

Position Paper

Brussels, 14 December 2023

Implementation of the ECM Regulation – Return of experience from the CER members

Position paper “Implementation of the ECM Regulation”

Introduction

This CER position paper summarises the CER members’ return of experience on the implementation of the COMMISSION IMPLEMENTING REGULATION (EU) 2019/779 of 16 May 2019 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798.

The position paper includes general remarks regarding the regulation as well as recommendations for improving the current legal framework.

This 2023 CER position paper builds on CER position papers and statements released in 2018 in the light of the revision of the ECM Regulation. In 2018, the Community of European Railway and Infrastructure Companies (CER) expressed its concern that the current findings for the legal provision for the extension of ECM certification are accompanied by an unclear proposal on safety critical components (SCC). As we are still facing the same problem in 2023, we dedicate a large part of this 2023 CER position paper to the topic “safety critical components”.

General remarks

The regulation 2016/798 has had some positive impacts. We recognise that to a larger extent the benefits of the regulation outweigh the disadvantages of the regulation. Notably, the regulation has contributed positively to enhancing railway safety, fostering a more harmonised approach in the assessment of the ability of entities in charge of maintenance for vehicles.

However, a more in-depth analysis reveals some notable challenges for the actors. Despite its positive effects, the regulation has not succeeded in reducing the overall costs and resource allocation associated with maintenance management. Furthermore, certification costs have not declined since the introduction of the ECM (Entity in Charge of Maintenance) regulation.

A crucial aspect of concern is the regulation's inherent vagueness, which often results in a lack of detail and leads to varying interpretations among stakeholders. This has sparked friction and disputes within the sector.

In short, the implementation of the COMMISSION IMPLEMENTING REGULATION (EU) 2019/779 has not delivered the desired results that were the driver for the revision in 2019:

- **Reducing the administrative burden and**
- **Reducing costs for entities in charge of maintenance.**

Increase of costs and administrative burden

From our point of view, the 2019 ECM Regulation has led to an increase of documentation, in particular regarding the identification of maintenance functions 1¹, 3² (within a railway undertaking) and function 4³.

In comparison to the previous ECM regime under the "old regulation", we noticed that ECMs are undertaking the same maintenance procedures, but due to the new functions being created, the amount of documentation has increased. Examples: the fulfilment of the SCC-Requirements and the use of SAIT. This has consequently led to a cost increase on the one hand, but we doubt that this has led to any increase of safety on the other hand.

We recommend when further developing railway specific certification schemes to first assess, consider and incorporate (if applicable) good practice from other sectors. Such synergies and learning from others would lead to significant improvements as well as reducing costs.

Assessment of specific issues of the ECM Regulation in force

ECM Function 1

ECM F1 represents the responsibility of the whole ECM functions towards all the external entities and ensures the conformity of the maintenance management system to the ECM Regulation through the set-up of procedures for all the processes.

In some cases, we experienced difficulties in the application of the above role when the ECM company is also a RU. The difficulty is linked to the overlapping of the Safety Management System (SMS) with the Maintenance Management System considering that before the entry in force of the ECM Regulation, the SMS covered also the maintenance management system as depicted in the Safety Directive. This led the RU to have a consolidated framework of procedures both covering both the SMS and the Maintenance Management System.

During the ECM certification process, some CBs are requesting to have a clear view of which document is valid for RU and SMS in respect of the documents of the maintenance management system to be certified.

¹ DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety – Article 14 - Maintenance of vehicles – Function 1: a management function to supervise and coordinate the maintenance functions

² DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety – Article 14 - Maintenance of vehicles – Function 3: a fleet-maintenance management function to manage the vehicle's removal for maintenance and its return to operation after maintenance

³ DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety – Article 14 - Maintenance of vehicles – Function 4: a maintenance delivery function to deliver the required technical maintenance of a vehicle or parts of it, including the release to service documentation

In this case, ensuring this requirement is quite difficult, because the 2 management systems are strictly integrated and the processes and roles are not distinguished as valid for RU or ECM.

On the other hand, the creation of a new set of procedures only valid for maintenance management system and on the other hand the whole revision of the SMS procedures for deleting the references to maintenance is challenging.

The problem is a practical problem when the ECM (also RU) company offers its ECM role to others, and for instance when others is another RU and also when the ECM company offers itself as outsourced maintenance function to other RU.

Our suggestion is to tackle this problem within a specific section of the ECM Application guide also with various number of cases for example.

ECM function 3

It is difficult to clearly identify the maintenance function 3 "fleet-maintenance management function to manage the vehicle's removal for maintenance and its return to operation after maintenance".

Distinguishing between maintenance function 3 and maintenance function 4 [maintenance delivery function to deliver the required technical maintenance of a vehicle or parts of it, including the release to service documentation] is challenging.

The respective responsibilities on the exchange of information between F3 and F2 should be further defined, mainly when the F2 needs operational data to upgrade maintenance files (i.e. maintenance plan) and return on experience on operation.

In reality, the main responsibilities of the Function 3 (i.e. removal of vehicles from operation for maintenance, notice of return to operation, composition of work package for maintenance order, ...) are normally and in many cases performed through administrative personnel of the workshop, where the workshop is addressed as covering the Function 4. This situation could affect the clear distinction of the 2 ECM functions affecting also the impartiality of the roles.

Furthermore, in case ECM and RU are the same company, some responsibilities of function 3 are performed in collaboration with or by the RU itself (i.e. the establishing of the restrictions of use to ensure the safe running, removal of vehicles from operation,...).

The above situations are identified even in large ECM companies and are emphasized if the ECM is a little company. In addition, the above situation is strongly complicated when one or both ECM functions are outsourced.

It should be further defined what the respective responsibilities are for the actor compared to maintenance functions 3 and 4 taking into account the real situation of the ECMs market.

It is recommended to further define this in the ECM Regulation application guide, in particular for the cases when the ECM and the RU are the same company.

Definition of Safety-critical components

With its June 2018 position paper on safety critical components, the CER assessed the EC proposal for the ECM Regulation, stated that the “new” ECM certification is “accompanied by an unclear proposal on safety critical components (SCC)” and highlighted that “the proposed provisions, create unnecessary cost and legal uncertainty, they will neither help to progress on maintenance nor on interoperability and safety.” CER strongly recommended that “a specific group dealing with safety critical components matters (definitions, common list and process to address common identification and maintenance principles) will be established, supported by a robust impact assessment demonstrating the economic and safety added value of the new regulatory provisions for the railway system.”

Five years later and well experienced, the CER members see their 2018 concerns confirmed, find the application of Article 4 difficult and constitute that the railway stakeholder apply it in different ways and with different understandings.

For example, we experienced long list of potential SCCs offered by some manufacturers, where in many cases they are questionable and of doubtful identification, or on the other hand very restricted list of SCCs only limited to the components linked to the vehicle movement (axle, wheel, bearings) that are obviously safety-critical and already well managed in maintenance all over in Europe.

Furthermore, when a long list is presented, a poor documentation is released (risk analysis, maintenance requirements) and this contribute to uncertainty of what ECM is called to do more than in the past.

This situation leads to continuous challenge and debate between the stakeholders (Manufacturer, ECM, holder of authorisation, owner) and considerable waste of time and resources and a significant overload of documents without any added value for maintenance and safety.

For the above reasons, regarding the definition of ‘safety-critical component’, we recommend to redraft a clear definition with the scope to avoid different understandings and mainly addressing a substantial increase of safety, if any.

In order to show the real situation affecting the stakeholders on the SCCs topic, we recommend exchanging at sector level on the return of experience of the ECMs, RU and the railway supply industry in this respect. The workshop shall facilitate a common understanding of the application of the ECM Regulation and of its article 4. We recommend to reflect about the real added value of Article 4 both for maintenance and safety. In short, we recommend in 2023, what we recommended in 2018 because exactly what we feared happened: the provisions, create unnecessary costs, burdens and legal uncertainty, they will neither help to progress on maintenance nor on interoperability and safety.

Special issue: the COMMISSION IMPLEMENTING REGULATION (EU) 2019/779 of 16 May 2019 in Spanish (ES)

Furthermore, regarding the consistency of the Spanish translation within the regulation, there appears to be variability in the terminology used to describe safety-critical components. At times, these components are referred to as “fundamental components for

security" (componentes fundamentales para la seguridad), such as in Recital 6 and Article 2. However, in Annex II, specifically in Function II points 1.b), 6.c), and 7.b), the translation changes to "essential components for security" (componentes esenciales para la seguridad). To ensure uniformity and precision in the translation, it is recommended that the term "fundamental components for security" is consistently employed throughout the regulation, particularly considering that no definition for "essential components for security" is provided within the regulatory framework. This adjustment would contribute to a more coherent and unambiguous interpretation of the regulation. The purpose of this remark is to indicate the mistakes in the Spanish translation of the concept "Safety Critical Component", requesting to include in Spanish version the term "Componente Crítico para la Seguridad" wherever "Safety Critical Components" appears in the English version. Furthermore, wherever the term "Criticality" or "Critical" appears, it should be translated as "Crítico" in the Spanish version.

Article 4: Safety-critical components – The use of SAIT

The European Union Agency for Railways (ERA) developed a Safety Alert IT tool (SAIT) to support the urgent reporting and sharing of unknown or poorly understood information about hazards and their consequences. The use of SAIT is mandatory for the Entities in Charge of Maintenance (ECMs) starting from 16th of June 2021 as stated in Article 4(6) of the Commission Implementing Regulation (EU) 2019/779 of 16 May 2019 laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011.

CER acknowledges that before the implementation of the SAIT tool there was no IT tool to exchange safety related information at European level between the actors. We believe that the requirement is justified and we have committed to an exchange of safety related information at European level and see the benefits.

Nonetheless, we see further room for improvement of the tool and its usage. Specifically requests from ECMs for additional information or documents often go unanswered. The exchange of safety related information shall be full covered by the CSM ASLP framework in future.

The implementation of the CSM ASLP and its added value is dependent on a database (ISS) gathering all the data requested by the CSM and enabling the processing and utilisation of the data. Now as the CSM ASLP is about to be adopted, we regret that a timely implementation of ISS is put at risk due to a lack of financial resources. ERA has been working on an interim data-collection approach based on Excel Templates to be filled-in by operators and uploaded onto a SharePoint Online workspace for data to be collected. The duration of the temporary ISS-solution is at least two years but could be longer depending on the resource allocation.

This temporary ISS-solution for the exchange of safety related information also requires temporary adaptations by all involved. This solution cannot replace the current practice for national event-data reporting. Regrettably, this means double reporting for the operators. The recording of event-data in Excel Templates is error-prone since the sheets are complex, require trained specialists, while options to support data-integrity are low. This will limit data quality and data-analysis. The recording of event data in Excel Templates is time-consuming as data-entry will be manual with little options for automated data import from the operator's own systems.

As a consequence, CER, EIM and UITP believe that the resources spent by operators, as well as authorities, on the temporary ISS-solution will not contribute to collective learning. To prevent resources and manpower being spent on a temporary solution without real added value, we suggest postponing the mandatory data-collection until the implementation of the permanent ISS.

Maintenance of components

The maintenance function 4 [maintenance delivery function to deliver the required technical maintenance of a vehicle or parts of it, including the release to service documentation] requires special attention, in particular when the maintenance of components is outsourced to suppliers. It is admittedly difficult to have an overview in case of outsourcing.

The “maintenance of components” workshop certification should be covered in the ECM Regulation. We recommend a reflection on how to consider the ECM Regulation for maintenance level 4 and 5 incl. components.

Compliance of entities in charge of maintenance

According to the ECM Regulation, 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 12 months visit cycle is generally regarded as rather positive but creates an issue concerning the needed resources for the ECM. This approach helps detecting procedural issues and mistakes and has positive outcome. Nonetheless, the “high frequency” required manpower preparation/follow-up efforts – that is a **cost driver**

We are in favour of regular supervision and fully acknowledge the positive effects but cost drivers need to be recognised.

We suggest to reflect on the approach to “minimum number of sites to be visited per audit” according to the “IAF Mandatory Document for the Audit and Certification of a Management System operated by a Multi-site organisation”.

6.1.3.3 The minimum number of sites to be visited per audit is:

- **Initial audit:** the size of the sample shall be the square root of the number of sites: ($y=\sqrt{x}$), rounded up to the next whole number, where y = number of sites to be sampled and x = total number of sites.
- **Surveillance audit:** the size of the annual sample shall be the square root of the number of sites with 0.6 as a coefficient ($y=0.6 \sqrt{x}$), rounded up to the next whole number.
- **Re-certification audit:** the size of the sample shall be the same as for an initial audit. Nevertheless, where the management system has proved to be effective over the certification cycle, the size of the sample could be reduced to, $y=0.8 \sqrt{x}$, rounded up to the next whole number.

Outsourcing maintenance functions (Articles 9 and 10)

We have identified the need to establish criteria or mechanisms allowing the ECM F1 to carry out its surveillance/monitoring activity of outsourcing activities, especially those related to the execution of the maintenance, in partial outsourcing carried out by FIV itself, when these activities may be applied to vehicles or component repair activities.

- Allowing the evaluation of the degree of implementation of the procedures presented for the certification of this outsourced company, when this company has the ECM-FIV certification.
- Setting requirements to ensure that a second level of outsourcing by the previous company, complies with the procedures with which the first company has been certified. Example: requirements for the management of competence in the implementation of maintenance (Annex II, chapter IV, point 8).
- harmonizing the ECM-F1 monitoring activity, when what has been outsourced is a partial maintenance execution activity, which does not require that the outsourced company has any type of certification/ qualification

Additionally, it would also be desirable to propose requirements or regulate ECM-F1 monitoring in the case of partial outsourcing of any of the 779 functions.

In any case, it is an improvement in the interfaces that arise due to the variability of outsourcing options, with the aim of continuing to comply with the CSM RA with the same degree of involvement.

Continuing with the problem of the application of surveillance methods by the ECM.F1 on outsourced activities, we find ourselves without tools that allow us to evaluate, for example, how this company carries out the application of the CSM RA, not being able to evaluate the implementation of mitigation measures against to changes of any kind.

In line with article 9, what is requested is that regulation allow the ECM-F1 to access to continuous monitoring the application of the procedure, most over the ones which the outsourced company has obtained the certification.

Potentials for improvements

Article 2: Definitions

Maintenance levels

Referring to Article 2, which deals with definitions, we propose the inclusion of a precise definition for "maintenance levels." A first definition of maintenance levels can be found in the guideline '*Certification scheme for ECM and outsourcing maintenance functions*' in chapter 2.2. Definitions under Level of Maintenance. It is essential to note that this guideline lacks legal binding force. Therefore, we recommend that this definition be incorporated into the regulation itself, rendering it legally binding. This adjustment would significantly enhance the clarity and consistency of the regulation.

Alternative: Proposal to have it in the application guide:

- Indicative "maintenance levels." can be found in the guideline 'Certification scheme for ECM and outsourcing maintenance functions' in chapter 2.2

The ECM is free to define its maintenance levels.

List of references

CER Position Paper "Safety critical components", Brussels, 25 June 2018

About CER

The Community of European Railway and Infrastructure Companies (CER) brings together railway undertakings, their national associations as well as infrastructure managers and vehicle leasing companies. The membership is made up of long-established bodies, new entrants and both private and public enterprises, representing 78% of the rail network length, 81% of the rail freight business and about 94% of rail passenger operations in EU, EFTA and EU accession countries. CER represents the interests of its members towards EU policy makers and transport stakeholders, advocating rail as the backbone of a competitive and sustainable transport system in Europe. For more information, visit www.cer.be or follow us on Twitter [@CER_railways](https://twitter.com/CER_railways) or [LinkedIn](https://www.linkedin.com/company/cer).

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