ATFM Annex A

Rules for certification and auditing of entities in charge of maintenance

ECM Regulation

Applicable from Click here to enter a date.
## Amendments record

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<td>Version 1</td>
<td>7.8.2019</td>
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Introductory provisions

1. Following their adoption by the Committee of Technical Experts in accordance with Article 15 § 2 of ATMF, these rules are declared equivalent with the provisions of European Union Commission Implementing Regulation (EU) 2019/779 of 16 May 2019, which repeals and replaces Regulation (EU) No 445/2011 with effect from 16 June 2020.

   These equivalence between ECM certificates issued in accordance with these rules and in accordance with the EU provisions shall be limited to the purpose and scope of ATMF.

2. The texts of these rules which appear across two columns are identical in substance to corresponding texts of the European Union regulations. Texts which appear in two columns differ; the left-hand column contains the OTIF rules, the right-hand column shows the text in the corresponding EU rules. Texts in the right-hand column are strictly for information only. For EU law consult the Official Journal of the European Union.

3. Annex A to ATMF which entered into force on 1 December 2015 is repealed with effect from the date of entry into force of these rules. However, previous versions of Annex A to ATMF may continue to be applied in accordance with the provisions set out in Article 15 of this Regulation.

4. Footnotes provide explanation and are not part of the rules.

Article 1
Subject matter and scope

1. This Regulation establishes rules for certification and auditing of ECM entities in charge of maintenance and maintenance workshops functions as referred to in Article 15 §2 of ATMF. 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 intended to be used in international traffic 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 definitions laid down in APTU and ATMF shall apply, in addition

the following definitions shall apply:

(a) [see ATMF] ‘accreditation’ means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008 of the European Parliament and of the Council;

(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;

(e) ‘safety critical component’ means components for which a single failure has a credible potential to lead directly to a serious accident as defined in Article 2 letter (z) of ATMF. The definition of ‘safety-critical component’ provided for in section 4.2.12.1 of Annex to

Article 3  
System of Certification

1. Any entity in charge of maintenance shall satisfy the requirements of Annex II, in respect of all vehicles which are used in international traffic on the basis of ATMF.

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

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 demonstrated⁴ either through an ECM certification or, without prejudice to paragraph 2, in case of railway undertakings through the process of safety certification.

2 "Safety critical components" are components for which a single failure has a credible potential to lead directly to a serious accident as defined in Article 3(12) of Directive (EU) 2016/798.

3 A railway undertaking or an infrastructure manager which is the ECM of one or more vehicles which are (also) operated by others is not 'maintaining vehicles exclusively for its own operations' and is therefore subject to mandatory ECM certification. E.g. if an RU is ECM of its own vehicles, and only of its own vehicles, and these vehicles are never operated by any other RU, this RU does not have to be certified as an ECM. Nevertheless, it must comply with Annex II. ECMs of freight wagons must be certified in any case.

4 If, according to § 2, it is not mandatory for RU/ECM to be ECM certified, it has three options to prove compliance with Annex II:
   a) ECM certification by an ECM certification body
in accordance with European Union law

or in case of infrastructure managers through the process of

safety authorisation in accordance with

European Union law.

In states which do not apply European Union law with respect to safety certification and safety authorisation, compliance with Annex II shall be demonstrated either through ECM certification or, without prejudice to paragraph 2, through the process defined at national level by which the Competent Authority ascertains and certifies compliance.

5. [reserved]

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 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

UTP GEN-C.

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.

b) Safety Certification in accordance with EU law, in which case it must be assessed for compliance with Annex II by the NSA.

c) For non-EU states a not-further detailed national procedure defined at national level in which the Competent Authority checks and confirms that Annex II is complied with.

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 keeper as holder of the Certificate of Operation and any holder of the Design Type Certificate

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.

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 UTP GEN-C; and 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 as defined in ATMF. 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 with place of business in a state that does not apply European Union law shall share this information also with the Competent Authority of that state. Where relevant the Competent Authority shall share this information with the Committee of Technical Experts.

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 Articles 15 and 15a of ATMF or with the requirements of this Regulation, it shall without delay inform the certification body and the relevant Competent Authority thereof. national safety authority thereof.

The certification body or, where the entity in charge of maintenance is not certified, the relevant Competent 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 of the vehicle register or, if the vehicle is registered in more than one register, registers referred to in Article 13 of ATMF in which the vehicle is registered referred to in Article 4(1) of Commission Decision 2007/756/EC⁶ and request the update of the vehicle register. In that situation:

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(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;

(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. Contracting States ensure that the Secretary General is notified of the ECM certification bodies having their place of business on their territory. This notification shall include the following information, which the Secretary General will forward to the Registrar of the ECM register:
   - name
   - address
   - contact details
   - the nature of their empowerment

   The nature of their empowerment refers to the method used by the Contracting States to assign the competences to an ECM certification body. It shall be one of the following options:
   - accreditation, or
   - recognition, or
   - the Competent Authority is designated as ECM certification body.

   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. Contracting States shall inform the Secretary General

   about any change in the situation within one month of the occurrence of that change.

3. Contracting States

   Member States

   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 adopted by the Committee of Technical Experts.

4. Contracting 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 in case such cooperation is facilitated through one or more cooperation platforms.

6. The European Union Agency for Railways may organise and facilitate cooperation between the certification bodies.

It may cover in these activities certification bodies of states which do not apply European Union law.

7. The certification bodies shall deliver an activity report in an electronic form every 3 years to the Competent Authority competent in the state where the certification body has its main place of business.

The request from a Competent Authority shall be limited to:

− certification bodies having their place of business on the territory where that Competent Authority is competent
− certification bodies which have issued the ECM certificate for the ECM of a vehicle operated on the territory
where that Competent Authority is competent.

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 possible additional rules in force in the state concerned.

   Regulation (EU) No 1078/2012.

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

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.

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7 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).
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 action:
   - 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 vehicle register referred to in Article 13 of ATMF
   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 Competent Authority and to the Committee of Technical Experts
   upon request. The requirements for this report are set out in Annex V.

Article 9
Outsourcing maintenance functions

1. One or more of
   the following functions:
   (a) a maintenance development function responsible to manage the maintenance documentation, including the configuration management, based on design and
operational data as well as on performance and return on experience;
(b) a fleet-maintenance management function to manage the vehicle's removal for maintenance and its return to operation after maintenance;
(c) a maintenance delivery function to deliver the required technical maintenance of a vehicle or parts of it, including the release to service documentation,
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 Article 9 (1) 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 Competent Authorities

If a Competent Authority

has knowledge that an entity in charge of maintenance does not comply with the requirements of

Annex VII

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

1. The European Agency for Railways may invite certification bodies with place of business in states which do not apply European Union legislation to participate in the activities related to the creating of a harmonised system of certification. This may include:

(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.

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

(via the European accreditation infrastructure established pursuant to Article 14 of Regulation (EC) No 765/2008).

Article 13
Provision of information

1. The registrar of the ECM register

shall collect, record and publish basic information on certification bodies and certified entities in charge of maintenance.

The registrar of the ECM register

shall create an IT tool for delivering this task.
The Committee of Technical Experts shall be competent to appoint the registrar of the ECM register.

2. Certification bodies shall notify

the registrar of the ECM register

the Agency

of all issued, amended, renewed, suspended or revoked ECM certifications or of all certifications for functions as referred to in

Article 9 (1),

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*

(Reserved)

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

to one of the previous versions of Annex A to ATMF with respective dates of entry into force of 1 May 2012 and 1 December 2015

shall be deemed accredited or recognised in accordance with this Regulation under the conditions for which those certification bodies have been accredited or recognised.

The scope of accreditation or recognition of previous versions of Annex A to ATMF was limited to the competence of certification bodies to issue certificates to ECMs of freight wagons. Certifications bodies which would like to extend their competence from certifying freight wagons ECMs to certifying...
also ECMs of other types of vehicles must be accredited or recognised for these additional tasks.

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, within one year after the entry into force of 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 to one of the previous versions of Annex A to ATMF with respective dates of entry into force of 1 May 2012 and 1 December 2015 issued by a certification body for vehicles other than freight wagons, before the entry into force of this Regulation 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 within three years after the entry into force of this Regulation 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 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.

5. All entities in charge of maintenance for the vehicles referred to in point (b) of Article 3 (2) 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,

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9 Article 15(1) of Directive (EU) 2016/798 lists the following vehicles:
- vehicles registered in a third country and maintained in accordance with the law of that country;
- vehicles used on networks or lines the track gauge of which is different from that of the main rail network within the Union and in respect of which fulfilment of the requirements laid down in Article 14(2) is ensured by international agreements with third countries;
shall comply with this Regulation by 16 June 2022 at the latest.

**Article 16**

**Repeal**

Previous versions of Annex A to ATMF are repealed from the date of entry into force of this Regulation. Regulation (EU) No 445/2011 is repealed with effect from 16 June 2020.

Certificates issued in accordance with one of the previous versions of Annex A to ATMF with respective dates of entry into force of 1 May 2012 and 1 December 2015 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 date indicated on the title page of this Regulation in accordance with the Depository Notification issued by the Secretary General of OTIF. on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 16 June 2020 This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 16 May 2019

- freight wagons and passenger coaches which are in shared use with third countries the track gauge of which is different from that of the main rail network within the Union;
- vehicles used on the networks referred to in Article 2(3), and military equipment and special transport requiring an ad hoc national safety authority permit to be delivered prior to their entry into service. In this case derogations shall be granted for periods not longer than 5 years.
ANNEX I

Criteria for accreditation or recognition of certification bodies involved in the assessment and award of ECM certificates

1. **ORGANISATION**
   The certification body shall document its organisational structure, showing the duties, responsibilities and authorities of management and other certification staff and any committees. Where the certification body is a defined part of a legal entity, the structure shall include the line of authority and the relationship to other parts within the same legal entity.

2. **INDEPENDENCE**
   The certification body shall be organisationally and functionally independent in its decision-making from railway undertakings, infrastructure managers, keepers, manufacturers and entities in charge of maintenance and shall not provide similar services.

   The independence of the staff responsible for the certification checks shall be guaranteed. No official shall be remunerated on the basis of either the number of checks performed or the results of those checks.

3. **COMPETENCE**
   The certification body and the staff deployed shall have the required professional competence, in particular regarding the organisation of the maintenance of vehicles and the appropriate maintenance system. The specific requirements addressing the personnel involved in the management and performance of assessment and in the certification shall be described in the accreditation scheme.

4. **IMPARTIALITY**
   The certification body’s decisions shall be based on objective evidence of conformity or non-conformity obtained by the certification body, and shall not be influenced by other interests or by other parties.

5. **RESPONSIBILITY**
   The certification body is not responsible for ensuring ongoing conformity with the requirements for certification.

   The certification body has the responsibility to assess sufficient objective evidence upon which to base a certification decision.

6. **OPENNESS**
   A certification body shall provide public access to, or disclosure of, appropriate and timely information about its audit process and certification process. It shall also provide information about the certification status (including the granting, extension, maintenance, renewal, suspension, reduction in scope, or withdrawal of certification) of any organisation, in order to develop confidence in the integrity and credibility of certification. Openness is a principle of access to, or disclosure of, appropriate information.
7. CONFIDENTIALITY

To gain the privileged access to information needed to assess conformity with the requirements for certification adequately, a certification body shall keep confidential any commercial information about a client.

8. RESPONSIVENESS TO COMPLAINTS

The certification body shall establish a procedure to handle complaints about decisions and other certification-related activities.

9. LIABILITY AND FINANCING

The certification body shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (including insurance or reserves) to cover liabilities arising from its operations in each field of its activities and the geographic areas in which it operates.
ANNEX II

Requirements and assessment criteria for organisations applying for an ECM certificate or for a certificate in respect of maintenance functions outsourced by an entity in charge of maintenance

I. Requirements and assessment criteria for the management function

1. Leadership — commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness

The organisation shall have procedures for:

(a) establishing a maintenance policy appropriate to the organisation’s type and extent of service and approved by the organisation’s chief executive or his or her representative;

(b) ensuring that safety targets are established, in line with the legal framework and consistent with an organisation’s type, extent and relevant risks;

(c) assessing its overall safety performance in relation to its corporate safety targets;

(d) developing plans and procedures for reaching its safety targets;

(e) ensuring that the resources needed to perform all processes are available to comply with the requirements of this Annex;

(f) identifying and managing the impact of other management activities on the maintenance system;

(g) ensuring that senior management is aware of the results of performance monitoring and audits and takes overall responsibility for the implementation of changes to the maintenance system;

(h) ensuring that staff and staff representatives are adequately represented and consulted in defining, developing, monitoring and reviewing the safety aspects of all related processes that may involve staff.

2. Risk management — a structured approach to assess risks associated with the maintenance of vehicles, including those directly arising from operational processes and the activities of other organisations or persons, and to identify the appropriate risk control measures

2.1. The organisation shall have procedures and arrangements in place to recognise the need and commitment to collaborate with keepers, railway undertakings, infrastructure managers, designers and manufacturers of vehicles and components or other interested parties.

2.2. The organisation shall have risk management procedures to manage changes in the maintenance file, including maintenance plans, equipment, procedures, organisation, staffing or interfaces, and to apply the common safety methods related to the risk evaluation and assessment methods

as laid down in UTP GEN-G.  as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798.

2.3. When assessing risk, an organisation shall have procedures to take into account the need to determine, provide and sustain an appropriate working environment which conforms to

3. Monitoring — a structured approach to ensure that risk control measures are in place, working correctly and achieving the organisation’s objectives

3.1. The organisation shall have a procedure to regularly collect, monitor and analyse relevant safety data, including:
   (a) the performance of relevant processes;
   (b) the results of processes (including all contracted services and products);
   (c) the effectiveness of risk control arrangements;
   (d) information on experience, malfunctions, defects and repairs arising from day-to-day operation and maintenance.

3.2. The organisation shall have procedures to ensure that accidents, incidents, near-misses and other dangerous occurrences are reported, logged, investigated and analysed.

3.3. For a periodic review of all processes, the organisation shall have an internal auditing system which is independent, impartial and acts in a transparent way. This system shall have procedures in place to:
   (a) develop an internal audit plan, which may be revised depending on the results of previous audits and monitoring of performance;
   (b) analyse and evaluate the results of the audits;
   (c) propose and implement specific corrective measures or actions;
   (d) verify the effectiveness of previous measures or actions.

3.4. The procedures mentioned in points 3.1, 3.2 and 3.3 of this Section shall comply with the common safety methods related to the risk evaluation and assessment methods as laid down in UTP GEN-G. as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 and to the methods for assessing the safety level and the safety performance of railway operators in accordance with applicable legislation. at national and Union level as adopted pursuant to point (d) of Article 6(1) of that Directive.

4. Continuous improvement — a structured approach to analyse the information gathered through regular monitoring, auditing, or other relevant sources and to use the results to learn and to adopt preventive or corrective measures in order to maintain or improve the level of safety

The organisation shall have procedures to ensure that:
   (a) identified shortcomings are rectified;
   (b) new safety developments are implemented;

(c) internal audit findings are used to bring about improvement in the system;
(d) preventive or corrective actions are implemented, when needed, to ensure compliance of the railway system with standards and other requirements throughout the lifecycle of equipment and operations;
(e) relevant information relating to the investigation and causes of accidents, incidents, near-misses and other dangerous occurrences is used to learn and, where necessary, to adopt measures in order to improve the level of safety;
(f) relevant recommendations from the national safety Competent Authority, from the national investigation body and from industry or internal investigations are evaluated and implemented if appropriate;
(g) relevant reports or information from railway undertakings/infrastructure managers, keepers or other relevant sources are considered and taken into account.

5. **Structure and responsibility** — a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation’s safety objectives

5.1. The organisation shall have procedures to allocate responsibilities for all relevant processes throughout the organisation.

5.2. The organisation shall have procedures to clearly define safety-related areas of responsibility and the distribution of responsibilities to specific functions associated with them as well as their interfaces. Those include the procedures indicated in point 2.1 above between the organisation and the keepers and, where appropriate, railway undertakings and infrastructure managers.

5.3. The organisation shall have procedures to ensure that staff with delegated responsibilities within the organisation have the authority, competence and appropriate resources to perform their functions. Responsibility and competence shall be coherent and compatible with the given role, and delegations shall be in writing.

5.4. The organisation shall have procedures to ensure the coordination of activities related to relevant processes across the organisation.

5.5. The organisation shall have procedures to hold those with a role in the management of safety accountable for their performance.

6. **Competence management** — a structured approach to ensure that employees have the competences required in order to achieve the organisation’s objectives safely, effectively and efficiently in all circumstances

6.1. The organisation shall set up a competence management system providing for:
(a) the identification of posts with responsibility for performing within the system all the processes necessary for compliance with the requirements of this Annex;
(b) the identification of posts involving safety tasks;
(c) the allocation of staff with the appropriate competence to relevant tasks.

6.2. Within the organisation’s competence management system, there shall be procedures to manage the competence of staff, including at least:
(a) identification of the knowledge, skills and experience required for safety-related tasks as appropriate for the responsibilities;
(b) selection principles, including basic educational level, mental aptitude and physical fitness;
(c) initial training and qualification or certification of acquired competence and skills;
(d) assurance that all staff are aware of the relevance and importance of their activities and how they contribute to the achievement of safety objectives;
(e) ongoing training and periodical updating of existing knowledge and skills;
(f) periodic checks of competence, mental aptitude and physical fitness where appropriate;
(g) special measures in the case of accidents/incidents or long absences from work, as required.

7. Information — a structured approach to ensure that important information is available to those making judgments and decisions at all levels of the organisation

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

7.2. To ensure an adequate exchange of information, the organisation shall have procedures for:
(a) the receipt and processing of specific information;
(b) the identification, generation and dissemination of specific information;
(c) making available reliable and up-to-date information.

7.3. The organisation shall have procedures to ensure that key operational information is:
(a) relevant and valid;
(b) accurate;
(c) complete;
(d) appropriately updated;
(e) verified;
(f) consistent and easy to understand (including the language used);
(g) made known to staff in accordance with their responsibilities, before it is applied;
(h) easily accessible to staff, with copies provided to them where required.

7.4. The requirements set out in points 7.1, 7.2 and 7.3 apply in particular to the following operational information:
(a) checks of the accuracy and completeness of national vehicle registers regarding the identification (including means) and registration of the vehicles maintained by the organisation;
(b) maintenance documentation;
(c) information on support provided to keepers and, where appropriate, to other parties, including railway undertakings/infrastructure managers;
(d) information on the qualification of staff and subsequent supervision during maintenance development;

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

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

(g) release to service and return to operation;

(h) maintenance orders;

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

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

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

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

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

8. Documentation — a structured approach to ensure the traceability of all relevant information

8.1. The organisation shall have adequate procedures in place to ensure that all relevant processes are duly documented.

8.2. The organisation shall have adequate procedures in place to:

(a) regularly monitor and update all relevant documentation;

(b) format, generate, distribute and verify changes to all relevant documentation;

(c) receive, collect and archive all relevant documentation.

9. Contracting activities — a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation’s objectives to be achieved

9.1. The organisation shall have procedures in place to ensure that safety-related products and services are identified.

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

(a) contractors, subcontractors and suppliers are competent;

(b) contractors, subcontractors and suppliers have a maintenance and management system that is adequate and documented.
9.3. The organisation shall have a procedure to define the requirements that such contractors and suppliers have to meet.

9.4. The organisation shall have procedures to monitor the awareness of suppliers and/or contractors of risks they entail to the organisation’s operations.

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

9.6. At least the basic principles for the following processes shall be clearly defined, known and allocated in the contract between the contracting parties:
   (a) responsibilities and tasks relating to railway safety issues;
   (b) obligations relating to the transfer of relevant information between both parties;
   (c) the traceability of safety-related documents.

II. Requirements and assessment criteria for the maintenance development function

1. The organisation shall have a procedure to identify and manage:
   (a) all maintenance activities affecting safety;
   (b) all safety-critical components.

2. The organisation shall have procedures to guarantee conformity with the essential requirements for interoperability, including updates throughout the lifecycle, by:
   (a) ensuring compliance with the specifications related to the basic parameters as set out in the relevant UTPs. for interoperability as set out in the relevant technical specifications for interoperability (TSIs);
   (b) verifying in all circumstances the consistency of the maintenance file with the information included in the Certificate of Operation as listed in Article 11 § 3 of ATMF. authorisation related to the vehicle (including any national safety requirements) including the conformity to the technical file and the type of records as in the European Register of Authorised Types of Vehicles (ERATV);
   (c) managing any substitution in the framework of maintenance;
   (d) identifying the need for risk assessment of the potential impact of the change in question on the safety of the railway system, by application of the common safety methods related to the risk evaluation and assessment as laid down in UTP GEN-G. methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798;
   (e) managing the configuration of all technical changes affecting the system integrity of the vehicle.

3. The organisation shall have a procedure to design and support the implementation of maintenance facilities, equipment and tools specifically developed and required for maintenance delivery. The organisation shall have a procedure to check that these facilities,
equipment and tools are used, stored and maintained according to their maintenance schedule
and in conformity with their maintenance requirements.

4. When vehicles start operations, the organisation shall have procedures to:
   (a) obtain access to the recommendations for maintenance of the initial documentation and
to collect sufficient information on planned operations;
   (b) analyse those recommendations for maintenance of the initial documentation and to
provide, by application of the common safety methods related to the risk evaluation and
assessment methods
       as laid down in UTP GEN-G, as adopted pursuant to point (a) of Article 6(1) of
       Directive (EU) 2016/798,
       the first maintenance file, also taking into account the information contained in any
       associated guarantees;
   (c) ensure that the implementation of the first maintenance file is done accordingly.

5. To keep the maintenance file updated throughout the lifecycle of a vehicle, the organisation
shall have procedures to:
   (a) collect at least the relevant information in relation to:
       (i) the type and extent of operations effectively performed, including, but not limited
to accidents, serious accidents and incidents,
       as defined in Article 2 of ATMF; as defined in Directive (EU) 2016/798;
       (ii) the detected failures on components;
       (iii) the type and extent of operations planned;
       (iv) the maintenance effectively performed.
   (b) define the need for updates, taking into account the limit values for interoperability;
   (c) make proposals for and approve changes and their implementation, with a view to a
decision based on clear criteria, taking into account the findings from risk assessment
performed by application of the common safety methods related to the risk evaluation
and assessment methods
       as laid down in UTP GEN-G; as adopted pursuant to point (a) of Article 6(1) of
       Directive (EU) 2016/798;
   (d) ensure that the implementation of changes is done accordingly;
   (e) monitor the effectiveness of the changes
       in accordance with the provisions applicable in the state concerned.
       through a process in consistency with the methods for assessing the safety level and the
       safety performance of railway operators at national and Union level as adopted pursuant to
       point (d) of Article 6(1) of Directive (EU) 2016/798.

6. When the competence management process is applied to the maintenance development
function, at least the following activities affecting safety shall be taken into account:
(a) application of the common safety methods related to the risk evaluation and assessment methods

as laid down in UTP GEN-G

as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798

for assessment of changes of the maintenance file;

(b) engineering disciplines required for managing the establishment and the changes of the maintenance file and the development, assessment, validation and approval of substitutions in the framework of maintenance;

(c) maintenance activities on safety-critical components;

(d) joining techniques (including welding and bonding);

(e) non-destructive testing.

7. When the documentation process is applied to the maintenance development function, the traceability of at least the following elements needs to be guaranteed:

(a) the documentation relating to the development, assessment, validation and approval of a substitution in the framework of maintenance;

(b) the configuration of vehicles, including, but not limited to, safety-critical components and on-board software modifications;

(c) records of the maintenance performed;

(d) results of studies concerning return on experience;

(e) all the successive versions of the maintenance file, including risk assessment;

(f) reports on the competence and supervision of maintenance delivery and fleet maintenance management;

(g) technical information to be provided to support keepers, railway undertakings and infrastructure managers.

III. Requirements and assessment criteria for the fleet maintenance management function

1. The organisation shall have a procedure to check the competence, availability and capability of the entity responsible for maintenance delivery before placing maintenance orders. This requires that the maintenance workshops are duly qualified to decide upon the requirements for technical competences in the maintenance delivery function.

2. The organisation shall have a procedure for the composition of the work package and for the issue and release of the maintenance order.

3. The organisation shall have a procedure to send vehicles for maintenance in due time.

4. The organisation shall have a procedure to manage the removal of vehicles from operation for maintenance or when safe operation is impaired or when needs of maintenance affect the normal operation.

5. The organisation shall have a procedure to define the necessary verification measures applied to the maintenance delivered and the release to service of the vehicles.

6. The organisation shall have a procedure to issue a notice of return to operation, including the definition of restrictions of use to ensure the safe running by taking into account the release to service documentation.
7. When the competence management process is applied to the fleet maintenance management function, at least the return to operation shall be taken into account including defining the restriction of use.

8. When the information process is applied to the fleet maintenance management function, at least the following elements need to be provided to the maintenance delivery function:
   (a) applicable rules and technical specifications;
   (b) the maintenance plan for each vehicle;
   (c) a list of spare parts, including a sufficiently detailed technical description of each part to allow like-for-like replacement with the same guarantees;
   (d) a list of materials, including a sufficiently detailed description of their use and the necessary health and safety information;
   (e) a dossier that defines the specifications for activities affecting safety and contains intervention and in-use restrictions for components;
   (f) a list of components or systems subject to legal requirements and a list of those requirements (including brake reservoirs and tanks for the transport of dangerous goods);
   (g) application of the common safety methods related to the risk evaluation and assessment methods

   as laid down in UTP GEN-G; as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798;

   for assessing changes affecting the fleet maintenance management function.

9. When the information process is applied to the fleet maintenance management function, interested parties shall be at least informed of the return to operation, including restrictions on use relevant to users (railway undertakings and infrastructure managers).

10. When the documentation process is applied to the fleet maintenance management function, at least the following elements need to be recorded:
    (a) maintenance orders;
    (b) return to operation, including restrictions on use relevant to railway undertakings and infrastructure managers.

**IV: Requirements and assessment criteria for the maintenance delivery function**

1. The organisation shall have procedures to:
   (a) check the completeness and appropriateness of the information delivered by the fleet maintenance management function in relation to the activities ordered;
   (b) verify the use of the required, relevant maintenance documents and other standards applicable to the delivery of maintenance services in accordance with maintenance orders;
   (c) ensure that all relevant maintenance specifications, as defined in applicable regulations and specified standards contained in the maintenance orders, are available to all involved staff (e.g. they are contained in internal working instructions).

2. The organisation shall have procedures to ensure that:
(a) components (including spare parts) and materials are used as specified in the maintenance orders and supplier documentation;
(b) components and materials are stored, handled and transported in a manner that prevents wear and damage and as specified in the maintenance orders and supplier documentation;
(c) all components and materials, including those provided by the customer, comply with relevant national and international rules as well as with the requirements of relevant maintenance orders.

3. The organisation shall have procedures to determine, identify, provide, record and keep available suitable and adequate facilities, equipment and tools to enable it to deliver the maintenance services in accordance with maintenance orders and other applicable specifications, ensuring:
   (a) the safe delivery of maintenance, including the health and safety of maintenance staff;
   (b) ergonomics and health protection, also including the interfaces between users and information technology systems or diagnostic equipment.

4. Where necessary to ensure valid results, the organisation shall have procedures to ensure that its measuring equipment is:
   (a) calibrated or verified at specified intervals, or prior to use, against international, national or industrial measurement standards — where no such standards exist, the basis used for calibration or verification shall be recorded;
   (b) adjusted or re-adjusted as necessary;
   (c) identified to enable the calibration status to be determined;
   (d) safeguarded from adjustments that would invalidate the measurement result;
   (e) protected from damage and deterioration during handling, maintenance and storage.

5. The organisation shall have procedures to ensure that all facilities, equipment and tools are correctly used, calibrated, preserved and maintained in accordance with documented procedures.

6. The organisation shall have procedures to check that performed tasks are in accordance with the maintenance orders and to issue the notice of release to service. The notice of release to service shall include all information that is useful to define restrictions of use.

7. When the risk assessment process (in particular points 2.2 and 2.3 of Section I) is applied to the maintenance delivery function, the working environment shall include not only the workshops where maintenance is done but also the tracks outside the workshop buildings and all places where maintenance activities are performed.

8. When the competence management process is applied to the maintenance delivery function, at least the following activities affecting safety where appropriate shall be taken into account:
   (a) joining techniques (including welding and bonding);
   (b) non-destructive testing;
   (c) final vehicle testing and release to service;
   (d) maintenance activities on brake systems, wheel sets and draw gear and maintenance activities on specific components of freight wagons for the transport of dangerous goods, such as tanks, valves, etc.;
9. When the information process is applied to the maintenance delivery function, at least the following elements shall be provided to the fleet maintenance management and maintenance development functions:

(a) works performed in accordance with the maintenance orders;
(b) any possible fault or defect regarding safety which is identified by the organisation;
(c) the release to service.

10. When the documentation process is applied to the maintenance delivery function, at least the following elements shall be recorded for the maintenance activities affecting safety, as referred to in point 1(a) of Section II:

(a) clear identification of all facilities, equipment and tools;
(b) all maintenance works performed, including personnel, tools, equipment, spare parts and materials used and taking into account:
   (i) relevant national rules where the organisation is established;
   (ii) requirements laid down in the maintenance orders, including requirements regarding records;
   (iii) final testing and the decision regarding the release to service;
(c) the control measures required by maintenance orders and the release to service;
(d) the results of calibration and verification, whereby, for computer software used in the monitoring and measurement of specified requirements, the ability of the software to perform the desired task shall be confirmed prior to initial use and reconfirmed as necessary;
(e) the validity of the previous measuring results when a measuring instrument is found not to conform to requirements.
## ANNEX III — Application forms

### APPLICATION FOR A CERTIFICATE OF CONFORMITY OF AN ENTITY IN CHARGE OF MAINTENANCE

Application for a certificate confirming that the maintenance system of an entity in charge of maintenance (ECM) is deemed to be in conformity with

- Appendix G to COTIF (the ATMF Uniform Rules) and Annex A to the ATMF Uniform Rules.

### CERTIFICATION BODY CONTACT INFORMATION

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### APPLICANT INFORMATION

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### CONTACT PERSON INFORMATION

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### APPLICATION DETAILS

4.1 Application reference (given by the applicant)

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OPERATIONAL DETAILS

5.1 Type of company:
5.11 RU  5.12 IM  5.13 Keeper  5.14 Maintenance supplier  5.15 Manufacturer  5.16 Other

5.2 Scope of ECM activities (category of vehicles: freight wagons, locomotives, multiple units, passenger carriages, high-speed vehicles, OTMs, other — specify):

5.3 Covers wagons specialised in transport of dangerous goods: YES/NO

5.4 ECM Operational functions

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SUBMITTED DOCUMENTS

6.1 Maintenance system documentation

6.2 Other specify:

SIGNATURES

Applicant

( first name, family name)

Date ___________________________ Signature ___________________________

Certification body

Internal reference number

______________________________ Date application received ______________________

Date ___________________________ Signature ___________________________

SPACE RESERVED FOR THE ADDRESSED OFFICE/AUTHORITY
APPLICATION FOR A CERTIFICATE OF CONFORMITY FOR MAINTENANCE FUNCTIONS

Application for a certificate confirming that the maintenance function is deemed to be in conformity with Appendix G to COTIF (the ATMF Uniform Rules) and Annex A to the ATMF Uniform Rules. The system within the European Union is deemed to be in conformity with Directive (EU) 2016/798 of the European Parliament and of the Council and Commission Implementing Regulation (EU) 2019/779.

CERTIFICATION BODY CONTACT INFORMATION

1.1 Name of the certification body addressed for the application

1.2 Certification body reference number

1.3 Complete postal address (street, postal code, city, country)

APPLICANT INFORMATION

2.1 Legal title

2.2 Complete postal address (street, postal code, city, country)

2.3 Phone number

2.4 Fax number

2.5 Email address

2.6 Website

2.7 Registration business number

2.8 VAT No

2.9 Other information

CONTACT PERSON INFORMATION

3.1 Family name and first name

3.2 Complete postal address (street, postal code, city, country)

3.3 Phone number

3.4 Fax number

3.5 Email address

APPLICATION DETAILS

4.1 Application reference (given by the applicant)

This application is for a

4.2 new certificate

4.3 updated/amended certificate

4.4 renewed certificate
OPERATIONAL DETAILS

5.1 Type of company:

5.11 RU  5.12 IM  5.13 Keeper  5.14 Maintenance supplier  5.15 Manufacturer  5.16 Other

5.2 Scope of ECM activities (category of vehicles: freight wagons, locomotives, multiple units, passenger carriages, high-speed vehicles, OTMs, other — specify):

5.3 Covers wagons specialised in transport of dangerous goods: YES/NO

5.4 Maintenance functions

5.5 Maintenance development YES  NO  Partial
5.6 Fleet maintenance management YES  NO  Partial
5.7 Maintenance delivery YES  NO  Partial

For partial maintenance functions, the sub-functions for which this application is submitted (see. list in Annex II to Commission Implementing Regulation (EU) …/… [indicate the number of this regulation]):

SUBMITTED DOCUMENTS

6.1 Maintenance system documentation

6.2 Other specify:

SIGNATURES

Applicant

(name)

Date

Signature

Certification body

Internal reference number

Date application received

Date

Signature

SPACE RESERVED FOR THE ADDRESSED OFFICE/AUTHORITY
ANNEX IV — Certification forms

CERTIFICATE OF CONFORMITY OF ENTITY IN CHARGE OF MAINTENANCE

confirming acceptance of the maintenance system of an entity in charge of maintenance (ECM) in conformity with Appendix G to COTIF (the ATMF Uniform Rules) and Annex A to the ATMF Uniform Rules.


1. EIN\(^{11}\) number

2. CERTIFIED ENTITY IN CHARGE OF MAINTENANCE

| Legal title: |  |
| Commercial designation or acronym (voluntary) |  |
| Complete postal address (street, postal code, city, country) |  |
| Registration business number: | VAT No: |

3. CERTIFICATION BODY

| Legal title: |  |
| Complete postal address (street, postal code, city, country) |  |
| Certification body reference number: |  |

4. CERTIFICATE INFORMATION

- new certificate
- renewed certificate
- updated/amended certificate

This is a

EIN number of the previous certificate:

Validity from: to:

Type of company:
(railway undertaking, keeper, maintenance supplier, etc.)

5. SCOPE OF ECM ACTIVITIES

Category of vehicles:
(freight wagons, locomotives, multiple units, passenger carriages, high-speed vehicles, OTMs, other)

Covers wagons specialised in transport of dangerous goods YES/NO

6. ADDITIONAL INFORMATION

\(^{11}\) The structure and content of the EIN number is defined in the OTIF specifications for vehicle registers.
CERTIFICATE OF CONFORMITY FOR MAINTENANCE FUNCTIONS


### 1. EIN number

### 2. CERTIFIED ORGANISATION

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### 3. CERTIFICATION BODY

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<td>Type of company:</td>
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### 5. SCOPE OF MAINTENANCE ACTIVITIES

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<td>Maintenance delivery</td>
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For partial maintenance functions, the sub-functions for which this certificate is valid (see list in Annex II to Commission Implementing Regulation (EU) …/… [indicate the number of this regulation]):

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7. ADDITIONAL INFORMATION

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ANNEX V

Report of the entity in charge of maintenance

1. The entity in charge of maintenance shall issue a report, which covers a period starting 2 months before the last surveillance and ending 2 months before the next planned surveillance.

2. The report shall include at least:
   − explanations and justification on how non-conformities have been addressed or solved, or both;
   − information on the volume of maintenance carried out during the prevailing period;
   − the feedback on experience in applying the common safety methods related to the risk evaluation and assessment as laid down in UTP GEN-G and as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 and to the methods for monitoring to be applied by railway undertakings, infrastructure managers and entities in charge of maintenance in accordance with the provisions applicable in the state concerned.
   − changes related to:
     − legal ownership of the company;
     − organisation (procedures in place);
     − vehicles for which the entity is in charge of maintenance;
     − sites and contractors including processes and equipment;
     − the balance between internal and external activities related to the three maintenance functions (maintenance development, fleet maintenance and maintenance delivery);
     − contractual arrangements with users (including the keepers and the exchange of data);
     − the maintenance system;
     − defects and failures of components related to safety, referred to in Section II of Annex II, and relevant information about maintenance exchanged pursuant to Article 5(3);
     − internal audit reports;
     − enforcement actions by competent authorities; the agency national safety authorities and other authorities enforcement actions or investigations including claims in accordance with Articles 8 and 12 of this legal act;
     − competence management.

3. The entity in charge of maintenance shall add to the report all information it considers relevant for the certification body.

4. The entity in charge of maintenance shall address the report to the certification body 1 month before the next planned audit surveillance.