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## ANNEX II

### **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**

#### **I. Requirements and assessment criteria for the management function**

1. **Leadership** — *commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness*

The organisation shall have procedures for:

- (a) establishing a maintenance policy appropriate to the organisation's type and extent of service and approved by the organisation's chief executive or his or her representative;
  - (b) ensuring that safety targets are established, in line with the legal framework and consistent with an organisation's type, extent and relevant risks;
  - (c) assessing its overall safety performance in relation to its corporate safety targets;
  - (d) developing plans and procedures for reaching its safety targets;
  - (e) ensuring that the resources needed to perform all processes are available to comply with the requirements of this Annex;
  - (f) identifying and managing the impact of other management activities on the maintenance system;
  - (g) ensuring that senior management is aware of the results of performance monitoring and audits and takes overall responsibility for the implementation of changes to the maintenance system;
  - (h) ensuring that staff and staff representatives are adequately represented and consulted in defining, developing, monitoring and reviewing the safety aspects of all related processes that may involve staff.
2. **Risk management** — *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*

- 2.1. The organisation shall have procedures and arrangements in place to recognise the need and commitment to collaborate with keepers, railway undertakings, infrastructure managers, designers and manufacturers of vehicles and components or other interested parties.
- 2.2. The organisation shall have risk management procedures to manage changes in the maintenance file, including maintenance plans, equipment, procedures, organisation, staffing or interfaces, and to apply the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798.
- 2.3. When assessing risk, an organisation shall have procedures to take into account the need to determine, provide and sustain an appropriate working environment which conforms to Union and national legislation, in particular Council Directive 89/391/EEC<sup>(1)</sup>.

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3. **Monitoring** — *a structured approach to ensure that risk control measures are in place, working correctly and achieving the organisation's objectives*
- 3.1. The organisation shall have a procedure to regularly collect, monitor and analyse relevant safety data, including:
  - (a) the performance of relevant processes;
  - (b) the results of processes (including all contracted services and products);
  - (c) the effectiveness of risk control arrangements;
  - (d) information on experience, malfunctions, defects and repairs arising from day-to-day operation and maintenance.
- 3.2. The organisation shall have procedures to ensure that accidents, incidents, near-misses and other dangerous occurrences are reported, logged, investigated and analysed.
- 3.3. For a periodic review of all processes, the organisation shall have an internal auditing system which is independent, impartial and acts in a transparent way. This system shall have procedures in place to:
  - (a) develop an internal audit plan, which may be revised depending on the results of previous audits and monitoring of performance;
  - (b) analyse and evaluate the results of the audits;
  - (c) propose and implement specific corrective measures or actions;
  - (d) verify the effectiveness of previous measures or actions.
- 3.4. The procedures mentioned in points 3.1, 3.2 and 3.3 of this Section shall comply with the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 and to the methods for assessing the safety level and the safety performance of railway operators at national and Union level as adopted pursuant to point (d) of Article 6(1) of that Directive.
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*

The organisation shall have procedures to ensure that:

- (a) identified shortcomings are rectified;
- (b) new safety developments are implemented;
- (c) internal audit findings are used to bring about improvement in the system;
- (d) preventive or corrective actions are implemented, when needed, to ensure compliance of the railway system with standards and other requirements throughout the lifecycle of equipment and operations;
- (e) relevant information relating to the investigation and causes of accidents, incidents, near-misses and other dangerous occurrences is used to learn and, where necessary, to adopt measures in order to improve the level of safety;

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- (f) relevant recommendations from the national safety authority, from the national investigation body and from industry or internal investigations are evaluated and implemented if appropriate;
  - (g) relevant reports or information from railway undertakings/infrastructure managers, keepers or other relevant sources are considered and taken into account.
5. **Structure and responsibility** — *a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation's safety objectives*
- 5.1. The organisation shall have procedures to allocate responsibilities for all relevant processes throughout the organisation.
  - 5.2. The organisation shall have procedures to clearly define safety-related areas of responsibility and the distribution of responsibilities to specific functions associated with them as well as their interfaces. Those include the procedures indicated in point 2.1 above between the organisation and the keepers and, where appropriate, railway undertakings and infrastructure managers.
  - 5.3. The organisation shall have procedures to ensure that staff with delegated responsibilities within the organisation have the authority, competence and appropriate resources to perform their functions. Responsibility and competence shall be coherent and compatible with the given role, and delegations shall be in writing.
  - 5.4. The organisation shall have procedures to ensure the coordination of activities related to relevant processes across the organisation.
  - 5.5. The organisation shall have procedures to hold those with a role in the management of safety accountable for their performance.
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*
- 6.1. The organisation shall set up a competence management system providing for:
    - (a) the identification of posts with responsibility for performing within the system all the processes necessary for compliance with the requirements of this Annex;
    - (b) the identification of posts involving safety tasks;
    - (c) the allocation of staff with the appropriate competence to relevant tasks.
  - 6.2. Within the organisation's competence management system, there shall be procedures to manage the competence of staff, including at least:
    - (a) identification of the knowledge, skills and experience required for safety-related tasks as appropriate for the responsibilities;
    - (b) selection principles, including basic educational level, mental aptitude and physical fitness;
    - (c) initial training and qualification or certification of acquired competence and skills;
    - (d) assurance that all staff are aware of the relevance and importance of their activities and how they contribute to the achievement of safety objectives;
    - (e) ongoing training and periodical updating of existing knowledge and skills;

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- (f) periodic checks of competence, mental aptitude and physical fitness where appropriate;
  - (g) special measures in the case of accidents/incidents or long absences from work, as required.
7. **Information** — *a structured approach to ensure that important information is available to those making judgments and decisions at all levels of the organisation*
- 7.1. The organisation shall have procedures to define reporting channels to ensure that, within the entity itself and in its dealings with other actors, including infrastructure managers, railways undertakings, keepers and designers or manufacturers of vehicles or components, or both, when appropriate, information on all relevant processes is duly exchanged and submitted to the person having the right role both within its own organisation and in other organisations, in a prompt and clear way.
- 7.2. To ensure an adequate exchange of information, the organisation shall have procedures for:
- (a) the receipt and processing of specific information;
  - (b) the identification, generation and dissemination of specific information;
  - (c) making available reliable and up-to-date information.
- 7.3. The organisation shall have procedures to ensure that key operational information is:
- (a) relevant and valid;
  - (b) accurate;
  - (c) complete;
  - (d) appropriately updated;
  - (e) verified;
  - (f) consistent and easy to understand (including the language used);
  - (g) made known to staff in accordance with their responsibilities, before it is applied;
  - (h) easily accessible to staff, with copies provided to them where required.
- 7.4. The requirements set out in points 7.1, 7.2 and 7.3 apply in particular to the following operational information:
- (a) checks of the accuracy and completeness of national vehicle registers regarding the identification (including means) and registration of the vehicles maintained by the organisation;
  - (b) maintenance documentation;
  - (c) information on support provided to keepers and, where appropriate, to other parties, including railway undertakings/infrastructure managers;
  - (d) information on the qualification of staff and subsequent supervision during maintenance development;

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- (e) information on operations (including mileage, type and extent of activities, incidents or accidents) and requests of railway undertakings, keepers and infrastructure managers;
  - (f) records of maintenance performed, including information on deficiencies detected during inspections and corrective actions taken by railway undertakings or by infrastructure managers such as inspections and monitoring undertaken before the departure of the train or en route;
  - (g) release to service and return to operation;
  - (h) maintenance orders;
  - (i) technical information to be provided to railway undertakings/infrastructure managers and keepers for maintenance instructions;
  - (j) emergency information concerning situations where the safe state of running is impaired, which may consist of:
    - (i) the imposition of restrictions of use or specific operating conditions for the vehicles maintained by the organisation or other vehicles of the same series even if maintained by other entities in charge of maintenance, whereby this information shall also be shared with all involved parties;
    - (ii) urgent information on safety-related issues identified during maintenance, such as deficiencies detected in a component common to several categories or series of vehicles;
  - (k) all relevant information or data needed to submit the annual maintenance report to the certification body and to the relevant customers (including keepers), whereby this report shall also be made available upon request to national safety authorities.
8. **Documentation** — *a structured approach to ensure the traceability of all relevant information*
- 8.1. The organisation shall have adequate procedures in place to ensure that all relevant processes are duly documented.
- 8.2. The organisation shall have adequate procedures in place to:
- (a) regularly monitor and update all relevant documentation;
  - (b) format, generate, distribute and verify changes to all relevant documentation;
  - (c) receive, collect and archive all relevant documentation.
9. **Contracting activities** — *a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation's objectives to be achieved*
- 9.1. The organisation shall have procedures in place to ensure that safety-related products and services are identified.
- 9.2. When making use of contractors or suppliers, or both, for safety-related products and services, the organisation shall have procedures in place to verify at the time of selection that:
- (a) contractors, subcontractors and suppliers are competent;

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- (b) contractors, subcontractors and suppliers have a maintenance and management system that is adequate and documented.
- 9.3. The organisation shall have a procedure to define the requirements that such contractors and suppliers have to meet.
- 9.4. The organisation shall have procedures to monitor the awareness of suppliers and/or contractors of risks they entail to the organisation's operations.
- 9.5. When the maintenance or management system of a contractor or supplier is certified, the monitoring process described in point 3 may be limited to the results of the contracted operational processes referred to in point 3.1(b).
- 9.6. At least the basic principles for the following processes shall be clearly defined, known and allocated in the contract between the contracting parties:
  - (a) responsibilities and tasks relating to railway safety issues;
  - (b) obligations relating to the transfer of relevant information between both parties;
  - (c) the traceability of safety-related documents.
- II. Requirements and assessment criteria for the maintenance development function**
- 1. The organisation shall have a procedure to identify and manage:
  - (a) all maintenance activities affecting safety;
  - (b) all safety-critical components.
- 2. The organisation shall have procedures to guarantee conformity with the essential requirements for interoperability, including updates throughout the lifecycle, by:
  - (a) ensuring compliance with the specifications related to the basic parameters for interoperability as set out in the relevant technical specifications for interoperability (TSIs);
  - (b) verifying in all circumstances the consistency of the maintenance file with the authorisation related to the vehicle (including any national safety requirements), including the conformity to the technical file and the type of records as in the European Register of Authorised Types of Vehicles (ERATV);
  - (c) managing any substitution in the framework of maintenance;
  - (d) identifying the need for risk assessment of the potential impact of the change in question on the safety of the railway system, by application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798;
  - (e) managing the configuration of all technical changes affecting the system integrity of the vehicle.
- 3. The organisation shall have a procedure to design and support the implementation of maintenance facilities, equipment and tools specifically developed and required for maintenance delivery. The organisation shall have a procedure to check that these facilities, equipment and tools are used, stored and maintained according to their maintenance schedule and in conformity with their maintenance requirements.
- 4. When vehicles start operations, the organisation shall have procedures to:

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- (a) obtain access to the recommendations for maintenance of the initial documentation and to collect sufficient information on planned operations;
  - (b) analyse those recommendations for maintenance of the initial documentation and to provide, by application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798, the first maintenance file, also taking into account the information contained in any associated guarantees;
  - (c) ensure that the implementation of the first maintenance file is done accordingly.
5. To keep the maintenance file updated throughout the lifecycle of a vehicle, the organisation shall have procedures to:
- (a) collect at least the relevant information in relation to:
    - (i) the type and extent of operations effectively performed, including, but not limited to accidents, serious accidents and incidents, as defined in Directive (EU) 2016/798;
    - (ii) the detected failures on components;
    - (iii) the type and extent of operations planned;
    - (iv) the maintenance effectively performed.
  - (b) define the need for updates, taking into account the limit values for interoperability;
  - (c) make proposals for and approve changes and their implementation, with a view to a decision based on clear criteria, taking into account the findings from risk assessment performed by application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798;
  - (d) ensure that the implementation of changes is done accordingly;
  - (e) monitor the effectiveness of the changes through a process in consistency with the methods for assessing the safety level and the safety performance of railway operators at national and Union level as adopted pursuant to point (d) of Article 6(1) of Directive (EU) 2016/798.
6. When the competence management process is applied to the maintenance development function, at least the following activities affecting safety shall be taken into account:
- (a) application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 for assessment of changes of the maintenance file;
  - (b) engineering disciplines required for managing the establishment and the changes of the maintenance file and the development, assessment, validation and approval of substitutions in the framework of maintenance;
  - (c) maintenance activities on safety-critical components;
  - (d) joining techniques (including welding and bonding);
  - (e) non-destructive testing.

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7. When the documentation process is applied to the maintenance development function, the traceability of at least the following elements needs to be guaranteed:
  - (a) the documentation relating to the development, assessment, validation and approval of a substitution in the framework of maintenance;
  - (b) the configuration of vehicles, including, but not limited to, safety-critical components and on-board software modifications;
  - (c) records of the maintenance performed;
  - (d) results of studies concerning return on experience;
  - (e) all the successive versions of the maintenance file, including risk assessment;
  - (f) reports on the competence and supervision of maintenance delivery and fleet maintenance management;
  - (g) technical information to be provided to support keepers, railway undertakings and infrastructure managers.
- III. **Requirements and assessment criteria for the fleet maintenance management function**
  1. The organisation shall have a procedure to check the competence, availability and capability of the entity responsible for maintenance delivery before placing maintenance orders. This requires that the maintenance workshops are duly qualified to decide upon the requirements for technical competences in the maintenance delivery function.
  2. The organisation shall have a procedure for the composition of the work package and for the issue and release of the maintenance order.
  3. The organisation shall have a procedure to send vehicles for maintenance in due time.
  4. The organisation shall have a procedure to manage the removal of vehicles from operation for maintenance or when safe operation is impaired or when needs of maintenance affect the normal operation.
  5. The organisation shall have a procedure to define the necessary verification measures applied to the maintenance delivered and the release to service of the vehicles.
  6. The organisation shall have a procedure to issue a notice of return to operation, including the definition of restrictions of use to ensure the safe running by taking into account the release to service documentation.
  7. When the competence management process is applied to the fleet maintenance management function, at least the return to operation shall be taken into account including defining the restriction of use.
  8. When the information process is applied to the fleet maintenance management function, at least the following elements need to be provided to the maintenance delivery function:
    - (a) applicable rules and technical specifications;
    - (b) the maintenance plan for each vehicle;



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- (c) a list of spare parts, including a sufficiently detailed technical description of each part to allow like-for-like replacement with the same guarantees;
  - (d) a list of materials, including a sufficiently detailed description of their use and the necessary health and safety information;
  - (e) a dossier that defines the specifications for activities affecting safety and contains intervention and in-use restrictions for components;
  - (f) a list of components or systems subject to legal requirements and a list of those requirements (including brake reservoirs and tanks for the transport of dangerous goods);
  - (g) application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 for assessing changes affecting the fleet maintenance management function.
9. When the information process is applied to the fleet maintenance management function, interested parties shall be at least informed of the return to operation, including restrictions on use relevant to users (railway undertakings and infrastructure managers).
10. When the documentation process is applied to the fleet maintenance management function, at least the following elements need to be recorded:
- (a) maintenance orders;
  - (b) return to operation, including restrictions on use relevant to railway undertakings and infrastructure managers.
- IV. Requirements and assessment criteria for the maintenance delivery function**
1. The organisation shall have procedures to:
- (a) check the completeness and appropriateness of the information delivered by the fleet maintenance management function in relation to the activities ordered;
  - (b) verify the use of the required, relevant maintenance documents and other standards applicable to the delivery of maintenance services in accordance with maintenance orders;
  - (c) ensure that all relevant maintenance specifications, as defined in applicable regulations and specified standards contained in the maintenance orders, are available to all involved staff (e.g. they are contained in internal working instructions).
2. The organisation shall have procedures to ensure that:
- (a) components (including spare parts) and materials are used as specified in the maintenance orders and supplier documentation;
  - (b) components and materials are stored, handled and transported in a manner that prevents wear and damage and as specified in the maintenance orders and supplier documentation;
  - (c) all components and materials, including those provided by the customer, comply with relevant national and international rules as well as with the requirements of relevant maintenance orders.

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3. The organisation shall have procedures to determine, identify, provide, record and keep available suitable and adequate facilities, equipment and tools to enable it to deliver the maintenance services in accordance with maintenance orders and other applicable specifications, ensuring:
  - (a) the safe delivery of maintenance, including the health and safety of maintenance staff;
  - (b) ergonomics and health protection, also including the interfaces between users and information technology systems or diagnostic equipment.
4. Where necessary to ensure valid results, the organisation shall have procedures to ensure that its measuring equipment is:
  - (a) calibrated or verified at specified intervals, or prior to use, against international, national or industrial measurement standards — where no such standards exist, the basis used for calibration or verification shall be recorded;
  - (b) adjusted or re-adjusted as necessary;
  - (c) identified to enable the calibration status to be determined;
  - (d) safeguarded from adjustments that would invalidate the measurement result;
  - (e) protected from damage and deterioration during handling, maintenance and storage.
5. The organisation shall have procedures to ensure that all facilities, equipment and tools are correctly used, calibrated, preserved and maintained in accordance with documented procedures.
6. The organisation shall have procedures to check that performed tasks are in accordance with the maintenance orders and to issue the notice of release to service. The notice of release to service shall include all information that is useful to define restrictions of use.
7. When the risk assessment process (in particular points 2.2 and 2.3 of Section I) is applied to the maintenance delivery function, the working environment shall include not only the workshops where maintenance is done but also the tracks outside the workshop buildings and all places where maintenance activities are performed.
8. When the competence management process is applied to the maintenance delivery function, at least the following activities affecting safety where appropriate shall be taken into account:
  - (a) joining techniques (including welding and bonding);
  - (b) non-destructive testing;
  - (c) final vehicle testing and release to service;
  - (d) maintenance activities on brake systems, wheel sets and draw gear and maintenance activities on specific components of freight wagons for the transport of dangerous goods, such as tanks, valves, etc.;
  - (e) maintenance activities on safety-critical components;
  - (f) maintenance activities on control-command and signalisation systems;
  - (g) maintenance activities on door control systems;

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- (h) other identified specialist areas affecting safety.
9. When the information process is applied to the maintenance delivery function, at least the following elements shall be provided to the fleet maintenance management and maintenance development functions:
- (a) works performed in accordance with the maintenance orders;
  - (b) any possible fault or defect regarding safety which is identified by the organisation;
  - (c) the release to service.
10. When the documentation process is applied to the maintenance delivery function, at least the following elements shall be recorded for the maintenance activities affecting safety, as referred to in point 1(a) of Section II:
- (a) clear identification of all facilities, equipment and tools;
  - (b) all maintenance works performed, including personnel, tools, equipment, spare parts and materials used and taking into account:
    - (i) relevant national rules where the organisation is established;
    - (ii) requirements laid down in the maintenance orders, including requirements regarding records;
    - (iii) final testing and the decision regarding the release to service;
  - (c) the control measures required by maintenance orders and the release to service;
  - (d) the results of calibration and verification, whereby, for computer software used in the monitoring and measurement of specified requirements, the ability of the software to perform the desired task shall be confirmed prior to initial use and reconfirmed as necessary;
  - (e) the validity of the previous measuring results when a measuring instrument is found not to conform to requirements.

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- (1) Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ([OJ L 183, 29.6.1989, p. 1](#)).

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- Regulation revoked in part by [S.I. 2020/786](#) reg. 11