

NEW ECM REGULATION (EU) 2019/779 IMPACT FOR ECMs ALREADY CERTIFIED UNDER (EU) 445/2011

31.05.2021

Report for certified ECMs of freight wagons

This UIP report should facilitate the transition to the new ECM regulation 2019/779/EU for companies already certified as ECM under regulation 445/2011/EU. The report has been prepared with the support of the TC Interoperability and Safety and is structured as follows:

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1 Introduction

This UIP report aims at supporting freight wagon keepers in **understanding the impact of Commission Regulation (EU) 2019/779 of 16 May 2019 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 (hereinafter **New ECM regulation**)**. It shall help freight wagon keepers certified as ECM to identify and meet the requirements of the New ECM regulation when applying for an update or a new certification of their maintenance system. *Commission Regulation (EU) No 445/2011* (hereinafter **Old ECM regulation**) was repealed by 30th of October 2020.

The UIP report also provides some insights on the impact the New ECM regulation may have on the certification of outsourced maintenance functions, or parts thereof.

This document must be understood as complementary guidance to any guidelines and/or schemes established by the Agency and may not be used in place of any legal requirements and shall not be used as interpretation¹ of ECM regulation.

2 Legal context

The 3rd Railway Package and in particular Directive 2004/49/EC introduced common provisions for the safety certification of Railway Undertakings (RUs) at European level. Unfortunately, the role of the keeper had been completely forgotten, leaving a hole in the Safety Management Systems (SMS) to be implemented by the RUs. As such, some Member States refused to issue any safety certificate according to Article 10 of Directive 2004/49/EC if RUs, within the frame of their SMS, were unable to demonstrate how the freight wagons integrated in their trains would meet the applicable maintenance requirements. To ensure a common and clear allocation responsibility regarding the maintenance of railway vehicles, a new Article 14a "Maintenance of Vehicles" was then inserted into Directive 2004/49/EC by Directive 2008/110/EC.

This article stipulates among others that:

- (paragraph 1) Each vehicle shall have an entity in charge of maintenance assigned to it and this entity shall be registered in the NVR;
- (paragraph 4) Each entity in charge of maintenance shall be certified for the maintenance of freight wagons (ECM Certification).

As it was clear that defining a proper certification scheme would require time, some Member States signed an MoU establishing the basic principles of a common system of certification of entities in charge of maintenance in May 2009.

With the entry into force of Commission Regulation (EU) 445/2011, the mandatory certification of ECM for freight wagons registered in an NVR (national vehicle register) became reality in May 2013. In parallel, to avoid rail freight business being severely disrupted, the three associations ERFA/UIC/UIP with the support of ERA introduced the concept of the "Keeper's ECM declaration" to address the problem of retrieving the relation between Wagon(number), Keeper and the certified ECM.

With the implementation of the 4th Railway Package and the introduction of the new Implementing Regulation (EU) 2019/779, the principle of the mandatory ECM certification has been extended to all ECMs irrespective of the categories of vehicles they are in charge of. This includes ECMs of passenger trains, locomotives, on-track machines, and any other vehicle to be used on the mainline.

Under the New ECM regulation, RUs holding a safety certification are not required to obtain an ECM certificate in relation to vehicles for which they are the ECM and the exclusive operator. Such RUs can demonstrate compliance with Annex II of Regulation 2019/779 during the safety certification process. However, if the vehicles might be operated by another RU, then it must under the new ECM regulation also obtain an ECM certificate².

Finally, following the COVID outbreak, the European Commission recognised in May 2020 the need to postpone the application of Article 4 of (EU) 2019/779 relating to the management of Safety-

¹ https://europa.eu/european-union/about-eu/institutions-bodies/court-justice_en

² See point 5.3 of the ECM Guidelines ERA version 9

Critical Components (SCC) and the use of the Safety Alert IT tool (SAIT) by one year until 16th of June 2021. Commission Regulation (EU) 2020/780 of 12 June 2020 provides the respective legal basis.

2.1 Safety Directive

The Railway Safety Directive (EU) 2016/798 defines the following objective in paragraph 34 of its introduction: *“The entity in charge of maintenance should be certified for freight wagons. Where the entity in charge of maintenance is an infrastructure manager, this certification should be included in the procedure for safety authorisation. The certificate issued to such an entity should guarantee that the maintenance requirements of this Directive are met for any freight wagon for which it is responsible. That certificate should be valid throughout the Union and should be issued by a body able to audit the maintenance system established by the entity. As freight wagons are frequently used in international traffic, and as the entity in charge of maintenance may want to use workshops established in more than one Member State, the certification body should be able to implement its controls throughout the Union. The Agency should evaluate the system of certification of the entity in charge of maintenance for freight wagons and should, if appropriate, recommend its extension to all rail vehicles.”*

Art. 14.3 of the Railway Safety Directive (EU) 2016/798 establishes the basis of the maintenance system approach, defining maintenance functions and the responsibility of the ECM as follows:

The entity in charge of maintenance shall carry out the management function itself but may outsource the maintenance functions referred to in points (b) to (d), or parts thereof, to other contracting parties such as maintenance workshops.

The entity in charge of maintenance shall ensure that all the functions set out in points (a) to (d) comply with the requirements and assessment criteria set out in Annex III.

Maintenance workshops shall apply relevant sections of Annex III as identified in the implementing acts adopted pursuant to point (a) of paragraph 8, which correspond to the functions and activities to be certified.

2.2 Commission Regulation on ECM

(EU) 2019/779 is replacing (EU) 445/2011 by 16 June 2020. Triggers for this update have been:

- Extension of scope to all railway vehicles
- Focus on exchange of information via among others content of the annual report, 1st maintenance file, use of SAIT tool, ...
- Focus on Safety Critical Components
- Focus on risk management approach by using CSM-RA.
- Focus on difference between release to service & return to operation.

According to Art. 14.3 of the Railway Safety Directive (EU) 2016/798, the Maintenance system is composed of a main management function (ECM-F1) supporting 3 core function activities [maintenance development function (ECM-F2), fleet-maintenance management function (ECM-F3) & maintenance delivery function (ECM-F4)]. Detailed provisions to be followed by each function are laid down in the ECM Regulation.

Consequently, detailed provisions need to be applied by all actors acting in a maintenance chain, resulting in a mandatory certification for all entities appointed as ECM in a Vehicle Register and by a voluntary certification for all entities providing services in respect of ECM-F2, ECM-F3 & ECM-F4 to an ECM (maintenance functions outsourced by an ECM).

2.3 Relationship Safety Directive & ECM Regulation

Safety Directive (EU) 2016/798 is mainly tackling the topic of ECM under its art. 14 related to the ‘Maintenance of vehicles’.

Being compliant with New ECM Regulation does not relieve an ECM from applying those Safety Directive provisions which apply to its business.

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Moreover, Annex III is defining high level requirements and assessment criteria for organisations applying for an ECM certificate or a certificate in respect of maintenance functions outsourced by an ECM.

Railway Safety Directive (EU) 2016/798 Annex III:

'The organisation management must be documented in all relevant parts and shall in particular describe the distribution of responsibilities

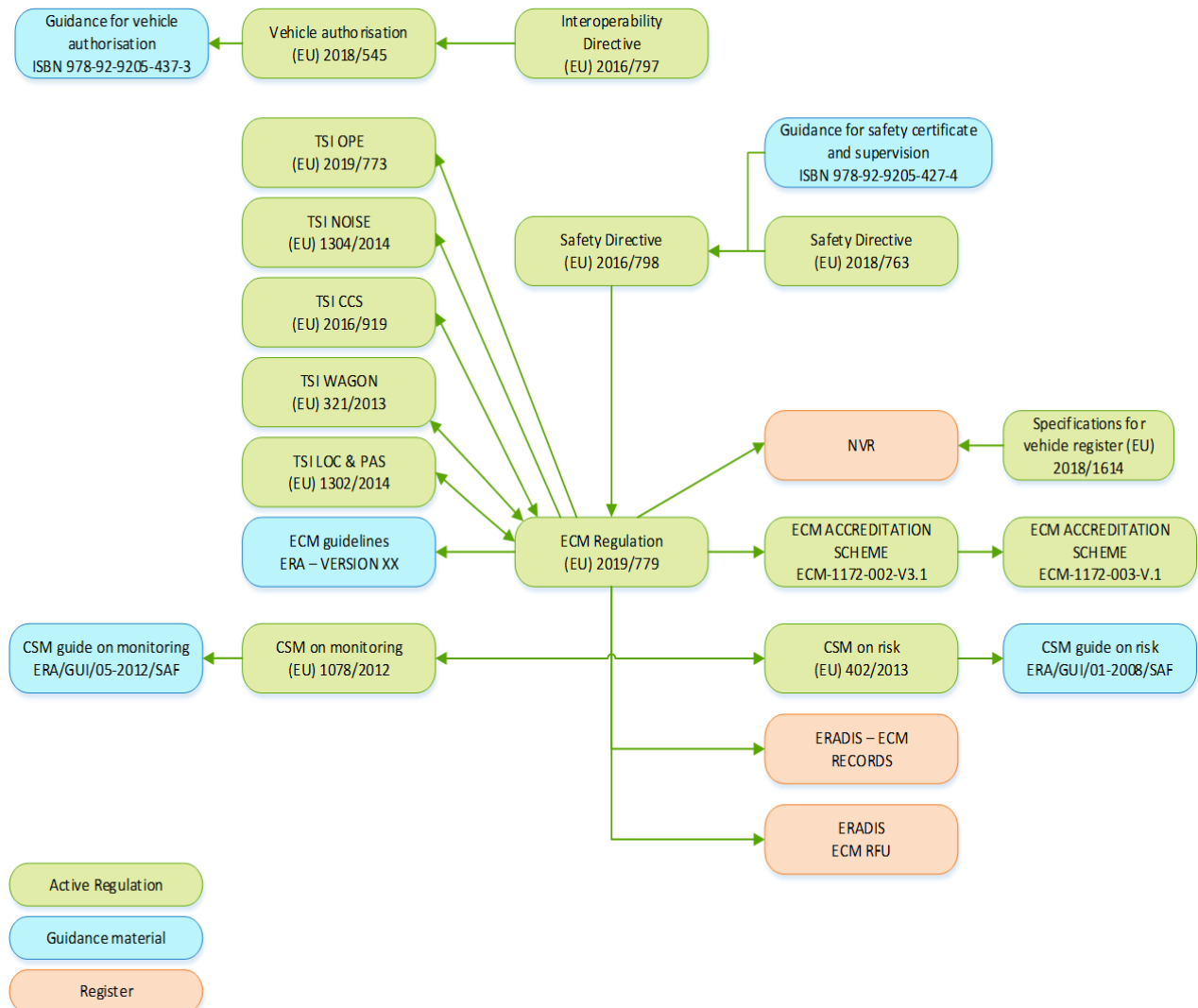
within the organisation and with subcontractors. It shall show how control by the management on different levels is secured, how staff and their representatives on all levels are involved and how continuous improvement is ensured.'

Correlation table between Annex III of Safety Directive & Annex II of ECM regulation is provided below.

Topic	Safety Directive (EU) 2016/798 Annex III	ECM Regulation (EU) 2019/779 Annex II
Leadership	1	I.1.a
Risk Assessment	2	I.2
Monitoring	3	I.3
Continuous improvement	4	I.4
Structure and responsibility	5	I.5
Competence management	6	I.6
Information	7	I.7
Documentation	8	I.8
	8	II.7
	8	III.10
Contracting activities	9.a	I.9
	9.b	I.9.2
Maintenance activities	10.1.a	II.1.a
	10.1.b	II.1.b
	10.1.c	II.2.d
	10.2	II.2
	10.3	II.3
	10.4.a	II.4.b
	10.4.b	III.2
	10.5	III.8
	10.5.a	III.8.c
	10.5.b	III.8.d
	10.5.c	III.8.e
	10.5.d	III.8.f
	10.6	IV.3
	10.6.a	IV.3.a
	10.6.b	IV.3.b
	10.7	IV.5
Control activities	11.1	III.4
	11.2	III.5
	11.3	IV.6
	11.4	I.3.4
	11.5	I.3.3

2.4 Supporting documents established by ERA

The relationship between the New ECM Regulation and the legal framework of the Technical Pillar of the 4th Railway Package is described in §2.2. of the ERA ECM Guide



2.5 Equivalence with OTIF Framework

Equivalence to the New ECM Regulation is provided at OTIF level by ATMF-A based on Appendix G to COTIF 1999 (ATMF).

All prescriptions & other rules established by OTIF are available under the following link:
http://otif.org/en/?page_id=194

Note: New ATMF Annex A aligned with the New ECM Regulation enters into force and will be applicable as of 01.04.2021.

2.6 Definitions

Only definitions impacted / clarified by the New ECM Regulation are listed in the table hereunder. For other definitions, please refer to the corresponding legal texts.

Release to service	Means the justified and recorded assurance, accompanied by documentation where appropriate, given by the entity delivering the maintenance to the fleet-maintenance manager that maintenance has been delivered according to the maintenance orders	(EU) 2019/779 art. 2.c
Return to operation	Means a notice given to the user, such as a railway undertaking or a keeper, by the entity in charge of maintenance, based on a release to service, assuring that all appropriate maintenance works have been completed and the vehicle, previously removed from operation, is in a condition to be used safely, possibly subject to restrictions of use	(EU) 2019/779 art.2.d
Safety-critical component	Safety critical components are components for which a single failure has a credible potential to lead directly to a serious accident as defined in Article 3(12) of Directive (EU) 2016/798	Annex of (EU) 1302/2014 - section 4.2.12.1 modified by (EU) 2019/776 Annex IV (39)
Serious accident	Means 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	EU) 2016/798 Art. 3 (12)

3 Gap analysis between (EU) 2019/779 & (EU) 445/2011

A Gap analysis between the New and Old ECM regulations is presented in the table below.

Updates and new parts have been marked in red in the text.

Extracts from the New ECM Regulation are on the left and corresponding ones of OLD Regulation are on the right side.

3.1 Updated requirements

3.1.1 Core text regulation

(EU) 2019/779	(EU) 445/2011
5. Obligations of parties involved in the maintenance process	<i>Completely redrafted</i>
7.1 The entity in charge of maintenance shall apply for ECM certification to a certification body. It shall use the relevant form in Annex III and provide documentary evidence for the requirements and procedures set out in Annex II. The application shall include the description of the strategy to ensure continued compliance with the requirements set out in Annex II, after the award of the ECM certification, including the compliance with Commission Regulation (EU) No 1078/2012	7.1. Certification shall be based on an assessment of the ability of the entity in charge of maintenance to meet the relevant requirements in Annex III and to apply them consistently. It shall include a system of surveillance to ensure continuing compliance with the applicable requirements after award of the ECM certificate.
7.3 The applicant shall submit supplementary information and documentation at the request of the certification body. The timeframe for providing supplementary information shall be reasonable, proportionate to the difficulty of providing the information requested and agreed with the applicant upon request.	7.2. The entities in charge of maintenance shall apply for certification using the relevant form in Annex IV and providing documentary evidence of the procedures specified in Annex III. They shall promptly submit all supplementary information requested by the certification body. In assessing applications, certification bodies shall apply the requirements and assessment criteria set out in Annex III.

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(EU) 2019/779	(EU) 445/2011
8.1 The certification body shall conduct surveillance activities in respect of the entity in charge of maintenance to verify continued compliance with the requirements set out in Annex II. It shall conduct site visits at least once every 12 months. The choice regarding the nature of surveillance activities and sites to be visited shall aim at ensuring overall continuing compliance and shall be based on a geographical and functional balance. It shall take account of previous surveillance activities of the entity in charge of maintenance under surveillance	7.6. The certification body shall conduct surveillance at least once a year at selected sites, geographically and functionally representative of all the activities of those entities in charge of maintenance it has certified, to verify that the entities still satisfy the criteria set out in Annex III.
10.3 In assessing applications for certification in respect of outsourced maintenance functions or parts thereof, certification bodies shall apply:	8.2 In assessing applications for certificates in respect of outsourced maintenance functions, or parts of them, certification bodies shall follow the principles set out in Annex I.
10.3.a) the requirements and assessment criteria set out in Section I of Annex II, adapted to the organisation's type and extent of service	
10.3.b) the requirements and assessment criteria describing the specific maintenance function or functions.	

3.1.2 Annex II

Many provisions have been updated by using the wording 'shall' instead of 'must'. These updates have not been listed below.

Other updated requirements listed below are not changed content wise, nevertheless it is recommended to check consistency of your

maintenance system to assure alignment with the New ECM regulation.

(EU) 2019/779	(EU) 445/2011
1.2.2. The organisation shall have risk management procedures to manage changes in the maintenance file, including maintenance plans , equipment, procedures, organisation, staffing or interfaces, and to apply the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 .	1.2.3. The organisation must have risk management procedures to manage changes in equipment, procedures, organisation, staffing or interfaces, and to apply Commission Regulation (EC) n° 352/2009.

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(EU) 2019/779	(EU) 445/2011
I.7.1. The organisation shall have procedures to define reporting channels to ensure that, within the entity itself and in its dealings with other actors, including infrastructure managers, railways undertakings, keepers and designers or manufacturers of vehicles or components, or both, when appropriate , information on all relevant processes is duly exchanged and submitted to the person having the right role both within its own organisation and in other organisations, in a prompt and clear way.	I.7.1. The organisation must have procedures to define reporting channels to ensure that, within the entity itself and in its dealings with other actors, including infrastructure managers, railways undertakings and keepers, information on all relevant processes is duly exchanged and submitted to the person having the right role both within its own organisation and in other organisations, in a prompt and clear way.
I.7.3.g) made known to staff in accordance with their responsibilities , before it is applied;	
II.2.b) verifying in all circumstances the consistency of the maintenance file with the authorisation related to the vehicle (including any national safety requirements), including the conformity to the technical file and the type of records as in the European Register of Authorised Types of Vehicles (ERATV);	II.2.b) verifying in all circumstances the consistency of the maintenance file with the authorisation of placing-in-service (including any national safety requirements), the declarations of conformity to TSIs, the declarations of verification, and the technical file.
II.2.d) identifying the need for risk assessment of the potential impact of the change in question on the safety of the railway system, by application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798;	II.2.d) identifying the need for risk assessment regarding the potential impact of the substitution in question on the safety of the railway system;
II.4.b) analyse those recommendations for maintenance of the initial documentation and to provide, by application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798, the first maintenance file , also taking into account the information contained in any associated guarantees;	II.4.b) analyse the initial documentation and to provide also taking into account the information contained in any associated guarantees;
II.5.a.i) the type and extent of operations effectively performed, including, but not limited to accidents, serious accidents and incidents, as defined in Directive (EU) 2016/798;	II.5.a.i) the type and extent of operations effectively performed, including, but not limited to operational incidents with a potential to affect the safety integrity of the freight wagon

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(EU) 2019/779	(EU) 445/2011
II.5.c) make proposals for and approve changes and their implementation, with a view to a decision based on clear criteria, taking into account the findings from risk assessment performed by application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798;	II.5.c) make proposals for and approve changes and their implementation, with a view to a decision based on clear criteria, taking into account the findings from risk assessment
II.6.a) application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 for assessment of changes of the maintenance file;	II.6.a) assessment of the significance of changes for the maintenance file and proposed substitutions in the course of maintenance;
II.7.b) the configuration of vehicles, including, but not limited to, safety-critical components and on-board software modifications;	II.7.b) the configuration of vehicles, including, but not limited to, components related to safety
III.4. The organisation shall have a procedure to manage the removal of vehicles from operation for maintenance or when safe operation is impaired or when needs of maintenance affect the normal operation.	III.4. The organisation must have a procedure to manage the removal of freight wagons from operation for maintenance or when a defect have been identified.
III.6. The organisation shall have a procedure to issue a notice of return to operation, including the definition of restrictions of use to ensure the safe running by taking into account the release to service documentation.	III.6. The organisation must have a procedure to issue a notice of return to operation, taking into account the release to service documentation.
III.7. When the competence management process is applied to the fleet maintenance management function, at least the return to operation shall be taken into account including defining the restriction of use.	III.7. When the competence management (CM) process is applied to the fleet maintenance management function, at least the return to operation must be taken into account.
III.8.g) application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 for assessing changes affecting the fleet maintenance management function.	III.8.g) all additional relevant information related to safety according to the risk assessment performed by the organisation.
III.9. When the information process is applied to the fleet maintenance management function, interested parties shall be at least informed of the return to operation, including restrictions on use relevant to users (railway undertakings and infrastructure managers).	III.9. When the information process is applied to the fleet maintenance management function, at least the return to operation, including restrictions on use relevant to users (railway undertakings and infrastructure managers, needs to be communicated to interested parties

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(EU) 2019/779	(EU) 445/2011
NIHIL	IV.1.d) ensure that all relevant maintenance specifications, as defined in applicable regulations and specified standards contained in the maintenance orders, are available to all involved staff (e.g. they are contained in internal working instructions).
IV.6. The organisation shall have procedures to check that performed tasks are in accordance with the maintenance orders and to issue the notice of release to service. The notice of release to service shall include all information that is useful to define restrictions of use.	IV.6. The organisation must have procedures to check that performed tasks are in accordance with the maintenance orders and to issue the notice of release to service that includes eventual restrictions of use.
IV.8. When the competence management process is applied to the maintenance delivery function, at least the following activities affecting safety where appropriate shall be taken into account:	IV.8. When the competence management process is applied to the maintenance delivery function, at least the following activities affecting safety must be taken into account:
IV.10. When the documentation process is applied to the maintenance delivery function, at least the following elements shall be recorded for the maintenance activities affecting safety, as referred to in point 1(a) of Section II:	IV.10. When the documentation process is applied to the maintenance delivery function, at least the following elements must be recorded

3.2 New requirements

3.2.1 Core text regulation

(EU) 2019/779	(EU) 445/2011
1.2 It applies to all vehicles and introduces the possibility for certification of outsourced maintenance functions.	
4. Safety-critical components	
4.1 For managing safety-critical components, the entity in charge of maintenance shall take into account the initial identification of safety-critical components by the manufacturer of the vehicle together with any specific maintenance instructions recorded in the technical files of subsystems referred to in Article 15(4) of Directive (EU) 2016/797.	
4.2 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.	

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(EU) 2019/779	(EU) 445/2011
4.3 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.	
4.4 To confirm if the component is safety critical the manufacturer, when it can be identified, shall perform a risk assessment. It shall take into account the component's intended use and the environment in which it is intended to be used. As appropriate, the entity in charge of maintenance shall adjust its maintenance procedures to ensure monitoring and the safe maintenance of the component.	
4.5 Safety critical components including those identified under paragraph 4 above, shall be recorded in and managed through the relevant vehicle documentation as follows:	
4.5.a) manufacturers shall manage 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; and	
4.5.b) entities in charge of maintenance shall manage safety critical components and appropriate maintenance instructions as well as relevant maintenance activities in the maintenance file or documentation referred to in Article 14 of Directive (EU) 2016/798.	
4.6 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.	
4.7 At the request of the entity in charge of maintenance or of the keeper of the vehicle, the manufacturers shall provide technical and engineering support for safety-critical components and their safe integration.	
7.2 The application for ECM certification may be limited to a specified category of vehicles	
8.4 In case of revocation of an ECM certification, the entity in charge of the national or European vehicle register shall ensure suspension of the registration of vehicles affected by the revocation, until a new entity in charge of maintenance is registered for the vehicles concerned	
8.5 Each entity in charge of maintenance shall submit an annual report of its activities to its certification body and make it available to the national safety authority and to the Agency upon request. The requirements for this report are set out in Annex V.	
Annex V. Report of the entity in charge of maintenance	
9. Outsourcing maintenance functions	

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(EU) 2019/779	(EU) 445/2011
9.1 One or more of the functions referred to in points (b), (c) and (d) of Article 14(3) of Directive (EU) 2016/798, or parts thereof, may be outsourced and the certification body shall be informed thereof.	
9.2 The entity in charge of maintenance shall demonstrate to the certification body how it complies with all the requirements and assessment criteria set out in Annex II with regard to the functions it decided to outsource	
9.3 The entity in charge of maintenance shall remain responsible for the outcome of the outsourced maintenance activities and shall establish a system to monitor their performance	
12. Cooperation with the certification bodies	

3.2.2 Annex II

(EU) 2019/779	(EU) 445/2011
II.1.a) all maintenance activities affecting safety	
II.1.b) all safety-critical components.	
II.5.a.ii) the detected failures on components	
II.5.e) monitor the effectiveness of the changes through a process in consistency with the methods for assessing the safety level and the safety performance of railway operators at national and Union level as adopted pursuant to point (d) of Article 6(1) of Directive (EU) 2016/798.	
II.6.c) maintenance activities on safety-critical components	
IV.8.e) maintenance activities on safety-critical components	

4 Guidance to update an already certified maintenance system

4.1 Implementation of Maintenance Function(s) requirements

When performing maintenance activities for railway vehicles and their components, all the requirements of function I need to be considered in the maintenance system of each actor. In addition, the requirements from functions II, III and/or IV have to be considered according to their business needs.

4.2 Monitoring

Even if IMs and ECMs are not directly obliged by the New ECM Regulation to apply Regulation (EU) 1078/2012 on a CSM for monitoring, it remains the recommended tool for controlling activities required by Annex III point 11 and Article 6(1) point (c) of the Safety Directive.

Being compliant with the New ECM Regulation does not relieve an ECM from applying these Safety Directive provisions relevant to its business.

For more information on the relationship between Safety Directive and New ECM Regulation, please refer to chapter 2.3 of this document.

The New ECM Regulation refers twice, in Annex II points I.3.4 and II.5, to the methods for assessing the safety level and the safety performance of railway operators at national and Union level. However, the network of Cooperation of ECM Certification Bodies adopted an ECM Recommendation For Use (RFU)³ clarifying that this reference should instead refer to the CSM on Monitoring and be read as follows: *"the methods for monitoring to be applied by railway undertakings, infrastructure managers and entities in charge of maintenance as adopted pursuant to point (c) of Article 6(1) of that Directive [(EU) 2016/798]"*. The CSM Monitoring is dealing with the methodologies to be applied for assessing and monitoring the effectiveness of the maintenance system.

4.3 Exchange of information

Annex II of the New ECM Regulation requires an exchange of information between each maintenance function applying to all maintenance activities.

7.1 of the New ECM Regulation

"The organisation shall have procedures to define reporting channels to ensure that, within the entity itself and in its dealings with other actors, including infrastructure managers, railways undertakings, keepers and designers or manufacturers of vehicles or components, or both, when appropriate, information on all relevant processes is duly exchanged and submitted to the person having the right role both within its own organisation and in other organisations, in a prompt and clear way."

New ECM regulation Annex II, I.7.4:

The requirements set out in points 7.1, 7.2 and 7.3 apply in particular to the following operational information:

(a) checks of the accuracy and completeness of national vehicle registers regarding the identification (including means) and registration of the vehicles maintained by the organisation.

(b) maintenance documentation.

(c) information on support provided to keepers and, where appropriate, to other parties, including railway undertakings/infrastructure managers.

(d) information on the qualification of staff and subsequent supervision during maintenance development.

(e) information on operations (including mileage, type and extent of activities, incidents or accidents) and requests of railway undertakings, keepers and infrastructure managers.

(f) records of maintenance performed, including information on deficiencies detected during inspections and corrective actions taken by railway undertakings or by infrastructure managers such as inspections and monitoring undertaken before the departure of the train or en route.

(g) release to service and return to operation.

³ RFU 30.1 Clarification on references to point (d) of Article 6(1) of the Directive (EU) 2016/798, adopted on 26/05/2021, available online on the ERADIS Website

(h) maintenance orders.

(i) technical information to be provided to railway undertakings/infrastructure managers and keepers for maintenance instructions.

(j) emergency information concerning situations where the safe state of running is impaired, which may consist of:

(i) the imposition of restrictions of use or specific operating conditions for the vehicles maintained by the organisation or other vehicles of the same series even if maintained by other entities in charge of maintenance, whereby this information shall also be shared with all involved parties.

(ii) urgent information on safety-related issues identified during maintenance, such as deficiencies detected in a component common to several categories or series of vehicles.

(k) all relevant information or data needed to submit the annual maintenance report to the certification body and to the relevant customers (including keepers), whereby this report shall also be made available upon request to national safety authorities.

Chapter 4.2.10.2. of the Annex of Regulation (EU) 1305/2014 on TSI relating to telematics applications for freight subsystem (TAF TSI) requires that

“The keeper of a rolling stock is responsible for the storage of the rolling stock data within a Rolling Stock Reference Database data.

The Information that must be included in the individual Rolling Stock Reference Databases is described in detail in Appendix I, Appendix C. They must contain all items for:

- Identification of rolling stock,
- Assessment of the compatibility with the infrastructure,
- Assessment of relevant loading characteristics,
- rake relevant characteristics,
- **Maintenance data,**
- Environmental characteristics

*The Rolling Stock Reference Databases must allow easy access (a single common access provided via the common interface) to the technical data to minimise the volume of data transmitted for each operation. Contents of the Databases must be accessible, based on structured access rights depending on privilege to all Service Providers (IMs, RUs, Logistic providers and Fleet managers) **in particular for purposes of fleet management and rolling stock maintenance**”.*

4.3.1 Release to service (IV -> III)

Release to service is a maintenance activity allocated to maintenance Function IV.

As Article 19 GCU is fully compliant⁴ with the applicable EU and COTIF ECM certification requirements, it is relevant to remind of the obligation of the acting RU in accordance with Art.19.5 GCU⁵ to “provide detailed information of the work carried out to the keeper’ allowing the keeper and – via the chain of responsibility established in Article 7.2 GCU – the ECM to monitor and evaluate the process and to initiate any corrective measures that may seem appropriate.

Art. 19.5 GCU

“In cases where the RU carries out measures in application of the provisions of Appendix 9, it shall do so with qualified staff and all due care. In the context of the preceding provision, “qualified staff” (operations staff) means staff possessing the competences and authorisations to take corrective measures, described in the RU’s safety management system (SMS).

Repair work in application of the provisions of Appendix 10 may only be performed by approved workshops.

4

<https://www.gcubureau.org/documents/10184/0/Statement+of+GCU+JC+r e++Art+19+5+GCU+and+ECM.pdf/247659f9-8b52-405c-80a4-fedf9c11ca91>

5

https://www.gcubureau.org/documents/10184/86786/20200101_GCU_EN .pdf/fede7003-008b-4d61-99d3-6cfc38876289

Approved workshops are:

- Workshops which have a valid certificate for an entity in charge of maintenance (ECM certificate) containing the maintenance delivery function as a minimum,

and

- are listed in the European Railway Agency Database of Interoperability and Safety (ERADIS)

and

- which are conversant with Appendices 7, 9, 10 and 13 to the GCU and instruct their employees on changes to the GCU on a regular basis.

The RU or his auxiliary must inform the keeper of the work performed, using the codes provided in Appendix 10, Annex 6.”

Therefore, structured exchange of information is supported by GCU Appendix 10⁶ on Wagons – Corrective and Preventive Maintenance, while Annex VI provides the codification of interventions performed on the wagon.

4.3.2 Return to operation (III -> RU)

Return to operation is a maintenance activity allocated to maintenance Function III.

Provisions on this activity are also defined in the TAF TSI.

Chapter 4.2.10.3 on Rolling Stock Operational Data of the Annex of Regulation (EU) 1305/2014 on TSI relating to telematics applications for freight subsystem (TAF TSI) requires that

“Beside the reference data for rolling stock, the data representing the actual status of the rolling stock is the most important data for operational purposes.

This data shall include temporary data, such as restrictions, current and projected maintenance actions, km and fault counters, etc.; and all data that could be considered as ‘status’ (temporary speed restrictions, brake isolated, needs for repair and fault description, etc.).

The operational rolling stock data is a part of the Wagon and Intermodal Unit Operational Database as described in Chapter 4.2.11.2 Other Databases”.

Today, no formal transmission of information between the ECM and RU is neither required nor foreseen. In practice, the markings on the wagon contain all the necessary information. In case of technical restrictions affecting operations, the ECM has the responsibility to inform the RU either directly or via the keeper.

Related obligations are also part of the GCU under Art. 7.2:

“Upon request, the keeper shall make available to any user RU without delay reliable information about maintenance (including Maintenance File and Maintenance Record File) and restrictions affecting operations, necessary and sufficient to support safe operations. For the purposes of this contract and vis-à-vis the other signatories, the keeper is considered to be, and have the responsibilities of, the ECM for his wagons.”

In addition, the General Contract of Use, in the framework of digitisation (the process of converting information from a physical format into a digital one), implements an additional method for complying with this obligation in the new Art. 7.4 (introduced in 2019):

“The keeper must provide the impacted user railway undertakings with the information on its wagons required for safe railway operations in electronic format as soon as possible. The provision of this information and additional data - where relevant - is provided for in Appendix 16.”

- In case of maintenance work initiated by a RU

In the case of maintenance works initiated directly by the user RU, based on art. 19 GCU, information on the return to operation has to be provided from the RU acting in a maintenance Function III. as reflected in Art. 19.4 GCU:

“The RU that initiated the maintenance in accordance with Appendix 10 shall check whether and to what extent the work requested has been

⁶ <https://www.gcubureau.org/documents/10184/67575/20170101+-+EN+-+GCU+appendix+10.pdf/04323a44-8177-4624-94e8-bec5b3e37f72>

completed on the basis of information received from the workshop.

Any restrictions on use (e.g., fitness to run, fitness for service) that become apparent after the repairs must be documented by the RU.

On completion of the repairs and failing any specific instructions from the keeper, the RU shall forward the wagon to the destination station for which it was initially bound."

To allow the ECM to document the maintenance works performed on its wagons, the RU must also inform the responsible ECM, either directly or via the keeper, about the extent of the intervention. Again, Appendix 10, Annex 6 GCU provides as a general solution:

"Coding of Interventions

This list comprises the interventions possible under the GCU. They must be communicated to the keeper by the RU or its auxiliary performing the work, using the coding given in column 2. All interventions are to be communicated, irrespective of the type of damage concerned. Codes shall be indicated on the invoice and/or sent separately to the keeper. Any additional information necessary and measurement values may be communicated with the codes or in a separate list. All reports mentioned shall be sent immediately."

- In case of maintenance work initiated by an ECM

When an ECM mandates a workshop to perform maintenance work, the ECM will collect and exchange information by applying its procedure according to:

Annex II, requirement III.6 of the New ECM regulation

"The organisation shall have a procedure to issue a notice of return to operation, including the definition of restrictions of use to ensure the safe running by taking into account the release to service documentation."

For this purpose, provisions of VPI08 Electronic data interchange are considered as a relevant means of compliance.

4.3.3 SAIT

Implementing Regulation (EU) 2020/780 amending Old and New ECM Regulations as regards measures to extend the validity of certain certificates of rail entities in charge of maintenance and certain transitional provisions due to the COVID-19 pandemic states in Art. 2 that:

"Implementing Regulation (EU) 2019/779 is amended as follows:

.....

It shall apply from 16 June 2020. However, Article 4 shall apply from 16 June 2021 and Article 15(6) shall apply from 1 March 2020."

Consequently, the application of Art. 4, including paragraph 6, of the New ECM Regulation regarding Safety-critical components (SCC) is postponed to 16 June 2021.

New ECM Regulation, Art.4.6

"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."

During the 1st ERA Task Force dedicated to SAIT, the Agency confirmed that the scope of Art.4 of the New ECM Regulation, is not limited to SCC but covers all unexpected safety relevant findings relating to maintenance activities.

Even if the mandatory use of SAIT⁷ is postponed to June 2021, it is highly recommended that each actor performing maintenance work should get access to the SAIT tool before Art 4.6 enters into force.

⁷ <https://webgate.ec.europa.eu/multisite/safetyalerts/>

Knowing that the tool is not yet fit for purpose, the Group of Representative Bodies (www.grbrail.eu) urged the Agency to launch a task force in order to allow all ECMs to make coherent use of the tool for exchanging new or unexpected safety relevant findings, including exceptional maintenance findings beyond wear and tear, in relation to vehicles, subsystems or other components.

For UIP, the actual guidelines⁸ are not sufficient to ensure an efficient and coherent use of the tool. In addition, the interfaces between SAIT, the JNS procedure and the new CSM ASLP still have to be clearly defined.

UIP, together with the other Representative Bodies, is currently working on providing detailed guidance “from the sector for the sector” on the use of SAIT and continues lobbying for sufficient resources for the tool against the background of the recent ERA budget cuts.

4.3.4 Contract management with manufacturer

Chapter 4.5 on maintenance rules of the Annex of the TSI WAG requires actors to exchange information. Those provisions include at contract management level also relationships with manufacturers, considering that as long as a manufacturer is able to build a wagon or a component, he is able to provide first maintenance plans and update them during the lifecycle and provide any other information from similar vehicles relevant for maintenance purpose of delivered wagons or components.

Nevertheless, the responsibility and liability of a manufacturer regarding a product he puts on the market remains applicable.

4.4 Management of competences

Annex II of the New ECM regulation sets out requirements on the competence management of each maintenance function when appropriate and in general terms:

4.4.1 Staff involved in safety-relevant tasks

New ECM Regulation Annex II, I.6.1

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

(a) the identification of posts with responsibility for performing within the system all the processes necessary for compliance with the requirements of this Annex.

(b) the identification of posts involving safety tasks.

(c) the allocation of staff with the appropriate competence to relevant tasks.”

The Identification of personal involved in safety-relevant tasks is key and requires each ECM to have an overview of the complete maintenance chain(s) and the organisation of each actor(s) involved in it. Moreover, this is a key issue in case of the outsourcing of maintenance functions according to Art. 9 New ECM Regulation.

New ECM Regulation Art. 9.3 and Annex II

“The entity in charge of maintenance shall remain responsible for the outcome of the outsourced maintenance activities and shall establish a system to monitor their performance.”

ECM staff performing activities on the national network are required to comply with national legislation, e.g. the requirements for ECM staff working on the national rail network.

Consequently, the ECM needs to be aware of the corresponding national regulations that may apply to its staff and needs to implement corresponding measures in its maintenance system.

Enhancing the identification of such regulations and national safety rules related to personnel performing safety-related activities, will be classified as type 5 rules in the SRD database.

Hereinafter, without being exhaustive, some examples of types of posts/activities involving safety tasks are provided.

⁸ https://webgate.ec.europa.eu/multisite/safetyalerts/page/guidelines_en

■ Function II

List based on New ECM Regulation Annex II, II.6

1. Example: Activities related to the change management
2. Example: Activities related to application of CSM-RA
3. Example: Activities on safety-critical components
4. Example: Activities on joining techniques (including welding and bonding)
5. Example: Activities on non-destructive testing

■ Function III

List based on New ECM Regulation Annex II, III.7

1. Example: Activities related to return to operation

■ Function IV

List based on New ECM Regulation Annex II, IV.8

1. Example: Activities on joining techniques (including welding and bonding)
2. Example: Activities on non-destructive testing
3. Example: Activities related to final vehicle testing and release to service.
4. Example: Activities on brake systems, wheel sets and draw gear
5. Example: Activities on specific components of freight wagons for the transport of dangerous goods, such as tanks, valves, etc.
6. Example: Activities on safety-critical components.
7. Example: Activities performed on national rail network.

4.4.2 Competence management system (CMS)

New ECM regulation Annex II, I.6.2

“Within the organisation's competence management system, there shall 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.”

Even if the minimum content of CMS is defined by the above requirements at function I level, a key issue for most of the ECMs is the interface with contractors and suppliers for safety-related products and services, according to point 9.2 of chapter I of Annex II New ECM Regulation. This is similar to the point related to the responsibilities of the ECM to its subcontractors.

New ECM Regulation Annex II, I.9.2

“When making use of contractors or suppliers, or both, for safety-related products and services, the organisation shall have procedures in place to verify at the time of selection that:

*(a) **contractors, subcontractors and suppliers are competent.***

*(b) **contractors, subcontractors and suppliers have a maintenance and management system that is adequate and documented.”***

If a subcontractor is not certified according to the New ECM Regulation, the ECM must check this provision itself.

If a subcontractor is certified according to the New ECM Regulation, the ECM shall only focus on the results of processes (including all contracted services and products).

New ECM Regulation Annex II, I.9.5

“When the maintenance or management system of a contractor or supplier is certified, the monitoring process described in point 3 may be limited to the results of the contracted operational processes referred to in point 3.1 (b).”

4.5 Safety critical components

To understand the background of the Safety Critical Components issue, please refer to the related report of ERA version 1 of 18/12/2017⁹.

The ERA ECM Guide §13 is dealing with this topic in detail.

CEN/TC 256/WG 48 in its guide on SSC is proposing a 2-step approach:

- 1st identification of the component
- 2nd Assessment of the ‘safety criticality’ of identified components.

Even if neither the railway sector nor the European institutions aim at providing an agreed single list of SCC, UIP has drafted together with the VERS guidelines on the issue and will provide, without being exhaustive, an analysis for defining Safety Critical Components relating to freight wagons, based among others on MATEC¹⁰ Web of Conferences 157 on ‘Use of risk assessment methods in maintenance for more reliable rolling stock operation’. The guidelines have been reviewed by an external 3rd party Assessment Body to confirm that the methodology applied corresponds to the requirements defined in the CSM on risk assessment (EU Regulation 402/2013).

4.6 BREXIT

The deadline for a hard Brexit ended in December 2020 and rail business was impacted even earlier as the UK did not transpose the 4th Railway Package Technical Pillar by the end of October 2020.

Here below, the dft.gov.uk message from 7 October 2020:

On 18 August, the Department shared new draft guidance on the application of the ECM Regulations

in the UK during and after the transition period ends on 31st December 2020.

We are grateful for the number of comments and views that we received on the guidance. We have now reviewed these and sought to address the comments raised in a revised version of the guidance. There were four common questions that we have sought to clarify, including the requirements that apply to different types of vehicles and what ECMs need to do to comply with them. These are listed below with our responses:

1) Will an ECM certificate issued in the EU under Commission Implementing Regulation (EU) 2019/779 be valid for both international and domestic only operations?

ECM certificates issued in the EU under Commission Implementing Regulation (EU) 2019/779 will be recognised in the UK for the purpose of operating domestic-only and international freight wagons. Existing EU ECM certificates issued under Commission Regulation (EU) 445/2011 will also be recognised in the UK for domestic-only wagons and for international traffic for their original period of validity.

This means that, after 31 December 2020, an EU ECM certificate will continue to cover both your UK domestic-only freight wagons and your international wagons. This was set out in the Department’s technical notice published in July 2020.

UK ECMs will be required to comply with Schedule 10 of The Railways and Other Guided Transport Systems (Safety) Regulations 2006 (ROGS) for domestic-only operations after the end of the transition period. If a UK ECM wishes to operate in international traffic after 31 December 2020, they will be required to comply with Commission Implementing Regulation (EU) 2019/779.

⁹

https://www.era.europa.eu/sites/default/files/library/docs/consultations/consultation_007rec1004_ecm_report_on_safety_critical_components_consultation_en.pdf

¹⁰ https://www.matec-conferences.org/articles/mateconf/pdf/2018/16/mateconf_mms2018_04002.pdf

2) Will ECM certificates issued in the UK in accordance with the retained version of Commission Implementing Regulation (EU) 2019/779 for the purposes of cross-border services be recognised for domestic operations in the UK?

ECMs assigned to vehicles used in cross-border traffic will be subject to the retained version of Commission Implementing Regulation (EU) 2019/779 after 31 December 2020. Certificates issued under this Regulation will not be recognised for the purposes of domestic operations in Great Britain. An ECM assigned to a freight wagon used in both domestic and international services will

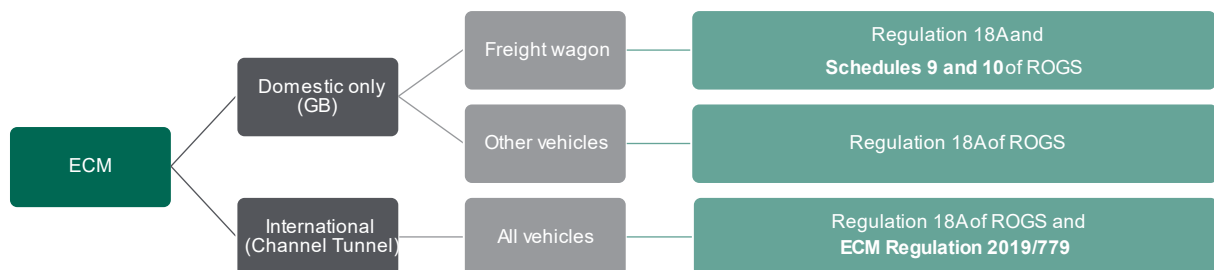
3) Can ECMs apply for ECM certification (for non-freight vehicles) under Commission Implementing Regulation (EU) 2019/779 on a voluntary basis in the UK after 31 December 2020?

Although Commission Implementing Regulation (EU) 2019/799 will be repealed except for the Channel Tunnel after 31 December 2020, ECMs operating on the GB mainland can voluntarily apply the requirements should they wish to do so. However, ECMs for freight wagons in use in domestic operations will still be required to be certified against Schedule 10 of ROGS, unless they hold an ECM certificate issued in the EU.



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ECMs: Legislation to be complied with



therefore need to hold both an ECM certificate issued in the UK in accordance with Schedule 10 of ROGS (covering domestic operations) and an ECM certificate issued in the UK in accordance with the retained version of ECM Regulation 2019/779 (covering cross-border operations). Alternatively, ECM certificates issued in the EU will be recognised in the UK for the purpose of operating domestic-only and international freight wagons.

The UK government has since issued its final version of guidance which can be accessed under <https://www.orr.gov.uk/guidance-compliance/rail/health-safety/laws/rogs/entities-charge-maintenance>

4.7 Knowledge of national laws that apply

a) To staff performing maintenance activities

As already mentioned in chapter 4.4.1 on staff involved in safety-relevant activities, an ECM needs to know the national regulations that may apply to its

staff and needs to implement corresponding measures in its maintenance system.

Some national laws may impact activities related to the first level of maintenance. This level is regulated by TSI OPE and is not on the responsibility of ECMs. Nevertheless, depending on contractual arrangements between an ECM and an RU, this level could impact the ECM organisation.

b) To the use of the vehicle

The ECM and/or RU must know the national laws which may apply to the use of the wagon as these laws may impact the maintenance system.

5 Impact of (EU)2019/779 regulation on certification activities

With regards to the certification process, no major change has been introduced by the New ECM Regulation.

Some recommendations allowing a smooth certification and/or transition process are described below.

5.1 Application

The ECM Certification scheme describes in §3.3.1 the content of the formal application to be performed by using the Annex III of the ECM Regulation and the following documents:

1) "A description of the organisational structure of the ECM applicant.

This provides the necessary information to the Certification Body on the size and complexity of the organisation. The description should contain:

- *Global organigrams of the organisation*
Human and technical resources available
Overall sites and organigrams of maintenance functions
A description of maintenance system specifying the internal entity performing the four functions described in Annex II of ECM Regulation. It also includes, where appropriate, the external entities performing any maintenance functions for the organisation.

- *For the external entities, the applicant shall indicate if they are:*
 - o *globally under its maintenance system or*
 - o *third party certified as compliant with the ECM Regulation*

The ECM applicant shall provide basic information on external entities and on the relationship and exchange with its organisation to monitor their performances.

2) *Structured description of the processes and procedures put in place by the ECM applicant and how they comply with the requirements for certification of the Annex II of ECM Regulation. The ECM applicant may provide a table/flow diagram for a better understanding of relations between its processes and the requirements stated in the Annex II of ECM Regulation.*

3) *Information on the maintenance policy relevant to the Annex II 1.1.(a) of ECM Regulation. The information should include a maintenance policy statement.*

4) *Description of the strategy to ensure continued compliance with the requirements set out in Annex II of ECM Regulation, after the award of the ECM certification, including the compliance with the CSM on Monitoring.*

5) *Information on vehicles:*

- *Structured information on vehicles the applicant is applying for ECM certification (categories, quantity, type and extent of operation planned).*

The information is based on categories of vehicles intended or planned to be maintained in the forthcoming years.

In case of application for certification of outsourced maintenance function, along with the form in the Annex III of the ECM Regulation, the applicant entity has to provide for the above information and documents as for ECM certification adapted to the function/s, or parts thereof, specifying in addition:

6) *Appropriate function/s covered and, if only parts of a function are covered,*

- *the processes/sub-functions of the related function (points of the relevant section of the function as in Annex II of ECM Regulation) covered or excluded.*

- *limitation indicating processes/parts of vehicle or component covered or excluded."*

It is recommended that each applicant for ECM certification provides as much documentation as possible to the CB together with their application form. This will reduce any ambiguity on the starting date of the 4 months period beginning from the end of the formal application review by the ECM certification body.

5.2 Assessment – Stage 1

No change regarding the initial audit for already certified entities according to the Old ECM Regulation.

Regarding the surveillance audit, the ECM Certification body shall take into account the annual report drafted according to the New ECM Regulation Annex V to be provided at least 1 month before the forecasted surveillance assessment (see ECM Certification scheme §3.3.5).

5.3 Assessment – Stage 2

Certification schemes^{11, 12} according to the Old ECM Regulation were making a distinction between the assessment of the maintenance system (Part 1) and inspections of selected processes (Part 2).

Certification schemes (ERA 1172/003 V1.1) according to the New ECM Regulation are no longer making this difference and consider inspections as an assessment method at the same level as audits.

Consequently, ECM Certification bodies could propose a 'reduced' assessment team competent to perform on-site assessments through audits and inspections activities. This could have an impact on the global certification time depending on the scope of application for ECM certification.

5.4 Certification

5.4.1 Newcomer

According to §3.3.4.2. of ERA 1172/003 V1.1 on the Decision on Certification of ECM certification scheme, a certificate may be awarded for an

outsourced maintenance function under the status of newcomer according to 3.4.8. This was only foreseen for ECM certificates in the Old ECM Regulation.

The validity of a newcomer certificate shall be limited to 1 year.

The same rules for newcomers apply also to certificates of outsourced maintenance functions as referred to in points (b), (c) and (d) of Article 14(3) of the Safety Directive and specified in Art. 9 and 10 of the New ECM Regulation.

The certification body shall clearly mention the validity of 1 year on the certificate with the mention 'newcomer – application of ECM certification scheme section 3.4.8.'

5.4.2 Certificates according to (EU) 445/2011

The transition provisions (deadlines) fixed by the New ECM regulation are explained in ERA ECM guide §8.2.

Concerning deadlines for ECM certificates for wagons delivered under the old ECM regulation, it says:

¹¹ https://www.era.europa.eu/sites/default/files/activities/docs/era_gui_092011_saf_ecm_certification_scheme_en.pdf

¹² https://www.era.europa.eu/sites/default/files/activities/docs/era_gui_112011_saf_ecm_maintenance_workshop_certification_scheme_en.pdf

‘Before 06/2020, ECM certificate for wagons delivered 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’.

There is no need to update your maintenance system prior to recertification if the scope remains the same.

5.5 Surveillance

An annual report needs to be provided to the certification body in due time (1 month prior to the surveillance activity). Elements to be included in the annual report are listed in Annex V of the New ECM Regulation. Here, the network of Cooperation of ECM Certification Bodies adopted an ECM RFU¹³ clarifying that the following four items should always be included in the report (not only in case of changes to them!):

1. defects and failures of components related to safety, referred to in Section II of Annex II, and relevant information about maintenance exchanged pursuant to Article 5(3)
2. internal audit reports
3. the agency, national safety authorities and other authorities enforcement actions or investigations including claims in accordance with Articles 8 and 12 of this legal act
4. competence management.

¹³ RFU 31.1 Clarification on point 2 of Annex V of Regulation 2019/779, adopted on 26/05/2021, available online on the [ERADIS Website](#)

6 Bibliography

Reference	Acronym
(EU) 2016/798 Directive of the European Parliament and of the Council of 11 May 2016 on railway safety And later amendments	Safety Directive
(EU) 2016/797 Directive of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system with the European Union And later amendments	IOD
(EU) 445/2011 Regulation of 10 May 2011 on a system of certification of entities on charge of maintenance for freight wagons	OLD ECM Regulation
(EU) 2019/779 Commission Implementing Regulation 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	NEW ECM Regulation
(EU) 2020/780 Commission Implementing Regulation of 12 June 2020 amending Regulation (EU) 445/2011 and Implementing Regulation (EU) 2019/779 as regards measures to extend the validity of certain certificates of rail entities in charge of maintenance and certain transitional provisions due to the COVID-19 pandemic.	
ERA 1172/003 V1.1 on certification scheme for ECM and outsourced maintenance functions under Regulation (EU) 2019/779.	ECM Certification Scheme
ECM Guidelines ERA version 9	ERA ECM Guide
The network of Cooperation of ECM Certification Bodies (CCB) has agreed on the need of a framework and methodology to formalise the seeking of consensus solutions for identified issues. For this purpose, the CCB network has developed a structured and formalised process for the creation of Recommendations For Use. The Recommendations approved by the CCB network shall be applied by the Certification Bodies in order to allow a harmonised implementation of the ECM Regulation. https://eradis.era.europa.eu/safety_docs/ecm/recommendationsForUse/default.aspx	ECM RFU
(EU) 321/2013 Commission Regulation of 13 March concerning the technical specification for interoperability relating to the subsystem 'rolling stock — freight wagons' of the rail system in the European Union. And later amendments	TSI WAG

IMPACT FOR ECMs ALREADY CERTIFIED UNDER (EU) 445/2011

31.05.2021

Reference	Acronym
(EU° 1305/2014 Commission Regulation of 11 December 2014 on the technical specification for interoperability relating to the telematics applications for freight subsystem of the rail system in the European Union And later amendments	TSI TAF
(EU) 1302/2014 Commission Regulation of 18 November 2018 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. And later amendments	TSI LOC& PAS
Statement of the GCU Joint Committee regarding the interpretation of Article 19 GCU in view of mandatory ECM certification requirement.	
General Contract of Use for Wagons	GCU ¹⁴
VPI-08 _ Rail freight – Practical Solutions 28.4.2014 – Brussels – European development of the VPI maintenance guide	
CEN TC256 WG48 N310 Draft Guideline for SSC Regulation 2019 779 (version 5 august 2020)	
ERA report on <Safety critical components> version 1 of 18/12/2017	
Use of risk assessment methods in maintenance for more reliable rolling stock operation. MATEC Web of Conferences 157, 04002 (2018)	
dft.gov.uk message to ECM UK stakeholders by 07 October 2020	
RSSB webinar – 22/02/2021 EU Exit Legislation and Standards https://www.sparkrail.org/Lists/Records/DispForm.aspx?ID=27119	

¹⁴ <https://www.gcubureau.org/web/portal/welcome>