Conformity of Production

Initial assessment, conformity of production arrangements, continuous verification and withdrawals.

Contents

1 Introduction

The National Standards Authority of Ireland (NSAI) are appointed by the Department of Transport as the Irish Type Approval Authority. As the appointed Type Approval Authority for Ireland, NSAI can issue type approval certification in accordance with National and International Automotive legislation (see legislative references).

Automotive manufacturers who attain Type approval certification are obliged to meet conformity of production requirements to ensure the vehicle, system or component maintains compliance with the relevant legislation it was approved against.

In accordance with the relevant legislation that the vehicle, system or component has or shall be approved against, NSAI shall assess the manufacturers systems and controls to ensure that the product produced and made available on the market complies with the relevant legislation approved to.

Prior to issuing type approval certification to manufacturers, NSAI shall verify that the manufacturer has established satisfactory arrangements and procedures for ensuring that vehicles, systems, components, separate technical units or parts and equipment are produced in conformity with the approved type. NSAI shall assess this during the Initial Assessment phase of application.

Once approval has been issued to the manufacturer and series production has commenced, manufacturers are obliged to ensure that the type produced continues to conform to the approved type. NSAI shall carry out assessments of the manufacturer to ensure that the type approved product continues to conform with the approved type in accordance with the relevant legislation. See section 4.3 below for further information as regards this.

Type approval certification issued to manufacturers may be withdrawn voluntarily by the manufacturer if production has discontinued. Manufacturers who are in breach of conformity of production obligations and have not addressed the issue shall be subject to forced withdrawal actioned by NSAI.

NOTE: This document is for information purposes only and is subject to change.

2 Legislative references

International legislation

2018/858 (EU) *on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles,*

167/2013 (EU) *on the approval and market surveillance of two- or three-wheel vehicles and quadricycles*

168/2013 (EU) *on the approval and market surveillance of agricultural and forestry vehicles*

2016/1628 (EU) *on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery*

E/ECE/TRANS/505/Rev.3 *Concerning the Adoption of Harmonized Technical United Nations Regulations for Wheeled Vehicles, Equipment and Parts which can be Fitted and/or be Used on Wheeled Vehicles and the Conditions for Reciprocal Recognition of Approvals Granted on the Basis of these United Nations Regulations*

UN Regulations (Addenda to the 1958 Agreement) *Regulations 0-171*

Irish Legislation

Statutory Instrument (S.I.) 556 of 2020 *European Union (Road Vehicles: Type-Approval And Market Surveillance) Regulations 2020*

Statutory Instrument (S.I.) 201 of 2024 *European Union (Road Vehicles: Type-Approval And Market Surveillance) (Amendment) Regulations 2024*

3 Definitions and abbreviations

See section 2 "Legislative references" also for definitions within

'COP' *Conformity of production*

'COC' *Certificate of conformity*

'QMS' *Quality management system*

'IA' *Initial assessment*

'Control plans' a *document outlining the actions (measurements, inspections, quality checks or monitoring of process parameters) required at each phase of a process to assure the process outputs will conform to pre-determined requirements.*

'Multi-stage approval' *means the procedure whereby one or more approval authorities certify that depending on its state of completion, an incomplete or completed type of vehicle satisfies the relevant administrative provisions and technical requirements*.

'***manufacturer***' Legal entity responsible for ensuring compliance with type-approval

'**manufacturer's representative**' *means any natural or legal person established in the Union who is duly appointed by the manufacturer to represent the manufacturer before the approval authority or the market surveillance authority and to act on the manufacturer's behalf in matters covered by this Regulation*.

'appointed representative of NSAI' *this may mean designated technical service of category C or equivalent*

4 Conformity of Production

4.1 Initial assessment

4.1.1 General

Before granting type-approval, NSAI shall verify that the manufacturer has established satisfactory arrangements and procedures for ensuring that vehicles, systems, components, separate technical units or parts and equipment to be submitted for approval shall be produced in conformity with the approved type.

NSAI shall verify that the manufacturer meets initial assessment requirements (Quality management system documentation) and the verification of the type approval subject and product-related controls i.e. "product conformity arrangements" (See 4.2 below)

The manufacturer can demonstrate that their Quality Management System meets the requirements above by either:

- An onsite initial assessment audit carried out by NSAI or an appointed representative
- Certified Quality Management System (QMS)

Recognisable QMS certification

- **ISO 9001:2015** *Quality management systems*
- **IATF 16949:2016** *Quality management system requirements for the design and development, production and, when relevant, installation and service of automotive-related products.*

Alternative Initial assessment requirements

The initial assessment and verification of product conformity arrangements may be carried out by the approval authority of another Member State. In this case, the manufacturer may submit to NSAI a valid "Statement of compliance" issued to the manufacturer from another EU member state Type Approval Authority satisfying initial assessment requirements

4.1.2 Specific Initial assessment requirements

Manufacturers must submit the following to NSAI prior to the granting of any EU/UNECE type approval certification:

- Initial assessment application form
    - Manufacturer and Assembly plant information
    - Listed EU/UNECE Type Approval Regulation(s) intend applying for
    - Manufacturer's representative details (if applicable) (See 4.1.2.6)
    - Declarations relating to COP obligations
- Quality management system documentation
    - Approval holder QMS documentation
    - Assembly plant QMS documentation
        - COP agreement for assembly plants
- Documented control plans (see 4.2)

- Multi-stage agreements (in the case of multi-stage approval)(See 4.1.2.5)
- In service monitoring plans for Non-Road mobile machinery (2016/1628 (EU) (See 4.1.2.7)

After positive review of the above documentation, NSAI can issue an Initial assessment "statement of compliance" to the manufacturer.

4.1.2.1 Initial assessment application form

An Initial assessment application form (*AD-AC-0301*) is available for manufacturers to complete at initial assessment. This form requires the following information:

- Approval holder/manufacturers name and address
- Approval holder/manufacturers contact details for person responsible for homologation (Name, position in company, email, telephone number)
- Assembly plant details
- Manufacturer's representative details (see 4.1.2.6 below for further details)
- List of the EU/UNECE Regulations that the manufacturer intends to submit to NSAI
- Declarations relating to COP requirements

4.1.2.2 Quality management system documentation for manufacturer

Option A: Certified quality management system

As per 4.1.1 above, the manufacturer may submit a recognisable certified quality system certificate i.e. ISO 9001:2015 or ISO/TS16949:2009 issued by an accredited certification body to demonstrate quality assurance as regards their management system.

Requirements:

- The scope of this certified quality system must be appropriate as regards the product to be approved and the list of EU/UNECE documented in Initial assessment application form
- The manufacturer must maintain same certification validity throughout the lifetime of the approval(s) granted by NSAI (or inform NSAI immediately of change to its validity)
- The manufacturer must submit to NSAI updated ISO certification to NSAI when an updated ISO certificate is issued
- The manufacturer must inform NSAI if there is any change of scope to the ISO certification issued to them

Option B: An onsite initial assessment audit

If the manufacturer does not have a certified quality management system as per option A, an onsite initial assessment audit is required. This shall be carried out by NSAI or an appointed representative of NSAI. The scope of audit shall be based on the principles of ISO 9001:2015 or ISO/TS16949:2009 also taking into account the product to be approved and the relevant legislation to be approved against.

Requirements:

- Arrange with NSAI or an appointed representative of NSAI to have onsite inspection carried out
- Address any non-conformities detected during the on site audit
- Have available for inspection all relevant quality documentation and procedures relevant to scope of audit
- Provide access for annual periodic inspections throughout the lifetime of the approval
- Inform NSAI of any changes to their QMS that may have an impact on the type approved product

4.1.2.2 Quality management system documentation for Assembly plants

Approval holder/manufacturers who have alternative assembly plants documented in their Initial assessment application form must submit adequate Quality system documentation for these assembly plants also

Requirements:

Assembly plants listed on the Initial assessment application form must either have:

Option A: Certified quality system (may be included on the manufacturers overall ISO certification) or their own stand alone ISO certification

or

Option B: Documentary evidence that an onsite quality assurance audit has been successfully carried out and is subject to periodic inspections

Only assembly plants cleared at Initial assessment can be included in subsequent type approval applications submitted to NSAI

4.1.2.3 COP agreement for assembly plants

A signed COP agreement between the manufacturer and assembly plants must be submitted with Initial assessment application. A template of this agreement is available. Alternative agreements not covered in NSAI template may be accepted also subject to agreement with NSAI

4.1.2.4 Declarations

The Initial assessment application form has declarations relating to the application to be submitted and a commitment by the manufacturer to adhere to COP obligations

NSAI require the manufacturer to declare that they are willing to comply with continuous verification requirements i.e. facilitate COP audits, COC inspection in the case of WVTA and willing to pay any associated fees and expenses to cover such activities.

4.1.2.5 Multistage agreements

In the case of an EU WVTA application, where it involves more than one stage of approval with different manufacturers, a multistage agreement between the relevant manufacturers is required for submission. This is to ensure that that suitable arrangements exist between the relevant manufacturers for the supply and interchange of documents and information, so that the completed type of vehicle meets the technical requirements of all the relevant regulatory acts listed in Annex II of 2018/858/EU. Such information must include details of relevant system, component and separate technical unit type-approvals and of vehicle parts that form part of the incomplete vehicle but have not yet been type-approved. (See Annex IX of 2018/858 (EU) for further information)

This agreement must be submitted to NSAI at Initial assessment and any changes to this agreement that may impact on the manufacturers obligations to ensure COP during the lifetime of the approval granted must be notified to NSAI

4.1.2.6 Manufacturers representative

(Partial extraction from Article 15 of 2018/858(EU)

A manufacturer established **outside the Union** shall appoint a single representative established within the Union to represent the manufacturer before the approval authority if applying for an EU Regulation/Directive. That manufacturer shall also appoint a single representative established within the Union for the purposes of market surveillance, who may be the same as the representative appointed for the purposes of EU type-approval.

Obligations of manufacturer's representatives:

The manufacturer's representative shall perform the tasks specified in the mandate received from the manufacturer. That mandate shall at least, provide for the representative to:

(a) have access to the EU type-approval certificate and its attachments referred to in Article 28(1) of 2018/858 (EU), and to the certificate of conformity in one of the official Union languages; such documentation shall be made available to the approval authorities and to the market surveillance authorities for a period of 10 years after the end of the validity of the EU type-approval of a vehicle and for a period of five years after the end of validity of the EU type-approval of a system, component or separate technical unit;
(b) provide an approval authority, following a reasoned request from that authority, with all information, documentation and any other technical specifications, including access to software and algorithms, that are necessary to demonstrate the conformity of production of a vehicle, system, component or separate technical unit;
(c) cooperate with the approval authorities or the market surveillance authorities, at their request, on any action taken to eliminate the serious risk posed by vehicles, systems, components, separate technical units, parts or equipment covered by that mandate;

(d) immediately inform the manufacturer about complaints and reports relating to risks, suspected incidents or non-compliance issues that relate to vehicles, systems, components, separate technical units, parts or equipment covered by that mandate;
(e) have the right to terminate the mandate without penalty if the manufacturer acts contrary to its obligations under this Regulation.

A manufacturer's representative who terminates the mandate on the grounds referred to in point (e) above shall immediately inform both NSAI and the Commission.

The information to be provided shall specify at least:

(a) the date of termination of the mandate;

(b) the date until which the outgoing manufacturer's representative may be indicated in the information supplied by the manufacturer, including any promotional material;

(c) the transfer of documents, including confidentiality aspects and property rights;

(d) the obligation of the outgoing manufacturer's representative after the end of the mandate to forward to the manufacturer or incoming manufacturer's representative any complaints or reports about risks and suspected incidents relating to a vehicle, system, component, separate technical unit, part or equipment for which the outgoing manufacturer's representative had been designated as manufacturer's representative.

NSAI shall require a copy of this mandate between both parties at the Initial assessment and full contact details for this representative.

4.1.2.7 In service monitoring (ISM) plans for Non-Road Mobile Machinery

Applications for non-road mobile engines in accordance with 2016/1628 (EU) shall also require submission of initial plan for monitoring in-service engines to NSAI for that engine type or, where applicable, engine family. This can be discussed with the technical service, NSAI and manufacturer during initial assessment.

The below listing is what NSAI is considering as being necessary to be included in a manufacturer's **ISM plan**.

- Scope of ISM Plan
- Details of document version and change history
- Details of engine families belonging to the ISM group
- Testing scheme selected for ISM
- Declared annual production figures for EU market and calculation of minimum no. of engines to be tested

- Testing plan/programme
- Selection of equipment/machinery for ISM testing and a detailed description of in-use typical operation
- Manufacturer's processes for checking the eligibility of equipment and machines e.g. maintenance records, proof/records of no misuse or tampering, (for ISM groups C, D, E, H and I) suitable evidence may include characteristics demonstrating normal wear and conformity with type-approval documentation. Ideally this will include details of how the ISM processes are incorporated with the manufacturer's QMS e.g. process flow diagram, checklists
- List and details of equipment/machinery identified for ISM testing including planned or scheduled test date
- List of completed ISM testing
- Equipment/machine test plan
    - Test site/facility
    - Equipment/Machine preparation for ISM testing
    - ISM test data collection
    - Equipment/Machine operators
- Reporting procedures/obligations
    - Test site (calibration of test equipment, accreditation of test site)
    - Sample ISM test report and report to be submitted to the Type-Approval Authority

4.1.2.8 Statement of Compliance

Manufacturers who have met the Initial assessment requirements of another member state type approval authority can submit to NSAI an Initial Assessment statement of compliance from this other Authority. This may satisfy NSAI Initial assessment requirements but shall be reviewed on a case-by-case basis

Manufacturers who have satisfied NSAI Initial assessment requirements can be issued with a statement of compliance from NSAI.

The validity of the initial assessment statement of compliance shall be two years from the date of issue.

Manufacturers who have had their type approval(s) withdrawn shall also have their IA Statement of compliance withdrawn.

4.2 Product Conformity Arrangements

4.2.1 General

Extract from Annex IV 2018/858(EU):

Every vehicle, system, component or separate technical unit, part or item of equipment approved pursuant to a UN Regulation annexed to the Revised 1958 Agreement and to this Regulation shall be so manufactured as to conform to the type approved by meeting the requirements of this Annex, the said UN Regulation and this Regulation.

Before granting a type-approval pursuant to this Regulation and to a UN Regulation annexed to the Revised 1958 Agreement, the approval authority shall verify the existence of ***adequate product conformity arrangements and documented control plans****, to be agreed with the manufacturer for each approval, to carry out at specified intervals the tests or associated checks that are necessary to verify continued conformity with the approved type, including, where applicable, tests specified in this Regulation and the said UN Regulation.*

The holder of the type-approval shall, in particular:

- *ensure the existence and application of procedures for effective control of the conformity of vehicles, systems, components, separate technical units, parts or equipment to the approved type;*
- *have access to the testing or other appropriate equipment necessary for checking the conformity to each approved type;*
- *ensure that the data resulting from tests or checks are recorded and that annexed documents remain available for a period of up to 10 years to be determined in agreement with the approval authority*
- *analyse the results of each type of test or check, in order to verify and ensure the stability of the product characteristics, making allowance for variation of an industrial production;*
- *ensure that for each type of product, at least the checks prescribed in this Regulation and the tests prescribed in the relevant regulatory acts listed in Annex II are carried out;*
- *ensure that any set of samples or test pieces that gives evidence of nonconformity in the type of test in question, gives rise to a further sampling and testing. All the necessary steps shall be taken to restore the production process to ensure conformity with the approved type.*

4.2.2 Specific Product Conformity Requirements

The manufacturer must submit documented control plans for each type of application submitted that meets the requirements of 4.2.1 above at Initial assessment. Where the initial assessment form lists multiple EU/UNECE regulations, control plans addressing each of these EU/UNECE regulations are required.

It is expected that these control plans at a minimum shall demonstrate that the manufacturer has adequate checks and controls in place. These control plans should include (but not limited to):

- Issued and controlled by the approval holder
- Have document control and be part of the overall approval holders QMS
- Reference the applicable type approval legislation
- Outline what tests and checks are to be done including the inspection of marking
- Outline the test frequency
- Specify the relevant personnel/section who conducts the test
- Indicate criteria for acceptance (pass/fail criterion)

Where the control plans make reference to "in house test reports" for checking these items, a template of these reports should be submitted along with the control plans.

Control plans should also identify any mandatory COP tests are required by specific type approval legislation. All records relating to control plans must be retained for inspection and review (also See 4.3.3)

4.3 Continued verification arrangements

4.3.1 General

Extract from 2018/858 (EU)

Article 31

…

2. An approval authority that has granted a whole-vehicle type-approval shall verify a statistically relevant number of samples of vehicles and certificates of conformity on their compliance with Articles 36 and 37 and shall verify that the data in those certificates of conformity are correct.

3. An approval authority that has granted an EU type-approval shall take the necessary measures to verify, if necessary in cooperation with the approval authorities of the other Member States, that the arrangements referred to in paragraphs 1 and 2 of this Article continue to be adequate so that vehicles, systems, components or separate technical units in production continue to conform to the approved type and that certificates of conformity continue to comply with Articles 36 and 37.

4. In order to verify that a vehicle, system, component or separate technical unit conforms to the approved type, the approval authority that granted the EU type-approval shall take the necessary measures to carry out the checks or tests on samples taken at the manufacturer's premises, including production facilities that are required for EU type-approval.

In accordance with Annex IV, the approval authority shall take the necessary measures to carry out such checks or tests with the frequency set out in the regulatory acts listed in Annex II, or, if no frequency is specified in those acts, at least once every three years.

5. In order to verify that a vehicle, system, component or separate technical unit conforms to the approved type, the approval authority or the technical services shall: (a) if a range of values is provided for in the test procedures laid down in the relevant regulatory acts listed in Annex II, set the values in a random manner within the provided range when carrying out checks or tests; and (b) have access to the software, algorithms, documentation and any additional information in accordance with Article 25(4).

6. An approval authority that has granted an EU type-approval shall take the necessary measures to verify that the manufacturer complies with the obligations set out in Chapter XIV. It shall verify in particular whether, in order to comply with those obligations, the manufacturer has amended or supplemented the vehicle OBD information and vehicle repair and maintenance information.

7. Where an approval authority that has granted an EU type-approval establishes that the manufacturer no longer produces the vehicles, systems, components or separate technical units in conformity with the approved type or with the requirements of this Regulation, or establishes that the certificates of conformity no longer comply with Articles 36 and 37, even though production is continued, it shall take the necessary measures to ensure that the arrangements for conformity of production are followed correctly or withdraw the type-approval. The approval authority may decide to take all necessary restrictive measures in accordance with Chapter XI.

Annex IV 2018/858/EU

The approval authority that has granted type-approval may at any time verify the conformity control methods applied in each production facility by means of periodic audits. The manufacturer shall for that purpose allow access to that authority to the manufacturing, inspection, testing, storage and distribution sites and shall provide all necessary information with regard to the quality management system documentation and records.

4.1.1. The normal arrangements for such periodic audits shall be to monitor the continued effectiveness of the procedures laid down in points 2 and 3 (initial assessment and product conformity arrangements).

4.1.1.1. Surveillance activities carried out by the technical services (qualified or recognised as required in point 2.3.3) shall be accepted as satisfying the requirement of point 4.1.1 with regard to the procedures established at initial assessment.

4.1.1.2. The normal frequency of verifications by the approval authority (other than those referred to in point 4.1.1.1) shall be such as to ensure that the relevant controls applied in accordance with points 2 and 3 are reviewed at intervals based on a risk assessment methodology that complies with the international standard ISO 31000:2018 – Risk Management – Principles and Guidelines, and such verification shall in any case be conducted at least once every three years. This methodology shall in particular take into account any non-conformity raised by other Member States in the context of Article 54(1).

4.2. At every review, records of tests or checks and records of production, in particular records of those tests or checks documented as required in point 2.2, shall be made available to the inspector.

4.3. The inspector may select samples at random manner to be tested in the manufacturer's laboratory or in the facilities of the technical service. In such a case only physical test shall be carried out. The minimum number of samples may be determined on the basis of the results of the manufacturer's own verification

4.3.2 Specific requirements

In accordance with the requirements within the applicable type approval legislation regarding conformity of production, NSAI shall use risk-based analysis of approvals held by manufacturers for frequency of COP audit selection. This risk-based analysis shall consider (but not limited to):

- Reports of non-conformity
- Safety related approval
- WVTA
- Volume of approvals held

NSAI or their authorised representative shall contact the manufacturer to arrange these periodic audits.

Approval holders of Whole Vehicle Type Approvals (WVTA) shall also be subject to periodic COC inspection to ensure that COCs issued are in accordance with requirements of articles 36 and 37 of 2018/858(EU). Some of these checks include (but not limited to):

- COC data accuracy, content and correct template
- the security elements to prevent forgery of the certificate of conformity
- manner in which COC signatory added and when obliged to generate an
- E COC requirements (when applicable)

5 Arrangements concerning software update

If the manufacturer has a UNECE R156 approval issued to them by NSAI, the software update management system of the manufacturer as well as the whole vehicle type shall comply with the requirements as set out in this UNECE Regulation.

NSAI shall periodically validate that the processes used, and decisions made by the vehicle manufacturer are compliant, particularly for instances where the vehicle manufacturer chose not to notify NSAI about an update. This may be achieved on a sampling basis.

6 Notification of non-compliance

General

Legal obligations on manufacturers:

Extract from 2018/858 (EU)

Article 14

Obligations of manufacturers concerning their vehicles, systems, components, separate technical units, parts and equipment that are not in conformity or that present a serious risk

1. Where a vehicle, system, component, separate technical unit, part or equipment that has been placed on the market or that has entered into service is not in conformity with this Regulation or where the type approval has been granted on the basis of incorrect data, the manufacturer shall immediately take the corrective measures necessary to bring that vehicle, system, component, separate technical unit, part or equipment into conformity, to withdraw it from the market or to recall it, as appropriate. The manufacturer shall immediately inform the approval authority that granted the type-approval in detail of the non-conformity and of any measures taken.

2. Where the vehicle, system, component, separate technical unit, part or equipment presents a serious risk, the manufacturer shall immediately provide to the approval authorities and market surveillance authorities detailed information on the risk and on any measures taken in relation thereto.

Specific requirements for notification of non-compliance

Approval holders of EU/UNECE type approval certification are obliged to ensure that products placed on the market comply with the specification of the type approval issued. As the approval holder of an EU/UNECE type approval, in accordance with article 14 2018/858 (EU), the manufacturer must inform NSAI as the issuing Type Approval Authority if they become aware of an approved product on the market that is in non-compliance with the type approved specification.

NSAI may also be notified by an external body i.e. Market Surveillance Authority, other member state Type Approval Authority etc. of a potential noncompliance with an approved product on the EU market. In this case, NSAI shall contact the manufacturer immediately and inform the manufacturer of the notified non-compliance. The manufacturer shall have an opportunity to respond to the issues raised. NSAI shall then review and decide on appropriate action. This may include a COP audit and/or randomly selected product retesting. If the issue is not addressed to NSAI satisfaction, the approval(s) may be withdrawn. Manufacturers can notify NSAI directly of potential non-compliant product on the market by submitting to NSAI the Nonconformity report to:

cop-reporting@nsai.ie

NSAI shall review this report and the remedial actions proposed by the manufacturer and revert back.

7 Withdrawal of approval

As the holder of an EU/UNECE approval, the approval may be withdrawn by either:

- Voluntary withdrawal (requested by manufacturer)
- Actioned withdrawal (NSAI forced withdrawal)

Voluntary withdrawals

Manufacturers who hold an E24/e24 type approval can request from NSAI to withdraw the approval for reasons such as "production discontinued" or some other reason. An official letter from the manufacturer must be submitted to NSAI outlining:

- Reason for withdrawal
- List of approval(s) and type(s), variant(s) and version(s)
- Date production ceased
- Last issued serial/batch number
- Signed and dated by authorised representative of manufacturer

On receipt of this, NSAI shall review and check the authenticity of the request. Once satisfied with its authenticity, NSAI will withdraw the relevant approvals and notify all the other EU Authorities of this withdrawal

Actioned withdrawal

NSAI may have to action a withdrawal on a manufacturer for reasons such as product noncompliance or unsatisfactory conformity of production arrangements. In such cases NSAI shall notify all other EU Authorities of this withdrawal. If an approval has been withdrawn, the manufacturer must cease to apply NSAI marking or NSAI association on their products