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| Provisions on sanctions for operations violating this Regulation are laid down in: |
| Implemented EU legislation: - |
| Modification details: Repeals the regulation on the procedures for monitoring the conformity of 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 production of a vehicle, system, component, separate technical unit, part and equipment

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# Introduction and scope of application

According to section 66, subsection 3 of the Vehicles Act, prior to granting a type-approval, the approval authority shall ensure that there are sufficient procedures in effect for ensuring an efficient control of conformity of production.

According to 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, UNECE, 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, UNECE, EC and EU type-approval as well as national small series type-approval and on sufficient product conformity arrangements.

This Regulation shall be applied to applicants and holders of national, UNECE, EC and EU type-approvals and national small series type-approvals.

# 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.

This Regulation also follows the definitions given in section 2 of the Vehicles Act (82/2021).

# Product conformity arrangements and their assessment - Procedures for controlling the conformity of production in national, UNECE, EC and EU type-approval and national small series type-approval

## 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 quality management system of the manufacturer’s representative holding the type-approval shall cover the production of the type-approved product to the extent to which the manufacturer’s representative is involved in manufacturing the product and ensuring compliance with the requirements related to conformity with the national type-approval.

## The product manufacturing process shall be controlled and managed by means of the quality management system.

### 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 the 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 equipment is monitored in a documented way;
3. the statutes and regulations applicable to the type-approved product and a documented examination of these statutes and regulations at determined intervals;
4. documented information about amendments to the statutes 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:
7. documents included in the quality management system;
8. internal documents related to product conformity;
9. external documents related to product conformity;
10. documents related to type-approval;
11. an agreement on the control of conformity of production if such an agreement is required;
12. a potential agreement on prior notification;
13. 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;
14. previous assessment reports on the conformity control of the production;
15. information leaflets and instructions provided by the approval authority;
16. the manner in which vehicles, systems, components, separate technical units, parts and equipment are identified, recognised, traced and linked to their manufacturing documents throughout the manufacturing process;
17. 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;
18. 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 revision or extension of the approval;
19. the manner in which non-compliant products or their non-compliant components are processed, marked and documented;
20. management review intervals and content; management reviews must be documented and the reviews must contain at least the following:
21. needs for changes in the quality management system;
22. customer feedback;
23. non-conformities and corrective actions;
24. results of audits (internal and external);
25. the adequacy of resources;
26. procedures for processing non-conformities;
27. the duties, responsibilities and authorisations of persons involved in the manufacturing process of type-approved products.

### The quality management system must contain the written control plans for type-approved products specified in section 4.

### The quality management system must be used to ensure that any components found to be non-conforming are not used in the manufacture of type-approved products or products that are found to be non-conforming are not made available on the market.

### 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. This 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.

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

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

### The tests related to the control of conformity of production, laid down in separate provisions, shall be performed and documented.

# Written control plan

## When applying for a national, UNECE, EC, EU or national small series type-approval for 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.

## The written control plan shall contain the following:

1. a description of the object examined;
2. an inspection method for the object;
3. the frequency of each inspection of the object to inspected;
4. inspection approval criteria;
5. itemisation of the record related to the inspection;
6. details of the persons responsible for each inspection and procedure.

## The documentation of the written control plan shall contain the following:

1. an itemisation of the object inspected;
2. identification of the person performing the inspection;
3. results of the inspection.

# Transitional provisions and entry into force

This Regulation will enter into force on DD Month 2023.

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