

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 (Text with EEA relevance)

### *Article 1*

#### **Subject matter and scope**

- 1 This Regulation establishes a system of certification of entities in charge of maintenance ('ECM certificate') including the maintenance functions described in Article 14(3) of Directive (EU) 2016/798.
- 2 It applies to all vehicles, and introduces the possibility for certification of outsourced maintenance functions.
- 3 This Regulation sets out the requirements to be met by the entities in charge of maintenance concerning the management of safety-critical components.

### *Article 2*

#### **Definitions**

For the purposes of this Regulation, the following definitions shall apply:

- (a) 'accreditation' means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008;
- (b) 'certification body' means a body, responsible for the certification of entities in charge of maintenance or for certification of the entity or organisation that fulfil maintenance functions referred to in points (b), (c) or (d) of Article 14(3) of Directive (EU) 2016/798, or parts of those functions;
- (c) '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;
- (d) '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;

The definition of 'safety-critical component' provided for in section 4.2.12.1 of Annex to Commission Regulation (EU) No 1302/2014<sup>(1)</sup> shall apply.

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### Article 3

#### System of Certification

1 Without prejudice to Article 15(1) of Directive (EU) 2016/798, any entity in charge of maintenance shall satisfy the requirements of Annex II, in respect of all vehicles subject to Directive (EU) 2016/798.

2 An ECM certification establishing compliance with the requirements of Annex II shall be mandatory for any entity in charge of maintenance:

- a responsible for the maintenance of freight wagons, or
- b which is not a railway undertaking or an infrastructure manager maintaining vehicles exclusively for its own operations.

3 Any entity in charge of maintenance of vehicles other than those mentioned in paragraph 2, may apply for ECM certification.

4 Compliance with Annex II shall be demonstrated either through an ECM certification or, without prejudice to paragraph 2, in case of railway undertakings through the process of safety certification or in case of infrastructure managers through the process of safety authorisation.

5 The ECM certificate granted to a railway undertaking or an infrastructure manager shall be deemed evidence of compliance with points 5.2.4 and 5.2.5 both of Annex I and Annex II to Commission Delegated Regulation (EU) 2018/762<sup>(2)</sup> as regards maintenance of vehicles.

### Article 4

#### Safety-critical components

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.

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.

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 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.

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5 Safety critical components including those identified under paragraph 4 above, shall be recorded in and managed through the relevant vehicle documentation as follows:

- 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
- 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.

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.

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.

#### *Article 5*

### **Obligations of parties involved in the maintenance process**

1 The entity in charge of the maintenance of the vehicle shall deliver information on the maintenance of a vehicle, and, where applicable on aspects relevant for the operation to the railway undertakings or infrastructure managers at request, either directly or via the keeper.

2 The railway undertaking or the infrastructure manager shall deliver information on the operation of a vehicle to the entity in charge of maintenance at request, either directly or via the keeper of the vehicle.

3 All parties involved in the maintenance process such as railway undertakings, infrastructure managers, keepers, entities in charge of maintenance, as well as manufacturers of vehicles, subsystems or components, shall exchange relevant information about maintenance in accordance with the criteria listed in Sections I.7 and I.8 of Annex II.

4 Where any involved party, in particular a railway undertaking or an infrastructure manager, has evidence that an entity in charge of maintenance does not comply with Article 14 of Directive (EU) 2016/798 or with the requirements of this Regulation, it shall without delay inform the certification body and the relevant national safety authority thereof. The certification body or, where the entity in charge of maintenance is not certified, the relevant national safety authority shall take appropriate action to check whether the claim of non-compliance is justified.

5 Where there is a change of entity in charge of maintenance, the keeper, in accordance with Article 47(6) of Directive (EU) 2016/797, shall inform without delay the registration entity referred to in Article 4(1) of Commission Decision 2007/756/EC<sup>(3)</sup> and request the update of the vehicle register. In that situation:

- (i) the former entity in charge of maintenance shall without delay deliver the maintenance documentation to the keeper;
- (ii) the former entity in charge of maintenance shall be relieved of its obligations when it is removed from the vehicle register;

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- (iii) in the absence of a new entity in charge of maintenance the registration of the vehicle shall be suspended.

## Article 6

### Certification bodies

1 Member States shall provide the Agency with the following information concerning the certification bodies:

- name
- address
- contact details
- the nature of their empowerment in accordance with Article 14 of Directive (EU) 2016/798 (accreditation, recognition or if they have taken on the task as the national safety authority)

2 Member States shall inform the Agency about any change in the situation within one month of the occurrence of that change.

3 Member States shall ensure that the certification bodies comply with the general criteria and principles set out in Annex I and with any specific sectoral accreditation schemes laid down by the relevant Union legislation.

4 Member States shall ensure that decisions taken by the certification bodies are subject to judicial review.

5 In order to harmonise approaches to the assessment of applications, the certification bodies shall cooperate with one another both within the Member States and across the Union.

6 The Agency shall organise and facilitate cooperation between the certification bodies.

7 The certification bodies shall deliver an activity report in an electronic form every 3 years to the Agency. The content of such a report shall be defined by the Agency (in collaboration with the certification bodies) and made available on 16 December 2020 and in accordance with any specific sectoral accreditation schemes laid down by the relevant Union legislation. The Agency shall publish the reports on its website.

8 A national safety authority, a national investigation body or the Agency may request information from any certification body on the situation concerning an individual ECM certification. The certification body shall reply within 2 weeks at the latest.

## Article 7

### Certification of entities in charge of maintenance

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<sup>(4)</sup>.

2 The application for ECM certification may be limited to a specified category of vehicles.

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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.

4 The certification body shall verify the fulfilment of the requirements set out in Annex II. To that end, it may undertake site visits of the entity in charge of maintenance.

5 The certification body shall take a decision to award or refuse ECM certification at the latest 4 months after all the information and documentation has been received.

6 The certification body shall give the reasons for its decisions. It shall notify its decision to the entity in charge of maintenance, with an indication of the appeal process, the time limit for an appeal and the contact details of the appeal body.

7 The decision to award the ECM certification shall be notified using the relevant form set out in Annex IV.

8 An ECM certification shall be valid for a maximum period of 5 years. The certified entity in charge of maintenance shall inform the certification body of any changes that might have an impact on the validity of its certification without delay.

#### *Article 8*

### **Compliance of entities in charge of maintenance**

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.

2 Where the certification body finds that an entity in charge of maintenance no longer complies with the requirements on the basis of which it issued the ECM certification, it can take one of the following actions:

- agree an improvement plan with the entity in charge of maintenance,
- decide to limit the scope of the ECM certification,
- suspend or revoke the certification, depending on the extent of non-compliance.

3 Where the entity in charge of maintenance does not follow the improvement plan or continues not to comply with the requirements set out in Annex II, the certification body shall decide to limit the scope of or revoke the ECM certification, depending on the extent of non-compliance.

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.

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.

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## Article 9

### Outsourcing maintenance functions

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.

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.

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.

## Article 10

### Certification for outsourced maintenance functions

1 A certification may be requested by any entity or organisation taking on one or more maintenance functions as referred to in points (b), (c) and (d) of Article 14(3). Such a certification shall confirm that the maintenance carried out by the entity or organisation concerned of one or more of those functions complies with the relevant requirements set out in Annex II.

2 Certification bodies shall apply the procedures set out in Articles 6, 7, 8 and 13(2) adapted to the particular case of the applicant.

In assessing applications for certification in respect of outsourced maintenance functions or parts thereof, certification bodies shall apply:

- a the requirements and assessment criteria set out in Section I of Annex II, adapted to the organisation's type and extent of service;
- b the requirements and assessment criteria describing the specific maintenance function or functions.

## Article 11

### Role of the national safety authorities

If a national safety authority has knowledge that an entity in charge of maintenance does not comply with the requirements of Annex III of Directive (EU) 2016/798 or with the certification requirements of this Regulation, it shall inform the national bodies or authorities responsible for the accreditation or recognition, the Agency, the certification body and other interested parties as appropriate.

## Article 12

### Cooperation with the certification bodies

The Agency shall support the harmonised system of certification through the provision of:

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- (a) assistance to national accreditation bodies and to the relevant national authorities recognising the certification bodies;
- (b) cooperation on appropriate accreditation and certification schemes. Those schemes shall set out evaluation criteria and procedures to assess compliance of certification bodies with the requirements set out in Annex I (via the European accreditation infrastructure established pursuant to Article 14 of Regulation (EC) No 765/2008).

### *Article 13*

#### **Provision of information**

1 The Agency shall collect, record and publish basic information on certification bodies and certified entities in charge of maintenance. The Agency shall create an IT tool for delivering this task.

2 Certification bodies shall notify the Agency of all issued, amended, renewed, suspended or revoked ECM certifications or of all certifications for functions as referred to in points (b), (c) and (d) of Article 14(3) of Directive (EU) 2016/798, within one week from its decision, using the forms set out in Annex IV.

### *Article 14*

#### **Reporting**

The Agency shall address to the Commission a first report on the implementation of this Regulation five years following its entry into force. The Agency shall address subsequent reports on the implementation of this Regulation every three years following the first report.

### *Article 15*

#### **Transitional provisions**

1 Certification bodies accredited or recognised pursuant to Regulation (EU) No 445/2011 shall be deemed accredited or recognised in accordance with this Regulation under the conditions for which those certification bodies have been accredited or recognised.

2 The attestation for an entity in charge of maintenance for vehicles other than freight wagons, issued by the certification body on the basis of national laws, applicable in the field governed by this Regulation, before 16 June 2020 shall be recognised as being equivalent to ECM certification for its original period of validity or at the latest, until 16 June 2023.

3 Attestations of conformity with the principles and criteria equivalent to the requirements of Annex III of Regulation (EU) No 445/2011 issued by a certification body for vehicles other than freight wagons, by 16 June 2019 at the latest, shall be deemed equivalent to ECM certifications issued under this Regulation for their original period of validity or at the latest, until 16 June 2023.

4 Attestations of conformity for outsourced maintenance functions for vehicles other than freight wagons, issued by the certification body by 16 June 2022 at the latest, on the basis of national laws applicable in the field governed by this Regulation before its entry into force

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shall be deemed equivalent to ECM certifications for outsourced maintenance functions issued under this Regulation for their original period of validity or at the latest, until 16 June 2025.

[<sup>F15</sup> All entities in charge of maintenance for vehicles other than freight wagons and vehicles listed in Article 15(1) of Directive (EU) 2016/798, which are not subject to paragraphs 2 to 4, shall comply with this Regulation by 16 June 2022 at the latest.]

[<sup>F26</sup> Without prejudice to any procedure that the certification body may take by virtue of the provisions of Article 7(7) of Regulation (EU) No 445/2011, the validity of ECM certificates and certificates in respect of outsourced maintenance functions issued in accordance with that Regulation, expiring between 1 March 2020 and 31 August 2020 shall be extended for 6 additional months.]

#### Textual Amendments

- F1** Substituted by [Commission Implementing Regulation \(EU\) 2020/780 of 12 June 2020 amending Regulation \(EU\) No 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 \(Text with EEA relevance\).](#)
- F2** Inserted by [Commission Implementing Regulation \(EU\) 2020/780 of 12 June 2020 amending Regulation \(EU\) No 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 \(Text with EEA relevance\).](#)

### Article 16

#### Repeal

Regulation (EU) No 445/2011 is repealed with effect from 16 June 2020.

Certificates issued under Regulation (EU) No 445/2011 by a certification body shall be deemed equivalent to certificates issued under this Regulation for their original period of validity.

### Article 17

#### Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

[<sup>F1</sup>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.]

#### Textual Amendments

- F1** Substituted by [Commission Implementing Regulation \(EU\) 2020/780 of 12 June 2020 amending Regulation \(EU\) No 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 \(Text with EEA relevance\).](#)



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This Regulation shall be binding in its entirety and directly applicable in all Member States.

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- (1) Commission Regulation (EU) No 1302/2014 of 18 November 2014 concerning a technical specification for interoperability relating to ‘rolling stock – locomotives and passengers rolling stock’ subsystem of the rail system in the European Union ([OJ L 356, 12.12.2014, p. 228](#)).
- (2) Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010 ([OJ L 129, 25.5.2018, p. 26](#)).
- (3) Commission Decision 2007/756/EC of 9 November 2007 adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC ([OJ L 305, 23.11.2007, p. 30](#)).
- (4) Commission Regulation (EU) No 1078/2012 of 16 November 2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance ([OJ L 320, 17.11.2012, p. 8](#)).

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**Changes and effects yet to be applied to :**

- Regulation revoked in part by [S.I. 2020/786](#) reg. 11