Issued:	Enters into force:	Validity:
_._.202_	_._.202_	until further notice

Legal basis:
Vehicles Act (82/2021), section 66, subsection 8

Provisions on sanctions for violating this regulation are laid down in: -

Implemented EU legislation: -

Amendment details:
Repeals the regulation on the procedures for monitoring the conformity of the production of a vehicle, system, component, separate technical unit, part and equipment (TRAFICOM/46660/03.04.03.00/2020) issued by the Finnish Transport and Communications Agency on 1 February 2021.

Procedures for monitoring the conformity of the production of a vehicle, system, component, separate technical unit, part and equipment

Contents

1 Introduction and scope of application

In accordance with section 66, subsection 3 of the Vehicles Act, prior to granting the type-approval, the approval authority shall ensure that there are sufficient procedures in effect for ensuring effective control of the conformity of production.

In accordance with section 66, subsection 4 of the Vehicles Act, the approval authority or a body designated for this purpose by the approval authority shall assess the functionality of the arrangements concerning the initial assessments and product conformity related to national, E, EC and EU type-approval once every 12 months. For a special reason, the assessment may be carried out less frequently, however, it shall be carried out at least once every 24 months.

By this regulation, the Finnish Transport and Communications Agency issues under section 66, subsection 8 of the Vehicles Act further regulations on the written control plans related to the control of conformity of production as regards national, E, EC and EU type-approval as well as national small series type-approval and on sufficient product conformity arrangements.

This regulation applies to applicants and holders of national, E, EC and EU type-approvals and national small series type-approvals.

2 Definitions

For the purposes of this regulation, a *written control plan* refers to a documented description of the methods and inspections that can be carried out to ensure that the product meets the requirements for type-approval throughout the validity of the type-approval.

The definitions given in section 2 of the Vehicles Act (82/2021) are also used for this regulation.

3 Product conformity arrangements and their assessment – procedures for controlling the conformity of production in national, E, EC and EU type-approval and national small series type-approval

3.1 The manufacturer or the manufacturer's representative shall have a documented quality management system. The manufacturer's quality management system shall cover the production of the type-approved product. The manufacturer's representative holding the type-approval shall ensure that its quality management system covers the production of the type-approved product to the extent to which the manufacturer's representative is involved in manufacturing the product and it must ensure compliance with the requirements related to conformity with the national type-approval.

3.2 The product manufacturing process is controlled and managed by means of the quality management system.

3.2.1 The quality management system shall define the following:

1) the facilities and equipment which are required for the manufacturing process of the type-approved product and which may be relevant to the conformity of type-approved product;

2) the measuring equipment with which the dimensions and properties related to the conformity of the type-approved product may be verified in connection with the production with sufficient accuracy, and the manner in which the measuring equipment is managed and, where necessary, the manner in which the state of the measuring devices is monitored in a documented way;

3) the provisions and regulations applicable to the type-approved product and a documented examination of these provisions and regulations at determined intervals;

4) documented information about amendments to the provisions and regulations and the impact of the amendments on the type-approved product;

5) the procedures used to manage the conformity of sub-contracted products and services and monitor it in a documented manner;

6) at least the procedures for the management of the following documents:

   a) documents included in the quality management system;

   b) internal documents related to product conformity;

   c) external documents related to product conformity;

   d) documents related to type-approval;

e) an agreement on the control of conformity of production if such an agreement is required:

f) a potential agreement on prior notification;

g) a copy of the document with which the manufacturer has authorised a representative to act as the representative under section 2, subsection 48 of the Vehicles Act (82/2021), if such a representative has been appointed or authorised;

h) previous assessment reports on the conformity control of the production;

i) information leaflets and instructions provided by the approval authority;

7) the manner in which vehicles, systems, components, separate technical units, parts and accessories are identified, recognised, traced and linked to their manufacturing documents throughout the manufacturing process;

8) the process of handling the certificate of conformity and the information required to draft it for vehicles that are required to have a certificate of conformity;

9) the manner in which modifications to a product are managed so that conformity is constantly maintained; the definitions shall include procedures used to examine whether the modification requires a review or extension of the approval;

10) the manner in which non-compliant products or their non-compliant components are processed, marked and documented;

11) the frequency and content of management reviews; Management reviews shall be documented and shall include at least the following:

a) needs for changes in the quality management system,

b) customer feedback,

c) non-conformities and the resulting measures,

d) the results of audits (internal and external),

e) the adequacy of resources,

12) procedures for processing non-conformities,

13) the duties, responsibilities and authorisations of persons involved in the manufacturing process of type-approved products.

3.2.2 The quality management system shall contain the written control plans for type-approved products specified in chapter 4.

3.2.3 The quality management system shall be used to ensure that components identified as abnormal are not used for manufacturing type-approved products, and products found to be non-conforming will not be made available on the market.

3.2.4 In the quality management system, it shall be determined in a documented manner how the conformity of products placed on the market will be ensured. The procedure is also applied to prior notifications for vehicles. The procedure shall include a comparison between the information and requirements determined in the type-approval and the approval documentation. If the procedure is based on sampling, it must be defined.

3.2.5 The quality management system shall include an auditing programme according to which internal audits will be performed.

3.2.6 If changes are made to the quality management system, the changes shall be implemented in a systematic manner.

3.2.7 The tests related to the control of conformity of production, prescribed or provided for in separate provisions, shall be carried out and documented.

4 Written control plan

When applying for national, E, EC or EU type-approval or for national small series type-approval of a vehicle, system, component, separate technical unit, part or equipment, the applicant for the type-approval shall have a written control plan suitable for the control of conformity of the product to be type-approved.

4.1 The written control plan shall contain the following:

1) a description of the item examined,

2) an inspection method for the item,

3) the frequency of each inspection of the item to be inspected,

4) the inspection approval criteria,

5) an itemisation of the record related to the inspection,

6) details of the persons responsible for each inspection and procedure.

4.2 The documentation of the written control plan shall include:

1) an identification of the item inspected,

2) identification of the person who performed the inspection,

3) results of the inspection.

5 Entry into force and transitional provisions

This regulation enters into force on [day] [month] 2023.

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