

ANNEX III

REQUIREMENTS AND ASSESSMENT CRITERIA FOR ORGANISATIONS APPLYING FOR AN ECM CERTIFICATE OR FOR A CERTIFICATE IN RESPECT OF MAINTENANCE FUNCTIONS OUTSOURCED BY AN ENTITY IN CHARGE OF MAINTENANCE

The organisation management must be documented in all relevant parts and shall in particular describe the distribution of responsibilities within the organisation and with subcontractors. It shall show how control by the management on different levels is secured, how staff and their representatives on all levels are involved and how continuous improvement is ensured.

The following basic requirements shall be applied to the four functions of an entity in charge of maintenance (ECM) to be covered by the organisation itself or through contracting arrangements:

1. Leadership — commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness;
2. Risk assessment — a structured approach to assess risks associated with the maintenance of vehicles, including those directly arising from operational processes and the activities of other organisations or persons, and to identify the appropriate risk control measures;
3. Monitoring — a structured approach to ensure that risk control measures are in place, working correctly and achieving the organisation's objectives;
4. Continuous improvement — a structured approach to analyse the information gathered through regular monitoring, auditing, or other relevant sources and to use the results to learn and to adopt preventive or corrective measures in order to maintain or improve the level of safety;
5. Structure and responsibility — a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation's safety objectives;
6. Competence management — a structured approach to ensure that employees have the competences required in order to achieve the organisation's objectives safely, effectively and efficiently in all circumstances;
7. Information — a structured approach to ensure that important information is available to those making judgments and decisions at all levels of the organisation and to ensure the completeness and appropriateness of the information;
8. Documentation — a structured approach to ensure the traceability of all relevant information;
9. Contracting activities — a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation's objectives to be achieved and all competences and requirements are covered;
10. Maintenance activities — a structured approach to ensure:
 - that all maintenance activities affecting safety and safety-critical components are identified and correctly managed and that all the necessary changes to those maintenance activities affecting safety are identified, properly managed based upon the return of experience and the application of Common Safety Methods for risk assessment in accordance with point (a) of Article 6(1) and properly documented;
 - conformity with the essential requirements for interoperability;

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- the implementation and check of maintenance facilities, equipment and tools specifically developed and required for maintenance delivery;
 - the analysis of the initial documentation related to the vehicle for providing the first maintenance file and to ensure its correct implementation through the development of maintenance orders;
 - that components (including spare parts) and materials are used as specified in the maintenance orders and supplier documentation; they are stored, handled and transported in an appropriate manner as specified in the maintenance orders and supplier documentation and comply with relevant national and international rules as well as with the requirements of relevant maintenance orders;
 - that suitable and adequate facilities, equipment and tools are determined, identified, provided, recorded and kept available to enable to deliver the maintenance services in accordance with maintenance orders and other applicable specifications, ensuring the safe delivery of maintenance, ergonomics and health protection;
 - that the organisation have processes to ensure that its measuring equipment, all facilities, equipment and tools are correctly used, calibrated, preserved and maintained in accordance with documented processes;
11. Control activities — a structured approach to ensure:
- that vehicles are removed from operation for scheduled, conditional or corrective maintenance in due time, or whenever defects or other needs have been identified;
 - the necessary quality control measures;
 - [^{X1}that maintenance tasks are performed in accordance with the maintenance orders and to issue the notice to return to operation including possible restrictions on use;]
 - that possible instance of non-compliance in the application of the management system that might result in accidents, incidents, near-misses or other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken in compliance with the common safety method for monitoring provided in point (c) of Article 6(1);
 - recurrent internal auditing and monitoring process compliant with the common safety method for monitoring provided in point (c) of Article 6(1).

Editorial Information

X1 Substituted by [Corrigendum to Directive \(EU\) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety \(Official Journal of the European Union L 138 of 26 May 2016\)](#).