

**Guidance on ECM
certification process**

Guide for the application of Article 14 of Directive (EU) 2016/798 and Commission Implementing Regulation (EU) No 2019/779 on a system of certification of entities in charge of maintenance for vehicles

*In accordance with Article 19(3) of Regulation (EU) 2016/796 of the
European Parliament and of the Council of 11 May 2016*

Released by European Union Agency for railways

This guide does not contain any legally binding advice. 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 [1] and should be helpful for understanding the approaches and rules described therein. However, it does not substitute for them.

The guide is publicly available, and it will be regularly updated to reflect progress with European standards and changes to the ECM Regulation [1].

The reader should refer to the website of the European Union Agency for railways for information about its latest available edition.

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1 INTRODUCTION

1.1 Scope

The guide provides explanations of the provisions within the ECM Regulation [1] and its interfaces with other railway stakeholders. It is intended to support understanding of the approach defined by the legislation. It also incorporates return of experience to illustrate practical applications and lessons learned.

This guide provides information on the application of the 'Commission Implementing Regulation (EU) 2019/779 of 16 May 2019 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011 [1]' as referred to in Article 14(6) and (8) of the Safety Directive [2]. 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 railway stakeholders 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.

This guide has been prepared by the European Union Agency for Railway (ERA) with the support of the Sector and ECM CB via a specific Task force. It represents a developed collection of information gathered by the Agency during internal meetings.

This update of the guide is also aimed to address the changes prompted by the analysis of the [First Agency Report on the assessment of the implementation of the Commission Implementing Regulation \(EU\) 2019/779 of 16 May 2019 on Entities in Charge of Maintenance \(ECM\) of vehicles](#).

1.2 Principle for this guide

Although the guide may appear to be a stand-alone document for reading purposes, it is not a substitute for the ECM Regulation [1]. For ease of reference, when relevant, the related article of the ECM Regulation or the Safety Directive [2] 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.

For further comments please send an email to certificationbody@era.europa.eu.

1.3 Innovation and opportunities related to Digitalization and Sustainability in maintenance

Digitalization and innovation in maintenance is progressing alongside railway technology, while the maintenance system should remain aligned with regulations framework and best practices. These elements should complement each other and incorporate forward-looking considerations for future ECM activities. Sustainability is already an obligation that needs attention of the ECM.

For instance, under the current legislation framework, the maintenance documentation and information, the data recordings and the traceability requirements are considered the cornerstone of a well-structured maintenance system, and the digitalisation supports the modern maintenance systems in ensuring those requirements and protecting the data and recordings from human errors and external threats.

To ensure resilience, safety, and interoperability, a modern maintenance system should also respond to the following key developments:

- ▶ **Data analysis:** Monitoring vehicle parameters and performing remote diagnostics need to be considered as an additional source of data for optimizing maintenance performances
- ▶ **Integration of Digital Twins:** Using virtual models of railway vehicles to simulate wear and predict maintenance needs.
- ▶ **Cybersecurity in Maintenance Data:** Protecting digital maintenance records and IoT-connected systems from cyber threats. Establish a Risk Analysis on your digital data, see NIS-2 Directive (EU) 2022/2555
- ▶ **Sustainability in Maintenance Practices:** Reducing environmental impact by adopting eco-friendly materials, recycling components and optimizing energy usage in maintenance processes.

These opportunities and future considerations will be embedded within the core principles of the legislation framework for ensuring the development of a maintenance system aligned with technology and innovation and also complying with the legislation framework for cross-border railway operations to ensure European harmonization.

2 DOCUMENTS

2.1 What legislative documents, standards and supporting documents are related to ECM certification?

[Ref. N°]	Title	Reference	Version
[1]	Commission Implementing Regulation (EU) 2019/779 of 16 May 2019 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011 (Hereafter called " ECM Regulation ")	(EU) 2019/779	16/06/2020
[2]	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (Railway Safety Directive) (Hereafter called " Safety Directive ")	(EU) 2016/798	23/10/2020
[3]	Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (Hereafter called " Interoperability Directive ")	(EU) 2016/797	28/05/2020
[4]	Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 as amended by Commission Implementing Regulation (EU) 2015/1136 of 13 July 2015. (Hereafter called " CSM-RA Regulation ")	402/2013/EC (EU) 2015/1136	30/04/2013 13/07/2015
[5]	COMMISSION REGULATION (EU) No 1302/2014 of 18 November 2014 concerning a technical specification for interoperability relating to the 'rolling stock-locomotives and passenger rolling stock' subsystem of the rail system in the European Union. (Hereafter called " TSI Loc&Pas ")	(EU) 1302/2014	27/04/2025
[6]	COMMISSION REGULATION (EU) No 321/2013 of 13 March 2013 concerning the technical specification for interoperability relating to the subsystem 'rolling stock-freight wagons' of the rail system in the European Union and repealing Decision 2006/861/EC. (Hereafter called " Wagon TSI ")	(EU) 321/2013	28/09/2023
[7]	Commission Implementing Regulation (EU) 2023/1695 of 10 August 2023 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union and repealing Regulation (EU) 2016/919 (Hereafter called " CCS TSI ")	(EU) 2016/919	08/09/2023
[8]	COMMISSION IMPLEMENTING REGULATION (EU) 2019/773 of 16 May 2019 on the technical specification for interoperability relating to the operation and traffic management subsystem of the rail system within the European Union and repealing Decision 2012/757/EU (Hereafter called " OPE TSI ")	(EU) 2019/773	31/03/2025
[9]	COMMISSION REGULATION (EU) No 1304/2014 of 26 November 2014 on the technical specification for interoperability relating to the subsystem 'rolling stock-noise' amending Decision 2008/232/EC and repealing Decision 2011/229/EU (Hereafter called " NOISE TSI ")	(EU) 1304/2014	28/09/2023
[10]	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	16/07/2021

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[Ref. N°]	Title	Reference	Version
[11]	COMMISSION IMPLEMENTING REGULATION (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council	(EU) 2018/545	16/06/2020
[12]	COMMISSION IMPLEMENTING DECISION (EU) 2018/1614 of 25 October 2018 laying down specifications for the vehicle registers referred to in Article 47 of Directive (EU) 2016/797 of the European Parliament and of the Council and amending and repealing Commission Decision 2007/756/EC	(EU) 2018/1614	25/10/2018
[13]	Commission Regulation (EU) No 1078/2012 of 16 November 2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance (Hereafter called “ CSM Monitoring ”)	1078/2012/EC	16/11/2012
[14]	Commission Delegated Regulation (EU) 2018/761 of 16 February 2018 establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012 (Hereafter called “ CSM Supervision ”)	(EU) 2018/761	16/06/2020
[15]	RID – 2025 The Regulation concerning the International Carriage of Dangerous Goods by Rail (RID) forms Appendix C to COTIF and has an Annex. This Regulation applies to international traffic.	RID 2025	01/01/2025
[16]	DIRECTIVE 2008/68/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 September 2008 on the inland transport of dangerous goods	2008/68/EC	01/07/2022
[17]	ECM certification scheme	ERA-1172-003 V1.1	15/06/2020
[18]	ECM accreditation scheme	ERA -1172-002 V3.1	15/06/2020
[19]	EN 17095 Railway applications – Rolling stock maintenance- Maintenance records	DS/EN 17095/2019	03/2019
[20]	EN 17023 Railway Applications-Railway vehicle maintenance- Creation and modification of maintenance plan	DS/EN 17023: 2018	12/2018
[21]	ISO 9712 “Non-destructive testing — Qualification and certification of NDT personnel”	ISO 9712	Edition 5 12/2021
[22]	Series of standards EN 15085 “Railway applications — Welding of railway vehicles and components”	Series EN 15085	Latest versions
[23]	Railway applications – Adhesive bonding of rail vehicles and their components	EN 17460	2023/01
[24]	EN ISO/IEC 17021-1 “Conformity assessment — Requirements for bodies providing audit and certification of management systems”	EN ISO/IEC 17021-1	2015/08
[25]	EN ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories”	EN ISO/IEC 17025	2018/01
[26]	EN ISO/IEC 17065 Conformity assessment- Requirements for bodies certifying products, processes, or services	EN ISO/IEC 17065	2012/09
[27]	EN ISO/IEC 17000 Conformity assessment – Vocabulary and general principles	EN ISO/IEC 17000	2020/05
[28]	EN ISO IEC 17011 Conformity assessment–Requirements for accreditation bodies accrediting conformity assessment bodies	ISO/IEC 17011:2017	2023
[29]	IAF MD 1:2023 Audit and certification of a Management System Operated by a Multiple-Site Organization	IAF MD 1:2023	2023

2 DOCUMENTS

[Ref. N°]	Title	Reference	Version
[30]	IAF MD 2:2023 Transfer of Accredited Certification of Management Systems	IAF MD 2:2023	2023
[31]	IAF MD 5:2023 Determination of Audit Time of Quality and Environmental Management Systems.	IAF MD 5:2023	2023
[32]	EN 13306:2018 Maintenance terminology	EN 13306:2018	2018
[33]	EN 17018:2019 Maintenance system	EN 17018:2019	2019
[34]	Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010 (Hereafter called “ CSM on SMS ”)	(EU) 2018/762	2018
[35]	Convention concerning International Carriage by Rail (COTIF) of 9 May 1980, as amended by the Protocol of Modification of 3 June 1999 (Vilnius Protocol), administered by the Intergovernmental Organisation for International Carriage by Rail (OTIF)	Adopted by the General Assembly at its 5th session from 26 May to 3 June 1999 (AG 5/3.1 and A 56-01/501.2006) Correction of 31.03.2000 (A 56-01/506.2000) Correction of 29.06.2001 (A 56-01/502.2001) Last unofficial consolidated version on OTIF site	01.07.2006 version of 1.11.2023
[36]	Appendix D to the Convention concerning International Carriage by Rail (COTIF) of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999 — Uniform Rules concerning Contracts of Use of Vehicles in International Rail Traffic (CUV).	Adopted by the General Assembly at its 5th session from 26.05 to 03.06.1999 (AG5-3.1) Correction of 31.03.2000 (A 56-01/506.2000) – Correction of 29.06.2001 (A 56-01/502.2001) Modifications adopted by the Revision Committee at its 25th session from 25 to 26.06.2014 (A 55-25/506.2014 and CR 25/NOT/Add.2) Last unofficial consolidated version on OTIF site	01.07.2015 version of 1.7.2015

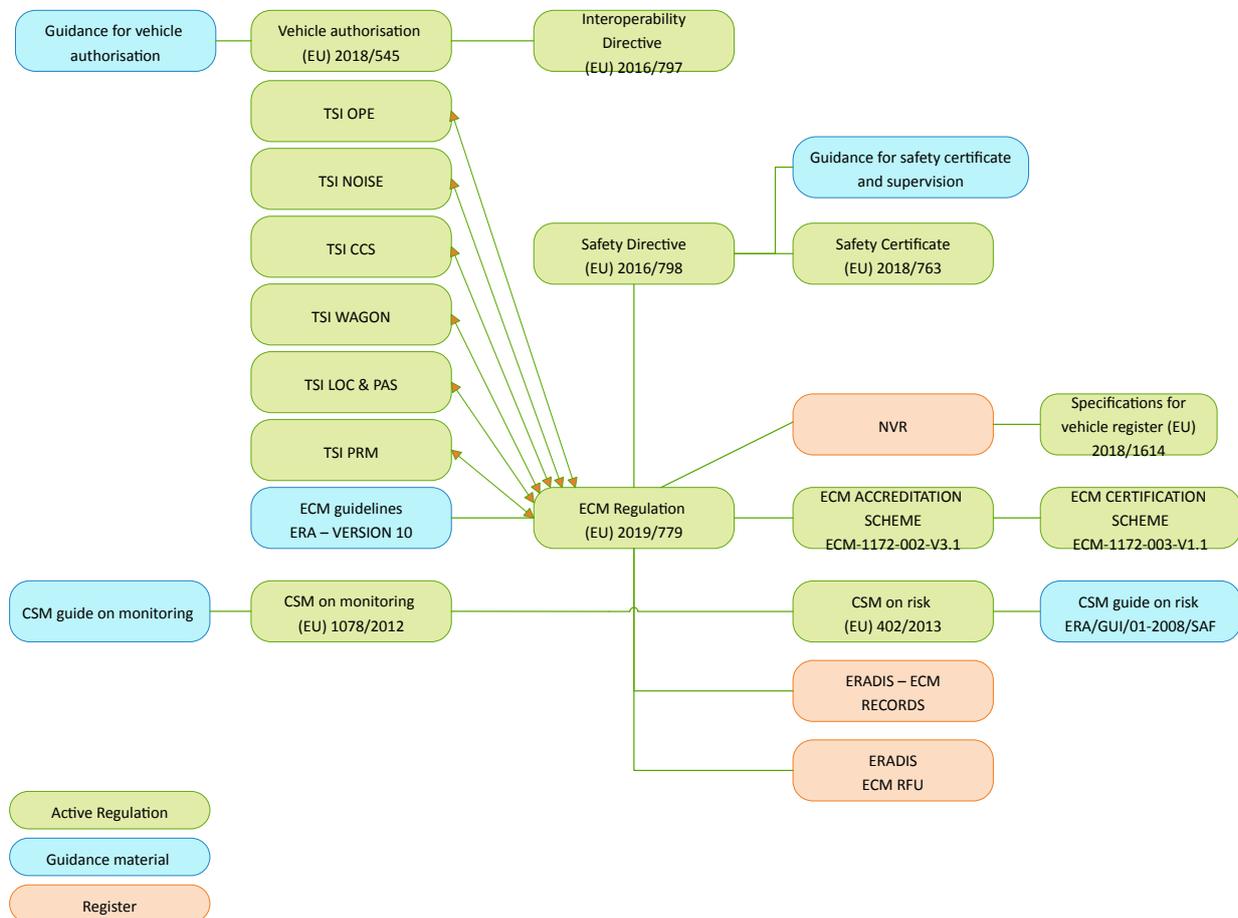
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[Ref. N°]	Title	Reference	Version
[37]	General Contract of Use for Wagons (GCU), effective from 1 July 2006, established as a multilateral agreement between railway undertakings and wagon keepers, based on the Uniform Rules concerning Contracts of Use of Vehicles in International Rail Traffic (CUV – Appendix E to COTIF 1999).	GENERAL CONTRACT OF USE FOR WAGONS GCU Edition dated 1 January 2025	01/01/2025
[38]	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 Regulation	17/06/2008
[39]	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 Regulation	11/01/2009
[40]	Commission Implementing Regulation (EU) 2018/763 of 9 April 2018 establishing practical arrangements for issuing single safety certificates to railway undertakings pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council	(EU) 2016/798	31/05/2018
[41]	Guidance for safety certification and supervision (Hereafter called “ Supervision guide ”)	Supervision guide	2022
[42]	Commission Regulation (EU) No 1300/2014 of 18 November 2014 on the technical specifications for interoperability relating to accessibility of the Union’s rail system for persons with disabilities and persons with reduced mobility. (Hereafter referred to as “ TSI PRM ”)	(EU) 1300/2014	28/09/2023
[43]	ISO 9879:2024 Railway applications–Rolling stock maintenance–Vocabulary	ISO 9879:2024	2024
[44]	EN 17018:2019 Railway applications–Rolling stock maintenance–Terms and definitions	EN 17018:2019	2019
[45]	ISO 22163:2023–Railway applications–Railway quality management system–ISO 9001:2015 and specific requirements for application in the railway sector	ISO 22163:2023	07/2023
[46]	CEN/TR 17696:2021 – Railway applications — Vehicle Maintenance — Guide for identification and management of Safety Critical Components for railway vehicles	CEN/TR 17696:2021	01/10/2021
[47]	EN 50126-1:2017–Railway Applications–The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS)– Part 1: Generic RAMS Process	EN50126-1-2017	11/2017
[48]	EN 50126-2:2017–Railway Applications–The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS)– Part 2: Systems Approach to Safety	CENELEC 50126-2:2017	01/10/2017
[49]	EN 50129:2018–Railway applications–Communication, signalling and processing systems–Safety related electronic systems for signalling	CENELEC 50129-2:2018	01/11/2018
[50]	ISO 14731:2019–Welding coordination–Tasks and responsibilities	ISO 14731:2019	02/2019
[51]	EN 17460:2022–Railway applications–Adhesive bonding of rail vehicles and their components	EN 17460:2022	09/09/2022
[52]	ISO 9001:2015–Quality management systems–Requirements	ISO 9001:2015	09/2015
[53]	ISO 14001:2015–Environmental management systems–Requirements with guidance for use	ISO 14001:2015	09/2015

2.2 What documents do you need to have in mind?

Here you can find the diagram describing the different regulations and the schemes associated:

Figure 1 Diagram describing different regulations



The different standards supporting the accreditation and recognition process of ECM certification bodies and ECM certification are:

- ▶ EN ISO/IEC 17065:2012 [26] Conformity assessment- Requirements for bodies certifying products, processes or services
- ▶ EN ISO/IEC 17021-1:2015 [24] Conformity assessment- Requirements for bodies providing audit and certification of management systems — Part 1: Requirements
- ▶ EN ISO/IEC 17025:2005 [25] General requirements for the competence of testing and calibration laboratories
- ▶ EN 17095 [19] Railway applications – Rolling stock maintenance- Maintenance records
- ▶ EN 17023 [20] Railway applications–Railway vehicle maintenance- Creation and modification of maintenance plan
- ▶ EN ISO/IEC 17000:2020 [27] Conformity assessment – Vocabulary and general principles
- ▶ IAF MD 1:2023 [29] Audit and certification of a Management System Operated by a Multiple-Site Organization
- ▶ IAF MD 2:2023 [30] Transfer of Accredited Certification of Management Systems

- ▶ IAF MD 5:2023 [31] Determination of Audit Time of Quality and Environmental Management Systems.

The accreditation and recognition scheme [18] [ECM accreditation scheme](#) precises in part 3.1.3.c the knowledge and skills addressing assessment principles, practices and techniques, and knowledge of the specific standards related to them.

The above documents should be understood as the latest valid version of each document – in case of modifications, the latest version applies.

2.3 Do you know the Wagon and LOC&PAS TSIs?

The Technical Specifications for Interoperability (TSIs) define the technical and operational standards which must be met by each subsystem or part of a subsystem in order to meet the essential requirements and ensure the interoperability of the railway system of the European Union.

The TSI LOC&PAS concerns the rolling stock subsystem and applies to the following types of rolling stock:

- ▶ Self-propelling thermal or electric trains.
- ▶ Thermal or electric traction units.
- ▶ Passenger carriages.
- ▶ Special vehicles, such as on-track machines (OTMs).

The TSI Wagon concerns the rolling stock subsystem and applies to freight wagons, including vehicles designed to carry lorries.

More information on these TSIs can be found at

https://www.era.europa.eu/activities/technical-specifications-interoperability_en

3 DEFINITIONS

3.1 Common acronyms in the day – to–day life in the ECM certification

Acronym	Meaning
AB	Accreditation Body
ACB	Accredited Certification Body
APOM/APIIS	Authorisation for the Placing on the Market / Placing in Service (of structural subsystems and vehicles)
CA	Conformity Assessment
CAB	Conformity Assessment Body
CSM	Common Safety Methods
CUV	Contract of Use of Vehicles
EA	European co-operation for Accreditation (http://www.european-accreditation.org)
EA (MLA)	EA Multi-Lateral Agreement
EC	European Commission (http://ec.europa.eu/index_en)
ECM	Entity in Charge of Maintenance
ECM–F1	Management function
ECM–F2	Maintenance Development function
ECM–F3	Fleet Maintenance Management function
ECM–F4	Maintenance Delivery function
EEA	European Economic Area
EFTA	European Free Trade Association (http://www.efta.int)
EMS	Electromagnetic System
EN	European Norm
ERA	European Railway Agency (http://www.era.europa.eu)
ERATV	European register of authorised types of vehicles referred to in Article 34 of Interoperability Directive (Commission Implementing Decision 2011/665/EU)
ERADIS	European Railway Agency Database of Interoperability and Safety
EVN	European vehicle Number
EVR	European Vehicle Register
EU	European Union
EVIC	European Visual Inspection Catalogue
EWT	European Wheelset traceability catalogue
GCU	General Contract of Use (http://www.gcubureau.org)
IAF	International Accreditation Forum (http://www.iaf.nu/)

GUIDANCE ON ECM CERTIFICATION PROCESS

Acronym	Meaning
(IAF) MD	Mandatory document of IAF
IM	Infrastructure Manager
IOD	Interoperability Directive
ISA	Independent Safety Assessment Body
ISO	International Organization for standardization
IT	Information Technology
LNG	Liquefied Natural Gas
MLA	Multilateral Agreements
MoU	Memorandum of Understanding
MRA	Mutual Recognition Agreements
MS	Member State
NAB	National Accreditation Body
NDT	Non-Destructive Test
NIB	National Investigation Body
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)
OTM	On-Track Machine Operation and maintenance
O&M	Operations and Maintenance
PA	Practical Application
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail, as adopted under Directive 2008/68/EC.
RFU	Recommendations for use (https://eradis.era.europa.eu/safety_docs/ecm/recommendationsForUse/default.aspx)
RS	Rolling Stock
RSD	Railway Safety Directive
RU	Railway Undertaking
SA	Safety Authorisation
SAIT	Safety Alert IT-Tool
SCC	Safety-critical components
SMS	Safety Management System
SSC	Single Safety Certificate
REX	Return of Experience
RTS	Release to Service
RTO	Return to Operation

4 VEHICLE AND MAINTENANCE

4.1 Which vehicles fall under the ECM Regulation [1]?

► 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.

Each freight wagon must have been assigned a unique EVN and one ECM in charge of this wagon in the EVR¹. As it is permissible in certain circumstances to assign a single EVN to a fixed formation of two or more wagon units (defined as multiple wagons in [6] and [12]), it is in turn possible that a “wagon”, from the perspective of the ECM can consist of more than one element. In each case, the EVN and the associated entry in the EVR will be the binding definition of what constitutes an individual “wagon”.

Figure 2 Example of a unit consisting of a (freight) wagon that can be operated separately, featuring an individual frame mounted on its own set of wheels.



¹ The EVR is the centralized EUwide register of railway vehicles, progressively replacing the NVRs maintained by Member States. While NVRs remain operational during the transition, the EVR is now the official reference managed by ERA.

Figure 3 Example of a freight wagon.



► **Locomotives (thermal or electric traction units)**

Locomotives (mentioned in TSI Loc&Pas §2.3.1) consists in the engine of a train designed for pulling or, sometimes, pushing a train or individual railway cars or freight wagons. These traction vehicles are not capable of carrying a payload. They are intended for freight and/ or passenger transport. Power sources can be one, or a combination, of the following: diesel engine, steam, electricity, LNG, battery or hydrogen (non-exhaustive list).

Figure 4 Example of a freight locomotive that is powered by electricity.



► Multiple units/Trainset

Multiple units or trainsets (mentioned in TSI Loc&Pas §2.3.1) consist of several vehicles formed into a fixed formation or set, with their own means of propulsion, and do not require a locomotive. Depending on the power source, these multiple units are sometimes known as Electric Multiple Units (EMUs), Diesel Multiple Units (DMUs), and Battery Electric Multiple Units (BEMUs). Other power sources and hybrids also exist, e.g. battery and hydrogen or LNG.

Figure 5 Example of an Electric Multiple Unit.



► Passenger coaches

Passenger coaches (mentioned in TSI Loc&Pas §2.3.1) are vehicles that contain no traction power and thus rely on locomotives to push or pull them. Their primary purpose is the transportation of passengers.

► Special vehicles

Special Vehicles are in the scope of the TSI Loc&Pas and shall demonstrate compliance with the requirements of the TSI when in running mode, and when:

- running on their own rail wheels (in running mode self-propelled or hauled), and
- designed and intended to be detected by a track-based train detection system for traffic management

Specific requirements laid down in chapter 4 and Appendix C for OTMs in the TSI Loc&Pas are also applicable to Infrastructure Inspection Vehicles, unless they are designed to be integrated into a fixed passenger train formation; in this case, they should be considered as non-passenger-carrying vehicles as defined in point (A) (3) of the TSI Loc&Pas.

Figure 6 Example of an On-Track Machine, often painted bright yellow.



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Figure 7 Example of an On-Track Machine.



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► Special cases

Case of TRAM –TRAIN

A tram-train is a public transport concept that allows for a combined operation on both light-rail infrastructure and heavy-rail infrastructure. When tram-trains use railway infrastructure, compliance with all essential requirements should be ensured, as well as compliance with the expected safety level on the relevant lines.

Figure 8 Example of tram-train.



4.2 What are the exclusions of vehicles from the application of ECM Regulation [1]?

It must be noted that some vehicles are excluded from the application of Commission Implementing Regulation 2019/779:

- Vehicles corresponding to the cases stated in the Article 2(2) of Safety Directive [2]. (Example: metros.)
- Upon decision of the MS when transposing Safety Directive, vehicles corresponding to the cases stated in Article 2(3) of Safety Directive. (Example: vehicles reserved for strictly local, historical, or tourist use. This reflects a choice by MS when transposing Safety Directive.)
- Upon derogation identified and justified in the NSA annual report according to Article 19 of Safety Directive, vehicles corresponding to the cases stated in the art 15(1) of Safety Directive. (Example: freight wagons operated under international agreement with third countries on the 1520 mm system. This reflects a choice by MS.)

As these vehicles are excluded from the scope of the ECM regulation and these categories are not foreseen in the certificate forms of Annex IV of the ECM Regulation, no certificates may be

granted to Entities in Charge of the Maintenance (ECMs) for these vehicles only, nor referring to them on certificates covering other vehicles that fall within the scope.

Nevertheless, voluntary assessment of maintenance management systems, according to the requirements of Annex II of the ECM Regulation, may be provided by certification bodies under the same conditions as foreseen in the certification scheme.

In this case however, the attestations possibly granted after the assessments shall not be called “certificate” and will not be registered in the ERADIS database.

4.3 What is an ECM?

Before a vehicle is used for the first time, and after the vehicle authorisation for placing on the market is released, an ECM has to be assigned and registered in the vehicle register in accordance with Article 47 of Interoperability Directive. (see also [Chapter 15](#))

The ECM shall ensure the vehicles for the maintenance of which it is in charge are in safe state of running, by means of the establishment of a maintenance system.

The maintenance system shall be composed of four functions (see [Section 4.9](#)).

In accordance with Article 3(1) of the ECM Regulation [1], any ECM shall satisfy the requirements of Annex II with respect to all vehicles subject to Safety Directive [2].

The vehicle keeper, registered as such in the EVR, is responsible for changing the ECM of a vehicle or a fleet of vehicles. (see also [chapter 9.1](#))

4.4 Who can be an ECM?

The ECM is the body registered as such in the EVR. There are no conditions of nationality to become an ECM. Even an ECM established outside the EU can provide maintenance to vehicles used on the railway system of the EU, provided that it is certified under the ECM Regulation [1].

4.5 How many ECMs can a vehicle have?

Article 47 of Interoperability Directive provides that the EVR is to contain, for each EVN, among other compulsory information, the identification of the owner, the keeper, and the **entity in charge of maintenance** of the vehicle.

Commission Implementing Decision (EU) 2018/1614 establishes the requirements for the information to be contained in the EVR and, **for each vehicle, the data relative to the ECM (and not several ECMs)** has to be compulsorily fulfilled. Therefore, a vehicle can only have **one ECM** assigned in the EVR at any given time.

4.6 What is an outsourced maintenance function?

An outsourced maintenance function is a relevant party involved in the process of vehicle maintenance, providing one or more of the functions as outlined in [chapter 9](#). The outsourced maintenance function does always need to consider the requirements of ECM-F1 adapted to the organisation's type and extent of service.

The outsourced maintenance function performs its scope as per its functions and as contracted by the ECM. An outsourced maintenance function can supply its services for one or more ECMs.

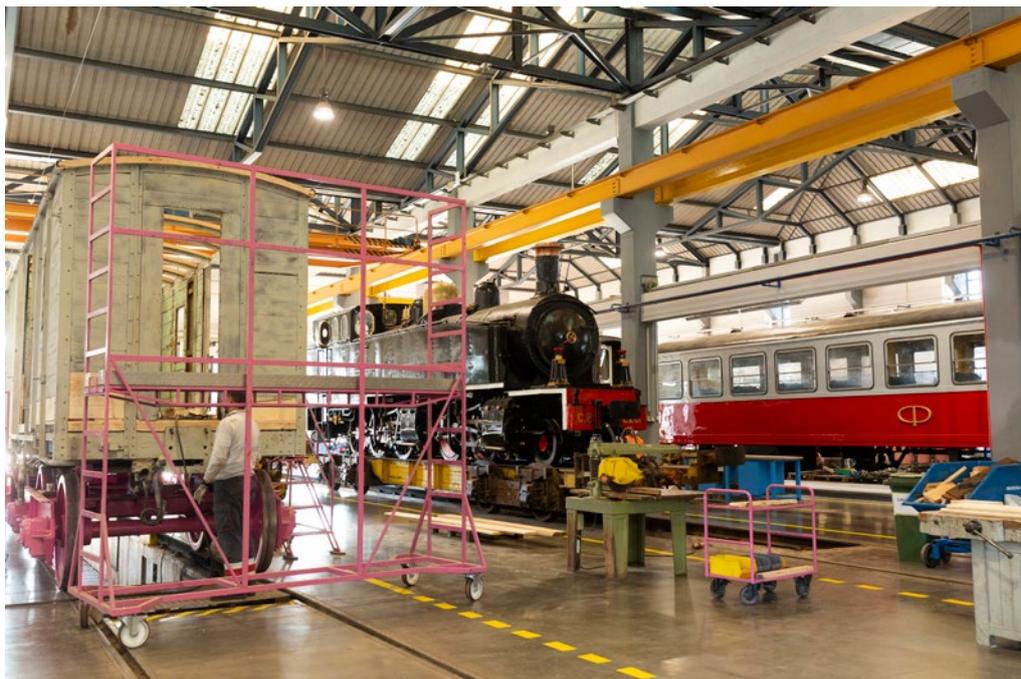
The outsourced maintenance function is responsible for the contracted part of the vehicle maintenance processes/activities under its provided functions. The entity in charge of maintenance is responsible for the outcome of the outsourced maintenance activities and shall establish a system to monitor their performance.

An outsourced maintenance function may request a voluntary certification according to Article 10 of ECM Regulation [\[1\]](#).

Examples of outsourced maintenance functions are i.e.: service providers which manage the maintenance files, parts of the maintenance development for an ECM or maintenance workshops or mobile maintenance teams providing their services to various ECM's or other service providers such as manufacturer of components/subsystems.

4.7 What is a maintenance workshop?

Figure 9 Fixed entity



© ERA

Figure 10 Mobile entity

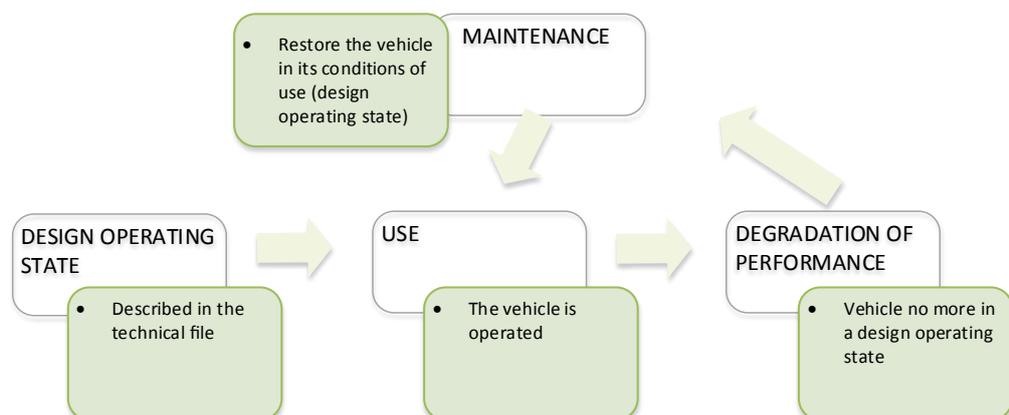


A maintenance workshop is a mobile or fixed entity having a management responsibility, staff, tools and facilities necessary to carry out maintenance operations on the vehicle itself or on parts and components of the vehicle. Mobile teams, either depending on a fixed structure where maintenance work is performed or being self-supporting, and fulfilling the requirements of the definition of a maintenance workshop as defined hereinbefore, are assimilated to maintenance workshops. (see also [chapter 5.7](#) multisite)

A maintenance workshop may be in charge of the whole maintenance delivery function (ECM-F4) or parts of it, as described in the Article 14(3)(d) of the Safety Directive [\[2\]](#).

4.8 What does “maintenance” mean?

Figure 11 What does “maintenance mean?”



Maintenance, as a functional subsystem (see Annex II of the IOD) of the Union rail system, is defined according to Interoperability Directive as the procedures, associated equipment, logistics centres for maintenance work, and reserves providing the mandatory corrective and preventive maintenance to ensure the interoperability of the Union rail system and guarantee the required performance.

In accordance with:

- ▶ EN 13306:2018 [32], *Maintenance terminology* defines maintenance as the combination of all technical, administrative and managerial actions during the life cycle of an item², intended to retain it in, or restore it to, a state in which it can perform the required function.
- ▶ EN 17018:2019 [33], *Maintenance system* is a complete set of technical, organisational and other specifications for fulfilment of the vehicle maintenance to ensure that the vehicles which are maintained are in a safe state of running.

The design operating state:

(Definition in the TSI wagon [6]) The 'design operating state' covers all conditions under which the unit is intended to operate and its technical boundaries. This design operating state may go beyond the specifications of the TSI in order that units may be used together in a train on the network under the safety management system of a railway undertaking.

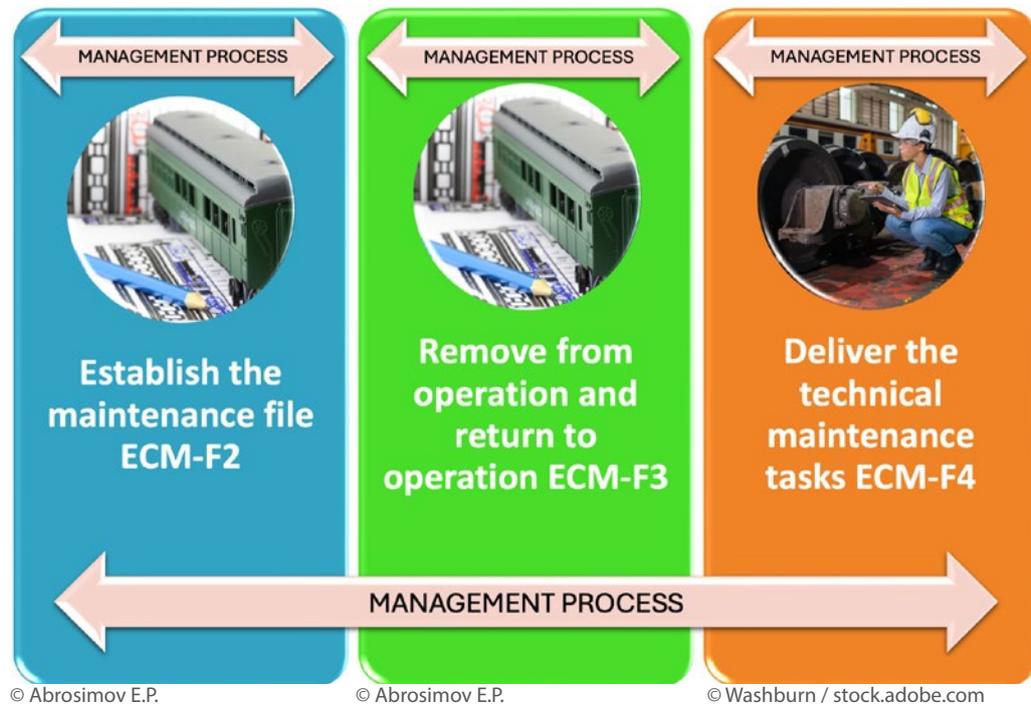
It means a state when a vehicle, subsystem, or part of subsystem is performing a required function for which it has been designed, manufactured and tested. It includes at least the nominal operating mode, it may include degraded operating modes, provided these modes have been designed, implemented and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

When the vehicle is used, it will be subject to wear and tear or may get more or less damaged and therefore will not remain fully conform to its design operating state. The goal of maintenance is to retain or restore this vehicle in its design operating state

² Item to be read as vehicle/component.

4.9 What is a maintenance system?

Figure 12 Management process

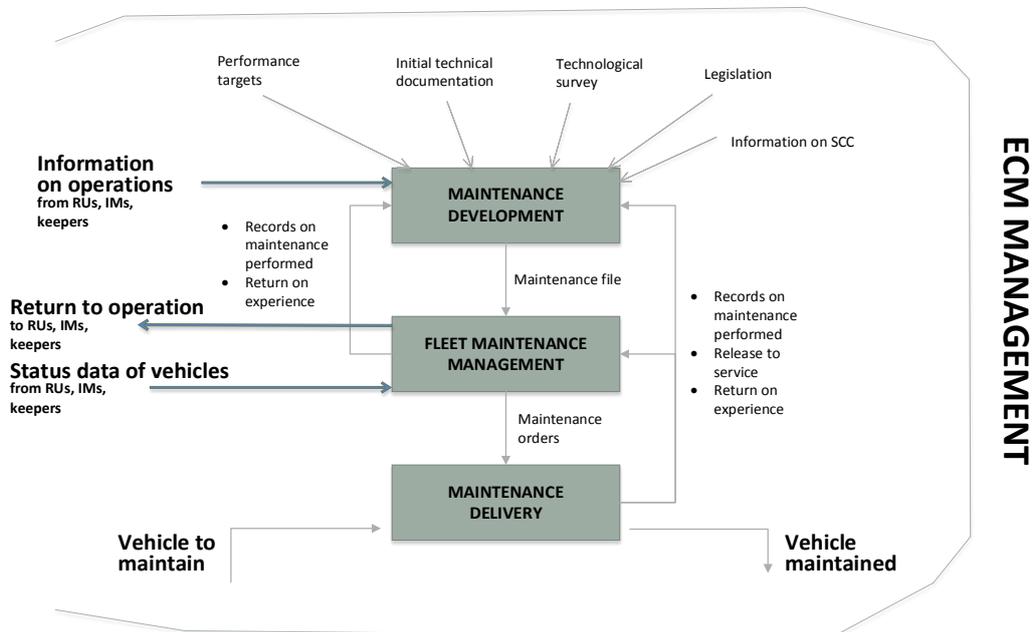


According to article 1(1) of the ECM Regulation [1], the maintenance system shall be composed of the following functions:

- the **ECM-F1**, which **supervises** and **coordinates** the maintenance functions referred to in points (b) to (d) and ensures the safe state of the vehicle in the railway system.
- the **ECM-F2**, which is responsible for the management of the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return on experience.
- the **ECM-F3**, which manages the vehicle's removal for maintenance and its return to operation after maintenance; and
- the **ECM-F4**, which delivers the required technical maintenance of a vehicle or parts of it, including the release to service documentation.

These 3 last functions are coordinated in the maintenance system through a **MANAGEMENT PROCESS**.

Figure 13 Management process



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

4.10 What is ECM-F1?

The Management Function ECM-F1 shall supervise and coordinate the functions ECM-F2, ECM-F3 and ECM-F4 of the ECM and ensure the safe state of the vehicle.

The ECM-F1 has, next to the requirements of Annex II.I of the ECM Regulation [1], two main duties:

- ▶ Coordination of the functions ECM-F2, ECM-F3 and ECM-F4, as defined in Article 14(3) of the Safety Directive [2], allowing the organization to achieve the maintenance targets defined in the Maintenance System (e.g. in the Maintenance Policy).
- ▶ Monitoring of the functions ECM-F2, ECM-F3 and ECM-F4 as defined in Article 14(3) of the Safety Directive, granting the conformity against legislation and standards and allowing the organization to improve its Maintenance System.

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

Coordination activities shall be performed according to processes and procedures defined within the Maintenance System. These provisions shall take into account the use of contractors to implement the functions, the allocation of responsibilities, the management and exchange of information, the management of documents and their traceability, the

management of staff competence, the definition of strategies and plans to define and to achieve the maintenance targets, etc.

ECM-F1 checks the implementation of the Maintenance System by defining a systematic monitoring process, based on the CSM for Monitoring [13], to check the performances of the ECM in the field of maintenance (and safety, as a consequence). When needed, the ECM-F1 creates the conditions to correct or to improve the maintenance performance by defining and implementing changes in the Maintenance System.

The impact of those changes on the maintenance processes shall be evaluated according to the CSM-RA Regulation [4]. Monitoring can be performed through checks of process results if a maintenance function is certified (Chapter 5)

A decision-making process should be managed by ECM-F1 on the basis of the results of the assessments of shared and owned risks. An initial process-based risk assessment, or equivalent, shall be used to identify such risks, whereas the CSM-RA Regulation [4] shall be used for all changes and the CSM Monitoring [13] shall be used for monitoring during the O&M phase.

4.11 What is ECM-F2?

During the lifecycle of the vehicle, the Maintenance Development Function (ECM-F2) covers the management of the maintenance documentation, including configuration management, based on design and operational data, as well as on required performance and return on experience.

It also covers the compliance with interoperability rules and the establishment and continuous updating of the maintenance file. (see also chapter 7 for maintenance file)

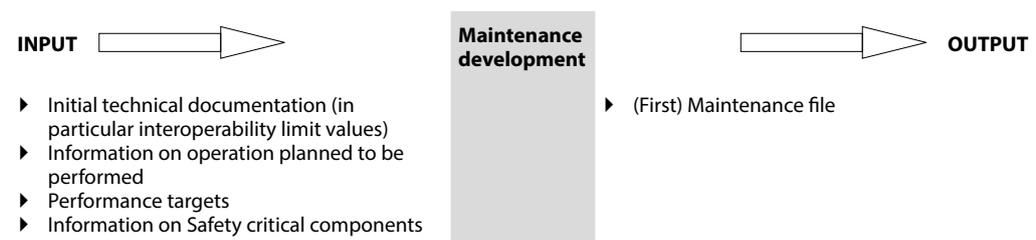
The maintenance development process can be described as follows:

► **At the moment when operation starts:**

The initial development of the maintenance file depends on the initial technical documentation (see chapter 7.2) and the pattern of operations planned.

The process may be described as following:

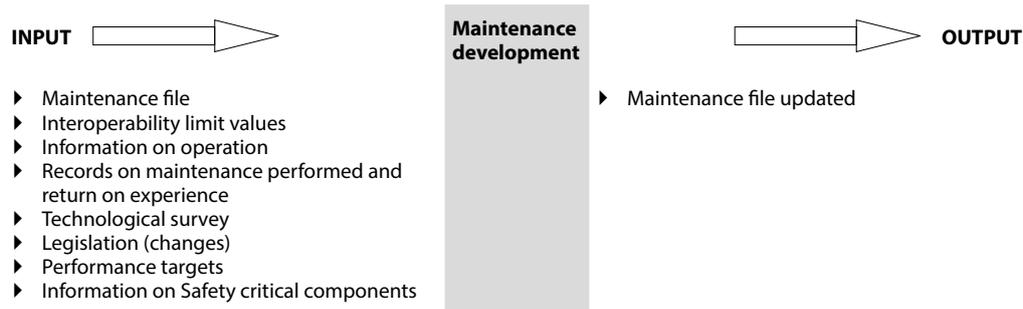
Figure 14 First maintenance file



When operation starts it is necessary to check if the initial technical documentation supplied by the manufacturer 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

Figure 15 Maintenance file updated



In accordance with Annex II.11.5 of the ECM Regulation [1], the update of the maintenance file (see also [chapter 7](#) for maintenance file) depends on:

- The limit values that have to be maintained to ensure the interoperability of the vehicle according to its authorisation for placing on the market/placing in service. These values are stated in the initial technical documentation and in every update of this documentation justified by a change in the design of the vehicle.
- Information on operation such as but not limited to:
 - Behaviour of the vehicle during operation.
 - type and extent of operations (passenger 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.
 - detected failures on components.
 - 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...)
 - behaviour and skills of drivers.
- Records of maintenance already performed, on inspections performed by RUs, IMs, keepers, ECM, owners and on studies related to return of experience. ECM-F4 is often requested to take part in return on experience studies.
- Technological survey. The lifecycle of rolling stock extends to 40-50 years. Technology evolves significantly during this long lifecycle. The technological survey may include:
 - Condition based monitoring. This monitoring considers the behaviour of the different components.

- Technological progress that includes the continuous progress of:
 - materials,
 - equipment,
 - spare parts,
 - tools and industrial equipment,
 - IT systems,
 - working and management methods.
- Availability of materials, equipment and spare parts. Spare parts or materials may become obsolete or unavailable. Generally, manufacturers give 10 years assurance regarding availability of electrical/electronic devices. Therefore, at a certain point, equivalent spare parts or materials have to be found.
- ▶ Evolution of applicable legislation:
 - Railway,
 - Environment,
 - Health and safety,
 - Safety of components,
 - Etc.
- ▶ Performance targets imposed by users (RU, IM, keeper):
 - reliability and availability of vehicles,
 - safety.

After taking into account all information, ECM-F2 updates the maintenance file (where relevant) and disseminates the updated documentation within the Maintenance System.

It should be pointed out, however, that the replacement of components with better functions or with better performance requires the evaluation process referred to in Article 16 of Regulation (EU) 2018/545. Regulation (EU) 2018/545 obliges the “entity managing the change” (holder of the authorized type of vehicle or other entity) appointed by the Owner/ Keeper to apply the CSM-RA Regulation [\[4\]](#).

The change manager may be ECM-F2, or other entity contractually assigned through the Owner/ Keeper. Moreover, it has to be noted that in the case ECM-F2 operates as change manager, the above-described change process is not covered by ECM Regulation [\[1\]](#).

4.12 What is ECM-F3?

Fleet Maintenance Management (ECM-F3) covers the removal from and return to operation before and after maintenance, as well as the management of relations with ECM internal/ external entities delivering maintenance (ECM-F4).

Return to operation is only possible when maintenance operations are completed, and the vehicles are back in a safe state of running. Regarding the exchange of information, the information on the completeness of maintenance activities performed on the vehicle must be received from ECM-F4. This is done through the **release to service**, which is the confirmation of the maintenance delivery that the maintenance activities ordered are completed.

ECM-F3 may be defined as the management of a company's vehicle fleet. Fleet Maintenance Management is then the part of the fleet management dedicated to the maintenance of vehicles.

This function means, in particular, the responsibility for:

- ▶ Applying the maintenance file to the vehicles through maintenance orders addressed to the maintenance delivery.
- ▶ Collecting and transferring to Maintenance Development information on maintenance and operations performed, including at least: defects, incidents, accidents and mileage.

The inputs for the ECM-F3 are:

- ▶ The maintenance file.
- ▶ The performance targets imposed by users (RUs, IMs, keepers), such as the reliability and availability of vehicles.

ECM-F3 must check the availability of the maintenance delivery. ECM-F3 will have the duty to ensure that maintenance orders are addressed only to duly qualified entities performing maintenance delivery.

The outputs of ECM-F3 processes are:

- ▶ Maintenance orders addressed to the maintenance delivery. The maintenance orders are addressed by applying internal procedures when ECM-F3 and ECM-F4 are both internal to the ECM and by contracts in other cases. Maintenance orders contain the complete information issued from the maintenance file that is necessary to perform the maintenance tasks required from the maintenance delivery.
- ▶ The organisation for the return to operation of the vehicle in due time, including any delays occurred in the maintenance work resulting in the implementation of additional provisions for ensuring a safe state of running to the vehicle.

ECM-F3 is responsible for declaring the vehicle fit for purpose (with or without restrictions of use) and fit for its RTO after the maintenance work has been completed by ECM-F4. This RTO is finally addressed to RUs generally through the keeper.

4.13 What is ECM-F4?

Maintenance Delivery (ECM-F4) is the technical execution of the ordered technical maintenance tasks. ECM-F4 may be done in Maintenance Workshops. ECM-F4 covers the management of maintenance orders issued by ECM-F3, the management of the supply chain,

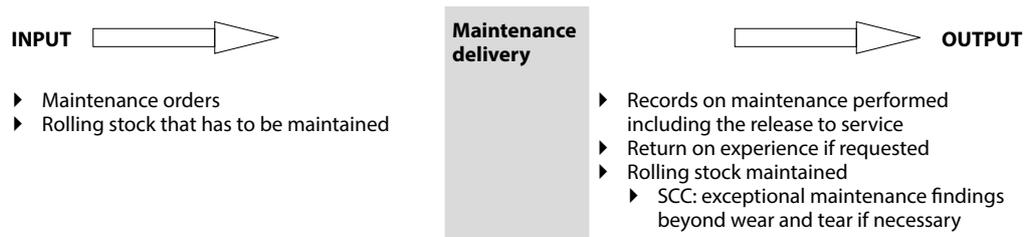
the management of facilities, industrial equipment and tools, management of competencies and the management of maintenance technical works.

This function means the technical execution of tasks/works defined in the maintenance file and ordered by the Fleet Maintenance Management. ECM-F4 must be competent to perform the maintenance works/tasks requested in the orders.

Generally, after completion of a maintenance order coming from ECM-F3, ECM-F4 addresses a report including: a summary of the activities performed, information about limitation affecting the operating state of the vehicle, and the release to service. This report may also be addressed directly to ECM-F2.

There is a huge need to request not only delivery but also information on return of experience between the ECM-F1 and ECM-F4. The requirements addressing the return on experience are based on the requests from ECM-F2 and should be part of the maintenance orders.

Figure 16 Maintenance delivery



4.14 What is release to service and return to operation?

Release to service

The “Release to Service” (RTS) is the confirmation by ECM-F4 to ECM-F3, that all maintenance work ordered has been performed according to the maintenance documentation. This confirmation can be noticed as documented information in paper or a defined electronic information channel. It must be traceable.

ECM-F3 defines what maintenance records are needed for the completion of the task. It delivers these documents together with its maintenance order as a basis for establishing an “RTS notice”. ECM-F4 executes the ordered work, completes the maintenance records and reports discovered but unresolved safety related deficiencies.

In addition to the formal RTS notice, the following information may possibly be needed by ECM-F3:

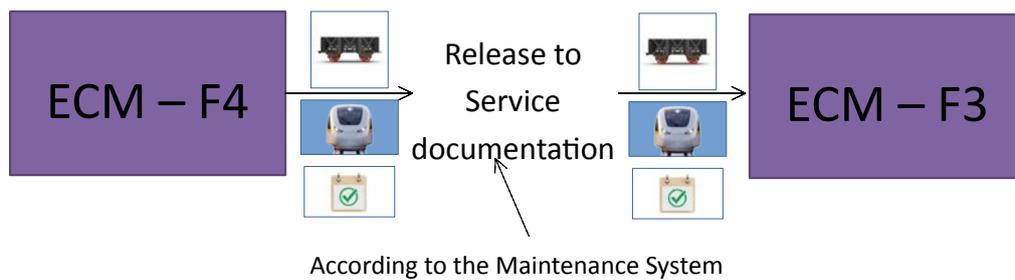
- ▶ Records on work performed incl. any findings, (extra-)time for execution, etc.
- ▶ Records of unplanned work performed due to findings and incl. the release by ECM-F4.
- ▶ Records on final vehicle testing.

- ▶ Records on main component testing (incl. used testing devices).
- ▶ Lists of exchanged parts (incl. their exact identification).
- ▶ List of deficiencies related to safety.
- ▶ List of deficiencies related to reliability, if requested.
- ▶ Any information on vehicle or component condition, as requested by ECM-F3 (in case of condition-based maintenance).

The RTS notice shall provide all relevant information concerning the maintenance activities affecting the vehicle. ECM-F4 delivers the RTS notice via the agreed channel to ECM-F3 and to ECM F2.

When this is completed, the vehicle is ready to leave the workshop and physically go back to commercial operation, however for this the “notice of return to operation” is issued by ECM-F3 (see next chapter).

Figure 17 Release to Service



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Return to operation

According to the definition, return to operation is issued on basis of the release to service. Thus, the release to service and return to operation should be treated as related records.

The “Return to Operation” is considered as a sensitive topic. It is formally the confirmation of the ECM that the vehicle is in a safe state for operation. The RU shall operate the vehicle on the network only with a “Return to Operation Notice”.

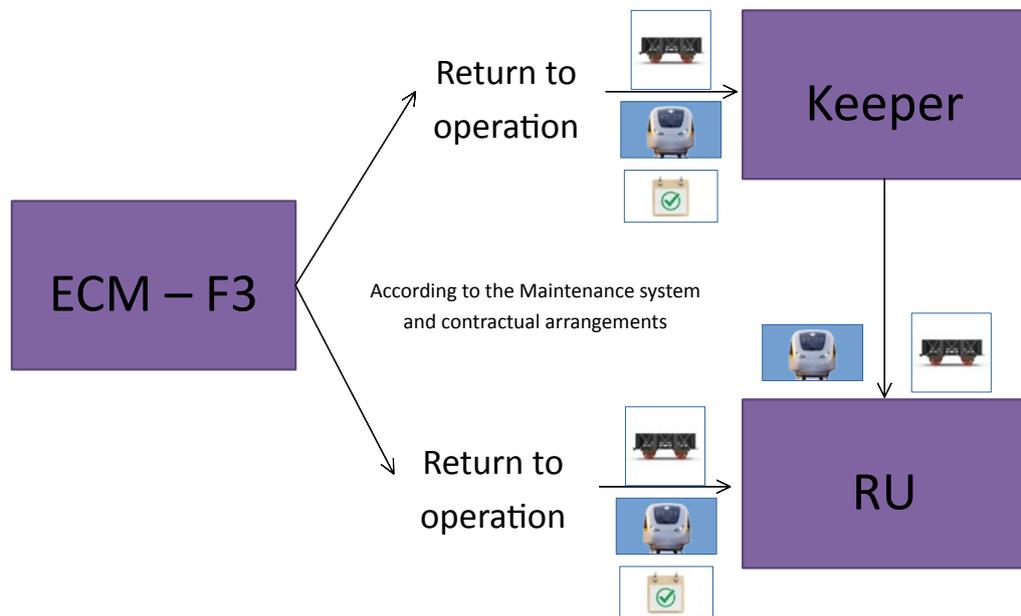
A formal approach would suggest that the vehicle is transferred by the ECM to the Keeper. Further the vehicle is transferred from the keeper to the RU, which is responsible to use correctly the vehicle. In reality, the vehicle is brought to an agreed transfer point, where from it is taken into commercial use after establishing the “return to operation notice”.

ECM-F3 establishes the Return to Operation Notice based on the Release to Service documentation from ECM-F4. The duty is to check the documentation for completeness and to clarify whether safety-relevant defects are listed which might cause a restriction of use. The Return to Operation Notice can be noticed as documented information in paper or a defined electronic information channel. It must be traceable.

The definition of the return to operation (Article 2(d) of the ECM Regulation [1]) states that it is possible to send the return to operation to the RU or to the keeper. Especially when a restriction of use is necessary it is the duty of ECM-F3 to make this available to the responsible RU or via keeper upon contractual agreement.

It is a duty of RUs to consider the information included in the Return to Operation in order to establish the restrictions for use to be applied for ensuring the operation of the vehicle in a safe state.

Figure 18 Return to operation



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In the reality the keeper is not practically involved in this process, so there is a functional direct contact between ECMs and RUs. **To avoid confusion in the distribution of responsibilities, only the RTO notice including the restrictions on use (where applicable) should be given to the RU.**

The minimum information that the keeper should receive is reported in [4.14.2](#)

4.14.1 Proposal of a minimum set of information to be exchanged during the “Release to Service.”

Minimum set of information to be addressed to the ECM-F3:

Figure 19 Minimum set of information to ECM-F3

1 Workshop	<i>(Name of the workshop)</i>
2 12 Digits vehicle N.	<i>(EVN)</i>
3 Check in date	<i>(Date of the check in of the vehicle in the workshop)</i>
4 Check out date	<i>(Date of the check-out of the vehicle (workshop))</i>
5 Maintenance File	<i>(Reference to the adopted maintenance file)</i>
6 Derogation against the technical instructions?	YES / NO
<i>Description of the derogation</i>	
7 List of safety related deficiencies as base for ECM-F3 for restrictions	
<i>This field contains the Safety related deficiencies that the ECM-F4 shall report to the ECM-F3 for restrictions.</i>	

4.14.2 Proposal of a minimum set of information to be exchanged during the “Return to operation”

Minimum set of information to be addressed to the keeper:

The keeper (and the RU) needs the information that the vehicle is in a safe state for operation. No need to transfer all the details to the keeper (or to the RU). The traceability of maintenance record is the ECM's responsibility. ECM is releasing a vehicle to operation with or without restrictions on use. This is the information the keeper (RU) needs for operation.

Note concerning the use of the vehicle

Notes concerning the use of the vehicle, this field contains the limitations that the keeper shall report to the RU. These limitations shall be related to the parameters used by the staff to compose trains.

Formal transmission of information between the ECM and RU is possible. The Return to Operation document accompanying the vehicle contains all the necessary information and the restrictions on use for the RU. In case of restrictions on use the keeper/ECM-F3 has the responsibility to inform/exchange with the RU.

It is a duty of RUs to consider the information included in the Return to Operation in order to establish and ensure the operation of the vehicle in a safe state. For responsibilities related to the RU please check the CSM on SMS [\[34\]](#).

When talking about Release to Service and Return to Operation, one should have in mind a supervised record, whether in paper or electronic form. The ECM Regulation [\[1\]](#) do not indicate any specific form of release to service and return to operation, leaving the decision in this regard to the ECMs competent entities.

The ECM-F1 determines within the maintenance management system the competence of employees and assigns them responsibilities. There are no regulations enforcing the issuance of release to service and return to operation by different persons. However, the person issuing in each case must be qualified. (see [chapter 11](#))

5 CERTIFICATION OF ECM

5.1 What does Certification mean?

It means: “Third-party attestation related to products, processes, systems or persons (ISO/IEC 17000:2020 [27]).”

In the application of the ECM Regulation [1], certification is the process to be applied by the tandem:

- ▶ The accredited or recognised certification body or the NSA (acting as certification body); and
- ▶ The applicant for the certificate: the ECM or the outsourced maintenance function.

The requirements to be fulfilled by the applicant during the certification process are described in Annex II of the ECM Regulation and the certification scheme ERA-1172-003 V1.1 [17].

5.2 What is an ECM certificate or a maintenance function certificate?

The certificate provided by the accredited or recognised certification body or by the NSA (acting as certification body) accordingly to the ECM Regulation [1], provides the assurance that the applicant fulfils the relevant requirements established in the Annex II of the ECM Regulation and the certification scheme. The ECM shall be registered in the EVR when it is assigned to vehicle(s).

There are two different forms: one is for the ECM certificate and the other one for the maintenance functions. The format of these certification forms is defined in the Annex IV of the ECM Regulation and is available in the ERA database ERADIS. This database is accessible in the following link:

http://eradis.era.europa.eu/safety_docs/ecm/default.aspx

Explanation of the content of the ECM certificate and maintenance function certificate forms is provided in the following table (for more details see ECM certification scheme ERA 1172/002 V3.1):

Certification of entities in charge of maintenance according to Article 3(2) and (3) (ECM certificate)

Certification of maintenance functions according to Article 10 (Certification for outsourced maintenance functions)

1. EIN number

The Certification Body shall identify each certification decision, i.e. award, renewal, amendment, suspension or revocation of certificates, in conformity with the European Identification Number (EIN). The structure of the EIN is defined by the Certification scheme for ECM and outsourced maintenance functions under Regulation (EU) 2019/779.

The EIN is structured as **XY/ab/cdef/ghij** where

The identification of the certificate includes the identification of the Certification Body.

'XY' = Country Code of the accreditation body or the recognition body or the NSA acting as certification body.

'ab' = type of documents (2 digits).

31 is the reserved code for ECM certification

32 is the reserved code for the certification of Workshops

33 is the reserved code for the certification of outsourced maintenance function/s

'cd' = counter that identifies the accredited Certification Body. This code is previously provided by the accreditation body or the recognition body. From '01' to '99', '00' is reserved for the NSA acting as certification body.

'ef' = year in which the certification decision is taken by the Certification Body (award, revocation, suspension, modification of scope). Example 2011: 'ef' = '11'

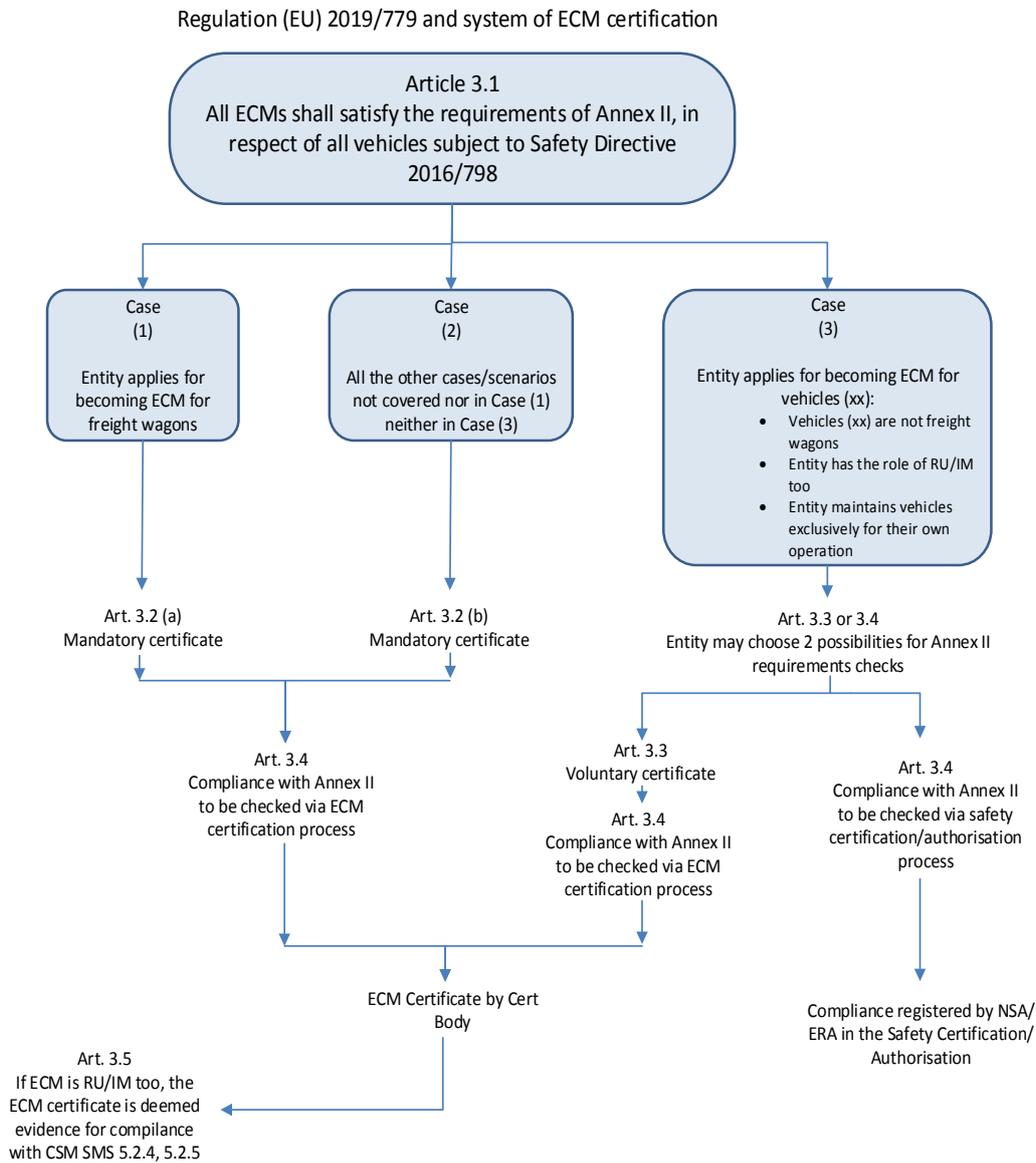
'ghij' = counter (4 digits). From '0001' to '9999'

Certification of entities in charge of maintenance according to Article 3(2) and (3) (ECM certificate)	Certification of maintenance functions according to Article 10 (Certification for outsourced maintenance functions)
<p>2. Certified Entity in charge of maintenance</p> <p>Information for the unique identification of the certified ECM. Certification bodies could check whether the name provided by the applicant matches the name in the Organisation Code Register (OCR) published by ERA. The organisation code of the ECM can be specified on the ECM certificate in the Acronym field, in brackets, such as in the following example: ACRONYM (XXXX).</p>	<p>2. Certified Organisation</p> <p>Information for the unique identification of the certified Organisation.</p>
<p>3. Certification body</p> <p>Information for the identification of the certification body. The certification bodies must be listed in the ERA database ERADIS. This database is accessible in the following link: https://eradis.era.europa.eu/safety_docs/ecm/default.aspx</p>	
<p>4. Certificate information</p> <p>Information on the history of the certification (new, renewed, updated/amended), EIN of previous certificates, validity of the certification and type of company (an Entity/Organisation can have multiple roles).</p>	
<p>5. Scope of ECM activities</p> <p>a) Category of vehicles for which the ECM is in charge. If a vehicle cannot be clearly assigned to one of the categories freight wagons, locomotives, multiple units, passenger carriages, high-speed vehicles or OTM's it should be recorded as other. In this case, it can be appropriate to specify the EVN of the vehicles or a description of the vehicle(s).</p> <p>b) Information about the maintenance of wagons specialized in transport of dangerous goods. These are mainly battery-wagons and tank-wagons as described in chapter 1.2 of the RID. "YES" means the certification covers maintenance activities on the tank and its equipment in accordance with the rules of the RID.</p> <p>Container wagons are not considered to be wagons for the carriage of dangerous goods, even if they can carry containers containing dangerous goods, such as tank containers.</p>	<p>5. Scope of maintenance activities</p> <p>a) Category of vehicles for which the maintenance activities of the organization are certified. If a vehicle cannot be clearly assigned to the categories freight wagons, locomotives, multiple units, passenger carriages, high-speed vehicles or OTM's it should be recorded as other. In this case, it can be appropriate to specify the EVN of the vehicles or a description of the vehicle(s).</p> <p>b) Information about the maintenance of wagons specialized in transport of dangerous goods. These are battery-wagons and tank-wagons as described in chapter 1.2 of the RID. "YES" means the certification covers maintenance activities on the tank and its equipment in accordance with the rules of the RID.</p> <p>Container wagons are not considered to be wagons for the carriage of dangerous goods, even if they can carry containers containing dangerous goods, such as tank containers.</p>
<p>6. Maintenance functions</p> <p>a) If the type of document (see EIN) is 32 only the maintenance delivery function can be ticked.</p> <p>b) If the type of document (see EIN) is 33 the development or the fleet management function or more than one function can be ticked.</p> <p>It should be noted here, that a outsourced maintenance function certificate could not replace an ECM certificate. If the scope of the certification only covers a part of an outsourced maintenance function, the certification body has to describe here which part and which maintenance activities are covered by the certification. The description of the activities can also be given in an Annex to the certificate.</p>	
<p>6. Additional information</p> <p>No comment shall be written in the field additional information except the identification of the final assessment report and the status of newcomer if applicable.</p>	<p>7. Additional information</p> <p>e.g. Information of the final assessment report, reference to Annex(es), information on type of component(s) maintenance covered by the certification, multisite organisations.</p>
<p style="text-align: center;">Formalities:</p> <p style="text-align: center;">Date of issue of the certificate.</p> <p style="text-align: center;">Internal reference number of the certification body.</p> <p style="text-align: center;">Signature of the decision maker of the certification body and stamp of the certification body.</p>	

5.3 Which ECMs have to be certified?

As mentioned in the diagram below, for case (1) and case (2), the certificate is mandatory.

Figure 20 ECM Regulation [1] and system of ECM certification



Case 3 is an exemption for RUs and IMs who maintain vehicles exclusively for their own operation (the RU/IM exclusively operates the vehicles; no other RU/IM operates the vehicles) from mandatory ECM certification. When an RU/IM operates vehicles in partnership with other RUs/IMs, Article 3(4) cannot be applied. If an RU/IM maintains vehicles exclusively for its own operations, the RU/IM has to be the registered ECM of the vehicles it operates, and keeper too, in the relevant EVR.

The operation of a vehicle does not only cover the transport of freight or passengers. Operation covers any authorised use of the vehicle like the transport of freight or passengers,

GUIDANCE ON ECM CERTIFICATION PROCESS

pulling/pushing other vehicles, movements for disposition, running of locomotives without a train, movement of empty wagons, running of an OTM from one construction site to the next (self-propelled or pulled by other traction / in a train).

RUs/IMs cannot use the compliance with Annex II of the ECM Regulation [\[1\]](#), assessed during the safety certification/authorisation process, to operate nor be the ECM for other vehicles not included in Article 3(2)b of the ECM Regulation, nor operate as outsourced maintenance function.

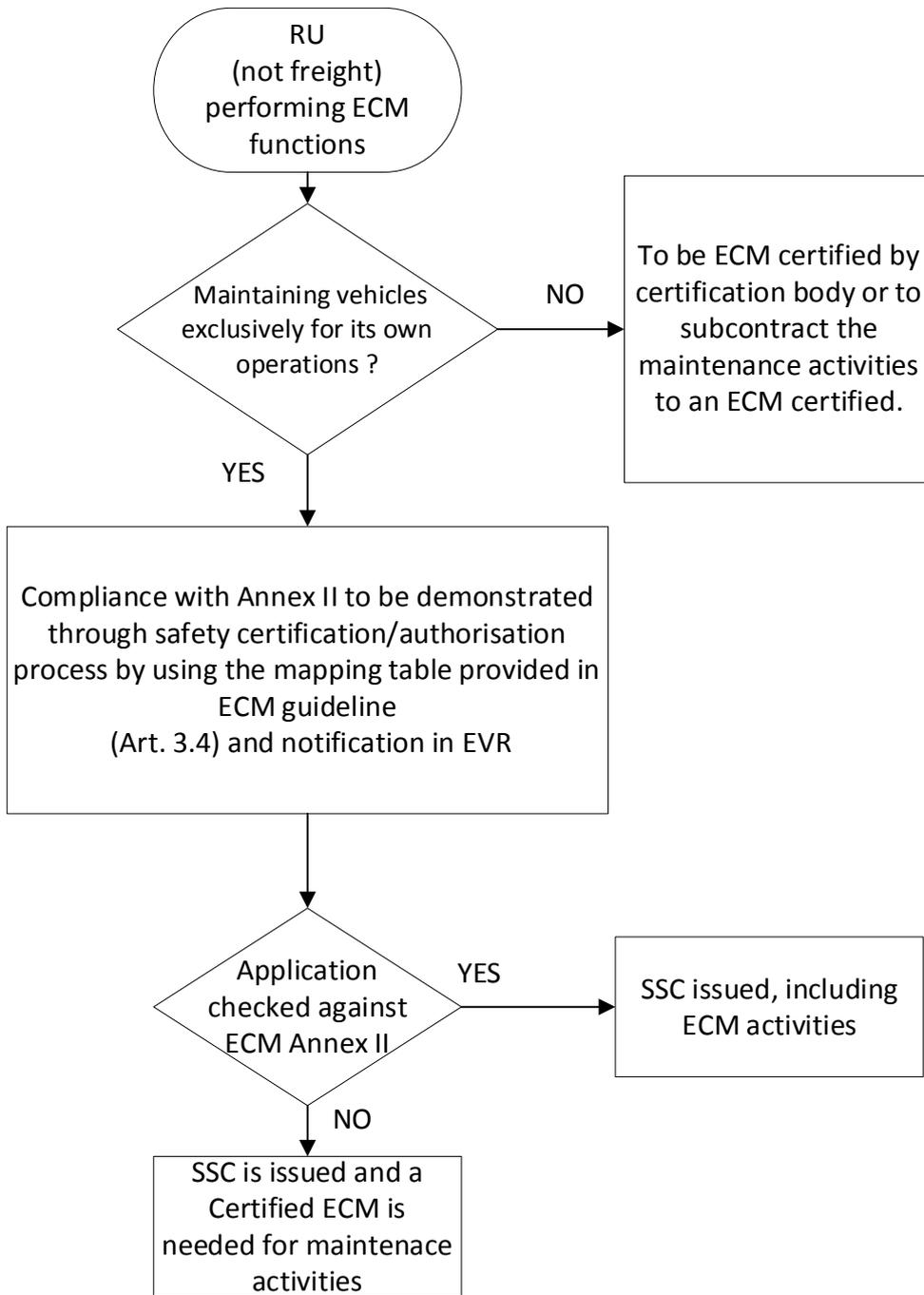
This RU/IM cannot use the compliance with Annex II to act as ECM for freight wagons. To do so, it needs a valid ECM certificate for freight wagons (see ECM Regulation, Article 3(2)(a)).

When the RU/IM wants to become, or continue as, an ECM maintaining vehicles exclusively for its own operations according to Article 3(4) of the ECM Regulation, it must notify its NSA or Safety Certification Body (NSA/ERA) thereof. The RU/IM must analyse the risks related to the changes according to its SMS and take proper risk mitigation measures.

If a RU/IM wants to demonstrate compliance with Annex II of the ECM Regulation during the process of safety certification/authorisation, it has to apply for the assessment to the safety certification body (ERA or NSA) /safety authorisation (NSA) in case of application for granting or renewal or update of a safety certificate/authorisation. The request for a safety certificate from a RU is submitted via the One Stop Shop (OSS), while the request for safety authorisation is submitted by the IM directly to the NSA involved following the national rules. It is necessary, when the RUs submit an application through the OSS for a new safety certificate or for the renewal or update of an existing safety certificate, or IMs submit an application to the NSA for a new safety authorisation or renewal or update of existing safety authorisation, to explicitly indicate if they intend to be checked as an ECM in the safety certification process/safety authorisation process. According to article 3(5) of the ECM Regulation, the ECM certificate granted to a railway undertaking or an infrastructure manager shall be part of the evidence of compliance with points 5.2.4 and 5.2.5 both of Annex I and Annex II of the CSM on SMS [\[34\]](#) as regards maintenance of vehicles.

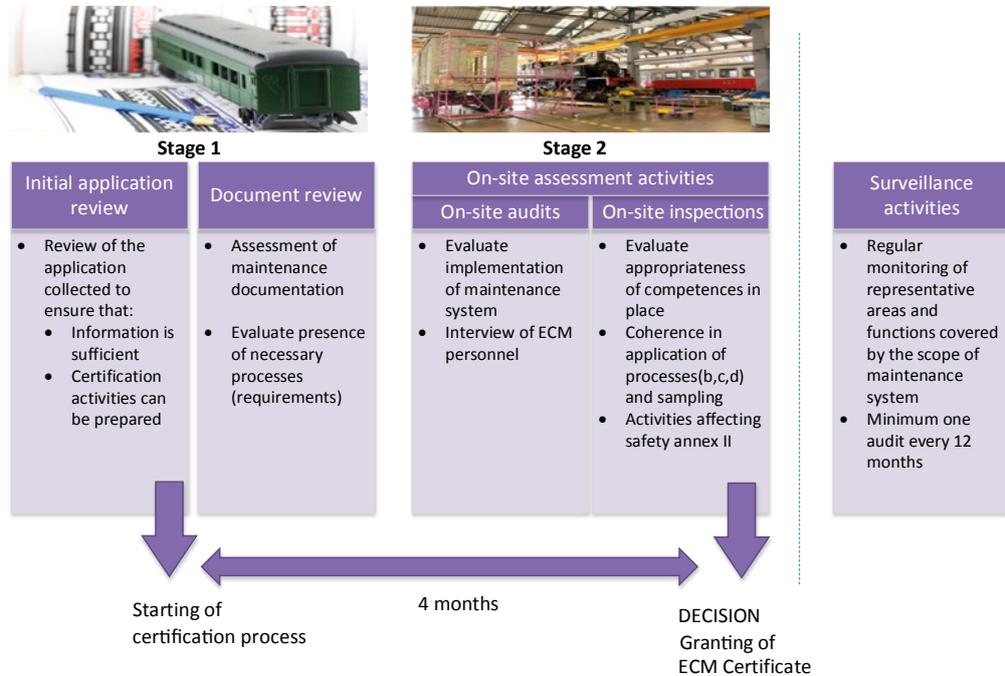
The following diagram describes different possibilities.

Figure 21 Application of article 3.4. of the ECM Regulation [1]



5.4 What are the steps to follow to obtain an ECM certificate?

Figure 22 Steps to obtain an ECM certificate



Top left: © Abrosimov E.P., top right: © Washburn / stock.adobe.com

For further information, see also the mandatory Certification scheme ERA-1172-003 V1.1 [17].

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

According to the Article 6(1) of the ECM Regulation [1], the Member States shall provide the Agency information concerning the ECM certification bodies. Therefore, there are different schemas to be chosen by each Member State:

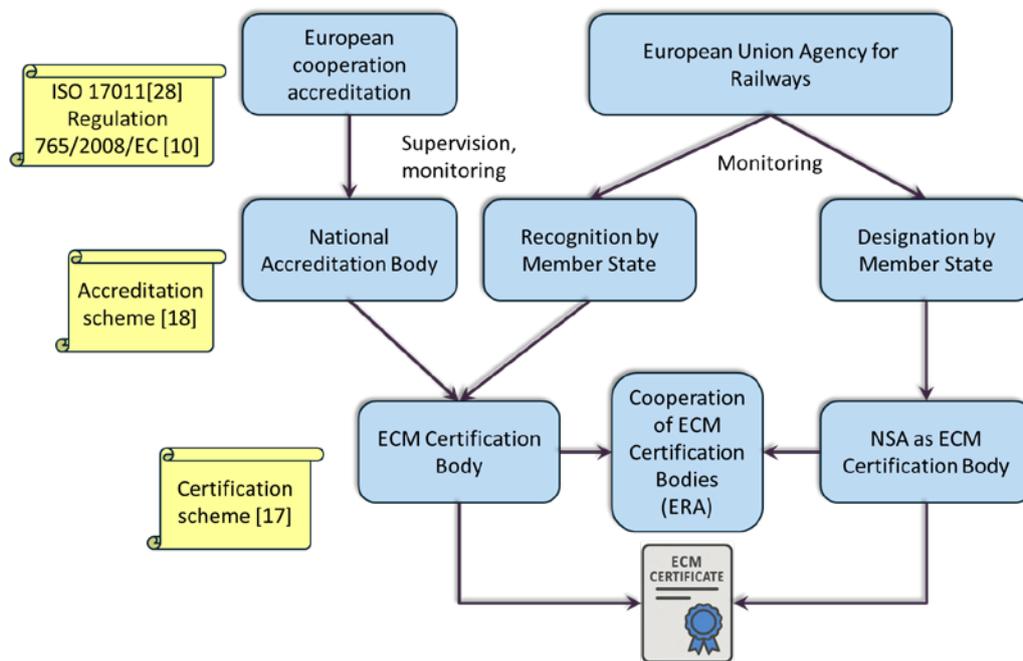
- ▶ “Accreditation”: it means accredited certification bodies will be able to perform ECM certification.
- ▶ “Recognition”: certification bodies recognised by the Member State will be able to perform ECM certification.
- ▶ NSA as certification body: the NSA designated by the Member State as a certification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

The sectoral scheme for accreditation and recognition, ERA-1172-002 V3.1 [18], contains requirements to be used by National Accreditation Bodies or by recognition bodies when assessing certification bodies performing ECM certification. It shall also be used by Members States when designating the NSAs to act as ECM certification body (according to Article 14 of the Safety Directive).

The ECM applicant is **free** to choose its certification body (Article (7)(1) of the ECM Regulation [1]). The ECM can contract body:

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

Figure 23 ECM certification process



5.6 Can the NSA of a Member State A give an ECM certificate in a Member State B?

An accredited or recognised ECM certification body can certify any ECM on the whole territory of the EU.

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

When a NSA acts as an ECM certification body, as NSA is a national (public) authority, it is also limited to its national territory.

The NSA of a member state A may certify ECMs with legal address in Member State A only. Nevertheless, the certificate granted by an NSA is valid on the whole territory of EU.

5.7 ECM Certification for multisite organisations.

- ▶ **What is a Multi-Site company?**

The Certification scheme for ECM and outsourced maintenance functions under ECM Regulation [1], ERA 1172-003 V1.1 [17] mandates the use of IAF MD1 – IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organisation as a reference for appropriately assessing ECM multi-site organisations (see ERA-1172-003 V1.1 [17] paragraph 3.3.3.2).

IAF MD 1 provides a definition for multi-site organisation (see IAF 3.3.1): “An organisation covered by a single management system comprising an identified central function (not necessarily the headquarters of the organisation) at which certain processes/activities are planned and controlled, and a number of sites (permanent, temporary or virtual) at which such processes/activities are fully or partially carried out”

► **Why applying Multi-Site sampling during the ECM certification process?**

By definition, an ECM management system audit is based only on a limited sample of the information available. However, it must be demonstrated that the ECM management system is capable of achieving its intended results for all sites involved.

The aim of multi-site sampling during the certification process is to ensure that the audit provides adequate confidence in the implementation of the ECM management system in line with the ECM Regulation [1] across all sites covered by the certificate and that the audit is both practical and feasible in economic and operative terms.

Therefore, the rationale for applying Multi-Site sampling during the ECM certification process is for the Certification Body to determine an appropriate sample size in accordance with IAF MD1 to be able to gain sufficient confidence in the effectiveness of the ECM management system under the audit, whilst limiting the amount of audits to an effective economic and operative level.

► **Guidance for sites linked to Mobile Maintenance activities**

ECM-F4 Mobile Maintenance (including the Mobile Maintenance teams) do perform several preventive and corrective maintenance at various locations.

In addition, ECM-F4 Mobile Maintenance teams do normally operate as part of a defined physical ECM site or do have a defined home base site from which they do operate, receive their orders, get their respective materials, tools, equipment and supplies.

► **Definition of Central function of the ECM organisation**

IAF MD 1 provides the following definition for central function: “The *function that is responsible for and centrally controls the management system.*”

The “central function” as described below is covered by ECM-F1 in the ECM Regulation [1].

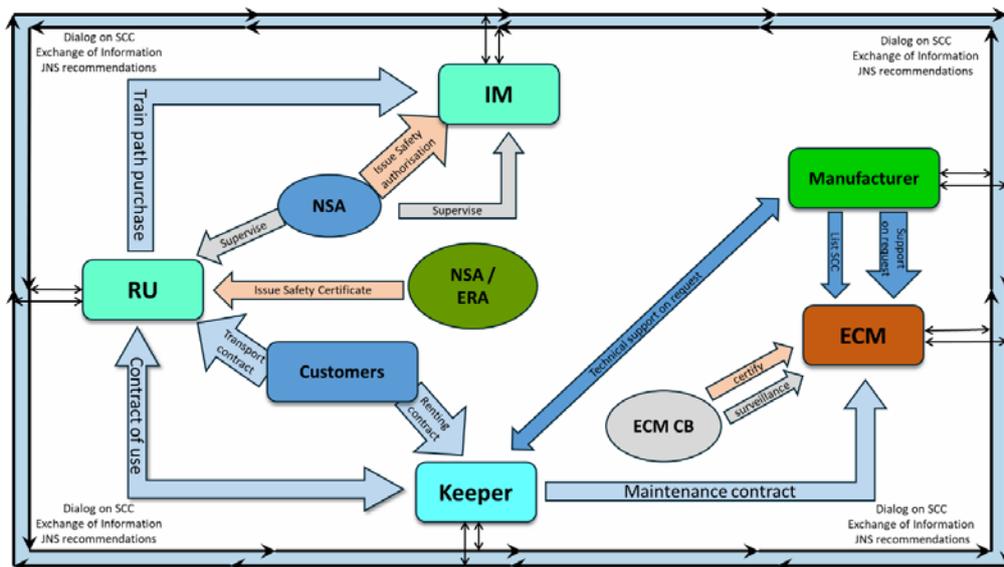
The organigram of the organisation should provide how the central management function is organised.

6 ORGANISATION OF THE RAILWAY SECTOR IN EUROPE AND RESPONSABILITIES OF ACTORS

6.1 Who are the different “Stakeholders” participating in the maintenance of vehicles?

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

Figure 24 Stakeholders Involved in Vehicle Maintenance



The responsibilities of railway parties are stated in the Safety Directive [2], in Articles 4(4)(a) and 16 (for NSAs) and the RID, Chapter 1.4 (for the transport of dangerous goods). Regarding the maintenance of vehicles, responsibilities are also stated in the ECM regulation [1].

For example, a railway undertaking encompassing the role of ECM of vehicles shall comply, in addition to its duties and responsibilities of railway undertaking, with the requirements of Annex II of the ECM Regulation. It is not regulated who should appoint the ECM; this is left to decisions of the 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.

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

6.2 You are a Keeper, what are your responsibilities?

The keeper is defined in the Article 3(19) of the Safety Directive [2] and in the article 3(21) of the Interoperability Directive [3].

Apart from the obligations of registration holder, the Safety or Interoperability Directive do not define any additional explicit responsibility for the keeper related to maintenance. In practical, unless otherwise specified in the registration documents, the keeper of the vehicle is considered to be the “registration holder” in the meaning of Article 47(6) of the Interoperability Directive (See Annex 3.2.3 of the EVR Decision [12]). Based on Article 4(4) of the Safety Directive it can be understood that responsibilities of the keeper are basically to implement the necessary risk control measures, where appropriate in cooperation with other actors, to assure in contractual way to RUs/IMs that vehicles (and when requested additional services) provided meet consistently safety requirements.

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

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

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

- ▶ a valid authorisation for placing on the market.
- ▶ an ECM registered in the EVR.
- ▶ all initial documentation of maintenance of vehicles involved was consigned to ECM in charged.

For freight wagons and for vehicles other than freight wagons, in the case of Art. 3(2)b of the ECM Regulation [1], the keeper should assure also to RUs/IMs that the ECM certificate is valid.

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

To avoid its vehicles being put out of operation, the keeper should pay attention to the following responsibilities:

- ▶ The keeper should appoint an ECM and contracts with it.
- ▶ The keeper may make contractual arrangements with subcontractors (e.g. maintenance workshops), but nevertheless the ECM is responsible to take the decision if the subcontractor is sufficiently competent to be authorised to perform maintenance tasks. To this end an agreement should be achieved between the keeper and the ECM.
- ▶ The keeper acting as registration holder has to ensure that the data it addresses to the registration entity is correct and has to get assurance that the ECM holds a valid certificate for freight wagons and for vehicles other than freight wagons, in the case of Art. 3(2)b of

the ECM Regulation. Nevertheless when the keeper is not the registration holder, as it is the main interlocutor for the RUs, it should assure that the vehicle is compliant with the legislation in force and thus that data stated in the EVR is correct and that the ECM holds a valid certificate (only for freight wagons and for vehicles other than freight wagons, in the case of Art. 3(2)b of the ECM Regulation).

- ▶ As main interlocutor of the RUs/IMs, the keeper should assure that a vehicle is put, in due time, at disposal of the ECM to perform maintenance tasks in consistency with the decisions of the Fleet Maintenance Management (ECM-F3).
- ▶ For freight wagons and for vehicles other than freight wagons, in the case of Art. 3(2)b of ECM Regulation: the keeper should take specific actions if ECM certificate is suspended or revoked (e.g. assign another ECM, inform its customers including RUs).
- ▶ Suspension and revocation of ECM certificates imply that the ECM registered in EVR is not compliant anymore to the legislation in force and therefore that the registration of the vehicle should be suspended forbidding this latter to be operated.
- ▶ The keeper should specify to the RUs/IMs the conditions of use of the wagons, especially if there are specific conditions (e.g. type of goods transportable, specific operational limitations).
- ▶ In any case the keeper should participate actively to the exchange of information between ECMs and RUs/IMs when there is no direct contractual arrangement on exchange of information between ECMs and RUs/IMs.
- ▶ The keeper has to implement the necessary risk control measures and has to cooperate with other actors.

For international transport the provisions of the OTIF [\[35\]](#) CUV [\[36\]](#) and GCU [\[37\]](#) apply to keepers and RUs as users of freight wagons. The obligations and rights of the keepers of freight wagons are described in Chapter II of the GCU [\[37\]](#).

6.3 You are a RU/IM, what are your responsibilities?

The Railway Safety Directive [\[2\]](#) states in Article 4(3) that RUs/IMs shall be made responsible for safe operation and to fulfil this responsibility, it requires that they establish a SMS.

According to the Art 9(2) of the Safety Directive, the RU/IM is responsible to control all the risks related to the supply of maintenance and therefore has to implement control measures to get assurance that vehicles are maintained in such a way that they can be used safely when put in trains.

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

This means in particular that:

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

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

- ▶ The ECM certification is the effective and efficient way to bring this assurance to the RUs/IMs. Therefore, the RUs/IMs should not be required to re-evaluate the maintenance system of ECM already being granted with ECM certificate.
- ▶ By virtue of point 5.1.3. c) of Annex I of the CSM on SMS [34], the RU/IM shall ensure the freight wagons and other vehicles in the case of Art. 3(2)b of the ECM Regulation [1] it operates, before their departure, have a certified ECM. The Certificate has to be delivered by a duly accredited or recognised certification body or by an NSA entitled by its MS as certification body. The certificate has also to be within its validity period. The ERADIS database provide data on certificates.

In addition the RUs/IMs check that the scope of the certificate corresponds to two kinds of wagons (wagon specialized in transport of dangerous goods and other type of wagons). Those checks could also be facilitated by contractual arrangements with the keeper or through sectorial arrangements in place, e.g. GCU.

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

The RU/IM is therefore responsible for taking additional control measures described here below. The RU/IM should undertake inspections before the departure of a train or on route. Those inspections have to comply with the processes described in its SMS. The RU must assure that each vehicle in its train will be in such a state that doesn't compromise the safe operations. It does not aim to control that maintenance was appropriate and done correctly but that vehicles are in a sufficient state for safe use.

Some of those inspections are carried out by the RU/IM itself (e.g., drivers and/or operational staff), for some the RU/IM may subcontract to other entities like loaders or maintenance workshops. 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/IM must decide how to fulfil its obligations and, if necessary, agree with the other players on rules for procedures that the other players take over for the RU/IM.

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

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

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

- ▶ By virtue of Article 5(4) of the ECM Regulation, if a contracting party, particularly a RU/IM, has a justified reason to believe that a particular ECM does not comply with the requirements of Article 14 of the Safety Directive [2] or with the certification requirements of this Regulation, it shall without delay inform the certification body and the relevant NSA thereof. The certification body or, where the ECM is not certified (see Art. 3.2(b)), the relevant NSA shall take appropriate action to check if the claim of non-compliance is justified and shall inform the parties involved. As a consequence, the certification body has to consider this claim within its surveillance activities (or, where the ECM is not certified (see Art. 3.2 (b)), the relevant NSA has to consider this claim within its supervision activity) and may take actions such as imposing an improvement plan, limiting the scope of application of the certificate, suspending the certificate, or revoking the certificate depending on the degree of non-compliance (See Article 8 of ECM Regulation).
- ▶ By virtue of Article 5(2) of the ECM Regulation, 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 between the RU/IM and the ECM or between the RU/IM and the keeper (the keeper plays the role of intermediate).
- ▶ By virtue of Article 5(3) of the ECM Regulation, all contracting parties shall exchange information on maintenance of vehicles in accordance with the criteria listed in section I.7 and I.8 of Annex II of ECM Regulation.
- ▶ The RU shall fulfil its duties about transmission of information with its commercial partners – i.e. other RUs/IMs, keepers and ECMs since there could be direct relations between RU and ECM (e.g. RU/IM assuming also the role of keeper or requesting for direct exchange of information).
- ▶ The RU/IM shall implement any other additional control measures that it considers necessary to keep the identified risks related to the supply of maintenance under control. Those risks could be highlighted through a structured approach to risks assessment and a systematic analysis of findings related to the routine monitoring put in place by the RU/IM as part of its SMS arrangements.

6.4 You are a manufacturer, what are your responsibilities?

Apart from the obligations in the role of “applicant”, the Interoperability Directive does not define any additional explicit responsibility for the manufacturer.

In the role of “applicant” as is defined in the Article 2(22) of the Interoperability Directive [3], the manufacturer shall provide to the keeper of vehicle:

- ▶ initial identification of safety-critical components.

- ▶ the complete technical file with specific maintenance instructions recorded in the technical files of subsystems referred to in Article 15(4) of the Interoperability Directive.
- ▶ recommendations for maintenance as part of the initial documentation.
- ▶ information on safety critical components and appropriate maintenance instructions related to them through reference in the technical file of subsystems referred to in Article 15(4) of the Interoperability Directive.
- ▶ technical and engineering support on SCCs and their safe integration when an ECM/ Keeper addresses a request; this can be done by agreement or contractual arrangements.

As previewed in the Article 5 of the ECM Regulation [\[1\]](#) the manufacturer shall exchange of information with the ECM and other actors when they address a request.

6.5 You are an ECM, what are your responsibilities?

The ECM must ensure:

- ▶ To set up and keep updated the maintenance file (maintenance development part II.4 b and II.5 Annex II).
- ▶ That the implementation of the first maintenance file is done correctly (maintenance development part II.4.c Annex II).
- ▶ The coordination of all those activities and supervise its subcontractors.
- ▶ The exchange of information–Article 5(1) of ECM regulation [\[1\]](#).
- ▶ the RTO is provided to RUs/IMs and keepers.

Regarding the vehicles, responsibilities are also stated in the ECM regulation. The ECM should ensure that it continuously meet the relevant requirements set out in Article 14(3) of the Safety Directive [\[2\]](#) and in article 4, 5(1), 5(3), 5(5) and Annex II of the ECM Regulation and applies them consistently. This assurance may be provided to other railway parties by mean of the ECM certification, when it is mandatory, or by means of the compliance related to the application of Article 3(4) of ECM Regulation.

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

As part of the maintenance management function (ECM-F1), the ECM has to perform itself the necessary coordination and monitoring of all its maintenance activities. These tasks may be partially outsourced, but coordination and monitoring as a whole remain one of the main and crucial task of the management function of the ECM in accordance with Article 14(3) of the Safety Directive. The other maintenance functions may be performed (totally or partially) internally or (totally or partially) outsourced. This includes the call for technical expertise when not available internally, for instance from manufacturers of vehicles or components, and the use of contracted maintenance workshops.

Regardless of the outsourcing arrangements in place, the ECM shall be responsible for the outcome of maintenance activities it manages and shall establish a system to monitor

performance of those activities (See Article 9(3) of ECM Regulation). In addition, the ECM has to apply the CSM on monitoring [\[13\]](#).

The ECM has to inform its clients about any change in the status of its certificate (amended, renewed or revoked) that may cause contractual liability issue.

All ECMs shall satisfy the requirements of Annex II of the ECM Regulation, even if they are not certified.

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

The ECM Regulation [\[1\]](#) does not regulate pre-departure inspections. They are not part of the maintenance activities of the ECM, but they are set up by the Railway Undertaking, as part of their SMS, to verify the vehicle is fit for the journey and the operation: the ECM Certification does not liberate the RU/IM from its responsibilities to manage the risks in operations and maintenance.

The pre-departure inspections are regulated in particular by the TSI OPE [\[8\]](#) and must be managed by Railway Undertakings within their SMS. There are some harmonising tools already in place. The GCU [\[37\]](#) (General Contract of Use) is a harmonised contract between Railway Undertakings and keepers regarding the provision of wagons (see [chapter 13](#)).

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

It is important for the ECM to know the content of those inspections and their possible differences when establishing and updating the maintenance file. For that purpose, cooperation between RUs/IMs and ECMs is crucial.

6.7 Use of Safety Alert IT tool

Safety Alerts IT tool is a platform, developed by Agency in the frame of the Safety Directive [\[2\]](#). It facilitates the exchange of information among the relevant actors who identify or are informed of a safety risk relating to defects and construction non-conformities or malfunctions of technical equipment, including those of structural subsystems.

SAIT is a secure website which grants registered users the ability to share information quickly about safety risks relating to defects of technical equipment between the European railway actors.

► Who shall report?

SAIT is for railway undertakings, infrastructure managers, entities in charge of maintenance and all other actors (**not including national or state bodies and authorities**), including manufacturers, maintenance suppliers, keepers, service providers, contracting entities, carriers, consignors, consignees, loaders, unloaders, fillers and unfillers.

Only employees or agents of one of the above-mentioned categories of organisations, will be granted access to the SAIT (Safety Alerts IT tool). Organisations may request as many user accounts as they require. Organisations should make their own internal arrangements for authorizing staff to publish, comment and receive safety alerts.

► What to report?

Users should report information about hazards that, in their own judgement and in accordance with the policies of their own organisation:

- Relate to defects and construction non-conformities or malfunctions of technical equipment, including those of structural subsystems
- The hazard, event or information is novel or unexpected and therefore the related risk is likely to be poorly controlled
- The related risk, if not controlled, has the potential to lead to an accident or incident involving serious injury or 1 or more fatalities
- The related risk is relevant for more than 1 actor

► Where to report?

When you for the first time use SAIT, you must create an EU Login account for your company. SAIT can be found at the following web address: <https://www.era.europa.eu/content/what-safety-alerts-it-tool-sait>

► When to report?

As soon as possible after detection of the defect, including out of business hours.

► Why to report?

The entity in charge of maintenance shall use the SAIT to inform the rail sector and the rail supply industry about new or unexpected safety relevant findings including exceptional maintenance findings beyond wear and tear (article 4(6) of the ECM Regulation [1])

6.8 You are an accredited or recognized ECM certification body or a NSA designated as ECM certification body. What are your responsibilities?

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 [1] and the ECM accreditation scheme. The Member State should also communicate on those control measures and their results with all interested parties to avoid creating doubts on the competence of NSAs.

For recognition, when applying the article 5(2) of the Regulation 765/2008 [10], 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 11 of ECM Regulation), RU or any other contracting party (Article 5(3) of the ECM Regulation) and take appropriate action to check if the claim of non-compliance is justified and shall inform the parties involved (including the relevant national safety authority) of the results of its investigation (Article 5(4) 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 (see Article 7(8) of ECM Regulation) or if the ECM no longer complies with the certification requirements or any improvement plan (see Article 8(2) of ECM Regulation).

6.9 You are an NSA supervising RUs and IMs. When supervision shows a non-compliance of an ECM with the requirements, what are your responsibilities in connection with Article 11 of the ECM regulation [1]?

According to Article 11 of the ECM Regulation, an NSA that has a justified reason to believe that an ECM does not meet the requirements of the ECM Regulation shall at first “take the necessary decision” and then afterwards inform the national bodies or authorities responsible for the accreditation or recognition, the Agency, the certification body and other interested parties as appropriate. As a general rule, an NSA shall not supervise certified ECMs as this would lead to a duplication of the surveillance regime of the ECM certification bodies, except when the NSA acts as ECM certification body. But, during its regular supervision activities directed towards IMs and RUs, an NSA can detect problems and defects that may put in question the compliance of the ECM’s with the requirements of ECM Regulation.

► Which decision shall be taken?

After requesting justification about the supposed lack of compliance with the requirements of ECM Regulation [1] and based on the information received from the RU/IM/keeper (and possibly ECM and ECM certification body), the NSA may take further action or decision is necessary.

The NSA, in a proportionate way, may take the following action:

- NSA decision towards RU/IM if measures from RU/IM are not satisfactory as regards technical aspects and timing.
- If measures from RU/IM are not satisfactory and the NSA has legal duty regarding ECMs: NSA decision against ECM if measures from ECM are not satisfactory as regards technical aspects and timing.

► Who shall be informed?

For informing the sector, it shall be sufficient that an NSA informs the RU/IM/keeper where the lack of compliance with requirements of ECM Regulation [1] occurred. According to Article 5 (5) of the ECM Regulation, it is the responsibility of the sector to take the necessary activities and spread this information to all parties involved. The NSA asks the RU/IM for confirmation

that the RU/IM has fulfilled its duties according to Article 5 (3). The RU/IM shall report back to the NSA.

Further information according to Article 11 shall follow a graduated approach depending on the safety criticality of lack of compliance with requirements of ECM Regulation and the corresponding actions of the RU/IM/ECM in response to the defect. To accommodate this, an example of a matrix that could be applied is the following:

Figure 25 Example of a matrix application

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

- o "1" means mild case, not safety critical (No further information by NSA necessary)
- o "2" means medium case, safety critical (NSA informs ECM certification body, NSA checks necessity of recording in ERA Safety Information System)
- o "3" means severe case, safety critical (NSA informs ECM certification body, NSA records case in ERA Safety Information System (= information to ERA), NSA informs ERA and national bodies or authorities responsible for the accreditation or recognition)

The examples provided here are specific only for wagons and focused only on the maintenance activities performed from ECM-F4:

- Low: Wrong/incomplete marking on wagons/vehicles, deadline for overhaul elapsed.
- Medium: Wrong tare/load spring installed (Y25 bogies), brake rigging wrongly plugged.
- High: Defect on axle or solid wheel repaired by welding, visibly different buffer types in wagon/vehicle ending, bogie frame rubbing against axle, axle box destroyed by loose screws.

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

The contractual and non-contractual liability issues, as private law in general, remain within the competence of the Member States, although the EU has intervened in such field where it appeared necessary to ensure the proper functioning of the internal market. In particular, the EU has adopted two regulations, one dealing with the law applicable to contractual obligations and the other 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) [38] 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) [39]). 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 [\[2\]](#)) or “without prejudice to existing national and international liability rules” (See Article 7(4) of the Safety Directive).

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

► Court jurisdiction

Article 6(4) of the ECM Regulation [\[1\]](#) 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(6) 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.

6.11 When a new authorisation for placing on the market is necessary?

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

The “new authorisation” is defined in the Art. 14, paragraph 1, letter d) of Regulation (EU) 2018/545 [\[11\]](#) as the vehicle type authorisation and/or vehicle authorisation for placing on the market issued by the authorising entity after a change of an already authorised vehicle and/or vehicle type, pursuant to Articles 21(12) or 24(3) of Interoperability Directive [\[3\]](#).

The criteria to apply for the decision when a “new authorisation” for placing on the market is necessary are set out in the Art. 15 of Regulation (EU) 2018/545 [\[11\]](#).

For instance, in the case of the substitution of a wheel by another one complying with the specification of the technical file, it would not be necessary to proceed to a new authorisation for placing on the market/placing in service neither a communication to the NSA. According to the Interoperability Directive this substitution is a “substitution in the framework of maintenance” means any replacement of components by parts of identical function and performance in the framework of preventive or corrective maintenance. It should only be

necessary to have this substitution recorded in the configuration file of the vehicle. This information is, of course, available to NSAs upon request.

The Interoperability Directive distinguishes between

- a) 'upgrading' means any major modification work on a subsystem or part of it which results in a change in the technical file accompanying the 'EC' declaration of verification, if that technical file exists, and which improves the overall performance of the subsystem and
- b) 'renewal' means any major substitution work on a subsystem or part of it which does not change the overall performance of the subsystem.

In case of upgrading or renewal, the ECM could be the applicant for this new authorisation. When an ECM assumes the role of applicant for a new vehicle authorization, this activity falls outside the scope of the ECM Regulation [1]. In such cases, the ECM operates not within its regulated maintenance responsibilities, but rather as an engineering company acting under authorization from the Keeper. Therefore, any involvement in the authorization process by the ECM must be recognized as a separate function, independent of its designated role under ECM Regulation. In any case, the ECM should manage it through contractual arrangements with the RU/keeper and taking in consideration:

- ▶ The existing authorisation for placing on the market.
- ▶ The guarantee of the vehicle by the manufacturer.

Activities in context of substitution in the framework of maintenance are covered by the ECM Regulation and by ECM-certification. Upgrading and renewal are not covered by the ECM-Regulation.

6.12 How to understand the article 3(4) (Assessment of RUs and IMs maintaining vehicles, other freight wagons, exclusively for their own operation)?

According to Article 3(2)b an ECM certification is not mandatory for an ECM which is RU or IM maintaining vehicles, other than freight wagons, exclusively for its own operations. However, these entities have to satisfy the Requirements of Annex II of the ECM Regulation [1].

They shall demonstrate compliance with Annex II of the ECM Regulation:

- a) By a voluntary ECM certification by the relevant certification body. The relevant certification body issues an ECM certificate. The certificate is included in the ECM Certificates Database of ERADIS and it shall be deemed evidence of compliance with points 5.2.4 and 5.2.5 both of Annex I and Annex II to the CSM on SMS [34] as regards maintenance of vehicles. The RU/IM is a regular ECM and treated as such. The RU/IM in this case shall communicate to the authorising entity the possession of the ECM Certificate as this could lead to the need for an update of the Safety Certificate/Authorisation.

- b) Through the process of safety certification/safety authorisation. In this case, the safety certification body will not issue an ECM certificate nor an entry in the ECM Certificates Database of ERADIS. The maintenance activities are limited to vehicles exclusively operated by the applicant for its own operations.

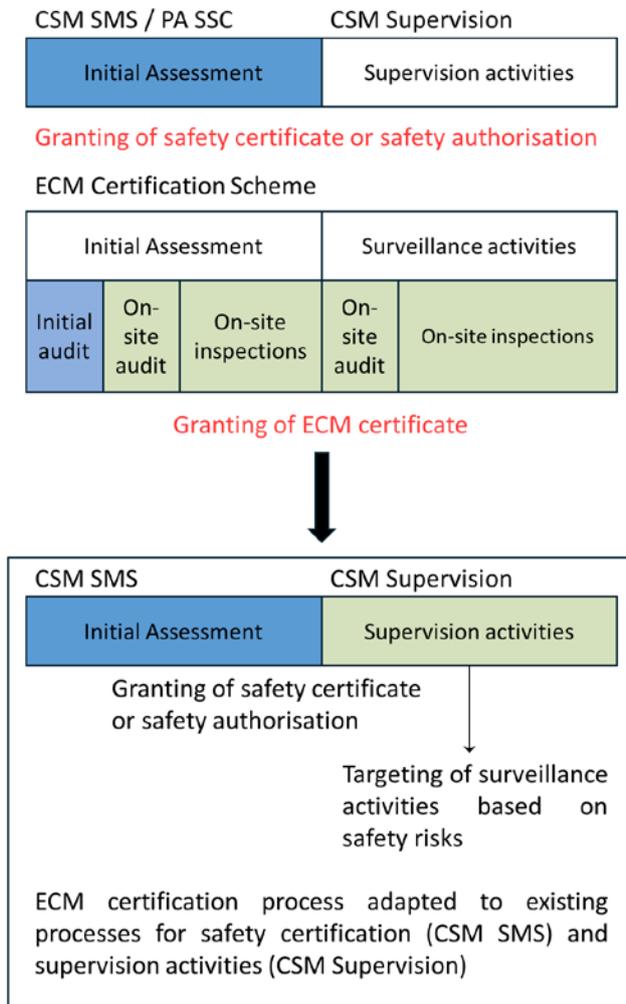
Although it is recommended to strictly apply the ECM Certification scheme, while assessing the compliance of the maintenance activities of a RU/IM with the ECM requirements together with the application for a safety certificate (or safety authorisation), the safety certification body should perform the assessment in compliance with Annex II of the ECM Regulation.

The safety certification body will incorporate all maintenance activities described in the ECM certification scheme and in particular will take into account its knowledge of the applicant and those risks related to:

- o the management system of the RU/IM.
- o the existing competences.
- o the assurance that the RU/IM address seriously the establishment and the updates of the maintenance files.
- o overlapping roles between the ECM function and RU/IM functions, potentially leading to procedural conflicts and compromised objectivity.

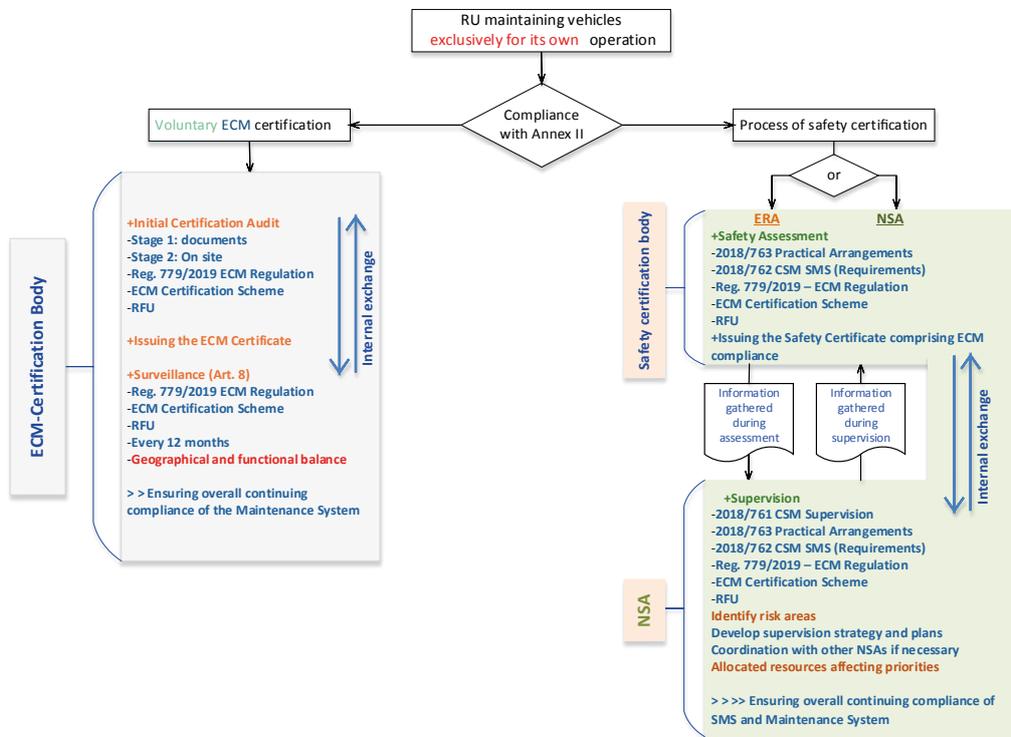
The principles underpinning this approach lie on the wide and detailed view the Agency and NSAs have, among stakeholders and interested parties, on the safety of the (European) railway system and in particular, on safety risks. The Agency and NSAs have then sufficient safety maturity and knowledge of the applicants to target the assessment of the maintenance system of the RU/IMs by using also a risk based approach.

Figure 26 Link between certification and supervision in case of application of Article 3.4.



This picture shows the possible adaptation of the ECM Certification Scheme by safety certification/authorisation bodies assessing together the application for a safety certificate (or safety authorisation) and the ECM requirements.

Figure 27 Compliance with Annex II of the ECM Regulation [1] for RU maintaining vehicles exclusively for its own operation



The picture shows that the process of safety certification is **different** from the process of ECM certification.

A RU/IM who demonstrates compliance with Annex II during the process of safety certification will **not** receive an ECM-Certificate.

The ECM activities of this RU/IM are **mandatory limited** to the vehicles exclusively for its own operations.

This RU/IM **cannot** act as ECM for freight wagons.

NSAs and ERA have been established as safety certification bodies. The CSM on SMS requirements and the CSM on supervision consider the implementation of processes for safety certification, which is different from the process of ECM certification.

The management system of an RU/IM that maintains vehicles exclusively for its own operations has to include methods and instruments for complying with both, the safety management system requirements and the requirements of ECM Regulation. Although the two management systems are designed for different actors there are overlaps.

The assessment of the ECM requirements should take the overlaps into account. It should be seen as an “add on” to the SMS assessment according to Regulation (EU) 2018/763 [40].

According to the Safety Directive [2], for RUs/IMs there are 2 different phases:

- ▶ safety assessment for the issuing of the safety certification / safety authorization; in this phase audits / inspections on site are possible and recommended, but not mandatory; the assessment is made by the certification body / NSA for the safety authorization;
- ▶ supervision process after issuing the safety certification / safety authorization, made by NSAs; in this phase audits and inspections on site are suitable techniques for assessing that RU / IM continues to duly apply their SMS and compliance of Maintenance System.

During supervision activities, after issuing a safety certification / authorisation, NSAs monitor the SMS effectiveness and the application of CSMs: it is not a conformity assessment for a certification process.

During the assessment process, the assessing body should examine these elements among many others related to the Annex II of ECM Regulation to ensure a comprehensive assessment,

- ▶ if the RU/IM is aware of the requirements of Annex II of the ECM Regulation
- ▶ if the RU/IM established procedures to supervise and coordinate its maintenance activities (management function)
- ▶ If the RU/IM has procedures to identify safety critical components.

6.13 What are the steps for the assessment of the ECM requirements during the process of safety certification/safety authorisation

1. Initial screen

The safety certification body checks an add-on to the SMS requirements if

- a) the provided basic information covers the maintenance of vehicles exclusively for RU/IM operations
- b) the application file contains sufficient evidence and is structured and internally cross-referenced so that it can be properly assessed against the requirements of ECM regulation [\[1\]](#)
- c) the maintenance report is available

2. Detailed assessment (on-site inspections are recommended) before issuing the safety certificate:

After the completion of the initial screen stage, the safety certification body shall proceed with the detailed assessment of the application file, using the safety management system requirements and as "add on" for maintenance and checking the compliance with ECM Regulation through the Safety Certification/Authorisation.

If the RU/IM would like to be an ECM, the company presents during Safety Certification/ Authorisation process (first issue/renewal by Agency/NSA) the mapping table with the requirements of Regulation EU 2018/762 (Annex I for RU or Annex II for IM) by adding a

column where the corresponding requirement of Regulation EU 2019/779 is allocated and accomplished by means of the company SMS documentation.

If the RU/IM is already registered as ECM, the company presents during Safety Certification/ Authorisation process (renewal by Agency/NSA or supervision activity by NSA) the mapping table already presented at the moment of the first issue/renewal of the Safety Certificate/ Authorisation by adding a column where the corresponding requirement of the ECM Regulation is allocated and accomplished by means of the company SMS documentation.

Where correspondence is not found, the RU/IM can present an adjunctive mapping table where the remaining ECM requirements are allocated and accomplished by means of the company specific maintenance system documentation.

Agency/NSA can also use the ECM Certification Scheme [17] to check in detail the compliance with ECM Regulation requirements and are recommended to arrange on-site visits, where appropriate, to gain evidence of the implementation of such requirements.

3. Supervision after issuing the safety certificate

During the period of validity of the safety certificate, the NSA(s) shall supervise the continued fulfilment of the safety management system requirements and the “add on” for all 4 maintenance functions as shown in the Annex II.

Supervision shall be carried out in accordance with the CSM for supervision by national safety authorities [14].

The ERA guide on supervision ([Supervision guide \[41\]](#)) sets out how NSAs can supervise their infrastructure managers and railway undertakings primarily, but also, where appropriate entities in charge of maintenance.

NSAs can also use the ECM Certification Scheme [17] during the supervision to check in detail the compliance with ECM Regulation requirements and are recommended to arrange on-site visits, where appropriate, to gain evidence of the implementation of such requirements.

7 WHAT IS THE MAINTENANCE FILE?

7.1 What documentation is needed to the ECM to provide for the Maintenance File for a TSI compliant vehicle?

It is essential to distinguish between the following key documents, for each, more explanations are provided in this chapter.

Considering the following description of Maintenance File

- ▶ Maintenance File: A structured set of documents specifically compiled by the ECM, based on recommendations for maintenance of the initial documentation – delivered by the manufacturer (see below)–and information on planned operations also taking into account the information contained in any associated guarantees, that includes relevant maintenance documentation necessary to perform the maintenance and to ensure safe and reliable operation throughout the vehicle's lifecycle. It is continuously updated based on operational experience and regulatory requirements.

In order to provide for the maintenance file for a TSI compliant vehicle, the ECM needs:

- a) recommendations for maintenance of the initial documentation
- b) information on planned operations
- c) to take into account the information contained in any associated guarantees

7.1.1 Which are and where are the “a) recommendations for maintenance of the initial documentation”?

In conformity with the Interoperability Directive [3], Article 15(4) (Procedure for establishing the 'EC' declaration of verification):

*“The applicant shall be responsible for compiling the **technical file** that is to accompany the 'EC' declaration of verification. That technical file shall contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents. It shall also contain all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and **maintenance**”.*

What are the Technical File and the maintenance documentation?

The Technical File is a legally required document prepared by the applicant for accompanying the EC declaration of verification in order to request the vehicle authorisation, containing all the documents as specified in Interoperability Directive [3], Article 15(4) and its Annex IV p. 2.4.

7 WHAT IS THE MAINTENANCE FILE?

The Maintenance Documentation is a collection of documents that describe how maintenance activities should be performed. It includes technical manuals, instructions, maintenance plans, and safety procedures. It is a part of the technical file.

For TSI compliant vehicles, the documentation described in the relevant TSIs as maintenance documentation, being part of the technical file, is:

- ▶ Freight vehicles under TSI wagon: There is the chapter 4.5 and 4.7 of Annex to TSI WAG [6].
- ▶ Vehicles other than freight wagons under TSI Loc&Pas: There are the chapters 4.2.12, 4.5 and 4.7 of Annex to TSI Loc&Pas [5].
- ▶ CCS on board subsystem of vehicles other than freight wagons under TSI CCS: There is the chapter 4.5, 4.6 and 4.7 of Annex to TSI CCS [7].
- ▶ TSI PRM subsystem applicable for rolling stock and covering the requirements for “person with reduced mobility”. There is the chapter 4.5 and 4.6 of Annex to TSI PRM.

In other words, it can be assumed that the **maintenance documentation** contained in the Technical File, necessary to apply for the APOM of the vehicle, is the collection of the necessary **recommendations for maintenance contained in the initial documentation**.

It is supplemented by **additional technical and maintenance documentation** for systems or parts of the vehicle non covered by any TSIs.

As a reminder, even the APOM released for the vehicle may contain any recommendations for maintenance and it needs to be considered by ECM to provide for the maintenance file (i.e. condition of use or restrictions of use influencing the Return to Operation).

Who ensures the conformity, completeness and consistency of the Technical File and of the maintenance documentation?

The Agency or, where applicable, the National Safety Authority by means of the releasing of the APOM ensures that they verified the completeness, relevance and consistency of the technical file (see Interoperability Directive [3], Article 21(5)) both for vehicles covered by TSI Loc&Pas and for freight wagon covered by TSI WAG.

In addition, during the releasing process of the APOM,

- ▶ for the vehicles covered by TSI Loc&Pas, it is also a responsibility of the NoBos to undertake the maintenance documentation to a conformity assessment, because maintenance documentation is quoted as element of rolling stock related to “*essential requirements*” in TSI Loc&Pas, Annex, p. 3.1 and also has to be undertaken to a conformity assessment during the “*rolling stock conformity assessment*” in the application of “*design phase*” module, as indicated in the Table H1 of Appendix H of the TSI Loc&Pas
- ▶ for the CCS subsystem, as specified in TSI CCS, Annex, p. 6.2.3, table 6.1.1, it is also a responsibility of the NoBos to undertake the technical maintenance documentation to a check for compliance with maintenance requirements indicated in TSI CCS, Annex, p. 4.2.20.1. In addition, it is also a responsibility of the NoBos to undertake the maintenance documentation to a conformity assessment, because the maintenance documentation

is quoted as element of CCS subsystem related to “*essential requirements*” in the TSI CCS, Annex, p. 3.1, table 3.1

- ▶ for the PRM subsystem (covering the requirements for persons with reduced mobility), as specified in TSI PRM, Annex, p. 6.2.5, it is also a responsibility of the NoBos to check if the maintenance documentation indicated in TSI PRM, Annex, p. 4.5 is provided

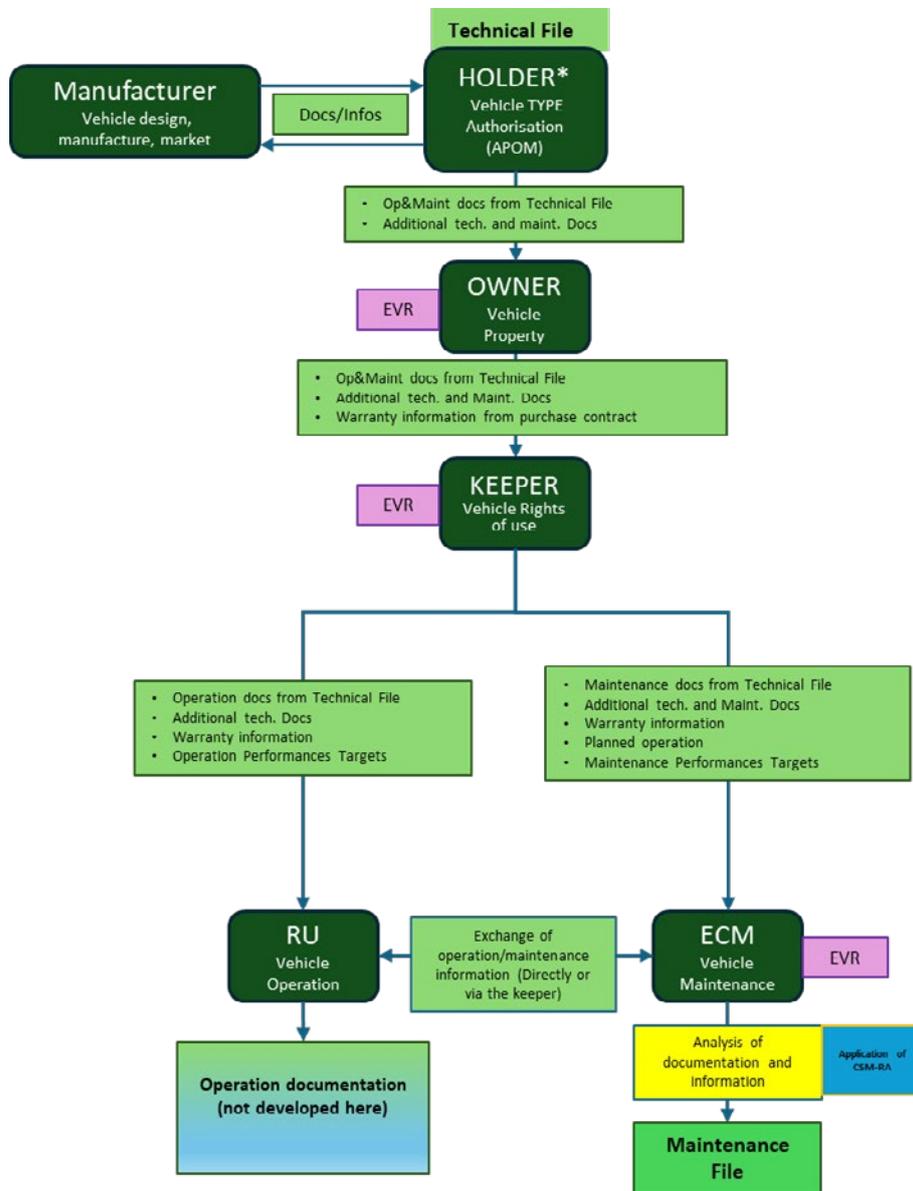
Who provides for releasing the maintenance documentation to the ECM?

Once the APOM is released to the applicant, the applicant becomes the Holder of the APOM and he has to release the maintenance documentation, and additional technical and maintenance documentation for systems or parts of the vehicle not covered by any TSIs, to the ECM, directly or via the Keeper, once the ECM is registered as such in the vehicle register (EVR or national register) and before the vehicle enters the operation.

The Keeper himself should be aware of its responsibility to ensure that the maintenance documentation on the vehicle is released to the contracted ECM which is filed in the EVR.

The scheme contained in [Figure 28](#) shows the exchange of documentation/information to build the Maintenance File.

Figure 28 Exchange³ of documents/information to build the first Maintenance File



7.1.2 Which are and who provides for the “b) information on planned operations”?

The information on planned operations are any set of data or documents where the Keeper and the Railway Undertakings specify the intended operation plan for the vehicles for which the ECM has been registered in the vehicle register (EVR or national register).

³ To be noted that different roles may be covered by the same company (i.e. Manufacturer may be the Holder of Vehicle Type Authorisation, and Owner and Keeper and RU may be the same company or Holder of Vehicle Type Authorisation and Owner and Keeper or even RU and ECM may be the same company or other combinations are possible in the market)

* To be noted that depending on contractual agreement, there can be a direct relationship between Holder of Type Authorisation and Keeper or even directly between Holder of Type Authorisation and RU/ECM for the exchange of documents/information

This set of information may contain:

- ▶ service profile (annual mileage, days, hours).
- ▶ planned services (routes, journeys plan, stops).
- ▶ category of passenger's service (local, metropolitan, regional, long distances, high speed) or goods transport (information on goods and tanks).
- ▶ safety conditions and reliability performances for operation.
- ▶ information contained in any associated guarantees and associated to operation.

Who provides for releasing the information on planned operations to the ECM?

The RUs release, directly or via the Keeper, the information on planned operations to the ECM before the vehicle enters the operation.

7.1.3 What is and who provides for the “c) information contained in any associated guarantees”?

Normally guarantees contain some applicable information or generic information related to maintenance.

This information may be mandatory or recommended for ensuring the validity of the guarantee offered by the Manufacturer or suppliers of parts, components of the vehicle.

Who provides for releasing the information contained in any associated warranty to the ECM?

The vehicle Manufacturer should provide for releasing to the ECM, directly or via the Keeper, any information related to maintenance and contained in the associated warranties of the vehicle or any part of it. Normally, the warranty and the conditions attached to it can be found in the vehicle purchase contract.

7.2 Maintenance documentation

The maintenance documentation plays a crucial role in ensuring the safe and efficient operation of railway vehicles. It forms part of the broader set of technical documentation required for vehicle authorisation and serves as a reference for maintenance planning and execution. A well-structured maintenance documentation enhances operational safety, optimises lifecycle costs, and ensures compliance with European railway regulations and industry best practices.

The maintenance documentation aims to support ECMs in developing and managing a comprehensive maintenance file that facilitates safe and reliable railway operations. It consists of several key components, each addressing different aspects of vehicle maintenance.

7 WHAT IS THE MAINTENANCE FILE?

The content of **maintenance documentation for TSI compliant vehicles** is described in detail in TSI Loc&Pas, Annex, p. 4.2.12, p. 4.5 and 4.7, in TSI Wagon, Annex, p. 4.5 and 4.7 and in TSI CCS, Annex, p. 4.5, p. 4.6 and p. 4.7 and in TSI PRM [\[42\]](#), Annex, p. 4.5 and 4.6.

It is supplemented by additional (if necessary) technical and maintenance documentation for systems or parts of the vehicle not covered by any TSIs.

The **maintenance documentation for non-TSI compliant vehicles** is composed by all the available technical documentation and information related to the whole vehicle containing any current and historical data, rules, activities and tasks, planning, return-on-experience, methods, records of performed maintenance and other technical data useful for ensuring through the maintenance the safe state of running of the vehicle.

7.2.1 Maintenance documentation for vehicles compliant with TSI Loc&Pas

The main structure of the maintenance documentation for vehicles compliant with TSI Loc&Pas is described in chapter 4.2.12 of its Annex, where there is also the main content. Other content, relevant for maintenance, is included in:

- ▶ TSI Loc&pas, Annex, p. 4.5 and 4.7.

In the case of application of TSI CCS and TSI PRM, other content is included in:

- ▶ TSI CCS: for control-command and signalling subsystem on board of vehicles other than freight wagons: There is the chapter 4.5, 4.6 and 4.7 of Annex to TSI CCS [\[7\]](#).
- ▶ TSI PRM: for subsystems of vehicles other than freight wagons and covering the requirements for “person with reduced mobility”. There is the chapter 4.5 and 4.6 of Annex to TSI PRM.

The main structure of the maintenance documentation for vehicles other than freight wagons, as indicated in TSI Loc&Pas, Annex, p. 4.2.12, is:

1. **General Documentation**, as indicated in TSI Loc&Pas, Annex, p. 4.2.12.2

The general documentation is intended to provide information on functioning and main characteristics of the vehicle and its components. It contains drawings, diagrams, description of functionality of the systems belonging to the vehicles and their interfaces, performances of braking, traction, EMS and so on. The functionalities and performances of the systems belonging to the vehicle are indicated in TSI Loc&Pas, Annex, p. 4.2.

2. **Maintenance Design Justification File (MDJF)**, as indicated in TSI Loc&Pas, Annex, p. 4.2.12.3.1

The MDJF explains how maintenance activities are defined and designed in order to ensure that the vehicle characteristics will be kept within permissible limits of use stated in the applicable TSI during its lifetime. In addition, it explains how maintenance activities are recommended to be performed

The MDJF gives input data in order to determine the criteria for inspection and the periodicity of maintenance activities.

It consists of:

- ▶ Precedents, principles and methods used to design the maintenance of the vehicle
- ▶ Precedents, principles and methods used to identify the safety critical components and their specific operational, servicing, maintenance and traceability requirements.
- ▶ Utilisation profile: Limits of the normal use of the unit (e.g. km/month, climatic limits, authorised types of loads etc.).
- ▶ Relevant data used to design the maintenance and origin of these data (return of experience).
- ▶ Tests, investigations and calculations carried out to design the maintenance.

3. Maintenance Description File as indicated in TSI Loc&Pas, Annex, p. 4.2.12.3.2

The maintenance description file describes how maintenance activities shall be conducted. Maintenance activities include all activities necessary such as inspections, monitoring, tests, measurements, replacements, adjustments, repairs.

Maintenance activities are split into:

- ▶ Preventive maintenance; scheduled and controlled
- ▶ Corrective maintenance.

Basically, the maintenance description file should contain at least:

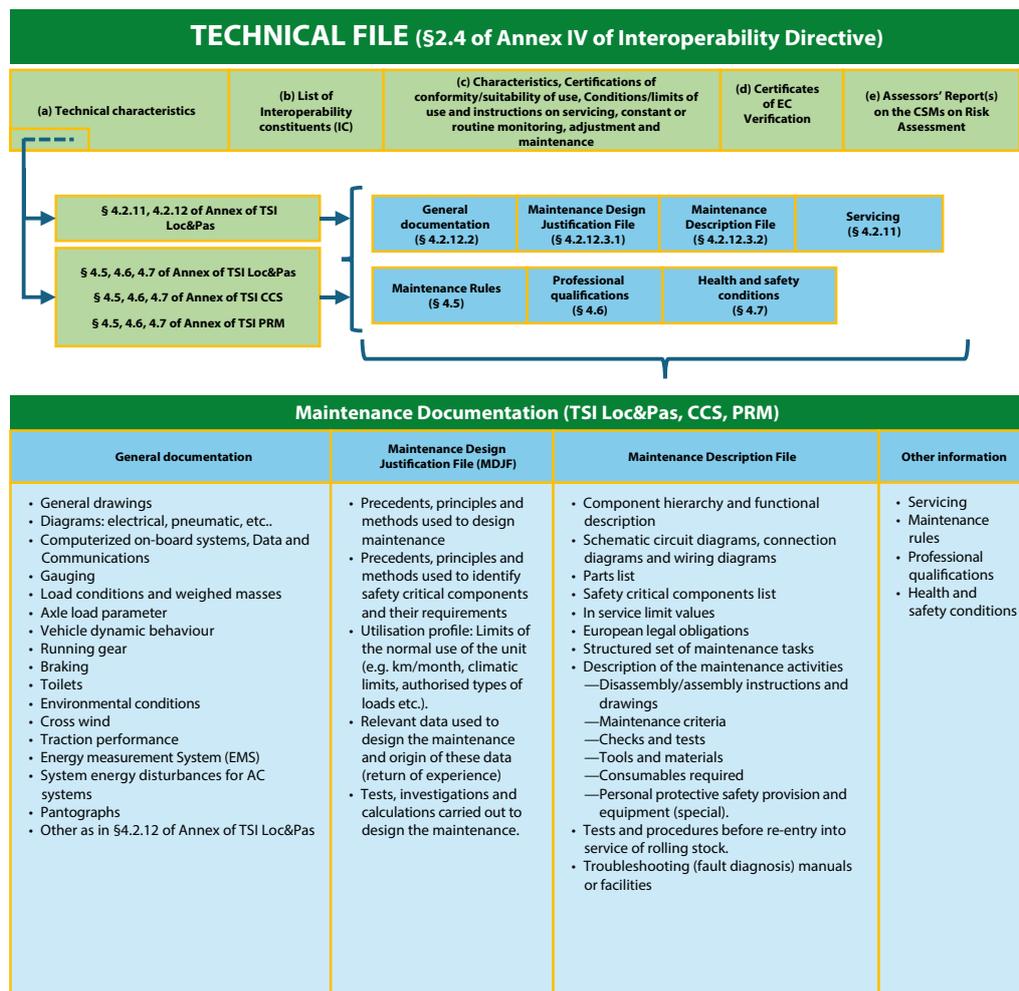
- ▶ Component hierarchy and functional description: The hierarchy sets up the boundaries of the rolling stock by listing all the items belonging to the product structure of that rolling stock and using an appropriate number of discrete levels. The lowest item of the hierarchy shall be a replaceable unit.
- ▶ Schematic circuit diagrams, connection diagrams and wiring diagrams
- ▶ Parts list: The parts list shall contain the technical and functional descriptions of the spare parts (replaceable units). The list shall include all parts specified for changing on condition, or which may require replacement following electrical or mechanical malfunction, or which will foreseeably require replacement after accidental damage (e.g. windscreen). Interoperability constituent shall be indicated and referenced to their corresponding declaration of conformity.
- ▶ Safety critical components list: The safety critical components list shall contain the specific servicing, maintenance and servicing/maintenance traceability requirements.
- ▶ The limit values for components which shall not be exceeded in service shall be stated; the possibility of specifying operational restrictions in degraded mode (limit value reached) is permitted (performances are indicated in TSI Loc&Pas, Annex, p. 4.2).
- ▶ European legal obligations: where components or systems are subject to specific European legal obligations these obligations shall be listed.

7 WHAT IS THE MAINTENANCE FILE?

- ▶ The structured set of tasks that include the activities, procedures, means proposed by the applicant to carry out the maintenance task.
- ▶ The description of the maintenance activities.
- ▶ The following aspects have to be documented (when they are specific to the application):
 1. Disassembly/assembly instructions drawings necessary for correct assembly/disassembly of replaceable parts
 2. Maintenance criteria
 3. Checks and tests
 4. Tools and materials required to undertake the task (special tools)

The scheme contained in [Figure 29](#) shows the links between Technical File and Maintenance documentation for vehicles compliant with TSI Loc&Pas, CCS, PRM.

Figure 29 Technical File and Maintenance Documentation for a vehicle compliant with TSIs Loc&Pas, PRM, CCS



7.2.2 Maintenance documentation for vehicles compliant with TSI Wagon

The main structure of the maintenance documentation for vehicles compliant with TSI Wagon is described in chapter 4.5 of its Annex, where there is also the main content.

The following documents being part of the technical file as required in Article 15(4) of and as set out in Annex IV of the Interoperability Directive [3] are necessary to undertake maintenance activities on the freight wagons:

- ▶ general documentation.
- ▶ the maintenance design justification file.
- ▶ the maintenance description file.

This documentation might be modified later in accordance with the corresponding EU legislation, taking into account the existing operating and maintenance conditions of the unit.

On the basis of these three documents, the entity in charge of maintenance shall define a maintenance plan and appropriate maintenance requirements at maintenance operational level under its sole responsibility (not in the scope of the assessment against the TSI WAG).

The documentation includes a list of safety critical components. Safety critical components are components for which a single failure has a credible potential to lead directly to a serious accident as defined in Article 3(12) of the Safety Directive [2].

The safety critical components and their specific servicing, maintenance and maintenance traceability requirements are identified by the designers/manufacturers at design phase and through a collaboration between designers/manufacturers and the concerned entities in charge of maintenance after vehicles have entered into operation.

1. **General Documentation**, as indicated in TSI WAG, Annex, p. 4.5.1

The general documentation is intended to provide information on functioning and main characteristics of the wagon and its components. It comprises:

- ▶ Drawings and description of the freight wagon and its components.
- ▶ Any legal requirement concerning the maintenance of the unit.
- ▶ Drawing of systems (electrical, pneumatic, hydraulic and control-circuit diagrams).
- ▶ Additional on-board systems (description of the systems including description of functionality, specification of interfaces and data processing and protocols).
- ▶ Configuration files for each vehicle (parts list and bill of material) to enable (in particular but not only) traceability during maintenance activities.

2. **Maintenance Design Justification File (MDJF)**, as indicated in TSI WAG, Annex, p. 4.5.2

The maintenance design justification file explains how maintenance activities are defined and designed in order to ensure that the rolling stock characteristics will be kept within

permissible limits of use stated in TSI WAG during its lifetime. The file shall give input data in order to determine the criteria for inspection and the periodicity of maintenance activities. The maintenance design justification file comprises:

- ▶ Precedents, principles and methods used to design the maintenance of the unit.
- ▶ Precedents, principles and methods used to identify the safety critical components and their specific operational, servicing, maintenance and traceability requirements.
- ▶ Limits of the normal use of the unit (e.g. km/month, climatic limits, foreseen types of loads, etc.).
- ▶ Relevant data used to design the maintenance and origin of these data (return of experience).
- ▶ Tests, investigations and calculations carried out to design the maintenance.

3. **Maintenance Description File** as indicated in TSI WAG, Annex, p. 4.5.3

The maintenance description file describes how maintenance activities can 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), and
- ▶ corrective maintenance.

The maintenance description file includes the following:

- ▶ Component hierarchy and functional description which sets up the boundaries of the freight wagon 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 which shall contain the technical and functional descriptions of the spare parts (replaceable units). The list shall include all parts specified for changing based on condition, which may require a replacement following electrical or mechanical malfunction or which will foreseeable require a replacement after an accidental damage. Interoperability constituents shall be indicated and referenced to their corresponding declaration of conformity.
- ▶ Safety critical components list: The safety critical components list shall contain the specific servicing, maintenance and servicing/maintenance traceability requirements.
- ▶ Limit values for components which are not to be exceeded in service. It is permitted to specify operational restrictions in degraded mode (limit value reached).
- ▶ List of reference to the European legal obligations to which components or subsystems are subject.

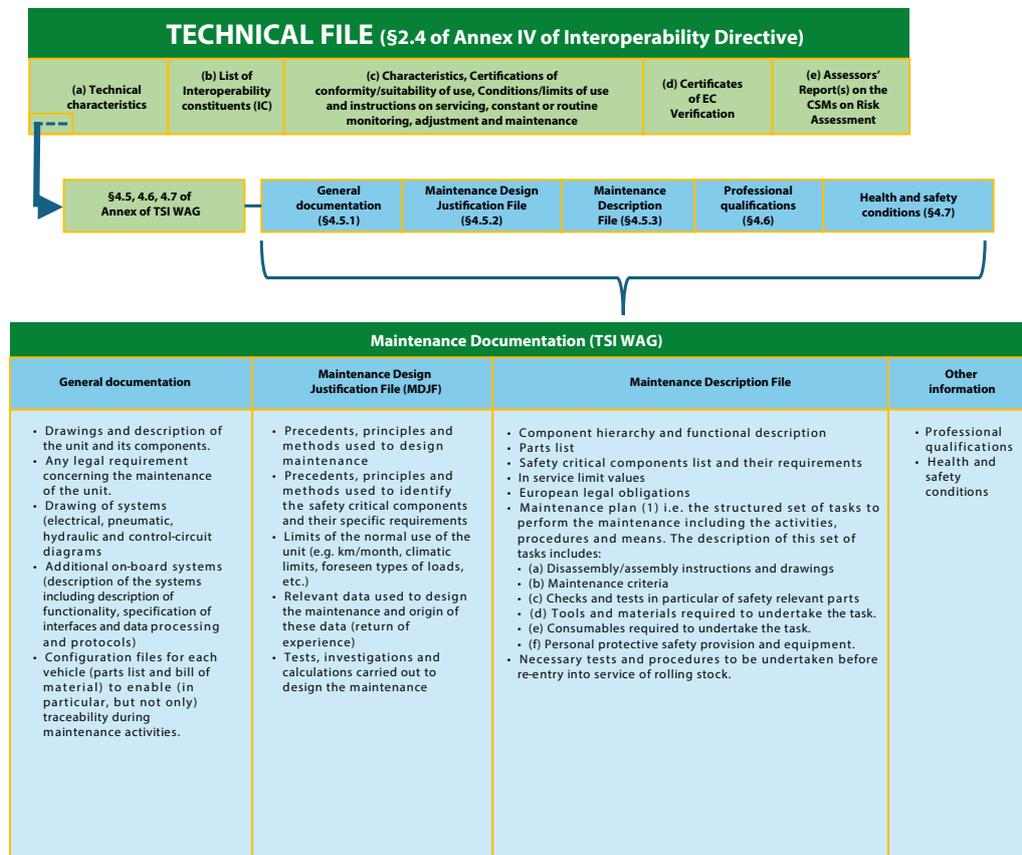
GUIDANCE ON ECM CERTIFICATION PROCESS

- ▶ Maintenance plan⁴, 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:
 - a) Disassembly/assembly instructions drawings necessary for correct assembly/disassembly of replaceable parts.
 - b) Maintenance criteria.
 - c) 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).
 - d) Tools and materials required to undertake the task.
 - e) Consumables required to undertake the task.
 - f) Personal protective safety provision and equipment.
- ▶ Necessary tests and procedures to be undertaken after each maintenance operation before re-entry into service of rolling stock.

The scheme contained in [Figure 30](#) shows the links between Technical File and Maintenance documentation for vehicles compliant with TSI Wagon.

⁴ *The maintenance plan shall take into accounts the findings of the ERA Task force on Freight Maintenance (see 'Final report on the activities of the Task Force Freight Wagon Maintenance' published on the ERA website <http://www.era.europa.eu>).*

Figure 30 Technical File and Maintenance Documentation for a vehicle compliant with TSIs Wagon



7.3 Maintenance File

7.3.1 The Maintenance File for TSI compliant vehicles

The maintenance file for TSI compliant vehicles is a set of documents, necessary to perform the maintenance and to ensure safe and reliable operation throughout the vehicle's lifecycle, compiled by the ECM through the application of CSM-RA during the analysis of the:

- ▶ recommendations for maintenance of the initial maintenance documentation,
- ▶ information on planned operations

and taking into account the information contained in any associated guarantees.

The recommendations for maintenance of the initial maintenance documentation are supplemented by additional technical and maintenance documentation for systems or parts of the vehicle not covered by any TSIs.

The maintenance file for TSI compliant vehicles shall take also into account the performance targets contractually required by the users: RUs and keepers.

GUIDANCE ON ECM CERTIFICATION PROCESS

The schemes contained in [Figure 31](#) and [Figure 32](#) show the process for creating the Maintenance File for vehicles compliant with TSI Loc&Pas and vehicles compliant with TSI Wagon.

Figure 31 Maintenance File for a new vehicle compliant with TSIs Loc&Pas, PRM, CCS

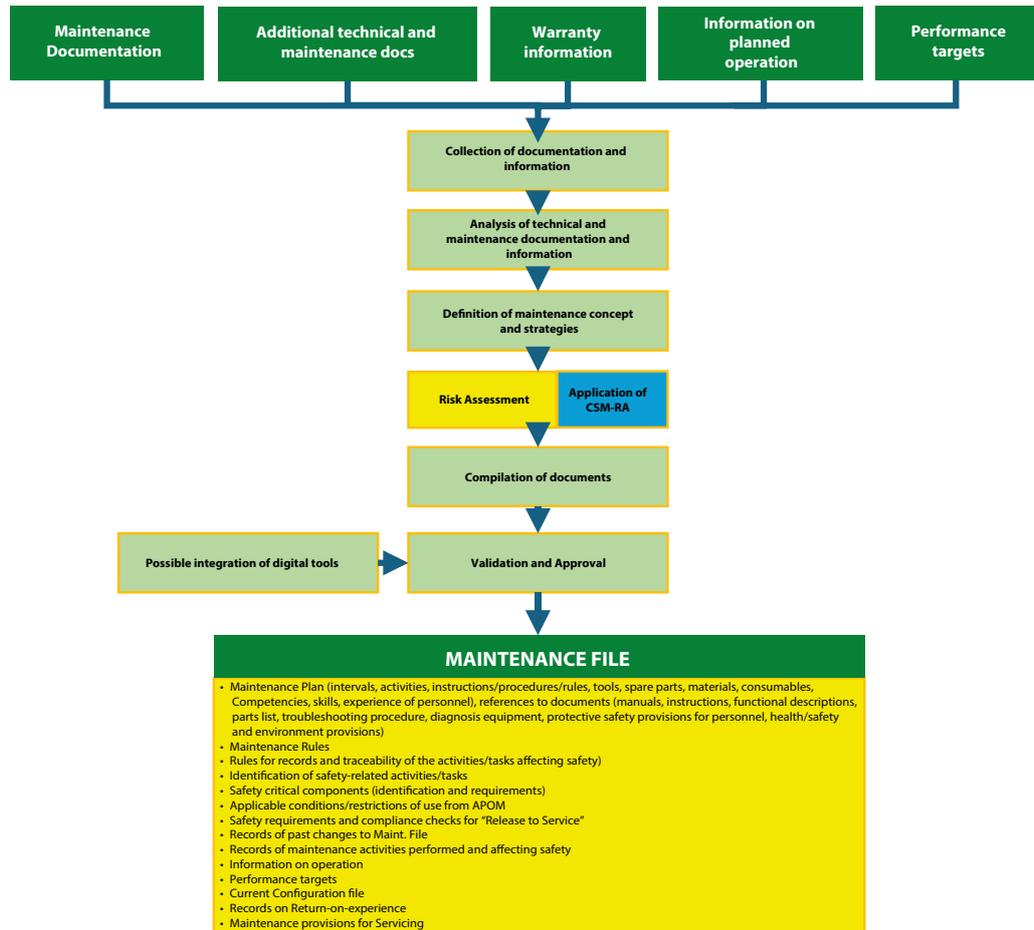
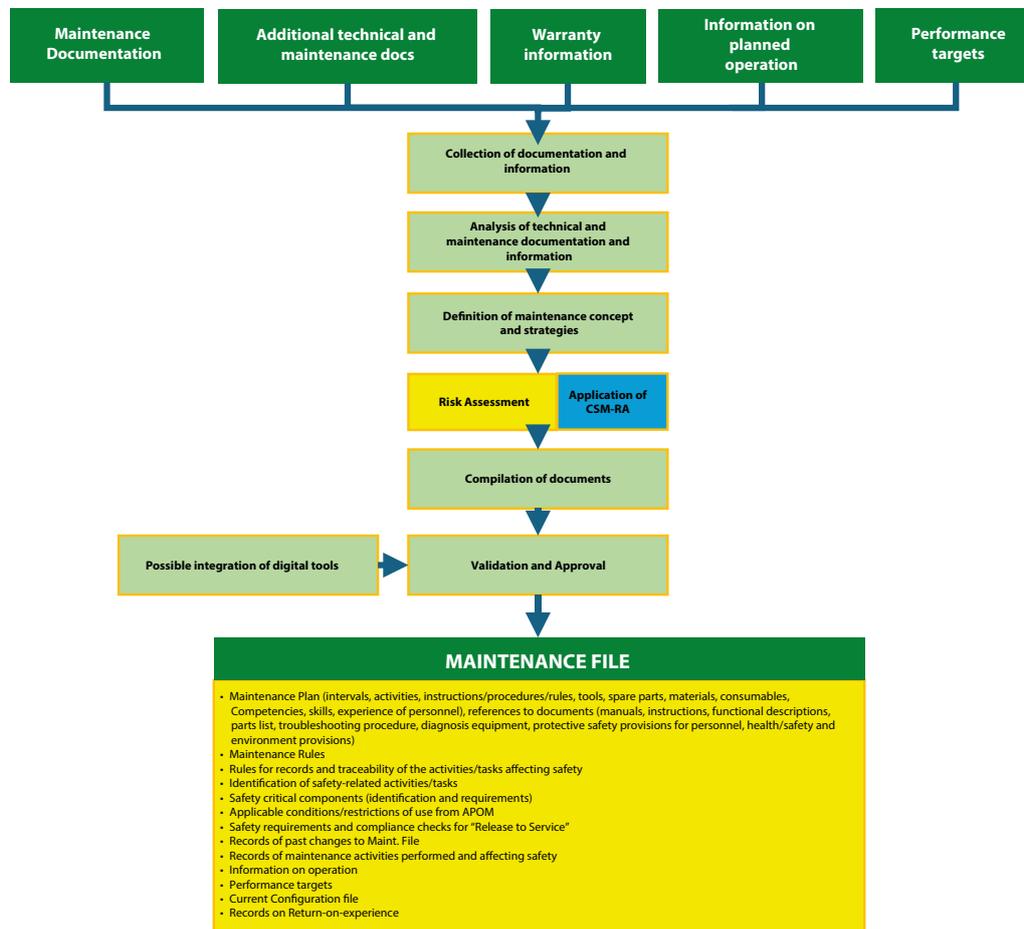


Figure 32 Maintenance File for a new vehicle compliant with TSI WAG



7.3.2 The Maintenance File for non-TSI compliant vehicles

The maintenance file for non-TSI compliant vehicles (the majority of the existing vehicles) is assumed not to have a well-defined structure and be complete in all its parts.

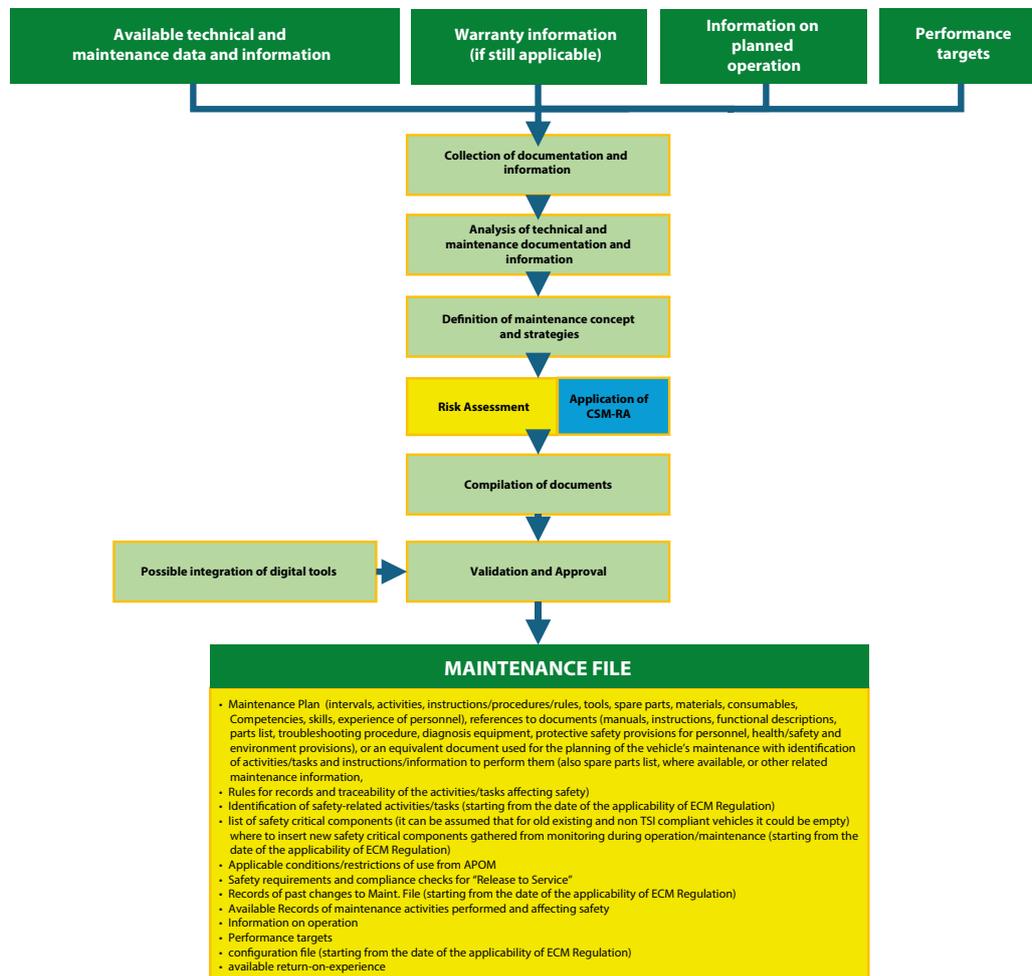
As a consequence, it can be assumed that the maintenance file for non-TSI compliant vehicles is the set of documents, containing the **available technical and maintenance data and information** used by the ECM to perform the maintenance (current and historical data, rules, activities and tasks, planning, return-on-experience, methods, records of performed maintenance and other technical data) and useful for ensuring safe and reliable operation throughout the vehicle’s lifecycle.

It also contains the available records of the changes performed on the maintenance file and the available records of the maintenance activities performed and affecting safety.

The maintenance file for non-TSI compliant vehicles shall take also into account the performance targets contractually required by the users: RUs and keepers.

The scheme contained in [Figure 33](#) shows the process for creating the Maintenance File for existing vehicles.

Figure 33 Maintenance File for an existing vehicle not compliant with any TSIs



7.3.3 Purpose and Scope of the Maintenance File

The maintenance file has to be established for each vehicle, both for TSI and non-TSI compliant vehicle, and contains all necessary information to carry out maintenance.

The maintenance file serves several key purposes:

- ▶ Ensuring compliance with European railway legislation, including ECM certification requirements.
- ▶ Providing a systematic approach to maintenance planning, execution, and record-keeping.
- ▶ Facilitating communication between stakeholders, including manufacturers, ECMs, and railway operators.
- ▶ Ensuring safety-critical components are monitored and maintained effectively.
- ▶ Supporting risk management by integrating safety analysis and failure prevention strategies.

The maintenance file is a dynamic document that evolves with operational experience, technical advancements, and regulatory updates.

What is the structure or format for the Maintenance File?

There is no standardised or recommended structure for the maintenance file. Each ECM is free to choose an appropriate structure for ensuring the maintenance file contains all the documents necessary to its scope.

As a reference,

- ▶ ISO 9879 [43] (EN 17018 [44]) is an international standard for term and definition for vehicle maintenance.
- ▶ EN 17023 [20] is a European standard for the creation and modification of **maintenance plan** and
- ▶ EN 17095 [19] is a European standard for the **maintenance records**.

7.3.4 Providing for the First Maintenance File for TSI compliant vehicles

The ECM is responsible for providing the first maintenance file before the vehicle enters operation and updating it throughout the vehicle life cycle. In conformity with the ECM Regulation [1], Annex II.4, the process for providing the first maintenance file has to be implemented through the application of specific procedure of the ECM maintenance system. That procedure may include the following steps of the process:

1. **Collection of Data:** Gathering technical and maintenance documentation from keeper, RUs, holder of the APOM, manufacturers, safety authorities, and regulatory bodies both related to applicable TSIs and additional technical and maintenance documentation for systems or parts of the vehicle non covered by TSIs
2. **Analysis of technical and maintenance documentation:** Collecting parameters, limit of use, maintenance and service limit values and all information useful to perform the maintenance tasks/activities (maintenance manuals, troubleshooting and fault-finding guides, diagnosis procedure and equipment, etc...), information on operation, performance targets, information related to any associated guarantees
3. **Definition of Maintenance Strategies:** Establishing corrective, preventive and predictive maintenance plans that balance reliability, availability, maintainability and cost-effectiveness in respect of safety.
4. **Risk Assessment:** Applying the Common Safety Method for Risk Assessment (CSM-RA) to identify potential hazards and necessary mitigations.
5. **Document Compilation:** Implementing mitigations and organizing a structured maintenance plan with intervals, steps, activities/tasks and references to documents (for instance, maintenance manuals or other documents belonging to the maintenance file) containing information on instructions for performing maintenance (including

documents with functional description of the system to be maintained and its position in the vehicle), tools and measuring equipment, skills and competences, parts list (configuration file, spare parts list), troubleshooting procedures and diagnosis equipment, protective safety provisions for personnel, health/safety and environment provisions, and rules for records and traceability of the activities/tasks affecting safety. It contains also:

- the identification of safety-related activities/tasks
 - the list of safety critical components and its requirements
 - the applicable conditions/restriction of use from APOM, safety requirements and compliance checks for release to service
 - information on operation (pattern, services, mileages...)
 - performance targets, where contractually required by the users: RUs and keepers.
6. **Validation and Approval:** Conducting internal and external reviews to ensure accuracy and adherence to safety standards before implementation.
7. **Possible integration of Digital Tools:** Using software solutions to manage maintenance records, scheduling, and real-time monitoring of vehicle performance.

Additional Continuous Improvement Measures:

- ▶ **Implementation of Predictive Maintenance:** Using data analytics and AI-driven models to anticipate failures and optimize maintenance schedules.
- ▶ **Benchmarking Against Industry Standards:** Comparing maintenance performance with best practices to identify improvement areas.
- ▶ **Collaboration with Research Institutions:** Engaging with technology developers to adopt innovative maintenance techniques and materials.

What is in practice the content of the Maintenance File in conformity with ECM Regulation [1] both for TSI and non-TSI compliant vehicles?

The maintenance file is a set of documents, necessary to perform the maintenance and to ensure safe and reliable operation throughout the vehicle's lifecycle.

The **maintenance file for TSI compliant vehicles** is composed of:

1. **maintenance plan** (intervals, steps, maintenance activities/tasks) and references to documents (for instance, maintenance manuals or other documents belonging to the maintenance file) containing information on instructions for performing maintenance (including documents with functional description of the system to be maintained and its position in the vehicle), tools and measuring equipment, skills and competences, parts list (configuration file, spare parts list), troubleshooting procedures and diagnosis equipment, protective safety provisions for personnel, health/safety and environment provisions, and rules for records and traceability of the activities/tasks affecting safety.

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2. safety-related activities/tasks
3. list of safety critical components and its requirements (it is assumed that it could be an empty list)
4. applicable conditions/restrictions of use from APOM, safety requirements and compliance checks for release to service
5. records of changes performed on the maintenance file, including the risk assessment performed in conformity with CSM-RA
6. records of the maintenance activities performed and affecting safety
7. information on operation (pattern, services, mileages,...)
8. performance targets, where contractually required by the users: RUs and keepers.

It can be assumed that for old existing and non TSI compliant vehicles not all the above-mentioned documents could be in the availability of the ECM.

In any case, in conformity with ECM Regulation, the ECM should have even for **old existing and non TSI compliant vehicles** a maintenance file containing at least:

- ▶ a **maintenance plan**, as described in item 1 above, or an **equivalent document** used for the planning of the vehicle's maintenance with identification of activities/tasks and instructions/information to perform them (also spare parts list, where available, or other related maintenance information)
- ▶ safety-related activities/tasks
- ▶ list of safety critical components (it can be assumed that for old existing and non TSI compliant vehicles) listing new safety critical components gathered from monitoring during operation/maintenance (starting from the date of the applicability of ECM Regulation)
- ▶ available applicable conditions/restrictions of use from APOM, safety requirements and compliance checks for release to service
- ▶ records of any change on the maintenance file, including the risk assessment performed in conformity with CSM-RA (starting from the date of the applicability of ECM Regulation)
- ▶ available records of performed maintenance
- ▶ information on operation (pattern, services, mileages....)
- ▶ performance targets, where contractually required by the users: RUs and keepers
- ▶ configuration file (starting from the date of the applicability of ECM Regulation)
- ▶ available return-on-experience.

7.3.5 Management of the Maintenance File

The ECM is responsible to keep up to date the maintenance file, both for TSI compliant and non-TSI compliant vehicles, during the life cycle of the vehicle.

The updating of maintenance file may be due to various occurrences.

This is a non-exhaustive list of events suggesting the need to update the maintenance file:

- ▶ vehicle change (managed by the holder of the APOM or by the entity entrusted by the Keeper in conformity with Art. 14 and 15 of Regulation EU 2018/545) or other changes impacting the APOM or the technical and maintenance documentation of the vehicle. In this case the entity managing the change has to release the updated maintenance documentation to the ECM, directly or via the Keeper, enabling it to update the Maintenance File and the Configuration File of the vehicle (see scheme in [Figure 34](#) for a diagram in case of vehicle change)
- ▶ modifications of operation (pattern, services, mileages...)
- ▶ return-on-experience from accidents, serious accidents and incidents, detected failures of components, maintenance activities performed (e.g. beyond wear and tear).
- ▶ information, findings or recommendation from experience or from European and national legislation or safety authority or actors of the railway sector (RUs, IMs, Manufacturers, Keepers, ECMs, NIB, JNS) or from information tools (SAIT, ISS, SIS) or other needs requesting or suggesting a change to the maintenance file for ensuring safe state of running
- ▶ modifications to maintenance targets, strategy, concept, criteria
- ▶ modifications to maintenance tasks/activities
- ▶ modifications to maintenance intervals, steps, frequency
- ▶ modifications to performance targets agreed with RUs/Keepers
- ▶ substitution in the framework of maintenance

ECM has to implement risk management procedure of its maintenance system for any change to the maintenance file, taking into account any information related to maintenance, and apply CSM-RA for ensuring safe state of running and determining, where required, mitigations necessary to accept the change to the maintenance file as safe.

Who is responsible for a change to the Maintenance File?

Only the ECM registered for the vehicle is allowed to change the Maintenance File. He operates the change of the Maintenance File through its Function ECM-F2 (Maintenance Development Function).

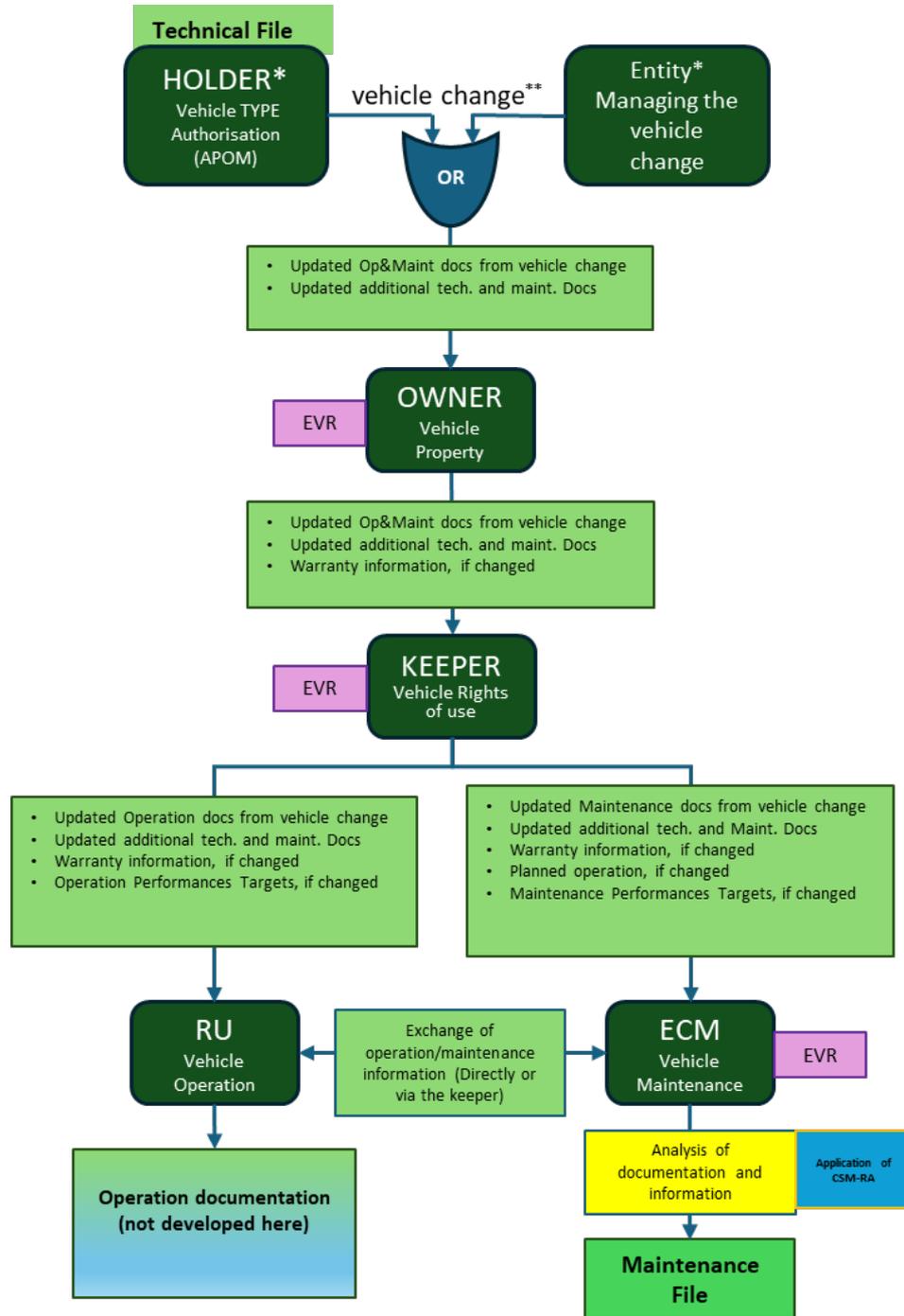
What is necessary in practice for ECM-F2 to change the Maintenance File?

In compliance with ECM Regulation [1], in order to change the Maintenance File, ECM-F2 needs to:

7 WHAT IS THE MAINTENANCE FILE?

- ▶ have an internal or external trigger event, as above represented in the non-exhaustive list of events, for determining the need to change the Maintenance File
- ▶ have a procedure of its maintenance system to manage the change in the Maintenance File and follow this procedure
- ▶ have specific competences in engineering disciplines and in the application of CSM-RA managed through the competence management process of the ECM maintenance system
- ▶ provide for managing the traceability of all the successive versions of the Maintenance File, including the risk assessment performed in conformity with CSM-RA
- ▶ manage the Vehicle Configuration, where necessary (for example in case of changes to the vehicle, managed by the entity managing the change, and impacting the vehicle configuration or in case of substitution in the framework of maintenance, managed by itself, or in other cases affecting the configuration of the vehicle)
- ▶ ensure that the implementation of changes to the Maintenance File is done accordingly
- ▶ monitor the effectiveness of the changes to the maintenance file through a process in consistency with the CSM on monitoring [\[13\]](#) and CSM-ASLP, when it will entry into force.
- ▶ to contract an AsBo when the change in the maintenance file is significant.

Figure 34 Exchange⁵ of documents/information to update the Maintenance File following a vehicle change



⁵ To be noted that different roles may be covered by the same company (i.e. Manufacturer may be the Holder of Vehicle Type Authorisation or the Entity managing the change, or Entity managing the change, Owner and Keeper and RU may be the same company or Holder of Vehicle Type Authorisation, Entity managing the change and Owner and Keeper or even RU and ECM may be the same company or other combinations are possible in the market)

* To be noted that depending on contractual agreement, there can be a direct relationship between the Entity managing the change (Holder of Type Authorisation or other entity) and Keeper or even directly between the Entity managing the change and RU/ECM for the exchange of documents/information

** Vehicle change is intended as defined in Art. 15 and 16 of Regulation EU 2018/545

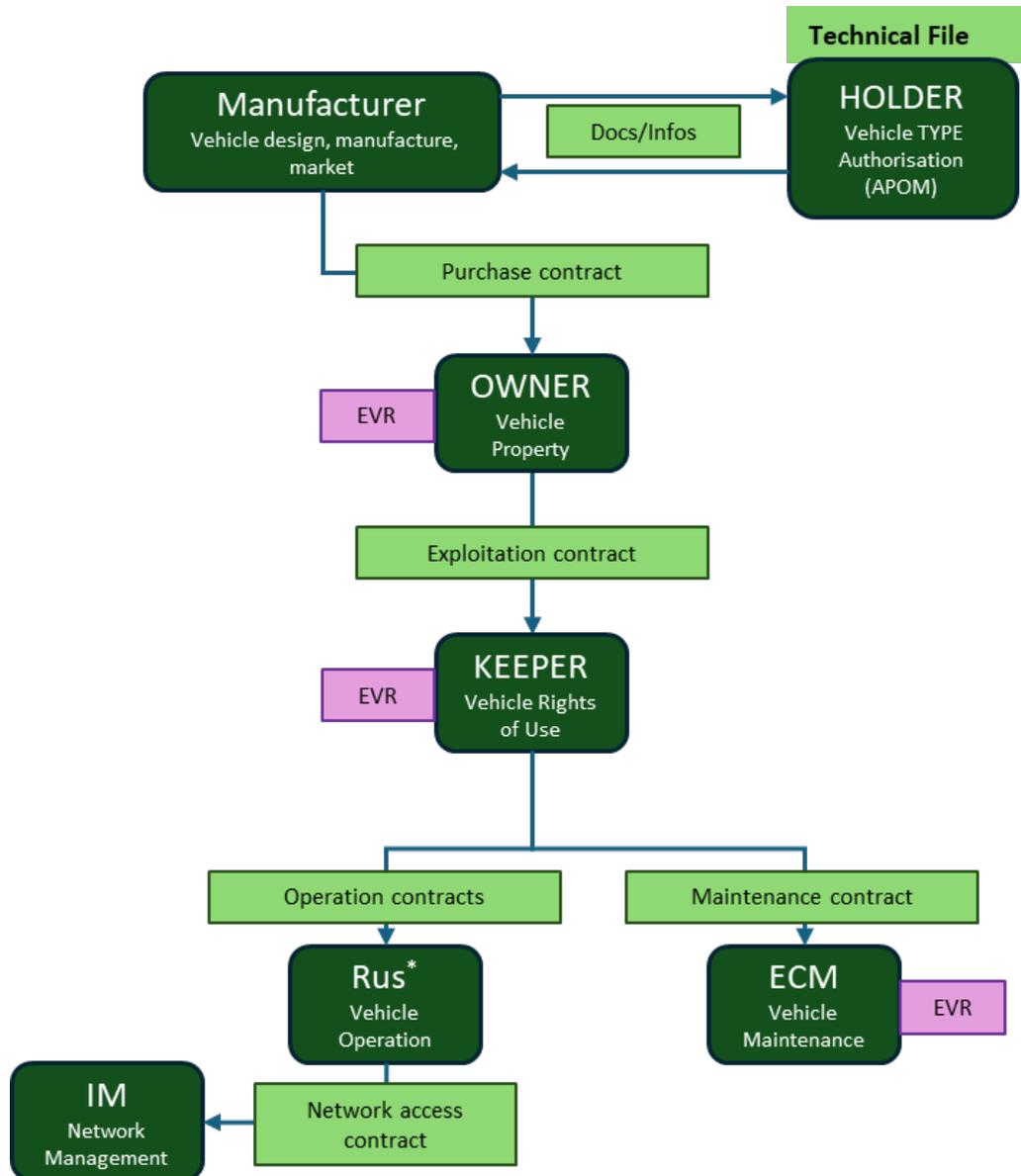
7.4 Responsibilities of Key Stakeholders

Several entities play a role in the preparation, implementation, and updating of the maintenance file:

- ▶ **Manufacturers:** Provide technical documentation, maintenance manuals, and initial maintenance recommendations/documentation. Also provide for information contained in any associated guarantees of the vehicle or parts of it.
- ▶ **ECMs:** Develop and update the maintenance file, ensuring compliance and implementation of maintenance for a safe state of running. Transfer the maintenance file on request of the keeper.
- ▶ **Keepers:** Ensure that maintenance documentation is transferred to the assigned ECM, once it is registered as such and before the vehicle enters the service. Establish contractually performance targets for maintenance. Assure that the maintenance file is transferred from the former ECM to the incoming ECM.
- ▶ **Railway Undertakings:** Provide operational feedback and ensure vehicles are used in safe state and adapt the operation to requests for removal from operation and notification of return to operation issued by ECM. They provide for information on planned operations and performance targets in agreement with Keeper.
- ▶ **ERA/National Safety Authorities:** Provide for ensuring completeness, relevance and consistency of the technical file and all related documentation (comprising maintenance documentation) before releasing the APOM of the vehicle
- ▶ **NoBos:** Undertake maintenance documentation to a conformity assessment against TSI and release its conformity report to the applicant of APOM for including it in the technical file
- ▶ **Regulatory Authorities:** Conduct inspections and audits to verify adherence to safety and compliance requirements
- ▶ **ECM Certification Bodies:** Release ECM certification and ECM function certification and conduct surveillance audits to verify and to ensure compliance of the maintenance system to the requirements of ECM regulation [1].
- ▶ **AsBo:** In case of significant change in the maintenance file, an AsBo has to be contracted by the ECM possibly at the beginning of the change.

The scheme contained in [Figure 35](#) shows the main Contract relationships in the vehicle railway field.

Figure 35 Main contract relationships in the vehicle railway field⁶



⁶ To be noted that different roles may be covered by the same company (i.e. Manufacturer may be the Holder of Vehicle Type Authorisation, or Owner and Keeper and RU may be the same company or Holder of Vehicle Type Authorisation and Owner and Keeper or even RU and ECM may be the same company or other combinations are possible in the market)

* Depending on market demand or business the operation of the same vehicle may be assigned by contract to different RUs

8 EXCHANGE OF INFORMATION BETWEEN RAILWAY ACTORS

8.1 What is the information that stakeholders have to exchange according to the maintenance of vehicles?

The exchange of information is critical. Therefore, this is an important requirement in the ECM Regulation [1] obliging RUs, IMs, manufacturers, keepers, ECMs, certification bodies and the relevant national safety authorities to exchange information. As established in the Article 5 of the ECM Regulation:

- ▶ *The entity in charge of the maintenance of the vehicle shall deliver information on the maintenance of a vehicle, and, where applicable on aspects relevant for the operation to the railway undertakings or infrastructure managers at request, either directly or via the keeper;*
- ▶ *The railway undertaking or the infrastructure manager shall deliver information on the operation of a vehicle to the entity in charge of maintenance at request, either directly or via the keeper of the vehicle;*
- ▶ *All parties involved in the maintenance process such as railway undertakings, infrastructure managers, keepers, entities in charge of maintenance, as well as manufacturers of vehicles, subsystems or components, shall exchange relevant information about maintenance in accordance with the criteria listed in Sections I.7 and I.8 of Annex II;*
- ▶ *Where any involved party, in particular a railway undertaking or an infrastructure manager, has evidence that an entity in charge of maintenance does not comply with Article 14 of Directive (EU) 2016/798 or with the requirements of this Regulation, it shall without delay inform the certification body and the relevant national safety authority thereof. The certification body or, where the entity in charge of maintenance is not certified, the relevant national safety authority shall take appropriate action to check whether the claim of non-compliance is justified;*
- ▶ *Where there is a change of entity in charge of maintenance, the keeper, in accordance with Article 47(6) of the Interoperability Directive [3], shall inform without delay the registration entity referred to in Article 4(1) of Commission Decision 2007/756/EC⁷ (9) and request the update of the vehicle register. In that situation:*
 - (i) the former entity in charge of maintenance shall without delay deliver the maintenance documentation to the keeper;*
 - (ii) the former entity in charge of maintenance shall be relieved of its obligations when it is removed from the vehicle register;*
 - (iii) in the absence of a new entity in charge of maintenance the registration of the vehicle shall be suspended.*

⁷ Commission Decision 2007/756/EC has been repealed and replaced by Commission Implementing Decision (EU) 2018/1614

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The exchange of information covers specifically **Safety Critical Components** too. As established in the Article 4(2), 4(3) and 4(6) of the ECM Regulation:

- ▶ *The entity in charge of maintenance shall, either directly or via the keeper provide **information** to the railway undertakings and infrastructure managers operating the vehicles, keepers, manufacturers, holders of vehicles authorisations and holders of the type authorisation of vehicles, subsystems or components, as most appropriate and shall in particular, inform them of exceptional maintenance findings beyond wear and tear;*
- ▶ *Where during the maintenance of a vehicle an entity in charge of maintenance becomes aware of evidence suggesting a component not previously identified as safety critical should be considered as such, it shall **inform** the manufacturer, the holder of the vehicle type authorisation and the holder of the vehicle authorisation without delay;*
- ▶ *The entity in charge of maintenance shall **inform** the rail sector and the rail supply industry about new or unexpected safety relevant findings including exceptional maintenance findings beyond wear and tear, in relation to vehicles, subsystems or other components, when the related risks are relevant for more actors and are likely to be poorly controlled. The entity in charge of maintenance shall use the Safety Alert IT or another informatics tool provided by the Agency for this purpose.*

The exchange of information covers also information between certification body, Member States and authorities as in article 6(1), 6(2), 6(8), 11 and 13 of the ECM Regulation:

- ▶ *Member States shall provide the Agency with the following **information** concerning the certification bodies:*
 - *name*
 - *address*
 - *contact details*
 - *the nature of their empowerment in accordance with Article 14 of Directive (EU) 2016/798 (accreditation, recognition or if they have taken on the task as the national safety authority);*
- ▶ *Member States shall **inform** the Agency about any change in the situation within one month of the occurrence of that change;*
- ▶ *A national safety authority, a national investigation body or the Agency may request **information** from any certification body on the situation concerning an individual ECM certification. The certification body shall reply within 2 weeks at the latest;*
- ▶ *If a national safety authority has knowledge that an entity in charge of maintenance does not comply with the requirements of Annex III of Directive (EU) 2016/798 or with the certification requirements of this Regulation, it shall **inform** the national bodies or authorities responsible for the accreditation or recognition, the Agency, the certification body and other interested parties as appropriate;*
- ▶ *The Agency shall collect, record and publish basic **information** on certification bodies and certified entities in charge of maintenance. The Agency shall create an IT tool for delivering this task.*

The exchange of information on changes related to ECM certificate is ruled in Article 7(8):

- ▶ *An ECM certification shall be valid for a maximum period of 5 years. The certified entity in charge of maintenance shall inform the certification body of any changes that might have an impact on the validity of its certification without delay.*

The exchange of information between the ECM and other actors may be done in various ways using various methods of communication. The traditional method is paper-based forms (e.g. defined proformas, train books, engineering documents e.g. change request documents, modifications, special checks, safety bulletins etc.). Digital data exchange is now increasingly the norm, this can be a commercial industrial software solution (e.g. SAP, Maximo), or ECM in-house system linked to the Maintenance Management Information System (MMIS) or customer's system (e.g. Rail fleet). Day-to-day information exchange also uses common methods such as e-mail (normal and certified), phone, text SMS and even verbal. What is important, whichever mixture of methods is chosen, is that the information is correct, complete, comprehensible by both parties and a record is generated to provide traceability.

8.2 How to find an ECM certification body, how to publish your ECM certificate, how to find an ECM certified?

See the ERADIS guide, part 5.

<http://eradis.era.europa.eu/help/docs/User%20Manual%20-%20ERADIS%20Safety%20Documents.pdf>

9 MANAGEMENT OF CHANGES

9.1 The Keeper wants to change the ECM of a vehicle; how does it proceed?

The vehicle Keeper, registered as such in the EVR (European vehicle Register), is responsible for changing the ECM of a vehicle or a fleet of vehicles.

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

In conformity with Art. 5.5 (i) of ECM Regulation [1], the former ECM shall, without delay, deliver the maintenance documentation to the Keeper.

For this purpose, the Keeper is recommended to request complete and updated maintenance documentation together with the vehicle's status, i.e., current operating status, and technical configuration, from the former ECM.

The Keeper needs directly to provide the incoming ECM with:

- ▶ Complete Vehicle Maintenance File (including records on maintenance performed and safety verifications, SCC list and requirements in force, mission profile, risk analysis done for defining maintenance activities and intervals, maintenance plan, historical changes to maintenance file, records of mileages, etc.) and including its modifications made by the former ECM. (see [chapter 7](#) maintenance file)
- ▶ Current operating status, where it is possible to find information on the exact operating conditions of the vehicle at the time of the change of the ECM (fault not solved, pending maintenance interventions, efficiency degradation or perfect efficiency status).
- ▶ Configuration files of the vehicle, where it is possible to find the updated status of the technical configuration of the vehicle and all the changes introduced and communicated, directly or via the Keeper, by the Entity managing the change⁸.

The complete Vehicle Maintenance File (see subparagraph 4.2.12 of the Annex of TSI Loc&Pas, subparagraph 4.5 of the Annex of TSI Wagons, and [section 7](#) of the present guide) and the configuration file are part of the vehicle's documentation and accompany the vehicle throughout its life.

The Keeper is responsible for ensuring that the above documents are released to the incoming ECM in a timely manner before it is registered on the EVR by the Keeper (or by the entity entrusted with the registration).

⁸ The entity managing a change to the vehicle is a company (Manufacturer or other, even if it is not the holder of the vehicle type authorization or the vehicle authorization) entrusted by the Keeper, in agreement with the Owner, for implementing a technical change on the vehicle in conformity with the current legislation (see Reg. UE 2018/545 and Interoperability Directive).

Furthermore, other additional information and data required by the contract between the Keeper and the 'former' ECM can be included.

Before accepting the role of ECM, the incoming ECM is recommended to check if the documentation released by the Keeper is complete. By using information included in that documentation and informing the Keeper, the ECM can ensure the maintenance of the vehicle can be performed.

Furthermore, the Keeper must provide for:

- ▶ updating, directly or through the entity entrusted for the registration, the EVR registration of the vehicle removing the former ECM and inserting the incoming ECM.
- ▶ giving official communication to the former ECM and to the incoming ECM, to the Owner and the RUs about the date of change of the ECM in the EVR.

The former ECM is relieved of its obligations from the date when it is removed from the vehicle register.

Consequently, it is strongly recommended that these details and issues be considered when negotiating and setting up contractual agreements between the parties involved.

9.2 I'm the ECM and want to outsource one or more functions of the maintenance system, the whole functions, or parts of them. How do I proceed?

In conformity with Art. 14 of the Safety Directive [2], the ECM cannot outsource the management function (ECM-F1), but it may outsource one or more of the other maintenance functions ECM-F2, ECM-F3 and ECM-F4, or parts thereof, to other contracting parties.

ECM needs to inform its Certification Body about the functions/processes/activities outsourced:

1. In conformity with Article 7(8) of the ECM Regulation [1] without delay in case the functions/processes/activities outsourced might have an impact on the validity of the certificate. The impact might be identified through a Risk Assessment process or other internal procedures of the ECM.
2. Anyway, through the annual report.

In both cases, the ECM CB could decide if a supplementary visit is requested to ensure the certificate's validity, and ECM-F1 shall demonstrate to the certification body how it complies with all the requirements of ECM Regulation regarding the functions (or parts thereof) it decided to outsource.

The outsourcing process can be differentiated between the cases when the external company (i.e. the contractor) has a Maintenance System certified in conformity with ECM Regulation, a generic maintenance or management system certified against a recognized international

standard (e.g. ISO 22163 [45]) and the case when the external company hasn't got any certified maintenance or management system.

NOTE: In case of multiple functions/processes/activities are outsourced to different contractors, the above-mentioned cases may be mixed depending on the real outsourcing pattern.

The following sections show some recommended steps to implement an outsourcing process with a contractor.

9.2.1 Outsourcing process by ECM-F1 perspective

The outsourcing process is identified as a contracting activity with contractors or suppliers and so the requirements of Annex II.I.9 of the ECM Regulation [1] apply.

The requirements to be applied are related to tasks to be made by ECM-F1 in conformity with Annex II.I.9 of ECM Regulation:

- ▶ Define the requirements to be met by the contractor (Annex II.I.9.3.).
- ▶ Monitor the awareness of the contractor entity of risks they entail to the Maintenance System operations (Annex II.I.9.4.).
- ▶ Define and allocate in the contract at least the following (Annex II.I.9.6.):
 - a) Responsibilities and tasks relating to railway safety issues.
 - b) Obligations relating to the transfer of relevant information between the parties involved.
 - c) The traceability of safety-related documents.

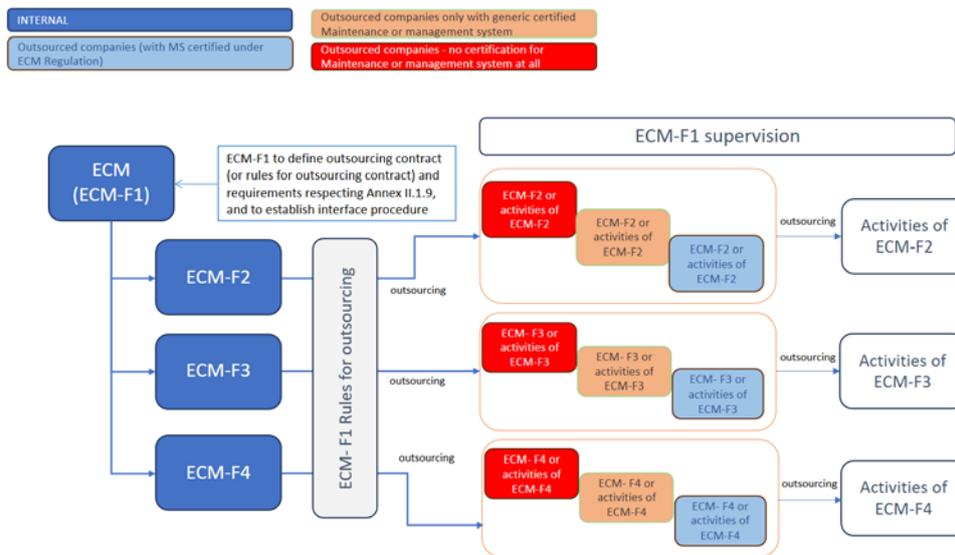
In addition to the steps as mentioned above, when ECM-F1 establishes that the outsourcing (functions/processes/activities, products and services) are **safety related**, the Annex II.I.9.2. applies and it needs to verify at the time of the selection of the contractor entity that:

- a) Contractors, subcontractors, and suppliers are competent.
- b) Contractors, subcontractors, and suppliers have an adequate and documented maintenance management system (MMS).

Intending to specify how to manage the outsourcing, ECM-F1 is recommended to establish a documented **interface procedure**, to specify the steps as mentioned above and the other requirements to be applied to the contractor, i.e. exchange of information, documentation, risk control procedure, competence management, monitoring, continuous improvement, etc....

In conformity with Art. 9.3 of the ECM Regulation, ECM-F1 shall remain responsible for the outcome of the outsourced maintenance activities and shall establish a system to monitor their performance.

Figure 36 Outsourcing process by ECM-F1 perspective



The following sections show some examples of the outsourcing process through the different cases and recommended contents for the interface procedure.

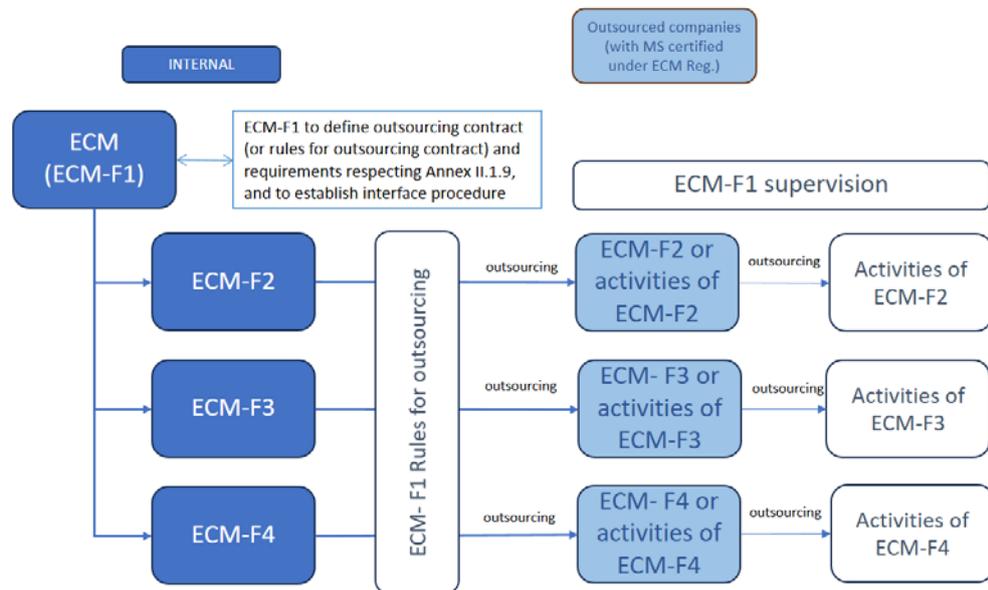
9.2.2 Example of outsourcing functions/activities/services to a company with ECM F2, F3 or F4 certified under ECM Regulation [1]

In this example, each company used for outsourced activities/functions has a Maintenance Management System (MMS) certified in conformity with ECM Regulation.

This is the case when the contractor has an:

- ▶ ECM certificate (valid for the vehicles related to the outsourcing)
- ▶ ECM Function certificate (valid for the function/processes/activities to be outsourced)

Figure 37 Example of outsourcing to a certified maintenance function



In brief, the following is a list of steps to implement the outsourcing with a contractor company with an ECM certification, valid for the vehicles related to the outsourcing, or an ECM Function certification, valid for the functions/processes/activities to be outsourced, in conformity with the ECM Regulation:

- ▶ ECM-F1 is recommended to check into the contractor’s procedures related to the outsourced functions/processes/activities. The organisations’ Management System (MS) does not have to be intended as a “black box”, even if MS is certified. This check into the contractor’s internal procedures related to the outsourced functions/processes/activities is helpful to create links between the Maintenance System of the ECM and the certified MS of the outsourced contractor to define, collect, monitor, and analyse the relevant process results and data, and to state all the requirements and relationships between all the processes and functions involved in terms of roles, responsibilities, information, documents, competencies, etc.....
- ▶ ECM-F1 must identify if **safety-related** activities are involved and, consequently, must apply specific requirements of Annex II.1.9. For example, when the outsourced processes are safety-related, ECM-F1 needs to check if the MS of the contractor is adequate and documented concerning the outsourced functions/processes/activities. When the check fails, ECM-F1 must cover the discrepancies within the interface procedure specifying how the functions/processes/activities have to be managed in conformity with the ECM Regulation. If the check is OK, ECM-F1 uses the outputs of the check within the interface procedure, creating the necessary links with its own maintenance system, and may limit monitoring of outsourced processes to just the results.
- ▶ ECM-F1 is responsible for establishing the rules, conditions, and constraints to manage contracting activities in compliance with Annex II.1.9. ECM-F1 can manage directly all the contracts (in case of a small ECM company) or may establish the rules to be followed, in

case the contracts are managed through internal office of its ECM Functions (in case of big ECM company, usually the different ECM-F2, F3 and F4 have their own contract office). This also applies in the case of subcontracting activities by the contractor.

- ▶ ECM-F1 may limit monitoring of outsourced processes to the results of outsourced processes/activities/functions and establishes in the interface procedure the measures to be applied if process results and data do not comply with stated requirements. Also, ECM-F1 specifies monitoring management in a section of the interface procedure.

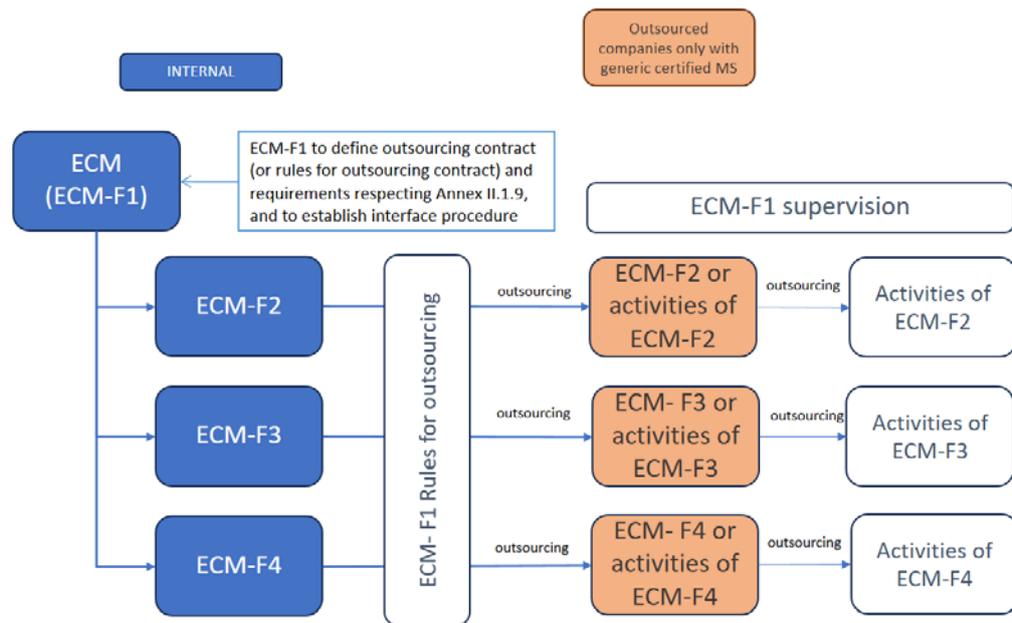
The above-mentioned **interface procedure** is necessary to set rules, requirements, and relationships between the contractor MS and the ECM MS. As a recommendation, the interface procedure should contain at least these points:

- ▶ Identification and definition of interfaces between the contractor's procedures in place for the functions/processes/activities outsourced and the ECM maintenance system (roles, responsibilities, information, documents, competencies, etc...). This part specifies who- what-where-when-how- and the personnel involved, documents that need to be exchanged, data and information exchanges, processes followed, and information that need to be exchanged in case of changes in the ECM MS and/or the MS of the contractor. The interface procedure is to be followed by the contractor together with the procedures of its MS. This requirement should be specified in the contract.
- ▶ Identification of safety-related activities and requirements to be followed in conformity with Annex II.I.9 of the ECM Regulation
- ▶ Identification of rules, conditions, and constraints to manage contracting activities in compliance with Annex II.I.9.
- ▶ Identification of requirements for monitoring and if Annex II.I.9.5 of the ECM Regulation applies
- ▶ Communication protocols between internal functions/processes of the ECM and outsourced functions/processes/activities. This part specifies the communication channels between the contractor, and each involved internal process/function. This part specifies if the exchange of data is made possible by software/electronic way or by direct/manual way or other, and it states the rules for traceability of documentation and information.
- ▶ How the outsourced contractor must apply the requirements of Annex II.I.1 to Annex II.I.9 (leadership, risk management, monitoring,) to its outsourced functions/processes/activities.

Example for applying requirement **1-Leadership** of Annex II.I.1(a) to (h) of the ECM Regulation in [Figure 40](#).

9.2.3 Example of outsourcing functions/processes/activities to a contractor with generic maintenance or management system certified against recognized international standard

Figure 38 Example of outsourcing functions/processes/activities



In brief, the following is a list of steps to implement the outsourcing with a contractor having a generic maintenance or management system certified against recognised international standard:

- ▶ ECM-F1 is recommended to check into the contractor’s procedures related to the outsourced functions/processes/activities. The Management System (MS) of the organisations does not have to be intended as a “black box”, even if MS is certified. This check into the contractor’s internal procedures related to the outsourced functions/processes/activities is useful to cover any discrepancies with the ECM Regulation [1] requirements through supplemented procedures and to create links between the Maintenance System of the ECM and the certified MS of the outsourced contractor to define, collect, monitor, and analyse the relevant process results and data and to state all the requirements and relationships between all the processes and functions involved in terms of roles, responsibilities, information, documents, competencies, etc.....
- ▶ ECM-F1 must identify if **safety-related** activities are involved and, consequently, must apply specific requirements of Annex II.1.9. For example, when the outsourced processes are safety-related, ECM-F1 needs to check if the MS of the contractor is adequate and documented in relation to the outsourced functions/processes/activities. When the check fails, ECM-F1 must cover the discrepancies within the interface procedure specifying how the functions/processes/activities have to be managed in conformity with ECM Regulation. If the check is OK, ECM-F1 uses the outputs of the check within the interface procedure,

creating the necessary links with its own maintenance system, and may limit monitoring of outsourced processes just to the results.

- ▶ ECM-F1 is responsible for establishing the rules, conditions, and constraints to manage contracting activities in compliance with requirements 9 of Annex II.I. ECM-F1 can manage directly all the contracts (in case of a small ECM company) or may establish the rules to be followed in case the contracts are managed through internal office of its ECM Functions (in case of big ECM company, usually the different ECM-F2, F3 and F4 have their own contract office). This applies also in case of subcontracting activities by the contractor.
- ▶ ECM-F1 may limit monitoring of outsourced processes to the results of outsourced processes/activities/functions and establishes in the interface procedure the measures to be applied if process results and data do not comply with stated requirements. Also, ECM-F1 specifies monitoring management in a section of the interface procedure.

The above-mentioned **interface procedure** is necessary to set rules, requirements, and relationships between the contractor MS and the ECM MS. As a recommendation, the interface procedure should contain at least these points:

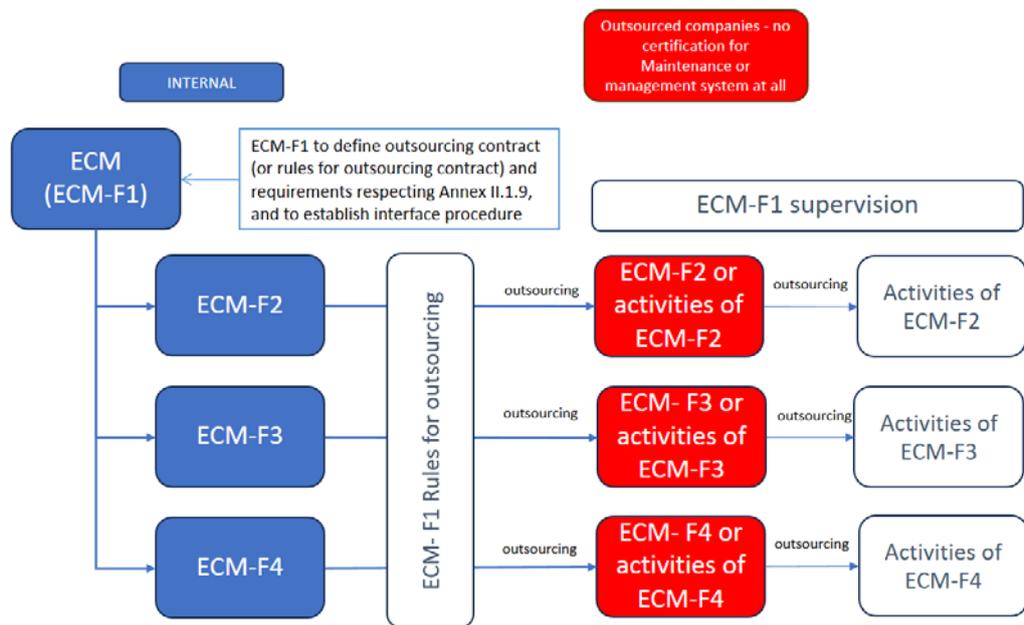
- ▶ Identification and definition of discrepancies between ECM Regulation requirements and the contractor's procedures in place for the functions/processes/activities outsourced. These discrepancies need to be covered with supplemented procedures to specify who- what-where-when-how- and the personnel involved, documents that need to be exchanged, data and information exchanges, processes followed, and when to perform the outsourced functions/processes/activities. The supplemented procedures are to be followed by the contractor together with the procedures of its MS and the interface procedure. This requirement should be specified in the contract.
- ▶ Identification and definition of interfaces between the ECM maintenance system and the functions/processes/activities outsourced (roles, responsibilities, information, documents, competencies, etc...). This part specifies who- what-where-when-how- and the personnel involved, maintenance documents and information that need to be exchanged, processes followed, and information that need to be exchanged in case of changes in the ECM MS and/or in the above-mentioned procedures to be followed by the contractor.
- ▶ Identification of safety-related activities and requirements to be followed in conformity with point 9 of Annex II.I of ECM Regulation
- ▶ Identification of rules, conditions, and constraints to manage contracting activities in compliance with requirements 9 of Annex II.I.
- ▶ Identification of requirements for monitoring and if requirement 9.5 of Annex II.I of ECM Regulation applies
- ▶ Communication protocols between internal functions/processes of the ECM and outsourced functions/processes/activities. This part specifies the communication channels between the contractor and each involved internal process/function. This part specifies if the exchange of data is made possible by software/electronic way or by direct/manual way or other, and it states the rules for traceability of documentation and information.
- ▶ How the outsourced contractor must apply the requirements of Annex II.I.1 to Annex II.I.9 (leadership, risk management, monitoring,) to its functions/processes/activities.

Example for applying requirement **1-Leadership** of Annex II.1(a) to (h) of ECM Regulation in [Figure 40](#).

9.2.4 Example of outsourcing functions/activities/services to non-certified contractor.

In this example, each contractor used for outsourced functions/processes/activities doesn't have any certified maintenance or management system.

Figure 39 outsourcing functions/activities/services to non-certified contractor



In brief, the following is a list of steps to implement the outsourcing with a contractor not having any maintenance or management system certification:

- ▶ ECM-F1 establishes the procedures to cover the conformity of the functions/processes/ activities outsourced with the ECM Regulation [1] and an interface procedure to create links between the Maintenance System of the ECM and the functions/processes/activities outsourced to define, collect, monitor, and analyse the relevant process results and data and to state all the requirements and relationships between all the processes and functions involved in terms of roles, responsibilities, information, documents, competencies, etc.
- ▶ ECM-F1 must identify if **safety-related** activities are involved and, consequently, must apply the specific requirements of Annex II.1.9. of ECM Regulation. In this case, ECM-F1 covers these requirements by establishing the set of procedures to be used by the contractor and needs to check the contractor's competency in advance of any contract agreement.
- ▶ ECM- F1 is responsible for establishing the rules, conditions, and constraints to manage contracting activities in compliance with requirements 9 of Annex II.I. ECM-F1 can manage directly all the contracts (in case of a small ECM company) or may establish the rules to be

followed in case the contracts are managed through internal office of its ECM Functions (in case of big ECM company, usually the different ECM-F2, F3 and F4 have their own contract office). This also applies in the case of subcontracting activities by the contractor.

- ▶ ECM-F1 must establish an interface procedure stating rules, requirements and relationships between the contractor and the ECM MS. In the interface procedure, ECM-F1 establishes all the requirements and relationships between all the processes and functions involved in terms of roles, responsibilities, information, documents, competencies, etc...

The above-mentioned **interface procedure** is necessary to set rules, requirements, and relationships between the contractor and the ECM MS. As a recommendation, the interface procedure should contain at least these points:

- ▶ Identification and definition of procedures for the functions/processes/activities outsourced to cover the conformity with the ECM Regulation requirements. These procedures specify who- what-where-when-how- and the personnel involved, documents that need to be exchanged, data and information exchanges, processes followed, and when to perform the outsourced functions/processes/activities. The contractor will follow this set of procedures for performing the outsourced functions/processes/activities along with the interface procedure. This requirement should be specified in the contract.
- ▶ Identify and define interfaces between the ECM maintenance system and the functions/processes/activities outsourced (roles, responsibilities, information, documents, competencies, etc...). This part specifies who- what-where-when-how- and the personnel involved, maintenance documents and information that need to be exchanged, processes followed, and information that need to be exchanged in case of changes in the ECM MS and/or in the above-mentioned procedures to be followed by the contractor.
- ▶ Identification of safety-related activities and requirements to be followed in conformity with point 9 of Annex II.I of ECM Regulation
- ▶ Identify rules, conditions, and constraints to manage contracting activities in compliance with requirements 9 of Annex II.I.
- ▶ Identification of requirements for monitoring, that can't be limited to the results of the contracted operational processes in this case.
- ▶ Communication protocols between internal ECM functions/processes and outsourced functions/processes/activities. This part specifies the communication channels between the contractor and each involved internal process/function of the ECM MS. It specifies whether the exchange of data is made possible by software/electronic means, direct/manual means, or other means, and it states the rules for traceability of documentation and information.
- ▶ How the outsourced contractor must apply the requirements of Annex II.I.1 to Annex II.I.9 (leadership, risk management, monitoring,) to its functions/processes/activities.

Example for applying requirement 1-Leadership of Annex II.I.1(a) to (h) of ECM Regulation:

Figure 40 Example for applying requirement 1-Leadership (a) to (h) as in the Annex II of ECM Regulation

Reg. EU 2019/779 Annex II.- I Requirements and assessment criteria for the management function	Example of action/procedure from ECM-F1 for applying the requirement to internal and outsourced functions/processes/activities of the organisation
<p>1. Leadership—commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness</p>	
<p>The organisation shall have procedures for:</p>	
<p>(a) establishing a maintenance policy appropriate to the organisation's type and extent of service and approved by the organisation's chief executive or his or her representative;</p>	<p>(a) ECM-F1 shall:</p> <ul style="list-style-type: none"> ▶ establish a maintenance policy appropriate to the organisation's type and extent of service and approved by the organisation's chief executive or his or her representative ▶ communicate it to all levels of the organisation (internal and outsourced functions/processes/activities of the organisation).
<p>(b) ensuring that safety targets are established, in line with the legal framework and consistent with an organisation's type, extent and relevant risks;</p>	<p>(b) (c) (d) ECM-F1 shall:</p> <ul style="list-style-type: none"> ▶ establish safety targets, in line with the legal framework and consistent with an organisation's type, extent and relevant risks ▶ develop plans and procedures for reaching them ▶ assess safety performance in relation to its corporate safety targets.
<p>(c) assessing its overall safety performance in relation to its corporate safety targets;</p>	<p>The above actions shall involve internal and outsourced functions/processes/activities of the organisation.</p>
<p>(d) developing plans and procedures for reaching its safety targets;</p>	<p>(e) ECM-F1 shall ensure that internal and outsourced functions/processes/activities of the organisation are equipped with the right resources to comply with the requirements of Annex II (resources in terms of plants, personnel, equipment, tools and materials).</p>
<p>(e) ensuring that the resources needed to perform all processes are available to comply with the requirements of this Annex;</p>	
<p>(f) identifying and managing the impact of other management activities on the maintenance system;</p>	<p>(f) ECM-F1 shall identify and manage the impact of external activities on internal and outsourced functions/processes/activities of the organisation</p>
<p>(g) ensuring that senior management is aware of the results of performance monitoring and audits and takes overall responsibility for the implementation of changes to the maintenance system;</p>	<p>(g) ECM-F1 shall communicate to and involve senior managers (managing internal and outsourced functions/processes/activities of the organisation) about the results of performance monitoring and audits and ensure they take overall responsibility for the implementation of changes to the maintenance system</p>
<p>(h) ensuring that staff and staff representatives are adequately represented and consulted in defining, developing, monitoring and reviewing the safety aspects of all related processes that may involve staff.</p>	<p>(h) ECM-F1 shall:</p> <ol style="list-style-type: none"> 1. ensure that staff and staff representatives are adequately represented 2. involve them in defining, developing, monitoring, and reviewing the safety aspects of all related processes that may involve staff <p>The above actions shall involve internal and outsourced functions/processes/activities of the organisation.</p>

10 HOW TO MANAGE SAFETY CRITICAL COMPONENTS (SCCs)?

To deal with Safety Critical Components, a Technical Report has been prepared by WG48 of CEN/TC256. This document is the CEN/TR 17696:2021 [\[46\]](#).

The objective of the “Guide for identification and management of Safety Critical Component for railway vehicle” (CEN/TR 17969:2021 SCCs guide) drafted by the above-mentioned WG48 is to provide an overview of the SCCs requirements captured from the legislation and the actors involved in their fulfilment.

In addition, the CEN/TR 17696:2021 aims to promote a common understanding of those requirements together with practical arrangements to fulfil them in a proper way and giving guidance for the SCC identification and management.

The objective of the SCCs Technical Report is neither to produce an applicable list of SCCs nor to provide for examples of SCC.

The CEN Technical Report is applicable to vehicles only. The definition of “vehicle” is as in Article 3(21) of the Safety Directive [\[2\]](#).

The use of the CEN/TR 17696:2021 is recommended to manage in a proper way the SCCs topic.

10.1 What is a safety critical component

Safety critical components are components for which a single failure has a credible potential to lead directly to a serious accident such as:

- ▶ any train collision or derailment of trains resulting in the death of at least one person or serious injuries to five or more persons or extensive damage to rolling stock, the infrastructure or the environment, and
- ▶ any other accident with the same consequences which has an obvious impact on railway safety regulation or the management of safety.
- ▶ ‘Extensive damage’ means damage that can be immediately assessed by the investigating body to cost at least EUR 2 million in total

The CEN TR 17696:2021 collects in a table a list of accidents related to the definition of SCCs applicable for vehicle’s components.

10.2 For which type of vehicle do the concept and requirements of SCCs apply?

The concept of SCC applies to new and existing vehicles.

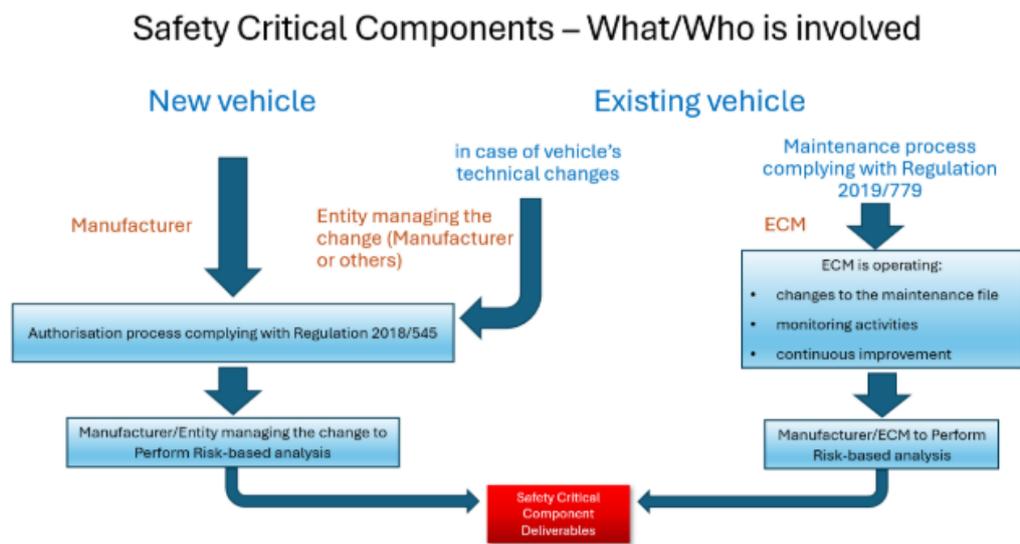
To make it clear the applicability of SCCs requirements in the field of railway vehicles, it is necessary to distinguish between these two categories of vehicles:

- ▶ new vehicle.
- ▶ existing vehicle.

For convenience, a new vehicle is intended as a vehicle for which an applicant has requested to the authorising entity a vehicle authorisation for placing on the market following the new legislation (complying with Regulation 2018/545)

An existing vehicle is a vehicle that does not meet the criteria of new vehicle and has obtained a valid authorization for placing on the market before the entry into force of Regulation 2018/545.

Figure 41 Safety Critical Components: Roles and Responsibilities



The SCCs requirements apply to new vehicles and to existing vehicles too.

In the case of new vehicles, the Manufacturer is responsible for providing the documentation to be inserted in the technical file (operation and maintenance documentation) to the applicant for the authorisation.

During the development of these documents, the Manufacturer is required to apply the SCCs requirements. The technical file is presented by the applicant for obtaining the vehicle type authorisation. Once the vehicle type authorisation is issued, the applicant becomes the holder of the vehicle type authorisation and keeps a copy of the technical file throughout the service life of the vehicle (see Annex IV 2.6 of the Interoperability Directive).

In order to make it able the use of the vehicle, the holder of the vehicle authorization is required to release operation and maintenance documentation, directly or via the vehicle Keeper, to respectively the RU and the ECM.

In case of existing vehicles, the SCCs requirements apply when the vehicles are involved in a technical change/renewal/upgrading/refurbishment and a risk-based analysis is provided for analysing the change/renewal/upgrading/refurbishment and its interfaces. In this case, the application of SCCs requirements is limited to only the parts of the vehicle related to engineering change/renewal/upgrading/refurbishment and the involved interfaces.

When an existing vehicle is undertaken to change/renewal/upgrading/refurbishment, the entity managing the change (Manufacturer, holder of the vehicle type authorisation or other entity commissioned for the change by the vehicle Keeper) is responsible to provide for the changes to the documentation inserted in the technical file (see cases of changes as in Art. 15 and 16 of Reg. 2018/545) and to update the vehicle configuration documents.

During the development of these changes to the documentation, the entity managing the change (Manufacturer, holder of the vehicle type authorisation or other entity commissioned for the change by the vehicle Keeper) is required to apply the SCCs requirements.

In order to make it able the use of the vehicle with the change made, the entity managing the change (Manufacturer, holder of the vehicle type authorisation or other entity commissioned for the change by the vehicle Keeper) is required to release the updated operation and maintenance documentation, directly or via the vehicle Keeper, to respectively the RU and the ECM.

The maintenance documentation is needed to the ECM to make it able to manage and implement the maintenance of the vehicle through the establishment of the so-called "maintenance file".

The ECM is responsible for preparing and managing the first "maintenance file" by adapting the maintenance documentation to the real operating conditions, performances required and return on experience and to keep updated the maintenance file throughout the lifecycle of the vehicle.

In the case of existing vehicle too, the ECM is responsible for managing the maintenance documentation (see Art. 14(3)b of Safety Directive [\[2\]](#)) and keeping it updated throughout the lifecycle of the vehicle.

The technical file and the maintenance file play a fundamental role in the accomplishment of the SCC requirements.

10.3 What is the SCC management process? What are the SCCs documents?

The identification and management of SCCs starts as part of the design phase under the responsibility of the Designer/Manufacturer⁹ from the concept phase and, when the vehicle is in operation/maintenance phases, through the collaboration and exchange of information

⁹ For the purposes of this section, please interpret Designers/Manufacturers as Vehicle Designers/Manufacturers.

with ECM/RU/Keeper (references on the life-cycle phases applicable to a vehicle can be found in EN50126-1-2017 [47]).

Generally, to guarantee the safety level in normal and degraded situations, as requested by the relevant TSIs, Designers/Manufacturers are requested to carry out design, construction or assembly for satisfying at least safety requirements.

As regards SCCs, it is expected that Designers/Manufacturers will seek to minimise or eliminate SCCs by means of architectural and functional design choices (see also 5.9 of EN50126-1:2017). However, where it is not practicable to 'design out' a SCC, it is crucial that the component is clearly identified, managed and notified. To do so for new vehicles, the Manufacturer is required to:

- ▶ identify SCCs during the concept/design phase by means of risk-based analysis.
- ▶ insert a SCCs list in the technical file/maintenance description file/operation documentation together with their specific requirements for:
 - operation, servicing, maintenance,
 - operational, servicing and maintenance traceability.
- ▶ specify precedents, principles and methods used to identify SCCs and their specific requirements inside the Maintenance Design Justification File.

These **SCCs deliverables**, being part of the technical documentation of the vehicle, need to be notified to ECMs/RUs/Keepers to support them during operation/maintenance phases and to update, where necessary, the technical file of the vehicle.

The same process is also valid in the case of engineering change/renewal/upgrading/refurbishment of the vehicle, where in this case the designer/Manufacturer/Entity managing the engineering change/renewal/upgrading/refurbishment is called to provide for the SCCs deliverables.

Neither Manufacturers/Entities managing the change nor ECMs are obliged to **identify retrospectively** SCCs for existing vehicles except in the case of engineering change/renewal/upgrading/refurbishment, only for the parts of the vehicle related to engineering change/renewal/upgrading/refurbishment.

However, for existing and new vehicles, if during its routine maintenance activities (see [Figure 42](#) ECM activities related to the SCCs list (new component or changes), changes to SCCs requirements and requests for support from Manufacturer for details) an ECM becomes aware of evidence suggesting a component not previously identified as safety critical should be considered as such, it must notify the:

- ▶ Manufacturer,
- ▶ the holder of the vehicle type authorisation and
- ▶ the holder of the vehicle authorisation.

After receiving this notification, the Manufacturer, when it can be identified, is required to confirm if the component is safety-critical¹⁰ through risk assessment taking into account use and environment of the component in the context of the vehicle's operation and maintenance.

In the case of confirmed SCC, the Manufacturer is required⁷ to collaborate with the ECM/RU/ Keeper to develop specific operational, servicing, maintenance and traceability requirements.

If the Manufacturer cannot be identified, the ECM may confirm the identification of the SCC through a risk assessment procedure as part of its maintenance system and develop specific operational, servicing, maintenance and traceability requirements in collaboration with RU/ Keeper.

As a consequence, the outcomes and deliverables of the confirmed SCC need to be notified to, at least:

- ▶ Keepers/RUs
- ▶ ECMs
- ▶ the entity managing the technical file and recorded in the relevant part of the technical file.

In addition, for existing and new vehicles, the Manufacturer is required to provide technical and engineering support on SCCs and their safe integration, when an ECM or a Keeper makes a request.

As detailed above, the ECM is involved to identify new potential SCC during its routine maintenance (reference to in Article 4(3) of ECM Regulation [1]) and, in addition, it may have need, based on REX or other ECM's activities, to change the SCCs list or their specific requirements (see Annex III.10 of Safety Directive [2]).

In these cases, the ECM is required to use the appropriate "SCCs identification procedure" of its maintenance system through the application of risk-based analysis as required in Annex II of the ECM Regulation.

The following table summarises the high-level activities during which the ECM could:

- ▶ become aware of evidence that a new SCC is identified as such and notifies it to the Manufacturer for confirmation
- ▶ change the SCCs list provided by the Manufacturer or their specific requirements
- ▶ make a request to the Manufacturer for technical and engineering support on SCCs and their safe integration:

¹⁰ the actions by the Manufacturer should be covered by commercial agreements when the vehicles are out of warranty or there are no other previous "service agreements" in place with the owner/keeper or ECM

GUIDANCE ON ECM CERTIFICATION PROCESS

Figure 42 ECM activities related to the SCCs list (new component or changes), changes to SCCs requirements and requests for support from Manufacturer

ID.	ECM Regulation – Annex II, referenced activities	Detail of activities
1	<i>Ref. to in:</i> ▶ 2.2, 2.3 part I, ▶ 2, 4, 5, 6 part II: <i>when managing changes to the maintenance file of the vehicle as a consequence of:</i>	Non-exhaustive list of examples: ▶ technical/operational change ▶ renewal/upgrading/refurbishment ▶ change of: ○ mission profile ○ Maintenance plan ○ authorization of the vehicle ○ vehicle's configuration ○ competence of personnel ▶ legislation's requirement
2	<i>Ref. to in:</i> ▶ 3, part I: <i>as an output of monitoring activities on:</i>	▶ collection and analysis of safety relevant data comprising unexpected or exceptional safety and maintenance findings ▶ reporting from accidents, incidents, near misses and other dangerous occurrences ▶ internal audit reporting
3	<i>Ref. to in:</i> ▶ 4, part I: <i>as an output of continuous improvement on:</i>	▶ collection and analysis of data from: ○ regular monitoring ○ auditing ○ recommendation from national safety authority, national investigation body, industry, internal investigation, ○ report or information from railway undertakings or other sources to determine measures to be adopted

The following flow diagrams show the SCCs management during the maintenance process.

Figure 43 Maintenance process complying with the ECM Regulation [1]

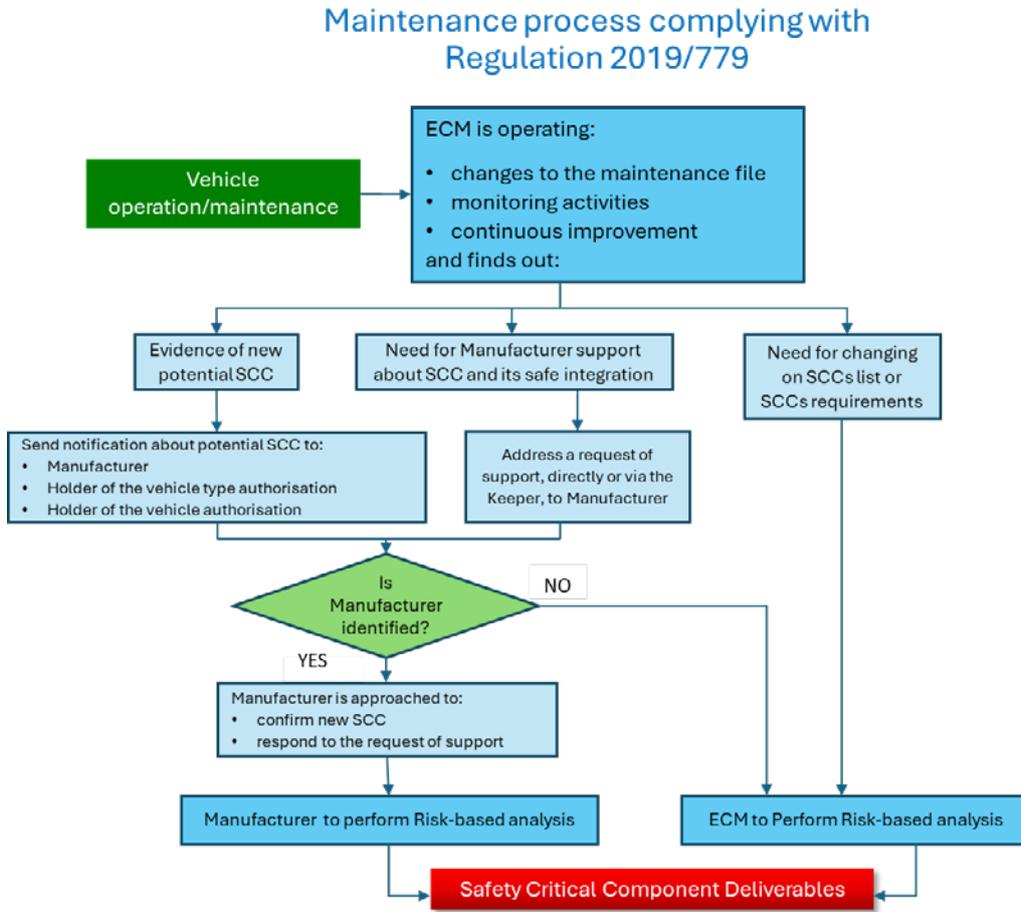
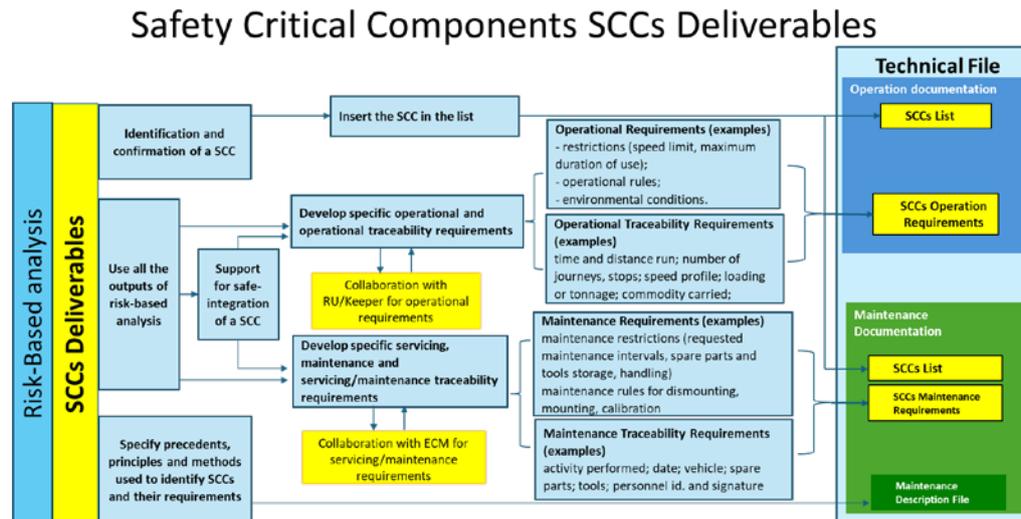


Figure 44 Safety Critical Components Deliverables

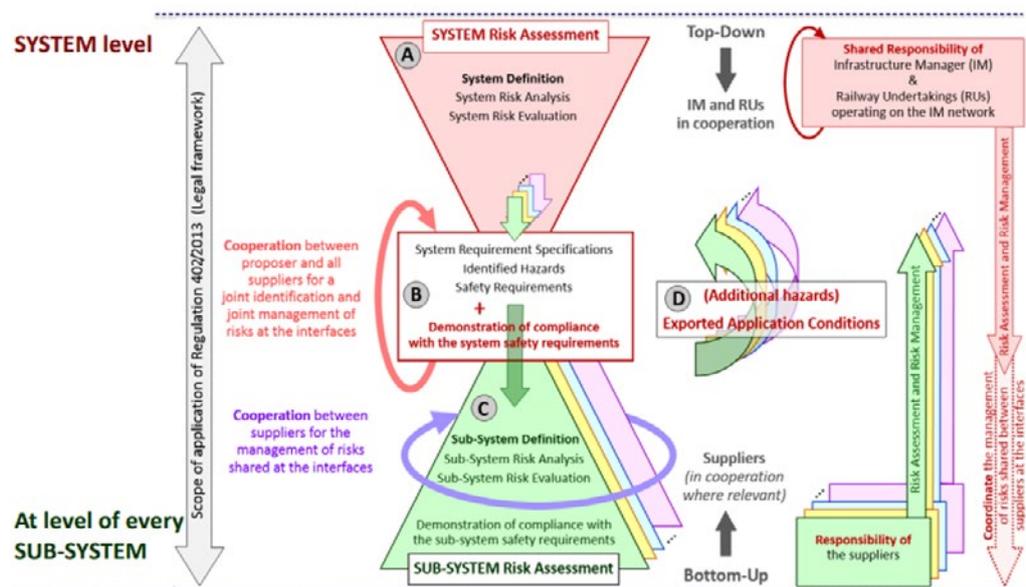


10.4 What are the possible methods for the identification of SCC?

Two approaches can be taken for the identification of SCC: the bottom-up one and the top-down one.

As represented in the following diagram, IMs and RUs usually adopt a top-down approach, which also provides inputs on operation conditions (environment, railway lines characteristics, etc.) that can be used by the manufacturers (suppliers) for the assessment of environmental and infrastructure impact in the identification of SCC through a bottom-up approach.

Figure 45 Global overview and “system based approach” to risk assessment – safe integration at system and sub-system levels (derived from figure 1 of CENELEC 50126-2:2017 [48] and figure A.2 of CENELEC 50129-2:2018 [49])



One of the two ways to identify safety critical components is to use a bottom-up method which has the characteristic to start from the point of view of the component and, by analysis, going through different levels up to the main effect of the component failure.

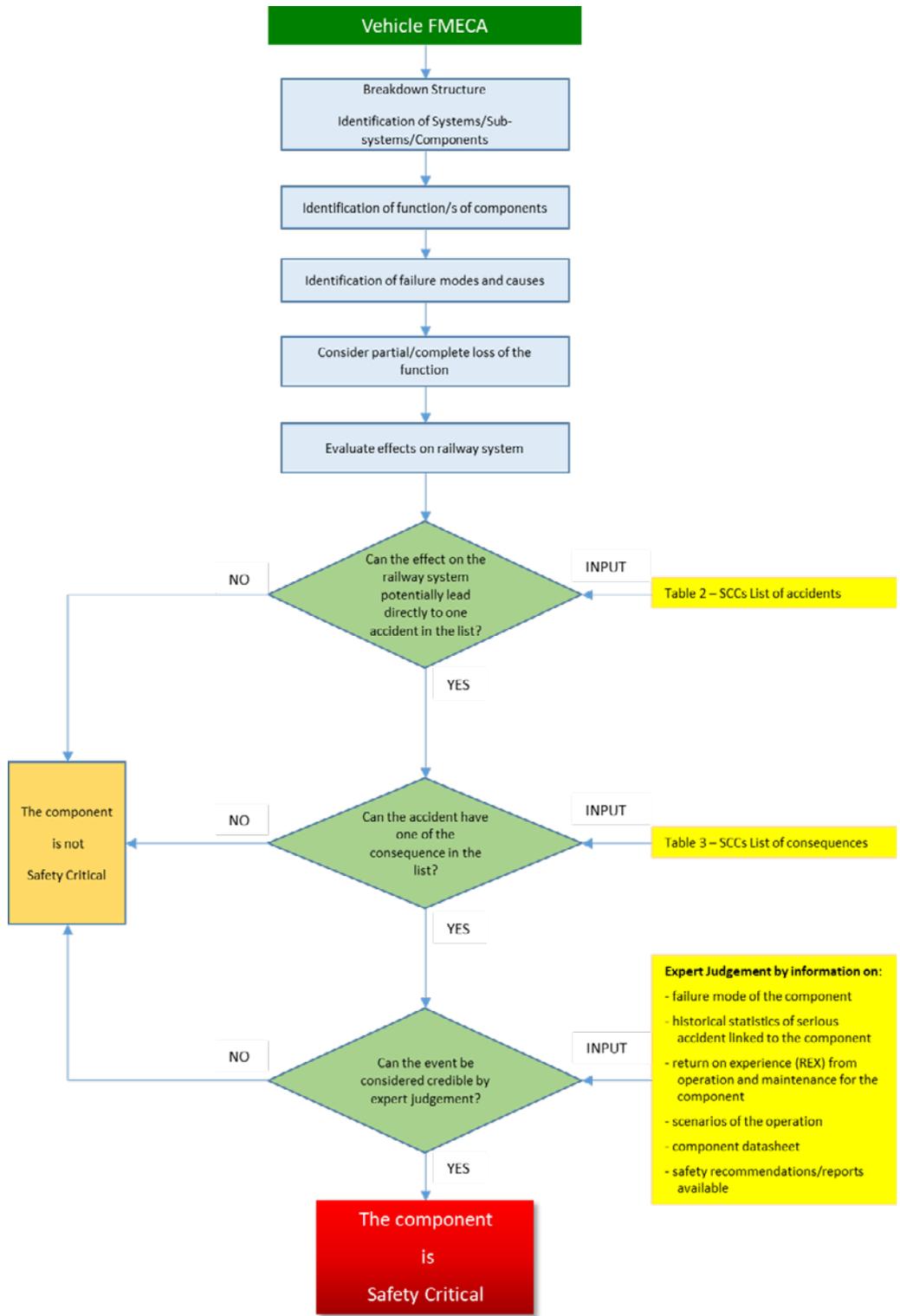
Using a bottom-up method implies 2 phases to be carried out:

- ▶ Phase 1 – Identification of vehicle’s components
- ▶ Phase 2–Analysis and identification of component’s criticality

One of the most common used bottom-up method is FMECA process

The FMECA process can be represented as a sequence of steps, illustrated in the following chart taken from the guide CEN/TR 17696:2021 [46], leading to the identification of components’ criticality.

Figure 46 Flow diagram for bottom-up process using FMECA for SCCs identification (ref. figure 3 of CEN/TR 17696:2021 [46])



Taking as example the wheel as component, the implementation of the FMECA process could confirm that this component is a safety critical one, because its failure would have catastrophic consequences (i.e. derailment of the vehicle).

Figure 47 Example of FMECA process analysis

Item	Function	Failure mode	Cause(s) of failure	Failure Effects / Consequences				Criticality Analysis					
				Subsystem (Local)	System (Overall)	Safety	Service/ Operation: A. Changeover B. Withdrawal C. Degraded service D. Line disruption E. Station disruption F. Operator actions G. Others	Time affected (minutes)	Severity Class	Affected		Design Safeguard or Procedures for Hazard Mitigation	
							S-Safety?	E-Environmental?	O-Operational (reliability)?				
Steel wheel	Respect the bogie gauge according to the customer standard. Transmit the traction effort to the carbody with respect to the specification. Transmit the brake effort to the carbody with respect to the specification. Support the carbody at the specified height.	Rupture	Undetected cracking	Loss of the geometrical characteristics and the wheel integrity	Rescue of the train	Risk of derailment	B. Withdrawal	>20 min	Catastrophic	Y	N	Y	Wheel calculation note Anti corrosion protection
Steel wheel	Respect the bogie gauge according to the customer standard. Transmit the traction effort to the carbody with respect to the specification. Transmit the brake effort to the carbody with respect to the specification. Support the carbody at the specified height.	Sliding between axle and wheel	Incorrect design Incorrect assembly	Excessive clearance between wheel and axle. Wrong positioning of the wheel	Rescue of the train	Risk of derailment	B. Withdrawal	>20 min	Catastrophic	Y	N	Y	Wheel fit calculation: Process: Monobloc wheel fitting parameters (radial interference calcul., final fitting forces, fitting diagram) calculation

The other way to identify critical components is to use a top-down method.

The top-down method does not start from the component's view as in the bottom-up method, but it starts from the main "top" effect and, by analysis, going through different levels down to the elementary event causing the main one.

In the top-down method, the starting point is the systematic identification of hazards, based on experience analysis (e.g. common lists of hazards) and operational conditions consideration.

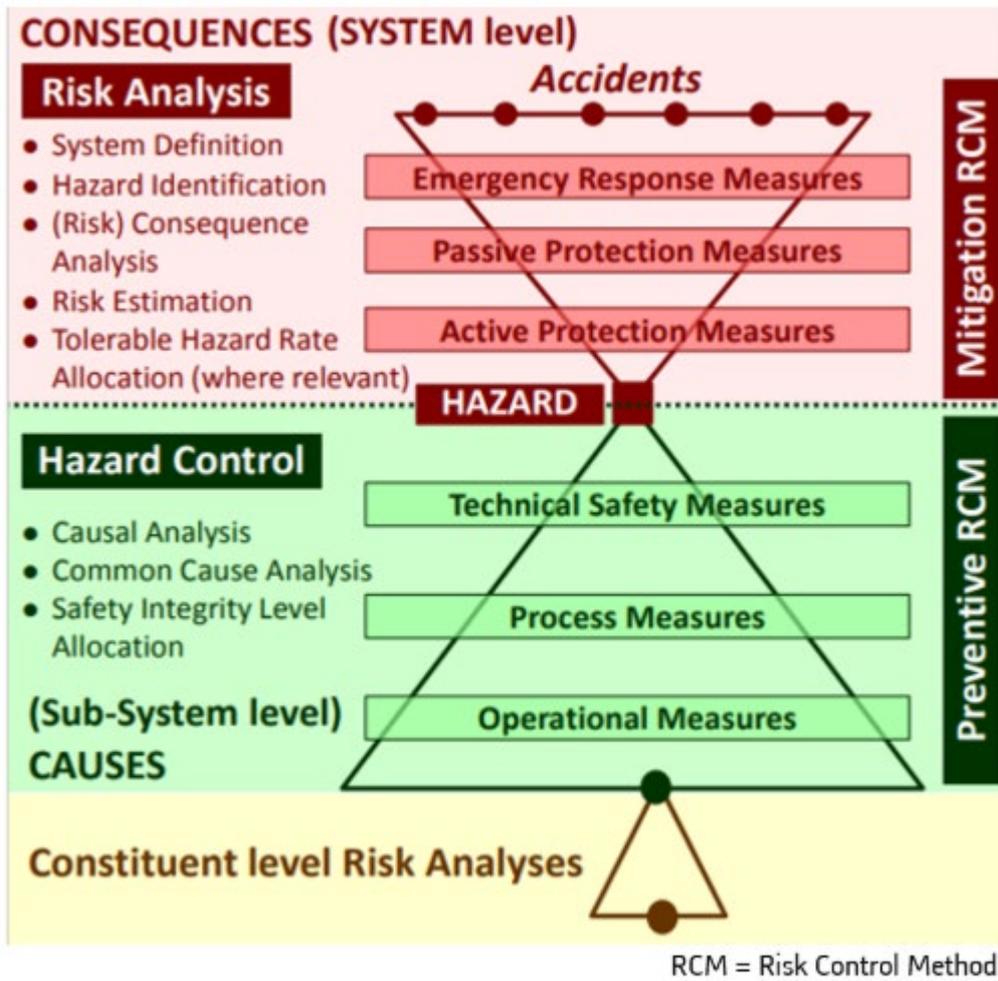
Past experience analysis is mainly based on the experience of people involved in it, on the REX of previous accidents, on the operational conditions' knowledge (e.g. characteristics of the railway line, environmental conditions, natural elements like earthquakes, etc.) and on common lists of hazards, leading to the identification of the hazards for the specific scope.

The hazards depend on the system definition; in particular, the system boundary and the hierarchical structure of hazards in respect to systems and sub-systems.

It means that hazard identification and causal analysis shall be performed at several levels of detail during the top-down analysis, depending on the complexity and criticality of each component.

The following diagram illustrates how hazard identification and causal analysis are integrated.

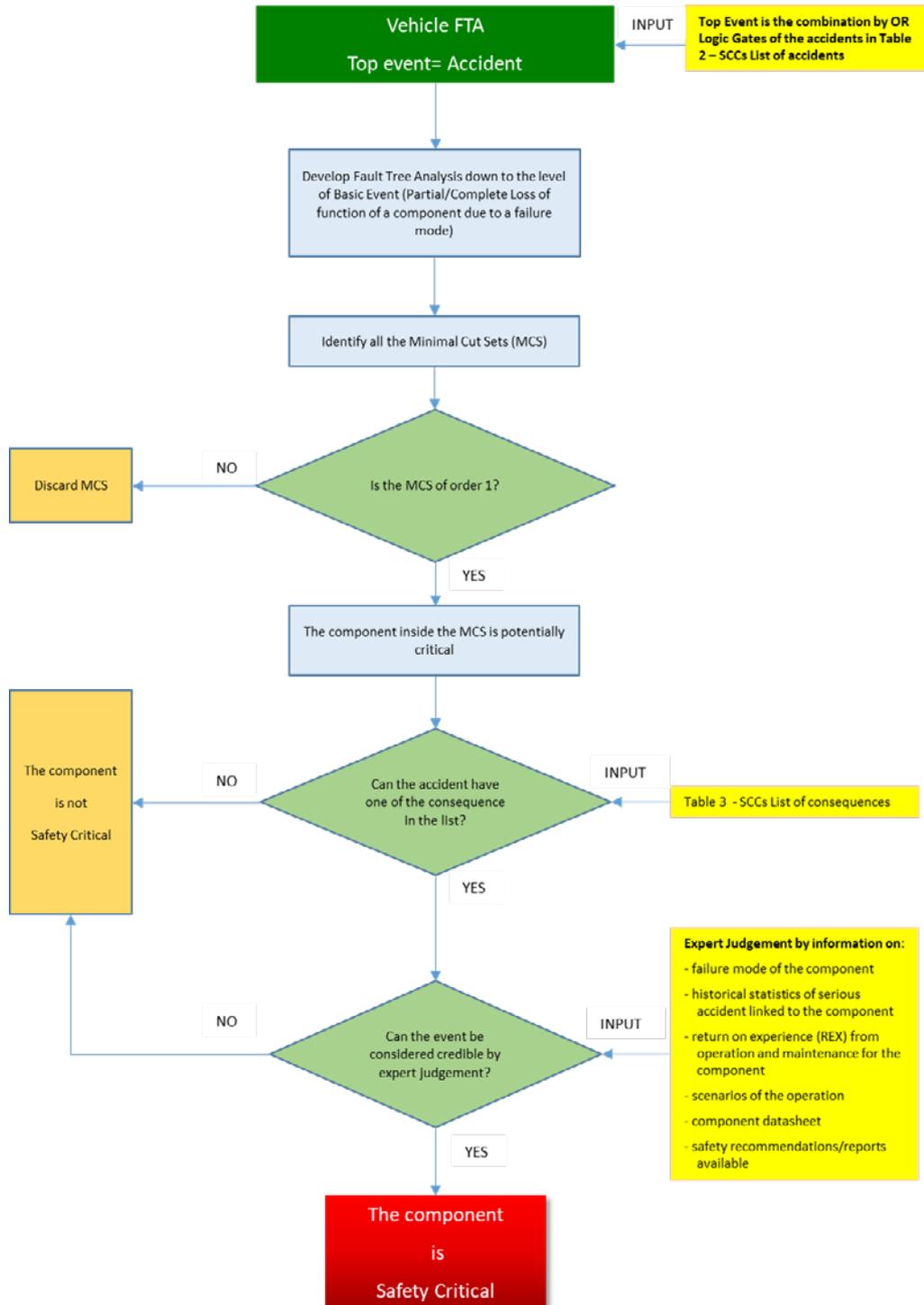
Figure 48 Vertical representation of the cause-hazard-consequence bow tie



One of the most common used top-down method is the Fault Tree Analysis

The FTA process can be represented as a sequence of steps, illustrated in the following chart taken from the guide CEN/TR 17696:2021 [46], leading to the identification of components' criticality.

Figure 49 Flow diagram for top-down process using FTA for SCCs identification (ref. figure 4 of CEN/TR 17696:2021 [46])



Taking as example the derailment of the vehicle as top event (hazard), the implementation of the FTA process would confirm that the wheel is a safety critical component, because the derailment of the vehicle could credibly be a consequence of its failure.

10 HOW TO MANAGE SAFETY CRITICAL COMPONENTS (SCCs)?

The top-down and the bottom-up analysis complement one another, increasing confidence that the potential hazards have been covered and that all significant hazards have been identified.

More explanations on these methods are in the "[Railway Applications–Vehicle Maintenance - Guide for identification and management of Safety Critical Components for railway vehicles](#)" Ref. CEN/TR 17696:2021 [\[46\]](#)

11 COMPETENCES OF STAFF

This part is focused on the competence management of maintenance staff as previewed in the Annex II, Section I, Point 6 of the ECM Regulation [1].

When designing the competency management system, the ECM and/or maintenance workshop should ensure that there is an alignment between safety responsibility and competency for staff at all levels of the ECM and/or maintenance functions. The qualifications and certifications must be aligned with the tasks a person may undertake and the safety responsibilities that person may be designated.

Competence management—a structured approach to ensure that employees have the competences required in order to achieve the organisation's objectives safely, effectively and efficiently in all circumstances.

1. The organisation shall set up a competence management system providing for:

- (a) the identification of posts with responsibility.
- (b) the identification of posts involving safety tasks.
- (c) the allocation of staff with the appropriate competence to relevant tasks.

2. Within the organisation's competence management system, there must be procedures to manage the competence of staff, including at least:

- (a) identification of the knowledge, skills and experience required for safety-related tasks as appropriate for the responsibilities.
- (b) selection principles, including basic educational level, mental aptitude and physical fitness.
- (c) initial training and qualification or certification of acquired competence and skills.
- (d) assurance that all staff are aware of the relevance and importance of their activities and how they contribute to the achievement of safety objectives.
- (e) ongoing training and periodical updating of existing knowledge and skills.
- (f) periodic checks of competence, mental aptitude and physical fitness where appropriate.
- (g) special measures in the case of accidents/incidents or long absences from work, as required.

The organisation, to set up a competence management system, must take into account:

- ▶ Requirements of TSIs about professional competences required for the maintenance (information designer/manufacturer of vehicles or part of vehicles to be included in the maintenance file).

For example, see the extract of chapter 4.5 (5) of Annex to TSI Loc&Pas [6] and chapter 4.6 of Annex to TSI CCS [8]):

The competence management system of the organisation should include at least the following points:

- ▶ Definition of requirements related to knowledge, skills and competences (level of education, work experience, specific trainings, etc.) to be included in job descriptions (at least, for posts requiring specific authorisations and/or certifications);
- ▶ Management of training needs identification, e.g. through reviews/meetings between managers and team members, with specific focus on the new-comers and/or temporary workers on-boarding process.
- ▶ Definition of training programs, including identification of internal or external resources delivering the trainings (e.g. internal specialists, recognised training centres, etc.) and recording of the delivered trainings;
- ▶ Management of qualification/certification of the acquired competences, monitoring and recording of acquired qualifications/certifications, monitoring and updating of skills and competences (including re-assessments in case of accidents/incidents or long absences from work);
- ▶ Where applicable, definition of requirements on competences management for organisations providing external resources covering out-sourced activities (e.g. specialised NDT services).

11.1 Develop a matrix of the qualifications according to the ECM functions and relevant key functions

The objective of this part is to provide a guidance to define, within the ECM's competence management system, the procedures to manage the competence of maintenance staff of four functions of ECM with a specific focus concerning the procedures to manage the competence of maintenance staff of the different functions.

Qualification of acquired competence and skills is a mixture of:

- ▶ Work experience: years of relevant experience (including specific experience in railways), maintenance processes and tools implementation (e.g. NDT, IT systems, maintenance engineering, maintenance delivering, maintenance management, etc.)
- ▶ Basic education (elementary school, university, ...): on mechanical, electrical, IT systems, etc.
- ▶ Additional training (activity-related): trainings to carry out the activities linked to the post, based on the relevant ECM function. For example:

- o ECM-F2: technical and technological training related to the vehicles to be maintained, risk assessment, regulations, FMECA, statistics, etc.
- o ECM-F3: training in railway operations, maintenance and workshop organization, IT systems, railway network and maintenance workshop locations knowledge, etc.
- o ECM-F4: railway technology training (components, vehicles), theoretical and practical training, training in maintenance documents to be applied, NDT execution, use of tools, etc.

The matrix below could be used as an example by ECM to be a part of their competence management system and to monitor and control the qualification of the staff.

Figure 50 Example of competence matrix

Roles	work experience rail sector				basic education				additional training				
	1 YEAR	3 YEAR	5 YEAR	X YEAR	unskilled worker, temporary employee (EQF level 1 and 2)	skilled workers (EQF level 3 and 4)	college with maturity exam (EQF level 5 and 6)	University (EQF level 7 and 8)	welding or adhesive engineer	Basic training fleet "xy"	NDT	ETCS components	xxx
ECM-F1 manager (maintenance engineer, quality manager, warehouse manager, etc.).													
ECM-F2 manager (maintenance engineer, quality manager, warehouse manager, etc.).													
ECM-F3 manager (maintenance engineer, quality manager, warehouse manager, etc.).													
ECM-F4 manager (maintenance engineer, quality manager, warehouse manager, etc.).													
Fleet manager													
Component engineer													
Workers/inspectors of safety-critical components													

11.2 Competences of maintenance management function (ECM-F1)

The maintenance management function (ECM-F1) is a managerial function, in charge of coordinating and monitoring the functions ECM-F2, ECM-F3 and ECM-F4 of the ECM and ensuring the safe state of vehicle.

The staff deployed in such a function, therefore, shall have strong and deep knowledge of ECM Regulation [1] and linked legislation in force along with managerial competences (e.g. leadership, communication, decision making, time management, problem solving, continuous improvement, interpersonal skills, etc.), associated with some technical competences and knowledge needed to fulfil the coordination and supervision role. Moreover, that staff will also need to have personal skills (mental aptitude, basic educational level, etc.) and be generally trained to work in railway vehicle maintenance field (competence on maintenance management).

The basic educational level also ensures the competence on the language of the country (general knowledge, speaking, speech comprehension, reading, writing), where this competence is required.

The competence on maintenance management can be recognized through the CMS of the ECM (internal process of training to issue a qualification) or through external resources (e.g., recognized training centre).

In detail, the following technical competences and knowledge are recommended for the staff deployed in ECM-F1:

- ▶ Ability in managing a management system (processes, procedures, responsibilities, exchange of information, monitoring activities, targets establishment, measuring of performances, continuous improvement, ...)
- ▶ Awareness of relevant legislation, standards, codes of practice and Maintenance Management Information System (MMIS)
- ▶ Knowledge of accident and incident management
- ▶ Ability to implement risk assessment and change management
- ▶ Ability to perform outsource/procurement management
- ▶ Working knowledge of monitoring/auditing and reporting, including REX management, collection and communication of information (internal and external, e.g. from NIB, SAIT, etc.), etc.

The recommended skills and competences requirements above detailed should be covered by the maintenance management function as a whole. However, based on the actual organisational structure of the maintenance management function, each organisation shall identify the basic skills and competences required for each position/role in the organisation (i.e. not everyone shall have all the listed skills and competences, but they shall be adapted to the actual role covered by the person).

11.3 Competences of maintenance development function (ECM-F2)

The staff deployed in maintenance development function (ECM-F2) needs to have personal skills (mental aptitude, basic educational level, etc.) and be generally trained to work in railway vehicle maintenance field (competence on maintenance development).

The basic educational level also ensures the competence on the language of the country (general knowledge, speaking, speech comprehension, reading, writing), where this competence is required.

In addition, high skill and competence may be required for people working on specific safety related activities (ref. to in Annex II, II.6 of the ECM Regulation [\[1\]](#)).

The competence on maintenance development can be recognized through the CMS of the ECM (internal process of training to issue a qualification) or through external resources (e.g., recognized training centre).

The general training program, covering the required competences and skills, shall be adapted to the actual staff members' background (work experience, competences and skills) and staff members' activities.

The most important targets of a training program for the maintenance development function should be to enable its staff members to:

- ▶ perform CSM risk assessment.
- ▶ write and update the maintenance plan.
- ▶ manage changes and configuration.
- ▶ manage technical and maintenance file.
- ▶ manage Return on Experience.

The recommended skills and competences requirements detailed here after should be covered by the maintenance development department as a whole. However, based on the actual organisational structure of the maintenance development department, each organisation shall identify the basic skills and competences required for each position/role in the organisation (i.e. not everyone shall have all the listed skills and competences, but they shall be adapted to the actual role covered by the person) or outsourced.

The basic requirements on skills and competences, gained from experience or education, covering railway maintenance development sector should be at least:

- ▶ Technical Skills:
 - Knowledge and experience in relevant technical fields (e.g. electrical, mechanical) and railway operations.
 - Understanding of systems integration with the train and their operating interfaces.
 - Awareness of relevant legislation, codes of practice and basic skills (e.g. math, literacy, Maintenance Management Information System–MMIS).
 - Knowledge of RAMS to understand the potential consequences of a failure of safety-critical components, risk evaluation and assessment methods (CSM), for change management.
 - Ability to manage and maintain documentation.
 - Skills on monitoring and reporting, including REX management, collection and communication of information (internal and external, e.g. from NIB, SAIT, etc.), etc.
- ▶ Maintenance Development Skills:
 - Understanding maintenance file contents and the process to obtain, update and handover it.
 - Knowledge of change and configuration management processes, including certification and authorization responsibilities and design changes.
 - Experience managing concessions.
 - Ability to conduct technical investigations (e.g. on railway safety incidents/accidents) and employ problem-solving methodologies.
 - Experience in the specification of maintenance facilities, equipment and tools.
 - Capability of validation of maintenance tasks and activities.

- ▶ Regulatory Knowledge:
 - Knowledge of technical standards and regulations for maintenance, including TSIs.
 - Knowledge of the registration systems for vehicles (e.g. EVR/ERATV).
 - Familiarity with the European Railway Agency Database of Interoperability and Safety (ERADIS) and the SAIT tool.

11.4 Competences of fleet maintenance management function (ECM-F3)

The staff deployed in fleet maintenance management function (ECM-F3) needs to have personal skills (mental aptitude, basic educational level) and be generally trained to work in railway fleet maintenance management field (competence on fleet maintenance management).

The basic educational level also ensures the competence on the language of the country (general knowledge, speaking, speech comprehension, reading, writing), where this competence is required.

In addition, high skill and competence may be required for people working on specific safety related activities (ref. to in Annex II, III.7 of the ECM Regulation [\[1\]](#)).

In particular, the fleet management personnel, at least, should have knowledge of how to issue maintenance orders and how to release the notices of return to operation. This includes–if applicable–knowledge of the IT applications to be used.

The competence on fleet maintenance management can be recognized through the CMS of the ECM (internal process of training to issue a qualification) or through external resources (e.g. recognized training centre).

The recommended skills and competences requirements detailed here after should be covered by the fleet management department as a whole. However, based on the actual organisational structure of the fleet management department, each organisation shall identify the basic skills and competences required for each position/role in the organisation (i.e. not everyone shall have all the listed skills and competences, but they shall be adapted to the actual role covered by the person) or outsourced.

The basic requirements on skills, gained from experience or education, covering fleet maintenance management, should be at least:

- ▶ Knowledge of maintenance plan, procedures, processes, IT applications (e.g. Maintenance Management Information System–MMIS) and best practices for managing the scheduling of maintenance of railway vehicles (e.g. preparation of long term, mid-term and short term maintenance program).
- ▶ Ability to check the competence, availability and capability of the entity responsible for maintenance delivery before placing maintenance orders.

- ▶ Understanding of the train fleet and its components, as well as their interaction with the operating interfaces (e.g., maintenance workshop organisation, service organisation, train schedules, lines conditions, etc.), to ensure timely and effective removal of vehicles from operation for maintenance delivery.
- ▶ Excellent organizational skills to manage the work package composition (including maintenance procedures and maintenance verification measures), issue maintenance orders to the maintenance delivery function, and request removal of vehicles from operation for maintenance (including priorities management in case of failures during service).
- ▶ Ability to issue notices of return to operation that include restrictions on use and their impact on vehicles operation to ensure the safe running of vehicles, taking into account the release to service documentation.
- ▶ Strong communication skills to work effectively with maintenance development and maintenance delivery functions, as well as external interested parties, such as railway undertakings and infrastructure managers, to inform them of maintenance orders and restrictions on use.
- ▶ Effective record-keeping skills to manage maintenance orders, release to service and return to operation records, including restrictions on use.

11.5 Competences of maintenance workers (ECM-F4)

The staff deployed in maintenance delivery function (ECM-F4) needs to have personal skills (physical fitness, mental aptitude, basic educational level and, where requested in the member state, a minimum age) and be generally trained to work in railway vehicle maintenance field (competence on maintenance).

The basic educational level also ensures the competence on the language of the country (general knowledge, speaking, speech comprehension, reading, writing), where this competence is required.

In addition, high skill and competence may be required for people working on specific safety components/activities (ref. to in Annex II, IV.8 of the ECM Regulation [\[1\]](#)).

The competence on maintenance can be recognized through the CMS of the ECM (internal process of training to issue a qualification) or through external resources (training centre).

The recommended skills and competences requirements detailed here after should be covered by the maintenance delivery department as a whole. However, based on the actual organisational structure of the maintenance delivery department, each organisation shall identify the basic skills and competences required for each position/role in the organisation (i.e. not everyone shall have all the listed skills and competences, but they shall be adapted to the actual role covered by the person) or out-sourced.

The basic requirements of a general training program covering railway vehicle maintenance sector should be at least:

- ▶ basic knowledge of vehicle's operation and maintenance execution (including theoretical and practical training on maintenance plan and associated procedures)
- ▶ basic knowledge on vehicle's main functions/systems,
- ▶ basic rules to carry out maintenance (repair, inspection, cleaning, lubrication, calibration, measuring, diagnosis, assembly and disassembly activities, testing),
- ▶ basic knowledge of the most common tools and equipment used in vehicle's maintenance
- ▶ general health and safety instructions, ergonomics and health protection, generic earthing provisions, provisions against electric shock, hot surface and other,
- ▶ organisation of vehicle's maintenance (maintenance plan, maintenance manuals and reference documents, use/handling of tools and equipment, maintenance orders, spare parts list),
- ▶ interfaces between the various processes within ECM-F4 and between function ECM-F4 and ECM-F3 (for the creation of the Maintenance orders / for the release to service) and between ECM-F4 and ECM-F2 (for the proposed changes / for applying changes).

Based on the organisation of the ECM, the general training program may be characterized in professional areas and structured/grouped with a technical view as the following non-exhaustive examples:

Group A – 'Release to service' skill with the following competence on:

- ▶ final vehicle testing procedure, methods and results,
- ▶ specific vehicle's operation and maintenance profile (scheduled operation profile, scheduled maintenance intervals),
- ▶ checking maintenance orders performed and restrictions applicable for safe running,
- ▶ current vehicle documentation applicable (legal requirements, technical specifications),
- ▶ preparing document accompanying vehicle for its release to service.

Group B – 'Brake and pneumatic system' skill with the following competence on:

- ▶ knowledge on vehicle's different brake systems, their functioning principles, interfaces, typical malfunctions and fault-finding procedure,
- ▶ comprehension of technical drawings and functional schemes related to brake and pneumatic system and knowledge on physical location of its components on the vehicle,
- ▶ knowledge on use of facilities and equipment, handling and storage of specific tools and equipment for calibration, measuring, testing, diagnostics and IT system devices.

Group C – 'Electric/electronic main power supply system' skill with the following competence on:

- ▶ knowledge on vehicle's power supply systems, their functioning principles, interfaces, typical malfunctions and fault-finding procedure,
- ▶ specific health protection measures for a safe maintenance (i.e. earthing provisions),

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- ▶ comprehension of technical drawings and functional schemes related to vehicle's power supply system and knowledge on physical location of its components on the vehicle,
- ▶ knowledge on use of facilities and equipment, handling and storage of specific tools and equipment for calibration, measuring, testing, diagnostics and IT system devices.

Group D – 'Mechanical parts related to movement and traction coupling' (bogie, wheel, axle, axle-boxes, running-gear, suspensions, shock-absorbers, buffing and draw gear, coupling system...) skills with the following competence on:

- ▶ knowledge on vehicle's mechanical components related to movement and traction coupling, their functioning, interfaces, typical malfunctions and fault-finding procedure,
- ▶ specific health protection measures for a safe maintenance,
- ▶ comprehension of technical drawings and functional schemes related to vehicle's movement and traction coupling and knowledge on physical location of its components on the vehicle,
- ▶ knowledge on use of facilities and equipment, handling and storage of specific tools and equipment for calibration, measuring, testing, diagnostics and IT system devices.

Additional specific training program may be required for particular maintenance activities related to safety (see Annex II, IV.8 of the ECM Regulation):

- (a) joining techniques (including welding and bonding).
- (b) non-destructive testing.
- (c) final vehicle testing and release to service.
- (d) maintenance activities on brake systems, wheel sets and draw gear.
- (e) Maintenance activities on firefighting system (such as portable fire extinguishers, fire detection systems, fire containment and control systems for passenger rolling stock, etc.)
- (f) maintenance activities on specific components of freight wagons for the transport of dangerous goods, such as tanks, valves, etc.
- (g) maintenance activities on specific components of OTMs (such as elevating platforms and other work equipment typical of OTMs)
- (h) maintenance activities on safety-critical components.
- (i) maintenance activities on control-command and signalisation systems.
- (l) maintenance activities on door control systems.
- (m) other identified specialist areas affecting safety.

Besides trainings fulfilling the Annex II, IV.8 of the ECM Regulation requirements, additional specific trainings and qualifications could be required, based on other regulations or notified national laws or national notified standards (e.g. Transportable Pressure Equipment Directive for maintenance of pressurized air reservoirs, etc.).

ECM should consider existing standards, where appropriate, and indications provided by Manufacturer to identify qualification requirements and issue specific qualification based on defined training process, for instance:

► **NON-DESTRUCTIVE TESTING**

Concerning the activities “non-destructive testing¹¹” on all safety-critical components and in general on all components listed above, at least evidence of compliance of maintenance workers competences with the relevant standard should be required:

In particular, should be necessary to give evidence of the competences in the industrial sector “railway maintenance” in compliance with standard ISO 9712. The criteria for the qualification of NDT staff regarding the application of the tests in “railway maintenance” is in addition to standard ISO 9712.

If there are notified national rules concerning this field each ECM or Maintenance workshop should respect them for its staff involved in the application of the NDTs in “railway maintenance”.

In absence of notified national rules, each ECM or Maintenance workshop should define a specific procedure for the qualification of NDT staff.

► **JOINING TECHNIQUES (INCLUDING WELDING AND BONDING)**

Concerning the activities joining techniques¹² in the case of “welding processes”, at least evidence of compliance with the relevant standard should be required.

In particular, in the case of “welding processes” are applied, at least for staff and maintenance workshop the certification in conformity to the series of standards EN 15085 [\[22\]](#) and EN ISO 14731 [\[50\]](#) is recommended.

The certification body should fulfil the requirements of the standard EN 15085-1.

In particular, in the case of “bonding processes” are applied, at least for staff and maintenance workshop the implementation of requirements stipulated in the standard EN 17460 [\[51\]](#), or equivalent is recommended.

If there are notified national rules concerning this field each ECM or Maintenance workshop should respect them for its staff and the organisation of workshop.

11 “Non-destructive testing”: qualification of NDT staff regarding the application of the tests in the industrial sector “railway maintenance”.

12 Joining techniques in the case of “welding processes”: certification of staff and maintenance workshop.

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In absence of notified national rules, each ECM or Maintenance workshop should define a specific procedure for the competences of the personnel involved in joining techniques.

It is recommended that the above rules are included in the maintenance system as they are considered as good practice.

12 WAGONS FOR DANGEROUS GOODS

You are an ECM dealing with wagons transporting dangerous goods; some requirements should be taken into account during the certification process.

Additional requirements for ECM, dealing with wagons transporting dangerous goods

- ▶ Competence management in Dangerous Goods as required in RID Chapter 1.3
- ▶ Maintenance system for tanks based on legal requirements (RID, Type approval) and return of experience
- ▶ Information management with RU and others e.g. customer/operator regarding checks between mandatory RID-inspections as defined in GCU [\[37\]](#) Annex 9 or suggested in RID 1.4.3.3 a
- ▶ Documentation system regarding tank file as required in RID 4.3.2.1.7

Only for ECM-F4 (Maintenance Delivery)

- ▶ Competence management system in Dangerous goods (RID Chapter 1.3)
- ▶ Qualification for welding of tanks acc. RID 6.8.2.1.23
- ▶ Particular proceedings/equipment related to these substances
- ▶ Occupational health and safety processes with regard to Dangerous Goods

13 APPLICATION OF ECM REGULATION [1] FOR GCU WAGONS

The General Contract of Use for Wagons (GCU) [37] is a voluntary multilateral contract based on the international convention COTIF 1999 and Annex CUV. The GCU specifies the mutual rights and obligations of Wagon Keepers (K) and Railway Undertakings (RU) with regard to the use of rail freight wagons as a means of transport throughout Europe and beyond.

The GCU only apply to the Keepers and Railway Undertakings that have signed the contract, and it does not change or replace any legal obligations of the stakeholders mentioned within the contract, i.e. the Railway Undertaking, the Keeper, the ECM or maintenance functions to fulfil the requirements of the ECM regulation for their parts.

The contract can be found on the GCU website <https://gcubureau.org/>.

Amongst various other things about the rights and obligations of Wagon Keepers and Railway Undertakings with regard to the use of rail freight wagons, the GCU defines the technical admission and maintenance of wagons (Article 7 of the GCU), the handling of wagons, especially when damage has been detected, the information to the keeper and the handling of the damage. (Articles 12 and 19 of the GCU)

The GCU defines within Appendix 9 technical inspections of the Railway Undertaking and a catalogue of irregularities including respective actions within Appendix 10 corrective maintenance activities and handling of wagons after an incident.

These activities outlined in the GCU do define specific handling within the first maintenance level, responsibility of the RU and within the second level, responsibility of the ECM, as outlined in ERA-1172-003 [17].

ECM with responsibility for GCU wagons need to ensure that the requirements of the ECM regulation are met for maintenance and handling of these GCU wagons.

The GCU provides the possibility for the RU to directly contract or directly perform corrective maintenance activities and repairs (see Article 19 of GCU).

This requires that the requirements of contracting activities according to the ECM Regulation Annex II Section I.9 are considered between the RU and ECM.

14 ANNUAL REPORT TO ECM CB

Each certified entity in charge of maintenance and certified outsourced maintenance function shall submit an annual report of its activities to the ECM CB. The report shall be submitted to the certification body and to the relevant customers (including keepers). The ECM shall make it available to the national safety authority and to the Agency upon request.

The requirements for this report are set out in Annex V of the ECM Regulation [\[1\]](#).

The certified entity in charge of maintenance and certified outsourced maintenance function shall issue a report, which covers usually a period of 12 months. Submission date may be agreed with the certification body.

In case of article 3(4) of the ECM Regulation the NSA can define other periods.

The entity in charge of maintenance shall address the report to the NSA one month before the next planned surveillance audit.

The report should include enforcement actions or investigations by the Agency, national safety authorities and other authorities, including claims under Articles 8 and 12 of the ECM Regulation. It shall cover the maintenance system and its results.

15 STATUS OF VEHICLES BETWEEN NEW BUILD AND ENTERING SERVICE

When a vehicle is placed into service for the first time, an ECM has to be designated and identified in the European Vehicle Register (EVR) and/or the European Vehicle Register (EVR). Being placed into service means that it is operating to carry out the function for which it was designed, e.g. a passenger vehicle carrying paying passengers.

Prior to entering service, there may be requirements for vehicles to run on the mainline, i.e.:

- ▶ Type testing and commissioning
- ▶ Acceptance testing
- ▶ Fault free running
- ▶ Staff training
- ▶ Etc.

There is no requirement during this period to register an ECM against the vehicle/s.

This doesn't mean that there is no requirement for maintenance activities, these still need to be carried out in accordance with the manufacturer's recommendations.

Note: During this period the maintenance plan may differ from the issued plan due to differences in the vehicle's operations.

During this period, the manufacturer or a body that has been designated to carry out the maintenance is responsible for carrying out the maintenance and essentially acts as the ECM but does not have to be Certified ECM.

The RU operating the vehicles during the testing phase has overall responsibility for safety under their SMS.

This applies both prior and post vehicle authorisation as units may be required to be tested throughout a build programme.

16 THIRD-PARTY CERTIFICATION VS ECM CERTIFICATION

There is evidence in the market of many organisations granted with third-party certification demonstrating compliance with various and different certification schemes and regarding management system or maintenance system or other.

For instance, examples of third-party certification could be the “Quality certification” (ISO 9001 [52]), the “Railway Quality certification” (so-called IRIS Certification (<https://www.iris-rail.org/>) in conformity with ISO 22163 [45]), the “Environmental certification” (ISO 14001 [53]) and so on.

The certification process as stated in the ECM Regulation [1] and in the certification scheme (ERA-1172-003 V1.1 [17]) applies to all applicants even in the case of a company granted with a third-party certification. There is neither any automatic restriction nor automatic fast-track procedure in case of application for ECM certification and ECM maintenance function certification.

The applicant may have implemented processes and procedures related to other certifications that partially or fully align with the ECM Regulation, thereby providing initial evidence of compliance. These existing processes from third-party certifications may be used to support the assumption of compliance when pursuing ECM certification.

A third-party certification could support the applicant during the preparation of its management system applying for ECM certification or ECM maintenance function certification.

However, in accordance with RFU 4.2 (see ERADIS, Recommendations for Use section), it is at the certification body’s discretion to determine how far it will rely on third-party conformity evidence when verifying compliance against ECM Regulation.

The ECM certification body must be satisfied that all applicable requirements of the ECM Regulation have been fulfilled even if the applicant has another certification against an acknowledged certification scheme.

In the cases in which the audit requirements are mapped as identical between various certification schemes, and in the spirit of effectiveness and avoiding redundant checks for the very same requirements, the Agency encourages the checking entities involved to explore mutual recognition of the outcomes of the checks already done by other entities. While the expected level of assurance shall be safeguarded in line with the defined roles and responsibilities, the opportunities to reduce time and redundant checks for the same requirements could be explored.

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Guidance for ECM certification:

- ▶ Understanding the concept of ECM
- ▶ Clarification on the obligation of parties involved in the maintenance process of vehicles