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Sectorial scheme for accreditation and recognition of ECM certification bodies under Regulation (EU) 2019/779

Version No	Changed Section	Date	Description of Change
1.0	All	28/10/2011	Final document after consultation
1.1	3.4	20/02/2012	Integration of EA comment ERA internal document only. Not for dissemination.
1.2	3.4.	23/02/2012	Integration of EA comment
2.0	all	11/02/2019	Amendments for the extension of scope
2.1	all	25/04/2019	Amendments for the extension of scope
2.2	all	23/07/2019	Revision before presentation to EA
3	all	11/05/2020	Integration of EA comments
3.1	3.13.1 3.3	15/06/2020	Amendment c of 3.1.3.1 Add reference of the certification scheme

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1. INTRODUCTION

This document contains requirements to be used by National Accreditation Bodies or by recognition bodies when assessing certification bodies performing ECM certification. It shall be also used by Members States when designating the NSAs to act as ECM certification body (according to article 14 of Directive (EU) 2016/798).

The Sectoral (ECM) Accreditation scheme shall be compliant with the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93¹.

¹ OJ L 218, 13.8.2008, p.30.

2 REFERENCE DOCUMENTS AND DEFINITIONS

2.1 Reference documents

2.1.1 Legal texts

‘Safety Directive’

Directive (EU) 2016/798 of the European parliament and of the council of 11 May 2016 on railway safety² (article 14 “ maintenance of vehicles”).

‘Interoperability Directive’

Directive (EU) 2016/797 of the European parliament and of the council of 11 May 2016 on the interoperability of the rail system within the European Union³

Commission Implementing Regulation (EU) 2019/779 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 445/2011⁴

Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93⁵.

2.1.2 Other reference documents

EN ISO/IEC 17065:2012 Conformity assessment-Requirements for bodies certifying products, processes and services

EN ISO/IEC 17021-1:2015 Conformity assessment -- Requirements for bodies providing audit and certification of management systems

ISO/IEC 17007:2009 Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment

EA-1/22 2016 EA procedure and criteria - For the evaluation of conformity assessment schemes by EA accreditation body members.

2.2 Definitions

The definitions of the Safety Directive and the ECM Regulation are applicable. The definitions of EN ISO 9000:2015 are applicable.

To ensure a good and clear understanding of this document, the following definitions are repeated here:

a) Accreditation

Means accreditation as defined in Article 2(10) of Regulation (EC) No 765/2008 of the European Parliament and of the Council.

b) Assessment team

Means a person or group of persons assigned by the certification body to perform the assessment work according to the provisions defined by applying the certification body quality management system.

² OJ L 138, 26.5.2016, p. 102

³ OJ L 138, 26.5.2016, p. 44

⁴ OJ L 139, 27.5.2019, p.360

⁵ OJ L 218, 13.8.2008, p.30

The assessment team shall be free from any commercial, financial and other pressures that might influence its tasks.

c) Category of vehicles

Means the scope of ECM activities indicated in the application forms (Annex III of the Regulation (EU) 2019/779).

The possible categories are: freight wagons, locomotives, multiples units, passenger carriages, high speed vehicles, On Track Machines (OTM) and must be specified in case of other.

d) Certification committee

Means a person or group of persons assigned by the certification body to make a certification decision based on all information related to the assessment, its review and any other relevant information.

The certification committee shall be free from any commercial, financial and other pressures that might influence decisions. It has not been involved in the process of assessment of item under certification

e) Certification decision

Granting, continuing, expanding the scope of, and reducing the scope of, suspending, restoring, withdrawing or refusing certification.

f) Certification scheme

Means certification system related to specified products, to which the same specified requirements, specific rules and procedures apply.

g) Certification scheme owner

Individual or organisation, which is responsible for developing and maintaining a certification scheme.

h) Certification system

Rules, procedures, and management for carrying out certification.

ECM Regulation is the mandatory criteria document for vehicle maintenance certification systems both for ECM certification and outsourced maintenance functions.

i) Conformity assessment system

Rules, procedures and management for carrying out conformity assessment

j) Conformity assessment scheme - Conformity assessment programme

Conformity assessment system related to specified objects of conformity assessment, to which the same specified requirements, specific rules and procedures apply

k) European Co-operation for accreditation (EA)

Means the European association of national accreditation bodies recognised against the Regulation (EC) 765/2008. All Member states of the European Union are members of EA.

(www.european-accreditation.org)

l) EA Multi-Lateral Agreement (EA MLA)

Means the agreement signed between the EA accreditation body members to recognise the equivalence, reliability and therefore acceptance of accredited certifications, inspections, calibration certificates and test reports across Europe.

m) Entity in charge of maintenance (ECM)

Means an entity in charge of maintenance of a vehicle, and registered as such in the national vehicle register.

(ECM regulation)

n) European Identification Number

Means the number for which the structure is ruled by Appendix 2 of 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 (including COMMISSION IMPLEMENTING DECISION (EU) 2018/1614 of 25 October 2018 laying down specifications for the vehicle registers referred to in Article 47 of Directive (EU) 2016/797 of the European Parliament and of the Council and amending and repealing Commission Decision 2007/756/EC)

o) European Union Agency for Railways (EUAR)

Means the European Agency providing the EU Member States and the Commission with technical assistance in the fields of railway safety and interoperability.

EUAR is established and ruled by the Regulation (EU) 2016/796 of the European parliament and of the council of 11 May 2016 on the European Union Agency for Railways and repealing regulation (EC) No 881/2004.

p) Vehicle

Means a railway vehicle suitable for circulation on wheels on railway lines with or without traction; a vehicle is composed of one or more structural and functional subsystems

q) Maintenance workshop

means a mobile or fixed entity composed of staff, including those with management responsibility, tools and facilities organised to deliver maintenance on vehicles, parts, components or sub-assemblies of vehicles

r) National safety authority (NSA)

means a safety authority as defined in Article 3(7) of Directive(EU) 2016/798;

s) Product

Result of a process.

Set of interrelated or interacting activities which transforms inputs into outputs

t) Service

Result of at least one activity necessarily performed at the interface between supplier and the customer, which is generally tangible

u) Outsourced maintenance function

Refers to entities performing outsourced maintenance function or parts thereof as considered in Article 14(3) of Directive (EU) 2016/798 on railway safety.

2.3 Abbreviations

CSM	Common Safety Methods
EA	European Co-Operation for Accreditation
EA MLA	EA Multi-Lateral Agreement
ECM	Entity in Charge of Maintenance
EIN	European identification member
EN	European Norm

EUAR / ERA	European Railway Agency (scheme owner)
GCU	General Contract of Use
IAF	International Accreditation Forum
IAF MD	Mandatory document of IAF
IM	Infrastructure Manager
ISO	International Organization for standardization
NDT	Non-Destructive Test
NVR	National vehicle Register
OTIF	Intergovernmental Organisation for International Carriage by Rail
RID	Regulation concerning the International Carriage of Dangerous Goods by Rail
RU	Railway undertaking
SCC	Safety Critical Components

3 SECTORAL SCHEME

The European Union Agency for Railways (ERA) is the scheme owner in consistency with the EA procedure (EA-1/22) and the article 13(2)(a) of Regulation (EC) No 765/2008.

This sectorial scheme aims at ensuring the competence of certification bodies to perform certification activities¹ stated in the ECM Regulation. The criteria of Annex I of the regulation (EU) 2019/779 are general criteria, if there are some specificities dedicated to the scope, they will be explained **in Bold** in this section.

This ECM sectorial scheme shall be applied in all countries where the EA MLA is in force.

3.1 Criteria for accreditation or recognition

3.1.1 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.

3.1.2 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.

3.1.3 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 are described below:**

The specific requirements described in this section address the personnel involved in:

- **3.1.3.1 the management and performance of assessment** (*assessment team of the certification body performing the certification of Entities in Charge of Maintenance and/or Separate Maintenance Functions*); and
- **3.1.3.2 the certification** (*Certification Committee of the certification body performing the certification of Entities in charge of maintenance and/or Separate Maintenance Functions*).

These specific requirements complete the requirements addressed in the section 7 including the annex A of EN ISO/IEC 17021-1:2015.

It is not required that each member of the assessment team has the full range of knowledge as mentioned in each section here below, but the composition of the assessment team shall be well balanced to ensure its competence for performing assessment in consistency with the ECM Certification Scheme and the scope of certification awarded.

Alternatively, in case the certification body cannot ensure that the assessment team meets the deep knowledge, it shall identify and implement the necessary support activities to assure that the assessment team is competent.

3.1.3.1 *Assessment team of the certification body performing the certification of Entities in Charge of Maintenance and/or outsourced Maintenance Functions*

a) Knowledge of the European railway sector

- › Safety Directive and Interoperability Directive;
- › CSMs compliant with the points (a,d) of Article 6(1) of the Safety Directive;
- › ECM Regulation;
- › Relevant technical specifications for interoperability according to the interoperability directive;
- › Maintenance aspects in GCU;
- › European legislation applicable to transport of dangerous goods
e.g. Responsibilities acc. 1.4 and competence requirements acc. 1.3 of RID.

They shall also have knowledge of documents which are used to support this European railway legal framework, such as for instance, ERA publications, implementation guides, guidelines, International standards relevant to maintenance of railway vehicles and risk assessment.

b) Knowledge and skills addressing the maintenance of railway vehicle

The members of the assessment team shall have demonstrated understanding and experience as below specified.

Furthermore, the members of the assessment team shall have specific knowledge on maintenance.

• *Demonstrated understanding and experience*

Each member of the assessment team shall comply with at least one of the following requirements related to base training and professional experience in:

- › maintenance management to supervise and coordinate the maintenance activities and to ensure the safe state of the vehicle in the railway system;
- › maintenance development to manage the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return of experience;
- › fleet maintenance management to manage the vehicle's removal for maintenance and its return to operation after maintenance;
- › maintenance delivery to deliver the required technical maintenance of a vehicle or parts of it, including the release to service documentation;
- › assessment of maintenance system in the railway;
- › designing and manufacturing of railway vehicles;
- › assessment of other maintenance system in other sectors such as automotive, civil aviation, energy, building technical equipment, industrial mechanical equipment. The relevance and efficiency should be applicable to the railway system;
- › assessment or management of welding/joining activities or non-destructive tests activities or safety critical components or SCC equipment;
- › providing railway vehicle maintenance training.

At least one member of the assessment team shall have a professional experience in maintenance of railway vehicles (management and engineering) and shall demonstrate ability of the application of risk management and monitoring process to maintenance of railway vehicle.

• *Knowledge on maintenance*

The members of the assessment team shall have knowledge of:

- › ECM regulation in terms of ECM activities, responsibilities, functions, documents, procedures, processes, information exchanged, skills and competences;
- › existing rules and relevant documents specific for assessing and delivering certificates to ECMs;
- › guides, recommendations for use elaborated by the ECM cooperation body, and maintenance plans, and its reference documents, which may be used as reference in order to set up an ECM maintenance file;
- › maintenance principles, activities and procedures practices for management of

safety critical components.

For instance:

- › welding/joining rules and good practices, for example standard EN 15085, or equivalent;
- › non Destructive Tests rules and good practices, for example standard ISO 9712 or equivalent;
- › braking system, electrical system, mechanical system: technology, design rules and maintenance including international or industry standards;
- › wheelset, running gear and draw gear technology, design rules and maintenance including international or industry standards;
- › protective coating;
- › control-command signaling;
- › vehicle-interior fittings.

c) Knowledge and skills addressing assessment principles, practices and techniques and knowledge of the specific standards related to them.

The members of the assessment team shall have knowledge and skills in:

- › Product, service and process certification in particular a sufficient knowledge of international assessment standards such as:
 - › 17065:2012
- › Assessment and certification of management systems as ruled by international standards and/or industry standards relevant to railway, in particular a sufficient knowledge of international assessment standards such as:
 - › 17021-1:2015
 - › IAF Mandatory Documents
 - › EN 19011:2018
- › And the reference standards (according which to assess) that they cover :
 - › EN ISO/IEC 9001:2015, ISO 45001:2018

d) Language skills

The assessment team shall have the required language proficiency to conduct verbal and documentary assessment of implemented ECM systems.

3.1.3.2 Certification Committee

a) Knowledge of the European railway sector

The Certification Committee shall have knowledge of the European railway legal framework (see details in 3.1.3.1(a)).

b) Knowledge and skills addressing the maintenance of railway vehicles

The Certification Committee shall have proven professional experience in maintenance of railway vehicles (management or engineering) and in monitoring and risk management.

c) Knowledge and skills addressing assessment principles, practices and techniques and knowledge of specific standards

The Certification Committee shall have experience in management and/or product certification.

The Certification Committee bases judgement on the assessment reports provided by the assessment team. For that reason no member of the assessment team involved in a certification project may take part to the Certification Committee for the same project and vice-versa (dual-control principle).

d) Language skills

For each submitted dossier, all the members of the Certification Committee shall have sufficient language skills to understand all assessment reports

3.1.4 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. **The certification body shall create and update an appropriate impartiality analysis which records identified risks and action.**

3.1.5 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.

3.1.6 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.

3.1.7 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.

3.1.8 RESPONSIVENESS TO COMPLAINTS

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

3.1.9 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. **For more clarification, a reference to part 4.3 of 17065:2012 can be made.**

3.2 Scope of the accreditation

The accreditation addresses two types of certification defined in the Regulation (EU) 2019/779:

- › the certification of Entity in Charge of Maintenance. The type of categories of vehicles shall be indicated;
- › the certification of outsourced maintenance functions as referred to in paragraphs (b), (c) and (d) of Article 14(3) of Directive (EU) 2016/798. The type of categories of vehicle shall be indicated.

These two types of certification are described in detailed manner in the ECM certification scheme (version 1172/003 V1.1).

The certification body may choose to be accredited or recognised for one or several types of certification depending on the vehicle categories covered and the functions.

The accreditation related to the certification of Entity in Charge of Maintenance covers automatically the certification of outsourced maintenance functions.

3.3 Requirements for certification bodies

The certification body shall apply ISO/IEC 17065:2012 and ISO/IEC 17021-1:2015 (chapter 7 and 9). The certification body shall apply the certification scheme (version 1172/003 V1.1)

The certification body shall maintain its process and competence for delivery of certification within the technical scope for which it is accredited by the National Accreditation Body or for which it is recognised by the recognition body.

4 IDENTIFICATION

The accreditation Body or recognition body shall identify each decision on accreditation or recognition, i.e. delivery, revocation or suspension, in conformity with the European Identification Number (EIN)

5 STRUCTURE OF EIN

The decision on accreditation or recognition shall be identified by an EIN and delivered by the accreditation body or recognition body.

The identification of the certificate includes the identification of the certification body.

The EIN is structured as **XY/ab/cdef/ghij** where

'XY' = Country Code of the accreditation body or recognition body. 'ab' = '30'

'**cd**' = counter that identifies the accredited body or recognised body. From '01' to '99'

'**ef**' = year when the decision on accreditation or recognition is taken by the accreditation body or recognition body (delivery, revocation, suspension).

'**ghij**'=counter (4 digits). From '0001' '9999'

Example:

- › FR/30/0211/0001: Accreditation decision '0001' taken in '2011' by the French Accreditation body (COFRAC) related to the certification body '02'.
- › SK/30/0117/0001: Recognition decision '0001' taken in 2017 by the Slovak recognition body (Ministry of Transport, Construction and Regional Development of Slovak Republic) related to the certification body '01'