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EUROPEAN COMMISSION

Brussels, xxx
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Draft

COMMISSION IMPLEMENTING REGULATION (EU) No .../..

of [...]

**on a system of certification of entities in charge of maintenance for vehicles and
amending Regulation (EU) No 445/2011**

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**on a system of certification of entities in charge of maintenance for vehicles and
amending Regulation (EU) No 445/2011**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety¹, and in particular Articles 14 and 15 thereof,

Having regard to the Recommendation of the European Railway Agency of 8 July 2010 on a System of Certification for Entities in Charge of Maintenance,

Whereas:

- (1) Directive 2004/49/EC aims to improve access to the market for rail transport services by defining common principles for the management, regulation and supervision of railway safety. Directive 2004/49/EC also provides for a framework to be put in place to ensure equal conditions for all entities in charge of maintenance for freight wagons through application of the same certification requirements across the Union.
- (2) The purpose of the certification system is to provide a framework for the harmonisation of requirements and methods to assess the ability of entities in charge of maintenance across the Union.
- (3) Without prejudice to the responsibility of railway undertakings and infrastructure managers for the safe operation of trains, the entity in charge of maintenance should ensure that the freight wagons for which it is in charge of maintenance are in a safe state of running by means of a system of maintenance. Taking into account the wide variety of design and maintenance methods, this system of maintenance should be a process-oriented system.
- (4) Infrastructure managers need to use freight wagons to transport materials for construction or for infrastructure maintenance activities. When they operate freight wagons for this purpose, infrastructure managers do so in the capacity of a railway undertaking. The assessment of the infrastructure manager's capacity to operate

¹ OJ L 138, 26.5.2016, p.102.

freight wagons for this purpose should be part of its assessment for a safety authorisation under Article 11 of Directive 2004/49/EC.

- (5) Inspections and monitoring undertaken before the departure of a train or en route are generally performed by operational staff of the railway undertakings or infrastructure managers, following the process described in their safety management system in accordance with Article 4(3) of Directive 2004/49/EC.
- (6) The railway undertakings or the infrastructure managers should ensure, through their safety management system, the control of all risks related to their activity, including the use of contractors. To this end, a railway undertaking should rely on contractual arrangements involving entities in charge of maintenance for all wagons it operates. This could be a contract between the railway undertaking and the entity in charge of maintenance or a chain of contracts involving other parties, such as the keeper. These contracts should be consistent with the procedures outlined by a railway undertaking or an infrastructure manager in its safety management system, including for the exchange of information.
- (7) In accordance with Directive 2004/49/EC, a certificate for an entity in charge of maintenance (ECM certificate) is valid throughout the Union. Certificates issued by bodies in third countries appointed under equivalent criteria and meeting equivalent requirements to those contained in this Regulation should normally be accepted as being equivalent to the ECM certificates issued in the Union.
- (8) The assessment by a certification body of an application for an ECM certificate is an assessment of the applicant's ability to manage maintenance activities and to deliver the operational functions of maintenance either by itself or through contracts with other bodies, such as maintenance workshops, charged with delivering these functions or parts of these functions.
- (9) A system of accreditation should provide a tool for managing risks by assuring that accredited bodies are competent to carry out the work they undertake. Furthermore, accreditation is regarded as a means to secure national and international recognition of ECM certificates issued by accredited bodies.
- (10) In order to have a system allowing certification bodies to perform checks on certified entities in charge of maintenance across the Union, it is important that all bodies able to award certificates to any entity in charge of maintenance (the 'certification bodies') should cooperate with each other in order to harmonise approaches to certification. Specific requirements for accreditation should be developed and approved in line with the provisions of Regulation 765/2008.
- (11) To evaluate the certification process set out in this Regulation, it is important that the European Railway Agency (the Agency) oversees the development of the system of certification. To be able to perform this function, the Agency needs to collect information on the nature of the certification bodies active in this field and the number of certificates issued to entities in charge of maintenance. It is also important for the Agency to facilitate coordination of the certification bodies.
- (12) Regulation (EC) No 653/2007 on the use of a common European format for safety certificates and application documents in accordance with Article 10 of Directive 2004/49/EC of the European Parliament and of the Council and on the validity of

safety certificates delivered under Directive 2001/14/EC provides the standard format for safety certificates. This format must be updated to include further information on entities in charge of maintenance. Regulation (EC) No 653/2007 should therefore be amended accordingly.

- (13) Pending the full application of the certification system of the entity in charge of maintenance provided for in this Regulation, the validity of existing practices to certify entities in charge of maintenance and maintenance workshops should be recognised during a period of transition in order to ensure the uninterrupted provision of rail freight services, in particular at international level. During this period the national safety authorities should pay particular attention to the equivalence and the consistency of the different certification practices.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 27 of Directive 2004/49/EC,
- (15) In the cases provided for in Article 14(4) of Directive (EU) 2016/798, the certification of entities in charge of maintenance and of maintenance workshops as appropriate provide sufficient evidence that railway undertakings are capable, through their safety management system, to control the risks related to the maintenance of vehicles, including the use of contractors.
- (16)

HAS ADOPTED THIS REGULATION:

Article 1

Purpose

1. This Regulation establishes a system of certification of entities in charge of maintenance for vehicles as referred to in Article 14(8) of Directive (EU) 2016/798.
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 vehicle 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 vehicles to be used on the railway network within the Union.
2. Maintenance workshops or any organisation who maintain vehicles or their components taking on a subset of the functions specified in Article 14(3) of the Directive (EU) 2016/798 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 vehicles for transporting materials for construction or for infrastructure maintenance activities. When it operates vehicles 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 (EU) 2016/798 apply.
2. In addition, the following definitions apply:
 - (a) ‘accreditation’ means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008 of the European Parliament and of the Council²;
 - (b) ‘ECM certificate’ means a certificate issued to an entity in charge of maintenance for the purposes of Article 14(4) of Directive (EU) 2016/798;
 - (c) ‘certification body’ means a body, notified to the Commission in accordance with Article 10, responsible for the certification of entities in charge of maintenance, on the basis of the criteria in Annex II;
 - (d) ‘vehicle’ means a railway vehicle suitable for circulation on wheels on railway lines, with or without traction; a vehicle is composed of one or more structural and functional subsystems;
 - (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, possibly subject to temporary restrictions of use;
 - (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 vehicle, previously removed from operation, is in a condition to be used safely, possibly subject to temporary restrictions of use.

² OJ L 218, 13.8.2008, p. 30.

Article 4

Maintenance system

1. The maintenance system is described in Article 14(3) of the Directive (EU) 2016/798.
2. The entity in charge of maintenance shall ensure that the maintenance system complies with the requirements and assessment criteria set out in Annex III.
3. Where the entity in charge of maintenance resorts to outsourcing of the maintenance functions referred to in Article 14(3)(b), (c) and (d) of the Directive (EU) 2016/798, the entity in charge of maintenance shall ensure that the principles set out in Article 8 and Annex I are applied.
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 vehicles it operates, before their departure, have a certified entity in charge of maintenance and that the use of the vehicle corresponds to the scope of the certificate.
2. All parties involved in the maintenance process including manufacturers 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 vehicle. The entity in charge of the maintenance of the vehicle 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 vehicle. 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 vehicles.
6. When a railway undertaking or an Infrastructure manager has an ECM certificate issued according to this regulation, applies for a safety certificate or safety authorisation, the safety management system requirements set in annex I or annex II (delegated Reg on supervision XXX) in points 5.2.4 and 5.2.5 should be assessed by safety certification body or national safety authority as met.

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 14 of Directive (EU) 2016/798 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.
8. When there is a change of entity in charge of maintenance, the keeper as indicated in Article 47(6) of Directive (EU) 2016/797, shall inform in due time the registration entity, as defined in article 4(1) of the commission decision 2007/756/EC, 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 keeper 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.
6. The certification bodies shall deliver a report every three years to the Agency. The content shall be precised by the Agency at the latest 18 months before the delivery date and in accordance with any subsequent sectoral accreditation schemes..

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.
3. The certification body shall take a decision not later than four 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.
4. An ECM certificate shall be valid for a period up to six years. The holder of the certificate shall inform the certification body of 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. The ECM shall deliver an annual report to its certification body. The content of this annual report is described in Annex VI.
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.
8. 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.

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 14(3)(b), (c) and (d) of the Directive (EU) 2016/798, 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 14 of the Directive (EU) 2016/798 or with the certification requirements of this Regulation, it shall take the necessary decision and inform the Commission, the Agency, other competent authorities, the certification body and other interested parties of its decision in consistency with the annex VII.

Article 10

Provision of information to the Commission and the Agency

1. By not later than [*insert date — six months from the date of entry into force of the Regulation*], Member States shall inform the Agency whether the certification bodies are accredited bodies, recognised bodies or national safety authorities. They shall also notify any change in this situation to the Agency within one month of the change.
2. By not later than [*insert date — 12 months from the date of entry into force of the Regulation*], Member States shall notify the Agency of the certification bodies recognised. The accreditation bodies as defined in Regulation 765/2008 shall inform the Agency of the certification bodies accredited. Any change shall also be notified to the Agency within one month of the change.

3. Certification bodies shall notify the Agency of all issued, amended, renewed, suspended or revoked ECM certificates or certificates for specific functions according to Article 4(1), within one week from its decision, using the forms in Annex V.
4. All information notified to the Agency under paragraphs 2 and 3 shall be done via the Agency database “ERADIS”. The Agency shall keep a record of all information notified under paragraphs 2 and 3 and shall make it publicly available.

Article 11

Transitional provisions

1. The following transitional provisions shall apply without prejudice to Article 9.
2. Starting from [*insert date — one year from the date of entry into force of the Regulation*], any ECM certificate shall be issued in accordance with this Regulation to entities in charge of maintenance for vehicles, without prejudice to Article 14 of the Directive (EU) 2016/798.
3. Certificates issued under (EU) 445/2011 by a certification body by not later than [*insert date — one year from the date of entry into force of the Regulation*] shall be recognised as being equivalent to ECM certificates issued under this Regulation for their original validity period .
4. The certificate of an ECM already certified for the maintenance of wagons could be extended to other vehicles for its original period of validity via the surveillance activity.
5. “Attestations of conformity with the requirements of Annex III of the Regulation 445/2011” issued by a certification body to ECMs and maintenance workshops by not later than [*insert date —the date of entry into force of the Regulation*] shall be recognised as being equivalent to certificates issued under this Regulation for their original period of validity.
6. Without prejudice to paragraphs 3 to 5, all entities in charge of maintenance for vehicles registered in the national vehicle register by not later than [*insert date —the date of entry into force of the Regulation*] shall be certified in according to this regulation by not later than [*insert date — 24 months from the date of entry into force of the Regulation*].

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.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER

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

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.

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 vehicles 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 three years of relevant experience in maintenance in general;
- (d) sufficient experience in vehicle 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.

6. OPENNESS

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.

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 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 must 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 must have risk management procedures to manage changes in maintenance file including maintenance plans, equipment, procedures, organisation, staffing or interfaces, and to apply Commission Implementing Regulation (EU) No 402/2013³.

2.3 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 Directive 89/391/EEC⁴.

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 and to apply Commission Regulation (EU) No 1078/2012⁵ 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;

³ OJ L 121, 3.5.2013, p. 8.

⁴ OJ L 183, 29.6.1989, p. 1.

⁵ OJ L 320, 17.11.2012, p. 8.

- (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;
- (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.

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.

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;
- (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 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 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.

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:

- (a) all maintenance activities affecting safety;

- (b) all safety-critical components
 - (i) identified as such by the organisation
 - (ii) in consistency with the annex VIII
- 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 2016/797/EC and the relevant TSIs;
 - (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 vehicles start operations, the organisation must have procedures to:
 - (a) obtain the 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 process described in annex I of the Commission regulation 402/2013, 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 accordingly.
- 5. To keep the maintenance file updated throughout the lifecycle of a vehicle, 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 vehicle;

- (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 process described in annex I of the Commission regulation 402/2013;
- (d) ensure that the implementation of changes is done accordingly.

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 vehicles for the transport of dangerous goods such as tanks and valves;
- (d) maintenance activities on specific components of vehicles such as :
 - i. door control systems;
 - ii. control-Command and signaling on-board system;
 - iii. traction;
 - iv. electrical equipment/ electromagnetic compatibility
 - v. fire safety

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 vehicles for maintenance in due time.
4. The organisation must have a procedure to manage the removal of vehicles 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 vehicles.
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 vehicle;
 - (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 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.

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) maintenance activities on safety critical components;

- (f) maintenance activities on control command and signalisation system;
- (g) maintenance activities on door control systems;
- (h) other identified specialist areas affecting safety.

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, equipment 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 (EU) 2016/798 and Commission Regulation No *[indicate the number and date of this regulation]*

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 Email 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 Email address _____

APPLICATION DETAILS

4.1 Application reference (given by the applicant)

This application is for a

- 4.1 new certificate 4.2 updated/amended certificate
- 4.3 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 wagons specialised in transport of dangerous goods: YES/NO

ECM Operational Functions

		own		Partially outsourced		Fully outsourced
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 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



APPLICATION FOR A MAINTENANCE FUNCTIONS CERTIFICATE

Application for a certificate confirming acceptance of the maintenance system within the European Union in conformity with Directive (EU) 2016/798 and Commission Regulation No [indicate the number and date of this regulation]

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 Email 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 Email address _____

APPLICATION DETAILS

- 4.1 Application reference (given by the applicant)

This application is for a

- 4.1 new certificate 4.2 updated/amended certificate
- 4.3 renewed certificate

Operational details

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

Scope of activities

5.4 Covers wagons specialised in transport of dangerous goods: YES/NO

Maintenance Functions

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 Commission Regulation No [indicate the number and date of this regulation]):

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 (EU) 2016/798 and Commission Regulation No [indicate the number and date of this regulation]

1. EIN number	
----------------------	--

2. 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:

3. CERTIFICATION BODY

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

4. CERTIFICATE INFORMATION

This is a	- new certificate <input type="checkbox"/>	EIN number of the previous certificate:
	- renewed certificate <input type="checkbox"/>	
	- updated/amended certificate <input type="checkbox"/>	
Validity from:		to:
Type of company: (railway undertaking, keeper, maintenance supplier, etc.)		

5. SCOPE OF ECM ACTIVITIES

Type of vehicles: (freight wagons, locomotives, multiple units, passenger carriages, high-speed vehicles, OTMs, other)	
Covers wagons specialised in transport of dangerous goods	YES/NO

6. ADDITIONAL INFORMATION

Date issued	Signature
Internal reference number	Certification body's stamp

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MAINTENANCE FUNCTIONS CERTIFICATE

confirming acceptance of the maintenance system within the European Union in conformity with Directive (EU) 2016/798 and Commission Regulation No [indicate the number and date of this regulation]

1. EIN number	
----------------------	--

2. CERTIFIED ORGANISATION

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

3. CERTIFICATION BODY

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

4. CERTIFICATE INFORMATION

This is a	- new certificate <input type="checkbox"/>	Identification Number of the previous certificate:
	- renewed certificate <input type="checkbox"/>	
	- updated/amended certificate <input type="checkbox"/>	
Validity from:	to:	
Type of company: (railway undertaking, keeper, maintenance supplier, etc)		

5. SCOPE OF MAINTENANCE ACTIVITIES

Type of vehicles: (freight wagons, locomotives, multiple units, passenger carriages, high-speed vehicles, OTMs, other)	
Covers wagons specialised in transport of dangerous goods	YES/NO

6. 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 Commission Regulation No [indicate the number and date of this regulation]):

7. ADDITIONAL INFORMATION

--	--

Date issued

--

Internal reference number

--

Signature

Certification body's stamp

--

ANNEX VI

THIS ANNEX DESCRIBES THE CONTENT OF THE ECM ANNUAL REPORT

- Explanations and justification on how non-conformities have been undertaken and/or solved
- Information on volume of maintenance carried out during the prevailing period
- Changes related to
 - Legal ownership of the company
 - Organisation (procedures in place)
 - Vehicles for which the ECM is in charge of maintenance
 - Sites and contractors including processes and equipments
 - Balance internal/external activities related to the three maintenance functions (maintenance development, fleet maintenance and maintenance delivery)
 - Contractual arrangements with users (including the keepers and the exchange of data)
 - Maintenance system
 - Defects and failures including information exchanged against article 5(5) of the ECM regulation
 - Internal audit reports
 - NSA and other authorities enforcement actions/investigations including claims according to article 9 of the ECM regulation
 - Competence management

The ECM has to add to the annual report all information it considers relevant for the certification body.

The ECM address the report in due time before the planned surveillance assessment upon an agreement with the certification body.

It is reasonable to consider a period of one month before planned surveillance for addressing annual report to the certification body.

Annex VII

According to Article 9 of the ECM Regulation, an NSA that has a justified reason to believe that an ECM does not meet the requirements of the ECM Regulation shall at first “take the necessary decision” and then afterwards “inform the Commission, the Agency, other competent authorities, the certification body and other interested parties of its decision”. As a general rule, an NSA shall not supervise ECMs as this would lead to a duplication of the surveillance regime of the ECM certification bodies. But, during its regular supervision activities directed towards IMs and RUs, an NSA can detect problems and defects that may put in question the ECM’s competencies.

Based on the information received from the RU/IM/keeper (and possibly ECM and ECM certification body), if the NSA is satisfied, no further action or decision is necessary.

If the NSA is not satisfied, the NSA, in a proportionate way, can take the following action:

- NSA decision towards RU/IM if measures from RU/IM are not satisfactory as regards technical aspects and timing;
- If measures from RU/IM are not satisfactory and the NSA has legal duty regarding ECMs: NSA decision towards ECM if measures from ECM are not satisfactory as regards technical aspects and timing.
- For informing the sector, it shall be sufficient that an NSA informs the RU/IM/keeper where the defect occurred. According to Article 5 (5) of the ECM Regulation, it is the responsibility of the sector to take the necessary activities and spread this information to all parties involved. The NSA asks the RU/IM for confirmation that the RU/IM has fulfilled its duties according to Article 5 (5). The RU/IM shall report back to the NSA.
- Further information according to Article 9 shall follow a graduated approach depending on the safety criticality of the defect and the corresponding actions of the RU/IM/ECM in response to the defect. To accommodate this, the following matrix shall be applied:
- In all cases, RU/IM/keeper/ECM already have notice of the defect that occurred.

		(re)action of the ECM / frequency of occurrence of the defect		
		ECM acts efficient and competent / isolated case	ECM actions show deficiencies / repeated cases	No or inadequate ECM actions / numerous cases
safety risk of the defect	high	2	3	3
	medium	1	2	3
	low	1	1	2

“1” means mild case, not safety critical

- No further information by NSA necessary

“2” means medium case, safety critical

- NSA informs ECM certification body
- NSA checks necessity of recording in ERA Safety Information System

“3” means severe case, safety critical

- NSA informs ECM certification body
- NSA records case in ERA Safety Information System (= information to ERA)
- NSA informs Commission by e-mail to Giordano.rigon@ec.europa.eu

Examples for defects with safety risk “high”, “medium” or “low”:

Low: - Wrong/incomplete signage on wagons- Deadline for overhaul elapsed

Medium: - Wrong tare/load spring installed (Y25 bogies) - Brake rigging wrongly plugged

High: - Defect on axle or solid wheel repaired by welding - Visibly different buffer types in wagon ending - Bogie frame rubbing against axle - Axle box destroyed by loose screw

Annex VIII

Safety critical components

Safety critical components are those components that are:

- Identified as such by the ECM as output of a risk-based process related to the systematic identification and management of all hazards that all components can present. The ECM shall identify criticalities by observing and analysing the detected and most credible failures on the maintained vehicles in a view to ensure a safe state of running. Following this identification, the ECM shall develop and implement maintenance control measures proportionate to the criticalities.

or

- Identified as such by the designers/manufacturers all along the lifecycle of the vehicle in consistency with the following common European definition:
 - Safety critical components means any component for which single failure has a credible potential to lead directly to a catastrophic accident.

Note 1: Accidents are derailment, collisions, and other accidents to persons caused by vehicles in motion, fire or other.

Note 2: Catastrophic is related to multiple fatalities. The most credible unsafe consequence of the failure must be taken into account”

A component shall be seen as:

- A technical system performing a function; or
- A technical subsystem performing a subfunction when the combination of subfunctions cover a function; or
- An individual (basic) component when it is convenient for systems with low complexity. Mainly for mechanical systems.
- Softwares should also be considered as component.
- Materials, tools and equipments used in maintenance

For the identification and management of safety critical components, the ECM shall cooperate with:

- Railway Undertakings reporting on in-operation detected failures and implemented operational control measures in application of the article 5.
- Designers/manufacturers
 - Supporting the ECM on technical and engineering aspects. This is crucial for complex technical systems and application of new technologies to ensure clear and effective understanding by the ECM.
 - By reporting on detected failures, operational and maintenance control measures that have been taken.

The ECM shall ensure that the configuration of vehicles in annex III. II. 7. (b) includes the safety critical components