

Making the railway system
work better for society.

ACCOMPANYING REPORT N° 007REC1004 TO THE RECOMMENDATION OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

on

*Extension/Revision of Commission Regulation (EU) No 445/2011 on
a system of certification of entities in charge of maintenance for
freight wagons.*

Disclaimer:

The present document is a non-legally binding report of the European Union Agency for Railways. It does not represent the view of other EU institutions and bodies, and is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

Contents

1.	Executive summary	3
2.	Introduction	3
2.1.	Composition of the working party	3
2.2.	Working party meetings participation	3
3.	Working methods.....	5
4.	Main aspects covered	5
4.1.	Mandatory or voluntary.....	6
4.2.	Introduction of concept of safety critical components	7
5.	Proposed amendments in regulation 445/2011.....	8
5.1.	Proposed amendment article 1	8
5.2.	Proposed amendment article 2	8
5.3.	Proposed amendment article 3	8
5.4.	Proposed amendment article 5	8
5.5.	Proposed amendment article 6	8
5.6.	Proposed amendment article 7	8
5.7.	Proposed amendment article 9	8
5.8.	Proposed a new article 10.....	9
5.9.	Proposed amendment article 11	9
5.10.	Proposed amendment article 12	9
5.11.	Proposed a new article 13.....	9
5.12.	Proposed amendment annex II.....	9
5.13.	Proposed amendment annex III.....	9
5.14.	Proposed amendment annex IV,V	9
5.15.	Proposed new annex VI	10
6.	Annex 1 Abbreviations	10
7.	Annex 2: Reference documents	11
8.	Annex 3: Reference legislation.....	11
9.	Annex 4: Contributions received as part of the consultation	12

1. Executive summary

This accompanying report complements the recommendation n° 007REC1004 of the European Union Agency for Railways on the amendment of Commission Regulation (EU) No 445/2011. It gives explanation on the legal basis for this revision/extension, the impact assessment, the workgroup parties, the working methods, the main aspects covered, the aspects to be considered in a revision of the regulation 445/2011. It also contains the reasoning behind each recommended text change in the regulation 445/2011.

2. Introduction

This accompanying report complements the recommendation

It deals with the technical and organisational aspects, which lead to the text of the recommendation whereas another accompanying document to the recommendation impact assessment deals with the related economic aspects.

A letter from the European Commission to the European Union Agency for Railways mandated the European Union Agency for Railways to analyse the feasibility to extend the current regulation 445/2011 to all vehicles by June 2018.

The legal base for the European Union Agency for Railways to issue the recommendation is in Article 14(7) of Directive (EU) 2016/798

2.1. Composition of the working party

According to rules in place a working party had to be established.

The invitation to participate to the working party was sent to the 12 representative bodies and to the 26 national safety authorities. From other organisations, the working group 48 of CEN:CENELEC TC 256 involved in maintenance of vehicles, representatives of CCB (Cooperation for ECM Certification bodies related to article 6 of Commission Regulation 445/2011) were also invited to participate and the OTIF Secretariat was invited to participate as an observer. Based on this invitation, the Agency received nominations of the interested stakeholders.

Four working party meetings were organised, to which participants came from 10 representative bodies, 19 national safety authorities, the OTIF Secretariat, CEN/CENELEC and 3 representatives of CCBs.

The European Commission participated to 3 meetings of the working party.

2.2. Working party meetings participation

The table 1 below summarises the attendance of all representative bodies, national safety authorities and other organisations, which replied to the Agency's invitation and appointed their representatives to the working party (WP).

Table 1 : Working party meetings participation

<i>Organisation</i>	<i>Kick-off meeting 23-24 May 2017</i>	<i>Meeting N°2 25-26 october 2017</i>	<i>Meeting N°3 7-8 March 2018</i>	<i>Meeting N°4 2 May 2018</i>
CER	X	X	X	X
EIM	X		X	X
ERFA	X	X	X	X

<i>Organisation</i>	<i>Kick-off meeting 23-24 May 2017</i>	<i>Meeting N°2 25-26 october 2017</i>	<i>Meeting N°3 7-8 March 2018</i>	<i>Meeting N°4 2 May 2018</i>
ETF	X	X	X	
EPTOLA	X	X	X	
UNIFE	X	X	X	X
UIP	X	X	X	
UITP	X	X	X	
UIRR	X			
NB-Rail AISBL	X		X	
CCB (cooperation of certification bodies)	X	X	X	X
CEN/CENELEC WG48	X	X	X	X
EC	X	X	X	
OTIF secretariat	X	X	X	
NSA AT	X	X	X	X
NSA BG	X			
NSA BE	X			
NSA CH				
NSA CZ				
NSA DE	X	X	X	X
NSA DK				
NSA EL				
NSA ES	X	X	X	X
NSA FI	X			
NSA FR	X	X	X	X
NSA HR	X	X	X	
NSA HU	X			
NSA IT	X	X	X	X
NSA IE	X	X	X	X
NSA NL	X			
NSA LU		X	X	
NSA NO	X	X	X	X

<i>Organisation</i>	<i>Kick-off meeting 23-24 May 2017</i>	<i>Meeting N°2 25-26 october 2017</i>	<i>Meeting N°3 7-8 March 2018</i>	<i>Meeting N°4 2 May 2018</i>
NSA PL	X	X	X	
NSA RO	X	X	X	X
NSA SE	X	X	X	X
NSA SI	X	X	X	
NSA UK	X	X	X	X

3. Working methods

The Agency managed and coordinated the Working Party and chaired the relevant meetings. It ensured interface with its other activities and tasks. It applied relevant internal procedures and guidelines (e.g. procedure on issuing a recommendation). It took into account the final output of the Working Party; however, it had the right to deviate from it, when justified (such deviations needed to be recorded in the minutes of the Working Party meetings).

The participant organisations were required to ensure continuity of their representative members for the duration of the Working Party. Whenever possible, the representative members were required to express their organisation's position in advance of the Working Party meetings through written methods, such as commenting on the draft documents or the draft minutes of the Working Party meetings. Representative members were also required to express the view of their organisation during the Working Party meetings. The organisations were also expected to facilitate the internal exchange of opinions and the elaboration of their position, for instance through 'mirror groups'.

The text of the recommendation was prepared by the Agency based on a working document, which gathered together the current regulation 445/2011 and the amendments to it needed for the extension of the scope to the other vehicles than freight wagons.

The working document was thoroughly discussed during every Working Party meeting. Before each Working Party meeting, the Agency prepared a new version and set a deadline for receiving comments to it from the Working Party members. After this deadline, the Agency incorporated all comments received and this document formed the basis for the discussions during the Working Party meeting. Based on these discussions, the Agency prepared a new version for the next Working Party meeting. The impact assessment was also discussed during every Working Party meeting.

To facilitate exchange of documents, an Extranet workspace of the project was established at:

<https://extranet.era.europa.eu/safety/REVECM/SitePages/Home.aspx>

This workspace gathers all documents of the project and is accessible to the working party members and their deputies as well as to all experts involved in other working parties organised by the Agency.

Finally a public consultation was organised between 22 December and 22 February 2018. The Agency received more than 300 comments and the detail is in annex 4.

4. Main aspects covered

The mandate for the revision of regulation 445/2011 addressed to the Agency requests in particular to:

- › examine the feasibility of extending the scope of the certification of the entities in charge of maintenance to all vehicles;

- › examine the feasibility of extending the scope of the certification of maintenance workshops to all vehicles
- › Making amendments to Regulation 445/2011 as necessary to ensure better understanding and avoid risks of misinterpretation
- › Identify common mandatory principles for the maintenance of the safety critical components (4th package);
- › Examine the feasibility of the certification of entities and workshops specialised in the maintenance of specific critical components

The output of these activities will be a draft of an implementing act revising the current regulation (EU) 445/2011

4.1. Mandatory or voluntary

The current ECM regulation 445/2011 covers only freight wagons and the main discussion in the WPs was on the choice of mandatory or voluntary certification for ECM for other railway vehicles .

Some stakeholders did not consider the extension of scope as an urgent need because currently the management of maintenance was clearly defined and controlled. But it is not the case, there is a diversity of customer or state certifications of ECMs for other vehicles than freight wagons.

As it was developed in the impact assessment, especially in its annex I on problem drivers, the maintenance of locomotives, DMUs/EMUs is a complex issue. It requires specific technical expertises from RUs to make sure that they fulfil their responsibility for safe operation in relation to maintenance of vehicles.

The mandatory option for scope extension of ECM certification favors a more harmonized and homogenous approach throughout Europe.

The preferred options of the impact assessment are option 4 (mandatory scope extension to all vehicles) and option 2 (voluntary scope extension to all vehicles but freight wagons). Although both options have positive net-benefits the order of magnitude for both benefits and costs are higher for option 4 compared to option 2. One particular factor that could be decisive for putting option 4 forward would be any provisions for Agency monitoring of ECMs and ECM certification bodies.

The global cost for a certification of an ECM (certificate and surveillance activities for 5 years) is very low (50000€) in comparaison with the cost of a general revision of a locomotive (500000€).

The ECM certification constitutes a means for presumption of conformity concerning the maintenance activity of/for RUs or IMs and must be taken into account in the supervision activity done by NSAs. A voluntary certification of ECMs would have as consequence two types of controls on ECMs on the base of one referential (new implementing act + schemes for which the Agency is the owner in the sense of regulation 765/2008, i.e. accreditation scheme including certification scheme):

- By ECM certification bodies for those ECMs certified
- BY NSAs for those ECMs not certified (including for application of art 17 of Safety Directive 2016/798) and for RUs/IMS regarding the management of assets.

Duplication of assessment by NSAs and ECM certification bodies must be avoided.

By consequence, to ensuere the system remains robust, there should be a huge control and support by the Agency to the NSAs regarding supervision activities and to ECM certification bodies.

The mandatory scope extension to all ECMs avoids this risk of duplication of assessment as only ECM certification bodies are entitled to perform it for ECMs, the supervision by NSAS becoming superfluous for

ECMs and is limited to RUs/IMS. Consequently it favors a more harmonized common and robust approach throughout Europe.

Considering these different points, the Agency recommends the mandatory certificate for all ECMs for the purpose to make the system more simple and more robust.

4.2. Introduction of concept of safety critical components

The mandate for the revision of regulation 445/2011 addressed to the Agency requests in particular to:

- › *Identify common mandatory principles for the maintenance of the safety critical components (4th package);*
- › *Examine the feasibility of the certification of entities and workshops specialised in the maintenance of specific critical components*

Five references to 'safety critical components' have been found in the Agency Regulation 2016/796 [1], Interoperability directive 2016/797 [2] and Safety Directive 2016/798[3]

But there is no definition or common understanding of safety critical components in the EU legislation. Therefore the Agency worked on priority on proposing one definition that could be agreed by the stakeholders.

The Agency made different proposals of approach for defining safety critical components, they are more or less complicated. They were submitted to consultation and discussion in 2016 and 2017.

Finally in the Working Party, the Agency has proposed that safety critical components address all structural mobile subsystems: Rolling stock, energy and CCS (on-board).

The railway system is moving away from rule based approach towards risk based approach. To facilitate this transition, the Agency decided to start with a 'danger-based' definition, i.e. on the principle that 'single failure leads to serious/catastrophic accident'. Introduction of probability and frequencies of occurrences and several gravity levels, as they are key aspects of risk-based approach, will be undertaken at a further step when there will be assurance that this 'risk-based' approach is understood and daily used by the railway stakeholders.

Considering continuous implementation of new technologies, the continually growing complexity of design of components used in the railway system and of the technical architecture of railway systems, the Agency identified also the needs for a strong established cooperation between Railway undertakings and ECMs on one side and designers/manufacturers of vehicles and components on the other side. Therefore it is proposed to regulate on the actors collaboration duty in the recommended implementing act. More detailed explanations will be further provided in guides and/or accreditation scheme to let the time for further discussions and maturation before the implementing act is adopted. Those guides and /or accreditation scheme will be developed in strong collaboration with the railway sector and authorities.

In addition, for completeness aim, the Agency recommends to revise the section relevant to maintenance within the TSIs addressing rolling stock subsystem by introducing the obligation for manufacturers to provide an (initial) list of safety critical components (see Agency recommendation 006REC1025).

However the discussion in the working party led also to the conclusion that there could be an added value, for further steps, of identifying EU common Safety Critical Components but on the base of following criteria:

- It is useless to identify Safety Critical Components without any mandatory design and/or manufacturing and/or operational and/or maintenance specific requirements and without any mandatory specific traceability rules.
- Safety Critical Components must in any case address a safety issue:

- Already identified: Is the railway system unsafe without a specific component being identified as safety critical?
- Potential for future: Is there a HIGH RISK for the railway system to becoming unsafe without a specific component being considered as safety critical?

Today axles, wheels, bearings and train management control software have been identified as candidate for being common EU Safety Critical Components .

For further steps, as the Agency considers that its proposal is an initial necessary step but that improvements have to be performed to accompany effectively the railway sector and the authorities to understand and manage the concept of safety critical components, The Agency recommends that it should be mandated for further developments.

5. Proposed amendments to regulation 445/2011

5.1. Proposed amendment article 1

For ensuring a better understanding, explanation is given that the system of certification applies to the maintenance functions (b,c,d) as referred to the article 14(3) of RSD.

5.2. Proposed amendment article 2

After discussions in the Working Party, for clarification, the Agency proposes to add a reference to Article 2(2), article 2(3) and Article 15 of the Directive 2016/798 to cover the same scope and possible exclusions as in the directive. One of these exclusions is “infrastructure and vehicles reserved for strictly local, historical or tourist use”.

5.3. Proposed amendment article 3

The definitions (f) ‘release to service’ and (g) ‘return to operations’ have been reworded to be aligned with the RSD 2016/798 and definitions in ATMF.

The definition of safety critical component has been included.

5.4. Proposed amendment article 5

Introduction of a mandatory collaboration between the ECMs and the designer/manufacturer for the managing the safety critical component and on the operational occurrences and maintenance findings.

Enforcement of the exchange of information about maintenance between the different parties involved as RUs, IMs, keepers, ECMs, designers or manufacturers.

5.5. Proposed amendment article 6

Introduction of a report (every three years) from the certification bodies to the Agency The content of this report will be detailed in cooperation with the cooperation of certification bodies.

5.6. Proposed amendment article 7

Article 7.6, 7 and 8: Proposal to include that the ECM annual report is also to be delivered to the NSA upon request. This will answer to some NSAs concerns who declared having difficulties to get information from ECMs to cover their responsibility as stated in art 9.

5.7. Proposed amendment article 9

There is no need to provide that the NSA shall inform the Commission. In case there is a need, the NSA can do it any way.

5.8. Proposed a new article 10

A new article was proposed concerning the monitoring of ECMs and ECM certification bodies for ensuring that the certification system is robust.

As in application of the Regulation 765/2008, the owner of the accreditation scheme that includes the certification scheme is the Agency, there is a need to support the ECMs, the ECM certification bodies, National Accreditation Bodies and the relevant national authorities that recognised the ECM certification bodies but also to monitor how the schemes are implemented through the monitoring of ECM and ECM certification bodies.

This monitoring will be done via audits and inspections as described in the article 10(2,3,4,5,6). This article has been inspired by the art 34 of the Agency Regulation 2016/796 (NoBo monitoring) for consistency purpose.

5.9. Proposed amendment article 11

Clarification on the information to send to the Agency on the certification bodies via the Agency database "ERADIS"

5.10. Proposed amendment article 12

The certificate of an ECM already certified for maintenance of wagons could be extended to other vehicles for its original period of validity. The extension to other vehicles shall be validated by the certification body.

The current attestations of conformity issued by a certification body for ECMs or maintenance functions, as described in the Existing ECM guidelines, shall be recognised as being equivalent to certificates issued under this implementing act for their original period of validity.

In the article 12(4,7) the certificates for ECMs or maintenance workshop for vehicles other than freight wagons on the basis of national laws exiting before the entry into force of this Implementing Act shall be recognized as being equivalent until 4 years for ECMs, 6 years for maintenance workshops fatre entry into force of the Implementing Act.

5.11. Proposed a new article 13

It mentions that the regulation (EU) N° 445/2011 is repealed.

5.12. Proposed amendment annex II

The requirement of the number of years of relevant experience in maintenance is not more in the annex but indicated in the accreditation scheme.

5.13. Proposed amendment annex III

There was a cleaning of the requirements to avoid duplication and misunderstanding. A requirement on maintenance activities on control command and signalisation system and on door control system has been added.

5.14. Proposed amendment annex IV,V

The type of company is updated (RU, IM keeper,maintenance supplier, manufacturer, others)

The scope of ECM activities is updated with the different types of vehicles.

5.15. Proposed new annex VI

This Annex describes the content of the ECM annual report. There was a strong demand from the WPs to report the experience of ECM in applying the ECM Regulation in compliance with Art. 5.3 of CSM on monitoring – Regulation 1078/2012 and with Art 17.2 of CSM on risk assessment – Regulation 402/2013”

6. Annex 1 Abbreviations

Table 2 : Table of abbreviations

<i>Abbreviation</i>	<i>Description</i>
AT	Austria
BG	Bulgaria
CER	Community of European Railway and Infrastructure Companies
CH	Switzerland
CZ	Czechia
DE	Germany
DK	Denmark
EIM	European Rail Infrastructure Managers
EL	Greece
ERFA	European Rail Freight Association
ES	Spain
ETF	European Transport Workers’ Federation
EU	European Union
FI	Finland
FR	France
IM	Infrastructure Manager
IT	Italy
NB-Rail AISBL	Notified Bodies Association
NL	The Netherlands
NO	Norway
NSA	National Safety Authority
ÖBB	Österreichische Bundesbahnen
OTIF	Intergovernmental Organisation for International Carriage by Rail
PL	Poland

<i>Abbreviation</i>	<i>Description</i>
RISC	Railway Safety and Interoperability Committee
RU	Railway Undertaking
SE	Sweden
SI	Slovenia
SNCF	Société nationale des chemins de fer français
TSI	Technical Specification for Interoperability
UK	United Kingdom
UIP	International Union of Wagon Keepers
UNIFE	The European Rail Industry
WP	Working Party

7. Annex 2: Reference documents

Table 3 : Table of reference documents

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
[1]	Request for modification of the mandate to the European Railway Agency for the revision of Commission Regulation (EU) No 445/2011 on a system of certification of entities in charge of maintenance for freight wagons	MOVE/B.2/GR/jt Ares (2016)977873	
[2]	Report on revision of the ECM certification -Preliminary Phase -Part 1: Analysis of NSA concerns and Part 2: Safety critical components	006REC1004 v0.1	20/12/2016
[3]	Implementation of Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2077	ERA-REP-125 V 1.0	23/02/2015
[4]	Report on National rules and practices on vehicle maintenance	Maintenance national rules 007REC1004 V 1.0	20/10/2017

8. Annex 3: Reference legislation

Table 4 : Table of reference legislation

[Ref. N°]	Title	Reference	Version
[1]	Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (Hereafter called "Agency regulation")	2016/796 (OJ L 138 of 26 May 2016)	11/05/16


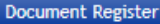

[Ref. N°]	Title	Reference	Version
[2]	Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (recast) (Hereafter called “Interoperability directive”)	2016/797 (OJ L 138 of 26 May 2016)	11/05/16
[3]	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast) (Hereafter called “Safety directive”)	2016/798 (OJ L 138 of 26 May 2016)	11/05/16

9. Annex 4: Contributions received as part of the consultation

The Agency launched a consultation on the draft of the limited revision of the regulation 445/2011 on 22nd December 2017 with a deadline 8 weeks , i.e. 20/02/2018:

Contact Us | Job Opportunities | Business with us | Extranet | Search | A- | A+

The Agency | Core Activities | Communication | Search

[Home](#) > Document Register

Consultation on the Agency draft recommendation on the revision of Regulation 445/2011

Reference:	007REC1004
Publication Date :	22/12/2017
Published by:	Safety
Document Types:	Consultations
Keywords:	Revision of Regulation 445/2011; Extension of the scope of ECM certification
Description:	<p>The Agency has received the mandate to draft recommendation on the revision of Regulation 445/2011 and possible extension of its scope by adding other types of vehicles. The mandate addresses in particular the following aspects:</p> <ol style="list-style-type: none"> 1) Examine the feasibility of extending the scope of the certification of entities in charge of maintenance to all vehicles; 2) Examine the feasibility of extending the scope of the certification of maintenance workshops to all vehicles; 3) Identify common mandatory principles for the maintenance of the safety-critical components; 4) Examine the feasibility of the certification of entities and workshops specialized in the maintenance of specific critical components 5) Making amendments to Regulation 445/2011 as necessary to ensure better understanding and avoid risks of misinterpretation; 6) Propose revision of articles 1,2,6,9 and 12 and annexes of Regulation 445/2011 <p>In accordance with Article 6 and Article 7 of Regulation (EU) 2016/796, the Agency shall consult the social partners and organisations representing rail freight customers and passengers. In accordance with the Commission mandate (C(2016) 5504), the Agency shall also consult the network of National Safety Authorities set up under Article 38(1) of Regulation (EU) 2016/796 and Article 18(4) of Directive (EU) 2016/798.</p>
Status:	Closed Consultations
Closing Date :	20/02/2018
Related documents:	<p>The following documents are submitted for consultation:</p> <ul style="list-style-type: none"> • Impact Assessment • Draft Implementing Act • Report on safety critical components • Annex III to the Report on safety critical components - not subject to consultation <p>Please use the following e-mail address consultation_007REC1004@era.europa.eu to return your comments to the Agency before 20/02/2018, using the relevant comment sheet below (one comment sheet per document):</p> <ul style="list-style-type: none"> • Comment sheet for Impact assessment • Comment sheet for Draft Implementing Act • Comment sheet for Safety critical components

The Agency has received contributions on Impact assessment :

- › 19 contributions providing 120 comments:
 - › 4 RBs: UNIFE, CER, EIM, FEDECRAIL
 - › 4 NSAs: Denmark, Italy, Sweden, UK
 - › Swedish Infrastructure Manager (Trakfikverket)
 - › Private Wagon Federation (PWF)
 - › Association of Swedish Train Operating Companies (ASTOC)
 - › SJ (Swedish passengers Railway Undertaking)

- › Norske Tog
- › Heritage Railway Association
- › EVR Cargo
- › VDMT (Verband Deutscher Museums- und Touristikbahnen)
- › GB Mirror Group
- › SQS
- › Transitio (Swedish ROSCO)

The Agency has received contributions on draft implementing act :

- › 29 contributions providing 350 comments:
 - › 4 RBs: UNIFE, CER, UIP-ERFA, ETF
 - › OTIF
 - › 12 NSAs: Austria, Denmark, France, Finland, Germany, Italy, Ireland, Spain, Sweden, the Netherlands, Romania, UK
 - › Other RU (AGILIS)
 - › CEN TC256 WG 48
 - › European Commission: DG MOVE
 - › Swedish Infrastructure Manager (Trakfikverket)
 - › Private Wagon Federation (PWF)
 - › Heritage railway association
 - › VDV
 - › European federation of museum and tourist railway (FEDECRAIL) and VDMT
 - › Association of Swedish Train Operating Companies (ASTOC)
 - › certification body (TÜV, SQS)

The Agency has received contributions on safety critical components approach

- › 15 reviewers from 14 organisations:
 - › 2 RBs: UNIFE, CER
 - › 7 NSAs: Denmark, France, Germany, Italy, Spain, Sweden, the Netherlands
 - › CEN TC256 WG 48
 - › European Commission: DG MOVE
 - › Swedish Infrastructure Manager (Trakfikverket)
 - › Private Wagon Federation (PWF)
 - › Association of Swedish Train Operating Companies (ASTOC)