

**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*

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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 TSIs 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 TSIs.

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

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 vehicles¹ 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. 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 actors² whose activities may have an impact on the safety of railway systems and who directly or indirectly need to apply the ECM Regulation. It may serve as a clarification tool without however dictating in any manner compulsory procedures to be followed and without establishing any legally binding practice. The guide provides explanations on the provisions contained in the ECM Regulation and should aid understanding of the approaches and rules described therein.

This guide has been prepared by the European Union Agency for Railways (ERA) with the support of Recognised Bodies and National Safety Authority experts. It represents a developed collection of information gathered by the Agency during internal meetings and meetings with ACBs (Accredited Certification Bodies), RCBs (Recognised Certification Bodies) and NSAs.

ERA will organise other workshops during 2021/2022, and when necessary, ERA will review and update the guide to reflect the progress with the return on experience on the implementation of the ECM Regulation received during these workshops. As it is not possible to give a timetable for this revision process at the time of writing, the reader should refer to the Agency for information about the latest available edition of the guide or consult the Agency website (<http://www.era.europa.eu>).

The ECM Regulation provides a framework for the harmonisation of requirements and methods to assess the ability of entities in charge of maintenance for 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. For ease of reference, when relevant, the related article of the ECM Regulation or the safety directive is copied or referred to in the guide. Guidance

¹ OJ L139/360 27/05/2019

² The concerned actors are the contracting entities as defined in Article 5 of ECM Regulation including their suppliers and service providers, or the certification bodies as defined in Article 6 of ECM Regulation.

1. INTRODUCTION

is then provided in the following paragraphs to help provide understanding where this is considered necessary.

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

1.3. Structure

The guide is divided into the following parts:

- ▶ Part 1 “Introduction” contains the scope and explains the structure of the guide;
- ▶ Part 2 “Documents” defines the documents useful for the guide;
- ▶ Part 3 “Definitions” contains a list of questions/answers relative to definitions, terms and abbreviations used throughout the guide;
- ▶ Part 4 “Vehicle and maintenance” explains the maintenance process;
- ▶ Part 5 “Certification of ECM” describes the different steps of the ECM certification;
- ▶ Part 6 “Where does the ECM certification apply ?” explains the geographical scope of ECM certificate;
- ▶ Part 7 “Accreditation – Recognition of certification bodies” contains a list of questions/answers relevant to better understand the environment of accreditation and recognition;
- ▶ Part 8 “Implementation of article 3 of the regulation 2019/779” System of certification.
- ▶ Part 9 “Organisation of the railway transport in Europe and responsibilities of actors”
- ▶ Part 10 “Maintenance file and technical file” contains a list of questions/answers to explain how to follow the requirements of the regulation 2019/779 to build the essential documents relative to the maintenance functions.
- ▶ Part 11 “Exchange of information between railway actors”
- ▶ Part 12 “Management of changes” It explains how to meet the different changes inherent to ECMs.
- ▶ Part 13 “Safety-critical components”
- ▶ Part 14 “Competences of maintenance workers”
- ▶ Part 15 “Wagons for Dangerous goods”
- ▶ Part 16 “ECM annual report”
- ▶ Part 17 “Annexes”

2. DOCUMENTS

2.1. What legislative 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 Current consolidated version: (Hereafter called "ECM Regulation")	(EU) 2019/779	27/05/2019 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	11/05/2016
[3]	Directive (EU) 2016/797 of the European Parliament and of the Council of 17 June 2008 on the Interoperability of the rail system within the Community (Hereafter called "Interoperability Directive")	(EU) 2016/797	11/05/2016
[4]	Commission Implementing Regulation (EU) N°402/2013 of 30 April 2013 on the common safety method on risk evaluation and assessment and repealing Regulation (EC) n° 352/2009 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 "Loc&Pas TSI") Amended by: Commission Regulation (EU) 2016/919 of 27 May 2016 Commission Implementing Regulation (EU) 2018/868 of 13 June 2018 Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 Commission Implementing Regulation (EU) 2020/387 of 9 March 2020	(EU) 1302/2014	18/11/2014

2. DOCUMENTS

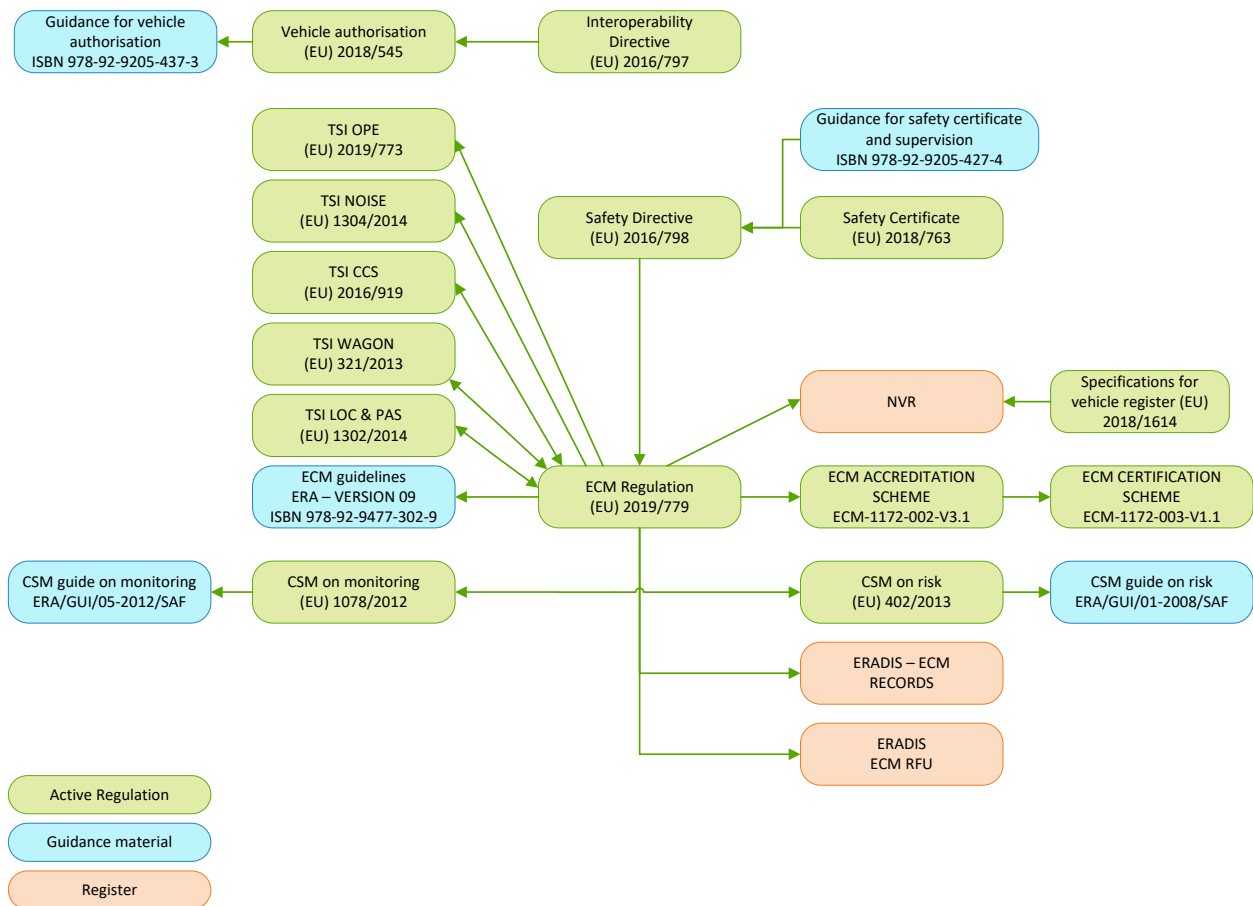
[Ref. N°]	Title	Reference	Version
[6]	COMMISSION REGULATION (EU) No 321/2013 of 13 March 2013 concerning the technical specification for interoperability relating to the subsystem 'rolling stock — freight wagons' of the rail system in the European Union and repealing Decision 2006/861/EC. (Hereafter called "Wagon TSI") Amended by: Commission Regulation (EU) No 1236/2013 of 2 December 2013 Commission Regulation (EU) 2015/924 of 8 June 2015 Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 Commission Implementing Regulation (EU) 2020/387 of 9 March 2020	(EU) 321/2013	09/03/2020
[7]	COMMISSION REGULATION (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union (Hereafter called "CCS TSI") Amended by: Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 Commission Implementing Regulation (EU) 2020/387 of 9 March 2020	(EU) 2016/919	09/03/2020
[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/E (Hereafter called "OPE TSI")	(EU) 2019/773	16/05/2019
[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") Amended by: Commission Implementing Regulation (EU) 2019/774 of 16 May 2019	(EU) 1304/2014	16/05/2019
[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	09/07/2008
[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	04/04/2018
[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	16/02/2018
[15]	RID – 2019 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 2019	01/01/2019

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[Ref. N°]	Title	Reference	Version
[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	30/09/2008
[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 4 2012/06
[22]	Series of standards EN 15085 “Railway applications — Welding of railway vehicles and components”	Series EN 15085	Last versions
[23]	EN ISO/IEC 17021 “Conformity assessment — Requirements for bodies providing audit and certification of management systems”	EN ISO/IEC 17021	2015/08
[24]	EN ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories”	EN ISO/IEC 17025	2018/01
[25]	EN ISO/IEC 17065 Conformity assessment- Requirements for bodies certifying products, processes or services	EN ISO/IEC 17065	2012/09
[26]	EN ISO/IEC 17000 Conformity assessment – Vocabulary and general principles	EN ISO/IEC 17000	2020/05

2.2. What documents do you need to have in mind?

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



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

- ▶ EN ISO/IEC 17065:2012 Conformity assessment- Requirements for bodies certifying products, processes or services
- ▶ EN ISO/IEC 17021-1:2015 Conformity assessment- Requirements for bodies providing audit and certification of management systems -- Part 1: Requirements
- ▶ EN ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories
- ▶ EN 17095 Railway applications – Rolling stock maintenance- Maintenance records
- ▶ EN 17023 Railway applications-Railway vehicle maintenance- Creation and modification of maintenance plan
- ▶ EN ISO/IEC 17000:2020 Conformity assessment – Vocabulary and general principles
- ▶ IAF MD 1:2018 Audit and certification of a Management System Operated by a Multiple-Site Organization

- ▶ IAF MD 2:2017 Transfer of Accredited Certification of Management Systems
- ▶ IAF MD 5:2015 Determination of Audit Time of Quality and Environmental Management Systems.

The accreditation and recognition scheme [18] precises in the 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 subsystem in order to meet the essential requirements and ensure the interoperability of the railway system of the European Union.

The LOC&PAS TSI 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;
- ▶ Mobile railway infrastructure construction and maintenance equipment.

The Wagon TSI 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/APIS	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	
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)
ECCM	European Common Criteria for Maintenance
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)
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
EU	European Union
ERA	European Union Agency for Railways
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/)
(IAF) MD	Mandatory document of IAF
IM	Infrastructure Manager

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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
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
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
SAIT	Safety Alert IT-Tool
SCC	Safety-critical components
SMS	Safety Management System
VTA	Vehicle Type Authorisation
RTS	Release to Service

4. VEHICLE AND MAINTENANCE

4.1. What vehicles fall under regulation 2019/779?

► 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 for this wagon in the NVR. As it is permissible in certain circumstances to assign a single EVN to a fixed formation of two or more wagon units (defined as multiple wagons in [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 NVR will be the binding definition on what constitutes an individual “wagon”.

Picture 1: 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



Picture 2: Example of a unit consisting of a rake of permanently connected two elements (blue and orange), those elements cannot be operated separately (articulated wagon)



Picture 3: Example of a unit consisting of a rake of permanently connected two elements, those elements cannot be operated separately



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

Locomotives (mentioned in TSI LocSPas 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).

4. VEHICLE AND MAINTENANCE

Picture 4: Example of a French freight locomotive that is powered by electricity.



► Multiple units/Trainset

Multiple units or trainset (mentioned in TSI LocSPas 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 Unit (BEMU). Other power sources and hybrids also exist e.g. battery and Hydrogen or LNG.

Picture 5 : Example of an Electric Multiple unit in Germany.



► Passenger coaches

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

Picture 6: Example of passenger coaches being pulled by an electric locomotive in Switzerland.



► **On Track Machines (OTM)**

An OTM (mentioned in TSI LocSPas 2.3.1) is a vehicle used for performing works on or around the tracks, running on its own rail wheels, designed and intended to be detected by a track-based train detection system for traffic management. When in transport (running) mode they are self-propelled or hauled.

Picture 8: Example of an On-Track Machine, often painted bright yellow.



4.2. What are the exclusion of vehicles from the application of Commission Implementing Regulation 2019/779

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

- The vehicles corresponding to cases stated in the article 2(2) of Directive 2016/798. Example: Metros. The reason is that the art 2(2) states the cases for which the Directive 2016/798 does not apply.
- Upon decision of the MS when transposing the Directive 2016/798, the vehicles corresponding to cases stated in the article 2(3) of Directive 2016/798. Example: Vehicles reserved for strictly local, historical or tourist use. This reflects a choice by MS when transposing the Directive 2016/798.

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- ▶ Upon derogation identified and justified in NSA annual report according to article 19 of directive 2016/798, the vehicles corresponding to the cases stated in the art 15(1) of Directive 2016/798. Examples: Freight wagons operated under international agreement with third countries on 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 on the certificate forms of annex IV of the regulation, no certificates may be granted to Entities in Charge of Maintenance of these vehicles only, nor should there be any reference to them on certificates covering other vehicles well on the scope.

Nevertheless, the services of voluntary assessment of Maintenance Management Systems according to the requirements of annex II of the 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 “certificates” and will not be registered in the ERADIS database.

4.3. What is an ECM?

After a vehicle is placed in service, an Entity in Charge of its Maintenance has to be designated and to be identified in the National Vehicle Register.

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

The maintenance system shall be composed of four functions (see section 4.8).

In accordance with article 3(1) of the regulation 2019/779 any ECM shall satisfy the requirements of Annex II, in respect of all vehicles subject to Directive (EU) 2016/798.

4.4. Who can be an ECM?

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

4.5. How many ECMs can a vehicle have?

Article 47 of Directive (EU) 2016/797 provides that the NVR is to contain, 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 NVR and, **for each vehicle, the data relative to the ECM (and not several ECM)** has to be compulsorily fulfilled. Therefore a vehicle can only have **one ECM** assigned in the NVR at any given time.

4.6. What is a maintenance workshop?

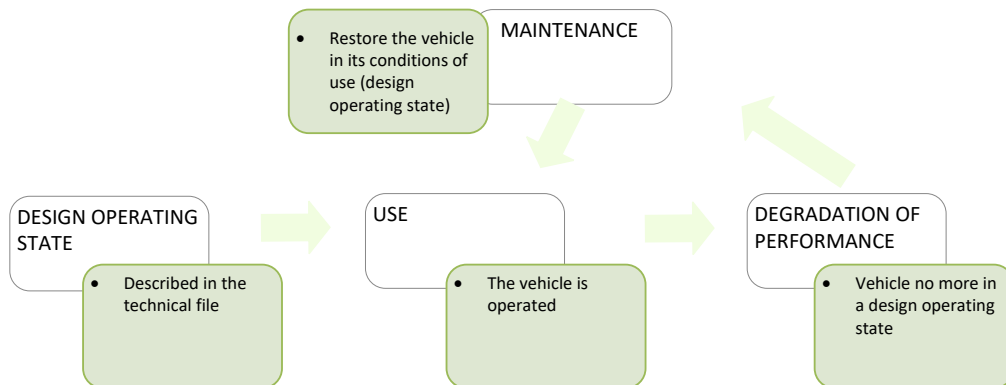


A Maintenance workshop is a mobile or fixed entity composed of staff, including those with management responsibility, tools and facilities organised to deliver maintenance on vehicles, parts, components or sub-assemblies of vehicles.

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

A maintenance Workshop may be in charge, of the whole maintenance delivery function (ECM-F4) or parts of it as described in the Art. 14(3)d of the Directive (EU) 2016/798.

4.7. What does “maintenance” mean?



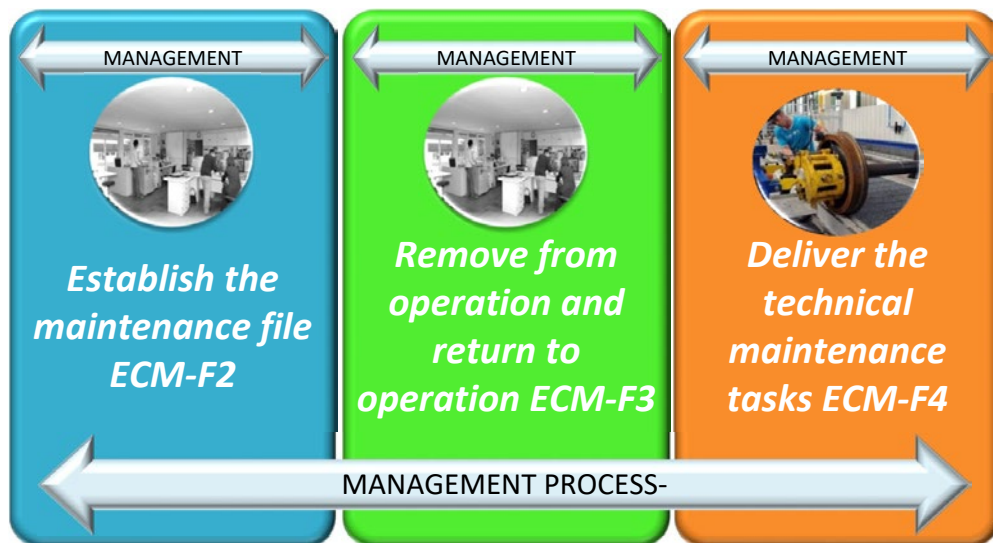
The design operating state:

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

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

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

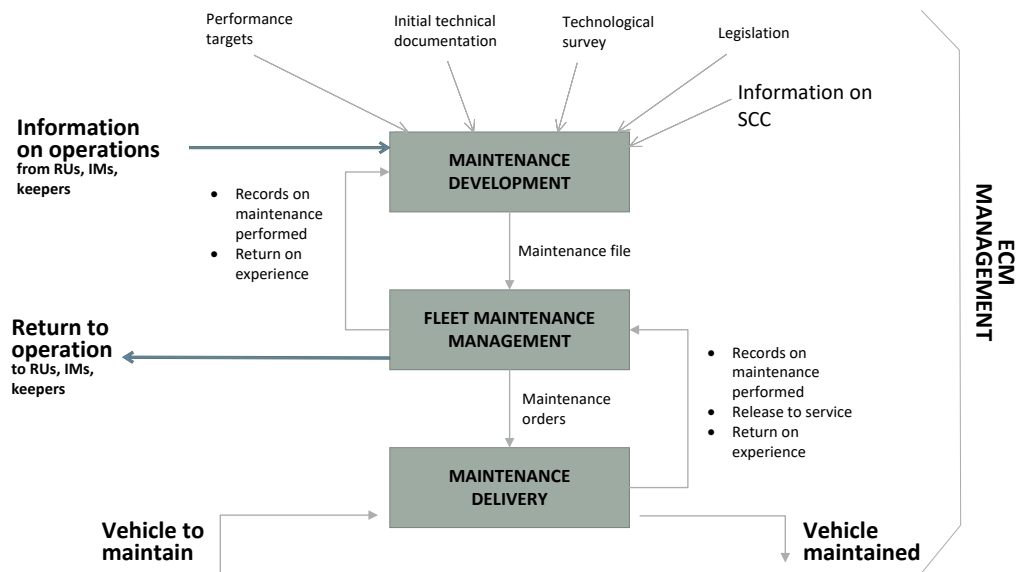
4.8. What is a maintenance system?



According to article 1(1) of the regulation 2019/779, the maintenance system shall be composed of the following functions:

- (a) 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;
- (b) 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;
- (c) the **ECM-F3**, which manages the vehicle's removal for maintenance and its return to operation after maintenance; and
- (d) 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**



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.

4.9. What is the 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 vehicle.

The ECM-F1 has two main tasks:

- ▶ Coordination of the functions ECM-F2, ECM-F3 and ECM-F4, as defined in the article 14(3) of Directive (EU) 2016/798, 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 the article 14(3) of Directive (EU) 2016/798, 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, the implementation and the improvement of the Maintenance System.

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

The ECM-F1 checks the implementation of the Maintenance System defining a systematic monitoring process, based on the CSM for Monitoring (Commission Regulation 1078/2012) to check the performances of the ECM in the field of maintenance (and safety, as consequence). When needed, the ECM-F1 creates the conditions to correct or to improve the Maintenance performances, defining and implementing changes in the Maintenance System. The impact of those changes on the maintenance processes shall be evaluated according to the CSM for Risk Assessment[4]. Monitoring can be performed through checks of results of processes if a maintenance function is certified (point 9.5)

A decision making process should be managed by the 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.

4.10. What is the ECM-F2?

The maintenance development function (ECM-F2) covers the management of the maintenance documentation, including the configuration management, based on design and operational data as well as on required performance and return on experience.

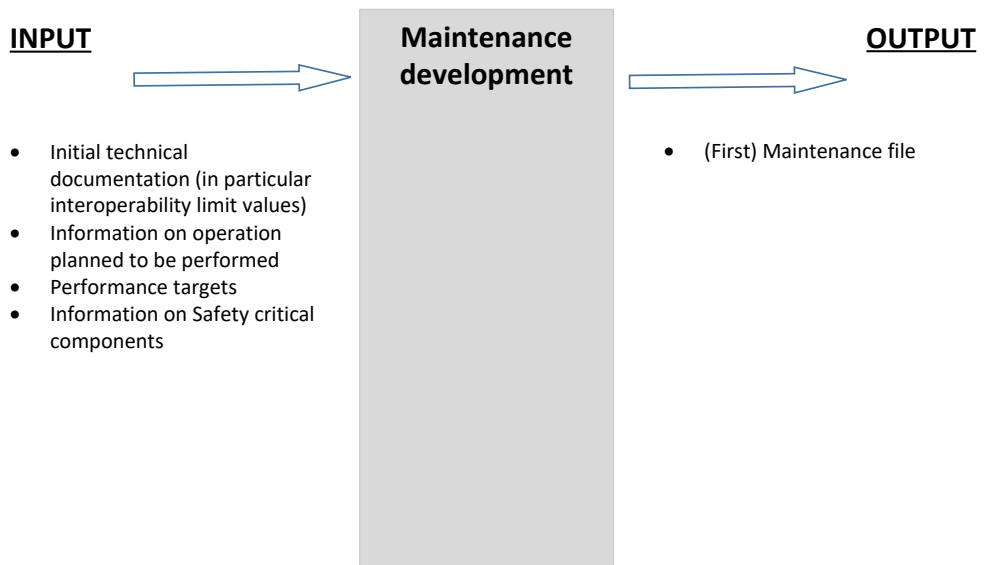
It also covers the compliance with interoperability rules and the establishment and continuous update of the maintenance file.

The maintenance development process can be described as follows:

At the moment when operation starts

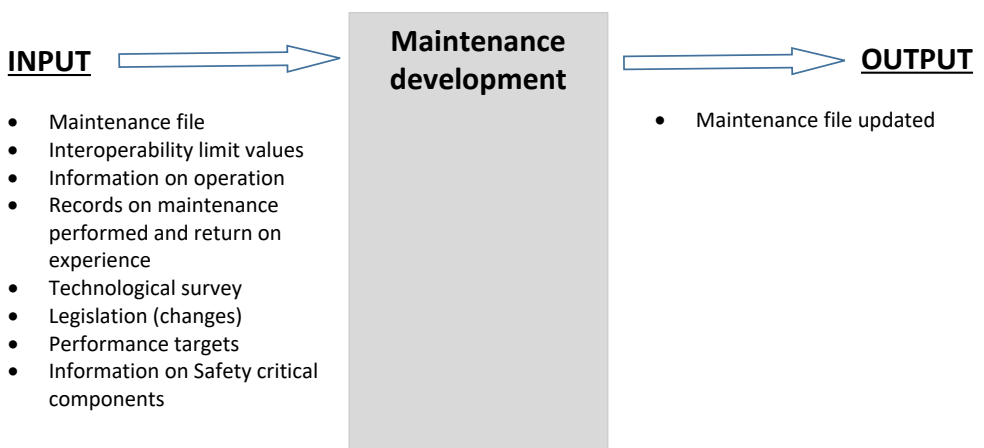
The initial development of the maintenance file depends on the initial technical documentation (see chapter 10) and the pattern of operations planned.

The process may be described as following:



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



4. VEHICLE AND MAINTENANCE

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

- ▶ The limit values that have to be maintained to assure the interoperability of the vehicle according to its authorisation of placing on the market/placing in service. They are stated in the initial technical documentation and every update of this documentation justified by a change in the design of the vehicle.
- ▶ Information on operation such as but not limited 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 on maintenance already performed, on inspections performed by RUs/IMs, keepers, ECM, owners and on studies related to return of experience. The ECM-F4 are often requested to take part to return on experience studies.
- ▶ Technological survey. The lifecycle of rolling stock extends to 40-50 years. Technology evolves a lot during this long lifecycle. The technological survey may include:
 - Condition based monitoring. This monitoring considers the behaviour of the different components.
 - Technological progress that includes the continuous progress of:
 - materials,
 - equipment,
 - spare parts,
 - tools and industrial equipment,
 - IT systems,
 - working and management methods.
 - Availability of materials, equipment and spare parts. Spare parts or materials may become obsolete or be unavailable. Generally the manufacturers give 10 years assurance regarding availability of electrical / electronic devices. So at certain time equivalent spare parts or materials have to be found.

- ▶ Evolution of applicable legislation:
 - Railway,
 - Environment,
 - Health and safety,
 - Safety of components,
 - Etc.
- ▶ Performance targets imposed by users (RU, IM, keeper):
 - reliability and availability of vehicles,
 - safety.

After taking into account all information, the ECM-F2 covers the update or not of the maintenance file and the dissemination of the updates of documentation to interested parties.

4.11. What is the ECM-F3?

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

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

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

This function means in particular the responsibility for:

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

The inputs for the ECM-F3 are:

- ▶ the maintenance file;
- ▶ the performance targets imposed by users (RU, IM, keeper), such as the reliability and availability of vehicles.

4. VEHICLE AND MAINTENANCE

The ECM-F3 must check the availability of the maintenance delivery.

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

The outputs of the ECM-F3 processes are:

- ▶ The 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. The 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).

The ECM-F3 is responsible for declaring the vehicle fit for purpose and fit for its return to operation after the maintenance work has been completed by the ECM-F4. This return to operation is finally addressed to RUs generally through the keeper.

Further the ECM-F3 has to give to RUs, directly or through the keepers, all the information obtained from the ECM-F4 about maintenance limitations due to maintenance activities affecting the operating state of the vehicle, in order to able the RUs in stating operation limitations/restrictions for use to ensure a safe operation.

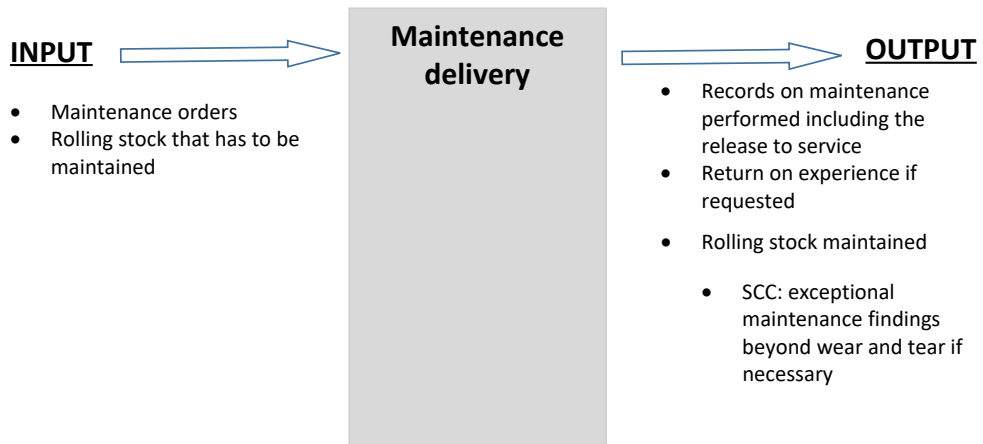
4.12. What is the ECM-F4?

The Maintenance Delivery (ECM-F4) is the technical execution of the ordered technical maintenance tasks. The ECM-F4 task may be done in Maintenance Workshops. The ECM-F4 covers the management of maintenance orders issued by the ECM-F3, the management of the supply chain, the management of facilities, industrial equipment and tools and the management of maintenance technical works.

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

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

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



4.13. What is release to service and return to operation?

Release to service

The “Release to Service” (RTS) is the confirmation by the ECM-F4 to the 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.

The 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”. The 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 the ECM-F3:

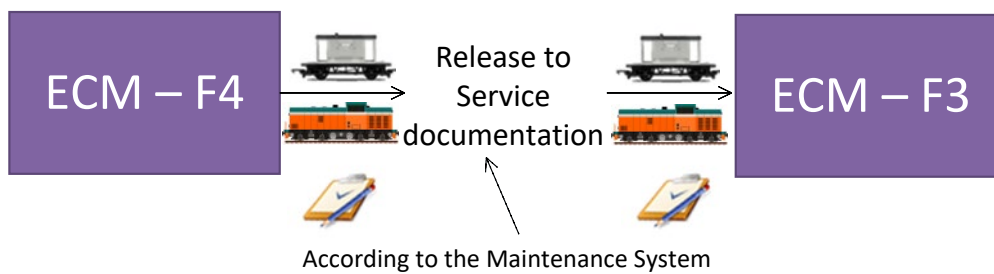
- ▶ Records on work performed incl. any findings, (extra-)time for execution, etc.
- ▶ Records of unplanned work performed due to findings and incl. the release by the ECM-F3
- ▶ Records on final vehicle testing
- ▶ Records on main component testing (incl. used testing devices)
- ▶ Lists of exchanged 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 the ECM-F3 (in case of condition-based maintenance)

4. VEHICLE AND MAINTENANCE

The ECM-F4 delivers the document set via the agreed channel to the ECM-F3.

The report shall include all the information related to maintenance limitations due to maintenance activities affecting the operating state of the vehicle, in order to able the RUs in deciding stating operation limitations/restrictions for use to ensure a safe operation.

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 requested by the ECM-F3 (see next chapter).



Return to operation

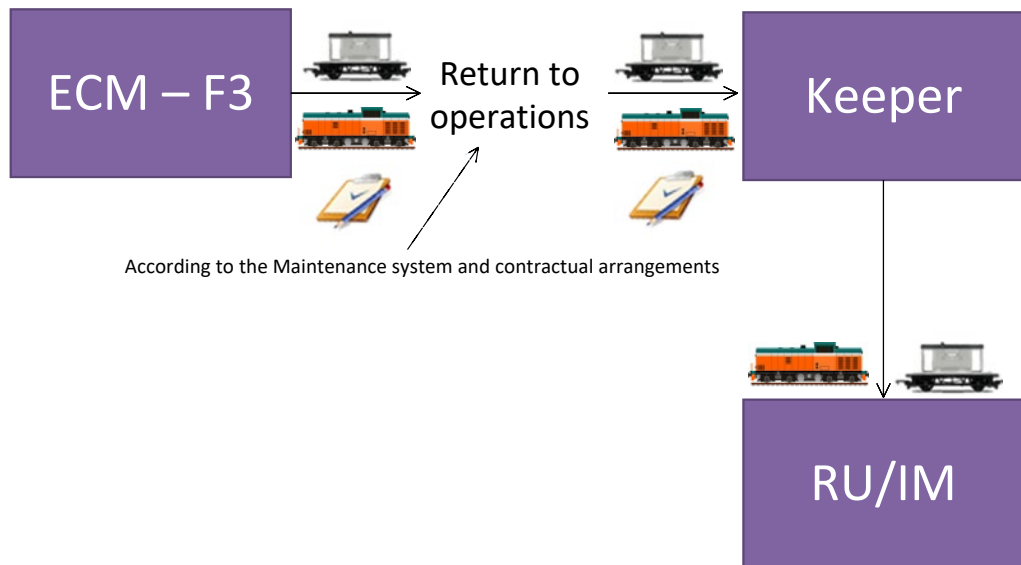
The “Return to Operation” is considered as a sensitive topic. It is formally the confirmation of the ECM that the vehicle is in a safe state for operation. The RU may operate the vehicle on the network only with a valid “Return to Operation Notice”.

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”.

The ECM-F 3 establishes the Return to Operation Notice based on the Release to Service documentation from the 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 regulation 2019/779) states that it possible to send the return to operation to the RU or to the keeper. Especially when a restriction of use be necessary it is the duty of the 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 and ensure the operation of the vehicle in a safe state.



In the reality the keeper is not practically involved in this process, so there is a functional direct contact between the ECMs and RUs. **To avoid confusion in the distribution of responsibilities, normally no information other than that reported about the vehicle should be given to the RU.**

The minimum information that the keeper should receive is reported in 4.12.2.

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

Minimum set of information to be addressed to the Fleet Management function:

Workshop	<i>(Name of the workshop)</i>
12 Digits vehicle N.	<i>(EVN)</i>
Check in date	<i>(Date of the check in of the vehicle in the workshop)</i>
Check out date	<i>(Date of the check out of the vehicle (workshop))</i>
Maintenance File	<i>(Reference to the adopted maintenance file)</i>

Derogation against the technical instructions?: YES / NO

Description of the derogation

list of safety related deficiencies as base for ECM-F3 for restrictions

This field contains the Safety related deficiencies that the ECM-F4 shall report to the ECM-F3 for restrictions.

4. VEHICLE AND MAINTENANCE

4.13.2. 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 restriction for 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 may be possible. The Return to Operation document accompanying the vehicle contains all the necessary information for the RU, in case of technical restrictions affecting operations, the keeper has the responsibility to inform the RU.

RU sets the restriction for use and communicates them on the agreed channel to keeper. (Normally it is the responsibility RU to take the operation restriction to ensure the safe state based on its Safety Management System)

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.

5. CERTIFICATION OF ECM

5.1. What does Certification mean?

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

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

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

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

5.2. What is an ECM certificate?

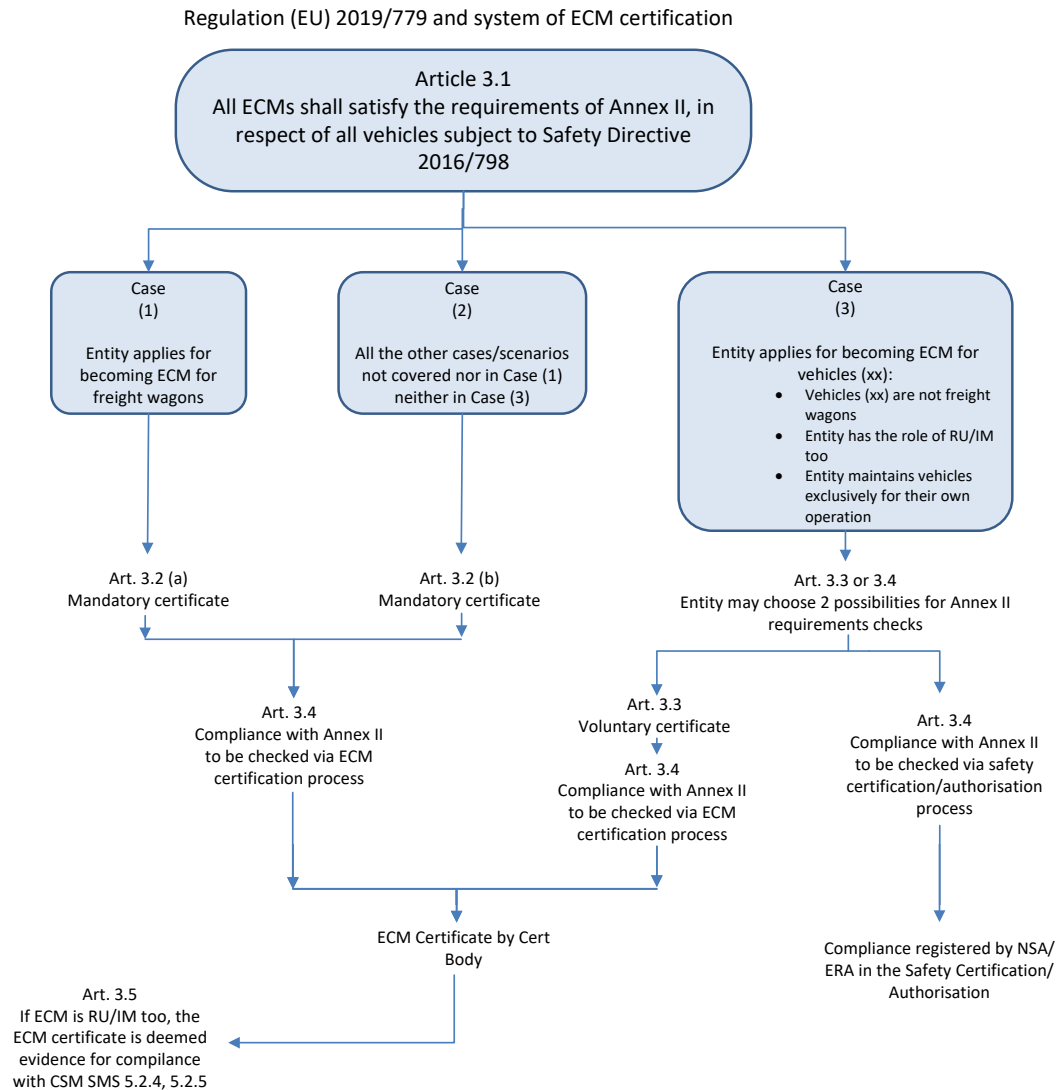
The certificate provided by the accredited or recognised certification body or by the NSA (acting as certification body) according to the ECM Regulation, provides the assurance that the applicant fulfills the requirements established in Annex II of the ECM Regulation and the certification scheme.

The format of this certificate is defined in the Annex IV of the ECM Regulation and available in the ERA database ERADIS. This database is accessible in the following link:

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

5.3. Which ECMs have to be certified

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



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

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

RU's/IMs cannot apply for an article 3(4) assessment for vehicles that they operate in partnership with other RU's/IMs.

RU's/IMs cannot use compliance with the Annex II of ECM Regulation assessed during safety certification/authorization process to operate nor be the ECM for other vehicles not included in art. 3(2)b of ECM Regulation nor operate as an outsourced maintenance function.

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

Possible exceptions are:

- ▶ Movements following an accident or incident to clean the track or as part of technical assistance if the vehicle used aren't registered in the NVR and they don't run as a train to arrive in the area affected by the accident or incident;
- ▶ Activities or shunting operations carried out by contractors (i.e. entities other than the railway undertaking or the infrastructure manager being ECM of the concerned vehicles) excluding any other railway undertakings or infrastructure managers operating these vehicles for their own railway activities.

When the RU/IM wants to become, or continue as, an ECM maintaining vehicles exclusively for its own operations according to Article 3(2)b of Regulation 2019/779, they must notify their NSA or Safety Certification Body (NSA/ERA) thereof. The RU/IM must analyse the risks related to the changes according to their SMS and take proper risk mitigation measures. The requirements in Annex II of the ECM Regulation 2019/779 must be fulfilled from 16th of June 2022, at the latest.

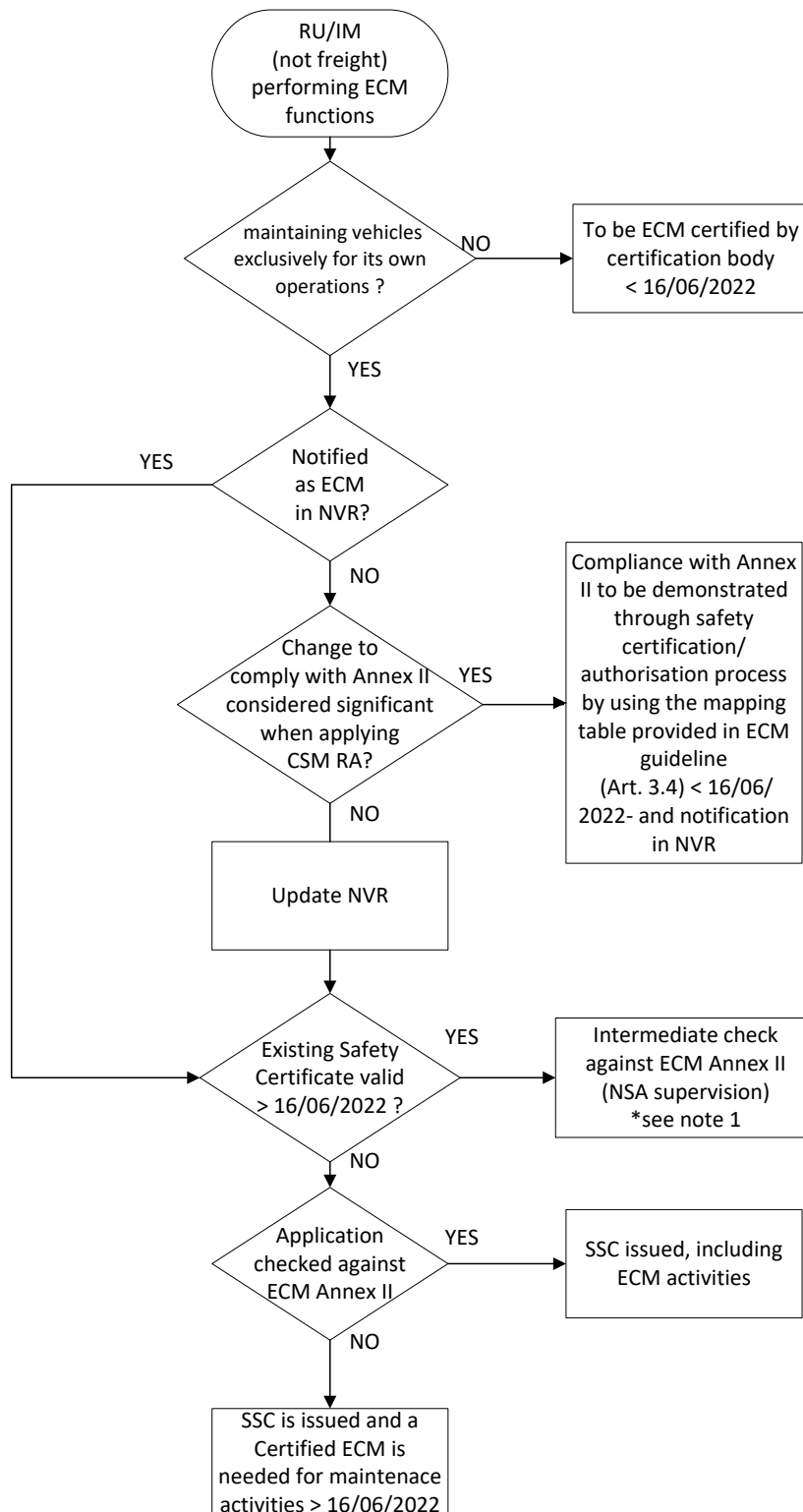
If the changes to the SMS are deemed as substantial changes by the RU/IM, they have to apply for an update of their SSC or SA. An NSA/ERA can also initiate the need for an updated SSC, or NSA in cases of an updated SA, if the changes to the SMS for a specific RU/IM are considered as substantial changes.

- a) NSAs will assess fulfilment of the obligations of the ECM Regulation during NSAs supervision activities.
- b) The mapping table in Annex I for the IM and Annex II for the RU to this guide presents a cross-reference between SMS (2018/762) and Annex II (2019/779) requirements, the template can be used by the RU/IM to easily understand the link between SMS and Annex II and provide necessary evidence where the corresponding requirement of Regulation EU 2019/779 is allocated and accomplished by means of the company's SMS documentation.
- c) The RU/IM need to at least fulfil requirements for the management function ECM-F1, in their own SMS and their own operation. Remaining functions as the maintenance development function ECM-F2, the fleet maintenance management function ECM-F3, and the maintenance delivery function ECM-F4 may be outsourced under the responsibility and monitoring of the management function ECM-F1.

5. CERTIFICATION OF ECM

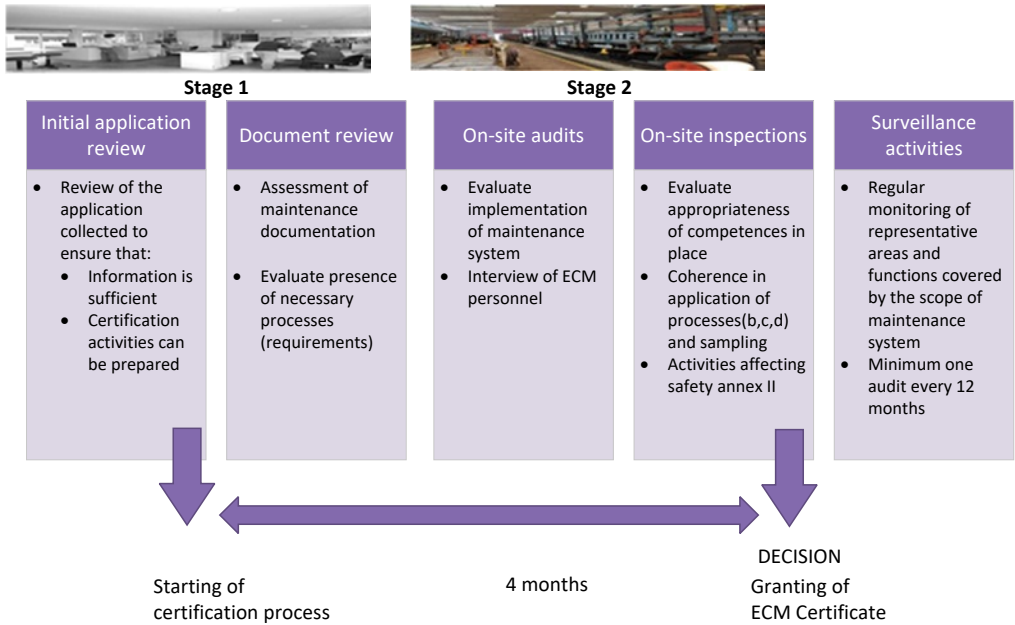
If an RU/IM wants to demonstrate compliance with Annex II of Regulation 2019/779 during the process of safety certification/authorisation, it has to apply for the assessment to the safety certification body (ERA or NSA) /safety authorisation (NSA) in the case of an application for the granting or renewal or update of a safety certificate/authorisation. The request for a safety certificate from the RU is made in the One Stop Shop, the request for the safety authorisation is made by the IM directly to the NSA involved following the national rules. It is necessary, when the RUs submit the application through the OSS for a new safety certificate or renewal/change update of safety certificate or IMs submit the application to the NSAs of new safety authorisation or renewal/update of safety authorisation, to make explicit if they intend to be checked as an ECM in the safety certification process/safety authorisation process. If not they should attach the ECM certificate issued by a certification body in the part 5.2.4 and 5.2.5 of the mapping table. According to article 3(5) of the ECM Regulation, the ECM certificate granted to a railway undertaking or an infrastructure manager shall be deemed evidence of compliance with points 5.2.4 and 5.2.5 both of Annex I and Annex II to Commission Delegated Regulation (EU) 2018/762 as regards vehicle maintenance of vehicles.

The following diagram describes the different options.



Note 1: Based on the knowledge of the safety performance of the RU/IM that the NSA has got from previous supervision activities, the NSA identifies the requirements of annex II of Regulation 2019/779 that it judges pertinent to be assessed. However it is not required to the NSA to assess the conformity to all the requirements of the annex II of Regulation 2019/779 during supervision'

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



For further information see also the Certification scheme ERA-1172/003 V1.1

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

According to the Article 6(1) of the ECM regulation, the Member States shall provide the Agency information concerning the ECM certification bodies.

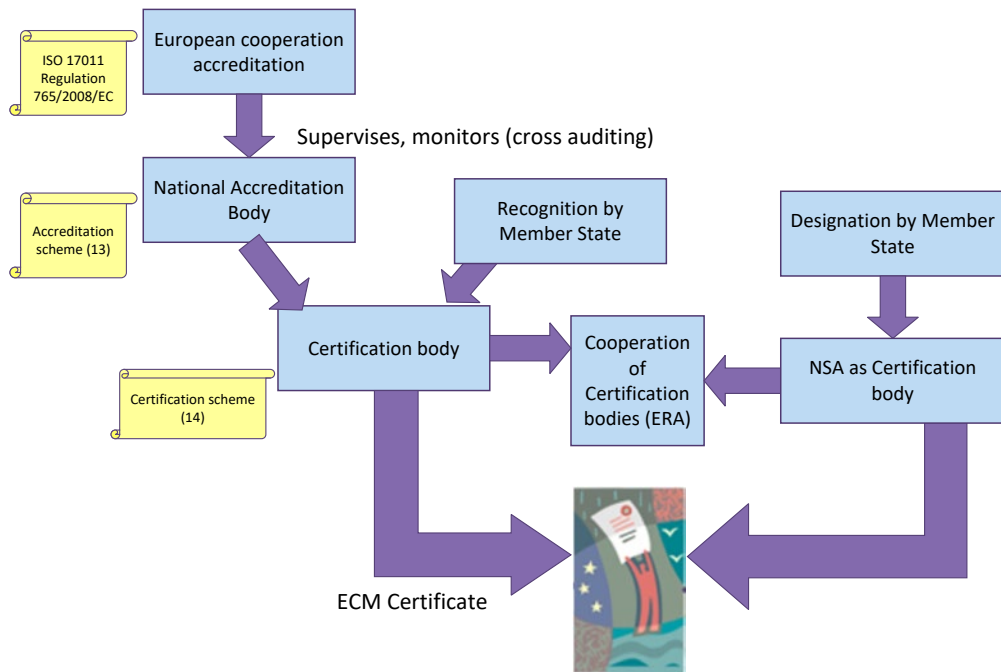
Therefore there are different schemas to be chosen by each Member State:

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

The sectoral scheme for accreditation and recognition ERA1172/002 V3.1 contains requirements to be used by National Accreditation Bodies or by recognition bodies when assessing certification bodies performing ECM certification. It shall be also used by Members States when designating the NSAs to act as ECM certification body (according to article 14 of Directive (EU) 2016/798).

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

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



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

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

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

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

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

6. RESERVED

6. RESERVED

7. RESERVED

8. IMPLEMENTATION OF THE REGULATION 2019/779

8.1. What does the transitional period mean?

Starting from 16.06.2020, any ECM certificate shall be issued in accordance with the ECM Regulation to entities in charge of maintenance, without prejudice to Article 15(1) of Directive 2016/798/EU.

Nevertheless, as defined in the Article 15 of the ECM Regulation 2019/779/EU, there are different transitional periods related to special cases in the implementation of the ECM Regulation.

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

8.2.1. Deadlines for certification bodies

Between 16 June 2020 and 15 June 2021, under Article 6(3) of Commission Implementing Regulation (EU) 2019/779, certification bodies may comply with either the previous or the new accreditation scheme, details can be found in the ERA clarification note ERA1172/001 .

That means that the certification bodies accredited or recognised or NSAs acting as ECM certification bodies in accordance with the sectoral accreditation scheme for Regulation (EU) No 445/2011, should be deemed accredited or recognised to perform the activity of certification also for the scope of other categories of vehicles until 16 June 2021.

The scope of activities of ECM certification bodies compliant with the sectoral accreditation scheme for Regulation (EU) No 445/2011 should be automatically extended to all vehicle categories but with a time limited validity (until 15 June 2021).

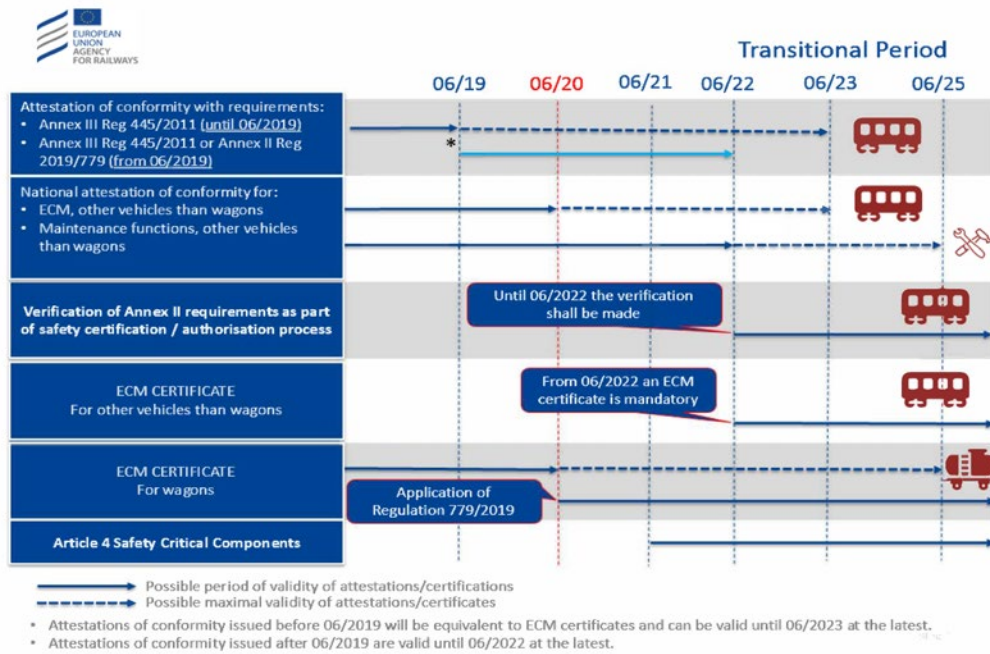
As of 16 June 2021, certification bodies shall be accredited or recognised in accordance with the new sectoral accreditation scheme in order to be able to perform the activity of certification also for the scope of other categories of vehicles.

In accordance with Article 15(1), certification bodies remain accredited or recognised under the conditions for which those certification bodies have been accredited or recognised. They are not affected by the 16 June 2021 deadline as regards performing the activity of certification for freight wagons.

For more information see the clarification ERA 1172/001 V2.0

8.2.2. Deadlines for ECM

The following figures show the details of the transitional period as foreseen by ECM Regulation EU 2019/779 and Regulation 2020/780.



For new RUs/IMs that intend to cover the role of ECM for vehicles other than wagons in accordance of application of article 3(4) of Regulation 2019/779 from 16 June 2020 they can do so by demonstrating compliance with the requirements of Annex II of Reg. 2019/779 during the SSC process from the 16th June 2020 on.

When you are an RU/IM and declared as an ECM in the NVR and maintaining vehicles exclusively for your own operations, you have a safety certificate or a safety authorisation, you can continue to be ECM and maintaining vehicles exclusively for your own operations until the end of validity of the existing safety certificate and at the moment of the renewal of certificate, the assessment done by the authorizing entity will cover all the requirements of annex II of Regulation 2019/779.

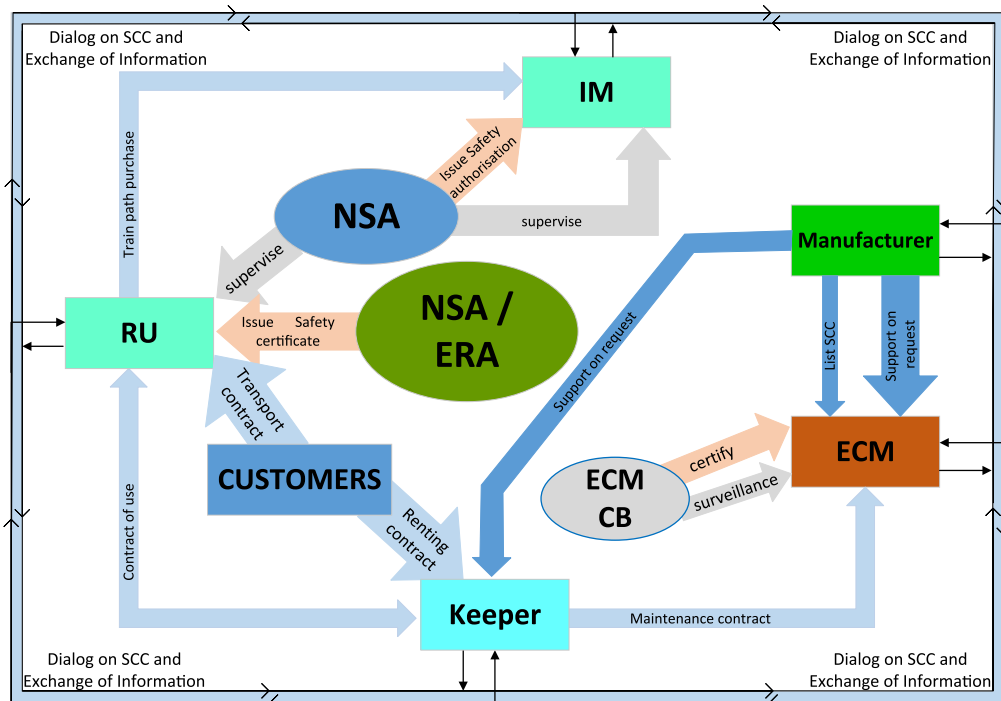
“When you are an RU/IM and not declared as an ECM in the NVR and you would like to become an ECM and maintaining vehicles exclusively for its own operations, either you need to have an ECM certificate (voluntary) or it will be done via notification to NSA/ERA as the Safety Certification Body for Safety Certificate or NSA for Safety Authorisation, and be “assessed” according point 5.3. It shall be done at latest 16 June 2022.

ECM certificates for freight wagons delivered before 16 June 2020 under the regulation 445/2011 keep the date of end validity (maximum until 06/2025). All the surveillance activities and amendments made during this time will be under the regulation 445/2011. It is recommended to the ECM certification bodies to prepare the ECM to the new requirements of the regulation 2019/779 during this phase of transition. (See different scenarios in Annex III)

9. ORGANISATION OF THE RAILWAY SECTOR IN EUROPE AND RESPONSABILITIES OF ACTORS

9.1. 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.

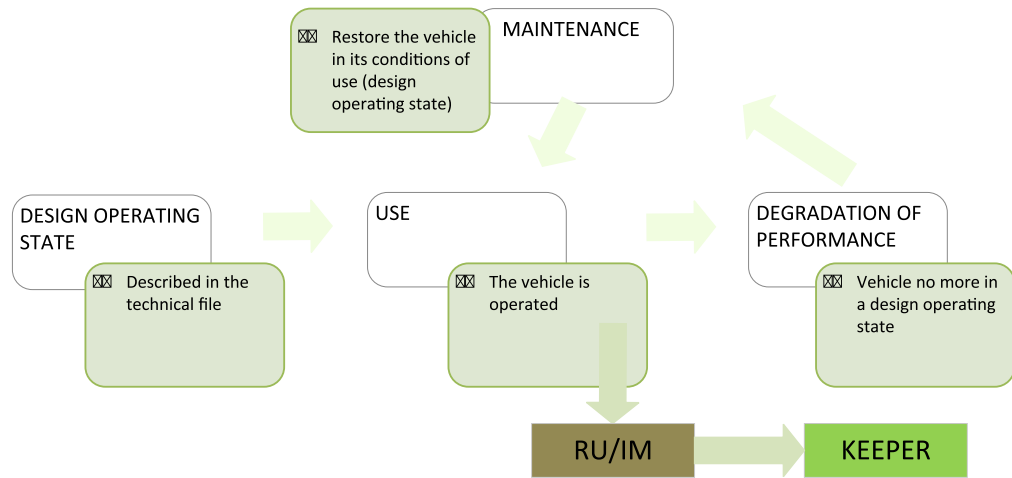


The responsibilities of railway parties are stated in the Safety Directive 2016/798, in Articles 4(14)a and 16 (for NSAs) and the RID, chapter 1.4 (for the transport of dangerous goods). Regarding the maintenance of vehicles, responsibilities are also stated in the ECM regulation.

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 2019/779. 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.

9.2. You are a Keeper, what are your responsibilities?



The keeper is defined in the article 3(19) of the Safety Directive and in the article 3(21) of the interoperability directive.

Apart from the obligations of registration holder, the Safety or Interoperability Directive does not define any additional explicit responsibility for the keeper. In practical terms, 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 NVR Decision [12]). Based on Article 4(4) of the Safety Directive it can be understood that the 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 authorization for placing on the market;
- ▶ an ECM registered in the NVR;
- ▶ all initial documentation of maintenance of vehicles involved was consigned to ECM uncharged.

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

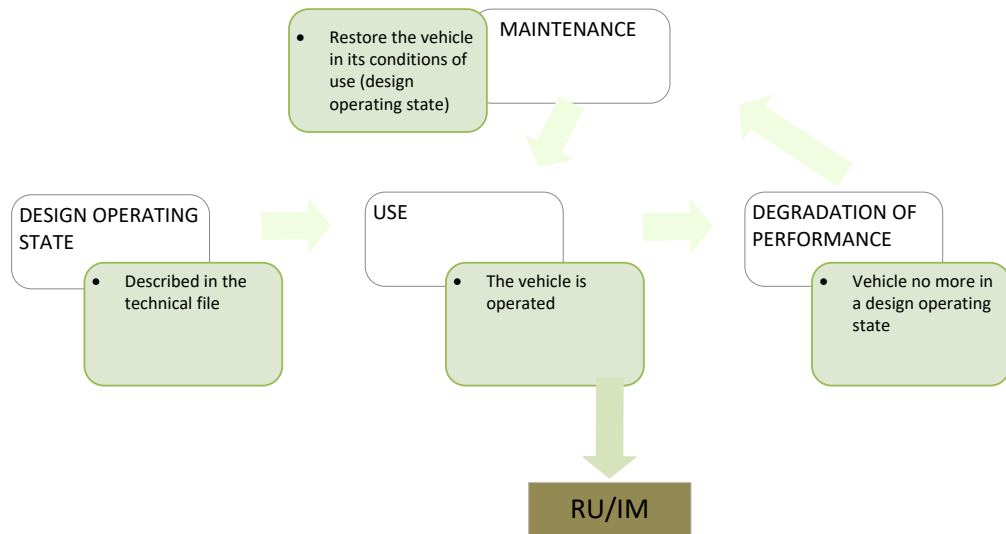
A keeper may be an ECM but it is not mandatory.

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

- ▶ The keeper may select an ECM and contracts with it
- ▶ The keeper may make contractual arrangements with subcontractors (e.g. maintenance workshops), but nevertheless the ECM is responsible to take the decision if the subcontractor is sufficiently competent to be authorised to perform maintenance tasks. To this end an agreement should be achieved between the keeper and the ECM.
- ▶ The keeper acting as registration holder has to ensure that the data it addresses to the registration entity is correct and has to get assurance that the ECM holds a valid certificate 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 NVR 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 NVRs 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 CUV and GCU (General Contract of Use) 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.

9.3. You are a RU/IM, what are your responsibilities?



The Railway Safety Directive states in Article 4(3) that RUs shall be made responsible for safe operation and to fulfill this responsibility, it requires that they establish a SMS.

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

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

This means in particular that:

- ▶ The RU must get assurance, that the maintenance provided by the ECM leads to a safe state of running of the vehicles. This may be achieved by getting assurance that the maintenance system put in place by the ECM ensures the safe state of running. In other words the RU must get assurance that the maintenance system makes the ECM capable 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, 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. Therefore the RUs 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 Regulation (EU) 2018/762, the RU shall ensure the freight wagons and other vehicles in the case of Art. 3(2)b of the ECM Regulation 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 check that the scope of the certificate corresponds to the three kinds of wagons (tank wagons for dangerous goods, other wagons for dangerous goods, or other wagons). Those checks could also be facilitated by contractual arrangements with the keeper or through sectorial arrangements in place, e.g. GCU.

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

The RU is therefore responsible for taking additional control measures described here below. The RU should undertake inspections before the departure of a train or 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 itself (e.g. drivers and/or operational staff), for some the RU may subcontract to other entities like loaders or maintenance workshops. But even by subcontracting some of the measures to other players the RU **keeps the responsibility** according to Article 4(3) of the Safety Directive. The RU must decide how to fulfil its obligations and, if necessary, agree with the other players on rules for procedures that the other players take over for the RU.

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

On the other hand, there could be specific information included in the maintenance file that could be seen as an input by the RU to update the content of pre-departure or 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, in particular a RU/IM, has a justified reason to believe that a particular ECM does not comply with the requirements of Article 14 of Directive (EU) 2016/798 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 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.

9.4. You are a manufacturer, what are your responsibilities?

Apart from the obligations in the role of “applicant”, the Interoperability Directive do 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, 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 Directive (EU) 2016/797;
- ▶ 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 Directive (EU) 2016/797 ;
- ▶ 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 the manufacturer shall exchange of information with the ECM and other actors when they address a request.

9.5. Is there a harmonised framework for the pre departure inspection?

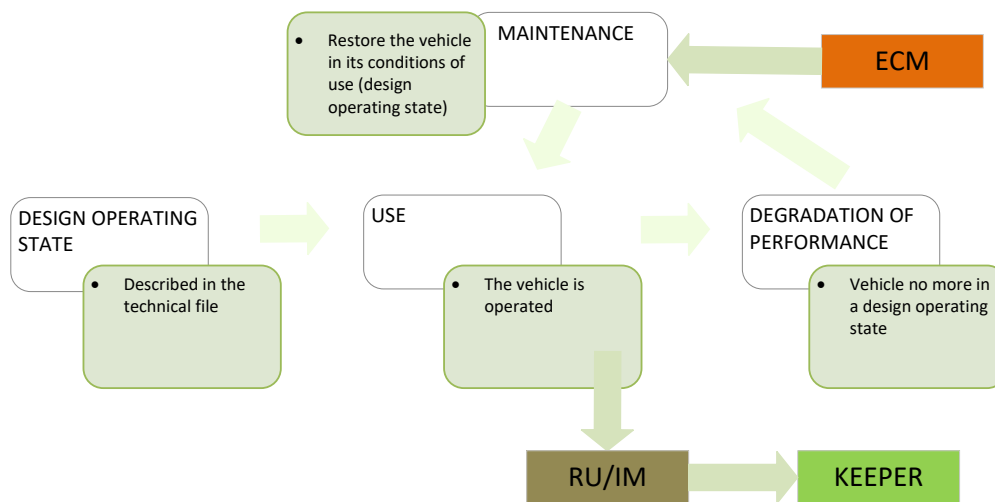
The ECM Regulation doesn't regulate the pre-departure inspections. They are not part of the maintenance activities of the ECM but they are set up by the Railway Undertaking, as part of their SMS, to verify the vehicle is fit for the journey and the operation: the ECM Certification does not liberate the 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 (General Contract of Use) is a harmonised contract between Railway Undertakings and keepers regarding the provision of wagons.

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

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

9.6. You are an ECM, what are your responsibilities?



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

ECM must set up and keep updated the maintenance file (maintenance development part II.4 b and II.5 annex II)

ECM must ensure that the implementation of the first maintenance file is done correctly (maintenance development part II.4 c annex II)

ECM must coordinate all those activities and supervise its subcontractors

Exchange of information - Article 5(1) of ECM regulation

The ECM has to address return to operation issues to RUs/IMs and keepers.

Regarding the vehicles, responsibilities are also stated in the ECM regulation. The ECM should ensure that it continuously meets the relevant requirements set out in Article 14(3) of the safety directive 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 means of the ECM certification, when it is mandatory, or by means of the compliance related to the application of Art. 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.

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

9.7. Application of Article 4(6) - Use of Safe Alert IT tool

Safety Alerts IT tool is a platform, developed by Agency in the frame of Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety. 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://safetyalerts.era.europa.eu/safetyalerts>

SAIT is overseen by Agency. SAIT was developed, is hosted and day to day support is provided by Directorate-General for Informatics of the European Commission (DIGIT).

► 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 [1])

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

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

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

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

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

The certification bodies have to examine and treat claims from the NSA (Article 11 of ECM Regulation), RU or any other contracting party (Article 5(7) of ECM Regulation) and take appropriate action to check if the claim of non-compliance is justified and shall inform the parties involved (including the 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 (Cf. Article 7(8) of ECM Regulation) or if the ECM no longer complies with the certification requirements or any improvement plan (Cf. Article 8(2) of ECM Regulation).

9.9. 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?

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 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 a decision is necessary.

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

- ▶ NSA decision against 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 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, the following matrix shall be applied:

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

- ▶ “1” means mild case, not safety critical (No further information by NSA necessary)
- ▶ “2” means medium case, safety critical (NSA informs ECM certification body, NSA checks necessity of recording in ERA Safety Information System)
- ▶ “3” means severe case, safety critical (NSA informs ECM certification body, NSA records case in ERA Safety Information System (= information to ERA), NSA informs 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.

9.10. 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) and Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II)). These two regulations establish a set of binding rules of private international law which determine which (national) law is applicable.

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

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

Court jurisdiction

Article 6(4) of the ECM Regulation provides that “Member States shall take the measures necessary to ensure that decisions taken by the certification bodies are subject to judicial review”. Article 7(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.

9.11. 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 (UE) 2018/545 [12] 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 Directive (EU) 2016/797.

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 (UE) 2018/545 [12].

Concerning the change in the framework of maintenance of the vehicle, “new authorisation”

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.

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

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. In any case, the ECM should manage it through contractual arrangements with the RU/keeper and taking in consideration:

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

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

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.

9.12. How to understand the article 3(2)b (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 (ECM requirements) according to the methods and times described in paragraph 8.2.2.

They shall demonstrate compliance with Annex II:

- 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. The RU/IM is a regular ECM and treated as such. By a voluntary ECM certification by a competent certification body. The competent 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 Commission Delegated Regulation (EU) 2018/762 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 possible 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 may follow a more flexible approach adapted to the safety certification (or authorisation) process."

If the safety certification body follows the adapted approach, it brings its assessment process for the maintenance activities of the applicant in consistency with its existing processes for safety certification/authorisation (in compliance with the practical arrangements for issuing single safety certificates to railway undertakings, the CSM on safety management system requirements and the CSM for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation).

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:

- ▶ the management system of the RU/IM;
- ▶ the existing competences;
- ▶ the assurance that the RU/IM address seriously the establishment and the updates of the maintenance files.

The principles underpinning this flexibility 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 a risk based approach.

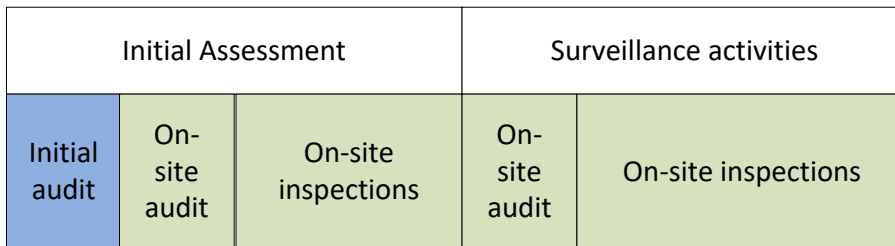
CSM SMS / PA SSC

CSM Supervision

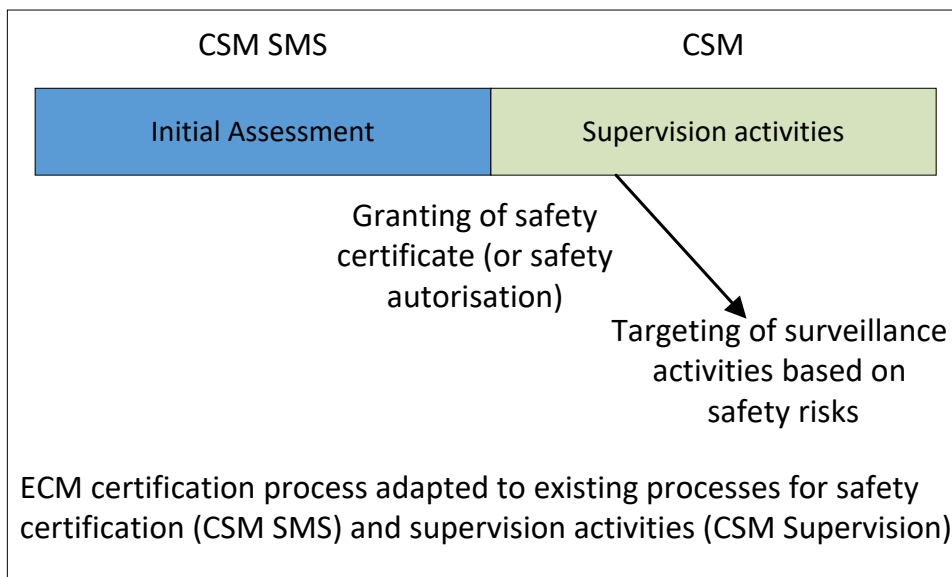


Granting of safety certificate or safety authorisation

ECM Certification Scheme-



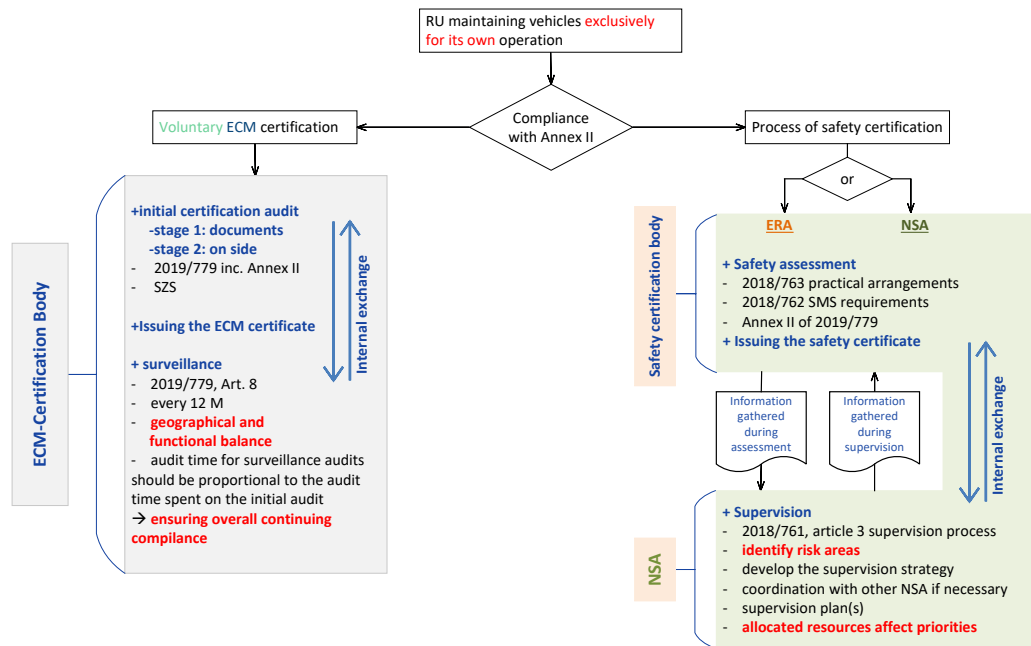
Granting of ECM certificate



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.

The Assessment of RU or IM during the process of safety certification

GUIDANCE ON ECM CERTIFICATION PROCESS



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 the 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 Annex II 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.

According Safety directive, for RUs/IMs there are 2 different phases:

- ▶ safety assessment for the issuing the safety certification / safety authorization; in this phase audits / inspections are possible but not mandatory; the assessment is made by the certification body / NSA for the safety authorization;

- ▶ supervision process after the issuing the safety certification / safety authorization, made by NSAs; in this phase audits and inspections are suitable techniques for assessing that RU / IM continues to duly apply their SMS.”

During supervision activities, after issuing a safety certification / authorization NSAs monitor the SMS effectiveness and the application of CSMs.

Before issuing a safety certificate, the safety certification body has to check,

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

Before issuing the safety authorization, the national safety authority has to check.

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

9.13. What are the steps for the assessment of the ECM requirements during the process of safety certification

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 annex II of ECM regulation
- c) the maintenance report is available

2) Detailed assessment 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 mapping table (see Annex I and Annex II).

If the RU/IM is a newcomer 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 Regulation EU 2019/779 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.

The ECM Regulation guide contains appendix 1 and appendix 2 with an example of a complete mapping table for RU/IM where corresponding ECM Regulation requirements are indicated.

Agency/NSA can also use the ECM Certification Scheme (doc. ERA 1172/003) to check in detail the compliance with ECM Regulation requirements and are enabled 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.

The NSA has develop a supervision strategy according to the specifications of the CSM Supervision.

10. WHAT IS THE MAINTENANCE FILE?

Article 14(2) of the Safety Directive introduces the maintenance file as follow:

“...the entity in charge of maintenance shall:

- (a) ensure that vehicles are maintained in accordance with the **maintenance file** of each vehicle;”*

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

Initial technical documentation

For vehicles compliant with TSIs, the initial development of the maintenance file is based on the technical file (Refer to section 2.4 of annex IV of the Interoperability Directive [3]) and on the APOM. The content of the technical file is described in detail in the relevant TSIs.

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

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

Initial technical documentation including initial maintenance documentation	
Technical file	Additional technical documentation requested contractually including the relevant maintenance documentation

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

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

- ▶ Freight vehicles under the revised TSI wagon: There is the chapter 4.5 of annex to TSI Vehicle [6];
- ▶ Vehicles other than freight wagons under revised TSI Loc&pas: There is the chapters 4.2.12 and 4.5 of annex to TSI Loc&Pas [5];
- ▶ CCS on board subsystem of vehicles other than freight wagons under revised TSI CCS: There is the chapter 4.5 of annex to TSI CCS [7].

For vehicles not compliant with TSIs (like the majority of existing vehicles) or partially compliant with TSIs, the technical file is replaced by all technical and existing maintenance information that accompany the vehicle.

Initial technical documentation including initial maintenance documentation	
Technical and existing maintenance information that accompany the wagon	Additional technical documentation requested contractually including the relevant maintenance documentation

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

Content of the maintenance file

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

The maintenance file is composed of the following four elements:

1 **General Documentation** (extract of chapter 4.5.1 of annex to TSI Wagons [6], chapter 4.2.12.2. of annex to TSI Loc&Pas [5] and chapter 4.5.1 of annex to TSI CCS [7])composed of:

- ▶ Drawings and description of the vehicle 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;
- ▶ the conditions for first line maintenance, i.e. the definition of Line Replaceable Units (LRUs), the definition of approved compatible versions of hardware and software, the procedures for replacing failed LRUs, the conditions for storing LRUs and for repairing failed LRUs.

This documentation may be updated by the ECM.

2 **Maintenance Design Justification File** (extract of chapter 4.5.2 of annex to TSI Wagons [6], chapter 4.2.12.3.1. of annex to TSI Loc&Pas [5] and chapter 4.5.1 of annex to TSI CCS [7]) explains how maintenance activities are defined, designed and updated in order to ensure that the vehicle characteristics will be kept within permissible limits of use during its lifetime and to ensure that the vehicle is in a safe state of running compliant with the planned pattern of operations. It shall give input data to determine the criteria for maintenance activities. It consists of :

- ▶ Precedents, principles and methods used to design the maintenance of the unit;
- ▶ Limits of the normal use of the unit (e.g. km/month, climatic limits, foreseen types of loads etc.) according to the planned pattern of operations;

10. WHAT IS THE MAINTENANCE FILE?

- ▶ Relevant data used to design the maintenance and origin of these data (e.g. return of experience);
- ▶ Tests, investigations and calculations carried out to design the maintenance;
- ▶ (first/initial) maintenance file (mostly created by the manufacturer): all safety verifications and risk analysis done for defining maintenance activities, intervals etc. shall be covered in the file, because it shall be transparent for the ECM. This is necessary for optimizations of the file by the ECM later on. This is also relevant in case of changing ECM;
- ▶ all maintenance requirements and procedures (including health monitoring, diagnosis of events, test methods and tools and also the required professional competence) necessary for achieving essential requirements and values quoted in the mandatory requirements of TSI CCS throughout the equipment life-cycle (transport and storage before installation, normal operation, failures, repair work, checking and maintenance, decommissioning, etc.).

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

3 **Maintenance Description File** (extract of chapter 4.5.3 of annex to TSI Wagons [6], chapter 4.2.12.3.2. of annex to TSI Loc&Pas [5] and chapter 4.5.1 of annex to TSI CCS [7]) describing how maintenance activities have to be conducted. Maintenance activities include, among others: inspections, monitoring, tests, measurements, replacements, adjustments and repairs. These activities are split into :

- ▶ Preventive maintenance; scheduled and controlled;
- ▶ Corrective maintenance;
- ▶ Light and heavy maintenance

Basically the maintenance description file should contain at least:

- ▶ Component hierarchy and functional description. The hierarchy sets up the boundaries of the vehicle by listing all the items belonging to the product structure of that vehicle and using an appropriate number of discrete levels. The lowest item of the hierarchy shall be a replaceable component;
- ▶ Parts list: the parts list shall contain the technical and functional descriptions of the spare parts (replaceable units) and the references from the spare part provider and manufacturer, in order to allow identification and procurement of the correct spare parts. The list shall include all parts specified for changing on condition, or which may require replacement following electrical or mechanical malfunction, or which will foreseeable require replacement after accidental damage. The spare parts list shall also cover component and software modification levels. Interoperability constituent shall be indicated and referenced to their corresponding declaration of conformity;
- ▶ The limit values for components which are not to be exceeded in service are to be stated; the possibility of specifying operational restrictions in degraded mode (limit value reached) is permitted;
- ▶ The checks to be carried out when maintaining equipment other than Control-Command and Signaling equipment and which influences the Control-Command and Signaling Subsystems (e.g. changing the wheel diameter);

- ▶ The checks to be carried out if CCS equipment is subject to exceptional stress (e.g. adverse environmental conditions or abnormal shocks);
- ▶ List of reference to the European legal obligations to which components or subsystems are subject.
- ▶ A maintenance plan i.e. the structured set of tasks to perform the maintenance including the activities, procedures and means. The description of this set of tasks includes:
 - Disassembly/assembly instructions drawings necessary for correct assembly/disassembly of replaceable parts;
 - Maintenance criteria;
 - Checks and inspections in particular of safety relevant parts; these include visual inspection and non-destructive tests (where appropriate e.g. to detect deficiencies that may impair safety);
 - Welding procedures;
 - Tools and materials required to undertake the task;
 - Consumables required to undertake the task;
 - Personal protective safety provision and equipment;
 - Necessary tests and procedures to be undertaken before release to service and return to operation.
- 4 **Configuration File** for each vehicle (parts list and bill of material) to enable (in particular but not only) traceability during maintenance activities all along the lifecycle. The configuration files contain the records on maintenance performed. Traceability of maintenance records depends on their impact on safety and has to be compliant with applicable legislation.

11. EXCHANGE OF INFORMATION BETWEEN RAILWAY ACTORS

11.1. 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 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 Directive (EU) 2016/797, shall inform without delay the registration entity referred to in Article 4(1) of Commission Decision 2007/756/EC (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.*

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:

- ▶ *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. Railfleet). 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.

11.2. 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>

12. MANAGEMENT OF CHANGES

12.1. I would like to change the ECM of my fleet, how to proceed?

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

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

Consequently, ERA recommends strongly taking in account these details and issues when negotiating and setting up contractual arrangements between all the involved parts, above all with contracts between the ECM and the client.

13. HOW TO MANAGE SAFETY CRITICAL COMPONENTS?

To deal with Safety Critical Components, a guidance has been prepared by WG48 of CEN/TC256.

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

In addition, the document SCCs guide 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 guide is neither to produce an applicable list of SCC components nor to provide for examples of SCC.

This SCCs guide is applicable to vehicles only. The definition of “vehicle” is as in Art. 3(21) Directive 2016/798 (Safety Directive).

13.1. 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 SCCs guide collects in a table a list of accidents related to the definition of SCCs applicable for vehicle’s components.

13.2. For which type of vehicle?

To make it clear the applicability of SCC requirements in the field of railway vehicles, it is necessary to distinguish between 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 authorizing entity a vehicle authorisation for placing on the market following the new legislation (complying with Regulation 2018/545)

The SCCs requirements for new vehicles also apply to existing vehicles that have a vehicle authorisation for placing in service following engineering change/renewal/upgrading/refurbishment of existing vehicles, which already have a vehicle authorisation for placing on the market, only for the parts of the vehicle related to engineering change/renewal/upgrading/refurbishment.

In that cases, the entity managing the change (holder of the vehicle type authorisation) plays the same role as the Manufacturer.

In addition, the applicant for the vehicle type authorisation is responsible for compiling the technical file that is to accompany the 'EC' declaration of verification to be submitted for the application.

Usually, the detailed content of the different documents of the technical file is prepared by the Manufacturer of the vehicle, where the Manufacturer may play the role of "applicant" itself.

The maintenance documentation is a part of the technical file and it is given by the applicant (directly or via the Keeper) to the ECM to make it able to manage and implement the maintenance of the vehicle.

The ECM is responsible for 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) 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.

13.3. What is the SCC management process?

The identification and management of SCCs starts as part of the design phase under the responsibility of the vehicle Designer/Manufacturer from the concept phase and, when the vehicle is in operation/maintenance phases, through the collaboration and exchange of information with ECM/RU/Keeper (references on the life-cycle phases applicable to a vehicle can be found in EN50126-1-2017).

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.

13. HOW TO MANAGE SAFETY CRITICAL COMPONENTS?

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 Table 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-critical 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 required 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) 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).

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:

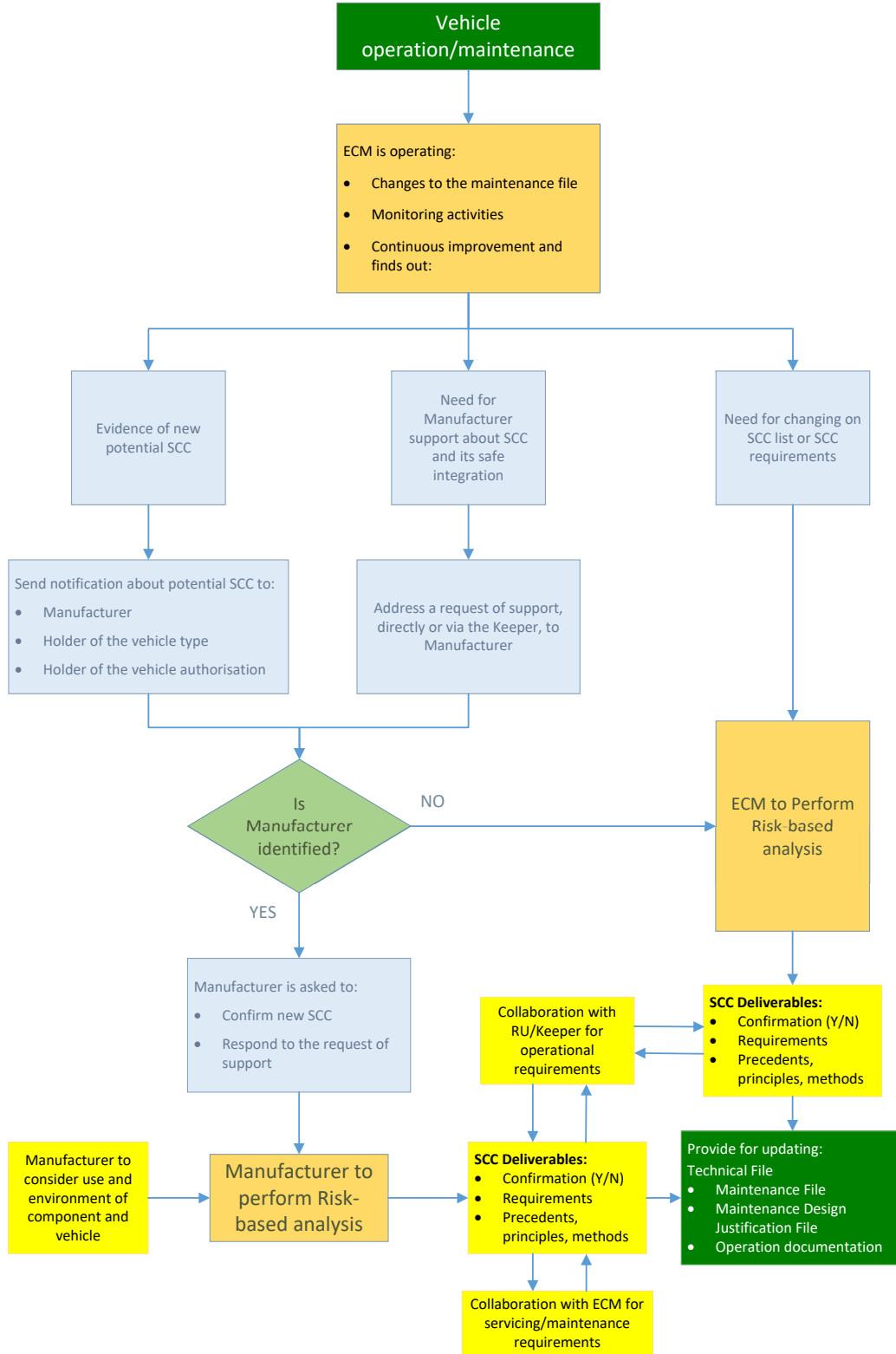
- ▶ become aware of evidence that a new SCC is identified as such and notifies it to the Manufacturer for confirmation
- ▶ change the SCCs list provided by the Manufacturer or their specific requirements
- ▶ make a request to the Manufacturer for technical and engineering support on SCCs and their safe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

ID.	ECM Regulation – Annex II, referenced activities	Detail of activities
1	<p><i>Ref. to in:</i></p> <ul style="list-style-type: none"> ▶ 2.2, 2.3 part I, ▶ 2, 4, 5, 6 part II: <p><i>when managing changes to the maintenance file of the vehicle as a consequence of:</i></p>	<p>Non-exhaustive list of examples:</p> <ul style="list-style-type: none"> ▶ technical/operational change ▶ renewal/upgrading/refurbishment ▶ change of: <ul style="list-style-type: none"> ○ mission profile ○ Maintenance plan ○ authorization of the vehicle ○ vehicle's configuration ○ competence of personnel ▶ legislation's requirement
2	<p><i>Ref. to in:</i></p> <ul style="list-style-type: none"> ▶ 3, part I: <p><i>as an output of monitoring activities on:</i></p>	<ul style="list-style-type: none"> ▶ 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	<p><i>Ref. to in:</i></p> <ul style="list-style-type: none"> ▶ 4, part I: <p><i>as an output of continuous improvement on:</i></p>	<ul style="list-style-type: none"> ▶ collection and analysis of data from: <ul style="list-style-type: none"> ○ 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

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

13. HOW TO MANAGE SAFETY CRITICAL COMPONENTS?

The following flow diagrams show the Manufacturer's and the ECM's perspective of the SCCs management process above described.



13.4. What are the possible methods for the identification of SCC?

A way 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 steps to be carried out:

- ▶ Step 1 – Identification of vehicle's components
- ▶ Step 2 - Analysis and identification of component's criticality

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

Another 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.

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

More explanations on these methods are in the "Railway Applications - Vehicle Maintenance - Guide for identification and management of Safety Critical Components for railway vehicles" drafted by the WG48 of CEN/CENELEC. The document is referenced as FprCEN/TR 17696, and the publication is forecasted for the end of 2021.

(The link when it will be available could be add in this part)

14. COMPETENCES OF MAINTENANCE STAFF

This part is focused on the competence management of maintenance staff as previewed in the Annex II, Section I, Point 6 of Regulation (EU) n. 2019/779.

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.

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

6.1. The organisation must set up a competence management system providing for:

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

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

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

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 shall include 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]):

- ▶ For on-board software, the designer/manufacturer shall specify, for any on-board software modification, all maintenance requirements and procedures (including health monitoring, diagnosis of events, test methods and tools and also the required professional competence) necessary for achieving essential requirements and values quoted in the mandatory requirements of this TSI throughout the life-cycle (Installation, normal operation, failures, repair work, checking and maintenance, decommissioning, etc.);
- ▶ The manufacturers of the equipment and of the subsystem shall provide information sufficient to define the professional competences required for the installation, final inspection and maintenance of the Control-Command and Signalling Subsystems.
- ▶ National rules if existing about professional competences required for the maintenance issued exclusively in the national territory.
- ▶ The risks manufacturers has indicated in the technical file for health and safety that arise from using and maintaining their equipment and subsystems.

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

Below some recommendations and examples as evidences for building an efficient competence management system and to respect the above requirements of ECM Regulation.

The following rules could be included in the maintenance system as they are considered as good practice.

If the ECM or Maintenance workshop can demonstrate through experience and risk assessment that it has more effective maintenance rules than the here-below recommended good practices, it should better introduce these in its maintenance system.

The objective of this part is to provide a guideline 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 ECM-F4."

Qualification of acquired competence and skills is a mixture of:

- ▶ Work experience
- ▶ Basic education (elementary school, university, ...)
- ▶ Additional training (activity-related)

14. COMPETENCES OF MAINTENANCE STAFF

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

Activities	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													
ECM-F2 manager													
ECM-F3 manager													
ECM-F4 manager													
Fleet engineer													
Component engineer													
Workers / inspectors of safety-critical components													

14.2. 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).

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

- ▶ basic knowledge of vehicle's operation and maintenance,
- ▶ 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, 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),
- ▶ 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, 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:

14. COMPETENCES OF MAINTENANCE STAFF

- ▶ 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, 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), where required by law or NSA or established by ECM itself:

- (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.

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 testing" 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:

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

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

In absence of national rules, each ECM or Maintenance workshop should define a specific procedure for the qualification of NDT staff regarding the application of the tests in the industrial sector “railway maintenance” issued by the relevant third part Certification Body.

JOINING TECHNIQUES (INCLUDING WELDING AND BONDING)

Concerning the activities joining techniques in the case of “welding processes”, at least evidence of compliance with the relevant standard is required:

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

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 and EN ISO 14731 is required.

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

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

In absence of national rules, each ECM or Maintenance workshop should define a specific procedure for the certification of staff and maintenance workshop issued by the relevant third part Certification Body.

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

If the ECM or Maintenance workshop can demonstrate through experience and risk assessment that it has more effective maintenance rules than the here-below recommended good practices, it should better introduce these in its maintenance system.

15. WAGONS FOR DANGEROUS GOODS

You are an ECM dealing with wagons transporting dangerous goods; some requirements shall 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 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 this substances
- ▶ Occupational health and safety processes with regard to Dangerous Goods

16. ECM ANNUAL REPORT

Each entity in charge of maintenance shall submit an annual report of its activities.

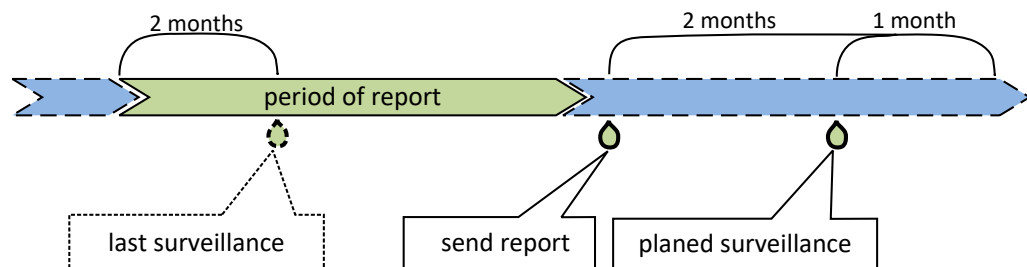
The requirements for this report are set out in Annex V of the ECM-Regulation.

If compliance with Annex II is demonstrated through an ECM certification, 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.

If compliance with Annex II is demonstrated through the process of safety certification or authorisation, the report shall be submitted to the safety certification body in case of application for granting or renewal of a safety certificate and to the NSA that does the surveillance.

The entity in charge of maintenance shall issue a report, which covers usually a period of 12 months, starting 2 months before the last surveillance and ending 2 months before the next planned surveillance. 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 1 month before the next planned surveillance audit.



In case of a requested renewal or amendment of an issued certificate the application should cover a current maintenance report.

Annex I Mapping Table IM

Definition	1.2. For the purpose of this Annex the following definitions are applied: (a) 'character' in relation to railway operations carried out by infrastructure managers means the characterisation of operation by its scope, including infrastructure design and construction, infrastructure maintenance, traffic planning, traffic management and control, and by the use of the railway infrastructure, including conventional and/or high speed lines, transport of passengers and/or goods; (b) 'extent' in relation to railway operations carried out by infrastructure managers means the extent characterised by the length of railway track and the estimated size of the infrastructure manager in terms of number of employees working in the railway sector.
Definition	1.2. For the purpose of this Annex the following definitions are applied:
NOTE(1)	(1) Point 2.1. of the Appendix to Annex I to Directive (EU) 2016/798.
NOTE(2)	(2) Point 2.2. of the Appendix to Annex I to Directive (EU) 2016/798.

Regulation EU 2018/762 (CSM on SMS) - Annex II - SMS requirements related to Infrastructure Managers				Reg EU 2019/779 - ECM Regulation	IM SMS documentation references
No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement
1	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(a) describe the character and extent of its operations;	Articles and Annex II - corresponding requirements
2	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(b) identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself, or by contractors, partners or suppliers under its control;	1.1.(a) (partially covered) 1.2 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
3	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(c) identify interested parties (e.g. regulatory bodies, authorities, railway undertakings, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;		I.2.1 (partially covered), I.9.1 (partially covered)
4	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);		I.1.(b) and (f), I.9.3
5	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(e) ensure that the requirements referred to in point (d) are taken into account in developing, implementing and maintaining the safety management system;		I.1.(d)
6	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(f) describe the scope of the safety management system, indicating which part of the business is included or not in its scope and taking into account the requirements referred to in point (d).		I.1.(a) (partially covered), I.9.1 (partially covered)
7	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(a) taking overall accountability and responsibility for safety;		I.5.5 and I.5 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
8	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(b) ensuring commitment to safety by management at different levels within the organisation through their activities and in their relationships with staff and contractors;		1.1.(g) and (h) (partially covered), 1.9.3
9	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(c) ensuring that the safety policy and safety objectives are established, understood and are compatible with the strategic direction of the organisation;		1.1(a) and (b), 1.9.3
10	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(d) ensuring the integration of the safety management system requirements into the organisation's business processes;		1.1(d)
11	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(e) ensuring that the resources needed for the safety management system are available;		1.1(e)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
12	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(f) ensuring that the safety management system is effective in controlling the safety risks posed by the organisation;		I.1.(c) (partially covered)
13	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(g) encouraging staff to support compliance with the safety management system requirements;		I.1.(g) and (h) (partially covered)
14	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(h) promoting continual improvement of the safety management system;		I.4 (partially covered)
15	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(i) ensuring that safety is considered when identifying and managing the organisation's business risks and explaining how conflict between safety and other business goals will be recognised and resolved;		I.2.2 and I.2.3 (partially covered), I.1.(f), I.9.1

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
16	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(j) promoting a positive safety culture.		
17	2. LEADERSHIP	2.2. Safety policy	2.2.1. A document describing the organisation's safety policy is established by the top management and is:	(a) appropriate to the organisation's character and extent of railway operations;	I.1.(a)	
18	2. LEADERSHIP	2.2. Safety policy	2.2.1. A document describing the organisation's safety policy is established by the top management and is:	(b) approved by the organisation's chief executive (or a representative(s) of the top management);	I.1.(a)	
19	2. LEADERSHIP	2.2. Safety policy	2.2.1. A document describing the organisation's safety policy is established by the top management and is:	(c) actively implemented, communicated and made available to all staff.	I.1.(a)	
20	2. LEADERSHIP	2.2. Safety policy	2.2.2. The safety policy shall:	(a) include a commitment to conform with all legal and other requirements related to safety;	I.1.(b) (partially covered) and I.1.(a) (in general)	
21	2. LEADERSHIP	2.2. Safety policy	2.2.2. The safety policy shall:	(b) provide a framework for setting safety objectives and evaluating the organisation's safety performance against these objectives;	I.1.(b) and (c), and I.1.(a) (in general), I.9.3	

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
22	2. LEADERSHIP	2.2. Safety policy	2.2.2. The safety policy shall:	(c) include a commitment to control safety risks which arise both from its own activities and those caused by others;		I.1.(f), and I.1.(a) (in general), I.9.4 (in general), I.9.5 (in general)
23	2. LEADERSHIP	2.2. Safety policy	2.2.2. The safety policy shall:	(d) include a commitment to continual improvement of the safety management system;		I.4 and I.1.(a) (in general)
24	2. LEADERSHIP	2.2. Safety policy	2.2.2. The safety policy shall:	(e) be maintained in accordance with the business strategy and the evaluation of the safety performance of the organisation.		I.1.(c) and I.1.(a) (in general)
25	2. LEADERSHIP	2.3. Organisational roles, responsibilities, accountabilities and authorities	2.3.1. The responsibilities, accountabilities and authorities of staff having a role that affects safety (including management and other staff involved in safety-related tasks) shall be defined at all levels within the organisation, documented, assigned and communicated to them.			I.5 (in general)
26	2. LEADERSHIP	2.3. Organisational roles, responsibilities, accountabilities and authorities	2.3.2. The organisation shall ensure that staff with delegated responsibilities for safety-related tasks shall have the authority, competence and appropriate resources to perform their tasks without being adversely affected by the activities of other business functions.			I.5 (in general), I.6 (in general), II.6 (in general), III.1, III.7, IV.8

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
27	2. LEADERSHIP	2.3. Organisational roles, responsibilities, accountabilities and authorities	2.3.3. Delegation of responsibility for safety-related tasks shall be documented and communicated to the relevant staff, accepted and understood.			1.5 (in general)
28	2. LEADERSHIP	2.3. Organisational roles, responsibilities, accountabilities and authorities	2.3.4. The organisation shall describe the allocation of roles referred to in paragraph 2.3.1. to business functions within and where relevant, outside the organisation (see 5.3. Contractors, partners and suppliers).			1.5 (in general), 1.9.4 and 1.9.6 (in general)
29	2. LEADERSHIP	2.4. Consultation of staff and other parties	2.4.1. Staff, their representatives and external interested parties, as appropriate and where relevant, shall be consulted in developing, maintaining and improving the safety management system in the relevant parts they are responsible for, including the safety aspects of operational procedures.			1.1.(h)
30	2. LEADERSHIP	2.4. Consultation of staff and other parties	2.4.2. The organisation shall facilitate the consultation of staff by providing the methods and means for involving staff, recording staff's opinion and providing feedback on staff's opinion.			1.5.4 and 1.1.(h)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
31	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(a) identify and analyse all operational, organisational and technical risks relevant to the character and extent of operations carried out by the organisation. Such risks shall include those arising from human and organisational factors such as workload, job design, fatigue or suitability of procedures, and the activities of other interested parties (see 1. Context of the organisation);	I.2.2, I.2.3, I.9.1 (in general)
32	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(b) evaluate the risks referred to in point (a) by applying appropriate risk assessment methods;	I.2.2
33	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(c) develop and put in place safety measures, with identification of associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);	I.3 (in general)
34	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(d) develop a system to monitor the effectiveness of safety measures (see 6.1. Monitoring);	I.3 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
35	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(e) recognise the need to collaborate with other interested parties (such as railway undertakings, infrastructure managers, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on shared risks and the putting in place of adequate safety measures;	1.2.1, 1.7 (in general)
36	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(f) communicate risks to staff and involved external parties (see 4.4. Information and communication).	1.1.(h) partially covered), 1.9.4 (partially covered)
37	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.2. When assessing risk, an organisation shall take into account the need to determine, provide and sustain a safe working environment which conforms to applicable legislation, in particular Directive 89/391/EEC.		1.2.3
38	3. PLANNING	3.1. Actions to address risks	3.1.2. Planning for change	3.1.2.1. The organisation shall identify potential safety risks and appropriate safety measures (see 3.1.1. Risk assessment) before the implementation of a change (see 5.4. Management of change) in accordance with the risk management process set out in Regulation (EU) No 402/2013, including consideration of the safety risks from the change process itself.		1.2.2

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
39	3. PLANNING	3.2. Safety objectives and planning	3.2.1. The organisation shall establish safety objectives for relevant functions at relevant levels to maintain and, where reasonably practicable, improve its safety performance.			1.1.(b) and (c)
40	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(a) be consistent with the safety policy and the organisation's strategic objectives (where applicable);		1.1.(b)
41	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(b) be linked to the priority risks that influence the safety performance of the organisation;		1.1.(b) and (c)
42	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(c) be measurable;		
43	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(d) take into account applicable legal and other requirements;		1.1.(b)
44	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(e) be reviewed as regards their achievements and revised as appropriate;		
45	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(f) be communicated.		
46	3. PLANNING	3.2. Safety objectives and planning	3.2.3. The organisation shall have plan(s) to describe how it will achieve its safety objectives.			1.1.(d)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
47	3. PLANNING	3.2. Safety objectives and planning	3.2.4. The organisation shall describe the strategy and plan(s) used to monitor the achievement of the safety objectives (see 6.1. Monitoring).			I.3 (in general)
48	4. SUPPORT	4.1. Resources	4.1.1. The organisation shall provide the resources, including competent staff and effective and useable equipment, needed for the establishment, implementation, maintenance and continual improvement of the safety management system.			I.1.(e), II.3, IV.3, IV.4, IV.5
49	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(a) identification of the competencies (including knowledge, skills, non-technical behaviours and attitudes) required for safety-related tasks;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
50	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(b) selection principles (basic educational level, psychological and physical fitness required);		I.6 (in general), II.6 (in general), III.1, III.7, IV.8

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
51	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(c) initial training, experience and qualification;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
52	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(d) ongoing training and periodic update of existing competencies;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
53	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(e) periodic assessment of competence and checks of psychological and physical fitness to ensure that qualifications and skills are maintained over time;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
54	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(f) specific training in relevant parts of the safety management system in order to deliver their safety-related tasks.		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
55	4. SUPPORT	4.2. Competence	4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:	(a) the training programme is delivered according to the identified competency requirements and individual needs of the staff;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
56	4. SUPPORT	4.2. Competence	4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:	(b) where applicable, the training ensures that staff can operate under all operating conditions (normal, degraded and emergency);		I.6 (in general), II.6 (in general), III.1, III.7, IV.8

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
57	4. SUPPORT	4.2. Competence	4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:	(c) the duration of the training and the frequency of the refresher training are appropriate for the training objectives;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
58	4. SUPPORT	4.2. Competence	4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:	(d) records are kept for all staff (see 4.5.3. Control of documented information);		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
59	4. SUPPORT	4.2. Competence	4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:	(e) the training programme is regularly reviewed and audited (see 6.2. Internal auditing) and changes made when necessary (see 5.4. Management of change).		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
60	4. SUPPORT	4.2. Competence	4.2.3. Back to work arrangements shall be in place for staff following accidents/incidents or long absences from work, including providing additional training where such a need is identified.			I.6 (in general), II.6 (in general), III.1, III.7, IV.8

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
61	4. SUPPORT	4.3. Awareness	4.3.1. Top management shall ensure that they and their staff having a role that affects safety are aware of the relevance, importance and consequences of their activities and how they contribute to the correct application and the effectiveness of the safety management system, including the achievement of safety objectives (see 3.2. Safety objectives and planning).			1.1.(g) (partially covered)
62	4. SUPPORT	4.4. Information and communication	4.4.1. The organisation shall define adequate communication channels to ensure that safety-related information is exchanged among the different levels of the organisation and with external interested parties including contractors, partners and suppliers.			1.7 (in general), I.9.6 (partially covered), II.5 (in general), III.9, IV.9, Art. 5(1), Art. 5(3)
63	4. SUPPORT	4.4. Information and communication	4.4.2. To ensure that safety-related information reaches those making judgements and decisions, the organisation shall manage the identification, receipt, processing, generation and dissemination of safety-related information.			1.7 (in general), I.9.6 (partially covered), II.5 (in general), III.9, IV.9, Art. 4(2), Art. 4(3), Art. 4(6)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
64	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(a) relevant, complete and understandable for the intended users; (b) valid;		1.7 (in general)
65	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(c) accurate;		1.7 (in general)
66	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(d) consistent;		1.7 (in general)
67	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(e) controlled (see 4.5.3. Control of documented information);		1.7 (in general)
68	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(f) communicated before it takes effect;		1.7 (in general)
69	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(g) received and understood.		1.7 (in general)
70	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:			
71	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(a) the identification and description of the processes and activities related to safety of rail operations, including safety-related tasks and associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);	1.8 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
72	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(b) the interaction of these processes;	1.8 (in general)
73	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(c) the procedures or other documents describing how these processes are implemented;	1.8 (in general)
74	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(d) the identification of contractors, partners and suppliers with a description of the type and extent of services delivered;	1.8 (in general), 1.9 (in general)
75	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(e) the identification of contractual arrangements and other business agreements, concluded between the organisation and other parties identified under (d), necessary to control the safety risks of the organisation and those related to the use of contractors;	1.8 (in general), 1.9 (in general)
76	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(f) reference to documented information required by this Regulation.	1.8 (in general)
77	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(a) a synthesis of the decisions on the level of significance of the safety-related changes, including an overview of significant changes, in accordance with Article 18(1) of Regulation (EU) No 402/2013;	Annex V (ECM Maintenance Report) (in general), Art. 8(5)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
78	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(b) the organisation's safety objectives for the following year(s) and how serious risks for safety influence the setting of these safety objectives;	Annex V (ECM Maintenance Report) (in general), Art. 8(5)
79	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(c) the results of internal accident/incident investigation (see 7.1. Learning from accidents and incidents) and other monitoring activities (see 6.1. Monitoring, 6.2. Internal auditing and 6.3. Management review), in accordance with Article 5(1) of Regulation (EU) No 1078/2012;	Annex V (ECM Maintenance Report) (in general), Art. 8(5)
80	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(d) details of progress on addressing outstanding recommendations from the national investigation bodies (see 7.1. Learning from accidents and incidents);	Annex V (ECM Maintenance Report) (in general), Art. 8(5)
81	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(e) the organisation's safety indicators set out to evaluate the organisation's safety performance (see 6.1. Monitoring);	Annex V (ECM Maintenance Report) (in general), Art. 8(5)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
82	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(f) where applicable, the conclusions of the annual report of the safety advisor, as referred to in RID (1), on the activities of the organisation relating to the transport of dangerous goods (2).	Annex V (ECM Maintenance Report) (in general), Art. 8(5)
83	4. SUPPORT	4.5. Documented information	4.5.2. Creating and updating	4.5.2.1. The organisation shall ensure that when creating and updating documented information related to the safety management system adequate formats and media are used.		1.8 (in general)
84	4. SUPPORT	4.5. Documented information	4.5.3. Control of documented information	4.5.3.1. The organisation shall control documented information related to the safety management system, in particular its storage, distribution and the control of changes, to ensure its availability, suitability and protection where appropriate.		1.8 (in general), 1.9 (in general), II.7, III.10, IV.10
85	4. SUPPORT	4.6. Integration of human and organisational factors	4.6.1. The organisation shall demonstrate a systematic approach to integrating human and organisational factors within the safety management system. This approach shall:	(a) include the development of a strategy and the use of expertise and recognised methods from the field of human and organisational factors;		

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
86	4. SUPPORT	4.6. Integration of human and organisational factors	4.6.1. The organisation shall demonstrate a systematic approach to integrating human and organisational factors within the safety management system. This approach shall:	(b) address risks associated with the design and use of equipment, tasks, working conditions and organisational arrangements, taking into account human capabilities as well as limitations, and the influences on human performance.		I.2.3 (in general), I.3 (in general), IV.3, IV.4, IV.5
87	5. OPERATION	5.1. Operational planning and control	5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:	(a) risk acceptance criteria and safety measures are applied (see 3.1.1. Risk assessment);		I.3 and I.9.6 (in general)
88	5. OPERATION	5.1. Operational planning and control	5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:	(b) plan(s) to achieve the safety objectives are delivered (see 3.2. Safety objectives and planning);		I.1.(d), I.3, I.9.3
89	5. OPERATION	5.1. Operational planning and control	5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:	(c) information is collected to measure the correct application and effectiveness of the operational arrangements (see 6.1. Monitoring).		I.3 (in general), I.9.6 (in general), I.9.5 (in general), I.7 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
90	5. OPERATION	5.1. Operational planning and control	5.1.2. The organisation shall ensure that its operational arrangements conform to the safety-related requirements of applicable Technical Specifications for Interoperability and relevant national rules and any other relevant requirements (see 1. Context of the organisation).			II.2, Art. 4(1)
91	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(a) identification of the safe boundaries of transport for traffic planning and control based on the design characteristics of the infrastructure;		
92	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(b) traffic planning, including timetable and train path allocation;		
93	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(c) real-time traffic management in normal mode and in degraded modes with the application of traffic restrictions of use and the management of traffic disruptions;		

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
94	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(d) setting of conditions for running exceptional consignments.		
95	5. OPERATION	5.1. Operational planning and control	5.1.4. To control the allocation of responsibilities where relevant for the safety of operational activities, the organisation shall identify responsibilities for planning and operating the rail network and define how relevant tasks affecting the safe delivery of all services are allocated to competent staff within the organisation (see 2.3. Organisational roles, responsibilities, accountabilities and authorities) and to other external qualified parties when appropriate (see 5.3. Contractors, partners and suppliers).			1.9.1 and 1.9.2 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
96	5. OPERATION	5.1. Operational planning and control	5.1.5. To control information and communication where relevant for the safety of operational activities (see 4.4. Information and communication), relevant staff (e.g. signallers) shall be informed about specific routing requirements for trains and movements of vehicles including relevant changes which may result in a hazard, temporary or permanent operational restrictions (e.g. due to track maintenance) and conditions for exceptional consignments where applicable.			I.7, II.5, III.6, III.9, III.10, IV.9, Art. 4(2), Art. 4(6)
97	5. OPERATION	5.1. Operational planning and control	5.1.6. To control competence where relevant for the safety of operational activities (see 4.2. Competence), the organisation shall ensure, in accordance with applicable legislation (see 1. Context of the organisation), for its staff:	(a) compliance with their training and work instructions and corrective actions are taken where required;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
98	5. OPERATION	5.1. Operational planning and control	5.1.6. To control competence where relevant for the safety of operational activities (see 4.2. Competence), the organisation shall ensure, in accordance with applicable legislation (see 1. Context of the organisation), for its staff:	(b) specific training in case of anticipated changes affecting the running of operations or their task assignment;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
99	5. OPERATION	5.1. Operational planning and control	5.1.6. To control competence where relevant for the safety of operational activities (see 4.2. Competence), the organisation shall ensure, in accordance with applicable legislation (see 1. Context of the organisation), for its staff:	(c) adoption of adequate measures following accidents and incidents.		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
100	5. OPERATION	5.2. Asset management	5.2.1. The organisation shall manage the safety risks associated with physical assets throughout their lifecycle (see 3.1.1. Risk assessment), from design to disposal, and fulfil the human factors requirements in all phases of the life cycle.			I.2 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
101	5. OPERATION	5.2. Asset management	5.2.2. The organisation shall:	(a) ensure that the assets are used for the purpose intended while maintaining their safe operational state and their expected level of performance;		
102	5. OPERATION	5.2. Asset management	5.2.2. The organisation shall:	(b) manage the assets in normal and degraded operations;		
103	5. OPERATION	5.2. Asset management	5.2.2. The organisation shall:	(c) detect as soon as reasonably practicable instances of non-compliance with operating requirements before or during the operation of the asset, including the application of restrictions of use as appropriate to ensure a safe operational state of the asset (see 6.1. Monitoring).		III.6, III.9, III.10
104	5. OPERATION	5.2. Asset management	5.2.3. The organisation shall ensure that its asset management arrangements, where applicable, conform to all essential requirements as set out in the relevant Technical Specifications for Interoperability and any other relevant requirements (see 1. Context of the organisation).			II.2 (in general), Art. 4(1)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
105	5. OPERATION	5.2. Asset management	5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(a) the identification of the need for maintenance to keep the infrastructure in a safe operational state, based on the planned and real use of the infrastructure and its design characteristics;	III.4	III.4
106	5. OPERATION	5.2. Asset management	5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(b) the management of the removal of the asset from operation for maintenance, when defects have been identified or when asset condition degrades outside the limits of a safe operational state as referred to in point (a);		III.4, Art. 4(2), Art. 4(4)
107	5. OPERATION	5.2. Asset management	5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(c) the management of the return to operation of the asset with eventual restrictions of use after maintenance has been delivered to ensure it is in a safe operational state;		III.4
108	5. OPERATION	5.2. Asset management	5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(d) the management of monitoring and measurement equipment to ensure that it is fit for its intended purpose.		II.3 (in general), III.6, III.9, III.10, IV.3, IV.4, IV.5

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
109	5. OPERATION	5.2. Asset management	5.2.5. To control information and communication where relevant for the safe management of assets (see 4.4. Information and communication), the organisation shall take into account:	(a) the exchange of relevant information within the organisation or with external entities responsible for maintenance (see 5.3. Contractors, partners and suppliers), in particular on safety-related malfunctions, accidents, incidents as well as on eventual restrictions of use of the asset;		1.7 (in general), 1.9.6, II.5, III.6, III.9, III.10, IV.9, Art. 4(2), Art. 4(6), Art. 5(1), Art. 5(2), Art. 5(3)
110	5. OPERATION	5.2. Asset management	5.2.5. To control information and communication where relevant for the safe management of assets (see 4.4. Information and communication), the organisation shall take into account:	(b) the traceability of all necessary information including the information related to point (a) (see 4.4. Information and communication and 4.5.3. Control of documented information);		1.7 (in general), 1.8, 1.9.6, II.5 (in general), II.7, III.4 (in general), III.9, IV.9, Art. 4(5)b
111	5. OPERATION	5.2. Asset management	5.2.5. To control information and communication where relevant for the safe management of assets (see 4.4. Information and communication), the organisation shall take into account:	(c) the establishment and maintenance of records including the management of changes affecting the safety of assets (see 5.4. Management of change).		1.7, 1.8, II.2 (in general), II.5 (in general), II.7, III.10, IV.10, Art. 4(5)b
112	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.1. The organisation shall identify and control safety risks arising from outsourced activities, including operations or cooperation with contractors, partners and suppliers.			1.9.1, Art. 9(2)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
113	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(a) the legal and other requirements related to safety (see 1. Context of the organisation);		1.9 (in general)
114	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(b) the level of competence required to deliver the tasks set out in the contract (see 4.2. Competence);		1.9.2
115	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(c) the responsibilities for the tasks to be performed;		1.9.6

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
116	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(d) the expected safety performance to be maintained during the contract;		1.9.3, Art. 9(3)
117	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(e) the obligations relating to the exchange of safety-related information (see 4.4. Information and communication);		1.9.6
118	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(f) the traceability of safety-related documents (see 4.5. Documented information).		1.9.6
119	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.3. In accordance with the process set out in Article 3 of Regulation (EU) No 1078/2012, the organisation shall monitor:	(a) the safety performance of all activities and operations of contractors, partners and suppliers to ensure that they comply with the requirements set out in the contract;		1.9.5, Art. 4(4), Art. 9(3)
120	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.3. In accordance with the process set out in Article 3 of Regulation (EU) No 1078/2012, the organisation shall monitor:	(b) the awareness of contractors, partners and suppliers of safety risks they entail to the organisation's operations.		1.9.2

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
121	5. OPERATION	5.4. Management of change	5.4.1. The organisation shall implement and control changes to the safety management system to maintain or improve the safety performance. This shall include decisions at the different stages of the change management and the subsequent review of safety risks (see 3.1.1. Risk assessment).			
122	5. OPERATION	5.5. Emergency management	5.5.1. The organisation shall identify the emergency situations and associated timely measures to be taken to manage them (see 3.1.1. Risk assessment) and to re-establish normal operating conditions in accordance with Regulation (EU) 2015/995.			
123	5. OPERATION	5.5. Emergency management	5.5.2. The organisation shall ensure that, for each identified type of emergency:	(a) the emergency services can be promptly contacted;		
124	5. OPERATION	5.5. Emergency management	5.5.2. The organisation shall ensure that, for each identified type of emergency:	(b) the emergency services are provided with all relevant information both in advance, to prepare their emergency response, and at the time of an emergency;		1.7.(j)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
125	5. OPERATION	5.5. Emergency management	5.5.2. The organisation shall ensure that, for each identified type of emergency:	(c) first aid is provided internally.		
126	5. OPERATION	5.5. Emergency management	5.5.3. The organisation shall identify and document the roles and responsibilities of all parties in accordance with Regulation (EU) 2015/995.			
127	5. OPERATION	5.5. Emergency management	5.5.4. The organisation shall have plans for action, alerts and information in case of emergency, including arrangements to:	(a) alert all staff with responsibility for emergency management;		
128	5. OPERATION	5.5. Emergency management	5.5.4. The organisation shall have plans for action, alerts and information in case of emergency, including arrangements to:	(b) communicate information to all parties (e.g. railway undertakings, contractors, authorities, emergency services), including emergency instructions for passengers;		I.7 (in general)
129	5. OPERATION	5.5. Emergency management	5.5.4. The organisation shall have plans for action, alerts and information in case of emergency, including arrangements to:	(c) take any decisions required in accordance with the type of emergency.		
130	5. OPERATION	5.5. Emergency management	5.5.5. The organisation shall describe how resources and means for emergency management have been allocated (see 4.1. Resources) and how training requirements have been identified (see 4.2. Competence).			

GUIDANCE ON ECM CERTIFICATION PROCESS

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
131	5. OPERATION	5.5. Emergency management	5.5.6. The emergency arrangements are regularly tested in cooperation with other interested parties and updated when appropriate.			
132	5. OPERATION	5.5. Emergency management	5.5.7. The organisation shall coordinate emergency plans with all railway undertakings that operate on the organisation's infrastructure, with the emergency services, so as to facilitate their rapid intervention, and with any other party that could be involved in an emergency situation.			
133	5. OPERATION	5.5. Emergency management	5.5.8. The organisation shall have arrangements to halt operations and railway traffic promptly, if necessary, and to inform all interested parties of the action taken.			I.7 (in general)
134	5. OPERATION	5.5. Emergency management	5.5.9. For cross-border infrastructure, the cooperation between the relevant infrastructure managers shall facilitate the necessary coordination and preparedness of the competent emergency services on both sides of the border.			

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
135	6. PERFORMANCE EVALUATION	6.1. Monitoring	6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:	(a) to check the correct application and the effectiveness of all the processes and procedures in the safety management system, including the operational, organisational and technical safety measures;		I.3 (in general), Art. 4(4), Art. 7(1), Art. 9(3)
136	6. PERFORMANCE EVALUATION	6.1. Monitoring	6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:	(b) to check the correct application of the safety management system as a whole, and if it achieves the expected outcomes;		I.3 (in general), Art. 4(4), Art. 7(1), Art. 9(3)
137	6. PERFORMANCE EVALUATION	6.1. Monitoring	6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:	(c) to investigate whether the safety management system conforms to the requirements in this Regulation;		I.3 (in general), Art. 4(4), Art. 7(1), Art. 9(3)
138	6. PERFORMANCE EVALUATION	6.1. Monitoring	6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:	(d) to identify, implement and evaluate the effectiveness of the corrective measures (see 7.2. Continual improvement), as appropriate, if any relevant instance of non-compliance to points (a), (b) and (c) is detected.		I.3 and I.4 (in general), Art. 4(4), Art. 7(1), Art. 9(3)
139	6. PERFORMANCE EVALUATION	6.1. Monitoring	6.1.2. The organisation shall regularly monitor at all levels within the organisation the performance of safety-related tasks and intervene if these tasks are not being properly performed.			I.3 and I.4 (in general), Art. 4(4), Art. 7(1), Art. 9(3)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
140	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(a) A schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance;		I.3 (in general)
141	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(b) The identification and selection of competent auditors (see 4.2. Competence);		
142	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(c) The analysis and evaluation of the results of the audits;		I.3 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
143	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(d) The identification of the need for corrective or improvement measures;		I.3 (in general)
144	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(e) The verification of the completion and effectiveness of these measures;		I.3 (in general)
145	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(f) The documentation pertaining to the execution and results of audits;		I.3 (in general)
146	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(g) The communication of the results of audits to the top management.		I.1.(g)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
147	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(a) details of progress on addressing outstanding actions from previous management reviews;		I.1 and I.3 (in general)
148	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(b) changing internal and external circumstances (see 1. Context of the organisation);		I.1 and I.3 (in general)
149	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(c) the organisation's safety performance related to:	(i) the achievement of its safety objectives;	I.1 and I.3 (in general)
150	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(c) the organisation's safety performance related to:	(ii) the results from its monitoring activities, including the internal audit findings, and internal accident/incident investigations and status of their respective actions;	I.1 and I.3 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
151	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(c) the organisation's safety performance related to:	(iii) the relevant outputs from supervisory activities conducted by the national safety authority;	I.1 and I.3 (in general)
152	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(d) recommendations for improvement.		I.1 and I.3 (in general)
153	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.2. Based on the outputs of its management review, the top management shall take overall responsibility for the planning and implementation of needed changes to the safety management system.			I.1.(g)
154	7. IMPROVEMENT	7.1. Learning from accidents and incidents	7.1.1. Accidents and incidents related to the organisation's railway operations shall be:	(a) reported, logged, investigated and analysed to determine their causes;		I.3 (in general)
155	7. IMPROVEMENT	7.1. Learning from accidents and incidents	7.1.1. Accidents and incidents related to the organisation's railway operations shall be:	(b) reported to national bodies as appropriate.		I.3 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
156	7. IMPROVEMENT	7.1. Learning from accidents and incidents	7.1.2. The organisation shall ensure that:	(a) recommendations from the national safety authority, the national investigating body and industry/internal investigations are evaluated and implemented if appropriate or mandated;		I.3 (in general), Art. 4(4)
157	7. IMPROVEMENT	7.1. Learning from accidents and incidents	7.1.2. The organisation shall ensure that:	(b) relevant reports/information from other interested parties such as railway undertakings, infrastructure managers, entities in charge of maintenance and railway vehicle keepers are considered and taken into account.		I.3 (in general), I.7 (in general), III.9, IV.9, Art. 4(4), Art. 5(2), Art. 5(3)
158	7. IMPROVEMENT	7.1. Learning from accidents and incidents	7.1.3. The organisation shall use information relating to the investigation to review the risk assessment (see 3.1.1. Risk assessment), to learn with the aim of improving safety and, where applicable, to adopt corrective and/or improvement measures (see 5.4. Management of change).			I.3 and I.4 (in general), Art. 4(4)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
159	7. IMPROVEMENT	7.2. Continual improvement	7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:	(a) monitoring (see 6.1. Monitoring);		I.4 (in general), Art. 4(4), Art. 7(1), Art. 9(3)
160	7. IMPROVEMENT	7.2. Continual improvement	7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:	(b) internal auditing (see 6.2. Internal auditing);		I.4 (in general)
161	7. IMPROVEMENT	7.2. Continual improvement	7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:	(c) management review (see 6.3. Management review);		I.4 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
162	7. IMPROVEMENT	7.2. Continual improvement	7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:	(d) learning from accidents and incidents (see 7.1. Learning from accidents and incidents).		I.4 (in general)
163	7. IMPROVEMENT	7.2. Continual improvement	7.2.2. The organisation shall provide means to motivating staff and other interested parties to be active in improving safety as part of its organisational learning.			
164	7. IMPROVEMENT	7.2. Continual improvement	7.2.3. The organisation shall provide a strategy to continually improve its safety culture, relying on the use of expertise and recognised methods to identify behavioural issues affecting the different parts of the safety management system and to put in place measures to address these.			

Annex II Mapping Table RU

NOTE (1)	(1) 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 (OJ L 121, 3.5.2013, p. 8).
NOTE (2)	(2) 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 (OJ L 320, 17.11.2012, p. 8).
NOTE (3)	(3) Point 2.1. of the Appendix to Annex I to Directive (EU) 2016/798.
NOTE (4)	(4) Point 2.2. of the Appendix to Annex I to Directive (EU) 2016/798.
NOTE (5)	(5) Commission Regulation (EU) 2015/995 of 8 June 2015 amending Decision 2012/757/EU concerning the technical specification for interoperability relating to the 'operation and traffic management' subsystem of the rail system in the European Union (OJ L 165, 30.6.2015, p. 1).

Regulation EU 2018/762 (CSM on SMS) - Annex I - SMS requirements related to Railway Undertakings			Reg EU 2019/779 - ECM Regulation	RU SMS documentation references		
No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
1	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(a) describe the type, extent and area of its operations;		1.1.(a) (partially covered)
2	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(b) identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself, or by contractors, partners or suppliers under its control;		1.2 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
3	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(c) identify interested parties (e.g. regulatory bodies, authorities, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;		I.2.1 (partially covered), I.9.1 (partially covered)
4	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);		I.1.(b) and (f), I.9.3
5	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(e) ensure that the requirements referred to in point (d) are taken into account in developing, implementing and maintaining the safety management system;		I.1.(d)
6	1. CONTEXT OF THE ORGANISATION	None	1.1. The organisation shall:	(f) describe the scope of the safety management system, indicating which part of the business is included or not in its scope and taking into account the requirements referred to in point (d).		I.1.(a) (partially covered), I.9.1 (partially covered)
7	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(a) taking overall accountability and responsibility for safety;		I.5.5 and I.5 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
8	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(b) ensuring commitment to safety by management at different levels within the organisation through their activities and in their relationships with staff and contractors;		1.1.(g) and (h) (partially covered), I.9.3
9	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(c) ensuring that the safety policy and safety objectives are established, understood and are compatible with the strategic direction of the organisation;		1.1.(a) and (b), I.9.3
10	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(d) ensuring the integration of the safety management system requirements into the organisation's business processes;		1.1.(d)
11	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(e) ensuring that the resources needed for the safety management system are available;		1.1.(e)
12	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(f) ensuring that the safety management system is effective in controlling the safety risks posed by the organisation;		1.1.(c) (partially covered)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
13	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(g) encouraging staff to support compliance with the safety management system requirements;		1.1.(g) and (h) (partially covered)
14	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(h) promoting continual improvement of the safety management system;		1.4 (partially covered)
15	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(i) ensuring that safety is considered when identifying and managing the organisation's business risks and explaining how conflict between safety and other business goals will be recognised and resolved;		1.2.2 and 1.2.3 (partially covered), 1.1.(f), 1.9.1
16	2. LEADERSHIP	2.1. Leadership and commitment	2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:	(j) promoting a positive safety culture.		
17	2. LEADERSHIP	2.2. Safety policy	2.2.1. A document describing the organisation's safety policy is established by the top management and is:	(a) appropriate to the organisation's type and extent of railway operations;		1.1.(a)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
18	2. LEADERSHIP	2.2. Safety policy	2.2.1. A document describing the organisation's safety policy is established by the top management and is:	(b) approved by the organisation's chief executive (or a representative(s) of the top-management);		1.1.(a)
19	2. LEADERSHIP	2.2. Safety policy	2.2.1. A document describing the organisation's safety policy is established by the top management and is:	(c) actively implemented, communicated and made available to all staff.		1.1.(a)
20	2. LEADERSHIP	2.2. Safety policy	2.2.2. The safety policy shall:	(a) include a commitment to conform with all legal and other requirements related to safety;		1.1.(b) (partially covered) and 1.1.(a) (in general)
21	2. LEADERSHIP	2.2. Safety policy	2.2.2. The safety policy shall:	(b) provide a framework for setting safety objectives and evaluating the organisation's safety performance against these objectives;		1.1.(b) and (c), and 1.1.(a) (in general), I.9.3
22	2. LEADERSHIP	2.2. Safety policy	2.2.2. The safety policy shall:	(c) include a commitment to control safety risks which arise both from its own activities and those caused by others;		1.1.(f), and 1.1.(a) (in general), I.9.4 (in general), I.9.5 (in general)
23	2. LEADERSHIP	2.2. Safety policy	2.2.2. The safety policy shall:	(d) include a commitment to continual improvement of the safety management system;		I.4 and 1.1.(a) (in general)
24	2. LEADERSHIP	2.2. Safety policy	2.2.2. The safety policy shall:	(e) be maintained in accordance with the business strategy and the evaluation of the safety performance of the organisation.		1.1.(c) and 1.1.(a) (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
25	2. LEADERSHIP	2.3. Organisational roles, responsibilities, accountabilities and authorities	2.3.1. The responsibilities, accountabilities and authorities of staff having a role that affects safety (including management and other staff involved in safety-related tasks) shall be defined at all levels within the organisation, documented, assigned and communicated to them.			I.5 (in general)
26	2. LEADERSHIP	2.3. Organisational roles, responsibilities, accountabilities and authorities	2.3.2. The organisation shall ensure that staff with delegated responsibilities for safety-related tasks shall have the authority, competence and appropriate resources to perform their tasks without being adversely affected by the activities of other business functions.			I.5 (in general), I.6 (in general), II.6 (in general), III.1, III.7, IV.8
27	2. LEADERSHIP	2.3. Organisational roles, responsibilities, accountabilities and authorities	2.3.3. Delegation of responsibility for safety-related tasks shall be documented and communicated to the relevant staff, accepted and understood.			I.5 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
28	2. LEADERSHIP	2.3. Organisational roles, responsibilities, accountabilities and authorities	2.3.4. The organisation shall describe the allocation of roles referred to in paragraph 2.3.1. to business functions within and where relevant, outside the organisation (see 5.3. Contractors, partners and suppliers).			1.5 (in general), 1.9.4 and 1.9.6 (in general)
29	2. LEADERSHIP	2.4. Consultation of staff and other parties	2.4.1. Staff, their representatives and external interested parties, as appropriate and where relevant, shall be consulted in developing, maintaining and improving the safety management system in the relevant parts they are responsible for, including the safety aspects of operational procedures.			1.1.(h)
30	2. LEADERSHIP	2.4. Consultation of staff and other parties	2.4.2. The organisation shall facilitate the consultation of staff by providing the methods and means for involving staff, recording staff's opinion and providing feedback on staff's opinion.			1.5.4 and 1.1.(h)
31	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(a) identify and analyse all operational, organisational and technical risks relevant to the type, extent and area of operations carried out by the organisation. Such risks shall include those arising from human and organisational factors such as workload, job design, fatigue or suitability of procedures, and the activities of other interested parties (see 1. Context of the organisation);	1.2.2, 1.2.3, 1.9.1 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
32	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(b) evaluate the risks referred to in point (a) by applying appropriate risk assessment methods;	1.2.2
33	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(c) develop and put in place safety measures, with identification of associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);	1.3 (in general)
34	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(d) develop a system to monitor the effectiveness of safety measures (see 6.1. Monitoring);	1.3 (in general)
35	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(e) recognise the need to collaborate with other interested parties (such as railway undertakings, infrastructure managers, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on shared risks and the putting in place of adequate safety measures;	1.2.1, 1.7 (in general)
36	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.1. The organisation shall:	(f) communicate risks to staff and involved external parties (see 4.4. Information and communication).	1.1.(h) partially covered), 1.9.4 (partially covered)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
37	3. PLANNING	3.1. Actions to address risks	3.1.1. Risk assessment	3.1.1.2. When assessing risk, an organisation shall take into account the need to determine, provide and sustain a safe working environment which conforms to applicable legislation, in particular Directive 89/391/EEC.	I.2.3	
38	3. PLANNING	3.1. Actions to address risks	3.1.2. Planning for change	3.1.2.1. The organisation shall identify potential safety risks and appropriate safety measures (see 3.1.1. Risk assessment) before the implementation of a change (see 5.4. Management of change) in accordance with the risk management process set out in the Regulation (EU) No 402/2013 (1), including consideration of the safety risks from the change process itself.	I.2.2	
39	3. PLANNING	3.2. Safety objectives and planning	3.2.1. The organisation shall establish safety objectives for relevant functions at relevant levels to maintain and, where reasonably practicable, improve its safety performance.		I.1.(b) and (c)	
40	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(a) be consistent with the safety policy and the organisation's strategic objectives (where applicable);	I.1.(b)	
41	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(b) be linked to the priority risks that influence the safety performance of the organisation;	I.1.(b) and (c)	
42	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(c) be measurable;		

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
43	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(d) take into account applicable legal and other requirements;	1.1.(b)	
44	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(e) be reviewed as regards their achievements and revised as appropriate;		
45	3. PLANNING	3.2. Safety objectives and planning	3.2.2. The safety objectives shall:	(f) be communicated.		
46	3. PLANNING	3.2. Safety objectives and planning	3.2.3. The organisation shall have plan(s) to describe how it will achieve its safety objectives.		1.1.(d)	
47	3. PLANNING	3.2. Safety objectives and planning	3.2.4. The organisation shall describe the strategy and plan(s) used to monitor the achievement of the safety objectives (see 6.1. Monitoring).		1.3 (in general)	
48	4. SUPPORT	4.1. Resources	4.1.1. The organisation shall provide the resources, including competent staff and effective and useable equipment, needed for the establishment, implementation, maintenance and continual improvement of the safety management system.		1.1.(e), II.3, IV.3, IV.4, IV.5	

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
49	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(a) identification of the competencies (including knowledge, skills, non-technical behaviours and attitudes) required for safety-related tasks;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
50	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(b) selection principles (basic educational level, psychological and physical fitness required);		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
51	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(c) initial training, experience and qualification;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
52	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(d) ongoing training and periodic update of existing competencies;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
53	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(e) periodic assessment of competence and checks of psychological and physical fitness to ensure that qualifications and skills are maintained over time;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
54	4. SUPPORT	4.2. Competence	4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:	(f) specific training in relevant parts of the safety management system in order to deliver their safety-related tasks.		I.6 (in general), II.6 (in general), III.1, III.7, IV.8

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
55	4. SUPPORT	4.2. Competence	4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:	(a) the training programme is delivered according to the identified competency requirements and individual needs of the staff;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
56	4. SUPPORT	4.2. Competence	4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:	(b) where applicable, the training ensures that staff can operate under all operating conditions (normal, degraded and emergency);		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
57	4. SUPPORT	4.2. Competence	4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:	(c) the duration of the training and the frequency of the refresher training are appropriate for the training objectives;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
58	4. SUPPORT	4.2. Competence	4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:	(d) records are kept for all staff (see 4.5.3. Control of documented information);		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
59	4. SUPPORT	4.2. Competence	4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:	(e) the training programme is regularly reviewed and audited (see 6.2. Internal auditing) and changes made when necessary (see 5.4. Management of change).		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
60	4. SUPPORT	4.2. Competence	4.2.3. Back to work arrangements shall be in place for staff following accidents/incidents or long absences from work, including providing additional training where such a need is identified.			I.6 (in general), II.6 (in general), III.1, III.7, IV.8

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
61	4. SUPPORT	4.3. Awareness	4.3.1. Top management shall ensure that they and their staff having a role that affects safety are aware of the relevance, importance and consequences of their activities and how they contribute to the correct application and the effectiveness of the safety management system, including the achievement of safety objectives (see 3.2. Safety objectives and planning).			1.1.(g) (partially covered)
62	4. SUPPORT	4.4. Information and communication	4.4.1. The organisation shall define adequate communication channels to ensure that safety-related information is exchanged among the different levels of the organisation and with external interested parties including contractors, partners and suppliers.			1.7 (in general), I.9.6 (partially covered), II.5 (in general), III.9, IV.9, Art. 5(1), Art. 5(3)
63	4. SUPPORT	4.4. Information and communication	4.4.2. To ensure that safety-related information reaches those making judgements and decisions, the organisation shall manage the identification, receipt, processing, generation and dissemination of safety-related information.			1.7 (in general), I.9.6 (partially covered), II.5 (in general), III.9, IV.9, Art. 4(2), Art. 4(3), Art. 4(6)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
64	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(a) relevant, complete and understandable for the intended users;		1.7 (in general)
65	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(b) valid;		1.7 (in general)
66	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(c) accurate;		1.7 (in general)
67	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(d) consistent;		1.7 (in general)
68	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(e) controlled (see 4.5.3. Control of documented information);		1.7 (in general)
69	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(f) communicated before it takes effect;		1.7 (in general)
70	4. SUPPORT	4.4. Information and communication	4.4.3. The organisation shall ensure that safety-related information is:	(g) received and understood.		1.7 (in general)
71	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(a) the identification and description of the processes and activities related to safety of rail operations, including safety-related tasks and associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);	1.8 (in general)
72	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(b) the interaction of these processes;	1.8 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
73	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(c) the procedures or other documents describing how these processes are implemented;	1.8 (in general)
74	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(d) the identification of contractors, partners and suppliers with a description of the type and extent of services delivered;	1.8 (in general), 1.9 (in general)
75	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(e) the identification of contractual arrangements and other business agreements, concluded between the organisation and other parties identified under (d), necessary to control the safety risks of the organisation and those related to the use of contractors;	1.8 (in general), 1.9 (in general)
76	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.1. There is a description of the safety management system including:	(f) reference to documented information required by this Regulation.	1.8 (in general)
77	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(a) a synthesis of the decisions on the level of significance of the safety-related changes, including an overview of significant changes, in accordance with Article 18(1) of Regulation (EU) No 402/2013;	Annex V (ECM Maintenance Report) (in general), Art. 8(5)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
78	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(b) the organisation's safety objectives for the following year(s) and how serious risks for safety influence the setting of these safety objectives;	Annex V (ECM Maintenance Report) (in general), Art. 8(5)
79	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(c) the results of internal accident/incident investigation (see 7.1. Learning from accidents and incidents) and other monitoring activities (see 6.1. Monitoring, 6.2. Internal auditing and 6.3. Management review), in accordance with Article 5(1) of Regulation (EU) No 1078/2012 (2);	Annex V (ECM Maintenance Report) (in general), Art. 8(5)
80	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(d) details of progress on addressing outstanding recommendations from the national investigation bodies (see 7.1. Learning from accidents and incidents);	Annex V (ECM Maintenance Report) (in general), Art. 8(5)
81	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(e) the organisation's safety indicators set out to evaluate the organisation's safety performance (see 6.1. Monitoring);	Annex V (ECM Maintenance Report) (in general), Art. 8(5)
82	4. SUPPORT	4.5. Documented information	4.5.1. Safety management system documentation	4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:	(f) where applicable, the conclusions of the annual report of the safety advisor, as referred to in RID (3), on the activities of the organisation relating to the transport of dangerous goods (4).	Annex V (ECM Maintenance Report) (in general), Art. 8(5)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
83	4. SUPPORT	4.5. Documented information	4.5.2. Creating and updating	4.5.2.1. The organisation shall ensure that when creating and updating documented information related to the safety management system adequate formats and media are used.		I.8 (in general)
84	4. SUPPORT	4.5. Documented information	4.5.3. Control of documented information	4.5.3.1. The organisation shall control documented information related to the safety management system, in particular its storage, distribution and the control of changes, to ensure its availability, suitability and protection where appropriate.		I.8 (in general), I.9 (in general), II.7, III.10, IV.10
85	4. SUPPORT	4.6. Integration of human and organisational factors	4.6.1. The organisation shall demonstrate a systematic approach to integrating human and organisational factors within the safety management system. This approach shall:	(a) include the development of a strategy and the use of expertise and recognised methods from the field of human and organisational factors;		
86	4. SUPPORT	4.6. Integration of human and organisational factors	4.6.1. The organisation shall demonstrate a systematic approach to integrating human and organisational factors within the safety management system. This approach shall:	(b) address risks associated with the design and use of equipment, tasks, working conditions and organisational arrangements, taking into account human capabilities as well as limitations, and the influences on human performance.		I.2.3 (in general), II.3 (in general), IV.3, IV.4, IV.5

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
87	5. OPERATION	5.1. Operational planning and control	5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:	(a) risk acceptance criteria and safety measures are applied (see 3.1.1. Risk assessment);		1.3 and 1.9.6 (in general)
88	5. OPERATION	5.1. Operational planning and control	5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:	(b) plan(s) to achieve the safety objectives are delivered (see 3.2. Safety objectives and planning);		1.1.(d), 1.3, 1.9.3
89	5. OPERATION	5.1. Operational planning and control	5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:	(c) information is collected to measure the correct application and effectiveness of the operational arrangements (see 6.1. Monitoring).		1.3 (in general), 1.9.6 (in general), 1.9.5 (in general), 1.7 (in general)
90	5. OPERATION	5.1. Operational planning and control	5.1.2. The organisation shall ensure that its operational arrangements conform to the safety-related requirements of applicable Technical Specifications for Interoperability and relevant national rules and any other relevant requirements (see 1. Context of the organisation).			11.2, Art. 4(1)
91	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(a) planning of existing or new train routes and new train services, including the introduction of new types of vehicles, the need to lease vehicles and/or to hire staff from external parties and the exchange of information on the maintenance for operational purposes with entities in charge of maintenance;		1.7 (in general), Art. 5(1), Art. 5(2), Art. 5(3)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
92	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(b) development and implementation of train timetables;		
93	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(c) preparation of trains or vehicles before movement, including pre-departure checks and train composition;		
94	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(d) running trains or movement of vehicles in the different operating conditions (normal, degraded and emergency);		
95	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(e) adaptation of the operation to requests for removal from operation and notification of return to operation issued by entities in charge of maintenance;		III.4, III.6, III.9, III.10
96	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(f) authorisations for movements of vehicles;		

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
97	5. OPERATION	5.1. Operational planning and control	5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(g) usability of interfaces in train driving cabs and train control centres and with equipment used by maintenance staff.		II.3, IV.3, IV.4, IV.5
98	5. OPERATION	5.1. Operational planning and control	5.1.4. To control the allocation of responsibilities where relevant for the safety of operational activities, the organisation shall identify responsibilities for coordinating and managing the safe running of trains and movements of vehicles and define how relevant tasks affecting the safe delivery of all services are allocated to competent staff within the organisation (see 2.3. Organisational roles, responsibilities, accountabilities and authorities) and to other external qualified parties when appropriate (see 5.3. Contractors, partners and suppliers).			I.9.1 and I.9.2 (in general)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
99	5. OPERATION	5.1. Operational planning and control	5.1.5. To control information and communication where relevant for the safety of operational activities (see 4.4. Information and communication), relevant staff (e.g. train crews) shall be advised of the details of any specified conditions of travel, including relevant changes which may result in a hazard, temporary or permanent operational restrictions (e.g. due to specific type of vehicles or to specific routes) and conditions for exceptional consignments, where applicable.			I.7, II.5, III.6, III.9, III.10, IV.9, Art. 4(2), Art. 4(6)
100	5. OPERATION	5.1. Operational planning and control	5.1.6. To control competence where relevant for the safety of operational activities (see 4.2. Competence), the organisation shall ensure, in accordance with applicable legislation (see 1. Context of the organisation), for its staff:	(a) compliance with their training and work instructions, and corrective actions are taken where required;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
101	5. OPERATION	5.1. Operational planning and control	5.1.6. To control competence where relevant for the safety of operational activities (see 4.2. Competence), the organisation shall ensure, in accordance with applicable legislation (see 1. Context of the organisation), for its staff:	(b) specific training in case of anticipated changes affecting the running of operations or their task assignment;		I.6 (in general), II.6 (in general), III.1, III.7, IV.8

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
102	5. OPERATION	5.1. Operational planning and control	5.1.6. To control competence where relevant for the safety of operational activities (see 4.2. Competence), the organisation shall ensure, in accordance with applicable legislation (see 1. Context of the organisation), for its staff:	(c) adoption of adequate measures following accidents and incidents.		I.6 (in general), II.6 (in general), III.1, III.7, IV.8
103	5. OPERATION	5.2. Asset management	5.2.1. The organisation shall manage the safety risks associated with physical assets throughout their life cycle (see 3.1.1. Risk assessment), from design to disposal, and fulfil the human factors requirements in all phases of the life cycle.			I.2 (in general)
104	5. OPERATION	5.2. Asset management	5.2.2. The organisation shall:	(a) ensure that the assets are used for the purpose intended while maintaining their safe operational state, in accordance with Article 14(2) of Directive (EU) 2016/798 where relevant, and their expected level of performance;		
105	5. OPERATION	5.2. Asset management	5.2.2. The organisation shall:	(b) manage the assets in normal and degraded operations;		
106	5. OPERATION	5.2. Asset management	5.2.2. The organisation shall:	(c) detect as soon as reasonably practicable instances of non-compliance with operating requirements before or during the operation of the asset, including the application of restrictions of use as appropriate to ensure a safe operational state of the asset (see 6.1. Monitoring).		III.6, III.9, III.10

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
107	5. OPERATION	5.2. Asset management	5.2.3. The organisation shall ensure that its asset management arrangements, where applicable, conform to all essential requirements as set out in the relevant Technical Specifications for Interoperability and any other relevant requirements (see 1. Context of the organisation).			II. 2 (in general), Art. 4(1)
108	5. OPERATION	5.2. Asset management	5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(a) the identification of the need for maintenance to keep the asset in a safe operational state, based on the planned and real use of the asset and its design characteristics;	III.4	
109	5. OPERATION	5.2. Asset management	5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(b) the management of the removal of the asset from operation for maintenance, when defects have been identified or when asset condition degrades outside the limits of a safe operational state as referred to in point (a);	III.4, Art. 4(2), Art. 4(4)	
110	5. OPERATION	5.2. Asset management	5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(c) the management of the return to operation of the asset with eventual restrictions of use after maintenance has been delivered to ensure it is in a safe operational state;	III.4	

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
111	5. OPERATION	5.2. Asset management	5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:	(d) the management of monitoring and measurement equipment to ensure that it is fit for its intended purpose.		II.3 (in general), III.6, III.9, III.10, IV.3, IV.4, IV.5
112	5. OPERATION	5.2. Asset management	5.2.5. To control information and communication where relevant for the safe management of assets (see 4.4. Information and communication), the organisation shall take into account:	(a) the exchange of relevant information within the organisation or with external entities responsible for maintenance (see 5.3. Contractors, partners and suppliers), in particular on safety-related malfunctions, accidents, incidents as well as on eventual restrictions of use of the asset;		I.7 (in general), I.9.6, II.5, III.6, III.9, III.10, IV.9, Art. 4(2), Art. 4(6), Art. 5(1), Art. 5(2), Art. 5(3)
113	5. OPERATION	5.2. Asset management	5.2.5. To control information and communication where relevant for the safe management of assets (see 4.4. Information and communication), the organisation shall take into account:	(b) the traceability of all necessary information including the information related to point (a) (see 4.4. Information and communication and 4.5.3. Control of documented information);		I.7 (in general), I.8, I.9.6, II.5 (in general), II.7, III.4 (in general), III.9, IV.9, Art. 4(5)b
114	5. OPERATION	5.2. Asset management	5.2.5. To control information and communication where relevant for the safe management of assets (see 4.4. Information and communication), the organisation shall take into account:	(c) the establishment and maintenance of records including the management of changes affecting the safety of assets (see 5.4. Management of change).		I.7, I.8, II.2 (in general), II.5 (in general), II.7, III.10, IV.10, Art. 4(5)b

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
115	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.1. The organisation shall identify and control safety risks arising from outsourced activities, including operations or cooperation with contractors, partners and suppliers.			I.9.1, Art. 9(2)
116	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(a) the legal and other requirements related to safety (see 1. Context of the organisation);		I.9 (in general)
117	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(b) the level of competence required to deliver the tasks set out in the contract (see 4.2. Competence);		I.9.2
118	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(c) the responsibilities for the tasks to be performed;		I.9.6

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
119	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(d) the expected safety performance to be maintained during the contract;		1.9.3, Art. 9(3)
120	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(e) the obligations relating to the exchange of safety-related information (see 4.4. Information and communication);		1.9.6
121	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:	(f) the traceability of safety-related documents (see 4.5. Documented information).		1.9.6
122	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.3. In accordance with the process set out in Article 3 of Regulation (EU) No 1078/2012, the organisation shall monitor:	(a) the safety performance of all activities and operations of contractors, partners and suppliers to ensure that they comply with the requirements set out in the contract;		1.9.5, Art. 4(4), Art. 9(3)
123	5. OPERATION	5.3. Contractors, partners and suppliers	5.3.3. In accordance with the process set out in Article 3 of Regulation (EU) No 1078/2012, the organisation shall monitor:	(b) the awareness of contractors, partners and suppliers of safety risks they entail to the organisation's operations.		1.9.2

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
124	5. OPERATION	5.4. Management of change	5.4.1. The organisation shall implement and control changes to the safety management system to maintain or improve the safety performance. This shall include decisions at the different stages of the change management and the subsequent review of safety risks (see 3.1.1. Risk assessment).			
125	5. OPERATION	5.5. Emergency management	5.5.1. The organisation shall identify the emergency situations and associated timely measures to be taken to manage them (see 3.1.1. Risk assessment) and to re-establish normal operating conditions in accordance with Regulation (EU) 2015/995 (5).			
126	5. OPERATION	5.5. Emergency management	5.5.2. The organisation shall ensure that, for each identified type of emergency:	(a) the emergency services can be promptly contacted;		
127	5. OPERATION	5.5. Emergency management	5.5.2. The organisation shall ensure that, for each identified type of emergency:	(b) the emergency services are provided with all relevant information both in advance, to prepare their emergency response, and at the time of an emergency;	1.7.(i)	
128	5. OPERATION	5.5. Emergency management	5.5.2. The organisation shall ensure that, for each identified type of emergency:	(c) first aid is provided internally.		

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
129	5. OPERATION	5.5. Emergency management	5.5.3. The organisation shall identify and document the roles and responsibilities of all parties in accordance with Regulation (EU) 2015/995.			
130	5. OPERATION	5.5. Emergency management	5.5.4. The organisation shall have plans for action, alerts and information in case of emergency including arrangements to:	(a) alert all staff with responsibility for emergency management;		
131	5. OPERATION	5.5. Emergency management	5.5.4. The organisation shall have plans for action, alerts and information in case of emergency including arrangements to:	(b) communicate information to all parties (e.g. infrastructure manager, contractors, authorities, emergency services), including emergency instructions for passengers;		1.7 (in general)
132	5. OPERATION	5.5. Emergency management	5.5.4. The organisation shall have plans for action, alerts and information in case of emergency including arrangements to:	(c) take any decisions required in accordance with the type of emergency.		
133	5. OPERATION	5.5. Emergency management	5.5.5. The organisation shall describe how resources and means for emergency management have been allocated (see 4.1. Resources) and how training requirements have been identified (see 4.2. Competence).			
134	5. OPERATION	5.5. Emergency management	5.5.6. The emergency arrangements are regularly tested in cooperation with other interested parties and updated when appropriate.			

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
135	5. OPERATION	5.5. Emergency management	5.5.7. The organisation shall ensure that competent staff in charge, with adequate language skills, can be contacted easily and without delay by the infrastructure manager and provide the latter with the right level of information.			
136	5. OPERATION	5.5. Emergency management	5.5.8. The organisation shall have a procedure to contact the entity in charge of maintenance or the railway vehicle keeper in the event of an emergency.			1.7 (in general)
137	6. PERFORMANCE EVALUATION	6.1. Monitoring	6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:	(a) to check the correct application and the effectiveness of all the processes and procedures in the safety management system, including the operational, organisational and technical safety measures;		1.3 (in general), Art. 4(4), Art. 7(1), Art. 9(3)
138	6. PERFORMANCE EVALUATION	6.1. Monitoring	6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:	(b) to check the correct application of the safety management system as a whole, and if it achieves the expected outcomes;		1.3 (in general), Art. 4(4), Art. 7(1), Art. 9(3)
139	6. PERFORMANCE EVALUATION	6.1. Monitoring	6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:	(c) to investigate whether the safety management system conforms to the requirements in this Regulation;		1.3 (in general), Art. 4(4), Art. 7(1), Art. 9(3)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
140	6. PERFORMANCE EVALUATION	6.1. Monitoring	6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:	(d) to identify, implement and evaluate the effectiveness of the corrective measures (see 7.2. Continual improvement), as appropriate, if any relevant instance of non-compliance to points (a), (b) and (c) is detected.		I.3 and I.4 (in general), Art. 4(4), Art. 7(1), Art. 9(3)
141	6. PERFORMANCE EVALUATION	6.1. Monitoring	6.1.2. The organisation shall regularly monitor at all levels within the organisation the performance of safety-related tasks and intervene if these tasks are not being properly performed.			I.3 and I.4 (in general), Art. 4(4), Art. 7(1), Art. 9(3)
142	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(a) A schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance;		I.3 (in general)
143	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(b) The identification and selection of competent auditors (see 4.2. Competence);		

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
144	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(c) The analysis and evaluation of the results of the audits;		1.3 (in general)
145	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(d) The identification of the need for corrective or improvement measures;		1.3 (in general)
146	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(e) The verification of the completion and effectiveness of these measures;		1.3 (in general)
147	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(f) The documentation pertaining to the execution and results of audits;		1.3 (in general)

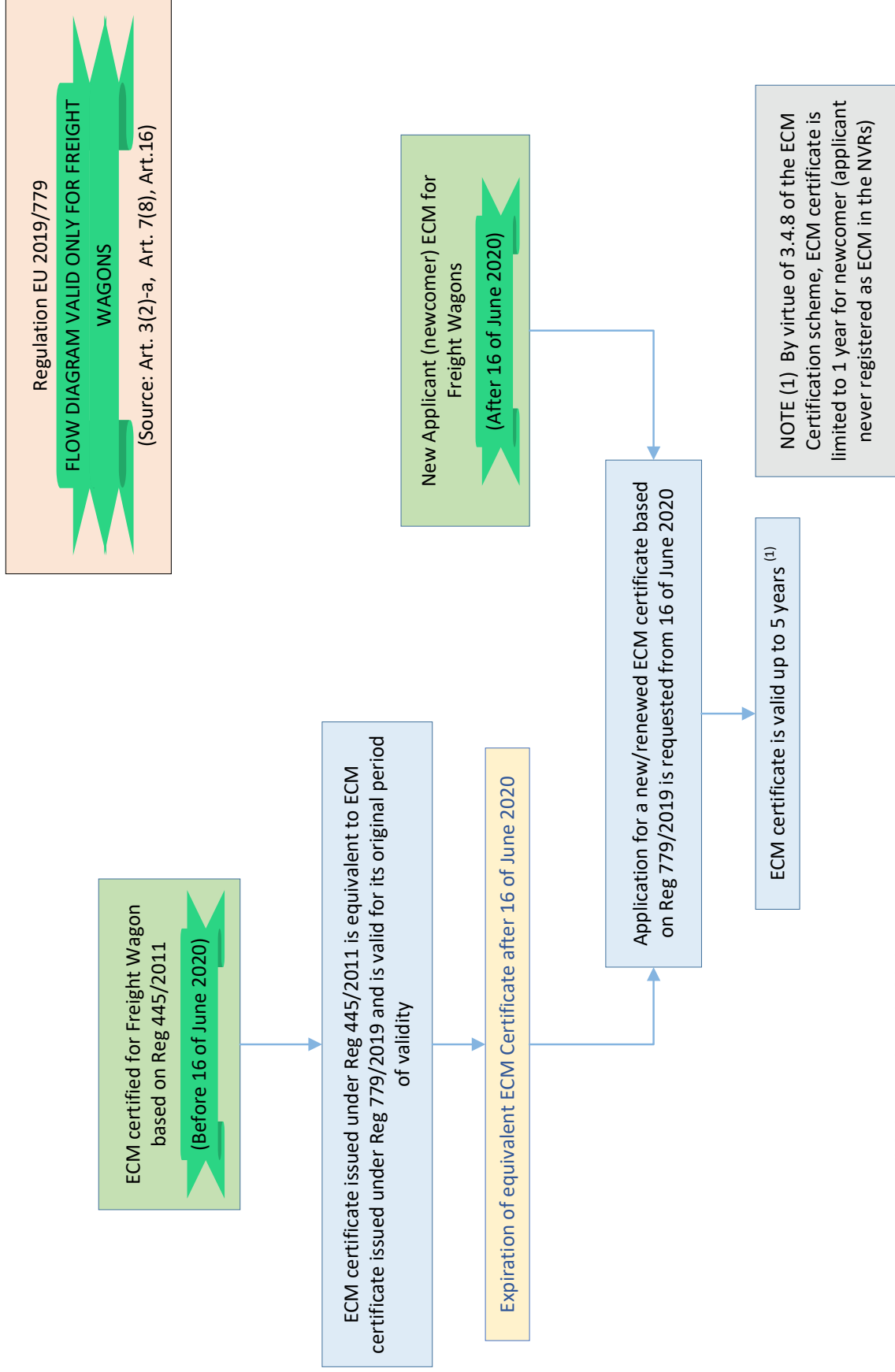
No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
148	6. PERFORMANCE EVALUATION	6.2. Internal auditing	6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:	(g) The communication of the results of audits to the top management.		I.1.(g)
149	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(a) details of progress on addressing outstanding actions from previous management reviews;		I.1 and I.3 (in general)
150	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(b) changing internal and external circumstances (see 1. Context of the organisation);		I.1 and I.3 (in general)
151	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(c) the organisation's safety performance related to:	(i) the achievement of its safety objectives;	I.1 and I.3 (in general)
152	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(c) the organisation's safety performance related to:	(ii) the results from its monitoring activities, including the internal audit findings, and internal accident/incident investigations and status of their respective actions;	I.1 and I.3 (in general)

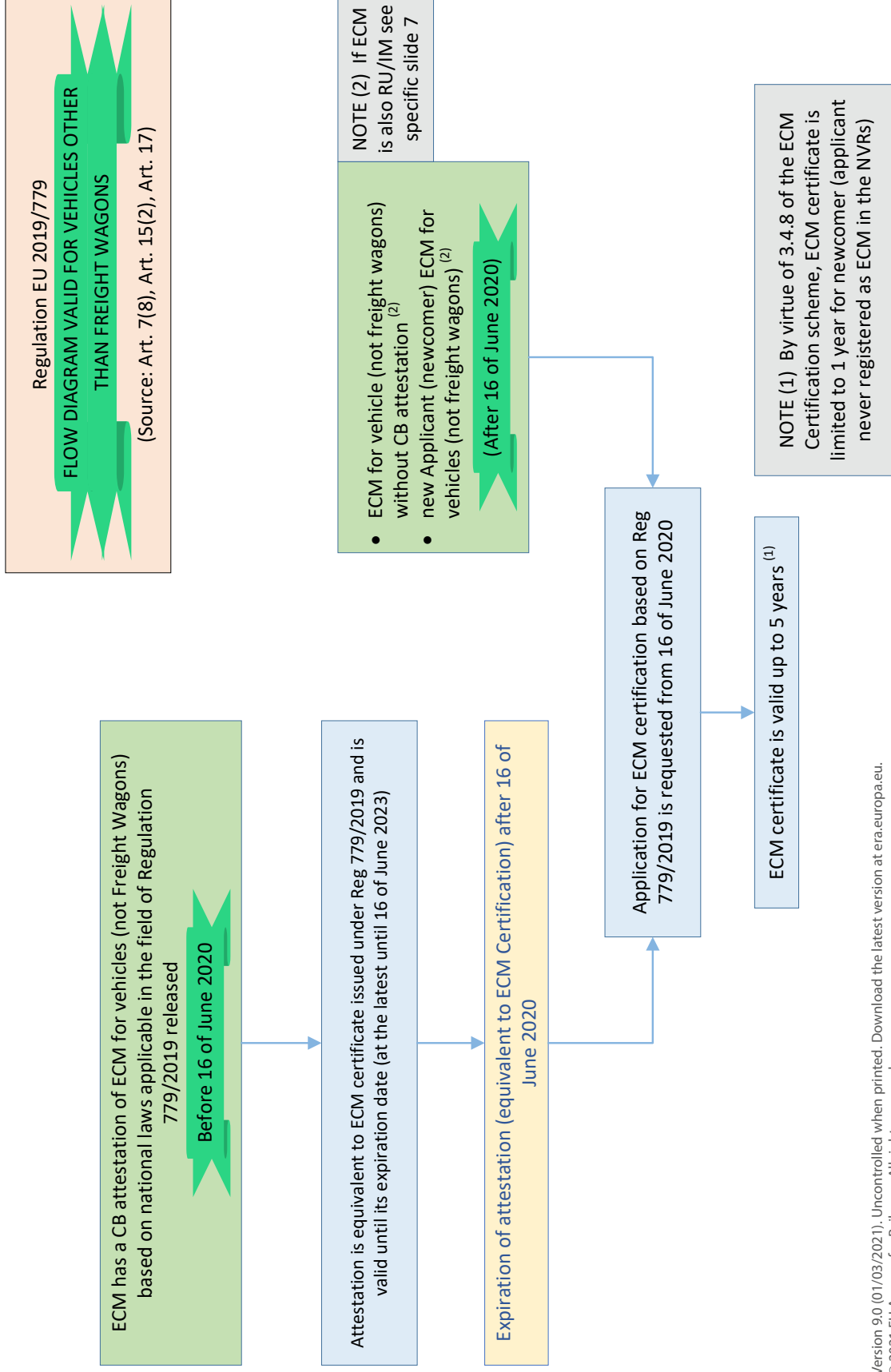
No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
153	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(c) the organisation's safety performance related to:	(iii) the relevant outputs from supervisory activities conducted by the national safety authority;	1.1 and I.3 (in general)
154	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:	(d) recommendations for improvement.		1.1 and I.3 (in general)
155	6. PERFORMANCE EVALUATION	6.3. Management review	6.3.2. Based on the outputs of its management review, the top management shall take overall responsibility for the planning and implementation of needed changes to the safety management system.			1.1.(g)
156	7. IMPROVEMENT	7.1. Learning from accidents and incidents		(a) reported, logged, investigated and analysed to determine their causes;		I.3 (in general)
157	7. IMPROVEMENT	7.1. Learning from accidents and incidents		(b) reported to national bodies as appropriate.		I.3 (in general)
158	7. IMPROVEMENT	7.1. Learning from accidents and incidents	7.1.2. The organisation shall ensure that:	(a) recommendations from the national safety authority, the national investigating body and industry/internal investigations are evaluated and implemented if appropriate or mandated;		I.3 (in general), Art. 4(4)

No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
159	7. IMPROVEMENT	7.1. Learning from accidents and incidents	7.1.2. The organisation shall ensure that:	(b) relevant reports/information from other interested parties such as railway undertakings, infrastructure managers, entities in charge of maintenance and railway vehicle keepers are considered and taken into account.		I.3 (in general), I.7 (in general), III.9, IV.9, Art. 4(4), Art. 5(2), Art. 5(3)
160	7. IMPROVEMENT	7.1. Learning from accidents and incidents	7.1.3. The organisation shall use information relating to the investigation to review the risk assessment (see 3.1.1. Risk assessment), to learn with the aim of improving safety and, where applicable, to adopt corrective and/or improvement measures (see 5.4. Management of change).			I.3 and I.4 (in general), Art. 4(4)
161	7. IMPROVEMENT	7.2. Continual improvement	7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:	(a) monitoring (see 6.1. Monitoring);		I.4 (in general), Art. 4(4), Art. 7(1), Art. 9(3)
162	7. IMPROVEMENT	7.2. Continual improvement	7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:	(b) internal auditing (see 6.2. Internal auditing);		I.4 (in general)

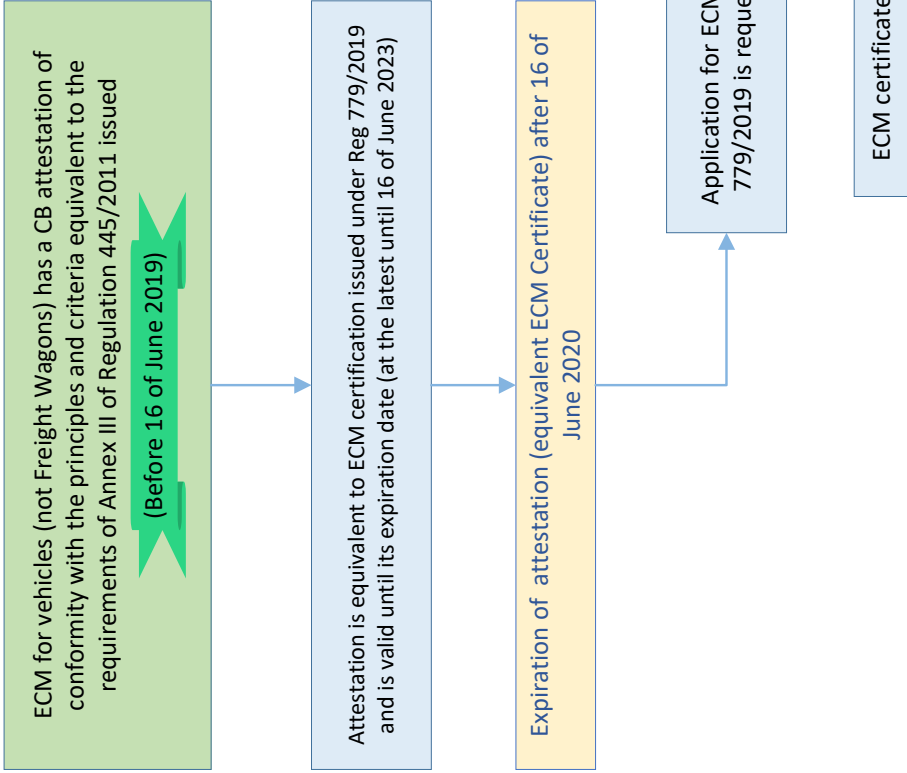
No.	Section	Sub-section	Main requirement	1st level requirement	2nd level requirement	Articles and Annex II - corresponding requirements
163	7. IMPROVEMENT	7.2. Continual improvement	7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:	(c) management review (see 6.3. Management review);		1.4 (in general)
164	7. IMPROVEMENT	7.2. Continual improvement	7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:	(d) learning from accidents and incidents (see 7.1. Learning from accidents and incidents).		1.4 (in general)
165	7. IMPROVEMENT	7.2. Continual improvement	7.2.2. The organisation shall provide means to motivating staff and other interested parties to be active in improving safety as part of its organisational learning.			
166	7. IMPROVEMENT	7.2. Continual improvement	7.2.3. The organisation shall provide a strategy to continually improve its safety culture, relying on the use of expertise and recognised methods to identify behavioural issues affecting the different parts of the safety management system and to put in place measures to address these.			

REGULATION 2019/779 Art.15





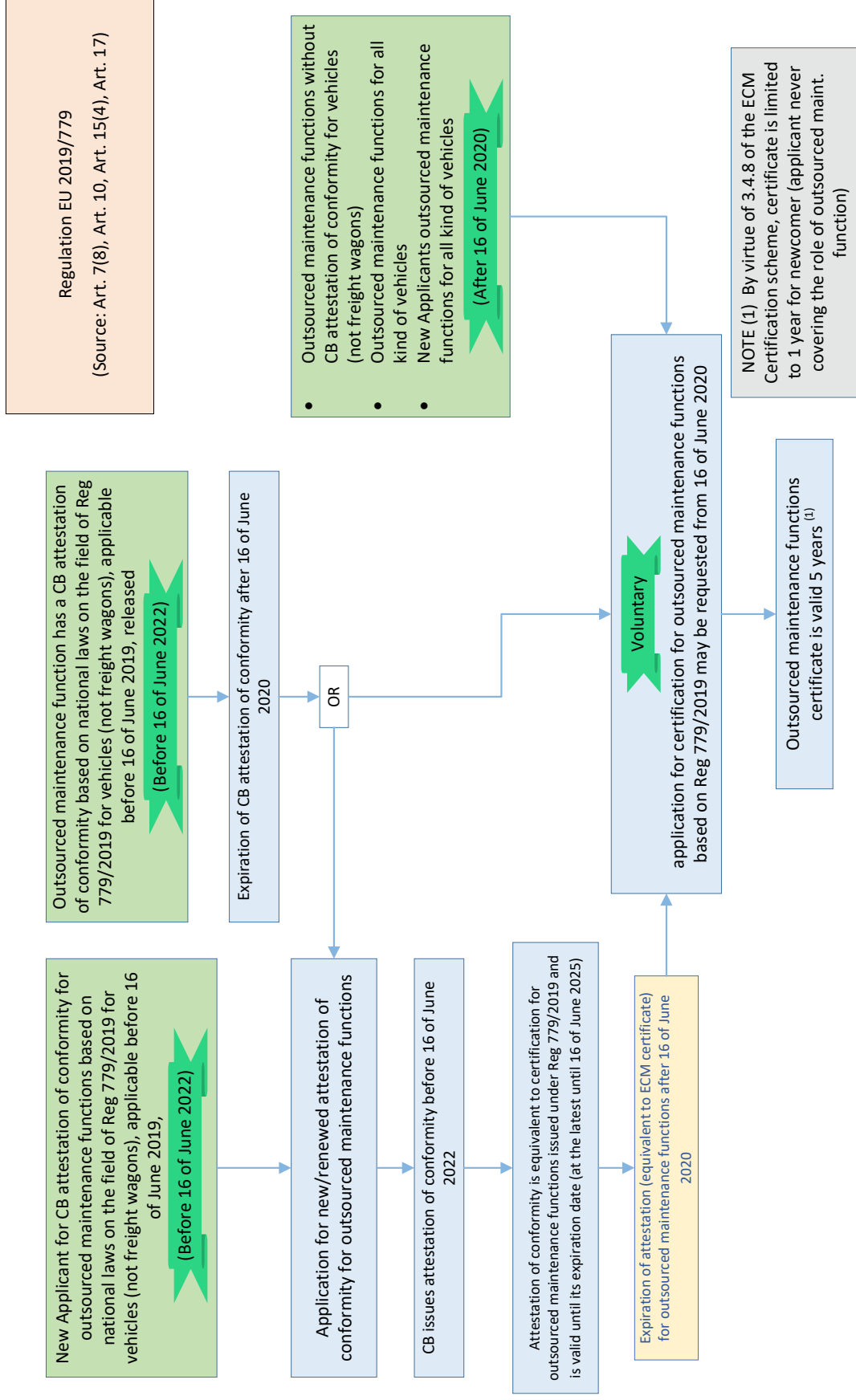
Regulation EU 2019/779
FLOW DIAGRAM VALID FOR VEHICLES OTHER THAN FREIGHT WAGONS
 (Source: Art. 7(8), Art. 15.3, Art. 17)



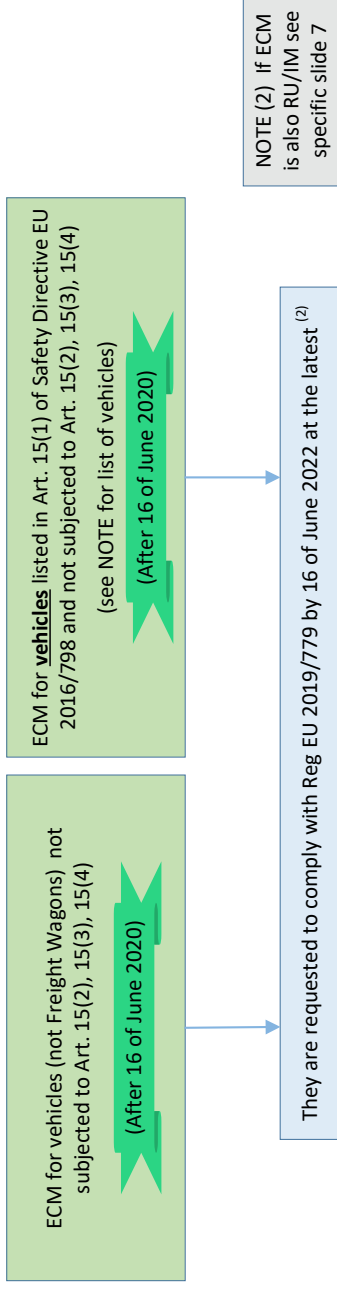
- ECM for vehicle (not freight wagons) without CB attestation ⁽²⁾
 - new Applicant (newcomer) ECM for vehicles (not freight wagons) ⁽²⁾
- (After 16 of June 2020)

NOTE (2) If ECM is also RU/IM see specific slide 7

NOTE (1) By virtue of 3.4.8 of the ECM Certification scheme, ECM certification is limited to 1 year for newcomer (applicant never registered as ECM in the NVRs)



Regulation EU 2019/779 and Regulation EU 2020/780
**FLOW DIAGRAM VALID FOR VEHICLES
 OTHER THAN FREIGHT WAGONS**
 (Source: Art. 15(5), Art. 17)

**NOTE**

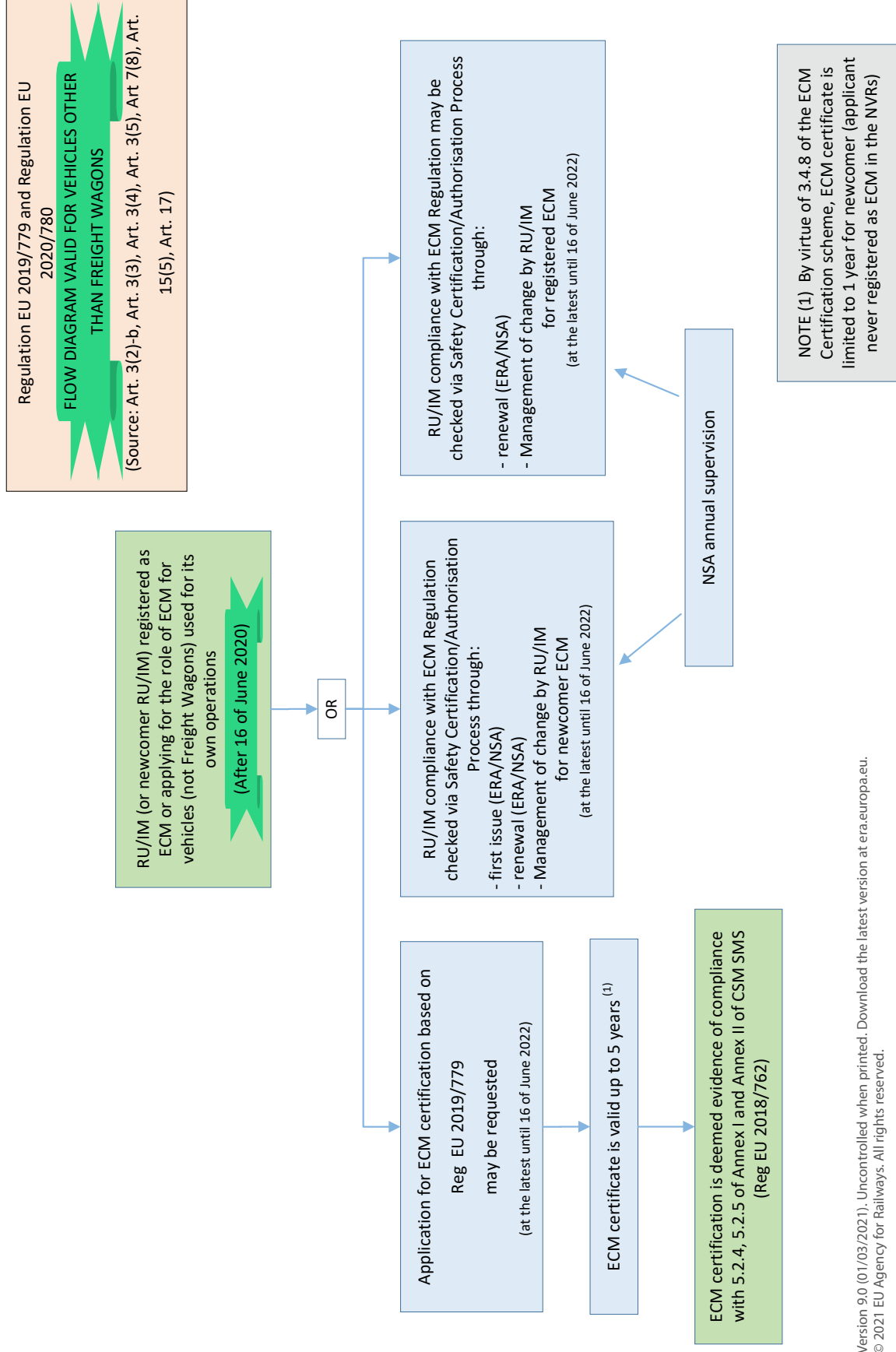
Vehicles as in Art. 15(1) of Safety Directive 2016/798

- (a) **vehicles** registered in a third country and maintained in accordance with the law of that country;
- (b) **vehicles** used on networks or lines the track gauge of which is different from that of the main rail network within the Union and in respect of which fulfilment of the requirements laid down in Article 14(2) is ensured by international agreements with third countries;
- (c) **freight wagons** and **passenger coaches** which are in shared use with third countries the track gauge of which is different from that of the main rail network within the Union;
- (d) **vehicles** used on the networks referred to in Article 2(3), and military equipment and special transport requiring an ad hoc national safety authority permit to be delivered prior to their entry into service. In this case derogations shall be granted for periods not longer than 5 years.

Sub-NOTE for vehicles used on particular network (letter (d) above) as in Art. 2(3) of Safety Directive 2016/798

- (a) privately owned railway infrastructure, including sidings, used by the owner or by an operator for the purpose of their respective freight activities or for the transport of persons for non-commercial purposes, and vehicles used exclusively on such infrastructure;
- (b) infrastructure and vehicles reserved for strictly local, historical or tourist use;
- (c) light rail infrastructure occasionally used by heavy rail vehicles under the operational conditions of the light rail system, where it is necessary for the purposes of connectivity of those vehicles only; and
- (d) vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit to be effected on a confined and limited section of heavy rail infrastructure for connectivity purposes only.

GUIDANCE ON ECM CERTIFICATION PROCESS





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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