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1. INTRODUCTION

1.1 Scope

This guide provides information on the application of the “Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons” as referred to in Article 14(a) of the Safety Directive. That regulation will be referred to in the present document as the “ECM Regulation”.

This guide aims at a correct and common understanding of the concepts of ECM developed in the ECM Regulation but does not contain any legally binding advice. It contains explanatory information of potential use to all actors whose activities may have an impact on the safety of railway systems and who directly or indirectly need to apply the ECM Regulation. It may serve as a clarification tool without however dictating in any manner compulsory procedures to be followed and without establishing any legally binding practice. The guide provides explanations on the provisions contained in the ECM Regulation and should aid understanding of the approaches and rules described therein.

The guide needs to be read and used only as a non-binding informative document and to help the different stakeholders with the application of the ECM Regulation. It should be used in conjunction with the ECM Regulation to facilitate its application but it does not replace it.

The guide has been prepared by the European Railway Agency (ERA) with the support of Recognised Bodies and National Safety Authority experts. It represents a developed collection of information gathered by the Agency during internal meetings and meetings with ACBs (Accredited Certification Bodies), RCBs (Recognised Certification Bodies) and NSAs, it has been amended with the feedbacks received during the different dissemination workshops in 2012 and 2013.

ERA will organise other workshops during 2013, and when necessary, ERA will review and update the guide to reflect the progress with the return from experience on the implementation of the ECM Regulation received during these workshops. As it is not possible to give a timetable for this revision process at the time of writing, the reader should refer to the Agency for information about the latest available edition of the guide or consult the Agency website (http://www.era.europa.eu).

The ECM Regulation provides a framework for the harmonisation of requirements and methods to assess the ability of entities in charge of maintenance for freight wagons. Even if the definition of

1 OJ L122/22, 11.5.2011
2 The concerned actors are the contracting entities as defined in Article 5 of ECM Regulation including their suppliers and service providers, or the certification bodies as defined in Article 6 of ECM Regulation.
ECM is not bounded to freight wagons but to all vehicles registered in the NVR, in accordance with the ECM Regulation, the scope of this document is limited to freight wagons. It does not mean however that the guidance may not also apply to other vehicles. Nevertheless, there is no assurance that the information provided is complete or fully applicable as such.

1.2 Principle for this guide

Although the guide may appear to be a stand-alone document for reading purposes, it is not a substitute for the ECM Regulation. For ease of reference, when relevant, the related article of the ECM Regulation or the safety directive is copied or referred to in the guide. Guidance is then provided in the following paragraphs to help provide understanding where this is considered necessary.

A first main structure of the present guide was proposed, discussed and approved during the “Task Force on the ECM Guidelines”. Because we received a lot of questions during the dissemination workshops, ERA has decided to change the structure and has suggested to present the guide like a structured list of questions/answers. All the parts of the previous version have been integrated in the new version. ERA thinks that the new structure is more didactic, friendly and more useful for all the stakeholders.

The content of this guide is complemented by other existing application guides and explanatory document as follows:
The Application Guide for the Sectoral Accreditation Scheme (called hereafter ECM accreditation scheme) contains guidelines (text in blue) to be used by national accreditation bodies when assessing certification bodies performing ECM certification in conformity with the ECM Regulation (Cf. Article 6(2)).

The Application Guide for the Certification Scheme contains the guidelines to be used by certification bodies when assessing ECM and applicants for separate maintenance functions in conformity with the ECM Regulation (Cf. Articles 7 and 8, Articles 5(2) to 5(5) and Annex III).

The Application Guide for the Maintenance Workshop Certification Scheme contains the guidelines to be used by certification bodies when assessing ECM and applicants for the specific maintenance delivery function in conformity with the ECM Regulation (Cf. Articles 7 and 8, Annex III.I and Annex III.IV).

1.3 Structure

The guide is divided into the following parts:

- Part 1 “Introduction” contains the scope and explains the structure of the guide;
- Part 2 “Documents” defines the documents useful for the guide;
- Part 3 “Definitions” contains a list of questions/answers relatives to definitions, terms and abbreviations used throughout the guide;
- Part 4 “Vehicle and maintenance” explains the maintenance process;
- Part 5 “Certification of ECM” describes the different steps of the ECM certification;
- Part 6 “Where does the ECM certification apply ?” explains the geographical scope of ECM certificate;
- Part 7 “Accreditation – Recognition of certification bodies” contains a list of questions/answers relevant to understand better the environment of accreditation and certification;
- Part 8 “Implementation of the regulation 445/2011” describes the transitional period;
- Part 9 “Organisation of the railway freight transport in Europe and responsibilities of actors”;
- Part 10 “Maintenance file and technical file” contains a list of questions/answers to explain how to follow the requirements of the regulation 445/2011 to build the essential documents relative to the maintenance functions.
- Part 11 “Exchange of information between railway actors”
- Part 12 “Management of changes” It explains also how to meet the different changes inherent to ECMs.
- Part 13 “Implementation of Regulation 352/2009 and 402/2013 on CSM on risk assessment
2 DOCUMENTS

2.1 What legislative documents are related to ECM certification?

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<thead>
<tr>
<th>Ref. N˚</th>
<th>Title</th>
<th>Reference</th>
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<td>Title</td>
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<td>[12]</td>
<td>Memorandum of Understanding (MoU) establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons</td>
<td>-</td>
<td>14/05/2009</td>
</tr>
<tr>
<td>[14]</td>
<td>Memorandum of Understanding (MoU) establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons</td>
<td>-</td>
<td>14/05/2009</td>
</tr>
</tbody>
</table>
2.2 What documents do you need to have in mind?

Here you can find the diagram describing the different regulations and the schemes associated:
The different standards supporting the ECM certification are:

- EN 13306 : 2010: Maintenance Terminology
- ISO/IEC 17000:2004 Conformity Assessment – Vocabulary and general principles
- EN ISO/IEC 17021:2011 Conformity assessment -- Requirements for bodies providing audit and certification of management systems
- EN ISO/IEC 17050-1:2010 Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements
- IAF MD 1:2007 Certification of Multiple Sites Based on Sampling
- IAF MD 2:2007 Transfer of Accredited Certification of Management Systems
- Terminology on Combined Transport. Economic Commission for Europe UN/ECE. 2001 (Website of International Union of Combined Road-Rail Transport Companies UIRR)
- EA-1/22 - EA Policy for Conformity Assessment Schemes

2.3 Do you know the TSI wagon?

It is the technical specification for interoperability relating to the subsystem rolling stock — freight wagons of the trans-European conventional rail system.


To provide information on the application of the TSI wagon, there is a guide at this address:


This guide should be read and used only in conjunction with the WAGTSI.
3 DEFINITIONS

3.1 Common acronyms in the day – to – day life in the ECM certification for freight wagons

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<thead>
<tr>
<th>Acronym</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>AB</td>
<td>Accreditation Body</td>
</tr>
<tr>
<td>ACB</td>
<td>Accredited Certification Body</td>
</tr>
<tr>
<td>APIS</td>
<td>Authorisation for the Placing in Service (of structural subsystems and vehicles)</td>
</tr>
<tr>
<td>CA</td>
<td>Conformity Assessment</td>
</tr>
<tr>
<td>CAB</td>
<td>Conformity Assessment Body</td>
</tr>
<tr>
<td>CSM</td>
<td>Common Safety Methods</td>
</tr>
<tr>
<td>EA</td>
<td>European co-operation for Accreditation (<a href="http://www.european-accreditation.org">http://www.european-accreditation.org</a>)</td>
</tr>
<tr>
<td>EA (MLA)</td>
<td>EA Multi-Lateral Agreement</td>
</tr>
<tr>
<td>EC</td>
<td>European Commission (<a href="http://ec.europa.eu/index_en">http://ec.europa.eu/index_en</a>)</td>
</tr>
<tr>
<td>ECCM</td>
<td>European Common Criteria for Maintenance</td>
</tr>
<tr>
<td>ECM</td>
<td>Entity in Charge of Maintenance</td>
</tr>
<tr>
<td>EEA</td>
<td>European Economic Area</td>
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<tr>
<td>EFTA</td>
<td>European Free Trade Association (<a href="http://www.efta.int">http://www.efta.int</a>)</td>
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<tr>
<td>EN</td>
<td>European Norm</td>
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<tr>
<td>ERA</td>
<td>European Railway Agency (<a href="http://www.era.europa.eu">http://www.era.europa.eu</a>)</td>
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<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>EVIC</td>
<td>European Visual Inspection Catalogue</td>
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<tr>
<td>EWT</td>
<td>European Wheelset traceability catalogue</td>
</tr>
<tr>
<td>FMM</td>
<td>Fleet Maintenance Management</td>
</tr>
<tr>
<td>GCU</td>
<td>General Contract of Use (<a href="http://www.gcubureau.org">http://www.gcubureau.org</a>)</td>
</tr>
<tr>
<td>HoS</td>
<td>Head of Sector (ERA organisation)</td>
</tr>
<tr>
<td>HR</td>
<td>Human Resources</td>
</tr>
<tr>
<td>IAF</td>
<td>International Accreditation Forum (<a href="http://www.iaf.nu/">http://www.iaf.nu/</a>)</td>
</tr>
<tr>
<td>(IAF) MD</td>
<td>Mandatory document of IAF</td>
</tr>
<tr>
<td>IM</td>
<td>Infrastructure Manager</td>
</tr>
<tr>
<td>ISA</td>
<td>Independent Safety Assessment Body</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for standardization</td>
</tr>
<tr>
<td>ISP</td>
<td>Interchangeable Spare Parts</td>
</tr>
<tr>
<td>ISV</td>
<td>Intermediate Statement Verifications</td>
</tr>
<tr>
<td>Acronym</td>
<td>Meaning</td>
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<tr>
<td>IT</td>
<td>Information Technology</td>
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<tr>
<td>MDL</td>
<td>Maintenance Delivery</td>
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<td>MDV</td>
<td>Maintenance Development</td>
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<tr>
<td>MF</td>
<td>Management Function</td>
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<tr>
<td>MLA</td>
<td>Multilateral Agreements</td>
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<td>MoU</td>
<td>Memorandum of Understanding</td>
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<tr>
<td>MRA</td>
<td>Mutual Recognition Agreements</td>
</tr>
<tr>
<td>MS</td>
<td>Member State</td>
</tr>
<tr>
<td>MW</td>
<td>Maintenance Workshop</td>
</tr>
<tr>
<td>NAB</td>
<td>National Accreditation Body</td>
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<tr>
<td>NANDO</td>
<td>New Approach Notified and Designated Organisations</td>
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<tr>
<td>NDT</td>
<td>Non-Destructive Test</td>
</tr>
<tr>
<td>NoBo</td>
<td>Notified Body</td>
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<tr>
<td>NSA</td>
<td>National Safety Authority</td>
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<tr>
<td>NVR</td>
<td>National Vehicle Register</td>
</tr>
<tr>
<td>PO</td>
<td>Project Officer (ERA organisation)</td>
</tr>
<tr>
<td>OTM</td>
<td>On–Track Machine</td>
</tr>
<tr>
<td>RID</td>
<td>Regulations concerning the International Carriage of Dangerous Goods by Rail, as adopted under Directive 2008/68/EC.</td>
</tr>
<tr>
<td>RS</td>
<td>Rolling Stock</td>
</tr>
<tr>
<td>RSD</td>
<td>Railway Safety Directive</td>
</tr>
<tr>
<td>RU</td>
<td>Railway Undertaking</td>
</tr>
<tr>
<td>SMS</td>
<td>Safety Management System</td>
</tr>
<tr>
<td>TEN</td>
<td>Trans-European Rail Network</td>
</tr>
<tr>
<td>TFEU</td>
<td>The Treaty on the Functioning of the European Union</td>
</tr>
<tr>
<td>VPI</td>
<td>Vereinigung der Privatgüterwagen-Interessenten (<a href="http://www.vpihamburg.de">http://www.vpihamburg.de</a>)</td>
</tr>
</tbody>
</table>
4 VEHICLE AND MAINTENANCE

4.1 What is a vehicle?

Def from “Uniform Rules concerning Contracts of Use of Vehicle in International Rail Traffic (CUV)” “vehicle” means a vehicle, suitable to circulate on its own wheels on railway lines, not provided with a means of traction

4.2 What is a freight wagon?

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 (Source: ECM regulation 445/2011/EU article 3(2)d)

Each freight wagon must have been assigned a unique EVN and one ECM in charge for this wagon in the NVR. As it is permissible in certain circumstances to assign a single EVN to a fixed formation of two or more wagon units (defined as multiple wagons in [8] und [23]), it is in turn possible that a “wagon” from the perspective of the ECM can consist of more than one element. In each case the EVN and the associated entry in the NVR will be the binding definition on what constitutes an individual “wagon”.

<table>
<thead>
<tr>
<th>Picture 1</th>
<th>Example of a unit consisting of a (freight) wagon that can be operated separately, featuring an individual frame mounted on its own set of wheels</th>
</tr>
</thead>
<tbody>
<tr>
<td>Picture 2</td>
<td>Example of a unit consisting of a rake of permanently connected two elements (blue and orange), those elements cannot be operated separately (articulated wagon)</td>
</tr>
</tbody>
</table>
4.3 What is an ECM?

After a vehicle is placed in service, an Entity in Charge of its maintenance has to be designated and to be identified in the National Vehicle Register. An ECM may be, but not limited to, a Railway Undertaking, an Infrastructure Manager or a keeper.

In accordance with the Railway Safety Directive and FOR FREIGHT WAGONS ONLY, the ECM shall be certified in accordance with the regulation 445/2011, article 2(1).

4.4 Who can be an ECM?

An ECM may be, but not limited confirmed by the European Commission, a Railway Undertaking, an Infrastructure Manager or a keeper.

The ECM is the body reguistered as such in the NVRs. There are no conditions of nationality to become an ECM. An ECM established outside the EU or outside the contracting countries of OTIF can provide maintenance to wagons used on the railway system of the EU or of the contracting countries of OTIF. In that case the ECM has to be certified against the ECM Regulation or its equivalent in OTIF rules.

4.5 How many ECMs can a vehicle have?

Article 33(2) of Directive 2008/57/EC provides that the NVR is to contain, among other compulsory information, the identification of the owner of the vehicle and the entity in charge of maintenance.

Decision 2007/756/EC, amended by the Decision 2011/107/EU, establishes the requirements for the information to be contained in the NVR and, for each vehicle, the data relative to the ECM (and not several ECM) has to be compulsorily fulfilled. Then a vehicle can only have one ECM assigned in the NVR
4.6 What is a maintenance workshop?

Maintenance workshop is a mobile or fixed entity composed of staff, including those with management responsibility, tools and facilities organised to deliver maintenance on vehicles, parts, components or sub-assemblies of vehicles (Source: Regulation 445/2011/EU article 3(2)e).

A Maintenance workshop is an entity having a management, staff, tools and facilities necessary to carry out maintenance operations on the vehicle itself or on parts and components of the vehicle. Mobile teams, depending on a fixed structure where maintenance works are performed or being self-supporting, and fulfilling the requirements of the definition of a maintenance workshop as defined hereinbefore, are assimilated to maintenance workshops.

A maintenance Workshop is in charge, of the maintenance delivery function as described in the Art.4(d) of the ECM Regulation.

4.7 What is A National Vehicle Register (NVR)?

As established in the Commission Decision 2007/756/EC of 9 November 2007 [11] and amended by the Decision 2011/107/EU, where Member States authorise the placing in service of rolling stock, they have to ensure that an identification code is assigned to each individual vehicle. This code should then be entered in a national vehicle register (hereafter NVR). This register must be accessible for consultation by authorised representatives from competent authorities and stakeholders. The different national registers should be consistent as regards data contents and data formatting. This requires their establishment on the basis of common operational and technical specifications.

Section 2.2 of the mentioned Decision also describes the implementation of the European global architecture for national vehicle registers (NVRs).

In addition, Article 3(2) of Decision 2011/107/EU mentions that the member states shall ensure that, for the vehicles registered before the entry into force of this decision, the registered business number of the entity in charge of maintenance is recorded in the national vehicle register.
This is an extract of the data format of the national vehicle register. The part 9 is the part dedicated to the information relative to the ECM.
4.8 What does “maintenance” mean?

**The design operating state:**

(Definition in the TSI wagon [7]) The ‘design operating state’ covers all conditions under which the unit is intended to operate and its technical boundaries. This design operating state may go beyond the specifications of the TSI in order that units may be used together in a train on the network under the safety management system of a railway undertaking.

It means a state when a vehicle, subsystem or part of subsystem is performing a required function for which it has been designed, manufactured and tested. It includes at least the nominal operating mode, it may include degraded operating modes, provided these modes have been designed, implemented and tested so that the essential requirements are met.

This definition is inspired by the definition in EN 13306 “Maintenance terminology”

When the vehicle is used, it will be more or less damaged and therefore will not remain fully conform to its design operating state. The goal of maintenance is to restore this vehicle in its design operating state.
4.9 What is a maintenance system?

According to Section 4 of the Regulation 445/2011/EU, 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.
These 3 last functions are integrated in the maintenance system through a **MANAGEMENT PROCESS**

![Diagram of maintenance process]

It should not be understood as a strictly mandatory organisational structure for ECMs. Nevertheless the structure put in place by the ECM has to reflect on this functional maintenance breakdown. The ECM has to attach all elements (internal services, subdivisions and contractors) of its organisational structure to one or more maintenance functions.

### 4.10 What is the management function?

The Management Function shall supervise and coordinate the functions b), c), and d) of the ECM and ensure the safe state of freight wagon.

The Management function has two main tasks:

- Coordination of the functions b, c and d, as defined in the article 4.1, allowing the organization to achieve the maintenance targets defined in the Maintenance System (e.g. in the Maintenance Policy);
Supervision of the of the functions b, c and d, as defined in the article 4.1, granting the conformity against legislation and standards and allowing the organization to improve its Maintenance System.

The safe state of wagons can be ensured through the design, the implementation and the improvement of the Maintenance System.

The coordination activities shall be performed according to processes and procedures defined within the Maintenance System, those provisions shall take into account the use of contractors to implement the functions, the allocation of responsibilities, the management of competence of the staff, the definition of strategies and plans to define and to achieve the maintenance targets, etc.

The Management Function checks the implementation of the Maintenance System defining a systematic monitoring process, based on the CSM for Monitoring (Commission Regulation 1077/2012) to check the performances of the ECM in the field of maintenance (and safety, as consequence). When needed, the Management Function creates the conditions to correct or to improve the Maintenance performances, defining and implementing changes in the Maintenance System. Those changes shall be managed according to the CSM for Risk Assessment.

A decision making process should be managed by the Management Function on the basis of the results of the assessments of shared and owned risks. The CSM for Risk Assessment shall be used to define the Risk Management Process used to identify and control those risks.

The management function is defined in the Commission Regulation 445/2011 in the Art. 4.1.a

4.1.11 What is a maintenance development function?

The maintenance development function (MDV) covers the management of the maintenance file, including the configuration management, based on design and operational data as well as on required performance and return on experience.

It also covers the compliance with interoperability rules and the establishment and continuous update of the maintenance file.

The maintenance development process can be described as follows:

**At the moment when operation starts**

The initial development of the maintenance file depends on the initial technical documentation (see previous chapter) and the pattern of operations planned.

The process may be described as following:
When operation starts it is necessary to check if the initial documentation is relevant in comparison with the operations performed or planned to be performed and the performance targets of the users of the vehicles (keepers, RUs, IMs).

During the lifecycle of the vehicle

In accordance with the Annex III(II)(5) of the ECM Regulation, the update of the maintenance file depends on:

- The limit values that have to be maintained to assure the interoperability of the vehicle according to its authorisation of placing in service. They are stated in the initial technical documentation and every update of this documentation justified by a change in the design of the vehicle.

- Information on operation such as but not limited:
  - Behaviour of the vehicle during operation
  - Type and extent of operations (passenger\textsuperscript{3} or freight, high speed or conventional, long straight lines or lots of curves, direct trains or lots of stop-start,…);
  - empty or loaded journeys;
  - Mileage / journey time
  - incidents, accidents or defects occurred during operation
  - Content of daily inspection performed by the RUs (maintenance level 1)
  - environmental conditions (mountains, climatic, dust conditions, sand along

\textsuperscript{3} Even if the ECM Regulation is only addressed to freight wagons, passenger vehicles and high speed are taken into account regarding the further development mentioned in the Railway safety directive.
coast,...)\(^4\);

- behaviour and skills of drivers\(^5\);

- Records on maintenance already performed, on inspections performed by RUs/IMs and on studies related to return of experience. The maintenance workshops are often requested to take part to return on experience studies.

- Technological survey. The lifecycle of rolling stock extends to 40-50 years. Technology evolves a lot during this long lifecycle. The technological survey may include:
  - Condition based monitoring. This monitoring considers the behaviour of the different components.
  - Technological progress that includes the continuous progress of:
    - materials,
    - equipment,
    - spare parts,
    - tools and industrial equipments,
    - IT systems,
    - working and management methods.
  - Availability of materials, equipments and spare parts. Spare parts or materials may become obsolete or be unavailable. Generally the manufacturers give 10 years assurance regarding availability of electrical / electronic devices. So at certain time equivalent spare parts or materials have to be found.

- Evolution of applicable legislation:
  - Railway,
  - Environment,
  - Health and safety,
  - Safety of components,
  - Etc.

- Performance targets imposed by users (RU, IM, keeper):
  - reliability and availability of vehicles,
  - safety.

After taking into account all information, the maintenance development function covers the update or not of the maintenance file and the dissemination of the updates of documentation to interested parties.

\(^4\) Given as example. Not entirely applicable for the moment

\(^5\) Mainly applicable for for locomotives and multiple units. For freight wagons, the behavior of drivers may also have an indirect influence.
4.12 What is a fleet maintenance management function?

The Fleet Maintenance Management (FMM) covers the removal from/return to operation before/after maintenance and the management of contracts with ECM internal/external entities delivering maintenance.

Return to operation is only possible when maintenance operations are completed and the vehicles are back in a safe state of running. With regard to the exchange of information, the information on the completeness of maintenance activities performed on the vehicle must be received from maintenance delivery, this is done through the releases to service that are the commitments of the maintenance delivery that the maintenance activities ordered are completed.

Fleet management may be defined as the management of a company's vehicle fleet. The fleet maintenance management is then the part of the fleet management dedicated to maintenance of vehicles.

This function means in particular the responsibility for:

- applying the maintenance file to the vehicles through maintenance orders addressed to maintenance delivery.
- collecting and transferring, to maintenance development, information on maintenance performed and operations performed, including at least defects, incidents, accidents, mileage.

The inputs for the FMM are:

- the maintenance file;
- the performance targets imposed by users (RU, IM, keeper), such as regarding the reliability and availability of vehicles, the safety, are also inputs for the fleet maintenance management function.

The FMM must control the availability of the maintenance delivery.

The FMM will have the duty to ensure that maintenance orders are addressed only to duly qualified entities performing maintenance delivery.

The outputs of the FMM processes are:

- The maintenance orders addressed to the maintenance delivery. There has to be a contract between the FMM and the maintenance delivery. The maintenance orders are addressed applying internal procedures when fleet maintenance management and maintenance delivery are both internal to the ECM and by contracts in other cases. The maintenance orders contains the complete information issued from the maintenance file that are necessary to perform the maintenance tasks required to the maintenance delivery.
- The organisation for the return to operation of the vehicle in due time (including any delays occurred in the maintenance work resulting in the implementation of additional provisions for ensuring a safe state of running to the vehicle).
The FMM is responsible for declaring the wagon fit for purpose and fit for its return to operation after the maintenance work has been completed by the maintenance delivery. This return to operation is finally addressed to RUs generally through the keeper. Further the FFM has to give all information's getting from the maintenance deliverer about limitations and restrictions for use.

4.13 What is a maintenance delivery function?

The Maintenance Delivery (MDL) is the technical making of the ordered technical maintenance tasks. Maintenance delivery may be done in Maintenance Workshops (MW). Maintenance delivery covers the management of contracts (maintenance orders) with fleet maintenance management, the management of the supply chain, the management of facilities, industrial equipments and tools and the management of maintenance technical works.

This function means the technical execution of tasks/works defined in the maintenance file and ordered by the fleet maintenance management. The maintenance delivery must be competent to perform the maintenance works/tasks requested in the orders.

Generally after completion of works/tasks requested in maintenance orders, the entity performing maintenance delivery addresses a report to the FMM that ordered it. This report may also be addressed directly to the maintenance development.

There is a huge trend today to request not only delivery but also information on return of experience between the ECM and MW. The requirements addressing the return on experience are based on the requests from the maintenance development and should be part of the maintenance orders.

<table>
<thead>
<tr>
<th>INPUT</th>
<th>Maintenance delivery</th>
<th>OUTPUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Maintenance orders</td>
<td>• Records on maintenance performed including the release to service</td>
<td></td>
</tr>
<tr>
<td>• Rolling stock that has to be maintained</td>
<td>• Return on experience if requested</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Rolling stock maintained</td>
<td></td>
</tr>
</tbody>
</table>
4.14 Is it possible that an ECM outsource a part of the maintenance system?

**Scope of ECM certification**

**scenario 1**

The 4 functions
- Maintenance management
- Maintenance development
- Fleet maintenance management
- Maintenance delivery
are carried out by the ECM itself.

**scenario 2 - annex 1 - 445**

The function
- Maintenance management
is carried out by the ECM itself (mandatory)
- the other functions may be outsourced

The ECM may outsource a function but not the responsibility!
5 CERTIFICATION OF ECM

5.1 What does Certification mean?

It means: “Third party attestation related to products, processes, systems or persons (ISO/IEC 17000:2004).”

In the application of the ECM Regulation 445/2011/EU the certification is the process to be applied by the tandem:

- The accredited or recognised certification body or the NSA (acting as certification body) and
- The applicant for the certificate: the ECM or the maintenance workshop

The requirements to be fulfilled by the applicant during the certification process are described in the Annex III of the ECM Regulation 445/2011/EU and the certification schemes [17] available in the ERA website:


5.2 What is an ECM certificate?

The certificate provided by the accredited or recognised certification body or by the NSA (acting as certification body) accordingly the ECM Regulation 445/2011/EU, provides the assurance that the applicant fulfills the requirements established in the Annex III of the ECM Regulation 445/2011/EU and the certification schemes.

The format of this certificate is defined in the Annex V of the ECM Regulation 445/2011/EU and available in the ERA database ERADIS. This database is accessible in the following link:
5.3 What are the steps to follow to obtain an ECM certificate?

![Diagram of ECM certification scheme]

For further information see also the Certification scheme available in the ERA website:


5.4 What does the schema “Schema chosen to award ECM certificates in each member state” in ERADIS mean?

According to the Article 10.1 of the Commission Regulation (EU) No 445/2011 of 10 May 2011, the Member States shall choose between accreditation or recognition or shall nominate the NSA as certification body.
For recognition, when applying the article 5(2) of the Regulation 765/2008, the Member State shall provide evidences to the Commission and the other Member States on equivalence with the ECM accreditation scheme.

Therefore there are different schemas to be chosen by each Member State:

- “Accreditation”: it means accredited certification bodies will be able to perform the ECM certification.
- “Recognition”: certification bodies recognised by the member state will be able to perform the ECM certification.
- NSA as certification body: the NSA designated by the member state as certification body will be able to perform the ECM certification

The following link to the database ERADIS provides the choice of the different Member States:


The applicant ECM is free to choose its certification body (Article 6(1) of ECM Regulation). The ECM can contract body:

- with a certification accredited or recognised in any Member state;
- With the NSA of the Member State where the ECM is established only if the NSA has been designated by its Member state to perform ECM certification
5.5 What are the standards to apply for granting the ECM certificate?

The standards supporting the ECM certification are:

- EN 13306 : 2010: Maintenance Terminology
- ISO/IEC 17000:2004 Conformity Assessment – Vocabulary and general principles
- EN ISO/IEC 17021:2011 Conformity assessment -- Requirements for bodies providing audit and certification of management systems
- EN ISO/IEC 17050-1:2010 Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements

\(^6\) In the future revision of the accreditation scheme, this standard will be replaced by the ISO 17065

• ISO/IEC Guide 2:2004 Standardization and related activities -- General vocabulary

• IAF MD 1:2007 Certification of Multiple Sites Based on Sampling

• IAF MD 2:2007 Transfer of Accredited Certification of Management Systems

• IAF MD 5: 2009 Duration of QMS and EMS Audits

• Terminology on Combined Transport. Economic Commission for Europe UN/ECE. 2001 (Website of International Union of Combined Road-Rail Transport Companies UIRR)

• EA-2/11 - EA Policy for Conformity Assessment Schemes

5.6 What does flexibility for NSAs mean?

Two options are offered to NSAs fulfilling the role of an ECM certification body:

- Option 1: NSAs strictly apply the ECM Certification Scheme.
- Option 2: NSAs respect the principles of the ECM Certification scheme within existing processes.

5.6.1 Option 1: NSA strictly apply the ECM Certification scheme

In this option the NSA applies completely the ECM certification scheme.

5.6.2 Option 2: NSA respects the ECM certification scheme within existing processes.

Two cases must be distinguished:

- Case 1: NSAs assessing together the application for a safety certificate (or safety authorisation) and for an ECM certificate by the same applicant concerning the freight wagons it uses and maintains according to the article 7(8)(a) of ECM Regulation.

Therefore a NSA, when assessing together the application of a RU/IM for a safety certificate/safety authorisation and for an ECM certificate (for freight wagons it uses and maintains), has the flexibility to bring its ECM certification process in consistency with its existing processes for safety certification (in compliance with the CSM conformity assessment [5]) and supervision activities (in compliance with the supervision principles of the CSM conformity assessment [5] and with the CSM on supervision [16]), The NSA will cover all activities described in the ECM certification scheme and in particular will take into account their knowledge of the applicant and those risks related to:

- the management system of the ECM;
✓ the existing competences;
✓ the assurance that the ECM address seriously the establishment and the updates of the maintenance files.

The principles underpinning this flexibility lies on the widest and more detailed view the NSAs have, among stakeholders and interested parties, on the safety of the (European) railway system and in particular, on safety risks. NSAs have then sufficient safety maturity and knowledge of the applicants to targeting by a risk based approach the assessment of the maintenance system of the ECMs.

This picture shows a possible adaptation of ECM Certification Scheme NSAs assessing together the application for a safety certificate (or safety authorisation) and for an ECM certificate.

- Case 2: NSAs assessing the application for an ECM certificate independently of the application for a safety certificate or safety authorisation. For instance when NSAs is certifying keepers as ECMs or other companies than RU/IMs.

Similarly to the case 1, the NSA has the flexibility to adapt its ECM certification process so as to deliver the ECM certificate to the applicant ECM after completing the initial audit. This flexibility is justified upon the knowledge the NSAs have on the safety risks of the railway system and therefore, lies on a risk based approach to targeting the assessment of the maintenance system of the ECMs. This can be illustrated by the following figure:
This picture shows a possible adaptation of ECM Certification Scheme NSAs assessing the application for an ECM certificate.

The NSAs have the possibility to undertake on-site audit and inspections (initially planned in the ECM Certification Scheme prior to the delivery of the ECM certificate) together with their intended purposes at the early stage of their surveillance activities. In that sense, the NSAs may deliver ECM certificate to the applicant after the completion of the initial audit (documentary review) on the maintenance system of the ECM and then, based on safety risks and their knowledge of the applicant, target their surveillance activities (on-site audit and inspections) on existing competences related to (selected) processes relevant to the main procedures of annex III of the ECM Regulation (See 3.2.2.1 of ECM Certification Scheme), coherence between the inputs and outputs of the selected processes and also on activities affecting safety.

The NSAs should also observe transparency in their decision-making process by setting out and publishing their decision-making criteria.

In any case, the NSA may always perform the on-site audits and the inspections required in the ECM certification scheme before granting the certificate. It would then be perfectly aligned with the certification scheme.

Nevertheless one target of the Network of Cooperation of Certification Bodies is to achieve a harmonised implementation of the ECM Regulation in the NSAs acting as certification bodies.
5.7 Can a NSA of a Member State A give an ECM certificate in a Member State B?

A private accredited certification body can certify any ECM for freight wagon on the whole territory of the EU. A private recognised body can also certify any ECM for freight wagon on the whole territory of the EU.

But if those certification bodies are NATIONAL (public) authorities/agencies, they are limited to the national territory for matters associated to national sovereignty.

When NSA acts as certification body, as NSA is a national (public) authority, it is also limited to its national territory.
6 WHERE DOES THE ECM CERTIFICATION APPLY?

6.1 What is the European Economic Area (EEA)?

The Agreement creating the European Economic Area (EEA) entered into force on 1 January 1994. It allows the EEA EFTA States (Norway, Iceland and Liechtenstein) to participate in the Internal Market on the basis of their application of Internal Market relevant acquis. All new relevant Community legislation is dynamically incorporated into the Agreement and thus applies throughout the EEA, ensuring the homogeneity of the internal market.

The EEA Agreement is concerned principally with the four fundamental pillars of the Internal Market, “the four freedoms”, i.e. freedom of movement of goods, persons, services and capital. But also “flanking policies” such as social policy, consumer protection, and environment policy may be covered. The EEA Agreement does not cover agriculture and fisheries.

The EEA Agreement allows for EEA EFTA participation in Internal Market relevant Community programmes and agencies, albeit with no right to vote. The EEA-EFTA states also make financial contributions towards the reduction of economic and social disparities in the EEA.

The Agreement covers most of the substance of the EU’s relations with the EEA EFTA States. The updating of the Agreement through the incorporation of new relevant Community legislation generally runs smoothly and thousands of legal acts have been extended to the EEA to date.

(Resource: http://eeas.europa.eu/eea/)

Further information will be found in http://eeas.europa.eu and http://www.efta.int/

6.2 What is a third country?

Is any country that is not a Member State of the European Union.

6.3 What is OTIF?

The Intergovernmental Organisation for International Carriage by Rail (OTIF) was set up on 1 May 1985. The Organisation’s basis under international law is the Convention of 9 May 1980 (COTIF). The predecessor of OTIF was the Central Office for International Carriage by Rail, which was set up in 1893.

Until the signature of the Protocol of 3 June 1999 (Vilnius Protocol) for the modification of COTIF, the objective of this Governmental Organisation was principally to develop the uniform systems of law which apply to the carriage of passengers and freight in international through traffic by rail. These systems of law have been in existence for decades and are known as the CIV and CIM Uniform Rules.
47 States are Members of OTIF at the present time (Europe/Middle East and North Africa) and one State is an Associate Member (Jordan). At present, international carriage by rail on railway infrastructure of around 250,000 km and the complementary carriage of freight and passengers on several thousand kilometres of shipping routes, inland waterways and (in domestic carriage) roads are concerned by the uniform law created by OTIF. The European Union acceded to this uniform law, COTIF, with effect from 1 July 2011.


Further information will be found in [http://www.otif.org/](http://www.otif.org/)

6.4 Are the countries in OTIF sharing data in their NVRs with the EU?

ERA is collaborating with OTIF to facilitate:

- the harmonised use of NVRs and
- sharing data between the EU and the OTIF area.

6.5 Is the ECM Regulation mandatory for other vehicles than freight wagons?

![Scope of ECM certification](image)

**Vehicle scope**

- **Freight Wagons**
  - ECM Regulation is applied on a compulsory base
  - Freight wagons for high speed or conventional rail (not those only limited to the TEN but all wagons)
  - Commercial transport of freight

- **Other Vehicles under the scope of the Safety Directive**
  - Not mandatory: provisions of the Articles 4, 5(2) to 5(5) and the Annex III of ECM Regulation should apply as best practises
  - Flat wagons for intermodal transport of containers, swap bodies and trailers

- **Vehicles out of the scope of the Safety Directive**

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The requirements of the ECM Regulation legally apply to the Entities in Charge of Maintenance for freight wagons. For other vehicles, it may apply on a voluntary basis. However, in accordance with Article 14a(1) of the Safety Directive, an ECM shall be assigned to all vehicles registered in the National Vehicle Register (NVR). The role of ECM (and associated responsibilities) is therefore not limited to freight wagons only.

In the European legislation there is no obligation that all types of vehicles have a certified ECM:

- Article 14a(1) of the Railway Safety Directive states that "Each vehicle, before it is placed into service or used on the network, shall have an entity in charge of maintenance assigned to it and this entity shall be registered in the NVR in accordance with Article 33 of the Railway Interoperability Directive".

- Article 14a(4) states that ECM for freight wagons shall be certified.

In addition, the Railway Safety Directive already identifies the possibility to extend in the future the scope of the certification to other vehicles than freight wagons:

- Article 14a(5) states that "Based on a recommendation by the Agency, the Commission shall, by 24 December 2018, review the measure in order to include all vehicles and to update, if necessary, the certification system applicable to freight wagons".

Thus, it is clear that according to the European legislation, each vehicle must have an ECM but only ECM for freight wagon shall be certified for the time being.

The Agency considers it a good practice if RUs and IMs decide on a voluntary basis to use certified ECMS also for vehicles other than freight wagons; nevertheless, presently for them there is no EU legal requirement which could oblige them to do so on a mandatory basis.

In addition, in order to apply the ECM Regulation to other vehicles than freight wagons, it is necessary to include in the Annex III of the mentioned Regulation some additional requirements. For instance, it would require for locomotives to take in account the signalling systems.

Thus, classical examples of vehicles to which the ECM Regulation does not apply for the time being are locomotives, passenger coaches, etc.

In summary it is possible that:

- At a national level, not only freight wagons but also other types of vehicles are obliged to have a certified ECM. Nevertheless, this could be seen as a discriminatory measure which closes the market to external companies or introduces obstacles to the open market. Depending on the extent of such measures, they should either be notified in draft to the European Commission as national safety rule or as a transposition of the Railway Safety Directive. They could thus be implemented if the European Commission agrees that the rule does not impose restrictions, which are not in compliance with the relevant Community legislation.

- At a railway sector level (organisation(s) and/or association(s) of RUs (e.g. CER), IMs (e.g. EIM), keepers (e.g. EPTTOLA), ECMS etc.), it may be decided to have on a voluntary basis certified ECMS for vehicles other than freight wagons.

In both cases, the proposer for the certification of ECMS for vehicles other than freight wagons (i.e. the Member State or the railway sector) would be responsible for developing, implementing and monitoring the whole certification process. This includes among others the adaptation of the existing ECM certification scheme (or the creation of a new one), its prospective validation by the...
European Co-Operation for Accreditation (EA), the selected type of certification body, the management of the certificates (template, registration and publication).

The revision of the ECM Regulation 445/2011/EU will take place in 2018. Based on the feedback collected from the implementation of this Regulation in the different Member States, decisions would be taken to extend (or not) the scope to other vehicles.

6.5.1 Regarding the vehicles operated by the Infrastructure Manager for its own needs:

Pursuant to Recital (4) of the ECM Regulation, when Infrastructure Managers need to use freight wagons to transport materials for construction or for infrastructure maintenance activities and when they operate freight wagons for this purpose, the Infrastructure Managers do so in the capacity of a railway undertaking. The assessment of the Infrastructure Manager’s capacity to operate freight wagons for this purpose should be part of its assessment for a safety authorisation under Article 11 of the Railway Safety Directive.

The Agency and EIM are working now to define more precisely which On-Track Machines (OTMs) should be included in the scope of the ECM Regulation and for which OTMs the ECM Regulation should be seen as good practices.

Today the approach is that the freight wagons, the non-self-propelled OTMs and the self-propelled OTMs operated in non-self-propelled mode on in-service tracks fall within the scope of the ECM Regulation.

Consequently, the other OTMs (i.e. self-propelled OTMs, OTMs used in lines out of service) would only fall within the ECM certification on a voluntary base (good practices). It would be the same situation for those vehicles operated by IMs under the exceptions of the Article 2.2 of the Safety Directive: For instance, privately owned railway infrastructure.

As an example, this approach applied to the type of vehicle known as “On-Track Machines (OTM)” would result in 4 possible situations:

<table>
<thead>
<tr>
<th>OTMs operated/transported exclusively on out-of-service tracks, independently if they are self-propelled or not</th>
<th>Is ECM certification required?</th>
<th>IMs are always able to apply the principles and criteria of the ECM Certification or to require their contractors to apply them</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not required</td>
<td>Not required</td>
<td>IMs are always able to apply the principles and criteria of the ECM Certification or to require their contractors to apply them</td>
</tr>
</tbody>
</table>

7 For instance Tampers, hauled by other traction-unit, transported on in service track under an “special transport authorization” only to reach the final place where they will have really to work: ECM Certification not required

8 The terms “used”, “transported” and “operated”, referring freight wagons and OTMs of infrastructure managers and their contractors, should be understood meaning that freight wagons and OTMs are performing any activity for which they were designed.
<table>
<thead>
<tr>
<th>Type of OTMs Operated/Transported</th>
<th>Is ECM Certification Required?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non self-propelled OTMs operated/transported partially or totally on in-service tracks</td>
<td>Required</td>
</tr>
<tr>
<td>Self-propelled OTMs operated(^9) partially or totally on in-service tracks in non-self-propelled mode (hauled by other traction-unit)</td>
<td>Required</td>
</tr>
<tr>
<td>Self-propelled OTMs operated/transported partially or totally on in-service tracks and operated in self-propelled mode on in-service tracks</td>
<td>Not required</td>
</tr>
</tbody>
</table>

This can still be modified as EIM and the Agency have not finalised their study yet.

1) The goal of the ECM certification is to facilitate the railway freight transport in providing assurance to RUs that maintenance is performed by competent ECM. Even if the ECM certification is an increase of costs for ECMs and keepers, it should result in a more important decrease of costs for RUs. Therefore a decrease of costs should be the result at the level of the freight transport.

For IMs and their maintenance contractors, the goal is the same. Even if there is an increase of costs at the level of contractors, it should result in a more important decrease of costs for IMs and therefore a global decrease of costs regarding the maintenance of railway infrastructure.

**6.5.2 Regarding the transport of dangerous goods:**

All freight wagons are under the scope. Then and in addition, the regulations concerning the International Carriage of Dangerous Goods by Rail (RID) apply specifically to the dangerous goods wagons.

**6.6 Is the ECM certification applicable for freight wagons operating outside the EU?**

There are 3 geographical areas to consider, in general, the obligations of vehicles and, specifically, the application of the ECM certification to entities in charge of maintenance:

\(^9\) For instance Tampers, hauled by other traction-unit, transported on in service track under an “special transport authorization” only to reach the final place where they will have really to work: ECM Certification not required
6.6.1 The EUROPEAN UNION and the European Economic Area EEA

(EU, Norway, Iceland, Liechtenstein) and Switzerland.

- Vehicles operating in this area (coming or not from 3rd countries) must be registered in the NVR with an ECM (with residence in or out this area) assigned
- ECMs (with residence in or out this area) maintaining vehicles that operate in this area (coming or not from 3rd countries)
  - must be identified in the NVR
  - must be certified if they are ECMs of freight wagons

6.6.2 THIRD COUNTRIES

(members of OTIF: f.i North Africa, Croatia, Serbia, Macedonia, Bosnia, Turkey…In OTIF It applies the ATMF – Annex A (from 01/05/2012) which is identical to ECM Regulation)

- Vehicles operating in members of OTIF (coming or not from countries outside OTIF): They must be registered in the NVR with an assigned ECM
- ECMs (with residence in or out OTIF) maintaining vehicles that operate in OTIF (coming or not from countries outside OTIF)
  - must be identified in the NVR
  - must be certified if they are ECMs of freight wagons

6.6.3 Rest of the World

ECM certification applicable on a voluntary base. Only in these specific cases:

- For vehicles going to areas A and B, mandatory application of EU legislation and OTIF rules
- For ECMs maintaining wagons going to areas A and B, mandatory application of EU legislation and OTIF rules
6.7 Is the ECM certification applicable for freight wagons coming into the EU from third countries and the OTIF area?

It is necessary to take in account that in the EUROPEAN UNION and the European Economic Area EEA (EU, Norway, Iceland, Liechtenstein) and Switzerland:

- Vehicles operating in this area (coming or not from 3rd countries) must be registered in the NVR with an ECM (with residence in or out this area) assigned
- ECMs (with residence in or out this area) maintaining vehicles that operate in this area (coming or not from 3rd countries)
  - must be identified in the NVR
  - must be certified if they are ECMs of freight wagons

Consequently the ECM certification is mandatory for all the for freight wagons coming into the EU from third countries and the OTIF area.
6.8 Is the ECM certification applicable for freight wagons in the EEA area?

Once an ECM has been certified according to the ECM Regulation, such ECM certificate is valid throughout the EU for the freight wagons used in the European Economic Area (EU, Norway, Iceland, Liechtenstein) and Switzerland.

Switzerland is going to transpose the Directives 2004/49/EC, 2008/57/EC into Swiss law. The according revision of the national law is actually in the parliament and planned for coming into force by the middle of 2013. The same situation applies for the Commission Regulation (EU) No 445/2011.

The transposition of the Commission Regulation (EU) No 445/2011 into COTIF law has been accepted by the OTIF Committee of Technical Experts on the 15th of September 2011. The according OTIF Rules for ECM certification has come into force on the 1st of May 2012. The OTIF Rules for ECM certification are legally binding for Switzerland without any delay from the 1st of May 2012 on.

Consequently, it is necessary to take in account that in the EUROPEAN UNION and the European Economic Area EEA (EU, Norway, Iceland, Liechtenstein) and Switzerland:

- Vehicles operating in this area (coming or not from 3rd countries) must be registered in the NVR with an ECM (with residence in or out this area) assigned

- ECMs (with residence in or out this area) maintaining vehicles that operate in this area (coming or not from 3rd countries)
  - must be identified in the NVR
  - must be certified if they are ECMs of freight wagons

Consequently the ECM certification is mandatory for all the for freight wagons operating the EEA area.
7 ACCREDITATION – RECOGNITION OF CERTIFICATION BODIES

7.1 What does Accreditation mean?

It means “third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (Source ISO/IEC 17000:2004)”

Accreditation, as defined in Article 2(10) of Regulation (EC) No 765/2008 of the European Parliament and of the Council, means that a National Accreditation body carries out a conformity assessment with the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectorial schemes.

Regarding specifically to the accreditation of the certification bodies to perform the certification of ECMs, ERA has developed, with the sector, the corresponding accreditation scheme [17], available in the following link:


7.2 What is EA (European cooperation for accreditation)?

EA, European co-operation for Accreditation, is a nonprofit association which was set up in November 1997 and registered as an association in the Netherlands in June 2000 and revised in November 2010 (Articles of Association).

EA is the European network of nationally recognised accreditation bodies located in the European geographical area.

EA has been established by the European Commission as the official European accreditation infrastructure. This became effective on 1st April 2009 in Brussels when the Guidelines for Cooperation between the European Commission (EC), the EFTA, EA and the competent national authorities were signed. These Guidelines set out the principles and objectives for the cooperation between EA, EC, EFTA and competent national authorities, and provide criteria for the effective and timely implementation of the reinforced role of EA.

The appointment of EA as the official European accreditation infrastructure follows the adoption of Regulation (EC) no 765/2008 of the European Parliament and the Council of 9 July 2008 establishing a legal framework for accreditation in the EU/EFTA member states. This regulation came into effect as of 1st January 2010.

A Framework Partnership Agreement between EA, EC and EFTA setting out the common cooperation objectives as well as the administrative and financial conditions relating to Community financing granted to EA for the implementation of European accreditation policy and of the new EC Regulation, was signed on 30 June 2010 in Brussels. A similar FPA was specifically signed with EFTA. These Partnership Agreements place EA in the same position as other organizations of major European interest (European Standardization Bodies, for instance).
7.3 What is MLA (Multilateral Agreement)?

The MLA is an agreement signed between the EA accreditation body members to recognise the equivalence, reliability and therefore acceptance of accredited certifications, inspections, calibration certificates and test reports across Europe.

The MLA eliminates the need for suppliers of products or services to be certified in each country where they sell their products or services, and therefore provides a means for goods and services to cross boundaries in Europe and throughout the world.

It delivers confidence in the service supplied by accredited laboratories, inspection and certification bodies, thereby providing the framework for goods and services to cross borders in Europe and throughout the world, acting as a "passport for trade".

The National Accreditation Body’s mark on test reports and certificates is your assurance of the benefits of the MLA.

The EA Multilateral Agreement accepts:

- the equivalence of the operation of the accreditation systems administered by EA Members;
- that the certificates and reports issued by organisations accredited by EA Members are equally reliable

7.4 Who are the NABs (National accreditation bodies)?

As defined in Article 2(11) of Regulation (EC) No 765/2008 of the European Parliament and of the Council, ‘National Accreditation Body’ shall mean the sole body in a Member State that performs accreditation with authority derived from the State.

7.5 What is the role of NABs and what is their applicable field?

In the same Regulation (EC) No 765/2008 it is established that:
A national accreditation body shall, when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity. Where it is found to be competent, the national accreditation body shall issue an accreditation certificate to that effect.

National accreditation bodies shall not compete with conformity assessment bodies.

National accreditation bodies shall not compete with other national accreditation bodies.

It is necessary to provide some clarifications on the mentioned accreditation scheme:

- NABs will perform the accreditation of certification bodies for ECMs and maintenance workshops accordingly the mentioned accreditation scheme.
- The competences of the CB are assessed by the NAB accordingly the point 3.4 of the accreditation scheme.
- For CBs using subcontractors, the CB is free to define the requirements for its subcontractor but, then, the NAB should accredit the CB taking this fact in account.

"Sufficient experience in railways" is explained in the point 3.4 of the Accreditation scheme

7.6 I would like to become an accredited certification body for ECM. To whom have I to apply for accreditation?

7.6.1 I have my residence in the EU

According the Regulation 765/2008 and, more specifically, pursuant to its Article 7(1), where a conformity assessment body requests accreditation it shall do so with the national accreditation body of the Member State in which it is established or with the national accreditation body to which that Member State has had recourse in accordance with Article 4(2). Consequently, a certification body should always request for accreditation only to EU National Accreditation Bodies.

Under this Regulation 765/2008, the principle is that an entity wishing to operate as a certification body should request accreditation from the National Accreditation Body (NAB) of the Member State in which it is established or from the NAB of another Member State which has been selected by its Member State to perform accreditation services (see Article 7 of Regulation 765/2008). It is however also possible that accreditation be done by another NAB in cases where:

- there is no NAB in its own Member State (Article 7(1)(a)), or;
- the NAB does not offer the requested accreditation service (Article 7(1)(b), or;
- the NAB has not received a positive outcome in the peer evaluation in relation to the certification for which accreditation is requested (Article 7(1)(c)).

Certification body with the residence in the EU can only request for accreditation to EU National Accreditation Bodies (See Article 7(1) of Regulation 765/2008).
7.6.2 I have my residence outside the EU

According to the recital (7) of ECM Regulation, "Certificates issued by certification 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". No other provision of the ECM Regulation deals with certificates issued by certification bodies in third countries.

This means that Member States should accept under certain conditions ECM certificates issued by certification bodies established in third countries. In doing so, the Member States should in principle:

- Ensure that such certification bodies comply with the general criteria and principles set out in Annex II of the ECM Regulation and any subsequent accreditation scheme and;
- Ensure that decisions taken by certification bodies established in third countries are subject to judicial review (as required under Art 6(3) of the ECM Regulation), and;
- Ensure that such certification bodies are themselves accredited by a national accreditation body in the sense of Regulation 765/2008.

Regulation No 765/2008 also allows for accreditation of non-EU certification bodies by non EU national accreditation bodies (See in particular the reference made to “a peer evaluation system among national accreditation bodies from the Member States and other European countries” in recital (23) of this Regulation).

Article 11(2) of Regulation 765/2008 provides that “National authorities shall recognise the equivalence of the services delivered by those accreditation bodies which have successfully undergone peer evaluation under Article 10, and thereby accept, on the basis of the presumption referred to in paragraph 1 of this Article, the accreditation certificates of those bodies and the attestations issued by the conformity assessment bodies accredited by them”. This means that accreditation certificates delivered by a recognized accreditation body and certificates issued by accredited certification bodies should be recognized within the EU.

Even if certification bodies established in third countries are not directly governed by the ECM Regulation, they still need to comply with the obligations and tasks imposed on certification bodies by the ECM regulation so that the certificates delivered to entities in charge of the maintenance for freight wagons used in the EU be recognised as valid.

For a certification body granting an ECM certificate or an accreditation body accrediting a certification body, the following cases may apply:

- The certification body has its residence inside or outside the EU;
- The accreditation body has its residence inside or outside the EU.

The table below presents the possible scenarios:
In the scenarios 1 and 2, the certification bodies, whatever their residence, are accredited by EU National Accreditation Bodies and therefore, apply the ECM accreditation scheme. Once accredited, the certification bodies are empowered to grant valid ECM certificates within the EU.

The scenario 3 is not applicable because EU certification body should always request for accreditation only to EU National Accreditation Bodies (See Article 7(1) of Regulation 765/2008).

In the scenario 4, the accreditation of non-EU certification bodies made by non-EU accreditation bodies is accepted within the EU provided that:

a) The non-EU accreditation body is recognised by the EU indirectly via worldwide multilateral recognition agreements between accreditation bodies.

b) The non-EU accreditation body is designated directly via international governmental agreements between the EU and some third countries (EFTA, EEA, Australia, Canada, Japan, New Zealand, the USA, Israel and Switzerland). Under such agreements, NABs are mutually recognised.

Details of accreditation bodies are maintained in the NANDO database available at http://ec.europa.eu/enterprise/newapproach/nando/index.cfm

7.7 I am an accreditation body and I have my residence outside the EU. Can I accredit certification bodies everywhere?

In the EU legal framework and more specifically the ECM Regulation and the Regulation 2008/765/EC, there is the possibility for non-EU certification bodies to operate in the EU and to be accredited to perform ECM certification. In the same way, non-EU accreditation bodies can also accredit non-EU certification bodies to perform equivalent ECM certification.

For a certification body granting an ECM certificate or an accreditation body accrediting a certification body, the following cases may apply:

- The certification body has its residence inside or outside the EU;
- The accreditation body has its residence inside or outside the EU.

The table below presents the possible scenarios:

<table>
<thead>
<tr>
<th>Certification body inside EU</th>
<th>Certification body outside EU</th>
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<tr>
<td>Scenario 1</td>
<td>Scenario 2</td>
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<tr>
<td>Scenario 3 (not applicable)</td>
<td>Scenario 4</td>
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Regulation 765/2008 allows for accreditation of non-EU certification bodies by non-EU accreditation bodies.
In the scenarios 1 and 2, the certification bodies, whatever their residence, are accredited by EU National Accreditation Bodies and therefore, apply the ECM accreditation scheme. Once accredited, the certification bodies are empowered to grant valid ECM certificates within the EU.

The scenario 3 is not applicable because EU certification body should always request for accreditation only to EU National Accreditation Bodies (See Article 7(1) of Regulation 765/2008).

In the scenario 4, the accreditation of non-EU certification bodies made by non-EU accreditation bodies is accepted\textsuperscript{11} within the EU provided that:

a) The non-EU accreditation body is recognised by the EU indirectly via worldwide multilateral recognition agreements between accreditation bodies.

The European co-operation for Accreditation (EA) has developed agreements with other European organisations (EFTA in particular). Several countries outside EU (Switzerland, Turkey, Norway, Croatia, Brazil, Australia etc.) are full members of the European co-operation for Accreditation (EA).

There are also multilateral agreements and multilateral recognition agreements between countries participating to EA under which reports and certificates issued by the accredited bodies are internationally recognised.

Consequently, it would be possible to accept a non-EU accreditation body under the provisions of the Multi-Lateral Agreement (MLA) developed by the EA. Then the Accreditation Body (AB) of the third country would be recognised by the network of ABs of EA (only if it is a signatory of the MLA). Nevertheless, in order to have mutual recognition of the accredited certifications, the following requirements shall be met:

- EA checks positively that the AB is applying the ECM accreditation and certification scheme with the same framework and procedures.

- Any accreditation of certification bodies of the third country granted by the AB is continuously performed accomplishing the requirements of the ECM accreditation and certification scheme.

As mentioned before, the Article 11(2) of Regulation N° 765/2008 provides that “National authorities shall recognise the equivalence of the services delivered by those accreditation bodies which have successfully undergone peer evaluation under Article 10, and thereby accept, on the basis of the presumption referred to in the first paragraph of this Article, the accreditation certificates of those bodies and the attestations issued by the conformity assessment bodies accredited by them”. This means that accreditation certificates delivered by a recognized accreditation body and certificates issued by its accredited certification bodies should be recognized within the EU.

\textsuperscript{11} Regulation 765/2008 allows for accreditation of non-EU certification bodies by non-EU accreditation bodies (See question 49. I would like to become an accredited certification body for ECM. To whom have I to apply for accreditation? Error! Reference source not found.).
The non-EU members who are candidates in the accession to the EU can always apply the ECM certification scheme and, even can apply the scheme recognised by the EA. Then, it would be possible to satisfy the request from these third countries to have specific agreements with the EU once the certification scheme has reached the sufficient maturity in these countries.

b) The non-EU accreditation body is designated directly via international governmental agreements between the EU and some third countries (EFTA, EEA, Australia, Canada, Japan, New Zealand, the USA, Israel and Switzerland). Under such agreements, NABs are mutually recognised.

Designation in this case enables non-EU certification bodies to assess, in line with EU directives and in accordance with the provisions of the MRA, products to be placed on the EU market.

Consequently, it would be possible to establish direct recognition of non-EU accreditation bodies by the EU Member States under the provisions of the Mutual Recognition Agreements (MRA). The procedure can be found on the European Commission website under the following link:


Such designation takes place according to the relevant terms of the MRA broadly on the basis of the same criteria as for “notified bodies”. In certain sectors, according to the terms of the MRA Framework Agreement and the relevant Sectoral Annexes, these ABs will be performing the same tasks as the EU “notified bodies”. In this case, and in line with the European Commission procedures applicable to “notified bodies”, they will be included in the NANDO database (including the list of NoBos under the Interoperability Directive [3]).

It is also worth to mention the role of the International Accreditation Forum (IAF) harmonising the international recognition between ABs. Under IAF MLA, there could be recognition of an AB of a third country by a NAB of an EU Member State (and reversely). Unlike the MRA between the EU Member States and the third countries or the EA MLA, these agreements are not legally binding for the National Authorities.

Details of accreditation bodies are maintained in the NANDO database available at http://ec.europa.eu/enterprise/newapproach/nando/index.cfm

7.8 What does Recognition mean?

Where harmonised Union legislation provides for the selection of certification bodies for its implementation, transparent accreditation, as provided for in regulation (EC) N° 765/2008, should be considered by the national public authorities as the preferred means of demonstrating the technical competence of those bodies. However, national authorities may consider that they possess the appropriate means to carry out this evaluation themselves. In such case, see the article 5(2) of (EC) N° 765/2008, the Member State should provide the Commission and the other Member States with all the documentary evidence necessary for verification of the competences of the recognition body it selects for implementation of the Union legislation. The requirements and rules for the evaluation and surveillance of certification bodies in the case of recognition should be equivalent to those used for accreditation.
Regarding specifically to the accreditation of the certification bodies to perform the certification of ECMs, ERA has developed, with the sector, the corresponding accreditation scheme [17]. This accreditation scheme shall be used in the same way for the recognition body.

Recognised certification bodies meaning certification bodies according to art 6 and 10 of the ECM Regulation 445/2011/EU and selected by Member States through a specific process of verification of competence (described in the accreditation scheme) put in place by public national authorities.

To assure this, the accreditation scheme remains a reference also for the recognition process (and also for the NSAs acting as ECM certification body) in order to ensure the recognised certification body is sufficiently competent for the tasks it must perform. The member states selecting other schemas than the accreditation scheme must justify their decision and ensure that their alternative system meets the requirements of the Regulation 445/2011/EU and the accreditation scheme. In the cooperation network of certification bodies the NSAs and the recognised certification bodies can collaborate with accredited certification bodies to harmonise the implementation of the certification system having the accreditation scheme as a reference.

7.9 I would like to become a recognised certification body for ECM. To whom have I to apply for recognition?

The use of an alternative to the accreditation is allowed by Article 5(2) of regulation 765/2008 which states that “when a Member State decides not to use accreditation, it shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the conformity assessment bodies it selects for the implementation of the Community harmonisation legislation in question”.

In the case of ECM certification, two possible alternatives are identified by the legislator (safety directive, art 14a): recognition or designation of NSA as ECM certification body.

ECM case

The regulation 445/2011 details the requirements and criteria related to the competence of each certification body: the art 6 introducing the accreditation scheme and the annex II. Therefore whenever the certification body is accredited, recognized or is a NSA, this certification body shall comply with the annex II and the art 6 of Regulation 445/2011 and consequently shall comply with the accreditation scheme.

The accreditation scheme has to be used for the accreditation (by the national accreditation body) or the recognition (by the recognition body put in place by the Member State) or by the Member states to provide assurance that the NSA designated as certification body is competent.

Either the Member States will use recognition or designate NSA as certification body. For these two choices, they shall provide to the Commission and the other Member states all the documentary evidence necessary for the competence of the conformity assessment bodies it selects for the implementation of the regulation 445. (point 2 of article 5 of the regulation 765/2008)
Therefore the Member State shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of ECM certification body **against the annex II and art 6 of Regulation 445/2011 and the accreditation scheme.**

**For the geographical scope of activity of certification bodies:**

An accredited certification body can certify any ECM for freight wagon on the whole territory of the EU. A **recognised body** can also certify any ECM for freight wagon on the whole territory of the EU. But if those certification bodies, accredited or recognized, are NATIONAL public authorities/agencies, they are limited to the national territory for matters associated to **national sovereignty.**

When NSA acts designated as certification body, as NSA is a national (public) authority, it is also limited to its national territory.
8 IMPLEMENTATION OF THE REGULATION 445/201

8.1 What does the transitional period mean?

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

Nevertheless, as defined in the Articles 12 of the ECM Regulation 445/2011/EU, there are different transitional periods related to special cases in the implementation of the ECM Regulation.

8.2 What are the deadlines you need to have in mind?

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

Nevertheless, as defined in the Articles 12 of the ECM Regulation 445/2011/EU, there are different transitional periods related to special cases in the implementation of the ECM Regulation.

These cases and periods can be summarised in the following ones:

- 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 (MoU) 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.

- 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.

- 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.

- Between 31st May 2012 and 31st May 2013, self-declarations of conformity of ECMs 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.

- 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.
(safety certificates and safety authorisations) 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.
9 ORGANISATION OF THE RAILWAY FREIGHT TRANSPORT IN EUROPE AND RESPONSABILITIES OF ACTORS

9.1 Who are the different “Stakeholders” playing in the maintenance of freight wagons?

The different roles (ECM, RU/IM, keeper, maintenance workshop) can be encompassed by one or several entities provided that they fulfil their intended responsibilities.

The responsibilities of railway parties are stated in the Safety Directive, in Articles 4, 14a and 16 (for NSAs) and the RID, chapter 1.4 (for the transport of dangerous goods). Regarding the freight wagons, responsibilities are also stated in the ECM regulation.

For example, a railway undertaking encompassing the role of ECM of freight wagons shall comply in addition to its duties and responsibilities of railway undertaking with the requirements of Article 14a(3) of the Railway Safety Directive and with the certification requirements of the ECM Regulation.
It is not regulated who should appoint the ECM. This is left to decisions of stakeholders. Article 33 of the Interoperability Directive indicates that the registration holder is responsible for providing the information for registration of vehicles to the registering entity. This information includes among others the denomination of the ECM.

Unless otherwise specified in the registration documents, the keeper of the vehicle is considered to be the “registration holder” in the meaning of Article 33(3) of the Interoperability Directive (See Annex 3.2.3 of the NVR Decision[11].

Nevertheless it is important to consider that, in practice, the tasks and obligations of RUs and ECMs have to be described in contractual arrangements. These contractual arrangements may also concern intermediaries such as keepers.

9.2 You are a Keeper, what are your responsibilities?
The keeper is defined in the article 3(s) of the Safety Directive and in the article 3(s) of the interoperability directive.

Apart from the obligations of registration holder, the Safety or Interoperability Directives do not define any additional explicit responsibility for the keeper. In practical, unless otherwise specified in the registration documents, the keeper of the vehicle is considered to be the “registration holder” in the meaning of Article 33(3) of the Interoperability Directive (See Annex 3.2.3 of the NVR Decision [11]).

Based on Article 4(4) of the Safety Directive it can be understood that responsibilities of the keeper are basically to assure in contractual way to RUs that vehicles (and when requested additional services) provided meet consistently safety requirements.

The contract of use established between a keeper and a RU should cover all the relevant requirements, including at least: Obligations and tasks related to safety issues including the obligations related to the exchange of relevant information or the traceability of safety related documents.

Also based on article 4(4) of the Safety Directive it can be understood that responsibilities of the keeper are to assure to RUs that vehicles provided meet consistently the appropriate legal requirements.

In particular the keeper should assure to RUs that the vehicles provided have:

- a valid authorization of placing in service; and
- an ECM registered in the NVR.

For freight wagons the keeper should assure also to RUs that the ECM certificate is valid.

A keeper may be an ECM as stated in the art 14a(2) of the Railway safety directive but it is not mandatory.

For not having his vehicles being put out of operation, the keeper should pay attention to the following responsibilities:

- The keeper may select an ECM and contracts with it
- The keeper may make contractual arrangements with subcontractors (e.g. maintenance workshops), but nevertheless the ECM is responsible to take the decision if the subcontractor is sufficiently competent to be authorised to perform maintenance tasks. To this end an agreement should be achieved between the keeper and the ECM.
- The keeper acting as registration holder has to ensure that the data it addresses to the registration entity is correct and has to get assurance that the ECM holds a valid certificate (only for freight wagons). Nevertheless when the keeper is not the registration holder, as it is the main interlocutor for the RUs, it should assure that the vehicle is compliant with the legislation in force and thus that data stated in the NVR is correct and that the ECM holds a valid certificate (only for freight wagons);
- As main interlocutor of the RUs, the keeper should assure that a vehicle is put, in due time, at disposal of the ECM to perform maintenance tasks in consistency with the decisions of the Fleet Maintenance Management.
- For freight wagons: the keeper should take specific actions if ECM certificate is suspended or revoked (e.g. assign another ECM, inform its customers including RUs).
Suspension and revocation of ECM certificates imply that the ECM registered in NVRs is not compliant anymore to the legislation in force and therefore that the registration of the freight wagon should be suspended forbidding this latter to be operated.

- The keeper should specify to the RUs the conditions of use of the wagons, especially if there are specific conditions (e.g. type of goods transportable, specific operational limitations).
- In any case the keeper should participate actively to the exchange of information between ECMs and RUs when there is no direct contractual arrangement on exchange of information between ECMs and RUs.

For international transport the provisions of the OTIF CUV and GCU (General Contract of Use) apply to keepers and RUs as users of freight wagons\(^\text{12}\). The obligations and rights of the keepers of freight wagons are described in chapter II of the GCU.

### 9.3 You are a RU, what are your responsibilities?

\[\text{GCU only for wagon keepers and RUs who signed up the GCU. For the others, the mutual obligations and rights of wagon keepers and RUs regarding the use of wagons contained in the GCU may be used as a base for setting up their contractual arrangements.}\]
The Railway Safety Directive states in Article 4(3) that RUs shall be made responsible for safe operation and to fulfill this responsibility, it requires that they establish a SMS. According to the Art 9(2) of the Safety Directive, the RU is responsible to control all the risks related to the supply of maintenance and therefore has to implement control measures to get assurance that vehicles are maintained in such a way that they can be used safely when put in trains.

Controlling the risks associated to the supply of maintenance is not equivalent to being responsible for the maintenance. Controlling the risks means that the RUs has identified hazards to its operations caused by maintenance, evaluated the risks associated with those hazards and define control measures to ensure the safe operation of its trains.

This means in particular that:

- The RU must get assurance, that the maintenance provided by the ECM leads to a safe state of running of the vehicles. This may be achieved by getting assurance that the maintenance system put in place by the ECM ensures the safe state of running. In other words the RU must get assurance that the maintenance system makes the ECM capable to provide maintenance making the vehicles in a safe state of running. Nevertheless ensuring this safe state of running through a maintenance system remains the unique responsibility of ECMs.

- The ECM is responsible for the maintenance and the RU, within its risk control, must get assurance that the ECM is capable to comply with its responsibility and that maintenance is sufficiently effective to make the vehicles in a safe state of running.

- For freight wagons the ECM certification is the effective and efficient way to bring this assurance to the RUs. Therefore the RUs should not be required to re-evaluate the maintenance system of ECM already being granted with ECM certificate.

- By virtue of Article 5(1) of the ECM Regulation, the RU shall ensure the freight wagons it operates, before their departure, have a certified ECM, meaning a certificate delivered by a duly accredited or recognised certification body or by an NSA entitled by its MS as certification body. The certificate has also to be within its validity period. The ERADIS database provide data on certificates.

In addition the RUs check that the scope of the certificate corresponds to the three kinds of wagons (tank wagons for dangerous goods, other wagons for dangerous goods, or other wagons). Those checks could also be facilitated by contractual arrangements with the keeper or through sectorial arrangements in place, e.g. GCU.

- The ECM certification, like any certification, doesn’t guarantee to RU that there will never be non-conformities on the wagons due to improper maintenance. In addition, between maintenance interventions a vehicle may also be damaged by users such as loaders.

The RU is therefore responsible for taking additional control measures described here below. The RU should undertake inspections before the departure of a train or en route. Those inspections have to comply with the processes described in its SMS (See recital (5) of ECM Regulation). The RU must assure that each vehicle in its train will be in such a state that doesn’t compromise the safe operations. It does not aim to control that maintenance was appropriate and done correctly but that vehicles are in a sufficient state for safe use.
Some of those inspections are carried out by the RU itself (e.g. drivers and/or operational staff), for some the RU may subcontract to other entities like loaders or maintenance workshops. But even by subcontracting some of the measures to other players the RU **keeps the responsibility** according to Article 4(3) of the Safety Directive. The RU must decide how to fulfil its obligations and, if necessary, agree with the other players on rules for procedures that the other players take over for the RU.

- The pre-departure and en-route inspections can be seen by the ECM as information on the minimum performance level required by the RUs or on the limitations the RUs meet in operating wagons. Therefore this information should be considered as an input by the ECM for updating the maintenance file.

On the other hand, there could be specific information included in the maintenance file that could be seen as an input by the RU to update the content of pre-departure or en-route inspections/monitoring measures.

Consequently exchange of technical information should be developed by railway parties.

- By virtue of Article 5(7) of the ECM Regulation, if a contracting party, in particular a RU, has a justified reason to believe that a particular ECM 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. In case of doubt about competencies of an ECM, the RU shall inform the certification body who certified the ECM and the keeper (commercial partner). It may inform the NSA but it is not mandatory. As a consequence, the certification body has to consider this claim within its surveillance activities and may take actions such as imposing an improvement plan, limiting the scope of application of the certificate, suspending the certificate, or revoking the certificate depending on the degree of non-compliance (See Article 7(7) of ECM Regulation).

- By virtue of Article 5(4) of the ECM Regulation, the RU shall provide information on the real operations performed. In particular the mileage and specific operational conditions are requested by the ECM to update the maintenance file. This provision of information should be organised through the contractual arrangements between the RU and the ECM or between the RU and the keeper (the keeper plays the role of intermediate).

- By virtue of Article 5(5) of the ECM Regulation, 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.

- The RU shall fulfil its duties about transmission of information with its commercial partners – i.e. other RUs/IMs, keepers and ECMs since there could be direct relations between RU and ECM (e.g. RU assuming also the role of keeper or RU imposing contractually the ECM and requesting for direct exchange of information).

- The RU should rely on contractual arrangements with its commercial partners for all wagons it operates. These contractual arrangements should be consistent with the
procedures outlined by a RU in its SMS, including those for the exchange of information (See recital (6) of ECM Regulation).

The RU shall implement any other additional control measures that it considers necessary to keep the identified risks related to the supply of maintenance under control. Those risks could be highlighted through a structured approach to risks assessment and a systematic analysis of findings related to the routine monitoring put in place by the RU as part of its SMS arrangements.

In practice, it will be up to the RU to consider its contractual arrangements to keep the risks associated to the supply of maintenance under control. The RU remains fully accountable for the control of risks inherent to the maintenance activities even if this control is subcontracted to a third party.

9.4 Is there a harmonised framework for the pre departure inspection?

The ECM Regulation doesn’t regulate the pre-departure inspections. They are not part of the maintenance activities of the ECM but they are set up by the Railway Undertaking, as part of their SMS, to verify the vehicle is fit for the journey and the operation: the ECM Certification does not liberate the Railway Undertaking from its responsibilities to manage the risks in operations and maintenance.

The pre-departure inspections are regulated in particular by the TSI Traffic Operation and Management and must be managed by Railway Undertakings within their SMS. There are some harmonising tools already in place. The GCU (General Contract of Use) is a harmonised contract between Railway Undertakings and keepers regarding the provision of wagons.

The harmonisation of the pre-departure inspections should be developed by the stakeholders themselves.

It is important for the ECM to know the content of those inspections and their possible differences when establishing and updating the maintenance file. For that purpose, cooperation between RUs and ECMs is crucial.
9.5 You are an ECM, what are your responsibilities?

- ECM must set up and keep updated the maintenance file (maintenance development part II.4 b annex III)
- ECM must ensure that the implementation of the first maintenance file is done correctly (maintenance development part II.4 b annex III)
- ECM must coordinate all those activities and supervise its subcontractors

Exchange of information - Article 5(2) of Commission Regulation 445/2011
The ECM has to address return to operation issues to RUs and keepers.

Certification - Commission Regulation 445/2011
For freight wagons:
- The ECM must be certified against the Commission Regulation 445/2011.
- The ECM must inform its partners, RUs, IMS and keepers, about all changes (amendment, renewal, suspension, revocation)
Regarding the responsibilities of an ECM the Article 14a(3) of the Railway Safety Directive applies to ECMs for all vehicles under the scope of the Safety Directive and considers that:

"Without prejudice to the responsibility of the railway undertakings and infrastructure managers for the safe operation of a train as provided for in Article 4, the entity shall ensure that the vehicles for which it is in charge of maintenance are in a safe state of running by means of a system of maintenance. To this end, the entity in charge of maintenance shall ensure that vehicles are maintained in accordance with:

a) the maintenance file of each vehicle;

b) the requirements in force including maintenance rules and TSI provisions.

The entity in charge of maintenance shall carry out the maintenance itself or make use of contracted maintenance workshops."

‘ensuring that the vehicles for which it is in charge of maintenance are in a safe state of running by means of a system of maintenance’ means that the ECM has to have a maintenance system that is able to ensure the safe state of running without any additional maintenance measures taken by other parties. But to achieve safe operation RU has to control also all the other risks related for instance to drivers or fitness of vehicles in the trains with planned journeys (see chapter 4.2.2.5. of the TSI OPE)

This means in particular that:

- Regarding the freight wagons, responsibilities are also stated in the ECM regulation. The ECM should ensure that it continuously meet the relevant requirements set out in article 4, 5(2), 5(4), 5(5) and Annex III of the ECM Regulation and apply them consistently. This assurance is provided to other railway parties by the mean of the mandatory ECM certification.

- The ECM has the responsibility for setting out the maintenance file for each vehicle and to ensure that this maintenance file is correctly applied.

- As part of the maintenance management function, the ECM has to perform itself the necessary coordination and monitoring of all its maintenance activities. These tasks may be partially outsourced but coordination and monitoring as a whole remain one of the main and crucial task of the management function of the ECM in accordance with Article 4(3) of ECM Regulation. The other maintenance functions may be performed (totally or partially) internally or (totally or partially) outsourced. This includes the call for technical expertise when not available internally, for instance from manufacturers of vehicles or components, and the use of contracted maintenance workshops.

- Regardless of the outsourcing arrangements in place, the ECM shall be responsible for the outcome of maintenance activities it manages and shall establish a system to monitor performance of those activities (See Article 4(4) of ECM Regulation). In addition the ECM has to apply the CSM on monitoring.

- The ECM has to inform its clients about any change in the status of its certificate (amended, renewed or revoked) that may cause contractual liability issue.
9.6 You are an accredited or recognized body or a NSA designated as certification body. What are your responsibilities?

The applicant ECM is free to choose its certification body (Article 6(1) of ECM Regulation). The ECM can contract body:

- With a certification accredited or recognised in any Member state;
- With the NSA of the Member State where the ECM is established only if the NSA has been designated by its Member state to perform ECM certification

The Member State shall be responsible for ensuring the competency of the NSA acting as ECM certification body when it is not accredited or recognised. To this end the Member State should base its control measures on the annex II of the ECM regulation and the ECM accreditation scheme. The Member State should also communicate on those control measures and their results with all interested parties to avoid creating doubts on the competence of NSAs.

For recognition, when applying the article 5(2) of the Regulation 765/2008, the Member State shall provide evidences to the Commission and the other Member States on equivalence between the scheme put in place with the Annex II of the ECM Regulation and the ECM accreditation scheme.

The certification bodies have to examine and treat claims from the NSA (Article 9 of ECM Regulation), RU or any other contracting party (Article 5(7) of ECM Regulation) and 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 (Article 5(7) of ECM Regulation).

The certification body is solely empowered to decide whether to amend, renew, limit the scope of application, suspend or revoke the ECM certificate based upon significant changes in the circumstances applying at the time the original certificate was awarded (Cf. Article 7(4) of ECM Regulation) or if the ECM no longer complies with the certification requirements or any improvement plan (Cf. Article 7(7) of ECM Regulation).

9.7 What other legal information do you need to have in mind when managing contracts?

The contractual and non-contractual liability issues, as private law in general, remain within the competence of the Member States, although the EU has intervened in such field where it appeared.
necessary to ensure the proper functioning of the internal market. In particular, the EU has adopted two regulations, one dealing with the law applicable to contractual obligations and the other dealing with the law applicable to non-contractual obligations (See respectively Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I) and Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II)). These two regulations establish a set of binding rules of private international law which determine which (national) law is applicable.

So EU Regulations applicable to ECM are “Without prejudice to civil liability in accordance with the legal requirements of the Member States” (See Article 4(3) of the Safety Directive) or “without prejudice to existing national and international liability rules” (See Article 7(4) of the Safety Directive).

An ECM is liable to its contract partners (RU, IM, keepers, etc.) for breaches of contract (as provided in the contract and in the law governing the contract) whereas it is liable for damages caused to others than its contract partners (or to its contract partners but outside the scope of the contract) under the national laws governing the damage and the resulting liability.

**Court jurisdiction**

Article 6(3) of the ECM Regulation provides that “Member States shall take the measures necessary to ensure that decisions taken by the certification bodies are subject to judicial review”. Article 7(5) of the same Regulation provides that “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”.

The “appeal body” referred to in the ECM Regulation is not a new body to be established by the Member States but rather an existing judicial (or administrative) body within the Member State where the certification body is established competent to hear appeal cases by applicants ECM against decisions of such certification body.

### 9.8 When a new authorisation for placing into service is necessary?

New authorisation for placing in service of vehicle is not required when substituted parts are compliant with references or specifications in the technical file.

For instance, in the case of the substitution of a wheel by another one complying with the specification of the technical file, it would not be necessary to proceed to a new authorisation for placing in service neither a communication to the NSA. It should only be necessary to have this substitution recorded in the configuration file of the vehicle. This information is, of course, available to NSAs upon request.

If the specification of the new parts impairs the design operating state, it is considered as a major change of the technical design and possibly leads to a new authorisation for placing in service according to the Interoperability Directive.
In case of such major change, the ECM could be the applicant for this new authorisation. In any case, the ECM should manage it through contractual arrangements with the RU/keeper and taking in consideration:

- The existing authorisation for placing in service;
- The guarantee of the vehicle by the manufacturer.

Other different question is if the fact, that the specification of the new parts impairs the design operating state, could be considered as a significant change affecting safety. In this case it is necessary to evaluate by the proposer (ECM) of the change if the change is relevant and, if it is the case, to apply the Common safety Method on Risk Assessment and Evaluation[4].
10 MAINTENANCE FILE AND TECHNICAL FILE

10.1 What is the maintenance file?

Article 14a(3) of the Safety Directive introduces the maintenance file as follow:

“...the entity in charge of maintenance shall ensure that vehicles are maintained in accordance with:

(a) the maintenance file of each vehicle;”

According to the sections II.4. and II.5. of annex III of the ECM Regulation \[1\], the ECM has the duty to develop and maintain (continuously update) the maintenance file. For building this document, the ECM needs to have:

- **Initial technical documentation**

  For vehicles compliant with TSIs, the initial development of the maintenance file is based on the technical file (Refer to section 4 of annex VI of the Interoperability Directive \[3\]) and on the APIS. The content of the technical file is described in detail in the relevant TSIs.

  As interoperability doesn’t cover all the technical characteristics of a wagon but only the ones making the wagon compliant with the essential requirements through the applicable TSIs, there may be additional technical information that has to be provided to the ECM. This additional technical information is requested contractually between the applicant and the manufacturer of the wagon.

  Therefore the **initial technical documentation** on which the maintenance file will be built is composed of:

  - Technical file
  - Additional technical documentation requested contractually including the relevant maintenance documentation

In case the complete technical file has not been provided to the ECM, access should be arranged contractually between the keeper and the ECM. The keeper himself should be aware of its responsibility to provide the appropriate and correct technical information on the vehicle.

**For vehicles compliant with TSIs**, the documentation described in the relevant TSIs as part of the technical file should be necessarily provided to the ECM, for instance:

- Freight wagons under the revised TSI Wagon: There is the chapter 4.5 of annex to Commission Decision 2013/321/EC
For vehicles not complaint with TSIs (like the majority of existing vehicles) or partially compliant with TSIs, the technical file is replaced by all technical and existing maintenance information that accompany the wagon.

The initial development of the maintenance file shall take also into account the pattern of operations planned. It includes also the performance targets required by the users: RUs and keepers.

- **Content of the maintenance file**

  The maintenance file has to be created for each vehicle and contains all the information that is necessary to carry out maintenance.

  The maintenance file is composed of the following four elements:

  1. **A General Documentation** (extract of chapter 4.5.1 of annex to Commission Decision 2013/321/EC [7]) composed of:
     - Drawings and description of the wagon and its components;
     - Any legal requirement concerning the maintenance of the unit;
     - Drawing of systems (electrical, pneumatic, hydraulic and control-circuit diagrams);
     - Additional on-board systems (description of the systems including description of functionality, specification of interfaces and data processing and protocols).
     - Configuration files for each vehicle (parts list and bill of material) to enable (in particular but not only) traceability during maintenance activities.

     This documentation may be updated by the ECM.

  2. **A Maintenance Design Justification File** (extract of chapter 4.5.2 of annex to Commission Decision 2013/321/EC [7]) explaining how maintenance activities are defined, designed and updated in order to ensure that the vehicle characteristics will be kept within permissible limits of use during its lifetime and to ensure that the vehicle is in a safe state of running compliant with the planned pattern of operations. It shall give input data to determine the criteria for maintenance activities. It consists of:
     - Precedents, principles and methods used to design the maintenance of the unit;
     - Limits of the normal use of the unit (e.g. km/month, climatic limits, foreseen types of loads etc.) according to the planned pattern of operations;

✓ Relevant data used to design the maintenance and origin of these data (e.g. return of experience);
✓ Tests, investigations and calculations carried out to design the maintenance.
✓ (first/initial) maintenance file (mostly created by the manufacturer): all safety verifications and risk analysis done for defining maintenance activities, intervals etc. shall be covered in the file, because it shall be transparent for the ECM. This is necessary for optimizations of the file by the ECM later on. This is also relevant in case of changing ECM.

This file must be updated by the ECM to enable traceability of changes in maintenance.

3 - A **Maintenance Description File** ( extract of chapter 4.5.3 of annex to Commission Decision 2013/321/EC [7] ) describing how maintenance activities have to be conducted. Maintenance activities include, among others: inspections, monitoring, tests, measurements, replacements, adjustments and repairs. These activities are split into:

✓ Preventive maintenance; scheduled and controlled;
✓ Corrective maintenance;
✓ Light and heavy maintenance

Basically the maintenance description file should contain at least:

✓ Component hierarchy and functional description. The hierarchy sets up the boundaries of the rolling stock by listing all the items belonging to the product structure of that rolling stock and using an appropriate number of discrete levels. The lowest item of the hierarchy shall be a replaceable component;
✓ Parts list: the parts list shall contain the technical and functional descriptions of the spare parts (replaceable units) and the references from the spare part provider and manufacturer, in order to allow identification and procurement of the correct spare parts. The list shall include all parts specified for changing on condition, or which may require replacement following electrical or mechanical malfunction, or which will foreseeable require replacement after accidental damage. The spare parts list shall also cover component and software modification levels. Interoperability constituent shall be indicated and referenced to their corresponding declaration of conformity.
✓ The limit values for components which are not to be exceeded in service are to be stated; the possibility of specifying operational restrictions in degraded mode (limit value reached) is permitted.
✓ List of reference to the European legal obligations to which components or subsystems are subject.
✓ A maintenance plan i.e. the structured set of tasks to perform the maintenance including the activities, procedures and means. The description of this set of tasks includes:
  - Disassembly/assembly instructions drawings necessary for correct assembly/disassembly of replaceable parts.
  - Maintenance criteria.
  - Checks and inspections in particular of safety relevant parts; these include visual inspection and non-destructive tests (where appropriate e.g. to detect deficiencies that may impair safety).
- Tools and materials required to undertake the task.
- Consumables required to undertake the task.
- Personal protective safety provision and equipment.
- Necessary tests and procedures to be undertaken before release to service and return to operation.

- **4 - A Configuration File** for each vehicle (parts list and bill of material) to enable (in particular but not only) traceability during maintenance activities all along the lifecycle. The configuration files contain the records on maintenance performed. Traceability of maintenance records depends on their impact on safety and has to be compliant with applicable legislation.

### 10.2 How to build the maintenance file?

**Interface between ECM Regulation and TSIs**

**Maintenance development process**

**Detailed process of continuous update/improvement of the maintenance file**

1. Collect information
2. Analyse the information
3. Analyse the needs for updating
4. Analyse the proposals of update
5. Take decisions
6. Disseminate the updates

- **Maintenance file updated**

- **CSM monitoring**
- **CSM Risk Assessment**

**Analysis of:**
- Information collected;
- Needs to update or not update the maintenance file because of safety reasons. This includes the evolution of safety regulations. The needs shall also be based on a risk
assessment.

- Needs to update or not update the maintenance file for other reasons than strictly safety:
  - Technological evolution
  - Modification of applicable legislation (other than safety)
  - Performance targets (such as availability, reliability)

- Proposals of update (or no change) of the maintenance documentation if necessary. Whenever the needs (related to safety or not), a safety risk assessment of the proposal and of its implementation has to be performed.

- Implementation of the proposed update of the maintenance documentation

  - Taking of decisions on the proposed updates (or no change) of the maintenance file.

10.3 Where does the technical file come from?

As stated in the Article 18 (3) of the Interoperability Directive 2008/57/EC: “The notified body shall be responsible for compiling the technical file that has to accompany the ‘EC’ declaration of verification. This technical file must contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents. It should also contain all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance.” For the DeBo section and the CSM-sections of the Technical File, the DeBo and CSM-Assessment Body are responsible in similar form. The format of a Technical File has been standardised within RFU-STR-011.

For vehicles compliant with TSIs, the initial development of the maintenance file is based on the technical file (Refer to section 4 of annex VI of the Interoperability Directive and on the APIS. The content of the technical file is described in detail in the relevant TSIs.

As interoperability doesn’t cover all the technical characteristics of a wagon but only the ones making the wagon compliant with the essential requirements through the applicable TSIs, there may be additional technical information that has to be provided to the ECM. This additional technical information is requested contractually between the applicant and the manufacturer of the wagon.

10.4 Where can I find the technical file?

For vehicles compliant with TSIs, the initial development of the maintenance file is based on the technical file (Refer to section 4 of annex VI of the Interoperability Directive[3]) and on the APIS. The content of the technical file is described in detail in the relevant TSIs.

As interoperability doesn’t cover all the technical characteristics of a wagon but only the ones making the wagon compliant with the essential requirements through the applicable TSIs, there may be additional technical information that has to be provided to the ECM. This additional technical information is requested contractually between the applicant and the manufacturer of the wagon.
Therefore the initial technical documentation on which the maintenance file will be built is composed of:

<table>
<thead>
<tr>
<th>Initial technical documentation including initial maintenance documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical file</td>
</tr>
<tr>
<td>Additional technical documentation requested contractually</td>
</tr>
<tr>
<td>including the relevant maintenance documentation</td>
</tr>
</tbody>
</table>

In case the complete technical file has not been provided to the ECM, access should be arranged contractually between the keeper and the ECM. The keeper himself should be aware of its responsibility to provide the appropriate and correct technical information on the vehicle.

10.5 How to take into account the obsolescence of equipment?

New authorisation for placing in service of vehicle is not required when substituted parts are compliant with references or specifications in the technical file.

For instance, in the case of the substitution of a wheel by another one complying with the specification of the technical file, it would not be necessary to proceed to a new authorisation for placing in service neither a communication to the NSA. It should only necessary to have this substitution recorded in the configuration file of the vehicle. This information is, of course, available to NSAs upon request.

If the specification of the new parts impairs the design operating state, it is considered as a major change of the technical design and possibly leads to a new authorisation for placing in service according to the Interoperability Directive.

In case of such major change, the ECM could be the applicant for this new authorisation. In any case, the ECM should manage it through contractual arrangements with the RU/keeper and taking in consideration:

- The existing authorisation for placing in service;
- The guarantee of the vehicle by the manufacturer.

Other different question is if the fact, that the specification of the new parts impairs the design operating state, could be considered as a significant change affecting safety. In this case it is necessary to evaluate by the proposer (ECM) of the change if the change is significant and, if it is the case, to apply the Common safety Method on Risk Assessment and Evaluation.

There are other situations under discussion if it would be necessary a new authorisation. For instance, in case of a second transformation of wagons to a previous state already
authorised by NSA: on the one hand, it is a modification but on the other hand there are the “rights of the grandfather”.

| Change management | Other technical modifications |

STILL UNDER DISCUSSION
Situations where no possibility to strictly follow the technical file:
- Obsolescence of the parts
- Replacement by parts conform to other specifications than those in technical file

Always considered as a major change
Application of the process related to renewal and upgrading (Article 20 of the Interoperability Directive 2008/57)
Remark:
The ECM may play the role of the applicant in the sense of Interoperability Directive 2008/57 but:
- Not mandatory
- This role is not taken into account in the ECM certification

10.6 How to deal with changes in the maintenance?
1. ECM responsible to manage the substitutions in the framework of maintenance.  
   *(Section II.2(c) of Annex III of Commission Regulation 445/2011)*  
   Remark: Vehicles in service may be TSI compliant or not.

**Interoperability Directive 2008/57, Article 2(p)**

Substitution in the framework of maintenance means:  
"any replacement of components by parts of identical function and performance in the framework of preventive or corrective maintenance"

Two types of parts:

- Parts with references in the technical file
- Parts with *(appropriate and sufficient)* specifications in the technical file

2. ECM responsible for "verifying in all circumstances the consistency of the maintenance file with the authorisation of placing-in-service".  
   *(Section II.2(b) of Annex III of Commission Regulation 445/2011)*  
   Remark: Vehicles in service may be TSI compliant or not.

Then the role of ECM is to verify that the vehicle is maintained in accordance with the design operating state with the parts mentioned in the technical file, also when proceeding with substitutions!!
Substitutions in the field of maintenance do not affect the technical file of the vehicle and therefore remain within the scope of the authorisation of the vehicle.

No obligation to inform authorities according to Article 20 of Interoperability Directive 2008/57!!

New authorisation for placing in service of vehicle is not required when substituted parts are compliant with references or specifications in the technical file.

For instance, in the case of the substitution of a wheel by another one complying with the specification of the technical file, it would not be necessary to proceed to a new authorisation for placing in service neither a communication to the NSA. It should only necessary to have this substitution recorded in the configuration file of the vehicle. This information is, of course, available to NSAs upon request.
STILL UNDER DISCUSSION

Situations where no possibility to strictly follow the technical file:
- Obsolescence of the parts
- Replacement by parts conform to other specifications than those in technical file

Always considered as a major change

Application of the process related to renewal and upgrading (Article 20 of the Interoperability Directive 2008/57)

Remark:
The ECM may play the role of the applicant in the sense of Interoperability Directive 2008/57 but:
- Not mandatory
- This role is not taken into account in the ECM certification

If the specification of the new parts impairs the design operating state, it is considered as a major change of the technical design and possibly leads to a new authorisation for placing in service according to the Interoperability Directive.

In case of such major change, the ECM could be the applicant for this new authorisation. In any case, the ECM should manage it through contractual arrangements with the RU/keeper and taking in consideration:

- The existing authorisation for placing in service;
- The guarantee of the vehicle by the manufacturer.

Other different question is if the fact, that the specification of the new parts impairs the design operating state, could be considered as a significant change affecting safety. In this case it is necessary to evaluate by the proposer (ECM) of the change if the change is relevant and, if it is the case, to apply the Common safety Method on Risk Assessment and Evaluation.

There are other situations under discussion if it would be necessary a new authorisation. For instance, in case of a second transformation of wagons to a previous state already authorised by NSA: on the one hand, it is a modification but on the other hand there are the “rights of the grandfather”.

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11 EXCHANGE OF INFORMATION BETWEEN RAILWAY ACTORS

11.1 What is the information that stakeholders have to exchange according to the maintenance of freight wagons?

The exchange of information is critical. Therefore, this is an important requirement in the ECM Regulation obliging both parts, RUs and ECMs, to exchange information. It must be understood that intermediates such as keepers are also concerned by this obligation. As established in the Article 5 of the ECM Regulation 445/2011/EU:

- 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.

- 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.

- 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.

- 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.

In addition, the Agency will upload all the received ECM certificates in ERADIS database to disseminate the information within the sector. It is also up to the sector to implement the TSI Telematic Application for Freight (TAF TSI) in order to harmonise all the information systems related to the transport of freight wagons. The UIP is developing a Rolling Stock Reference Database (RSRD²) adapted to the needs.
11.2 How to find an ECM certification body?

http://eradis.era.europa.eu

ERA main website – Registers – ERADIS

Click on the link
11.3 How to publish your ECM certificate?

Certification Bodies page

Each organisation (Accreditation Body, Recognition Body and Member State Body):
→ submit the details on Certification Bodies accredited or recognised or NSA

11.4 How to find an ECM certified?

ECM Certificates

Click on the link
11.5 What does the schema “Schema chosen to award ECM certificates in each member state” in ERADIS mean?

According to the Article 10.1 of the Commission Regulation (EU) No 445/2011 of 10 May 2011, the Member States shall choose between accreditation or recognition or shall nominate the NSA as certification body.

For recognition, when applying the article 5(2) of the Regulation 765/2008, the Member State shall provide evidences to the Commission and the other Member States on equivalence with the ECM accreditation scheme.

Therefore there are different schemas to be chosen by each Member State:

- “Accreditation”: it means accredited certification bodies will be able to perform the ECM certification.
- “Recognition”: certification bodies recognised by the member state will be able to perform the ECM certification.
- NSA as certification body: the NSA designated by the member state as certification body will be able to perform the ECM certification.

The following link to the database ERADIS provides the choice of the different Member States:


The applicant ECM is free to choose its certification body (Article 6(1) of ECM Regulation). The ECM can contract body:

- with a certification accredited or recognised in any Member state;
- With the NSA of the Member State where the ECM is established only if the NSA has been designated by its Member state to perform ECM certification.
For further information see the questions:

**I would like to become a recognised certification body for ECM. To whom have I to apply for recognition?**

**Can a NSA of a Member State A give an ECM certificate in a Member State B?**
12 MANAGEMENT OF CHANGES

12.1 How to proceed with a change of ECM?

Commission Regulation 445/2011, Article 5(8)

“When there is a change of entity in charge of maintenance, the registration holder as indicated in Article 33(3) of Interoperability Directive, shall inform in due time the registration entity, as defined in Article 4(1) of Commission Decision 2007/756, so that the latter may update the national vehicle register.

The former ECM shall deliver the maintenance documentation to either the registration holder or the new ECM.

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

The change may be motivated:

- For business purposes
- Bankruptcy
- By revocation/suspension of ECM certificate

Minimum information to be transferred to the new ECM:

- (sufficient) information on the maintenance file including records on maintenance performed
- The technical documentation (technical file is not the property of ECM)
- The configuration files of each vehicle
- All additional information required by contract between keeper and ‘former’ ECM
12.2 I would like to change the ECM of my fleet freight wagons, how to proceed?

The critical aspect when changing of ECM is the proper transfer of information between the former ECM and the new ECM.

- (sufficient) information on the maintenance file including records on maintenance performed and safety verifications and risk analysis done for defining maintenance activities, intervals etc.
- The technical documentation (technical file is not the property of ECM)
- The configuration files of each vehicle
- All additional information required by contract between keeper and ‘former’ ECM

Consequently, ERA recommends strongly taking in account these details and issues when negotiating and setting up contractual arrangements between all the involved parts, above all with contracts between the ECM and the client.
13 How an ECM can act as Assessment Body in accordance with regulation 352/2009?

Yes it is the case. Accordingly the Regulation 352/2009/EC, the independent assessment body may be internal to the company (i.e. the proposer's organization for the significant change), but this internal assessment body must fulfil the criteria in Annex II of the CSM Regulation 352/2009/EC on Risk Evaluation and Assessment.