

**COMMISSION REGULATION (EU) No 445/2011****of 10 May 2011****on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007****(Text with EEA relevance)***Article 1***Purpose**

1. This Regulation establishes a system of certification of entities in charge of maintenance for freight wagons as referred to in Article 14a of Directive 2004/49/EC.
2. The purpose of the system of certification is to provide evidence that an entity in charge of maintenance has established its maintenance system and can meet requirements laid down in this Regulation to ensure the safe state of running of any freight wagon for which it is in charge of maintenance.

*Article 2***Scope**

1. The system of certification shall apply to any entity in charge of maintenance for freight wagons to be used on the railway network within the Union.
2. Maintenance workshops or any organisation taking on a subset of the functions specified in Article 4 may apply the system of certification on a voluntary basis, based on the principles specified in Article 8 and Annex I.
3. References to an infrastructure manager in Articles 5, 7 and 12 shall be understood as relating to its operations with freight wagons for transporting materials for construction or for infrastructure maintenance activities. When it operates freight wagons for this purpose, an infrastructure manager shall be deemed to do so in the capacity of a railway undertaking.

*Article 3***Definitions**

1. For the purposes of this Regulation, the definitions laid down in Article 3 of Directive 2004/49/EC apply.
2. In addition, the following definitions apply:
 - (a) ‘accreditation’ means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;
 - (b) ‘ECM certificate’ means a certificate issued to an entity in charge of maintenance for the purposes of Article 14a(4) of Directive 2004/49/EC;
 - (c) ‘certification body’ means a body, designated in accordance with Article 10, responsible for the certification of entities in charge of maintenance, on the basis of the criteria in Annex II;

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- (d) ‘freight wagon’ means a non-self-propelled vehicle designed for the purpose of transporting freight or other materials to be used for activities such as construction or infrastructure maintenance;
- (e) ‘maintenance workshop’ means a mobile or fixed entity composed of staff, including those with management responsibility, tools and facilities organised to deliver maintenance of vehicles, parts, components or sub-assemblies of vehicles;
- (f) ‘release to service’ means the assurance given to the fleet maintenance manager by the entity delivering the maintenance that maintenance has been delivered according to the maintenance orders;
- (g) ‘return to operation’ means the assurance, based on a release to service, given to the user, such as a railway undertaking or a keeper, by the entity in charge of maintenance that all appropriate maintenance works have been completed and the wagon, previously removed from operation, is in a condition to be used safely, possibly subject to temporary restrictions of use.

*Article 4***Maintenance system**

1. The maintenance system shall be composed of the following functions:
 - (a) the management function, which supervises and coordinates the maintenance functions referred to in points (b) to (d) and ensures the safe state of the freight wagon in the railway system;
 - (b) the maintenance development function, which is responsible for the management of the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return on experience;
 - (c) the fleet maintenance management function, which manages the freight wagon’s removal for maintenance and its return to operation after maintenance; and
 - (d) the maintenance delivery function, which delivers the required technical maintenance of a freight wagon or parts of it, including the release to service documentation.
2. The entity in charge of maintenance shall ensure that the functions referred to in paragraph 1 comply with the requirements and assessment criteria set out in Annex III.
3. The entity in charge of maintenance shall carry out the management function itself, but may outsource the maintenance functions referred to in points (b) to (d) of paragraph 1, or parts of them, to other contracting parties subject to the provisions of Article 8. Where it resorts to outsourcing, the entity in charge of maintenance shall ensure that the principles set out in Annex I are applied.

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4. Regardless of the outsourcing arrangements in place, the entity in charge of maintenance shall be responsible for the outcome of the maintenance activities it manages and shall establish a system to monitor performance of those activities.

*Article 5***Relationships between parties involved in the maintenance process**

1. Each railway undertaking or infrastructure manager shall ensure that the freight wagons it operates, before their departure, have a certified entity in charge of maintenance and that the use of the wagon corresponds to the scope of the certificate.

2. All parties involved in the maintenance process shall exchange relevant information about maintenance in accordance with the criteria listed in sections I.7 and I.8 of Annex III.

3. Following contractual arrangements, a railway undertaking may request information for operational purposes on the maintenance of a freight wagon. The entity in charge of the maintenance of the freight wagon shall respond to such requests either directly or through other contracting parties.

4. Following contractual arrangements, an entity in charge of maintenance may request information on the operation of a freight wagon. The railway undertaking or the infrastructure manager shall respond to such requests either directly or through other contracting parties.

5. All contracting parties shall exchange information on safety-related malfunctions, accidents, incidents, near-misses and other dangerous occurrences as well as on any possible restriction on the use of freight wagons.

6. The certificates of entities in charge of maintenance shall be accepted as proof of the ability of a railway undertaking or infrastructure manager to meet the requirements governing maintenance and the control of contractors and suppliers specified in Annex II, points B.1, B.2, B.3 and C.1, to Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railways safety certificates⁽¹⁾ and Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railways safety authorisation⁽²⁾, unless the national safety authority can demonstrate the existence of a substantial safety risk.

7. If a contracting party, in particular a railway undertaking, has a justified reason to believe that a particular entity in charge of maintenance does not comply with the requirements of Article 14a(3) of Directive 2004/49/EC or with the certification requirements of this Regulation, it shall promptly inform the certification body thereof. The certification body shall take appropriate action to check if the claim of non-compliance is justified and shall inform the parties involved (including the competent national safety authority if relevant) of the results of its investigation.

⁽¹⁾ OJ L 326, 10.12.2010, p. 11.

⁽²⁾ OJ L 327, 11.12.2010, p. 13.

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8. When there is a change of entity in charge of maintenance, the registration holder as indicated in Article 33(3) of Directive 2008/57/EC of the European Parliament and of the Council ⁽¹⁾, shall inform in due time the registration entity, as defined in Article 4(1) of Commission Decision 2007/756/EC ⁽²⁾, so that the latter may update the national vehicle register.

The former entity in charge of maintenance shall deliver the maintenance documentation to either the registration holder or the new entity in charge of maintenance.

The former entity in charge of maintenance is relieved of its responsibilities when it is removed from the national vehicle register. If on the date of de-registration of the former entity in charge of maintenance any new entity has not acknowledged its acceptance of entity in charge of maintenance status, the registration of the vehicle is suspended.

*Article 6***Certification bodies**

1. ECM certificates shall be awarded by any competent certification body, chosen by the applicant entity in charge of maintenance.
2. Member States shall ensure that the certification bodies comply with the general criteria and principles set out in Annex II and with any subsequent sectoral accreditation schemes.
3. Member States shall take the measures necessary to ensure that decisions taken by the certification bodies are subject to judicial review.
4. In order to harmonise approaches to the assessment of applications, the certification bodies shall cooperate with each other both within the Member States and across the Union.
5. The Agency shall organise and facilitate cooperation between the certification bodies.

*Article 7***System of certification for entities in charge of maintenance**

1. Certification shall be based on an assessment of the ability of the entity in charge of maintenance to meet the relevant requirements in Annex III and to apply them consistently. It shall include a system of surveillance to ensure continuing compliance with the applicable requirements after award of the ECM certificate.
2. The entities in charge of maintenance shall apply for certification using the relevant form in Annex IV and providing documentary evidence of the procedures specified in Annex III. They shall promptly submit all supplementary information requested by the certification body. In assessing applications, certification bodies shall apply the requirements and assessment criteria set out in Annex III.

⁽¹⁾ OJ L 191, 18.7.2008, p. 1.

⁽²⁾ OJ L 305, 23.11.2007, p. 30.

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3. The certification body shall take a decision no later than 4 months after all the information required and any supplementary information requested has been submitted to it by the entity in charge of maintenance applying for the certificate. The certification body shall undertake the necessary assessment at the site or sites of the entity in charge of maintenance prior to the award of the certificate. The decision on the award of the certificate shall be communicated to the entity in charge of maintenance using the relevant form in Annex V.

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4. Without prejudice to the provisions of Article 15(6) of Commission Implementing Regulation (EU) 2019/779 ⁽¹⁾, an ECM certificate shall be valid for a period up to 5 years. The holder of the certificate shall without delay inform the certification body of all significant changes in the circumstances applying at the time the original certificate was awarded to allow the certification body to decide whether to amend, renew or revoke it.

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5. The certification body shall set out in detail the reasons on which each of its decisions is based. The certification body shall notify its decision and the reasons to the entity in charge of maintenance, together with an indication of the process, time limit for appeal and the contact details of the appeal body.

6. The certification body shall conduct surveillance at least once a year at selected sites, geographically and functionally representative of all the activities of those entities in charge of maintenance it has certified, to verify that the entities still satisfy the criteria set out in Annex III.

7. If the certification body finds that an entity in charge of maintenance no longer satisfies the requirements on the basis of which it issued the ECM certificate, it shall agree an improvement plan with the entity in charge of maintenance, or limit the scope of application of the certificate, or suspend the certificate, depending on the degree of non-compliance.

In the event of continuous non-compliance with the certification requirements or any improvement plan, the certification body shall limit the scope of or revoke the ECM certificate, giving reasons for its decision, together with an indication of the process and time limit for appeal and the contact details of the appeal body.

8. When a railway undertaking or an infrastructure manager applies for a safety certificate or safety authorisation, the following shall apply concerning the freight wagons it uses:

- (a) where the freight wagons are maintained by the applicant, either the applicant shall include as part of its application a valid ECM certificate, if available, or its capacity as entity in charge of maintenance shall be assessed as part of its application for a safety certificate or safety authorisation;

⁽¹⁾ Commission Implementing Regulation (EU) 2019/779 of 16 May 2019 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011 (OJ L 139I, 27.5.2019, p. 360).

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- (b) where the freight wagons are maintained by parties other than the applicant, the applicant shall ensure, through its safety management system, the control of all risks related to its activity, including the use of such wagons, whereby, in particular, the provisions of Article 5 of this Regulation shall apply.

Certification bodies and national safety authorities shall conduct an active exchange of views in all circumstances in order to avoid any duplication of assessment.

*Article 8***System of certification for outsourced maintenance functions**

1. Where the entity in charge of maintenance decides to outsource one or more of the functions referred to in Article 4(1)(b), (c) and (d), or parts of them, voluntary certification of the contractor under the certification system of this Regulation shall create a presumption of conformity of the entity in charge of maintenance with the relevant requirements set out in Annex III, as far as these requirements are covered by the voluntary certification of the contractor. In the absence of such certification, the entity in charge of maintenance shall demonstrate to the certification body how it complies with all the requirements set out in Annex III with regard to the functions it decides to outsource.

2. Certification in respect of outsourced maintenance functions, or parts of them, shall be issued by the certification bodies, following the same procedures in Articles 6, 7, and 10(3), adapted to the specific case of the applicant. They shall be valid throughout the Union.

In assessing applications for certificates in respect of outsourced maintenance functions, or parts of them, certification bodies shall follow the principles set out in Annex I.

*Article 9***Role of the supervision regime**

If a national safety authority has a justified reason to believe that a particular entity in charge of maintenance does not comply with the requirements of Article 14a(3) of Directive 2004/49/EC or with the certification requirements of this Regulation, it shall immediately take the necessary decision and inform the Commission, the Agency, other competent authorities, the certification body and other interested parties of its decision.

*Article 10***Provision of information to the Commission and the Agency**

1. By no later than 30 November 2011, Member States shall inform the Commission whether the certification bodies are accredited bodies, recognised bodies or national safety authorities. They shall also notify any change in this situation to the Commission within 1 month of the change.

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2. By no later than 31 May 2012, Member States shall notify the Agency of the certification bodies recognised. The accreditation bodies as defined in Regulation (EC) No 765/2008 shall inform the Agency of the certification bodies accredited. Any change shall also be notified to the Agency within 1 month of the change.

3. Certification bodies shall notify the Agency of all issued, amended, renewed or revoked ECM certificates or certificates for specific functions according to Article 4(1), within 1 week from its decision, using the forms in Annex V.

4. The Agency shall keep a record of all information notified under paragraphs 2 and 3 and shall make it publicly available.

*Article 11***Amendment to Regulation (EC) No 653/2007**

Annex I to Regulation (EC) No 653/2007 is replaced by the text set out in Annex VI to this Regulation.

*Article 12***Transitional provisions**

1. The following transitional provisions shall apply without prejudice to Article 9.

2. Starting from 31 May 2012, any ECM certificate shall be issued in accordance with this Regulation to entities in charge of maintenance for freight wagons, without prejudice to Article 14a(8) of Directive 2004/49/EC.

3. Certificates issued by a certification body by no later than 31 May 2012 on the basis of principles and criteria equivalent to those of the Memorandum of Understanding establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons, signed by Member States on 14 May 2009, shall be recognised as being equivalent to ECM certificates issued under this Regulation for their original validity period until at the latest 31 May 2015.

4. Certificates issued by a certification body to entities in charge of maintenance by no later than 31 May 2012 on the basis of national laws existing before the entry into force of this Regulation and equivalent to this Regulation, in particular Articles 6 and 7 and Annexes I and III, shall be recognised as being equivalent to ECM certificates issued under this Regulation for their original period of validity until at the latest 31 May 2015.

5. Certificates issued to maintenance workshops by no later than 31 May 2014 on the basis of national laws existing before the entry into force of this Regulation and equivalent to this Regulation shall be recognised as being equivalent to certificates for maintenance workshops taking on the maintenance delivery function issued under this Regulation for their original period of validity until at the latest 31 May 2017.

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6. Without prejudice to paragraphs 3 to 5, entities in charge of maintenance for freight wagons registered in the national vehicle register by no later than 31 May 2012 shall be certified in accordance with this Regulation by no later than 31 May 2013. During this period, self declarations of conformity of entities in charge of maintenance to the relevant requirements of the present Regulation or of the Memorandum of Understanding establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons, signed by Member States on 14 May 2009 shall be recognised as being equivalent to ECM certificates issued under this Regulation.

7. Railway undertakings and infrastructure managers which are already certified in accordance with Articles 10 and 11 of Directive 2004/49/EC by no later than 31 May 2012 need not apply for an ECM certificate for the original period of validity of their certificates for maintaining the wagons they are responsible for as entity in charge of maintenance.

*Article 13***Entry into force**

This Regulation shall enter into force on the 20th day following the date of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

*ANNEX I***Principles to be used for organisations applying for a certificate in respect of maintenance functions outsourced by an entity in charge of maintenance**

1. For certification of an entity or organisation taking on one or more maintenance functions of an entity in charge of maintenance (maintenance development, fleet maintenance management, maintenance delivery) or parts of them, the following requirements and assessment criteria contained in Annex III apply:
 - (a) requirements and assessment criteria set out in section I of Annex III, adapted to the organisation's type and extent of service;
 - (b) requirements and assessment criteria describing the specific maintenance function or functions.
2. For certification of a maintenance workshop taking on the maintenance delivery function, the following requirements and assessment criteria contained in Annex III apply:
 - (a) the requirements and assessment criteria set out in section I of Annex III, which must be adapted to the specific activity of a maintenance workshop providing the maintenance delivery function;
 - (b) the processes describing the maintenance delivery function.

*ANNEX II***Criteria for accreditation or recognition of certification bodies involved in the assessment and award of ECM certificates****1. ORGANISATION**

The certification body must document its organisational structure, showing the duties, responsibilities and authorities of management and other certification staff and any committees. Where the certification body is a defined part of a legal entity, the structure must include the line of authority and the relationship to other parts within the same legal entity.

2. INDEPENDENCE

The certification body must be organisationally and functionally independent in its decision-making from railway undertakings, infrastructure managers, keepers, manufacturers and entities in charge of maintenance and shall not provide similar services.

The independence of the staff responsible for the certification checks must be guaranteed. No official must be remunerated on the basis of either the number of checks performed or the results of those checks.

3. COMPETENCE

The certification body and the staff deployed must have the required professional competence, in particular regarding the organisation of the maintenance of freight wagons and the appropriate maintenance system.

The certification body must demonstrate:

- (a) sound experience in assessing management systems;
- (b) knowledge of the applicable requirements of the legislation.

The team established for surveillance of the entities in charge of maintenance must be experienced in the relevant fields, and in particular must demonstrate:

- (a) appropriate knowledge and understanding of the applicable European legislation;
- (b) relevant technical competence;
- (c) a minimum of 3 years of relevant experience in maintenance in general;
- (d) sufficient experience in freight wagon maintenance or at least in maintenance in equivalent industrial sectors.

4. IMPARTIALITY

The certification body's decisions must be based on objective evidence of conformity or non-conformity obtained by the certification body, and must not be influenced by other interests or by other parties.

5. RESPONSIBILITY

The certification body is not responsible for ensuring ongoing conformity with the requirements for certification.

The certification body has the responsibility to assess sufficient objective evidence upon which to base a certification decision.

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A certification body needs to provide public access to, or disclosure of, appropriate and timely information about its audit process and certification process. It also needs to provide information about the certification status (including the granting, extension, maintenance, renewal, suspension, reduction in scope, or withdrawal of certification) of any organisation, in order to develop confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of, appropriate information.

7. CONFIDENTIALITY

To gain the privileged access to information needed to assess conformity with the requirements for certification adequately, a certification body must keep confidential any commercial information about a client.

8. RESPONSIVENESS TO COMPLAINTS

The certification body must establish a procedure to handle complaints about decisions and other certification-related activities.

9. LIABILITY AND FINANCING

The certification body must be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (including insurance or reserves) to cover liabilities arising from its operations in each field of its activities and the geographic areas in which it operates.

*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****I. Management function requirements and assessment criteria****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 must 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 the availability of the resources needed to perform all processes 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 assessment — *a structured approach to assess risks associated with the maintenance of freight wagons, 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 must have procedures for:

- (a) analysing risks relevant to the extent of operations carried out by the organisation, including the risks arising from defects and construction non-conformities or malfunctions throughout the lifecycle;
- (b) evaluating the risks referred to in point (a);
- (c) developing and putting in place risk control measures.

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- 2.2. The organisation must have procedures and arrangements in place to recognise the need and commitment to collaborate with keepers, railway undertakings, infrastructure managers, or other interested parties.
- 2.3. The organisation must have risk assessment procedures to manage changes in equipment, procedures, organisation, staffing or interfaces, and to apply Commission Regulation (EC) No 352/2009 ⁽¹⁾.
- 2.4. When assessing risk, an organisation must 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 ⁽²⁾.
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 must 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 must 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 must have an internal auditing system which is independent, impartial and acts in a transparent way. This system must have procedures in place to:
- (a) develop an internal audit plan, which can 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/actions;
 - (d) verify the effectiveness of previous measures/actions.
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 must 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;

⁽¹⁾ OJ L 108, 29.4.2009, p. 4.

⁽²⁾ OJ L 183, 29.6.1989, p. 1.

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- (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;
 - (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/information from railway undertakings/infrastructure managers and 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 must have procedures to allocate responsibilities for all relevant processes throughout the organisation.
- 5.2. The organisation must 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. These include the procedures indicated above between the organisation and the keepers and, where appropriate, railway undertakings and infrastructure managers.
- 5.3. The organisation must 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 should be coherent and compatible with the given role, and delegation must be in writing.
- 5.4. The organisation must have procedures to ensure the coordination of activities related to relevant processes across the organisation.
- 5.5. The organisation must 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 must 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.

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- 6.2. Within the organisation's competence management system, there must 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;
 - (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 must 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 and keepers, 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 must have procedures:
- (a) for the receipt and processing of specific information;
 - (b) for the identification, generation and dissemination of specific information;
 - (c) for making available reliable and up-to-date information.
- 7.3. The organisation must have procedures to ensure that key operational information is:
- (a) relevant and valid;
 - (b) accurate;
 - (c) complete;
 - (d) appropriately updated;
 - (e) controlled;
 - (f) consistent and easy to understand (including the language used);
 - (g) made known to staff before it is applied;
 - (h) easily accessible to staff, with copies provided to them where required.

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- 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 freight wagons 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;
 - (e) information on operations (including mileage, type and extent of activities, incidents/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 freight wagons maintained by the organisation or other vehicles of the same series even if maintained by other entities in charge of maintenance, whereby this information should 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 types or series of vehicles;
 - (k) all relevant information/data needed to submit the annual maintenance report to the certification body and to the relevant customers (including keepers), whereby this report must 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 must have adequate procedures in place to ensure that all relevant processes are duly documented.
- 8.2. The organisation must have adequate procedures in place to:
- (a) regularly monitor and update all relevant documentation;
 - (b) format, generate, distribute and control changes to all relevant documentation;
 - (c) receive, collect and archive all relevant documentation.

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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 must have procedures in place to ensure that safety related products and services are identified.
 - 9.2. When making use of contractors and/or suppliers for safety related products and services, the organisation must have procedures in place to verify at the time of selection that:
 - (a) contractors, subcontractors and suppliers are competent;
 - (b) contractors, subcontractors and suppliers have a maintenance and management system that is adequate and documented.
 - 9.3. The organisation must have a procedure to define the requirements that such contractors and suppliers have to meet.
 - 9.4. The organisation must 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/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 must 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 must have a procedure to identify and manage all maintenance activities affecting safety and safety-critical components.
 2. The organisation must 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 of placing-in-service (including any national safety authority requirements), the declarations of conformity to TSIs, the declarations of verification, and the technical file;
 - (c) managing any substitution in the course of maintenance in compliance with the requirements of the Directive 2008/57/EC and the relevant TSIs;

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- (d) identifying the need for risk assessment regarding the potential impact of the substitution in question on the safety of the railway system;
 - (e) managing the configuration of all technical changes affecting the system integrity of the vehicle.
3. The organisation must have a procedure to design and to support the implementation of maintenance facilities, equipment and tools specifically developed and required for maintenance delivery. The organisation must 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 freight wagons start operations, the organisation must have procedures to:
- (a) obtain the initial documentation and to collect sufficient information on planned operations;
 - (b) analyse the initial documentation and to provide the first maintenance file, also taking into account the obligations contained in any associated guarantees;
 - (c) ensure that the implementation of the first maintenance file is done correctly.
5. To keep the maintenance file updated throughout the lifecycle of a freight wagon, the organisation must 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, operational incidents with a potential to affect the safety integrity of the freight wagon;
 - (ii) the type and extent of operations planned;
 - (iii) 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;
 - (d) ensure that the implementation of changes is done correctly.
6. When the competence management process is applied to the maintenance development function, at least the following activities affecting safety must be taken into account:
- (a) assessment of the significance of changes for the maintenance file and proposed substitutions in the course of maintenance;
 - (b) engineering disciplines required for managing the establishment and the changes of maintenance file and the development, assessment, validation and approval of substitutions in the course of maintenance;
 - (c) joining techniques (including welding and bonding), brake systems, wheel sets and draw gear, non-destructive testing techniques and maintenance activities on specific components of freight wagons for the transport of dangerous goods such as tanks and valves.

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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 course of maintenance;
 - (b) the configuration of vehicles, including, but not limited to, components related to safety;
 - (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 must 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 must have a procedure for the composition of the work package and for the issue and release of the maintenance order.
3. The organisation must have a procedure to send freight wagons for maintenance in due time.
4. The organisation must have a procedure to manage the removal of freight wagons from operation for maintenance or when defects have been identified.
5. The organisation must have a procedure to define the necessary control measures applied to the maintenance delivered and the release to service of the freight wagons.
6. The organisation must have a procedure to issue a notice to return to operation, taking into account the release to service documentation.
7. When the competence management (CM) process is applied to the fleet maintenance management function, at least the return to operation must be taken into account.
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 freight wagon;
 - (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;

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- (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 these requirements (including brake reservoirs and tanks for the transport of dangerous goods);
 - (g) all additional relevant information related to safety according to the risk assessment performed by the organisation.
9. When the information process is applied to the fleet maintenance management function, at least the return to operation, including restrictions on use relevant to users (railway undertakings and infrastructure managers), needs to be communicated to interested parties.
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 must 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) control 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 in the maintenance orders are available to all involved staff (e.g. they are contained in internal working instructions);
 - (d) 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 must 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 must 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 must 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 must 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 must 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 must have procedures to check that the performed maintenance tasks are in accordance with the maintenance orders and to issue the notice to release to service that includes eventual restrictions of use.
7. When the risk assessment process (in particular point 2.4 of section I) is applied to the maintenance delivery function, the working environment includes 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 must 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) other identified specialist areas affecting safety.

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9. When the information process is applied to the maintenance delivery function, at least the following elements must 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 must be recorded:
 - (a) clear identification of all facilities, equipments and tools related to activities affecting safety;
 - (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 decision regarding 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 must 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.



ANNEX IV


**APPLICATION FOR AN ENTITY IN CHARGE OF MAINTENANCE
CERTIFICATE**

Application for a certificate confirming acceptance of the maintenance system of an entity in charge of maintenance (ECM) in conformity with Directive 2004/49/EC and Regulation (EU) No 445/2011

Certification body contact information

- 1.1 Organisation addressed for the application _____
- 1.2 Certification body reference number _____
- 1.3 Complete postal address (street, postal code, city, country) _____

Applicant information

- 2.1 Legal title _____
- 2.2 Complete postal address (street, postal code, city, country) _____
- 2.3 Phone number _____ 2.4 Fax number _____
- 2.5 E-mail address _____ 2.6 Website _____
- 2.7 Registration business number _____ 2.8 VAT No _____
- 2.9 Other information _____

Contact person information

- 3.1 Family name and first name _____
- 3.2 Complete postal address (street, postal code, city, country) _____
- 3.3 Phone number _____ 3.4 Fax number _____
- 3.5 E-mail address _____

Application details

- 4.1 Application reference (given by the applicant)

This application is for a

- 4.1.1 new certificate 4.1.2 updated/amended certificate
- 4.1.3 renewed certificate

Operational details

- Type of company 5.1 RU/IM 5.2 Keeper
- 5.3 others specify: _____

Scope of ECM activities

- 5.4 Covers tank wagons for dangerous goods: YES/NO
Covers other wagons specialised in transport of dangerous goods: YES/NO

ECM operational functions

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	own	partially	fully
5.5 Maintenance development	5.4.1 <input type="checkbox"/>	5.4.2 <input type="checkbox"/>	5.4.3 <input type="checkbox"/>
5.6 Fleet maintenance management	5.5.1 <input type="checkbox"/>	5.5.2 <input type="checkbox"/>	5.5.3 <input type="checkbox"/>
5.7 Maintenance delivery	5.6.1 <input type="checkbox"/>	5.6.2 <input type="checkbox"/>	5.6.3 <input type="checkbox"/>

Submitted documents6.1 Maintenance system documentation 6.2 Other

specify: _____

Signatures**Applicant** _____

(first name, family name)

Date _____ Signature _____

Certification body _____

Internal reference number _____ Date application received _____

Date _____ Signature _____

<p style="text-align: center;"><i>SPACE RESERVED FOR THE ADDRESSED OFFICE/AUTHORITY</i></p>

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APPLICATION FOR A MAINTENANCE FUNCTIONS CERTIFICATE

Application for a certificate confirming acceptance of the maintenance system within the European Union in conformity with Directive 2004/49/EC and Regulation (EU) No 445/2011

Certification body contact information

- 1.1 Organisation addressed for the application _____
- 1.2 Certification body reference number _____
- 1.3 Complete postal address (street, postal code, city, country) _____

Applicant information

- 2.1 Legal title _____
- 2.2 Complete postal address (street, postal code, city, country) _____

- 2.3 Phone number _____ 2.4 Fax number _____
- 2.5 E-mail address _____ 2.6 Website _____
- 2.7 Registration business number _____ 2.8 VAT No _____
- 2.9 Other information _____

Contact person information

- 3.1 Family name and first name _____
- 3.2 Complete postal address (street, postal code, city, country) _____

- 3.3 Phone number _____ 3.4 Fax number _____
- 3.5 E-mail address _____

Application details

- 4.1 Application reference (given by the applicant)

This application is for a

- 4.1.1 new certificate 4.1.2 updated/amended certificate
- 4.1.3 renewed certificate

Operational details

- Type of company 5.1 RU/IM 5.2 Keeper
- 5.3 others specify: _____
- Scope of activities
- 5.4 Covers tank wagons for dangerous goods: YES/NO
Covers other wagons specialised in transport of dangerous goods: YES/NO
- Maintenance functions

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5.5	Maintenance development	YES <input type="checkbox"/>	NO <input type="checkbox"/>	Partial <input type="checkbox"/>
5.6	Fleet maintenance management	YES <input type="checkbox"/>	NO <input type="checkbox"/>	Partial <input type="checkbox"/>
5.7	Maintenance delivery	YES <input type="checkbox"/>	NO <input type="checkbox"/>	Partial <input type="checkbox"/>

For partial maintenance functions, the sub-functions for which this application is submitted (cf. list in Annex III to Regulation (EU) No 445/2011):

Submitted documents

- 6.1 Maintenance system documentation
- 6.2 Other specify: _____

Signatures

Applicant _____

(first name, family name)

Date _____ Signature _____

Certification body _____

Internal reference number _____ Date application received _____

Date _____ Signature _____

*SPACE RESERVED FOR THE ADDRESSED
OFFICE/AUTHORITY*



ANNEX V

**ENTITY IN CHARGE OF MAINTENANCE CERTIFICATE**

confirming acceptance of the maintenance system of an entity in charge of maintenance (ECM) within the European Union in conformity with Directive 2004/49/EC and Regulation (EU) No 445/2011

1. CERTIFIED ENTITY IN CHARGE OF MAINTENANCE

Legal title:	
Commercial designation or acronym (voluntary)	
Complete postal address (street, postal code, city, country)	
Registration business number:	VAT No:

2. CERTIFICATION BODY

Legal title:
Complete postal address (street, postal code, city, country)
Certification body reference number:

3. CERTIFICATE INFORMATION

This is a <ul style="list-style-type: none"> — new certificate <input type="checkbox"/> — renewed certificate <input type="checkbox"/> — updated/amended certificate <input type="checkbox"/> 	ECM Identification Number of the previous certificate:
Validity from:	to:
Type of company: (railway undertaking, keeper, maintenance supplier, etc.)	

4. SCOPE OF ECM ACTIVITIES

Covers tank wagons for dangerous goods	YES/NO
Covers other wagons specialised in transport of dangerous goods	YES/NO

5. ADDITIONAL INFORMATION

--

Date issued and validity

--

Signature

--

Internal reference number

--

Certification body's stamp

--



MAINTENANCE FUNCTIONS CERTIFICATE

confirming acceptance of the maintenance system within the European Union in conformity with Directive 2004/49/EC and Regulation (EU) No 445/2011

1. CERTIFIED ORGANISATION

Legal title:	
Commercial designation or acronym (voluntary)	
Complete postal address (street, postal code, city, country)	
Registration business number:	VAT No:

2. CERTIFICATION BODY

Legal title:
Complete postal address (street, postal code, city, country)
Certification body reference number:

3. CERTIFICATE INFORMATION

This is a <ul style="list-style-type: none"> — new certificate <input type="checkbox"/> — renewed certificate <input type="checkbox"/> — updated/amended certificate <input type="checkbox"/> 	ECM Identification Number of the previous certificate:
Validity from:	to:
Type of company: (railway undertaking, keeper, maintenance supplier, etc.)	

4. SCOPE OF MAINTENANCE ACTIVITIES

Covers tank wagons for dangerous goods	YES/NO
Covers other wagons specialised in transport of dangerous goods	YES/NO

5. MAINTENANCE FUNCTIONS

Maintenance development	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Fleet maintenance management	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Maintenance delivery	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>

For partial maintenance functions, the sub-functions for which this certificate is valid (cf. list in Annex III to Regulation (EU) No 445/2011):

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6. ADDITIONAL INFORMATION

Date issued and validity

Signature

Internal reference number

Certification body's stamp



ANNEX VI

ANNEX I



SAFETY CERTIFICATE — PART A

Safety Certificate confirming acceptance of the Safety Management System within the European Union in conformity with Directive 2004/49/EC and applicable national legislation

EU IDENTIFICATION NUMBER:

1. CERTIFIED RAILWAY UNDERTAKING

Legal title:	
Railway undertaking name:	Acronym:
National registration number:	VAT No:

2. ORGANISATION ISSUING CERTIFICATE

Organisation:
Country:

3. CERTIFICATE INFORMATION

This is a — new certificate <input type="checkbox"/> — renewed certificate <input type="checkbox"/> — updated/amended certificate <input type="checkbox"/>	ECM (entity in charge of maintenance) certificate Yes/No ECM certificate number: EU Identification Number of the previous Part A certificate
Validity from:	to:
Type(s) of service(s):	
Transportation volume:	
Railway undertaking size:	
Scope of ECM activities:	
Covers tank wagons for dangerous goods: YES/NO	
Covers other wagons specialised in transport of dangerous goods: YES/NO	

4. APPLICABLE NATIONAL LEGISLATION

5. ADDITIONAL INFORMATION

Date issued

Signature _____

Internal reference number

Authority's stamp