# ANNEX IV

## CONFORMITY OF PRODUCTION PROCEDURES

4. Continued verification arrangements

4.1. 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.

4.4. The inspector who is of the opinion that the level of control is unsatisfactory, or who deems it necessary to verify the validity of the tests carried out in accordance with point 4.2, shall select samples to be sent to a technical service to perform physical tests in accordance with the requirements on conformity of production, set out in the regulatory acts listed in Annex II.

4.5. Where unsatisfactory results are found during an inspection or a monitoring review, the approval authority shall take all necessary steps to ensure that the manufacturer restores the conformity of production as rapidly as possible.

4.6. In cases where compliance with UN Regulations is required by this Regulation, the manufacturer may choose to apply this Annex as an equivalent alternative to the conformity of production requirements in the respective UN Regulations. However, if points 4.4. or 4.5. apply, all separate conformity of production requirements in the UN Regulations have to be complied with to the satisfaction of the approval authority until it decides that conformity of production has been restored.