

## ANNEX X

## CONFORMITY OF PRODUCTION PROCEDURES

## 0. OBJECTIVES

The conformity of production procedure aims to ensure that each produced vehicle, system, component and technical separate unit is in conformity with the approved type.

Procedures include inseparably, the assessment of quality management systems, referred to below as the initial assessment<sup>(1)</sup> and verification of the approval subject and product-related controls, and referred to as product conformity arrangements.

## 1. INITIAL ASSESSMENT

1.1. The EC type-approval authority of a Member State must verify, before granting EC type-approval, the existence of satisfactory arrangements and procedures for ensuring effective control so that components, systems, separate technical units or vehicles when in production conform to the approved type.

1.2. The requirements in point 1.1 shall be verified to the satisfaction of the authority granting EC type-approval.

That authority shall be satisfied with the initial assessment and the initial product conformity arrangements at section 2 below, taking account, as necessary, of one of the arrangements described at paragraphs 1.2.1 to 1.2.3, or a combination of those arrangements in full or in part as appropriate.

1.2.1. The actual initial assessment and/or verification of product conformity arrangements shall be carried out by the EC type-approval authority granting the approval or an appointed body acting on behalf of the EC type-approval authority.

1.2.1.1. When considering the extent of the initial assessment to be carried out, the EC type-approval authority may take account of available information relating to:

- the manufacturer's certification described in 1.2.3 below, which has not been qualified or recognised under that paragraph,
- in the case of component or separate technical unit EC type-approval, quality system assessments performed in the component or separate technical unit manufacturer's premises by vehicle manufacturer(s), according to one or more of the industry sector specifications satisfying the requirements in harmonised standard EN ISO 9002-1994, or EN ISO 9001-2000 with the permissible exclusion of the requirements related to the concepts of design and development, sub-clause 7.3 'Customer Satisfaction and Continual Improvement'.

1.2.2. The actual initial assessment and/or verification of product conformity arrangements may also be carried out by the EC type-approval authority of another Member State or the appointed body designated for this purpose by the EC type-approval authority. In that case, the EC type-approval authority of the other Member State shall prepare a statement of compliance outlining the areas and production facilities it has covered as relevant to the product(s) to be EC type-approved and to the directive or regulation according to which these products are to be approved<sup>(2)</sup>. On receiving an application for a compliance statement from the EC type-approval authority of a Member State granting EC type-approval, the EC type-approval authority of another Member State shall send forthwith the statement of compliance or advise that it is not in a position to provide such a statement. The statement of compliance should at least include:

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*Status: This is the original version (as it was originally adopted).*

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Group or company:	(e.g. XYZ Automotive)
Particular organisation:	(e.g. European Division)
Plants/Sites:	(e.g. Engine Plant 1 (United Kingdom) Vehicle Plant 2 (Germany))
Vehicle/Component range:	(e.g. All Category M <sub>1</sub> models)
Areas assessed:	(e.g. Engine assembly, body pressing and assembly, vehicle assembly)
Documents examined:	(e.g. Company and site quality manual and procedures)
Assessment:	(e.g. Conducted: 18-30.9.2001) (e.g. Planned monitor visit: March 2002)

1.2.3. The EC type-approval authority must also accept the manufacturer's suitable certification to harmonised standard EN ISO 9002-1994 (whose scope covers the locations of production and product(s) to be approved), or EN ISO 9001-2000 with the permissible exclusion of the requirements related to the concepts of design and development, sub-clause 7.3 'Customer Satisfaction and Continual Improvement', or an equivalent harmonised standard as satisfying the initial assessment requirements of point 1.2. The manufacturer must provide details of the certification and undertake to inform the EC type-approval authority of any revisions to its validity or scope.

1.3. For the purpose of the whole vehicle EC type-approval, the initial assessments carried out for granting of approvals for systems, components and technical units of the vehicle need not be repeated, but shall be completed by an assessment covering the locations and activities relating to the assembly of the whole vehicle not covered by the former assessments.

## 2. PRODUCT CONFORMITY ARRANGEMENTS

2.1. Every vehicle, system, component or separate technical unit approved pursuant to this Directive or a separate directive or regulation must be so manufactured as to conform to the type approved by meeting the requirements of this Directive or a separate directive or regulation contained in the complete list set out in Annex IV or XI.

2.2. The EC type-approval authority of a Member State, at the time of granting an EC type-approval, must verify the existence of adequate arrangements and documented control plans, to be agreed with the manufacturer for each approval, to carry out at specified intervals those tests or associated checks necessary to verify continued conformity with the approved type including specifically, where applicable, tests specified in the separate directives or regulations.

2.3. The holder of the EC type-approval must, in particular:

2.3.1. ensure the existence and application of procedures for effective control of the conformity of products (vehicles, systems, components or separate technical units) to the approved type;

2.3.2. have access to the testing or other appropriate equipment necessary for checking the conformity to each approved type;

- 2.3.3. ensure that test or check results data are recorded and that annexed documents remain available for a period to be determined in agreement with the type-approval authority. This period is not required to exceed 10 years;
- 2.3.4. 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;
- 2.3.5. ensure that for each type of product, at least the checks prescribed in this Directive and the tests prescribed in the applicable separate directives or regulations contained in the complete list set out in Annex IV or XI, are carried out;
- 2.3.6. ensure that any set of samples or test pieces, giving evidence of non-conformity in the type of test or check in question gives rise to a further sampling and test or check. All the necessary steps shall be taken to restore conformity of the corresponding production;
- 2.3.7. in the case of whole-vehicle EC type-approval, the checks referred to in point 2.3.5 are restricted to those verifying the correct build specification in relation to the approval and especially to the information document laid down in Annex III and the information required for certificates of conformity given in Annex IX to this Directive.

### 3. CONTINUED VERIFICATION ARRANGEMENTS

- 3.1. The authority which has granted EC type-approval may at any time verify the conformity control methods applied in each production facility.
  - 3.1.1. The normal arrangements shall be to monitor the continued effectiveness of the procedures established at 1.2 (initial assessment and product conformity) of this Annex.
    - 3.1.1.1. Surveillance activities carried out by a certification body (qualified or recognised as required by paragraph 1.2.3 of this Annex) must be accepted as satisfying the requirements of 3.1.1 with regard to the procedures established at initial assessment (paragraph 1.2.3).
    - 3.1.1.2. The normal frequency of verifications by the EC type-approval authority (other than those at 3.1.1.1) shall be such as to ensure that the relevant controls applied in accordance with Sections 1 and 2 of this Annex are reviewed over a period consistent with the climate of trust established by the type-approval authority.
- 3.2. At every review, records of tests or checks and records of production shall be made available to the inspector; in particular, records of those tests or checks documented as required by point 2.2 of this Annex.
- 3.3. Where the nature of the test is appropriate, the inspector may select samples at random to be tested in the manufacturer's laboratory (or by the technical service where the separate directive or regulation so provides). The minimum number of samples may be determined according to the results of the manufacturer's own verification.
- 3.4. Where the level of control appears unsatisfactory, or when it seems necessary to verify the validity of the tests carried out in application of point 3.2, the inspector must select samples to be sent to the technical service which conducted the EC type-approval tests.

- 3.5. In cases where unsatisfactory results are found during an inspection or a monitoring review, the EC type-approval authority must ensure that all necessary steps are taken to restore conformity of production as rapidly as possible.

- (1) Guidance on the planning and conduct of assessment is to be found in harmonised standard ISO 10011, Parts 1, 2 and 3, 1991.
- (2) For example, the relevant separate directive or regulation, if the product to be approved is a system, component or technical unit, and Directive 2007/46/EC if it is a whole vehicle.