

# Entities in Charge of Maintenance (ECM) - guidance on the introduction of Regulation (EU) 2019/779

On 16 June 2019 the European Commission introduced Commission Implementing Regulation (EU) 2019/779 to replace Commission Regulation (EU) 445/2011, which sets out a system of certification of entities in charge of maintenance (ECM) of freight wagons (the 'ECM Regulation'). This document sets out the key changes, timescales for implementation of the new Regulation and answers frequently asked questions. Further guidance on the application and practical implementation of Regulation (EU) 2019/779 is also available from the Rail Safety and Standards Board (RSSB)<sup>1</sup>.

## Introduction

1. All ECMs (including those that are not certificated), certification bodies, railway undertakings and infrastructure managers are affected by the changes the new regulation introduce.
2. The new Regulation entered into force in June 2019 but does not become applicable to duty holders until 16 June 2020. Until that date the existing Regulation (EU) 445/2011 remains in effect.
3. There are transitional arrangements which allow additional time for duty holders to obtain certificates under the new Regulation. These are detailed later in this guidance.

## Brexit

4. At the time of writing the UK is set to leave the EU in 2020. It is not known whether there will be a future relationship (deal) with the EU and an associated transition period during which the UK will remain subject to EU legislation or whether the UK will leave with no future relationship (no deal) on that date.
5. Therefore, there are two likely outcomes in respect of the new ECM Regulation:
  - The UK leaves the EU with a deal and transition period extending beyond 20 June 2020. In this case the new ECM Regulation (2019/779) will become part of UK legislation and will apply in the UK for at least the duration of the transition period.

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<sup>1</sup> <https://www.rssb.co.uk/RSSB-and-the-rail-industry/Complying-with-Legislation/Certification-of-entities-in-charge-of-maintenance-in-Great-Britain>

- The UK leaves the EU without a deal. In this case the new ECM Regulation will not apply in the UK and the existing ECM Regulation (445/2011) will be substantially reproduced into UK legislation. Technical Standards for Interoperability (TSIs) will also be reproduced as National Technical Specification Notices (NTSNs). However, the requirements for ECMs under ROGS will still refer to TSIs as well as to NTSNs. Further information on TSIs can be found later in this guidance.

## Key changes

6. The new ECM Regulation (EU) 2019/779 makes the following key changes:
  - The widening of the scope of the ECM certification scheme to include all vehicles in use on the mainline railway;
  - The introduction of a new system for the management of components deemed to be safety critical;
  - A new requirement for certification bodies to include an assessment of the management function (Section I of Annex II) when a maintenance function certificate is issued in respect of outsourced maintenance functions or parts thereof;
  - Removing from the ECM Regulation the requirement for the maintenance system to contain the four ECM functions [(a) maintenance; (b) maintenance development; (c) fleet-maintenance management; and (d) maintenance delivery] – this is now in Article 14 of Directive (EU) 2016/798, which will require transposition into ROGS.
7. There are also additional requirements for the ECM in Article 14 of Directive (EU) 2016/798 to:
  - implement the necessary risk evaluation and assessment methods established in CSMs, where appropriate in cooperation with other actors;
  - ensure that its contractors implement risk control measures through the application of the CSM for monitoring and that this is stipulated in contractual arrangements to be disclosed on request of the Agency or the national safety authority; and
  - ensure the traceability of the maintenance activities.

## Scope of the ECM certification scheme

8. Whereas the current ECM certification scheme in Regulation (EU) 445/2011 only requires ECMs of freight wagons to obtain an ECM certificate, the new ECM Regulation (EU) 2019/779 widens the requirement to ECMs of all vehicles on the mainline railway. This includes ECMs of passenger trains, locomotives, on track machines and any other vehicle on the mainline.
9. Railway undertakings who hold safety certification under ROGS are not required to obtain ECM certification in relation to vehicles for which they are the ECM and the exclusive operator (although they may seek certification voluntarily). However, such railway undertakings must still demonstrate conformity with Annex II of Regulation 2019/779. If an RU's maintenance activity extends to vehicles that are operated by other RU's, then it must also obtain ECM certification.

## On track machines

On track machines (such as tampers, regulators, monitoring trains etc.) which are used outside of engineering possessions on the mainline railway are treated in the same way as other vehicles. Generally, when machines are moving between engineering possessions interacting with infrastructure in the same way as 'conventional' passenger/freight rolling stock (e.g. 'Running Mode') they are treated as locomotives if they are moving under their own power and wagons if they are being towed. ECMs of these vehicles will be required to obtain a certificate (subject to paragraph 8). When on track plant (such as excavators, etc.) are only used within engineering possessions they are outside the scope of the ECM regulation.

10. An exception is made for ECMs that are also railway undertakings (RU) or infrastructure managers (IM) maintaining vehicles other than freight wagons exclusively for their own operations. These ECMs will still need to demonstrate that they comply with the requirements of the ECM Regulation, in particular Annex II, but they have the option of doing this as part of safety certification/safety authorisation instead of separately obtaining an ECM certificate. If this option is chosen, the RU/IM will need to be able to demonstrate that it is managing compliance with Annex II through its safety management system (SMS). ECMs that share a name or parent company with the RU/IM but are functionally separate and not covered by the RU/IMs SMS will need to obtain an ECM certificate from a certification body.

## ECM management function

The ECM management function (i.e. supervision and coordination of the maintenance functions and ensuring, by means of a system of maintenance, that a vehicle for which it is in charge of maintenance is in a safe state of running) must be carried out by the nominated ECM registered on the national vehicle register and cannot be contracted to another party.

**There is no obligation for a railway undertaking (RU) operating a vehicle to be the ECM for that vehicle.** If the RU is the ECM, then it must take on the management function itself and it must ensure that, through a system of maintenance, the vehicles for which it is responsible are safe to run on the mainline railway. If the RU is not the ECM, then it is the ECM that must take on the management function and that ECM has this direct responsibility.

Under regulation 5(1)(d) of ROGS the safety management system of the RU, whether or not it is an ECM, must ensure:

*“the control of all categories of risk including new or existing risks associated with the operation in question which, without prejudice to the generality of the foregoing, shall include such risks relating to the (i) supply of maintenance and material; and (ii) use of contractors”.*

Railway undertakings holding a safety certificate (including infrastructure managers who operate vehicles on the mainline) are responsible for the safe operation of trains and will have to demonstrate compliance with this duty to control risks associated with the supply of maintenance and material, and the use of contractors. The route to demonstrating compliance will differ depending on whether the RU or a contractor is the registered ECM for the vehicles operated.

Whenever an organisation carrying out an outsourced maintenance function (or part of it) applies to a certification body for a maintenance function certification, it must also demonstrate that meets the requirements of the management function as well as the requirements for the maintenance function.

## Attestations of conformity

Previously, ECMs of vehicles other than freight wagons could voluntarily apply to a certification body to be assessed against the requirements of Annex III of Regulation (EU) 445/2011 in the same way that ECMs of freight wagons did. Instead of being issued with an ECM certificate they were issued with an ‘Attestation of Conformity’. Under the new

regulation any attestations issued before 16 June 2019 will be deemed equivalent to an ECM certificate for their original period of validity or at the latest, until 16 June 2023. Attestations issued after 16 June 2019 will not be automatically recognised beyond 16 June 2020.

11. ECM certificates already issued under the current regulation are unaffected and will continue to be recognised during their original period and scope of validity when the new regulation becomes effective. ECMs that are brought into scope of the regulation will have until 16 June 2022 to obtain an ECM certificate from an ECM Certification Body.

## Certification bodies

Certification bodies must be accredited by an accreditation body or recognised. In the UK certification bodies are accredited by the United Kingdom Accreditation Service (UKAS). Certification bodies currently accredited to assess the ECM arrangements for freight wagons will continue to be recognised to perform this activity for that vehicle type. If existing certification bodies wish to broaden the scope of their activities to include vehicles other than freight wagons, they will need to undergo further accreditation. We are working with UKAS, the Department for Transport and the EU Agency for Railways to ensure there are criteria in place to enable UKAS to begin issuing accreditations for ECMs of vehicles other than freight wagons in due time.

## Management of safety critical components

12. Safety critical components are defined in the locomotives and passenger rolling stock TSI (Commission Regulation (EU) 1302/2014, as amended<sup>2</sup>) (LOC & PAS TSI) as *'components for which a single failure has a credible potential to lead directly to a serious accident'*<sup>3</sup>. The new ECM Regulation, the LOC& PAS TSI and the freight wagon rolling stock TSI (Commission Regulation (EU) 321/2013, as amended) (WAG

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<sup>2</sup> Paragraph 4.2.12.1 of Annex to [Regulation \(EU\) 1302/2014](#) (Technical Specification for Interoperability – Locomotives and Passenger rolling stock)

<sup>3</sup> '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. *Article 3(12) of Directive (EU) 2016/798*

TSI) introduce new specific requirements for the management of safety critical components that apply to all parties whether or not the ECM is certificated.

13. The new requirements fall in to broadly three categories
  - The initial identification of safety critical components
  - The management and identification of safety critical components after the vehicle enters service
  - The recording of maintenance and sharing information related to safety critical components

### Initial identification

14. Generally, it is expected that designers will seek to minimise or eliminate safety critical components. However, where it is impossible to ‘design out’ a safety critical component it is important that the components are clearly identified and notified to operators, owners, keepers etc.
15. For new vehicles it is expected that the designer/manufacture will carry out an initial assessment to identify components that are safety critical. We expect this to have occurred as part of the risk assessment carried out during the design and construction of the vehicle using the Common Safety Method for Risk Evaluation and Assessment<sup>4</sup>.
16. For vehicles being modified it is expected that the designer/manufacture will carry out a risk assessment to identify components that are safety critical within the scope of the modification. The designer/manufacture of the modification is not expected to reassess the whole vehicle again, however, it is important that all of the impacts the modification could have on other vehicle systems and components are identified and understood.
17. For older vehicles, the designer/manufacture may no longer be in business or supporting the vehicle and therefore cannot be available or relied upon to identify and support the maintenance of safety critical components. In this situation it is likely that the designer/manufacture (or other railway actors who subsequently had responsibility for the vehicle e.g. national railway, owners, keepers) will have since put adequate and appropriate technical instructions in place for the management and maintenance of components that were recognised to be critical for safety (even if not

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<sup>4</sup> Further information on the Common Safety Method for Risk Evaluation and Assessment is available [on our website](#).

necessarily called 'safety critical'). These instructions must be taken into account by the ECM.

## Assessing criticality

The criticality of a component is likely to depend on the vehicle design and its application. A component that is not safety critical on one vehicle may be safety critical on another. Similarly, a component on a vehicle may not be safety critical when it is being used for one purpose but becomes safety critical when it is used for another purpose. Therefore, when identifying safety critical components it is essential that each vehicle and the use it is put to is also considered.

### Management and identification of safety critical components after the vehicle enters service

18. ECMs are expected to take the designer/manufacture's initial identification of safety critical components and technical instructions contained in the technical file into account when planning maintenance. This could be documented in the maintenance plan.
19. If an ECM becomes aware of new or unexpected safety relevant findings including exceptional maintenance findings beyond normal wear and tear it must notify the:
  - Railway undertakings and/or infrastructure managers operating the vehicle(s)
  - Owners
  - Keepers
  - Manufacturers
  - Holders of the vehicle(s) authorisation
  - Holder of the type authorisation of the vehicle(s), subsystems or componentsas it deems appropriate.
20. ECMs are not expected to identify safety critical components retrospectively. However, if during the course of its routine maintenance activities 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

- Holder of the type authorisation
- Holder of the vehicle authorisation

without delay.

21. Once a new safety critical component has been identified by an ECM the manufacturer (if it can be identified) must carry out an assessment taking into account the component's intended use and environment it is used in and feed back to the ECM and other operators of the vehicle as appropriate. The ECM must adjust its maintenance procedures and apply other engineering controls e.g. modification, if it deems appropriate.
22. Modifications have the potential to impact on other systems on a vehicle. It is important that modifications are designed to minimise safety critical components and as far as possible do not introduce new safety critical components either within the modification or other systems. Where possible, the ECM should notify the manufacturer of the modification and any changes to safety critical components.

## Technical Specifications for Interoperability (TSIs)

TSIs contain the technical specifications for many items of railway infrastructure such as signalling systems, track and rolling stock. Under the LOC & PAS and Wagon TSIs, the designer/manufacturer is responsible for identifying safety critical components and their specific servicing, maintenance and operational traceability requirements at both the design phase and after vehicles have entered into operation through collaboration with the concerned ECM. In the event of a No Deal Brexit TSIs will be reproduced in UK legislation as National Technical Specification Notices (NTSNs). However, the ECM requirements in ROGS, as amended by the Rail Safety (Amendment etc.) (EU Exit) Regulations 2019 will still refer to TSIs as well as to NTSNs. This is because of the UK's obligations under the Convention concerning International Carriage by Rail (COTIF) mean that retaining the reference to TSIs is necessary to ensure UK ECM certification remains functionally equivalent under COTIF.

### Recording of maintenance and sharing information

23. Manufacturers and ECMs must keep records of safety critical components and maintenance instructions. In the case of the manufacturer this needs to be kept in the technical file and in the case of the ECM in the maintenance file.



24. ECMs must inform the rail sector and the rail supply industry about new or unexpected safety relevant findings including exceptional maintenance findings beyond normal wear and tear, in relation to vehicles, subsystems or other components. They are expected to use the Safety Alert Information Tool (SAIT)<sup>5</sup> provided by the EU Agency for Railways. ECMs that have not already registered for an account on SAIT will need to do so.

## In summary

### Scope of the ECM certification scheme:

- By 16 June 2022 ECMs of vehicles other than freight wagons will need to demonstrate compliance with the ECM regulation and obtain an ECM certificate from a certification body unless they are an RU/IM operating the vehicles exclusively for their own operations.
- ECMs that are also RU/IMs and operating vehicles exclusively for their own operations will still need to demonstrate compliance with the ECM Regulation but can choose to do so through their safety certificate/safety authorisation instead of obtaining an ECM certificate through a certification body.
- Certificates and attestations issued under the current regulation will continue to be valid.
- Certification bodies with existing accreditation for freight wagon ECM certification will need the scope of their accreditation extended before they can issue certificates for vehicles other than freight wagons.

### Management of safety critical components:

- Components on a vehicle in scope where a single failure has a credible potential to lead to a serious accident must be identified, managed and recorded.
- The specific vehicle and the use it is being put to must be taken in to account when assessing components.
- Designers/manufacturers have initial responsibility for identifying safety critical components. ECMs have the ongoing responsibility for managing safety critical

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<sup>5</sup> <https://webgate.ec.europa.eu/multisite/safetyalerts/>

components and identifying new safety critical components once the vehicle is in service.

- When unexpected or exceptional maintenance findings are discovered and/or new safety critical components are identified the ECM and manufacturer must notify those parties involved in the maintenance of the vehicle and the relevant wider industry.



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