

together with all required other documents (see 2.1). RDW will issue an Initial Assessment Statement with a validity of 1 year.

- When the assessment is performed by RDW a Compliance Statement will be issued. Validity is one year. Before this year ends the factory inspection needs to be repeated to ensure the implementation of the measures to ensure the Conformity of Production.

3 Surveillance and Conformity of Production

After the type-approval has been granted, the manufacturer must implement the arrangements and procedures and gather the evidence to proof the produced products conform to the approved type. The holder of the type approval (the manufacturer) is always fully responsible for the CoP and must be able to show compliance with the CoP requirements stated in the applicable legislation.
The manufacturer must also ensure other provisions of the legislation:

- maintain the validity of the issued type approvals,
- report changes in organisation, products, procedures and other information related to the type approvals and CoP,
- check the correctness of the type-approval markings and labelling information,
- check the correctness of the requirements (if applicable),
- check the correctness of the information on the manufacturing plate and type identification (plate) for vehicles,
- check the information on the Certificate Of Conformity (CoC) information (if applicable),
- traceability of the production, material and products with lot numbers, serial numbers (if applicable),
- check the content of manuals (languages), (operating) instructions, labels, exemptions in use of the product (if applicable).

RDW will verify if the CoP requirements are met by means of a CoP assessment.
A CoP assessment can be performed by means of:

- RDW surveillance and CoP audit,
- CoP verification by an appointed company on behalf of RDW,
- Administrative CoP verification.

3.1 RDW surveillance and CoP audit

- A CoP audit will normally be performed within 1 year after issuing the first type approval.
- During a CoP audit the implementation of the procedures, instructions and plans submitted during the initial assessment will be verified.
- If the CoP audit is finished without finding of non-conformities, a Compliance Statement will be issued. Validity will be three years.
- When non conformities or observations are found during the CoP audit the manufacturer shall send the corrective and preventive actions to RDW by e-mail within a certain period (agreed during the audit).
- If all requirements are fulfilled a Compliance Statement will be issued. Validity will be one or two years depending on the severity of the findings during the CoP audit.

3.2 CoP verification by an assigned company on behalf of RDW

- A CoP audit will normally be performed within 1 year after issuing the first type approval.
- During a CoP audit the implementation of the procedures, instructions and plans submitted during the initial assessment will be verified.
- If the CoP audit is finished without finding of non-conformities, a Compliance Statement will be issued. Validity will be three years.
- When non conformities or observations are found during the CoP audit the manufacturer shall send the corrective and preventive actions to RDW by e-mail within a certain period (agreed during the audit).
- If all requirements are fulfilled a Compliance Statement will be issued. Validity will be one or two years depending on the severity of the findings during the CoP audit.

3.3 Administrative CoP verification

- In case a document verification is selected by RDW, the manufacturer will be contacted by e-mail. Normally the following documents are requested:
  - overview of CoP test results from the previous 3 year,
  - selection of CoP test reports from the previous 3 year,
  - production volumes of previous 3 year,
  - new ISO certificate or FIR, if applicable,
  - new filled and signed application form
  - current COP control plan
  - any information relevant for CoP that has been modified since previous verification.
- If all requirements are fulfilled a Compliance Statement will be issued. Validity is one or two years depending on the severity of the findings during the CoP verification.

3.4 Surveillance by another Member State

The initial assessment and/or verification of product conformity arrangements may also be carried out by the approval authority of another Member State, if mentioned in the applicable legislation.
In such cases, the approval authority of the other Member State shall prepare a Compliance Statement outlining the areas and production facilities and the Directives/Regulations it has covered as relevant to the product(s) to be type-approved.
If a manufacturer request the use of a Compliance Statement of another Member State, he shall provide RDW with the following information:

- Compliance Statement of the other Member State,
- latest audit report from the other Member State,
- completed and signed "Form for surveillance and CoP clearance"
- the confirmation the e4/ E4 type approvals are within the scope of the Compliance Statement,
- on request an overview of annual production volume, overview of CoP tests and individual CoP tests reports.

RDW decides whether the information is sufficient and of an equivalent level compared to the verification arrangements RDW is normally applying. If RDW accepts the information, a conformation letter will be issued.

4 Surveillance and CoP audit

- CoP audits are performed generally at the manufacturer's production location. The manufacturer is fully responsible for the type approval, production, design, changes of design, CoP and corrective and preventive actions.. The manufacturer is expected to present all the traceable evidence the CoP requirements are met. The manufacturer must perform all the necessary product verifications as planned, which must demonstrate the Conformity of Production
- The purpose of the audit is to gather the evidence and information the requirements for CoP mentioned in the relevant EC Directives / ECE Regulations are met for the type approvals issued by the RDW.
- When personnel of a different part of the manufacturer's internal organization (e.g. headquarters, homologation department and others) are involved in fulfilling the CoP requirements, presence and assistance from personnel from these departments during the audit is required.
- If a third party (not part of the internal organization) is involved in fulfilling the CoP requirements it is allowed this third party assists during the audit only in case the responsibilities are clearly assigned by means of a contract and indicated during the Initial Assessment.
- In case the production is performed at an external production location (not part of the organization of the manufacturer) the "RDW policy on external manufacturers" shall be followed (see Annex 1). Still the manufacturer needs to prove the CoP is ensured and other provisions are complied with.

4.1 Audit agenda

Before the audit is performed an agenda will be send to the manufacturer. Based on the findings during the audit the agenda may be altered by the auditor.
Normally, the audit covers the following items:

- opening meeting: introduction, purpose, scope, agenda,
- short presentation by both RDW and the manufacturer about the company and its activities,
- document review: CoP control plan, test results, handling of non-conformities, corrective/preventive actions, design/engineering changes, legislation updates, control method on external production locations etc.,
- plant tour: incoming goods, production, end-of-line testing, laboratory,
- checking a sample (comparing of production sample to type-approval),
- witnessing CoP test(s), where required,
- closing meeting: summary of the audit results, confirming agreements in relation to any follow-up of non-compliance(s), etc.

After receipt of the agenda the manufacturer can propose an altered agenda if efficiency can be improved. Before the agenda can be altered RDW needs to receive the proposal on time and needs to confirm the changes.

4.2 Execution of the audit

During the opening and closing meeting, the person(s) responsible for CoP and (representatives of) the management must be present.

For other activities, it is sufficient if a responsible person is present to explain the quality system in general and CoP procedures in particular, and has access to filled check- and test records. Also for the activities mentioned above responsible person(s) able to explain these activities are to be available.
The manufacturer must present all information (procedures, records, reports, etc.) that is regarded necessary by the auditors. The audit will be held in English and the manufacturer must provide translation in to their own language.

4.3 Category of audit findings

- During the audit all findings will be clearly communicated and mentioned in the audit report and are based on the principle: 'requirement', 'deviation from requirement' and 'evidence'.
- In case of more extensive audits with multiple audit teams, short meetings can be organised to discuss the findings. This is done in agreement with the manufacturer.
- Detailed discussions about the findings should be held before the closing meeting.
- During the closing meeting the results of the audit will be presented by the RDW auditors. The manufacturer is given the opportunity during the closing meeting to ask questions. This will not alter the audit report, however.
- Findings must be clear and agreed between the auditee and auditor. They are categorized as follows:
    - **Conformity**; does fulfil the requirements of the Directives and Regulations.
    - **Observation**; an acceptable (procedural) risk. No safety issue.
    - **Minor Non Conformity**; Procedures and/or requirements of regulations/directives not always implemented. Potential safety risk.
    - **Major Non Conformity**; Procedures and/or requirements of regulations/directives not implemented. Safety risk.
    - **Remark**; notification, point of interest (for next audit), future changes. A remark has no influence on the audit result.

5 Surveillance costs

5.1 Costs for CoP audits and verifications

Since the manufacturer is responsible for assuring the conformity of production including the legally required verification of this by the approval authority, all costs involved for the audits or verifications are charged to the manufacturer. The charges concern the hours spent for travelling, preparation, the audit itself and follow-up. Also travel expenses are charged.
RDW attempts to combine CoP audits for several manufacturers within one travel in order to reduce the costs.
When RDW contacts the manufacturer for planning an audit, the details of the costs will be explained.
COP verifications can also be performed by assigned companies on behalf of the RDW.

5.2 Contribution fee

Al manufacturers who have RDW issued type approvals will be charged on an annual basis with the contribution fee. This contribution fee covers the costs for:

- (extensions to) Initial Assessment communication and Compliance Statements,
- handling of all the modifications by the manufacturer concerning CoP relevant information (with exception from the Type Approval Statement (TAS),
- periodical document reviews (up to solid two hours per review),
- supply of information from RDW regarding legislation.

The contribution fee is independent from the amount of type-approvals granted to the manufacturer. For details, see the latest pricelist at http://rdw.nl/sites/tgk/englishversionThe contribution fee does not cover the costs for the COP audits and verifications.

6 Withdrawal of type approvals and production definitively discontinued

Type approvals become invalid in the following circumstances:

- when the legislation for which the type approval is issued is repealed or replaced
- when the requirements of the legislation become more stringent
- when the manufacturer stops the production definitively
- when the provisions of the legislation are not complied with by the manufacturer.
-

6.1 Withdrawal of type-approvals

In case the manufacturer fails to solve the non-conformities or refuses to settle the mandatory payments, RDW may decide to withdraw the type-approval(s).
A withdrawal is irreversible and the consequence is that production and placing on the market of the motor vehicles and their trailers, and/ or systems, components and separate technical units is not permitted anymore.

In case type approvals of separate technical units, systems and/ or components are used in Whole Vehicle Type Approvals (WVTA) these WVTA's become invalid after such withdrawal.

All other member states will be informed about the withdrawal and a risk analysis, market surveillance or inspection will be performed. A recall will be imposed if the motor vehicles and their trailers, and/ or systems, components and separate technical units that are already in the field are considered to be unsafe or a risk to the environment.

Despite the withdrawal the manufacturer remains responsible for all the provisions mentioned in the relevant legislation for motor vehicles and their trailers, and/ or systems, components and separate technical units produced before the withdrawal.

6.1.1 Production definitely discontinued

In case the manufacturer definitely ends the production of any product for which RDW has granted type-approval, RDW needs to be notified. This notification must include the following information:

- the applicable type approval number(s),
- the date when the production was discontinued,
- the last VIN produced in case of vehicles,
- the last production serial numbers, batch codes or production codes.

RDW will issue a confirmation about the production definitively being discontinued. After this confirmation it is not possible to produce this specific product and it is not possible to use the corresponding type-approval certificate, number or marking anymore.
The manufacturer still remains responsible for all the vehicles, components or separate technical units produced before the production has been definitely discontinued. All other Member States will be informed. RDW may decide to investigate if all COP requirements have been met before the communication is issued to the manufacturer.

7 Changes in manufacturers information

The manufacturer is responsible for informing RDW about any CoP and type-approval relevant changes. In particular:

- Manufacturers/ production locations name and/or address changes,
- important organisation changes (including merges, taking overs, etc.),
- change of CoP responsible persons,
- change of contact persons,
- change in personnel responsible for signing the Certificate of Conformity (CoC),
- change of Technical Service used for type approval testing,
- update of ISO or quality system certificates,
- adding production locations or legislation.

The form “Form for surveillance and CoP clearance” must be used to inform RDW about any of the above mentioned changes. In any case the information on the type approval certificates does not match with the actual situation, the type approvals are not valid.

7.1 Type approval statement (TAS)

In case of manufacturers name or address change, a ‘Type-Approval Statement’ can be issued when the manufacturer holds three type approval certificates or more. This statement explains the modification and lists the type-approvals it applies to. The applicant shall apply for the TAS by sending the information to the Technical Service mentioned on the type approvals.

RDW

Annex

Additional information to the "Form for surveillance and CoP clearance"

The 'Form for surveillance and CoP clearance' needs to be completed and signed. All applicable documents as requested by this form shall be submitted to RDW. Documents sent to RDW such as procedures, control plans, etc, shall be controlled documents showing, as a minimum, identification and revision status. All CoP relevant information of these documents shall be translated into English, Dutch or German language.

"Documents to be submitted to RDW by the manufacturer"

The documents requested here are intended to cover, as a minimum, the arrangements and procedures required to fulfil the initial assessment. These arrangements and procedures are:

"A: Required information for ALL manufacturers to be submitted to RDW"

- Company/organization diagram clearly showing the relation between the manufacturer and production location(s) and the CoP responsibilities in the production process. It must also be indicated to what department de COP responsible person belongs.

- The COP responsible person is the person (function) who has the responsibility for the COP. This person must review the effectiveness of the COP procedure and arrangement periodically (with the minimum frequency mentioned in the legislation or a frequency agreed upon with RDW). The review must also include: COP planning and follow-up, COP test results and follow up and corrective and preventive actions in case a COP test fails the requirements. The result of the

- Copy of entry in Chamber of Commerce trade register

- In case of external production location(s) an EC/ECE agreement

between the manufacturer and the external production location including a clear description of the relation between manufacturer/ production location(s) (see Annex 2)

- Copy of quality certificate acc. to EN ISO 9001:2008, ISO/TS 16949 or equivalent or a FIR

Applies to the manufacturer and all his (external) production locations (if applicable). The scope of the certificate shall be relevant to the product(s) to be type-approved and must be valid.
A manufacturer solely making use of (external) production facilities does not have to be certified himself as long as the external production location(s) are certified and the manufacturer, as being responsible, has implemented procedures and takes measures that fully assures the CoP and the surveillance at the external production location(s).

- CoP procedure / control plan(s)

A control plan in general describes the tests and checks necessary to be carried out to verify continued conformity with the approved type. It shall also include the sample size and frequency, acceptance criteria (test result limit values), when and where the tests are performed and the responsibilities for the evaluation of the results and follow up on the findings.

The control plan shall, as a minimum, cover the physical tests and corresponding frequency, specified in the EC Directives or ECE Regulations (in case any specific CoP requirement is indicated). If the CoP test frequency is not specified in the relevant legislation the manufacturer must propose a frequency (based on analyses) to RDW.
Furthermore it shall be assured by arrangements or procedures that results of tests and checks are recorded, stored and analysed. Evidence of such arrangements or procedures are to be sent to RDW.

- Procedure for handling non-conformities

The manufacturer shall assure that products found to be not conforming to the type-approved products are identified and controlled to prevent their unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities for dealing with non-conforming products. The procedure shall describe:

- the actions to eliminate the detected non-conformity and to preclude its original intended use or application,
- the actions to the (potential) effects of the non-conformity when detected after delivery or use,
- the process for re-verification to demonstrate conformity to the requirements after correction of nonconforming products,
- to record the non-conformities and the actions taken. It shall include informing RDW if this is specifically requested by the legislation for which type-approval is granted.

- Procedure for handling corrective/preventive actions

In case CoP test results do not meet the requirements, the cause should be found and corrective actions taken and evaluated. Preventive actions are taken to prevent future CoP-related problems are arising.

- Procedure for handling design/engineering changes

It is to be assured that any modification to the type-approved product, initiated by anyone within the manufacturer's organization or its supplier, is always evaluated for its compliance with the legislation for which type-approval was granted. The evaluation needs to include the requirement of re-testing and updating of the type-approval. A procedure is to be laid down to describe this process, the responsibilities and requirement to inform the Technical Service or approval authority, where applicable.

- Procedure for type-approvals (discontinued) and legislation updates

In the case that production of a type-approved component or vehicle is to be discontinued, it is to be assured that recurring checks are performed to relevant changes made to the legislation for which the type-approval was granted. The procedure shall, as a minimum, describe the source the updates of legislation are obtained from (e.g. websites, technical service), the interval at which the checks are performed, the responsibilities, the evaluation and treatment of the results and the recording of the checks and results.
Furthermore the manufacturer shall establish a procedure in case of ending the production of any product for which RDW has granted type-approval. See also paragraph 6.

"B: Required additional information for COMPONENT manufacturer"

- Procedure(s) for sampling per product type covering estimate production volume per year, sampling rate and minimum sampling rate

The number of test samples taken for the checks and tests as described in 2.1.5. shall be described.. If physical tests are required in the EC Directives or ECE Regulations, they must, as a minimum, be performed on the number of samples indicated in those Directives or Regulations. In all other cases the number of test samples shall be chosen by the manufacturer to make sure that testing as such ensures the compliance for the complete production. If sample rates depend on previous check or test results, this must be described

- CoP test reports format(s)

The format indicating which test results are recorded. This shall include all aspects to be able to reproduce these tests and to compare the results to the requirements and/or acceptance criteria.

"C: Required additional information for VEHICLE manufacturer"

- CoP control plan overview (matrix) in case of WVTA for 2/3-wheeled vehicles, 4-wheeled vehicles, agricultural vehicles

A control plan overview/matrix includes a complete overview of all the CoP checks to be done per subject (Directive or Regulation).

- Documents which proves the WMI code assigned to the manufacturer

The name and address on the document indicating the WMI code shall correspond to the name and address data of the copy of entry in the Chamber of Commerce trade register.

- Procedure for CoC verification versus vehicle specification configurator

The manufacturer shall explain (procedures, arrangements) how it has assurance(by procedures, checks, etc.) that the information on the CoC is correct.

- For vehicle category M, N, O: a declaration/contract between the manufacturer (outside EU) and his representative

A manufacturer established outside the European Community shall appoint a representative established in the Community to represent him before the approval authority and to act on his behalf in matters covering the legislation for which type-approval is to be granted.
RDW shall receive a declaration or contract with the name and address of this representative.
An example of such a document can be found at http://www.rdw.nl/sites/TGK/Englishversion.
Also the copy of entry in the Chamber of Commerce trade register of the representative is requested.

- For vehicle category M1, N1,O1, O2: recall procedure

A manufacturer is obliged to recall vehicles already sold, registered or put into service in case one or more systems, components or separate technical units fitted to a vehicle presents a serious risk to road

safety, public health or environmental protection. He also shall immediately inform the approval authority that granted the vehicle approval.
RDW shall receive procedures and/or descriptions describing, as a minimum, the arrangements covering this requirement. This shall include making use of the 'RapEx' (Rapid Exchange) website, (see http://ec.europa.eu/consumers/safety/rapex/index_en.htm).

- For vehicle category M, N, O, T: management of end-of-series vehicles and small series

End-of-life
Member States may register and permit the sale or entry into service of vehicles conforming to a type of vehicle whose EC type-approval is no longer valid. A manufacturer who wishes to benefit from this shall submit a request to the competent authority of each Member State concerned by the entry into service of the vehicles in question. The request must specify any technical or economic reasons preventing those vehicles from complying with the new technical requirements.
RDW shall receive procedures and/or descriptions describing, as a minimum, the arrangements covering this requirement.

Small Series approvals
The manufacturer may request type-approval according to the 'small-series' regime. It shall be ensured that the number of vehicles registered, sold or entered into service in the course of a single year does not exceed the quantitative limits set out in the legislation for which type-approval is applied for. The CoC shall accordingly be marked with the production year and sequential number (to start with "1" at each production year). RDW shall receive the procedures/arrangements for ensuring this requirement.

- For vehicle category M, N, O, T: arrangements and contracts between multi stage manufacturers

RDW shall receive descriptions concerning the arrangements made by the manufacturer of the completed vehicle and contracts between the manufacturers of the completed vehicle and preceding stages, ensuring each manufacturer's responsibility for the approval and Conformity of Production of the systems, components or separate technical units added at the stage of vehicle completion handled by him. It shall as well be ensured that each manufacturer receives all required type-approval related information from the manufacturer of preceding stage(s).

"D: Required additional information for a manufacturer WITHOUT quality certificate"

- General description with following required contents: purchase and/or supplier verification / incoming goods inspection; control of production (e.g. in-process and final inspection) and calibration of measurement equipment.

For manufacturers not having a valid certificate according to EN ISO 9001:2008, ISO/TS 16949 or equivalent or having a FIR (Factory Inspection report, RDW shall receive, as a minimum, documents proving arrangements made and procedures laid down to ensure:

- purchase and/or supplier verification / incoming goods inspection:

The manufacturer shall ensure that purchased products conform to specified purchase requirements. The manufacturer shall evaluate and select suppliers based on their ability to supply products in accordance with the manufacturer's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.
The manufacturer shall establish and implement the inspection or other activities necessary for ensuring that purchased products meet specified purchase requirements. Where the manufacturer intends to perform verification at the supplier, he shall state the intended verification arrangements and method of product release in the purchasing information.

- control of production (e.g. in-process and final inspection) and calibration of measurement equipment:

The manufacturer shall plan and carry out production under controlled conditions. Controlled conditions shall include, as applicable:
the availability of information that describes the characteristics of the product,
the availability of work instructions, as necessary,
the use of suitable equipment,
the availability and use of monitoring and measuring equipment,
the implementation of monitoring and measurement,
the implementation of product release, delivery and post-delivery activities.
Where necessary to ensure valid test and check results, measuring equipment shall be calibrated (or verified, or both), at specified intervals, or prior to use, against known measurement standards. Records of the results of calibration and verification shall be maintained.

RDW

Annex 2

RDW Policy on external production locations

Introduction
Approvals according to EC-Directives and/or ECE-Regulations, can only be issued to the manufacturer of the product. The manufacturer – as the holder of the type approval – is fully responsible for the Conformity of Production (COP) as described in the relevant Directives and Regulations. A manufacturer must have and demonstrate active involvement in production processes. Vehicles, systems, components and technical units which are manufactured by a third party or a legally independent subsidiary company (hereafter called "making company") can only be approved by RDW if the following requirements are fulfilled. The "making company" can then be considered as "production location".
Requirements
The manufacturer and "making company" must have a legal contract in which they lay down all the agreements, requirements and responsibilities regarding the requirements as described in the Directives and Regulations. The manufacturer can not assign any of the responsibilities in connection to the type approval to any other party.
Both the manufacturer and making company must inform RDW immediately in writing about any change or deviation from the documents submitted to and accepted by RDW.
This contract must have indefinite validity.
In the situation that the contract between the manufacturer and making company is terminated, the issued type approvals will be withdrawn, unless the manufacturer demonstrates that suitable measures are taken to ensure that the requirements are still fulfilled. This to the discretion of RDW.
Both the manufacturer and the making company must have, implement and maintain a quality system as required by RDW's Initial Assessment procedures.
The manufacturer must ensure the making company maintains its quality system.
The manufacturer must ensure and demonstrate that the control plans and COP procedures are implemented and executed.
The manufacturer must ensure and demonstrate that all the vehicles, systems, components and technical units manufactured at the making company comply with the type approval before they come on the market.
In case of manufacturing of vehicles the manufacturer is responsible for contents and issuance of the Certificate of Conformity.
If non-conforming products have been brought to the market, the recall of the products must be co-ordinated by the manufacturer and RDW must be informed.
The manufacturer must define, implement and follow procedures to cover all the requirements as described in "Information for manufacturers: Conformity Of Production" issued by RDW.
RDW or their accredited Technical Service(s) are authorised at any time to check the effectiveness of the implemented quality system, COP plans and procedures at the facilities of the manufacturer and making company.
All costs for inspections and audits are to be born by the manufacturer and will be charged according to the current RDW price list.

Remarks
This policy excludes trade companies and import-export organisations as manufacturer or making company.
If at any moment it should become clear that the requirements of this policy have not been met, RDW will withdraw the issued Compliance Statement and approvals. This requires recall actions to be taken by the manufacturer of all relevant products delivered under the approval. All Type Approval Authorities will be informed.