

Guide for the application of the Commission Regulation No 445/2011 on a system of certification of entities in charge of maintenance for freight wagons

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Table 1 : Status of the Document.

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Version 0.1 23/09/2011	MS, ECG	Restricted to the members of the TF ECM Guidelines	All	First draft of the document.
Version 0.2 23/10/2011	MS, ECG	Restricted to the members of the TF ECM Guidelines	See track changes	Document updated according to the comments received on version 0.1 from the following members (or organisations) of the Task Force on ECM Guidelines: <ul style="list-style-type: none"> • CER; • Claude PIANA; • NSA Italy; • NSA Spain.
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Table 1 : Status of the Document.

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Version 0.5 17/12/2011	MS	For consultation	1.1, 1.2, 2.3.1, 3.1.2, 3.1.3.1, 3.7.2, 3.7.4	Editorial amendments.
			2.2	Reference to 2011/665/EU added
			2.3.2	Deletion of unused terms, definitions adapted to revised WAG TSI
			3.1, 3.3	Chapters revised.
			3.2.2.2, 3.2.2.3	Terms revised in consistency with ISO terminology ('products' includes 'services').
			Annex	Traceability matrix between ECM guidelines and ECM Regulation added.

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1. INTRODUCTION

1.1. Scope

This guide provides information on the application of the "Commission Regulation on a system of certification of entities in charge of maintenance for freight wagons [1]" 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 actors¹ 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 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 is prepared by the European Railway Agency (ERA) with the support of railway association and national safety authority experts from the "Task Force on ECM Guidelines". It represents a developed collection of ideas and information gathered by the Agency during internal meetings and meetings with the ECM Working Group and the aforementioned Task Force. When necessary, ERA will review and update the guide to reflect the progress with the European standards, the possible changes to the ECM Regulation and return from experience on the use of the ECM Regulation. 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 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 does not also apply to other vehicles. Nevertheless, there is no assurance that the information provided is complete or fully applicable as such. The content of this document will be revised if compulsory certification is required for ECMs of other vehicles.

When Infrastructure Managers (IMs) need to use freight wagons to transport materials for construction or for infrastructure maintenance activities, they do so in the capacity of a railway undertaking (See recital (5) of ECM Regulation). For the sake of consistency with the ECM Regulation, the term 'IM(s)' will be used throughout the document for designating infrastructure managers assuming a role of railway undertaking for their own needs.

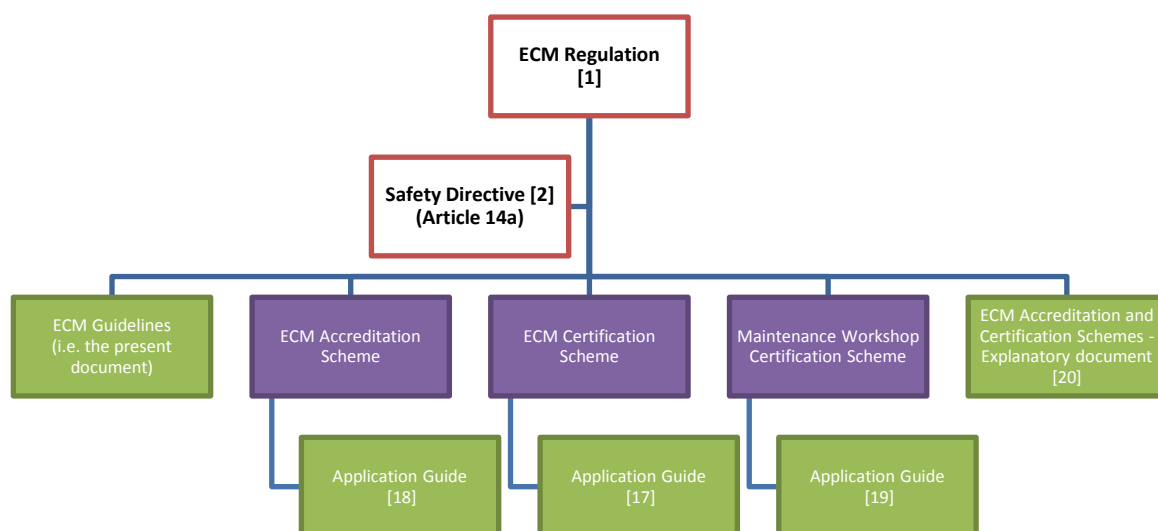
¹ *The concerned actors are the contracting entities as defined in Article 5 of ECM Regulation including their suppliers and service providers, or the certification bodies as defined in Article 6 of ECM Regulation.*

1.2. Principle for this guide

Although the guide may appear to be a standalone 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 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.

The main structure of the present guide was proposed, discussed and approved during the first “Task Force on the ECM Guidelines”.

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) [18] contains guidelines 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* [17] 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* [19] 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).
- The *explanatory document* [20] intends to provide information to understand why and how the ECM accreditation scheme, the ECM certification scheme, the maintenance workshop certification scheme and the specific process for NSAs acting as certification bodies have been developed.

2. DOCUMENT INFORMATION

2.1. Document description

The document is divided into the following parts:

- (a) Chapter 1 defines the scope and content of the guide;
- (b) Chapter 2 contains the list of reference documents, definitions, terms and abbreviations used throughout the document;
- (c) Chapter 3 details the content of the application guide.

2.2. Reference documents

Table 2 : Table of Reference Documents.

[Ref. N°]	Title	Reference	Version
[1]	Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2077 (Hereafter called "ECM Regulation")	445/2011/EU	10/05/11
[2]	Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) (Hereafter called "Safety Directive")	2004/49/EC (as amended by 2008/57/EC and 2008/110/EC)	16/12/2008
[3]	Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the Interoperability of the rail system within the Community (Hereafter called "Interoperability Directive")	2008/57/EC	17/06/2008
[4]	Commission Regulation (EC) N°352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council	352/2009/EC	24/04/2009
[5]	Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates	1158/2010/EU	9/12/2010
[6]	Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation	1169/2010/EU	10/12/2010
[7]	Technical Specification for Interoperability relating to the 'rolling stock' sub-system of the trans-European conventional rail system (WAG TSI)	IU-WAG-TSI Final draft (29/07/2011)	Under revision
[8]	Commission Decision of 12 May 2011 concerning the technical specification for interoperability relating to the 'operation and traffic management' subsystem of the trans-European conventional rail system	2011/314/EU	12/05/2011
[9]	Commission Decision of 4 April 2011 concerning the technical specifications of interoperability relating to the subsystem 'rolling stock – noise' of the trans-European conventional rail system	2011/229/EU	04/04/2011

Table 2 : Table of Reference Documents.

[Ref. N°]	Title	Reference	Version
[10]	Commission Recommendation of 29 March 2011 on the authorisation for the placing in service of structural subsystems and vehicles under Directive 2008/57/EC of the European Parliament and of the Council	2011/217/EU	29/03/2011
[11]	Commission Decision of 9 November 2007 adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC	2007/756/EC (as amended by 2011/107/EU))	10/02/2011
[12]	Memorandum of Understanding (MoU) establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons	-	14/05/2009
[13]	Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93	765/2008/EC	09/07/2008
[14]	Final report on the activities of the Task Force Freight Wagon Maintenance	-	1.0 05/10/2010
[15]	Recommendation on a common safety method (CSM) on monitoring for the railway sector	ERA/REC/SAF/01-2011	0.9
[16]	Recommendation on a common safety method (CSM) on supervision for the national safety authorities	ERA/REC/SAF/02-2011	0.7
[17]	ECM certification - Application guide including explanations on ECM certification scheme	ERA/GUI/09-2011/SAF	1.0
[18]	ECM certification - Application guide with additional explanations on Sectoral Accreditation Scheme	ERA/GUI/10-2011/SAF	1.0
[19]	ECM certification - Application guide including explanations on maintenance workshop certification scheme	ERA/GUI/11-2011/SAF	1.0
[20]	ECM accreditation and certification schemes - Explanatory document	-	1.0 21/10/2011
[21]	Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates	(EU) No 1158/2010	09/12/2010
[22]	Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation	(EU) No 1169/2010	10/12/2010
[23]	Commission Implementing Decision of 4 October 2011 on the European register of authorised types of railway vehicles	2011/665/EU	04/10/2011

2.3. Definitions, terminology and abbreviations

2.3.1. Standard terms and abbreviations

The general terms and abbreviations used in the present document can be found in the Oxford English dictionary (or equivalent). Furthermore, a glossary of railway terms that focuses primarily on safety and interoperability terminology, but also on other areas that the Agency can use in its day-to-day activities as well as in its Working Parties for the development of future publications, is available on the Agency website (<http://www.era.europa.eu/Document-Register/Pages/Glossary-of-railway-terms.aspx>).

Specific terms and abbreviations are defined in the sections below.

2.3.2. Specific terms and abbreviations

This section defines specific terms and abbreviations that are used frequently throughout the document.

Table 3 : Table of Terms.

Term	Definition
Accreditation	Third party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks ((ISO/IEC 17000:2004).
Accreditation body	Authoritative body that performs accreditation (ISO/IEC 17000:2004 - clause 2.6).
Accreditation scheme	Documented and publicly available system of rules which establish the requirements on accreditation bodies above and beyond ISO/IEC 17011, if applicable (Adapted from EA 2-11).
Agency	The European Railway Agency (ERA).
Appeal body	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.
Certification	Third party attestation related to products, processes, systems or persons (ISO/IEC 17000:2004).
Certification body	A body, designated in accordance with Article 10, responsible for the certification of entities in charge of maintenance, on the basis of the criteria in Annex II (ECM regulation). An impartial organisation possessing the necessary competence to operate a certification program (ISO).
Certification scheme	Certification system related to specified products, to which the same specified requirements, specific rules and procedures apply (ISO).
Container	Generic term for a box to carry freight, strong enough for repeated use, usually stackable and fitted with devices for transfer between modes (Terminology on Combined Transport. Economic Commission for Europe UN/ECE. 2001. Website of International Union of Combined Road-Rail Transport Companies UIRR).
Dangerous goods	Those substances and articles the carriage of which is prohibited by RID, or authorised only under the conditions prescribed therein (Directive 2004/49/EC).
ECM	An entity in charge of maintenance of a vehicle, and registered as such in the NVR (Railway Safety Directive).
ECM certificate	A certificate issued to an entity in charge of maintenance for the purposes of Article 14a(4) of Directive 2004/49/EC (ECM regulation).
ERATV	European register of authorised types of vehicles referred to in Article 34 of Interoperability Directive (Commission Implementing Decision 2011/665/EU).
EA Multi-Lateral Agreement (EA MLA)	The 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.
European Co-operation for accreditation (EA)	The European association of national accreditation bodies recognised against the European Regulation 765/2008. All Member states of the European Union are members of EA.
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 (ECM regulation)
Keeper	“keeper” means the person or entity that, being the owner of a vehicle or having the right to use it, exploits the vehicle as a means of transport and is registered as such in the National Vehicle Register (NVR) provided for in Article 33 of Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (recast) (*), (article 3(s) of the safety directive

Table 3 : Table of Terms.

Term	Definition
Maintenance	Activities which restore or upgrade a vehicle or component to a state in which it can perform its required function, ensuring continued integrity of safety systems, and compliance with applicable Standards and appropriate maintenance file or upgrading specification (ERA). OR Combination of all technical, administrative and managerial actions during the life cycle of an item intended to retain it in, or restore it to, a state in which it can perform the required function (EN 13306:2001).
Maintenance level	Maintenance may be divided in 5 levels: <ul style="list-style-type: none"> • The first level includes the actions of checking and monitoring undertaken before the departure (pre-departure) or en route. • The second level includes inspections, checks, tests, fast exchanges of replaceable units and preventative and corrective operations of limited duration between two scheduled journeys. • The third level corresponds to the operations carried out mainly in specialised facilities of a maintenance centre. It includes interventions of preventative and corrective maintenance and scheduled exchanges of components. The vehicle is not in active service during this level of maintenance. • The fourth level comprises the major maintenance operations, generally called overhauls (of modular subsystems or of the complete vehicle). • The fifth level comprises the refurbishment, modifications, very heavy repairs, renewal or upgrading, except where they are the subject to authorisation under the Interoperability Directive.
Maintenance plan	Structured set of tasks to perform the maintenance including the activities, procedures and means (Revised WAG TSI). The description of this set of tasks includes: <ul style="list-style-type: none"> • Disassembly/assembly instructions drawings necessary for correct assembly/disassembly of replaceable parts. • Maintenance criteria. • Checks and tests 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.
Maintenance rules	The national and European laws and standards related to the maintenance of freight wagons.
Maintenance schedule	Describes schedule of the different maintenance tasks as defined in the maintenance specification of the ECM.
Maintenance specification	ECM specific document which contains all the necessary information to technically maintain the wagon. Note: the same maintenance specification might be used by several ECMs, e.g. VPI maintenance specification.
Maintenance workshop	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 (ECM Regulation).
OTM (On-Track Machine)	A vehicle specially designed for construction and maintenance of the track. OTMs can be used in 3 different modes: working mode, transport mode as self-propelling vehicle, transport mode as hauled vehicle.
Recognition	Recognised certification bodies meaning certification bodies according to art 6 of the ECM Regulation and selected by Member States through a specific process of verification of competence put in place by public national authorities except the NABs.

Table 3 : Table of Terms.

Term	Definition
Recognition body	Legal or administrative entity that has specific tasks and composition, with acknowledged authority for publishing standards (adapted from ISO 17000 and ISO/IEC Guide 2 for definitions of "recognition" and "body").
Registration holder	Entity in charge of declaring any modification to the data entered in the national vehicle register, the destruction of a vehicle or its decision to no longer register a vehicle, to the authority of any Member State where the vehicle has been authorised (Interoperability Directive).
Release to service	The assurance given to the fleet maintenance manager by the entity delivering the maintenance that maintenance has been delivered according to the maintenance orders (ECM regulation).
Return to operation	The assurance, based on a release to service, given to the user, such as a railway undertaking or a keeper, by the entity in charge of maintenance that all appropriate maintenance works have been completed and the wagon, previously removed from operation, is in a condition to be used safely, possibly subject to temporary restrictions of use (ECM regulation).
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail, as adopted under Directive 2008/68/EC.
Rolling Stock	The rolling stock shall comprise all the stock likely to travel on all or part of the trans-European conventional rail network, including self-propelling thermal or electric trains, thermal or electric traction units, passenger carriages, freight wagons including rolling stock designed to carry lorries, track maintenance and laying machines. Each of the above categories must be subdivided into rolling stock for international use, rolling stock for national use (taking due account of the local, regional or long-distance use of the stock) and special vehicles (Interoperability Directive).
Service	Result of at least one activity necessarily performed at the interface between the supplier and the customer and is generally intangible (ISO).
Swap body	A freight carrying unit optimised to road vehicle dimensions and fitted with handling devices for transfer between modes, usually road/rail (Terminology on Combined Transport. Economic Commission for Europe UN/ECE. 2001. Website of International Union of Combined Road-Rail Transport Companies UIRR).
Third party	This third party makes assessments of other tasks on the behalf of somebody. Its work must be independent and professional in the respect of the work to be executed.
Trailer	A non-powered vehicle for the carriage of goods, intended to be coupled to a motor vehicle, excluding semi-trailers (Terminology on Combined Transport. Economic Commission for Europe UN/ECE. 2001. Website of International Union of Combined Road-Rail Transport Companies UIRR).
Type of vehicle	A vehicle type defining the basic design characteristics of the vehicle as covered by a single type examination certificate (Interoperability Directive).
Unit	Generic term used to name the rolling stock. It is subject to the application of this TSI, and therefore subject to the EC verification procedure (Revised WAG TSI). A unit can consist of: <ul style="list-style-type: none"> • a freight wagon or wagon that can be operated separately, featuring an individual frame mounted on its own set of wheels, or • a rake of permanently connected elements, those elements cannot be operated separately, or • separate rail bogies connected to a compatible road vehicle the combination of which form a rake of a rail compatible system.
Vehicle	Any single item of rolling stock, for example a locomotive, coach, MU, carriage or wagon (Interoperability Directive).

Table 4 : Table of Abbreviation.

Abbreviation	Meaning
AB	Accreditation Body
APIS	Authorisation for the Placing in Service (of structural subsystems and vehicles)
CA	Conformity Assessment
CAB	Conformity Assessment Body
CSM	Common Safety Method
EA	European co-operation for Accreditation (http://www.european-accreditation.org)
EC	European Commission (http://ec.europa.eu/index_en)
ECCM	European Common Criteria for Maintenance
ECM	Entity in Charge of Maintenance
EEA	European Economic Area
EFTA	European Free Trade Association (http://www.efta.int)
ERA	European Railway Agency (http://www.era.europa.eu)
EU	European Union
EVIC	European Visual Inspection Catalogue
EWT	European Wheelset traceability catalogue
FMM	Fleet Maintenance Management
GCU	General Contract of Use (http://www.gcubureau.org)
HoS	Head of Sector (ERA organisation)
HR	Human Resources
IAF	International Accreditation Forum (http://www.iaf.nu/)
IM	Infrastructure Manager
ISP	Interchangeable Spare Parts
ISV	Intermediate Statement Verifications
IT	Information Technology
MDL	Maintenance Delivery
MDV	Maintenance Development
MF	Management Function
MLA	Multilateral Agreements
MoU	Memorandum of Understanding
MRA	Mutual Recognition Agreements
MS	Member State
MW	Maintenance Workshop
NAB	National Accreditation Body
NANDO	New Approach Notified and Designated Organisations
NoBo	Notified Body
NSA	National Safety Authority
NVR	National Vehicle Register
OTIF	Organisation intergouvernementale pour les Transports Internationaux Ferroviaires - Intergovernmental Organisation for International Carriage by Rail (http://www.otif.org)
PO	Project Officer (ERA organisation)

Table 4 : Table of Abbreviation.

Abbreviation	Meaning
OTM	On-Track Machine
RISC	Railway Interoperability and Safety Committee provided for under Article 21 of Directive 96/48/EC on interoperability of trans-European high speed rail system. (or Article 29 of the Interoperability Directive 2008/57/EC (recast)) and Article 27 of the Railway Safety Directive.
RS	Rolling Stock
RSD	Railway Safety Directive
RU	Railway Undertaking
SMS	Safety Management System
TEN	Trans-European Rail Network
TFEU	The Treaty on the Functioning of the European Union
VPI	Vereinigung der Privatgüterwagen-Interessenten (http://www.vpihamburg.de)

3. EXPLANATIONS

3.1. Scope of the certification

This chapter is intended to provide clarifications about different aspects related to the geographical situation of the actors (ECMs, certification bodies, accreditation bodies) and products (freight wagons) involved in the ECM certification.

It also includes the categories of vehicle satisfying to the definition of 'freight wagon' in force and falling under the scope of ECM certification.

3.1.1. Freight wagons from third countries

When ECMs registered in the EU are maintaining freight wagons coming from third countries, the need for an ECM certification and a NVR registration for these wagons can be questioned. In this context, the following regulatory framework applies:

- 1) Article 33(5) of the Interoperability Directive stipulates "*In the case of vehicles placed in service for the first time in a third country and authorised in a Member State for placing in service on its territory, that Member State shall ensure that the data listed in paragraph 2(d) to (f) can be retrieved through the national vehicle register. Data referred to in paragraph 2(f) (the entity in charge of maintenance) may be substituted by safety critical data relating to the maintenance schedule*". The Interoperability Directive is not legislating about the ECM certification. Basically, it could mean an exception to include the ECM in the NVR registration. However, it does not prevent these freight wagons coming from third countries to have an ECM assigned and certified accordingly.
- 2) Pursuant to Article 14(a)(8) of the Safety Directive, *Member States may decide to fulfill the obligations to identify the entity in charge of maintenance and to certify it through alternative measures, in the following cases:*
 - a) *vehicles registered in a third country and maintained according to the law of that country;*
 - b) *vehicles which are used on networks or lines (e.g. the 1520) the track gauge of which is different from that of the main rail network within the Community and for which fulfillment of the requirements referred to in paragraph 3 are ensured by international agreements with third countries;*
 - c) *vehicles identified in Article 2(2), and military equipment and special transport requiring an ad hoc national safety authority permit to be delivered prior to the service.*

In this case, there is still a need to have assigned and certified ECM but the Member State could define alternative measures against the ECM Regulation. Regarding to the network in 1520 mm, the ECM certification framework implemented will depend on the existing agreements and laws.

In conclusion, ECMs operating with freight wagons coming from third countries must be, in any case, assigned and certified and no exceptions are allowed in this senses.

3.1.2. Framework inside EU and EEA

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 has introduced the transposition of the Directives 2004/49/EC, 2008/57/EC and ECM Regulation into its national laws. Consequently, the ECM Regulation applies on a legal and compulsory base.

3.1.3. ECM with residence in a Member State and operating in other Member State(s)

ECMs benefit like any other economic operator of the freedom of establishment (Article 49 of TFEU) and the freedom of services (Article 56 of TFEU). This means they can exercise their activity in several Member States, in addition to the one where their main office is located. They can do so in another Member State either on a temporary basis by providing services in different situations, for instance:

- there without having subsidiary or a branch in such Member State, or;
- they can establish subsidiaries (with a distinct legal personality), or;
- branches (without legal personality) in other Member States.

In addition to covering the activities of an ECM in the Member State of its head office, the certificate also covers the activities of any branches or subsidiaries the ECM may have in other Member States, but only where these are the same legal entity as the parent company. Obviously, it would be the case of subsidiaries established by an ECM in other Member States and not assuming the “ECM management function”, which an ECM cannot delegate to others (see Article 4.3 of the ECM Regulation)

If the subsidiary does not assume the ECM management function but undertakes other maintenance functions which have been assigned to it by its parent company by contract, then only the parent company needs to be certified as an ECM (although the subsidiary may ask for its own certification (maintenance function certification) on a voluntary basis and thus providing the ECM with a presumption of conformity).

On the contrary, if the subsidiary performs such ECM management function, then it is itself an ECM which needs to be certified (in addition to the certification of its parent company). Consequently, this subsidiary would be different from the parent company, in terms of ECM role, and it should be assigned ECM and therefore, included in the NVR (See also chapter 3.2.1.).

Finally, there is only one assigned ECM. If other functions are partly or fully certified on a voluntary base by contractors, it is not legally binding to include the reference to those certificates in the ECM certificate. However, if the contractors or subsidiaries make certification of some functions on a voluntary base, it is not forbidden to add this additional information in the ECM certificate.

3.1.4. Certification and accreditation bodies

In the EU legal framework and more specifically the ECM Regulation and the Regulation 2008/765/EC [13], 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.

3.1.4.1. Legal base

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.

Under 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)).

Pursuant to Article 7(1) of Regulation 765/2008, *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 EU certification body should always request for accreditation only to EU National Accreditation Bodies.

Regulation No 765/2008 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.

3.1.4.2. Residence inside or outside the EU

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:

	Certification body inside EU	Certification body outside EU
Accreditation body inside EU	Scenario 1	Scenario 2
Accreditation body outside EU	Scenario 3 (not applicable)	Scenario 4

In the scenarios 1 and 2, the certification bodies having or not their residence inside or outside the EU 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 can be accepted² 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 recognise 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.

² *Regulation 765/2008 allows for accreditation of non-EU certification bodies by non-EU accreditation bodies (See chapter 3.1.4.1.).*

- 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.

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 and “notified bodies” 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:

http://ec.europa.eu/enterprise/policies/single-market-goods/international-aspects/mutual-recognition-agreement/conformity-assessment/index_en.htm

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.

The rules of OTIF for certification and auditing on Entity in Charge of Maintenance, adopted on the 4th session of the Committee of Technical Experts in Berne (on 14-15th of September 2011) are equivalent in terms of requirements to ECM Regulation. It means that certificates of Entities in Charge of Maintenance granted under OTIF rules could be considered “technically”, **but not “legally”**, equivalent to the ECM certificates granted under EU law. The legal “recognition” of such framework should be developed through the aforementioned scenario 4.

Even if certification bodies established in third countries are not directly governed by the ECM Regulation, they need to comply with the obligations and tasks imposed on certification bodies by such regulation. This situation may be guaranteed by the Accreditation bodies of the third countries in any specific agreement with the EU.

3.1.5. Vehicle scope

The following vehicles satisfy to the definition of ‘freight wagon’ in force and therefore, fall under the scope of the ECM Regulation:

- Freight wagons for high speed or conventional rail. Even if high speed freight wagons don’t exist today, the Regulation needs to anticipate possible future developments.
- Freight wagons in the sense of the ECM Regulation are not those only limited to the TEN but all wagons authorised on the railway network under the safety directive..
- Commercial transport of freight is included.
- Freight wagons used by infrastructure managers or their contractors for purposes of maintenance or construction of the infrastructure. Three types of freights wagons should be considered:
 - All non-self-propelled units/wagons which are to be used in-service tracks shall be under ECM certification.
 - Units/wagons, which are only to be used on tracks that are not in-service are not required to be under ECM certification.

By opposition to in-service tracks, the not in-service (or out-of-service) tracks are those ones under construction or maintenance. This could also include tracks only used within the confines of a depot. Anyway, the Member State shall decide whether those tracks are part of the rail network.

- Each wagon/unit that can be operated, transported or hauled separately as a vehicle by a traction-unit on in-service tracks shall be under ECM certification.

Without prejudice to the freedom let to the Member States for excluding vehicles in accordance with Article 1(3) of Interoperability Directive and Article 14a(8) of Safety Directive:

1. Every unit/wagon that is transported on in-service tracks (perhaps to be used on out-of-service tracks) is under ECM certification.
2. Individual units/wagons that are part of a fixed or non-fixed combination that can be transported separately over in-service tracks are under ECM certification. A combination of units/wagons that can only be transported and operated as a fixed combination can be considered as one unit under ECM certification.

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

	Is ECM certification required?
OTMs used exclusively on out-of-service tracks, independently if they are self-propelled or not	Not required
Non self-propelled OTMs used partially or totally on in-service tracks	Required
Self-propelled OTMs operated partially or totally on in-service tracks in non-self-propelled mode (hauled by other traction-unit)	Required

	Is ECM certification required?
Self-propelled OTMs used partially or totally on in-service tracks and operated in self-propelled mode on in-service tracks	Not required

Passenger carriages which occasionally transport freight are not in the scope because they are designed and used mainly for passengers transport and are not subject to continuous exchange between RUs.

- Flat wagons for intermodal transport of containers, swap bodies and trailers. They are not included in the category of dangerous goods wagons because they are not specifically designed for the transport of dangerous goods and they are rarely used for that purpose.
- The sector could decide to extend the scope of the ECM certification to other vehicles than freight wagons on a voluntary base.

Article 14a(3) of the Safety Directive [2] applies to all vehicles while Article 14a(4) only applies to freight wagons. Consequently, obligations of the ECM are the same for all vehicles but certification only applies to freight wagons. Consequently, at the moment, other type of vehicles cannot be dealt with under the scope of freight wagons. If ECM certification is extended to other type of vehicles, under national law, these implementation rules shall be notified to the European Commission so as to check that these rules do not impair interoperability.

3.2. Entity in charge of maintenance

3.2.1. Definition

Pursuant to Article 3(t) of the Railway Safety Directive, an entity in charge of maintenance (ECM) is an “*entity in charge of maintenance of a vehicle, and registered as such in the NVR*”. Article 14a(2) of this Directive also clarifies that: “A railway undertaking, an infrastructure manager or a keeper **may** be an entity in charge of maintenance”. The options in this list are not exclusive.

Therefore, all bodies registered as such in the NVR are ECMs. This may include (without being exclusive): railway undertaking, infrastructure manager, keeper, maintenance workshop, manufacturer or even an industrial company. However, the registration of the ECM in the NVR is not sufficient as it must assume the corresponding responsibilities (set forth in Article 14a(3) of the Railway Safety Directive) and tasks (as a minimum the management function, refer to chapter 3.3 for more details). In any case, the ECM shall meet the relevant requirements set out in Annex III of the ECM Regulation and apply them consistently, this assurance being provided by the compulsory ECM certification.

A common business model illustrating the relationships between an ECM, a keeper and one or more RUs may be as follows:

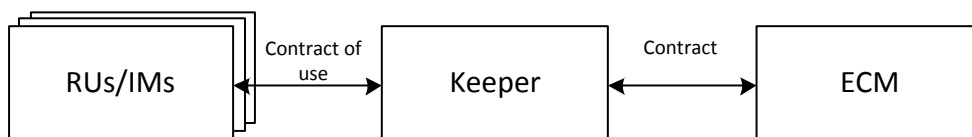


Figure 1: Common relationships between ECM, keeper and RUs.

Other possible business models (not exclusive) may be as follows:

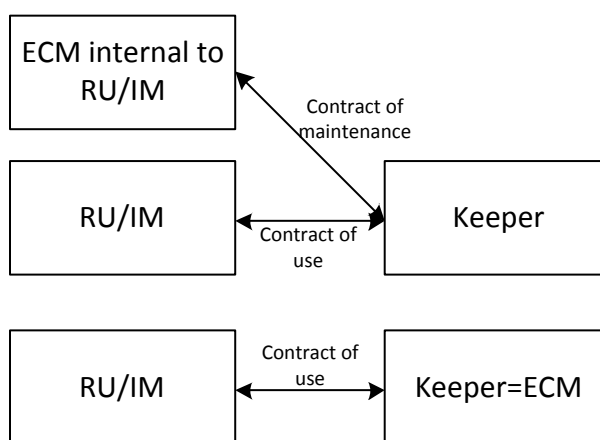


Figure 2: Other possible relationships between ECM, keeper and RU.

The different roles (ECM, RU/IM, keeper, maintenance workshop, registration holder) can be encompassed by one or several entities provided that they fulfil their intended responsibilities (See chapter 3.2.2.). For example, a railway undertaking encompassing the role of ECM 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 (See chapter 3.2.2.).

3.2.2. Responsibilities

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

Even if the ECM Regulation applies only to freight wagons, it is functionally justified to consider that the provisions of the Article 4 and the Annex III describing the maintenance system should apply to all vehicles under the scope of the safety directive.

Also the provisions of the Articles 5(2) to 5(5) describing the obligations related to exchange of information between parties should apply to all vehicles under the scope of the Safety Directive.

For vehicles outside the scope of the safety directive, those provisions of Articles 4, 5(2) to 5(5) and annex III should be regarded as good practises for setting up and maintain a maintenance system.

3.2.2.1. ECM

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:

“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. The safe state of running is a condition to safe operation as the overall safe design is. But to achieve safe operation RU/IM has to control also all the other risks related for instance to drivers or fitness of vehicles in the trains with journeys (see chapter 4.2.2.5. of the TSI OPE)

The ECM has the responsibility for setting out the maintenance file for each vehicle (See also chapter 3.3.2.1.) 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 the main 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 (See also chapter 3.3.6.). 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.

For freight wagons, the certification of ECM covers the four functions defined in Article 4(1) of the ECM Regulation and recalled in chapter 3.3. of this document. The certification of a whole function is also possible for parts or components of the wagon or for a specific level of maintenance, e.g. maintenance delivery for heavy maintenance of brake components or wheelsets.

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). Contracting with an ECM does not make the keeper necessarily accountable to the RU.

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 issues (See also chapter 3.2.2.7.).

For the other vehicles under the scope of the safety directive, the ECM certification doesn't apply. Nevertheless railway parties may set-up initiatives to certify ECMs. Those initiatives should be based on the certification principles described in the ECM Regulation and on the appropriate application documents, i.e. the ECM accreditation scheme. It is evident that these certifications are not legally mandatory.

3.2.2.2. Keeper

The keeper is defined in the article 3(s) of the safety directive. According to this definition the term 'keeper' applies to all vehicles.

Article 4(4) of the Safety Directive broadly defines the responsibilities of the keeper. Basically, the keeper must assure that products offered consistently meet safety requirements. The contract established between a keeper and a RU/IM/ECM shall cover all the relevant requirements, including at least: responsibilities and tasks relating to safety issues, the obligations related to the transfer of relevant information, the traceability of safety related documents and possibly compliance to specific maintenance rules (e.g. national standards).

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]).

A keeper may be an ECM but it is not mandatory.

With regard to the European legislation, the keeper has also the following responsibilities:

- Because there is no legal provision for a keeper to assign ECM, the following cases may apply:
 - To select an ECM and contract with it and when applicable, to contract with subcontractors (e.g. maintenance workshops);
 - To establish working relations with an ECM that is imposed to the keeper (e.g. by the owner).
- To ensure the information it addresses to the registration entity is correct and must get assurance for freight wagons that the ECM holds a valid certificate. When the keeper is not the registration holder, it must still ensure that the vehicle is compliant with the legislation in force (as commercial partner of the RU) and thus, that information stated in the NVR is correct;
- To assure that vehicle is put, in due time, at disposal of the ECM to perform maintenance activities in consistency with the decisions of the Fleet Maintenance Management;
- To implement corrective actions (e.g. contact ECM) in case technical problems are detected on the vehicle. RU/IM informs the keeper who informs in turn the ECM unless decided otherwise by contract (e.g. RU informing directly the ECM);
- For freight wagons: to take specific actions if ECM certificate is suspended or revoked (e.g. notify another ECM, perform verification on freight wagons). 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 is suspended forbidding this latter to be operated. Keeper must then inform its commercial partners(i.e. the RU/IM);

- To specify the conditions of use of the wagons, especially if there are particular conditions (e.g. type of goods transportable).
- To 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

The provisions of the GCU apply to keepers of freight wagons and RUs as users of freight wagons³. The obligations and rights of the keepers of freight wagons are described in chapter II of the GCU (See also chapter 3.7.5.).

3.2.2.3. RU/IM

The Railway Safety Directive states in Article 4(3) that RUs and IMs shall be made responsible for safe operation and to fulfil this responsibility, it requires that they establish a SMS. The RUs/IMs are responsible for the safe operation and therefore have to check that vehicles are maintained in such a way so that they can be used safely.

The RUs or IMs should ensure, through their SMS, the control of all risks related to their activity, including the supply of maintenance and material and the use of contractors (See Article 9(2) of the Safety Directive).

This means in particular that:

- For all vehicles The RU/IM must get assurance, through appropriate monitoring, that the products offered meet consistently the maintenance requirements (especially for the activities affecting safety).

This may be achieved by getting assurance that the maintenance system (put in place by the ECM) ensures the safe state of running. Nevertheless ensuring this safe state of running through a maintenance system remains the unique responsibility of ECMs. Therefore the ECM has the responsibility of the outcomes of the maintenance.

For freight wagons The ECM certification is one effective and efficient way to support the control of risks associated to the supply of maintenance and provides assurance that freight wagons are maintained by a competent entity and staff. Therefore RU is not requested to re-evaluate ECM already being granted with ECM certificate. By virtue of Article 5(1) of the ECM Regulation, the RU/IM shall ensure the freight wagons it operates, before their departure, have a certified ECM and that the use of the freight wagon corresponds to the scope of the certificate. This could be facilitated by contractual arrangements with the keeper.

- The ECM certification, like any certification, doesn't guarantee to RU/IM that there will never be non-conformities in the wagons due to wrong maintenance. Between maintenance interventions a vehicle may also be damaged by users.

³

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 are always a base for setting up their contractual arrangements.

For all vehicles the RU/IM is therefore responsible for taking additional measures described here below. The RU/IM should undertake inspections and monitoring measures before the departure of a train or en route. Those inspections and monitoring measures shall comply with the process described in its SMS (See recital (5) of ECM Regulation). They are performed to ensure that the train is fully functional before and throughout the train run (See chapter 4.2.2.5 of TSI OPE). In other words, the RU/IM must ensure that all vehicles as well as the combination of vehicles to a train or a train set fulfil all requirements regarding safety and the route that the train shall be operated on. It does not aim to control that maintenance was appropriate and done correctly but that vehicles are fit for use.

Some of the inspection and monitoring measures are carried out by the RU/IM itself (e.g. drivers and/or operational staff), for some the RU/IM subcontracts to other entities like keepers, maintenance workshops, ECM or even the IM⁴. But even by subcontracting some of the measures to other players the RU/IM 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 takes over for the RU.

The pre-departure and en-route inspections/monitoring measures can be seen by the ECM, on one hand, as an input for updating the maintenance file since the RU can require a minimum performance level (through contractual arrangements). On the other hand, the maintenance file may be seen as an input by the RU/IM to update the content of pre-departure or en-route inspections/monitoring measures since the ECM creates a certain state of the vehicle after performing maintenance. This state should then be used to elaborate or adapt the pre-departure or en route inspections/monitoring measures. Therefore content of inspections and monitoring measures may interest ECMs while some aspects of maintenance files may interest RUs/IMs. Therefore exchange of 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/IM 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 may limit the scope of application of the certificate, suspend the certificate, or revoke the certificate depending on the degree of non-compliance (See Article 7(7) of ECM Regulation).
- By virtue of Article 5(3) the RU/IM 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

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Case of RU subcontracting to IM maintenance of vehicles, train departure procedures etc.

other dangerous occurrences as well as on any possible restriction on the use of freight wagons.

The RU/IM 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/IM 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/IM 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 or IM in its SMS, including those for the exchange of information (See recital (6) of ECM Regulation).

However, the RU/IM cannot be permanently informed of every arrangement concluded between the keeper and the ECM (and in some cases directly with maintenance workshops without any contractual link with ECM) for all wagons it operates.

- The RU/IM shall implement any other control measures 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/IM as part of its SMS arrangements.

In practice, it will be up to the RU/IM 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.

After the award of the safety certificate/authorisation, the National Safety Authority (NSA) supervision activity can target at those activities of the RU/IM which the NSA believes give rise to serious risks or where hazards are least well-controlled (See Annex IV of EU 1158/2010, Annex III of EU 1169/2010 and future CSM on supervision). Pursuant to Article 9 of the ECM Regulation, during its supervision activities, the NSA may also claim, upon justified reason, that the ECM does not comply with the requirements of Article 14a(3) of the Safety Directive or with the certification requirements of this Regulation. The NSA must then inform the certification body who in turn may take the necessary actions and/or depending on the criticality of the risk, the NSA may request from the RU/IM the enforcement of complementary provisions to control the risk or may limit the scope of application of the certificate (amended authorisation) or even revoke the certificate (suspended authorisation). Pursuant to Article 16(2) of the Safety Directive, the NSA is entrusted with checking that the structural subsystems (e.g. the rolling stock) are operated and maintained in accordance with the relevant essential requirements provided for in the respective TSIs (e.g. WAG TSI). Therefore, the NSA may also supervise the maintenance system put in place by the ECM, whether these activities relate to freight wagons or to other categories of vehicles, with the same potential consequences.

When contracting with a keeper, the RU may apply the obligations described in chapter III of the GCU (See also chapter 3.7.5.).

3.2.2.4. Maintenance workshop

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.

The maintenance workshop delivers maintenance meaning performing the technical execution of works defined in the maintenance file and ordered by the ECM or possibly the RU/IM (See chapter 3.7.5.).

The maintenance workshop must be competent to perform the maintenance tasks requested in the orders. Generally the maintenance workshop will address a report with the maintenance records to the entity who ordered it. This report contains the details on the release to service.

The release to service is defined in the article 3(f) of the ECM regulation as the *assurance given to the fleet maintenance manager by the entity delivering the maintenance that maintenance has been delivered according to the maintenance orders*. The release to service may include proposals of temporary restrictions for use.

There is a known tendency in large contracts for the orders to request not only maintenance delivery but also return of experience information. The maintenance workshops should answer positively to these requests.

Maintenance is delivered by maintenance workshops for maintenance level 2 to 5 in different locations:

- Industrial buildings with the necessary industrial equipments and tools;
- Tracks around the industrial buildings belonging to the same entity;
- Tracks under the responsibility of IM (stations or lines)/RU/keepers/other organisations (e.g. industrial plant belonging to clients).

Maintenance may be delivered permanently, temporarily at regular intervals, on-condition or as “one-of” (i.e. a contract made by a customer who doesn't intend to consider the maintenance workshop as an usual contractor) in each location.

3.2.2.5. Registration holder

Article 33 of the Interoperability Directive stipulates that the registration holder is responsible to provide information (among which the denomination of the ECM, the keeper and the owner) for registration of vehicles to the registration entity (i.e. the entity designed by each MS, in accordance with Article 33(1)(b) of Interoperability Directive, for keeping and updating the NVR). The registration holder shall keep up to date the data in the NVR by updating information on 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]). A keeper may be an ECM but it is not mandatory.

3.2.2.6. Certification body

Article 14a(4) of the Safety Directive imposes that the ECM certificate is delivered by a certification body, that is:

- an accredited body, or;

- a recognised body, or;
- a NSA.

The applicant ECM is free to choose its certification body (Article 6(1) of ECM Regulation). The type of certification body (accredited, recognised or the NSA) is selected on a case-by-case basis by each Member State (Article 10(1) of ECM Regulation). However, it does not prevent the ECM to contract with a certification body accredited in another Member state or even outside the EU (See also chapter 3.1.4.) by virtue of free movement of products in the European Union.

The Article 6(2) of the ECM Regulation imposes that the certification bodies comply with Annex II of the ECM Regulation and the ECM accreditation scheme (subsequent Sectoral Accreditation Scheme).

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 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).

3.2.2.7. Liability

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 one 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.

3.2.2.8. 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. Note that nothing prevents an applicant ECM to apply for certification by two or more certifications bodies established in different countries (whether within or outside the EU).

3.3. Maintenance system

Article 1(2) of the ECM Regulation indicates that the purpose of the system of certification is to provide evidence that an ECM has established its **maintenance system** and can meet requirements laid down in the ECM Regulation to ensure the safe state of running of any freight wagon for which it is in charge of maintenance.

As stated in the chapter 3.2.2., the provisions of the ECM regulation addressing the maintenance system should be extended to all vehicles under the scope of the safety directive. Therefore this chapter addresses also all vehicles under the scope of the Safety Directive if not otherwise mentioned.

According to Article 4 of ECM Regulation, the maintenance system is composed of four functions:

- **Management;**
- **Maintenance development;**
- **Fleet maintenance management, and;**
- **Maintenance delivery.**

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.

This functional maintenance breakdown is helpful to set up the framework for voluntary certifications on a subset of the maintenance functions and in particular the certification of maintenance workshops (See chapter 3.3.6.).

3.3.1. Management function

The **management function (MF)** covers the coordination and monitoring of all the ECM maintenance activities:

- The management processes that are common to all certification of management systems but here detailed taking into account specific aspect: leadership, risk assessment, monitoring, organisational learning. Implementation of CSM risk assessment is made mandatory (See also chapter 3.7.6.).
- The processes that are common to all certification of management systems but customised to the specific application: structure and responsibility, competence management, information management, documentation management.
- The processes related to the management of outsourced activities. This is a crucial point because ECMs may call for external technical expertise and may have fleet maintenance management and maintenance delivery often outsourced following contracts between keepers and RUs.

3.3.2. Maintenance development function

The **maintenance development (MDV)** covers the compliance with interoperability rules and the establishment and continuous update of the **maintenance file**.

3.3.2.1. 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;”*

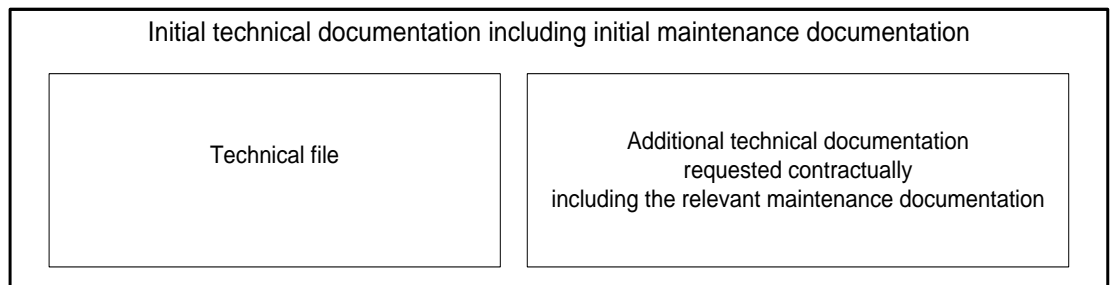
According to the sections II.4. and II.5. of annex III of the ECM Regulation [1], the ECM has the duty to develop and maintain (continuously update) the maintenance file.

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 (Refer to [10]). 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:

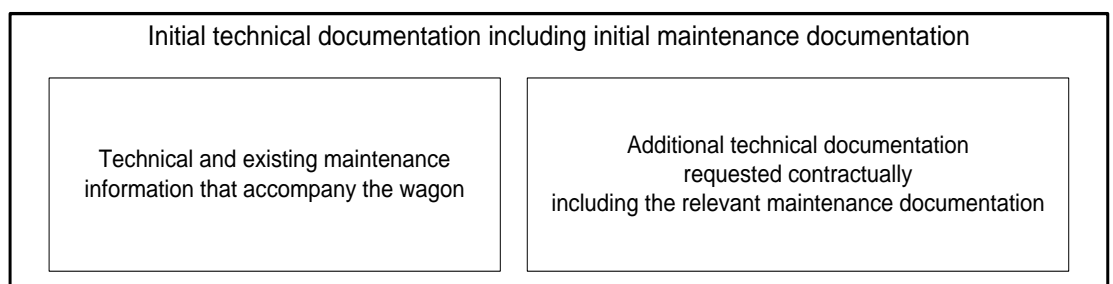


In general the ECM may not have access to the complete technical file. Access for an ECM to the technical file should be arranged contractually with the keeper. The keeper himself should be aware of its responsibility to provide the appropriate and correct technical information on the vehicle.

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: chapter 4.2.8. of Annex to Commission Decision 2006/861/EC concerning the technical specification of interoperability relating to the subsystem rolling stock — freight wagons of the trans-European conventional rail system;
- Locomotives and passenger carriages: chapter 4.2.12 of Annex to Commission Decision 2011/291/EU concerning a technical specification for interoperability relating to the rolling stock subsystem — ‘Locomotives and passenger rolling stock’ of the trans-European conventional rail system.

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.

Content of the maintenance file

The maintenance file is unique 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) The **General Documentation** 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).

This documentation may be updated by the ECM.

- 2) The **Maintenance Design Justification File** 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.

The maintenance design justification file shall give input data in order to determine the criteria for maintenance activities. The maintenance design justification file 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.

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

- 3) The **Maintenance Description File** describing how maintenance activities have to be conducted. Maintenance activities include, among others: inspections, monitoring, tests, measurements, replacements, adjustments and repairs.

Maintenance 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. 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.
- European legal obligations: where components or systems are subject to specific European legal obligations these obligations shall be listed.
- 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 tests 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) The **Configuration Files** 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.

3.3.2.2. Process of maintenance development

The maintenance development becomes effective when the vehicle begins its operational service.

3.3.2.2.1. Detailed process

The maintenance development process can be described as follow:

At the moment when operation starts

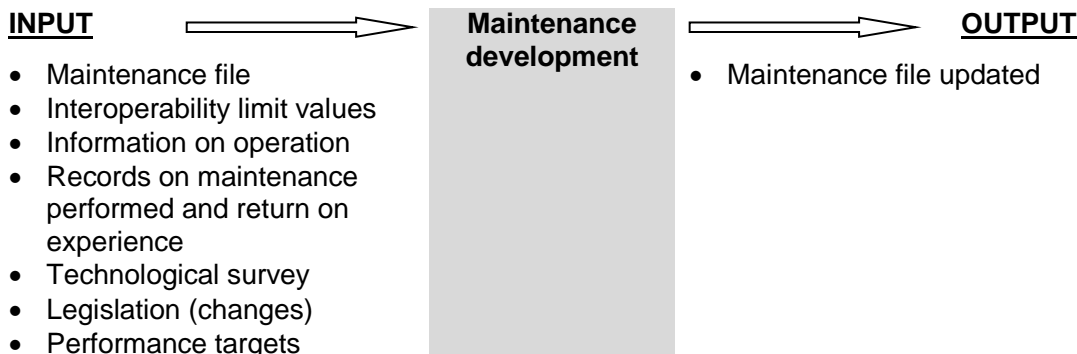
The initial development of the maintenance file depends on the initial technical documentation (see previous chapter) and the pattern of operations planned.

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 (passenger⁵ 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 coast,...)⁶;
 - behaviour and skills of drivers⁷;
 - etc.
- 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,
 - equipments,

⁵ *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.*

⁶ *Given as example. Not entirely applicable for the moment*

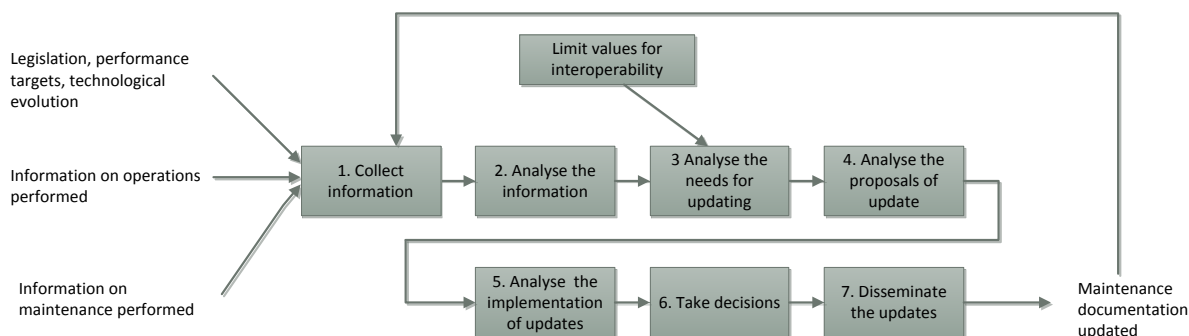
⁷ *Not applicable for freight wagon but important for locomotives and multiple units.*

- 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,
 - cost.

After taking into account all information, the **maintenance development** has to be competent to update the maintenance file or to decide that no updating is necessary.

The key stages of the maintenance development process are as follow:

- Collecting information on:
 - Operations performed;
 - Maintenance performed;
 - Inspections made by RUs/IMs
- 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.
- Dissemination of the updates (or no change) of documentation to interested parties.



Steps 2 to 6 are based on risk assessment

Figure 3: Process of maintenance development.

The process may lead to no change of the documentation. The analysis of the inputs may lead to the decision that an update is not necessary. As the process has been applied in such a case, there is properly speaking an update since the maintenance design justification file will be updated anyway.

3.3.2.2.2. **Subcontracting maintenance development to entities specialised for components**

Maintenance of some components may be developed by specialised entities. In particular the components the ECM considers as critical for safety and for which the ECM judges that it is not sufficiently skilled.

These entities specialised for components shall comply with the same requirements as maintenance development. The process for maintenance development should be the same as described in chapter 3.3.2.2.1. This implies that an effective exchange of information on the pattern of operation planned and on the pattern of operations effectively performed is necessary between the ECM and its contractor.

3.3.2.2.3. **Results of the Task Force on Freight Wagon Maintenance**

For freight wagons, it is strongly recommended that the following results of the Task Force on Freight Wagon Maintenance are included in the maintenance file as they are considered as good practice:

- The harmonised maintenance program of inspection of axles, **EVIC** (See Annex III of [14]).
- The identification of the data that needs to be collected in the European Wheelset Traceability Catalogue, **EWT** (See Annex IV of [14]):
 - a. The traceability of wheelsets involved in incidents/accidents and therefore to reduce the risk for further incidents/accidents due to similar reasons;
 - b. In case of incidents/accidents the traceability of the service conditions of an involved wheelset in the past and also its core item, the axle;
 - c. The traceability of the applied maintenance regime and which non-destructive tests have been done on the wheelset.

- The European Common Criteria for Maintenance for freight wagon axles, **ECCM** (See Annex V of [14]).

Those three documents⁸ on railway maintenance, which were developed by the railway sector, should be taken into account by the ECM in the maintenance file respectively for:

- The development and update of visual inspections on axles (EVIC).
- Defining the content of the part of the configuration file addressing wheelsets (EWT).
- Harmonising the maintenance plans (ECCM) when appropriate.

However, if an ECM can demonstrate through experience and risk assessment that it has more effective maintenance rules in its maintenance file than the here-above recommended good practises, it should better use them.

3.3.3. 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 internal ECM services/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 entity in charge 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. It includes a range of activities, such as vehicle financing, vehicle maintenance, vehicle telematics (tracking and diagnostics), driver management, energy management and health & safety management. 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.
- Collecting and transferring, to maintenance development, information on maintenance performed and operations performed, including at least defects, incidents, accidents, mileage.

The input for the FMM is the maintenance file.

The FMM must control:

- The capability including competence of the **maintenance delivery** to perform maintenance works;
 - in consistency with the maintenance file, and;

⁸ *The results of the Task Force on Freight Wagon Maintenance are described in the final report on the activities of the Task Force Freight Wagon Maintenance [14]. As part of it, detailed arrangements for the freight wagon/axle maintenance were developed by the Joint Sector Group (JSG) and appended to the aforementioned report (Cf. Annexes III to V). These annexes to the report are subject to modifications by the JSG. Latest issues are made publicly available on their website (<http://www.jsgrail.eu>).*

- in due time.

The technical and management competence of the maintenance delivery will be ensured through a qualification process performed in general by the maintenance development.

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

- The operational possibility to send vehicles that have to be maintained to the maintenance delivery premises in due time.

The outputs are:

- The maintenance orders addressed to the maintenance delivery. There has to be contract between the FMM and the maintenance delivery. The contract has to include the maintenance orders that mean the complete information issued from the maintenance file that are necessary to perform the maintenance tasks.
- 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 work has been executed by the maintenance delivery. This return to operation is finally addressed to RUs generally but not exclusively through the keeper.

The return to operation granted by the FMM provides assurance to the RU who will operate the vehicle, that the vehicle is:

- is compliant with the legislation;
- is maintained in a way to assure a safe state of running and therefore safe operation (to this end the return to operation may contain restrictions on operations); and
- is at disposal for use.

The FMM must take into account the release to service granted by the maintenance delivery. This release to service shows only that the maintenance has been correctly performed against the maintenance orders.



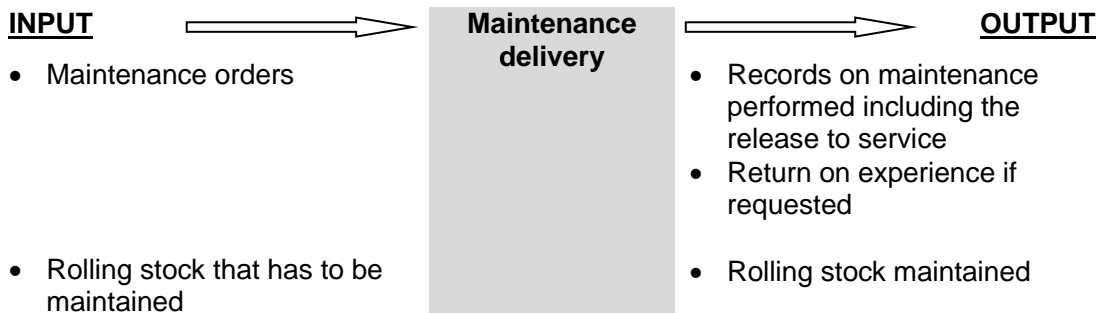
3.3.4. Maintenance delivery function

The **maintenance delivery (MDL)** is the technical making of the ordered technical maintenance tasks. Maintenance delivery may be done in **maintenance workshops (MW)** or by other entities to which maintenance delivery may be contracted such as manufacturers of vehicles or components. 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.



3.3.5. Links between the functions

The functions of the maintenance system are linked as follows:

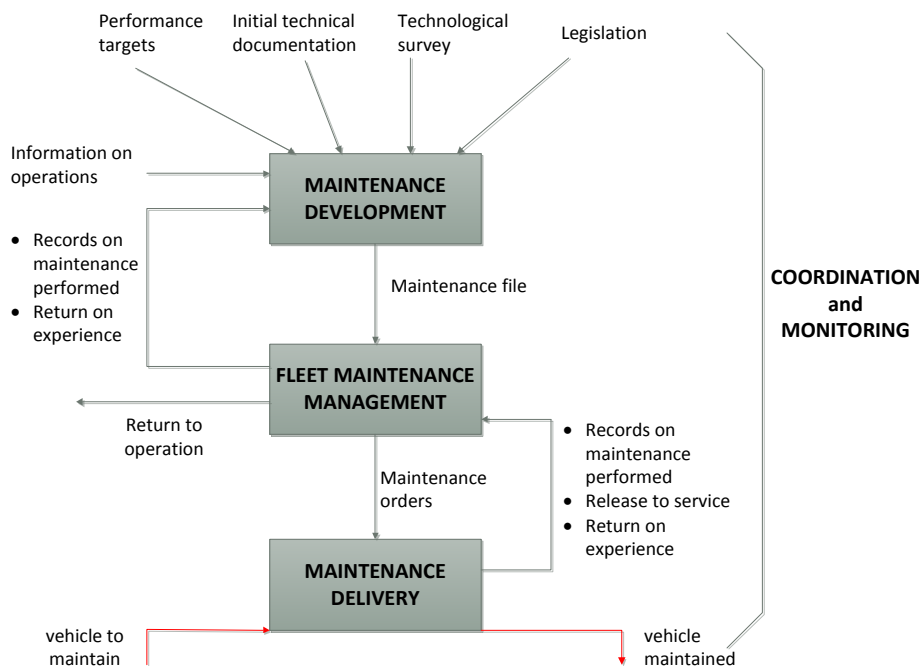


Figure 4: links between the functions of the maintenance system.

The coordination and monitoring is the internal control each ECM management function implements.

With regard to the maintenance of freight wagons, the following figure is applicable:

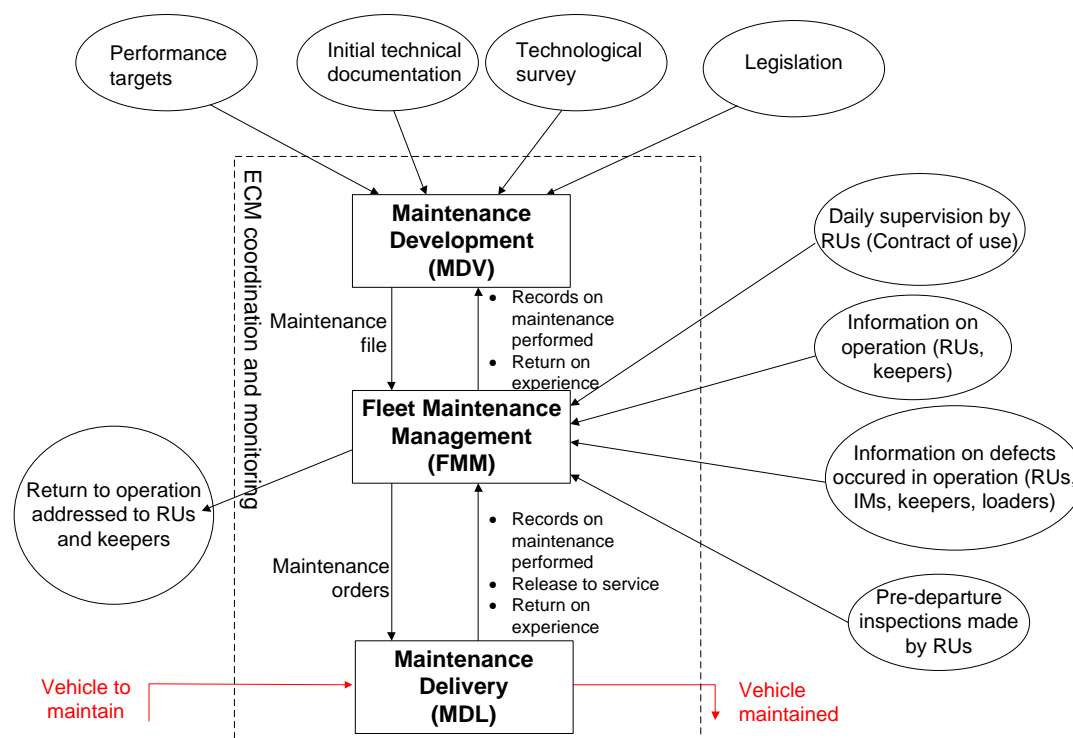


Figure 5: Example of links between the functions of the maintenance system for freight wagons.

It includes the relations with keepers and RUs.

3.3.6. Outsourcing of the functions

3.3.6.1. Introduction

Outsourcing is common practice in today business organisation. For the maintenance of freight wagons, maintenance delivery is largely outsourced to independent maintenance workshops. But the concept of outsourcing may be enlarged to all activities performed by the ECM.

Indeed, an ECM may outsource by contract one or more of the maintenance functions, in whole or in part. The entities performing such outsourced functions do not need to be certified although they may apply the system of certification on a voluntary basis (See Article 2(2) of the ECM Regulation).

If an entity performing outsourced maintenance functions does not ask for voluntary certification, the ECM must demonstrate to the certification body how it complies with all the requirements imposed by Annex III of the ECM Regulation with regard to the functions it decides to outsource. The ECM must ensure that the principles set forth in Annex I of the ECM Regulation are applied by its contractor(s) (See Article 4(3) of the ECM Regulation).

In any case, the ECM remains responsible for the outcome of the maintenance activities of its contractor(s) (See Article 4(4) of the ECM Regulation). The ECM will take great

consideration of contractual arrangements with a keeper and/or a RU/IM that may choose for instance the outsourcing of the maintenance delivery to a given qualified workshop (even if the ECM is able to perform itself the maintenance delivery in one of its workshops).

3.3.6.2. Business models

The following business models are possible:

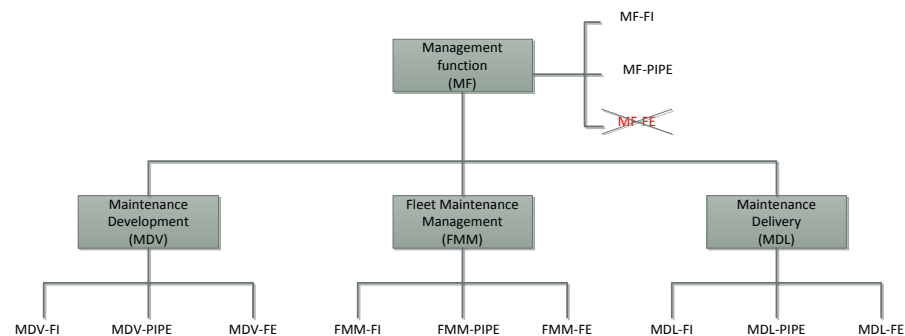


Figure 6: Outsourcing of maintenance functions.

The maintenance functions may be fully internal (FI), partially internal-partially external (PIPE) or fully external (FE).

The management function may only be fully internal (FI) or partially internal-partially external (PIPE). **In any case, the management function cannot be fully external (FE)** because a level of coordination must be assured by the ECM itself. This is developed in Article 4(3) of the ECM Regulation.

However, nothing prevents the ECM to call for expertise or to contract administrative tasks for some parts of the management function: e.g. welding training, IT infrastructure, documentation and HR management, independent assessment (in accordance with Article 6 of the CSM Regulation on risk assessment). In any case the ECM remains fully responsible of its decisions taken on basis of external expertise and on outcomes of contracted administrative tasks.

Moreover establishing and revising the procedures requested in the annex III(I) of the ECM regulation remains always the responsibility of the ECM. It is obviously to the ECM to establish and revise its own (organisational) procedures.

Examples

Those following examples are not exhaustive. They aim to help the understanding between which activity linked to the management function can be contracted and which ones cannot be contracted.

- 1) Annex III(I)(1) of ECM Regulation: Leadership:

Decisions on leadership cannot obviously be contracted. Nevertheless the ECM may call for consultancy to set-up his leadership.

- 2) Annex III(I)(2) of ECM Regulation: Leadership Risk assessment.

Following the Commission Regulation 352/2009 (CSM risk assessment), the independent safety assessment body compliant with the article 5 may be external to the ECM.

3) Annex III(I)(5) of ECM Regulation: structure and responsibility:

Establishing the structure of its organization and allocating the responsibilities within this structure remain obviously activities that can only be internal to the ECM. Nevertheless the ECM may call for consultancy but final decisions related to the structure and to the allocation of responsibilities may only be done by the management of the ECM.

4) Annex III(I)(6) of ECM Regulation: competence management

Identification of competences, taking decisions on competences and taking decisions on all activities permitting to the ECM to decide on the staff competences may only be performed by the ECM itself. Nevertheless the ECM may call for consultancy and also contracts activities such as the human resources administrative tasks and the organisation and the provision of trainings.

5) Annex III(I)(8) of ECM Regulation: Documentation

Administrative storage of documentation may be contracted in particular for IT storage.

6) Annex III(I)(9) of ECM Regulation: contracting activities

It is obvious that evaluation of contractors may always be contracted, for instance when certification against international standards, industry standards or against the ECM regulation (maintenance functions certifications against article 8 and annex I). Nevertheless decision on working with each contractor remains the only responsibility of the management of the ECM.

3.3.6.2.1. All activities managed internally

All the activities are performed internally by the ECM. It is characterised by: MF-FI + MDV-FI + FMM-FI + MDL-FI.

In that case the certification body chosen to award the ECM certification will make its assessment against the full list of requirements in the annex III of the ECM regulation.

3.3.6.2.2. When operational functions are outsourced (partially or fully) or when management function is partially outsourced

For what remains internal, section 3.3.6.2.1. applies.

For what is outsourced, the ECM has to define its requirements to get assurance that the:

- The contractor is competent and capable to perform contracted activities.
- The tasks contracted are really performed according to the ECM requirements.

These requirements have to comply with the requirements of annex I but relevant and appropriate to the activities contracted. For instance the management of an external workshop must be compliant with the requirements of the MDL function or must be such to give assurance to the ECM that the ECM can meet the requirements of the MDL function.

Following it, the ECM has to put in place the procedures to perform an assessment of the contractors against the previous defined requirements.

Two possibilities are offered to the ECM:

- 1) The ECM performs itself the assessment.
- 2) The ECM:
 - a) performs itself the assessment but partially, **and**;
 - b) relies on an assessment performed by a third party (practically, third party certification) for the requirements that the ECM does not want to assess itself. In fact it is an outsourcing of the assessment that the ECM has to perform in item 1).

Therefore the ECM has to verify that the third party is competent and capable and that the assessment performed by this third party is appropriate to the ECM needs.

In case of third party assessment, three cases must be distinguished:

- The ECM relies on existing certifications (e.g. ISO 9001) or develops its own third party certification (alone or within an organisation (e.g. VPI). The ECM has to verify that these existing certifications are in consistency with its needs.
- The ECM relies on the voluntary certification as proposed in the ECM Regulation. This gives him a presumption of conformity that the contractor has put in place the procedures of Annex I. This voluntary certification facilitates really the ECM in verifying the consistency with its needs through the requirements of the Annex I of the Regulation.
- For maintenance activities performed by a RU/IM upon contractual arrangements (see also chapter 3.7.5.), the ECM relies on the safety certification consistent with the Articles 10 and 11 of the Safety Directive. Those maintenance activities performed by the RU are evidently under the scope of the SMS according to the Article 9(2) of the Safety Directive and therefore are covered by the conformity assessment and supervision performed by NSAs.

3.3.7. Relations between entities and functions

Two cases may be envisaged to show that the approach defined in the section 3.3. is applicable in the 'old' railway system:

- Integrated RU.
- Freight wagons in the old railway system.

For all of them the basic principle of dividing the maintenance in functions is applicable but the way the sector is organised may differ significantly.

3.3.7.1. Integrated RU in the old railway system

The 4 functions are implemented internally by the integrated RU.

3.3.7.2. Freight wagons in the old railway system

Under COTIF 80 and RIV rules, the maintenance of freight wagons was organised as follows:

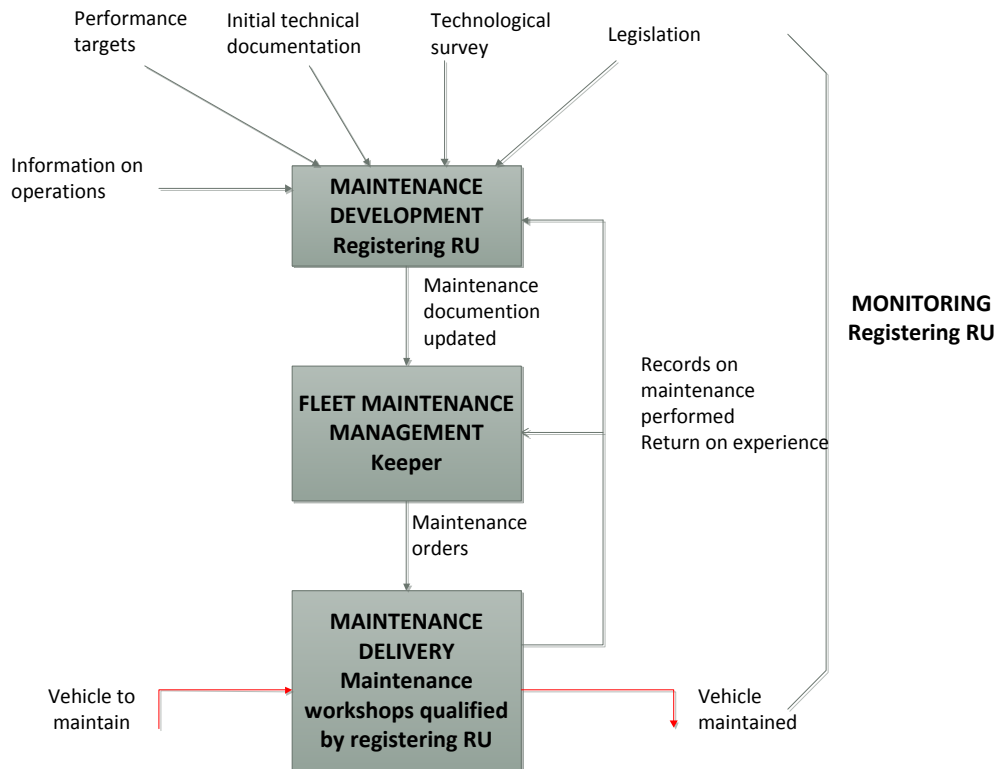


Figure 7: Relations between entities and maintenance functions in the old railway system.

In the 'old' system of integrated companies, the maintenance management function was undertaken by the RU that registered the vehicles (i.e. registering RU). The RU had to monitor the keepers through assessments (controls on the fleet maintenance management) and ensure that the vehicles applied their maintenance files in maintenance workshops only authorised by them.

The registering RU was responsible for the maintenance development and for the qualification of the maintenance workshops.

Generally the keeper was responsible for the fleet maintenance management that ought to be compliant with the RIV rules. He had to strictly apply the rules imposed by the registering RU.

3.3.8. Transfer of existing vehicles from one ECM to another

The maintenance of vehicles may be transferred from one ECM to another ECM. This is generally motivated by business reasons or by limitation of the scope, suspension or revocation of an ECM certificate (only valid for freight wagons)

Minimum documentation has to be transferred. It should include:

- Information of the maintenance file;
- The initial technical documentation (amended considering all the technical modifications that have been done on the vehicles), and;
- All additional information requested by contract between the entity who assigned the former ECM and the new ECM.

As far as possible, agreement should be found between the former ECM and the new ECM.

In any case when accepting the maintenance on vehicles, the new ECM takes its own responsibility and the necessary provisions to set out maintenance file for each vehicle.

The technical file is not the property of the ECM but of applicants in the sense of Interoperability Directive. The entity who assigns the ECM should get the property or the right of use of the initial technical documentation. The ECM will receive the right of use of the initial technical documentation from the entity that assigns it.

It should be the same for all modifications of the vehicle design.

The maintenance file remains basically the property of the ECM that developed and updated it. There are poor chances that the ECM will provide the full content of maintenance file to one competitor. It is a matter of transfer of know-how. Each ECM will obviously be reluctant to transfer its know-how to a competitor. To avoid problems the entity that assigns the ECM should contractually define with the ECM which information contained in the maintenance file are property of each contractual party (the entity that assigns the ECM and the ECM). At least the configuration files should remain the property of the entity that assigns ECM.

In case of bankruptcy, there is always a risk that no information on maintenance is communicated to the new ECM. In that case the new ECM should put in place the necessary measures to make a diagnostic of the state of running of the vehicle before accepting to maintain it. When accepting, as stated here above, the new ECM takes its own responsibility and the necessary provisions to set out maintenance file for each vehicle.

NSAs may still be informed of the change of ECM through the notification of the changes made to the registering entity.

3.4. Exchange of information

The exchange of information is ruled by the ECM Regulation.

In particular the ECM has to notify the return to operation including restrictions of use justified by maintenance. The notifications have to be communicated by the ECM to users and in particular to RUs. The tools dedicated to the exchange of information and developed by the sector are recommended for use.

It might be interesting for ECMs to know about the content and results of pre-departure inspections and other checks performed by the RUs to check that vehicles are fit for planned operations. This knowledge offers to the ECM the opportunity to know about the limits in which the RUs are performing and consequently to update maintenance files in a more effective and efficient way. Active exchange on information between ECMs and RUs should be promoted by sector associations.

3.5. Transitional provisions

The transitional provisions are described in Article 12 of ECM Regulation.

3.6. Application and certification forms

The application and certification forms are appended in Annex IV, V and VI of ECM Regulation.

Detailed information to be provided as part of the application for an ECM certificate can be found in both the ECM certification scheme and the maintenance workshop certification scheme.

Pursuant to Article 10(3) of ECM Regulation, the *certification bodies shall notify the Agency of all issued, amended, renewed or revoked ECM certificates or certificates for specific functions according to Article 4(1), within 1 week from its decision, using the forms in Annex V.* From the 1st of June 2012, all ECM certificates issued in accordance with the ECM Regulation shall therefore be notified to the Agency. These ECM certificates as well as the certificates issued by a certification body by no later than 31 May 2012 on the basis of principles and criteria equivalent to those of the Memorandum of Understanding establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons (signed by Member States on 14 May 2009) will be made publicly available in the ERADIS database (<https://pdb.era.europa.eu>) for which an update will be available mid-2012.

3.7. Interfaces

3.7.1. Interface with WAG TSI (including ISP)

To be completed when revised WAG TSI will be adopted.

The content of the technical file that has to be used by ECM to set-up the maintenance file is described in sections 4.5 and 4.6. of the current drafts of the revised WAG TSI.

For information on current wag TSI in force, see chapter 3.3.2.1.

3.7.2. Interface with TSI OPE

In principle, if any maintenance or design change is affecting operational rules and conditions, the ECM should establish an exchange of information with the RU.

However, it is the RU, with the application of its SMS, who is responsible to check that the vehicle accomplishes the operational constraints to return to operation and respects the conditions for operation: “the Railway Undertaking is responsible for ensuring that the train is technically fit for the journey to be undertaken and remains so throughout the journey” as stated in the Article 4.2.2.5 of the TSI OPE (Commission Decisions 2006/920/EC, replaced by 2011/314/EU and 2008/231/EC),

3.7.3. Interface with NVR Decision

Pursuant to Article 3(t) of the Railway Safety Directive, an entity in charge of maintenance (ECM) is an “entity in charge of maintenance of a vehicle, and registered

as such in the NVR". Article 14a(2) of this Directive also clarifies that: "A railway undertaking, an infrastructure manager or a keeper may be an entity in charge of maintenance". The options in this list are not exclusive.

Therefore, all bodies registered as such in the NVR are ECMs. This may include (without being exclusive): railway undertaking, infrastructure manager, keeper, maintenance workshop or even any industrial or financial body.

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: "The registration holder shall immediately declare any modification to the data entered in the national vehicle register, the destruction of a vehicle or its decision to no longer register a vehicle, to the authority of any Member State where the vehicle has been authorized." (See Annex 3.2.3 of the NVR Decision 2011/107/EU)

3.7.4. Interface with ERATV

All the necessary guidelines will be defined in relevant documents supporting the Commission Implementing Decision 2011/665/EU [23].

3.7.5. Interface with GCU

When applying the Article 19(5) of the GCU it stipulates that *in all cases where the RU carries out, or arranges to have carried out, repair work in application of the provisions of preventive and corrective maintenance (See Appendix 10 of GCU), it shall do so with all due care, making use of approved workshops and approved materials.* The RU shall then provide detailed information of the work carried out to the keeper. If the repair work does not exceed the amount of 750 euros, the RU may carry out work to make the wagon fit for use again without the keeper's agreement (See Article 19(3) of the GCU). The keeper should then be provided with the maintenance records (and the invoice!) after the execution of the repair works of the wagon and should communicate it to its assigned ECM so as to integrate it to the maintenance file of the vehicle. If the cost of repairs is more than 750 EUR, the agreement of the keeper must first be sought, except in the case of brake block replacements (See Article 19(1) of the GCU). In any case, the RU should communicate the damage report of the wagon to the keeper whom in turn notifies it to its ECM. The keeper should seek for the authorisation of its ECM in case the RU decides to undertake the necessary repair works on its own in a (qualified) maintenance workshop.

There could also be specific cases where the ECM requests to the maintenance workshop under control of the RU complementary provisions to the ones already set out in the Appendix 10 of the GCU.

3.7.6. Interface with CSM Risk Assessment

To be completed when revision of CSM Risk Assessment will be adopted (2012).

3.7.7. Interface with Commission Recommendation 2011/217/EU

The sections 5.2.1, 5.2.2 and 8.4 of Commission Recommendation 2011/217/EU [10] explain how to consider maintenance at the level of APIS and at operational level.

ANNEX A : TRACEABILITY MATRIX

This annex provides a traceability matrix between the ECM Regulation and the ECM guidelines (i.e. the present document). The following table might help the concerned actors in their demonstration of compliance with the criteria and requirements set out in the aforementioned Regulation. The absence of traceability means that additional guidance is not deemed necessary with regard to the ECM Regulation or is developed in other guidance/explanatory documents (See also chapter 1.2.).

Table 5 : Traceability matrix between the ECM guidelines and the ECM Regulation.

ECM Regulation [1]	ECM Guidelines (i.e. the present document)	
	Chapter/ Section Ref.	Comments
Article		
1	-	Purpose of ECM Regulation.
2	1.1, 1.2, 3.1.1, 3.1.4	Further information on certification of maintenance workshop can be found in the Application Guide for the Maintenance Workshop Certification Scheme [19]
3	2.3.2	
4	3.3	
4.1(a)	3.3.1	
4.1(b)	3.3.2, 3.3.5.2	
4.1(c)	3.3.3, 3.3.5.1	
4.1(d)	3.3.4, 3.3.5.3	
4.2	3.2.1	
4.3	3.2.2.1, 3.3.6	
4.4	3.2.2.1	
5		
5.1	3.2.2.3	
5.2	3.2.2, 3.4	
5.3	3.2.2.3	Part related to pre-departure checks/inspections
5.4	3.2.2.3	Part related to pre-departure checks/inspections
5.5	3.2.2.3	
5.6	-	Further information on presumption of conformity with the assessment criteria of the CSM on Conformity Assessment related to the demonstration of fulfilment of the requirements governing maintenance and the control of contractors and suppliers can be found in the explanatory document [20]
5.7	3.2.2.3	
5.8	3.3.8	
6	3.1.3, 3.1.4	ECM with subsidiaries in other Member States, case of non-EU certification bodies accredited by non-EU accreditation bodies
6.1	3.2.2.6	
6.2	3.2.2.6	
6.3	3.2.2.8	
6.4	-	Managed through the co-ordination meeting of certification bodies
6.5	-	Managed through the co-ordination meeting of certification bodies
7		
7.1	-	
7.2	-	
7.3		Further information can be found in the Application Guide for the Certification Scheme [17]
7.4		
7.5	-	
7.6	-	
7.7	3.2.2.3, 3.2.2.6	
7.8(a)	-	Further information on presumption of conformity with the assessment criteria of the CSM on Conformity Assessment related to the demonstration of fulfilment of the requirements governing maintenance and the control of contractors and suppliers can be found in the explanatory document [20]
7.8(b)	-	

ECM Regulation [1]	ECM Guidelines (i.e. the present document)	
	Chapter/ Section Ref.	Comments
8		
8.1	3.2.2.1, 3.3.1, 3.3.6	Further information can be found in the Application Guide for the Certification Scheme [17] and the Application Guide for the Maintenance Workshop Certification Scheme [19]
8.2	-	
9	3.2.2.3	
10		
10.1	-	
10.2	-	
10.3	3.6	
10.4	-	
11	-	
12	-	
12.1	-	
12.2	-	
12.3	-	
12.4	-	
12.5	-	
12.6	-	
12.7	-	
13	-	
Annex		
I.1	3.3.6	Further information can be found in the Application Guide for the Certification Scheme [17]
I.2	3.2.2.4, 3.3.6	Further information can be found in the Application Guide for the Maintenance Workshop Certification Scheme [19]
II	-	Further information can be found in the Application Guide for the Sectoral Accreditation Scheme (also known as ECM accreditation scheme) [18]
III.I	3.3.1	
III.II	3.3.2	
III.III	3.3.3	
III.IV	3.3.4	
IV	3.6	
V	3.6	
VI	3.6	