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Certification scheme for ECM and outsourced maintenance functions under Regulation (EU) 2019/779

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1. Introduction

This document is the **ECM certification scheme** to release ECM certification and certification of outsourced maintenance functions, or parts thereof, in compliance with the *Commission Regulation (EU) 2019/779 of 16 May 2019 on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 798/2016 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011* (in this document referenced as ECM Regulation).

It aims at providing:

- to the **Certification Bodies**
the necessary common rules, criteria and methods to manage the process for releasing ECM certification against the requirements specified in the ECM Regulation
- to the **applicant entities**
information on the certification, surveillance and re-certification processes, their structure, organisation, timing, requirements to be verified, documents and other common rules adopted helping the applicant in preparing its organisation to face in a proper way the certification, surveillance and re-certification processes.

This document has been developed as part of the sectorial ECM accreditation scheme related to ECM certification.

This document addresses:

- the **ECM certification for vehicles**
- the **certification of outsourced maintenance functions**, or parts thereof, as referred to in points (b), (c) and (d) of Article 14(3) of Safety Directive and specified in Art. 9 and 10 of ECM Regulation.

The management function ECM – F1, as referred to in point (a) of Art. 14(3) of the Safety Directive, cannot be certified alone.

This document covers all vehicles as stated in the Article 1(2) of ECM Regulation.

ERA is the scheme owner in consistency with the rules of EA.

2. References

2.1. Reference documents

2.1.1. Legal texts

1) Safety Directive

means the Directive (EU) 798/2016 of the European Parliament and of the Council of 11 May 2016 on railway safety

2) ECM Regulation

means the Commission Regulation (EU) 2019/779 of 16 May 2019 on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 798/2016 of the European Parliament and of the Council and repealing Commission Regulation (EU) 445/2011

3) **Regulation 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) 339/93.

4) CSM REA Regulation

means the Commission Regulation (EU) 402/2013 of 30 April 2013 on a common safety method for risk evaluation and assessment and repealing Regulation (EC) 352/2009

5) CSM on Monitoring

means the Commission Regulation (EU) 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 entity in charge of maintenance

6) Interoperability Directive

means the Directive (EU) 797/2016 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (recast)

7) CSM on SMS

means the Commission Delegated Regulation (EU) 762/2018 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 798/2016 of the European Parliament and of the Council and repealing Commission Regulations (EU) 1158/2010 and (EU) 1169/2010

2.1.2. Other documents

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

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

3) EN ISO/IEC 17000:2005 Conformity assessment – Vocabulary and general principles

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

7) IAF MD 1:2018 Audit and certification of a Management System Operated by a Multiple-Site Organization

8) IAF MD 2:2017 Transfer of Accredited Certification of Management Systems

9) IAF MD 5:2015 Determination of Audit Time of Quality and Environmental Management Systems.

The above documents should be understood as the latest valid version of each document – in case of modifications, the latest version applies.

2.2. Definitions

The definitions of the Safety Directive and ECM Regulation are applicable.

The definitions of ISO 9000:2015 and ISO 17000:2005 are applicable and mentioned in the definition.

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) 765/2008 of the European Parliament and of the Council.

(b) Assessment

means the conformity assessment resulting of the combination of audits of a maintenance system and inspections as described in this document.

(c) Audit

Systematic, independent and documented **process** for obtaining **objective evidence** and evaluating it objectively to determine the extent to which **audit criteria** are fulfilled.

(ISO 9000:2015, §3.13.1)

(d) 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) 798/2016, or parts of those functions; it is accredited or recognised or be a national safety authority and in his role is called to be compliant with the general criteria and principles set out in Annex I of ECM Regulation.

(e) 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

(f) Certification decision

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

(g) Certification scheme

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

(h) Certification scheme owner

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

For certifications of ECM or outsourced maintenance functions according to the ECM Regulation, ERA is the scheme owner.

(i) Certification system

Rules, procedures and management for carrying out certification.

ECM Regulation is the mandatory document for vehicle maintenance certification system, both, for ECM certification and certification of outsourced maintenance functions.

(j) 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.

(k) European Co-operation for accreditation (EA)

means the European association of national accreditation bodies recognised against the European Regulation 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) International Accreditation Forum (IAF)

means The IAF is the world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment

(www.iaf.nu)

(n) Inspection

Examination of a product, service, process or installation and/or their design and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements

NOTE Inspection of processes may include personnel, facilities, technology or methodology.

(ISO 17000:2005, § 4.3.)

(o) Keeper

means the person or entity that, being the owner of a vehicle or having the right to use it, exploits the vehicle as a means of transport and is registered as such in the national vehicle register referred to in Article 22 and 47 of the Interoperability Directive.

(p) Levels of maintenance

Maintenance may be divided in 5 levels:

- The **first level** includes the actions of checking (including technical inspections) and monitoring undertaken before the departure (pre-departure) or on route. This level is regulated in TSI OPE and is not on the responsibility of ECMs.
- The **second level** includes inspections, checks, tests, fast exchanges of replaceable units and preventative and corrective operations of limited duration between two scheduled journeys.
- The **third level** corresponds to the operations carried out mainly in specialised facilities of a maintenance centre. It includes interventions of preventative and corrective maintenance and scheduled exchanges of components. The vehicle is not in active service during this level of maintenance.
- The **fourth level** comprises the major maintenance operations, generally called overhauls (of modular subsystems or of the complete vehicle).
- The **fifth level** comprises the refurbishment, modifications, very heavy repairs, renewal or upgrading, except where they are the subject to new authorisation under the interoperability Directives.

The levels of maintenance are usually combined and grouped as following:

- **Light maintenance**
Also called line maintenance. Represents all measures carried out on the **complete** vehicle subsystem and replacement works (including related measurements and testing).
Light maintenance may include level 2 and level 3.
- **Heavy maintenance**
Also called base maintenance (including renovation). Represents all measures, undertaken to establish the actual condition and/or to reinstate the nominal condition, that necessitate partially or completely disassembling of the vehicle (including related measurements and the associated measuring and testing).
It represents also all measures to recondition components or spare parts.
Heavy maintenance may include level 4 and level 5.

(q) Maintenance system

A Maintenance system is defined as a formalised system that documents processes, procedures, and responsibilities for achieving the maintenance policies and objectives. A maintenance system

helps to assure that the organisation's activities related to the maintenance of railway vehicles meet customer and regulatory requirements and to improve its effectiveness and efficiency on continuous basis.

(r) 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.

(s) National safety authority (NSA)

means a safety authority as defined in Article 3(g) of the Safety Directive.

(t) Process

Set of interrelated or interacting activities that uses inputs to deliver an intended result.

(ISO 9000:2015, §3.4.1)

(u) Product

Result of a process.

(v) outsourced maintenance function, or parts thereof

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

(w) Scope of ECM certification

The scope of the ECM certification (point 5 of forms as in Annex IV of ECM Regulation) generally includes;

– categories of vehicles

In case of certification of outsourced maintenance function, or parts thereof, it is complemented in the related form of Annex IV of ECM Regulation by compiling point 6 with:

– appropriate function/s covered and, if only parts of a function are covered,

– the processes/sub-functions of the related function (points of the relevant section of the function as in Annex II of ECM Regulation)

– limitation indicating processes/parts of vehicle or component covered/excluded.

(x) Specified requirement

Need or expectation that is stated

NOTE Specified requirements may be stated in normative documents such as regulations, standards and technical specifications.

(ISO 17000:2005, § 3.1.)

(y) Surveillance

Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity

(ISO 17000:2005, § 6.1)

(z) category of vehicle

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.

2.3. Standardisation bodies

IAF: International Accreditation Forum: www.iaf.nu

CEN: European Committee for Standardization. www.cen.eu

ISO: International Organization for Standardization www.iso.org

CENELEC: European Committee for Electrotechnical Standardization www.cenelec.eu

IEC: International Electrotechnical Commission www.iec.ch

2.4. Abbreviations

CSM	Common Safety Methods
EA	European Co-Operation for Accreditation
EA (MLA)	EA Multi-Lateral Agreement
ECM	Entity in Charge of Maintenance
EN	European Norm
ECM - F1	Management function
ECM - F2	Maintenance Development function
ECM - F3	Fleet Maintenance Management function
ECM - F4	Maintenance Delivery function
ERA	European Union Agency for Railways (scheme owner)
ERATV	European Register of Authorised Types of Vehicles
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
RU	Railway Undertaking
SCC	Safety Critical Components
TSI	Technical Specifications for Interoperability

3. Certification scheme for ECM certification

3.1. The legal basis for the certification process

According to recital (2) of ECM Regulation, “*the purpose of the certification system is to provide a framework for harmonising requirements and methods to assess the ability of entities in charge of maintenance across the Union.*”

Furthermore, according to recital (11) of ECM Regulation, “*the assessment by a Certification Body of an application for an ECM certificate is an assessment of the applicant’s ability to manage maintenance activities and to deliver the operational functions of maintenance either by itself or through contracts with other bodies, such as maintenance workshops, charged with delivering those functions or parts of those functions.*”

The art 7(1) of ECM Regulation points out that the applicant for an ECM certification “*shall provide documentary evidence for the requirements and procedures set out in Annex II.*”

The art 7(4) of ECM Regulation points out that “*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.*”

The previous legal references make it clear that the process to obtain **ECM certification** is based on **2 stages**:

1. *an assessment of maintenance system through system documentary evidences and*
2. *an assessment of the implementation of the maintenance system comprising on-site visits*

both with the aim to verify the fulfilment of the requirements set out in the ECM Regulation and with reference to Annex II of ECM Regulation.

3.2. Structure, purpose and type of ECM certification and outsourced maintenance function certification

The certification process described in the present document is a process for which the conformity assessment with the requirements of ECM Regulation is performed.

It comprises also rules and methods applicable from the application presented to a Certification Body to the award of the certification and covers also the surveillance activities during the validity period of the certification and re-certification process to ensure continuity of the certification.

According to Art. 1(1) and 1(2), the system of certification is applicable to all vehicles and to the award of the certification for:

- ECM
- Outsourced maintenance functions, or parts thereof.

According to Art. 7(2) of ECM Regulation, the application for ECM certification may be limited to a specified category of vehicles, to be set out in the certification application form (Annex III of ECM Regulation) both for ECM certification and for outsourced maintenance function/s, or parts thereof, certification.

The assessment (stage 1 and 2) is carried out to demonstrate conformity with the requirements of ECM Regulation.

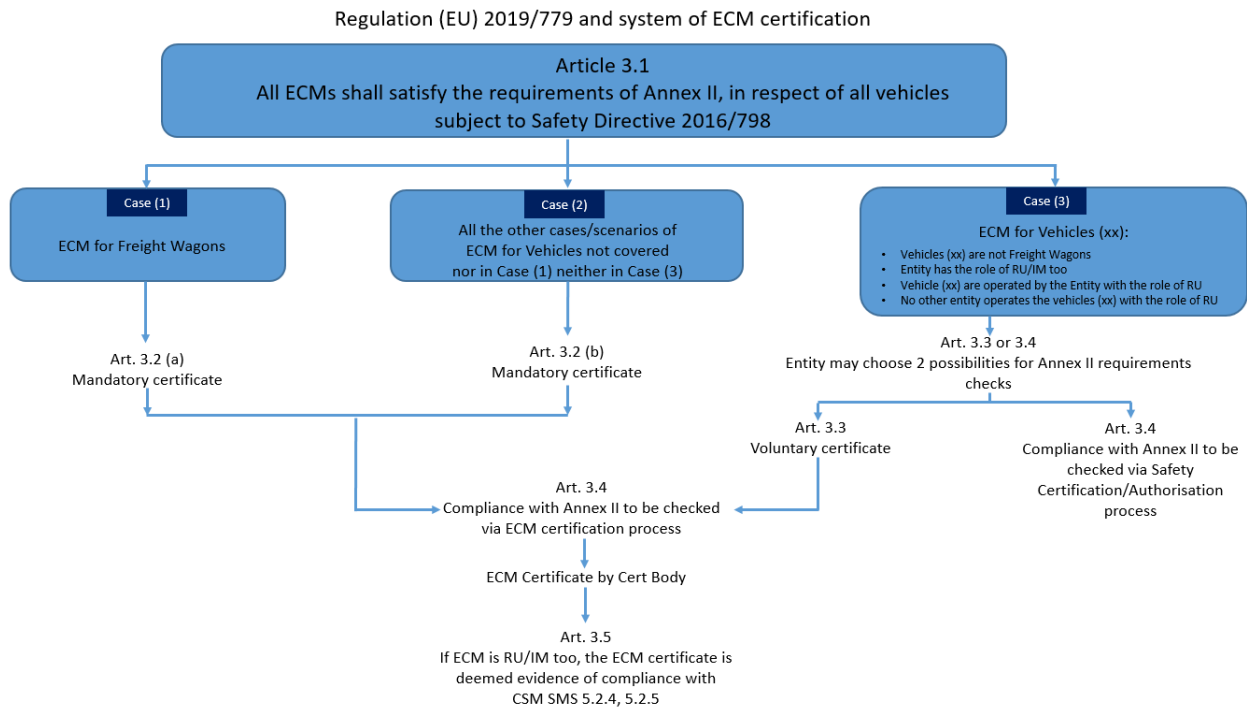
The award of the ECM certification gives evidence that the maintenance system of the applicant meets the requirements stated in the ECM Regulation.

The requirements to award the **ECM certification** are defined within ECM Regulation and with specific references to all the section of Annex II and summarized in:

- 3.3.3 – rules and requirements for stage 1 and 2

- 3.3.3.3 – specific requirements for ECM – F1
- 3.3.3.4 – specific requirements for ECM – F2
- 3.3.3.5 – specific requirements for ECM – F3
- 3.3.3.6 – specific requirements for ECM – F4

The **ECM certification** is **mandatory** for all entities in charge of maintenance and for all categories of vehicles with the applicability as stated in Art. 3 of ECM Regulation as summarized in the following diagram:



The requirements to award the **certification for outsourced maintenance function/s**, or parts thereof, are stated by the following:

- Art. 1(2) and Art. 10(1) of ECM Regulation, where it is stated that the ECM system of certification is applicable, on voluntary basis, to “entity or organisations taking on one or more maintenance functions, or parts thereof, as referred to in points (b), (c) and (d) of Article 14(3) of Directive (EU) 798/2016.”
- Art. 10(1) of ECM Regulation, “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”.
- Art. 10(2) of ECM Regulation, “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.”

Based on the previous references, the requirements to award the **voluntary certification for outsourced maintenance function/s**, or parts thereof, are defined within ECM Regulation and with specific references to:

- Section I of Annex II as summarized in 3.3.3.3 (specific requirements for ECM – F1)
- Section(s) of Annex II related to the specific outsourced maintenance function(s), or parts thereof, as summarized in 3.3.3.4 (specific requirements for ECM – F2), 3.3.3.5 (specific requirements for ECM – F3), 3.3.3.6 (specific requirements for ECM – F4)

In addition, to be considered rules and requirements for stage 1 and 2 as summarized in 3.3.3.

3.3 Structure of the certification process

The ECM certification process as defined in the preceding section is structured as:

- Formal application (3.3.1.)
- Application Review (3.3.2.)
- Certification Assessment (3.3.3.) and sub-sections
- Delivery of certificate (3.3.4.) and sub-sections
- Surveillance activities (3.3.5.) and sub-sections
- Re-certification process (3.3.6.)

Additional necessary criteria and principles are added in section 3.4 and its sub-sections for:

- Used language
- Assessment time
- Access, traceability of reports, confidentiality
- Consideration on Existing certification
- Certification decision identification number
- Use of certificate
- Transfer of certificate

This structure is compliant with the ECM Regulation and uses, where appropriate, the common good practices in the certification domain such as the section 9 of ISO 17021:2015 and section 7 of ISO 17065:2012.

This structure, rules, criteria and requirements are also applicable in case of certification process of outsourced maintenance function/s, or parts thereof, adapted to the scope of certification intended and according to rules and approach as in section 3.2.

3.3.1. Formal application

The entity or organisation applies for the first time for ECM certification by providing to the Certification Body the form in the Annex III of the ECM Regulation and the following documents:

- A description of the organisational structure of the ECM applicant.
This provides the necessary information to the Certification Body on the size and complexity of the organisation.
The description should contain:
 - Global organigrams of the organisation
 - Human and technical resources available
 - Overall sites and organigrams of maintenance functions
 - A description of maintenance system specifying the internal entity performing the four functions described in Annex II of ECM Regulation. It also includes, where appropriate, the external entities performing any maintenance functions for the organisation.
 - For the external entities the applicant shall indicate if they are:
 - globally under its maintenance system or
 - third party certified as compliant with the ECM Regulation;The ECM applicant shall provide basic information on external entities and on the relationship and exchange with its organisation to monitor their performances.

- Structured description of the processes and procedures put in place by the ECM applicant and how they comply with the requirements for certification of the Annex II of ECM Regulation. The ECM applicant may provide a table/flow diagram for a better understanding of relations between its processes and the requirements stated in the Annex II of ECM Regulation.
- Information on the maintenance policy relevant to the Annex II I.1.(a) of ECM Regulation. The information should include a maintenance policy statement.
- Description of the strategy to ensure continued compliance with the requirements set out in Annex II of ECM Regulation, after the award of the ECM certification, including the compliance with the CSM on Monitoring.
- Information on vehicles:
 - Structured information on vehicles the applicant is applying for ECM certification (categories, quantity, type and extent of operation planned).
The information is based on categories of vehicles intended or planned to be maintained in the forthcoming years.

In case of application for **certification of outsourced maintenance function**, along with the form in the Annex III of the ECM Regulation, the applicant entity has to provide for the above information and documents as for ECM certification adapted to the function/s, or parts thereof, specifying in addition:

- appropriate function/s covered and, if only parts of a function is covered,
 - the processes/sub-functions of the related function (points of the relevant section of the function as in Annex II of ECM Regulation) covered or excluded
 - limitation indicating processes/parts of vehicle or component covered or excluded.

3.3.2. Application review

The application presented by the ECM applicant is reviewed by the Certification Body to verify if the information and documents provided are enough to set up the certification process.

Based on the application form and information and documents provided, the Certification Body shall determine all the input information it needs to support the certification process and, where appropriate, shall request further necessary detailed documentation to perform the certification assessment.

The documents may be provided in electronic format.

If the documents received and integrated by the ECM applicant are not sufficient to able the Certification Body in starting the certification process and no other document is available from ECM applicant, the Certification Body may ask to postpone the certification process until it receives the missing documentation or, alternatively, it may refuse the application.

Once the Certification Body has closed positively the review of the application, it shall be able to determine:

- the scope of the certification,
- the assessment program,
- the necessary resources (competencies and quantity) and organisation of the assessment team
- the duration of the assessment (number of assessment days)
- sites to be visited

and take the necessary arrangements with the ECM applicant to finalize the date/s and notify the assessment plan.

When the Certification Body notifies to the ECM applicant the assessment plan, **the period of 4 months to deliver the ECM certificate** as stated in the Article 7(5) of the ECM Regulation starts.

Based on the arrangements with the ECM applicant, the Certification Body communicates the assessment plan for the scope of ECM certification intended comprising, at least:

- the date/s and sites of the assessment,
- the assessment team composition,
- the assessment program day by day

3.3.3. Certification Assessment

The Certification Body undertakes the conformity assessment through audits (to the applicable requirements of ISO17021) and through certification (to ISO17065).

The audits shall evaluate the conformity of the ECM's maintenance system against the specified requirements of (EU) 2019/779 by using a suitable combination of the audit methods

- *review of ECM documentation,*
- *interview of ECM personnel,*
- *observation of ECM activities,*
- *inspection of ECM activity results.*

The assessment is composed of 2 stages:

1. *an assessment of maintenance system through system documentary evidences and*
2. *an assessment of the implementation of the maintenance system comprising on-site visits.*

The 2 stages of assessment are based on the following simply rules and requirements:

- The assessment team shall perform the assessment according to the application
- The assessment team shall have access to all necessary documents and sites related to the ECM applicant maintenance system
- The assessment team may request to interview staff members and, in general, people involved in all the maintenance processes
- In particular, the assessment team shall verify for all the four ECM functions during each stage of the assessment the following requirements:
 - 1) the **consistency of the maintenance system** in terms of structure, processes, procedures and relations between them against the requirements of ECM Regulation
 - 2) if the **structure of the processes and procedures** of the maintenance system are known by the personnel
 - 3) the **suitability of the personnel** within each ECM function and their knowledge of the structure of maintenance system (functions, sites, activities...), their awareness about the commitment, role, competence and responsibility
 - 4) the **knowledge of the requirements** of Annex II of ECM Regulation and if the procedures related to each maintenance function are known and duly used by the personnel on a permanent basis
 - 5) if the procedures are applied and reviewed regularly based on a **continuous monitoring** process
 - 6) the **effectiveness of the procedures** through the analysis of the applicable outputs of internal auditing, management review, leadership commitment and policy, performance objectives, performance targets, performance monitoring and operational controls
 - 7) if the **coordination and exchange of information** within each maintenance functions and between them, the functions and the external actors is implemented and monitored regularly
 - 8) if the **documentation** is traceable, monitored regularly and updated when necessary
 - 9) if the **contracting activities** are clearly defined and monitored

Specific requirements, according to the ECM Regulation, are defined for each maintenance function in the following sections of the document:

- 3.3.3.3 – specific requirements for ECM – F1
- 3.3.3.4 – specific requirements for ECM – F2
- 3.3.3.5 – specific requirements for ECM – F3
- 3.3.3.6 – specific requirements for ECM – F4

3.3.3.1. Assessment of the maintenance system through the documentary evidences (stage 1 as mentioned in 9.3.1.2 of ISO-IEC 17021-1)

The assessment of the maintenance system through the documentary evidences is the first part of the assessment process.

It is performed primarily by a documentation examination and exchange of information with the ECM applicant.

Depending on the size, nature and complexity and sites of the applicant organisation, the assessment may be composed of different audit sessions with different objectives and scope.

The assessment team shall assess, by an examination of the consistency and relevancy of the documents to the requirements for certification as stated in the ECM Regulation, if the procedures put in place by the ECM applicant in its maintenance system are in conformity with the requirements of Annex II of the ECM Regulation and are established, documented and reviewed regularly.

The assessment team shall have access to any assessment reports of outsourced maintenance function(s) when they are certified according to the ECM Regulation.

The assessment team shall have access to all reports related to other certifications of the ECM applicant or outsourced maintenance function/s.

The procedures put in place by the ECM applicant include all supporting documents such as vehicle maintenance instructions, forms, templates, process diagrams, ...

If the documentation is found to be inadequate, the assessment team leader should inform the ECM applicant. A decision should be made as to whether the assessment should be continued or suspended until documentation concerns are resolved.

The assessment team shall take into account that:

- A single document presented by the ECM applicant may address one or more procedures of Annex II of the ECM Regulation.
- A single requirement of Annex II of the ECM Regulation may be covered by more than one document presented by the ECM applicant.

For this purpose, the ECM applicant may provide a table/process diagram for a better understanding of relationships between its processes/procedures and the requirements stated in the Annex II of the ECM Regulation.

The assessment team may request additional documents to perform its tasks, if they have justified doubts on the compliance with requirements of ECM Regulation.

During assessment activities, the assessment team shall make aware the ECM applicant of any relevant findings, emerging issues and, based on objective evidence, any diverging opinions that have arisen.

3.3.3.2. Assessment of the implementation of the maintenance system comprising site visits (stage 2 as mentioned in 9.3.1.2 of ISO-IEC 17021-1)

The assessment is performed by examination of the practical application of the processes.

The assessment team shall assess if the procedures put in place by the ECM applicant in its maintenance system are known and duly used by the staff (management, engineering, specialists and all workers) on a permanent basis.

Depending on the size, nature and complexity and sites of the ECM applicant organisation, the assessment shall be composed of different audit methods such as : interview of ECM personnel, observation of ECM activities, inspection of ECM activities.

In a multi-site organisation, the assessment team shall perform different assessment sessions choosing appropriately the sites to be inspected to cover adequately the different processes and procedures, the IAF MD 1:2018 shall be used as reference.

The assessment seeks to obtain evidence that management system activities are being performed based on the relevant procedure(s) and instructions. The practical application of procedures and instructions should ensure the requirements of the ECM Regulation are met.

The assessment team may require evidence to demonstrate the application of the procedures; this may include documentation, instructions, logbooks, check-lists or electronic records. These will be used to assess if procedures are effective in delivering the intended results of the management system.

The assessment team shall make the ECM applicant aware of any findings, emerging issues and, based on objective evidence, any diverging opinions that have arisen.

3.3.3.3 Specific requirements for Management Function – ECM - F1 - (Section I Annex II of ECM Regulation)

The assessment team shall verify along each phase of the certification process through audit methods the following:

1. the establishment, dissemination, and understanding of the **leadership commitment and policy** about the maintenance system in relation to the following:
 - its ongoing development
 - implementation
 - continuous improvement of its effectiveness by establishing safety targets and plans/procedures to meet them
 - monitoring safety performances
 - ensuring appropriate resources to perform all processes and meeting the requirements of Annex II of ECM Regulation
 - identifying and managing impact of other management activities on the maintenance system
 - ensuring that management is aware and responsible of the results of performance monitoring and audits and implements the necessary corrective action on the maintenance system, when necessary
2. the establishment and effectiveness of **procedures related to risk management activities** in terms of identification and management of risk emerging from changes in the **maintenance file** taking into account also the working environment and, where appropriate, the collaboration with keepers, railway undertakings, infrastructure managers, designers and Manufactures of vehicles and components and other interested parties
3. the establishment of **procedures to collect, monitor and analyse safety data** (results and performances of processes, data from field such as accident, incidents, near misses or other dangerous events comprising malfunctions, defects and repairs, findings about SCC), if they are in place, working correctly and meeting the organisation's objectives
4. the establishment of **procedures to ensure monitoring and safe maintenance of SCC**
5. the establishment of procedures to ensure **monitoring the safety performances of outsourced maintenance functions**, or parts thereof
6. if the **auditing activities** are regularly planned, implemented and monitored (corrective actions implemented and verification of its effectiveness performed)

7. if **continuous improvement approach** is adopted and supported whenever any potential improvement input is detected (internal or external)
8. the establishment of **procedures related to structure and responsibility** verifying if appropriate responsibility is allocated to the personnel and if the responsibility is correctly related to the competence and resources necessary to perform the function
9. the establishment of **procedures related to competence management**, if they are regularly adopted and competences are periodically checked and updated
10. the establishment and effectiveness of **procedures related to the exchange of information** within the organisation (covering all functions, sites, processes) and externally dealing with other actors, including:
 - infrastructure managers,
 - railways undertakings and keepers,
 - designers or manufacturers of vehicles or components and contractors for maintenance services or products,
 - holder of the vehicle type authorisation and holder of the vehicle authorisation,
 - outsourced maintenance functions,with particular reference to any **findings on SCC or when a new potential SCC is identified** during maintenance, if procedures are clearly defined and structured appropriately to the size and complexity of the organisation
11. the establishment of **procedures to alert rail sector and rail supply industry** about new or unexpected safety relevant findings, when the related risk is relevant for more actors and is likely to be poorly controlled, by using Safety Alert IT System or other provided by Agency
12. the establishment of **procedures to inform** Manufacturer, the holder of the vehicle type authorisation and the holder of the vehicle authorisation **when new potential identified SCC** and to request to Manufacturer technical and engineering support for SCC and their safe integration
13. the establishment of **procedures to manage all documents related to the processes**, if the traceability is guaranteed in each phase and documents are monitored regularly and updated when necessary
14. the establishment of **procedures to select contractors/suppliers** appropriately to the products or services intended to be contracted, if they include identification of products and services, requirements to be satisfied, evaluation criteria on the competence requested and on the maintenance system of the potential contractor/supplier including monitoring of the processes
15. the adequacy of contracts with basic principles on responsibility and tasks related to safety issues, exchange of information and document, traceability of safety-related documents
16. the establishment of **procedures to compile and send the annual report** to its Certification Body using the relevant form and content as specified in Annex V of ECM Regulation.

3.3.3.4 Specific requirements for Maintenance Development Function – ECM - F2 (Section II Annex II of ECM Regulation)

The assessment team shall verify along each phase of the certification process through audit methods the following:

- 1) the establishment of procedures to identify and manage **safety critical components (SCC)** of vehicles and **maintenance activities affecting safety** of vehicles considering initial identification of SCC by Manufacturer (if the manufacturer doesn't exist or if the ECM cannot manage to collaborate with it, the identification has to be made by the ECM) together with any specific maintenance instructions in the vehicle technical file
- 2) the establishment of procedures to guarantee **conformity** of the vehicles to the relevant TSI parameters assuring regular checks of the consistency of the **maintenance file** with the vehicle authorisation, the technical file and records as in ERATV, managing any substitution during maintenance by safety risk assessment and its reflections on configuration of the vehicle

- 3) the establishment of procedures to design and support implementation of **maintenance facilities, equipment and tools** specifically developed and required for maintenance delivery function, monitoring their correct use, storing and maintaining according to specifically defined requirements, instructions and documents
- 4) the establishment of procedures to gain access to all **initial maintenance documentation**, including any list of SCC from Manufacturer, and to collect all necessary information about the vehicle operation performing on this information a risk evaluation to finalize the **first maintenance file** by taking into account also any information of associated guarantees
- 5) the establishment of procedures to ensure the correct implementation of the **first maintenance file** of the vehicle
- 6) the establishment of procedures to collect relevant **data from the vehicle operation and maintenance** (effective railway service performed, malfunctions, defects and faults reported, findings about SCC, accidents and incidents, maintenance performed), to analyse these data and make proposal of change and, if the change is decided to be implemented, to follow its correct implementation and monitor the effectiveness and any results of the change
- 7) if the **personnel** involved on risk evaluation, engineering to establish a change, maintenance activities on SCC, joining techniques and Non-Destructive-Testing is **competent** according to the established competence management procedure and is aware of the role assigned
- 8) if the **documentation** related to substitution during maintenance, changes to vehicle configuration, data from return on experience of the operation and maintenance, versions of the maintenance file, records of the maintenance performed together with reports on competence and supervision of fleet maintenance management function and maintenance delivery function, exchange of technical information with keepers, railway undertakings and infrastructure managers is adequately traced, regularly monitored and updated when necessary.

3.3.3.5 Specific requirements for Fleet Maintenance Management Function – ECM - F3 (Section III Annex II of ECM Regulation)

The assessment team shall verify along each phase of the certification process through audit methods the following:

- 1) the establishment of procedures to check **competence, availability and capability** of maintenance delivery function before the placing of maintenance orders
- 2) the establishment of procedures to **manage removal of vehicles from operation** (when need of planned or corrective maintenance is required or when safe operation is impaired), to organise the maintenance work package and release of maintenance orders, to send vehicle for maintenance in due time
- 3) the establishment of procedures to define the necessary **verification measures** to be applied to the maintenance delivered, to define release to service of vehicles and notice of return to operation (including, where necessary, restriction measures for a safe operation)
- 4) if the **personnel** involved is **aware** and **competent** about the content of **maintenance plan** of the vehicle and of **impact on the safe operation** of malfunctions, defects and faults reported, accidents and incidents and any reported finding related to SCC
- 5) if the **personnel** involved in operating verification measures to the maintenance delivered and defining appropriately the release to service and notice of return to operation is **competent** according to the established competence management procedure and is aware of the role assigned
- 6) if the **exchange of information** with the maintenance delivery function covers, at least, applicable rules and technical specification, maintenance plan of the vehicle, spare parts and materials documents, specification of interventions and restrictions of use to be applied to activities or components affecting safety, with particular reference to SCC, list of components/systems subject to legal requirements and requirements to be met, results of the application of risk evaluation to changes affecting the fleet maintenance management function

- 7) if the **exchange of information** with railway undertakings and infrastructure managers covers the notice of return to operation, including any restriction of use on the vehicle operation, where necessary
- 8) if the **documentation** regarding maintenance orders, release to service, notice of return to operation, including any restriction of use on the vehicle operation, where necessary, is recorded and traceable.

3.3.3.6 Specific requirements for Maintenance Delivery Function – ECM - F4 (Section IV Annex II of ECM Regulation)

The assessment team shall verify along each phase of the certification process through audit methods the following:

- 1) the establishment of procedures to check if **information** contained in **maintenance orders** released by fleet maintenance are clear, complete and appropriate to the maintenance required, to verify if the maintenance documents, standards, specifications and other documents related to the required maintenance are available and used by the personnel involved
- 2) the establishment of procedures to check if **spare parts and materials** are stored, handled and transported as to prevent wear and damage, used as specified in maintenance orders and supplier documentation and are compliant with national or international rules and requirements contained in the maintenance orders
- 3) the establishment of 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 the safe delivery of maintenance including health and safety of personnel by means of ergonomics and health protections, interfaces between users and IT systems or diagnostic equipment
- 4) the establishment, where necessary to ensure valid results, of procedures related to **measuring equipment** to ensure its calibration, periodic verification against international, national or industrial measurement standards or other document used to ensure the measuring equipment is perfectly calibrated to perform a valid result before each use, to acknowledge its need of adjusting and calibration, to avoid its inappropriate adjustments, to protect it from damage and deterioration during handling, maintenance and storage
- 5) the establishment of procedures to ensure that all **facilities, equipment and tools** are correctly used, calibrated, preserved and maintained in accordance with documented procedures
- 6) the establishment of procedures to **check that performed tasks**, with particular reference to SCC, are in accordance with the maintenance orders and to **issue the notice of release to service** including all information that is useful to define restrictions of use
- 7) if the personnel involved is aware and competent about the content of **maintenance plan** of the vehicle and of **impact on the safe operation** of malfunctions, defects and faults reported, accidents and incidents, any reported finding related to SCC in order to provide for **information** useful to define **restriction of use**
- 8) If during **risk evaluation** the personnel involved is aware to consider in the **working environment** not only the workshops where maintenance is done but also the tracks outside the workshop buildings and all places where maintenance activities are performed
- 9) If the personnel involved about, at least, the **activities affecting safety**:
 - joining techniques,
 - Non-Destructive-Testing,
 - final vehicle testing and release to service;
 - 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.;
 - maintenance activities on SCC;
 - maintenance activities on control-command and signalisation systems;
 - maintenance activities on door control systems;

- other identified specialist areas affecting safety (point 1(a) Section II of Annex II of ECM Regulation) is **competent** according to the established competence management procedure and is aware of the role assigned
- 10) if the **exchange of information** with fleet maintenance management function and maintenance development function covers at least the maintenance performed in accordance with the maintenance orders, any fault or defect affecting safety identified, any reported finding on SCC or when any potential SCC is identified, the notice of release to service including all information that is useful to define restrictions of use,
- 11) if the **documentation** on maintenance activities affecting safety addresses a clear identification of facilities, equipment and tools and is traceable
- 12) if the **documentation** on maintenance activities affecting safety covers maintenance works performed (including information on personnel, tools, equipment, spare parts and materials used) according to:
- relevant national rules
 - requirements stated in the maintenance orders including requirements regarding records
 - final testing and decision regarding release to service including all information that is useful to define restrictions of use
 - control measures required by maintenance orders and release to service
 - results of calibration and verification
 - validity of the previous measuring results when a measuring instrument is found not conform to requirements
- is correctly recorded and traceable.

3.3.4. Delivery of certificate

3.3.4.1. Certification Assessment report

The assessment team shall issue a certification report that will be the basic input for the decision on certification. The certification report is compiled using the assessment results based on evidences. The section 9.4.8 of the ISO 17021-1:2015 gives more details for the content of the report.

The certification report shall contain at least the following common points:

- the list of the assessment team members with their scope of activity;
- applicant data indicated in the application form;
- the scope of the certification
- the list of the sites under the scope of the certification with indication of type of activities performed, outsourced function/s, categories of vehicles;
- the assessment plan as performed
- the assessment synthesis – list of requirements examined for each site and non-conformities
- the assessment conclusions (justification on recommendation for certification)

If a Non-Conformity is found, the assessment team shall indicate the following in the draft certification report for each Non-Conformity (see Annex 2 for example of Non-Conformity form);

- the relevant conformity requirement impacted
- the causes and consequences of the non-conformity (in the opinion of the team)
- a description of the related safety risk
- an indication if recovery actions by the ECM applicant are possible within time allowed for decision.

The draft certification report is provided to the ECM applicant at the end of the assessment together with any Non-Conformity found or at the latest within 2 weeks after the end of the assessment.

In case of Non-Conformities, the assessment team shall indicate the causes and consequences and safety risk linked to this Non-Conformity. It shall also be stated if the corrective actions by the ECM applicant are credible and realistic within time allowed for certification decision.

Where corrective actions are possible, the ECM applicant has to address an action plan to the assessment team within 2 weeks after receiving the Non-Conformity.

The action plan includes the measures intended on how and within which period the Non-Conformities will be closed out (for treatment of Non-Conformities and time allowed for decision see Annex 1).

The final certification report, where appropriate, shall contain the action plan agreed with ECM applicant, where proposed corrective actions are described and implementing time defined.

The final certification report is recorded and transmitted to the Certification Committee for decision.

3.3.4.2. Decision on certification

The Certification Committee issues recommendation to the Certification Body based on the final certification report and recommendation provided by the assessment team.

The Certification Body takes its decision within 2 weeks at the latest after final certification report is issued by assessment team. The date of start of validity of a certificate can be at the earliest the date of decision of the Certification Committee without prejudice for Art 7(5) of the ECM regulation. In case of renewal, see chapter 3.3.6.

According to Art. 7(8) of ECM Regulation, an ECM certificate shall be valid for a maximum period of 5 years.

The Certification Body shall identify each certificate delivered according to Annex IV of ECM Regulation.

According to Art. 7(5) of ECM Regulation, “*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*” giving the reasons of its decision.

As defined in 3.3.2, **the 4 months’ period** starts when “*the Certification Body notifies to the ECM applicant that he has received all the necessary documents to perform the assessment and it takes the necessary arrangements with the ECM applicant for the assessment*”.

Within this time stated in Art. 7(5) of ECM Regulation, the Certification Body can take one of the following decision:

- decide to award the ECM certification
- agree on action plan with the ECM applicant, as proposed in the final certification report, and postpone its decision (max 4 months) after action plan verification
- decide to refuse the award of the ECM certification,
- decide to release the ECM certification with modifications of the scope of the certificate

In case of agreement on action plan, the Certification Body will postpone its final decision respecting the time limit of 4 months as stated in Art. 7(5) of ECM Regulation.

In case of agreement on action plan to solve Non-Conformity, see Annex 1 for treatment of Non-Conformity and time allowed for decision.

The conditions for releasing the ECM certification are reported in 3.3.4.3.

The conditions for refusing the ECM certification, releasing the ECM certification with modifications of the scope of the certificate or postpone the certification decision are reported in 3.3.4.4.

According to Art. 7(6) of ECM Regulation “*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.*”

According to Art. 13(2) of ECM Regulation “*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) 798/2016, within one week from its decision, using the forms set out in Annex IV.” No content shall be written in Additional Information field except the identification of the final certification report and the status of newcomer, if applicable, according to chapter 3.4.8.

In case of first certification refused or decision postponed for implementation of action plan, no information is due to Agency.

3.3.4.3. Conditions for releasing/confirming/renewing the ECM certification:

Certification can only be released/confirmed/renewed if:

- No one Non-Conformity found.
- Every Non-Conformity has been verified as successfully solved within the time available for Certification Body decision.

For the treatment of Non-Conformity and time allowed for decision, see Annex 1.

3.3.4.4. Conditions for refusing, revoking, suspending the ECM certification, releasing/confirming/renewing the ECM certification with modifications of the scope of the certificate and for postponing certification decision

Non-observance of the requirements for ECM certification may lead to:

- certification being refused/revoked
- certification being released/confirmed/renewed with modifications of the scope of the certificate
- certification being temporarily confirmed or suspended for implementation of action plan
- certification decision being postponed for implementation of action plan.

The section 9.6.5 of ISO 17021-1:2015 gives more details about suspension of certification.

Request of suspension and modification of the scope of the ECM certification may also be triggered by voluntary communication to the Certification Body.

The **suspension** is a temporary invalidity of the ECM certificate. It does not postpone the overall validity of the ECM certification, stated in maximum 5 years.

Normally, the suspension should not exceed 6 months and Certification Body has the duty to restore the ECM certificate suspended after verification of the issues resulted in the suspension have been resolved or to decide if condition for revoking or modifying the scope of the certification are incurred.

The decision of suspension is taken when non-conformities found:

- may affect the on-going and planned maintenance activities with incumbent and potential risk of unsafe running vehicle operation and
- no other immediate remedial actions can be taken for ensuring safety.

The **modification of the scope of ECM certificate**, point 5 of the certificate form as in Annex IV of ECM Regulation, may be operated:

- when parts of the scope of the maintenance system of the ECM does not meet the requirements of ECM Regulation (**limitation of scope**) or
- when other parts outside the scope of the maintenance system meeting the requirements of ECM Regulation are included (**expansion of scope**).

If the certificate is revoked, it loses its validity immediately.

The following criteria for refusing, revoking or suspending the certificate, modifying the scope of the certificate shall be taken into account depending on the extent of non-compliance with the requirements of ECM certification:

- **ECM Regulation requirements not satisfied:**
 - Absence of, and/or deficiencies in: documentation, procedures, processes (leadership, risk management, continuous improvement, monitoring, competence and responsibility, information, contracting activities management, safety activities and safety critical components).
 - Maintenance system not effectively implemented (procedures not used in a permanent base, not monitored regularly, input/output of processes out of control).
- **Recurrent improper maintenance output**
 - Major incidents due to (systematically) improper maintenance.
 - Recurrent bad / low quality of the executed work (complaints to NSA, customer complaints (keepers, RUs)).
- **Poor compliance and lack of development**
 - Not solved Non-Conformities after verification of implemented action plan.
 - Action plan agreed with the Certification Body not implemented.
 - Persistent insufficiency in existing competences or coherence. (non-critical Non-Conformity not solved within 6 months shall be considered as persistent).
- **Economical aspects**
 - Bankruptcy. In case of bankruptcy, the Certification Body and the NSA shall be informed. The certificate shall be suspended until successful re-assessment by the Certification Body.

Depending on the extent of non-compliance, the nature of Non-Conformities and the organisation of the management system, the **implementation of action plan** may be decided if corrective actions are possible, realistic and credible within time allowed for final decision.

For the treatment of Non-Conformity and time allowed for decision, see Annex 1.

3.3.5. Surveillance activities

The principles, criteria and requirements defined for certification assessment in section 3.3.3 and its sub-sections also apply for surveillance activities adapted to the assessment to be performed.

The Certification Body shall conduct surveillance activities on the certified ECM to verify continued compliance with the requirements set out in Annex II of ECM Regulation.

According to Art. 8(1) of ECM Regulation, it shall conduct site visits at least once every 12 months counting from the date of issuing the certificate.

According to Annex V of ECM Regulation, the certified ECM shall address an annual report to the Certification Body at least 1 month before the forecasted surveillance assessment and inform without delay the Certification Body about changes might have a significant impact on the certification of the ECM.

Based on communication from the certified ECM, the Certification Body shall immediately evaluate the changes notified and decide the need of immediate surveillance actions.

Once the annual report is received, the Certification Body activates arrangements with the certified ECM for surveillance date/s and the process will follow the same steps of the certification process as in section 3.3.3.

Based on the arrangements with the certified ECM, the Certification Body communicates the **assessment plan** for surveillance activities intended comprising, at least:

- the date/s and sites of the assessment,
- the assessment team composition,
- the assessment program day by day

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 into account:

- past assessment activities for the release of ECM certification
- all previous surveillance activities of the certified ECM under surveillance.

The assessment team defines the scope, depth and extent of the surveillance activities based on:

- The non-conformities identified in the certification assessment and in any other preceding surveillance activities
- The annual report provided by the certified ECM compliant with Annex V of the ECM Regulation and changes communicated by certified ECM.
- The appropriate actions put in place by the Certification Body to check claims according to Articles 5(4) and 11 of the ECM regulation.

For surveillance activities section 9.6.2. of ISO 17021-1:2015 give further applicable details.

The surveillance activities consist mainly of on-site assessment through audits and inspections, but a supplementary assessment of the documentation of the maintenance system cannot be excluded if surveillance findings show that the processes put in place by the certified ECM and their effectiveness may be not compliant with requirements of ECM Regulation.

3.3.5.1. Surveillance activities Report

The assessment team shall issue a report of the surveillance activities undertaken. The surveillance report is compiled using the assessment results based on evidences during the surveillance.

The rules and composition of the surveillance report are the same of the certification report (see section 3.3.4.1) adapted to the surveillance activities performed.

3.3.5.2. Surveillance Decision

The same rules defined for decision on certification are applicable (see 3.3.4.2).

The Certification Committee issues recommendation to the Certification Body based on the final surveillance report and recommendation provided by the assessment team.

The Certification Body takes its decision within 2 weeks at the latest after final surveillance report is issued by assessment team.

The Certification Body can take one of the following decision:

- confirm the ECM certification
- agree on action plan with the certified ECM, as proposed in the final surveillance report, and confirm temporarily or suspend (max 6 months), depend on the extent of non-compliance, the ECM certification up to the final decision after action plan verification
- confirm the ECM certification with modifications of the scope of the certificate,
- revoke the ECM certification, depending on the extent of non-compliance

In case of agreement on action plan, a limit of maximum 6 months for final decision to revoke, confirm or modify the scope of the ECM certification is acceptable.

This 6 months period starts from the notification of the assessment plan and does not postpone the overall validity of the ECM certification, stated in maximum 5 years.

In case of agreement on action plan to solve Non-Conformity, see Annex 1 for treatment of Non-Conformity and time allowed for decision.

In case of suspension, the ECM certificate is temporary invalid. The suspension period does not postpone the overall validity of the ECM certification, stated in maximum 5 years.

Normally, the suspension should not exceed the 6 months period and Certification Body has the duty to restore the ECM certificate suspended after verification of the issues resulted in the suspension have been resolved or to decide if condition for revoking or modifying the scope of the ECM certification are incurred.

The conditions for confirming the ECM certification are reported in 3.3.4.3.

The conditions for revoking, confirming temporarily or suspending, confirming with modifications of the scope of the ECM certification are reported in 3.3.4.4.

According to Art. 7(6) of ECM Regulation *“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.”*

According to Art. 13(2) of ECM Regulation *“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) 798/2016, within one week from its decision, using the forms set out in Annex IV.”*

In case of ECM certification confirmed or temporarily confirmed, no information is due to Agency.

3.3.6. Re-certification process

The principles, criteria and requirements defined for certification assessment in section 3.3.3 and its sub-sections also apply for re-certification process adapted to the assessment to be performed.

The ECM certificate may be renewed when its original duration period of 5 years expires.

Re-certification is formally requested by the certified ECM and it shall be planned and conducted in due time to enable for timely the renewal before previous ECM certificate expiry date and to ensure continuity of certification.

The certified ECM will specify, where applicable, changes to maintenance system or to the scope of re-certification in the request.

The re-certification may need a new formal application (application form, information and documentation) and consequently a full re-assessment against the ECM Regulation depending on:

- Results of surveillance activities
- Annual Reports of the certified ECM
- Performance of the maintenance system
- Changes to the maintenance system or to the scope of re-certification.

The Certification Body will justify the need of new formal application and full re-assessment against the ECM Regulation at formal request of re-certification.

Once request of re-certification or new formal application is received, the Certification Body activates arrangements with the certified ECM for date/s and the process will follow the same steps of the certification process as in section 3.3.3.

Based on the arrangements with the certified ECM, the Certification Body communicates the **assessment plan** for the re-certification intended comprising, at least:

- the date/s and sites of the assessment,
- the assessment team composition,
- the assessment program day by day

In any case, the annual reports, preceding surveillance activities and performance of the maintenance system of the certified ECM shall be considered by the Certification Body to set-up the re-assessment activities.

The re-certification process should not impair surveillance activities during last year of validity of the certificate.

As regards the timetable for the re-certification:

- a) If the re-certification process is finished before the expiration date of the current certificate, a renewed certificate can be issued. In this case the date of start of validity of the renewal is the date of its decision or at the latest the expiry date of the previous certificate.
- b) If the re-certification process is not finished before the expiration date of the current certificate, but within 6 months after the expiration date, a renewed certificate can be issued. In this case the date of start of validity of the renewal is the renewal decision date, the date of end of validity counts from expiry date of the previous certificate.
- c) After 6 months of the expiration date of the current certificate, a new certification process (initial certification) shall be started.

3.3.6.1. Re-certification Report

The assessment team shall issue a report of the re-certification undertaken. The re-certification report is compiled using the assessment results based on evidences during the re-certification assessment.

The rules and composition of the re-certification report are the same of the certification report (see section 3.3.4.1) adapted to the re-certification assessment performed.

3.3.6.2. Re-certification Decision

The same rules defined for decision on certification are applicable (see 3.3.4.2).

The Certification Committee issues recommendation to the Certification Body based on the final re-certification report and recommendation provided by the assessment team.

The Certification Body takes its decision within 2 weeks at the latest after final re-certification report is issued by assessment team.

The Certification Body can take one of the following decision:

- renew the ECM certification
- agree on action plan with the certified ECM, as proposed in the final re-certification report, and postpone its final decision or suspend the ECM certification (max 6 months), depend on the extent of non-compliance, after action plan verification
- renew the ECM certification with modifications of the scope of the certificate,
- revoke the ECM certification, depending on the extent of non-compliance

In case of agreement on action plan, a limit of maximum 6 months is acceptable for final decision to revoke, renew or renew with modification of the scope of the ECM certification.

This 6 months period starts from the notification of the assessment plan and does not postpone the overall validity of the ECM certification, stated in maximum 5 years.

In case of agreement on action plan to solve Non-Conformity, see Annex 1 for treatment of Non-Conformity and time allowed for decision.

In case of suspension, the ECM certificate is temporary invalid. The suspension period does not prolong the overall validity of the ECM certification. The date of validity remains the same.

Normally, the suspension should not exceed the 6 months period and Certification Body has the duty to restore the ECM certificate suspended after verification of the issues resulted in the suspension have been resolved or to decide if condition for revoking, renew or renew with modification of the scope of the certification are incurred.

The conditions for renewing the ECM certification are reported in 3.3.4.3.

The conditions for revoking, postponing the final decision, suspending and renewing with modifications of the scope of the ECM certification are reported in 3.3.4.4.

According to Art. 7(8) of ECM Regulation, an ECM certificate shall be valid for a maximum period of 5 years.

The Certification Body shall identify each certificate delivered according to Annex IV of ECM Regulation.

According to Art. 7(6) of ECM Regulation *“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.”*

According to Art. 13(2) of ECM Regulation *“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) 798/2016, within one week from its decision, using the forms set out in Annex IV.”*

In case of decision postponed for implementation of action plan, no information is due to Agency.

3.4. General points

The following sections take care of generic aspect applicable to activities for certification, surveillance and re-certification processes.

3.4.1. Used language

The activities shall be conducted in one language agreed with the ECM. In case the ECM uses more than one working language, the audit shall be conducted in all languages agreed with the ECM.

All reports and communications will be written in the language(s) agreed between the Certification Body and the ECM.

3.4.2. Assessment time

The assessment cannot impair the 4 month period stated in the ECM Regulation to deliver certificates.

The Certification Body must ensure that the assessment time is sufficient and based on size and complexity of the ECM applicant and on this basis it proposes an assessment plan containing schedule and time to the ECM applicant.

In case the Certification Body considers that no agreement on assessment plan (limited to schedule and time) may be achieved, he is free to refuse the contract.

The same principles are applicable for surveillance and re-certification activities.

3.4.3. Access, traceability of reports, confidentiality

The reports of the activities are property of the Certification Body. The ECM has an unlimited right of use of the reports.

The reports shall be kept at least 6 years by the ECM and by the Certification Body.

The ECM may address copies of reports or part of them to any entity upon request.

The Certification Body has to ensure the respect of the rules of confidentiality (see Annex I.7 of ECM Regulation) accessing ECM data and information with specific references for keeping confidential any commercial data or information related.

3.4.4. Consideration of Existing certification

This section applies when the ECM applicant has already got third party certifications, before applying for ECM certification, such as:

- ISO certifications: EN ISO/IEC 9001:2008, EN 9100:2009, EN ISO/IEC 14001:2004, ...
- Industry certifications such as IRIS, RISAS or VPI,...
- National certifications: national certifications related to vehicle maintenance

The Certification Body should consider existing certification and then may adapt the certification assessment plan taking into account:

- The scope of the existing certifications
- The validity time of the existing certification
- The content of all assessment reports and any relevant documents provided to the ECM by the preceding Certification Body who delivered the existing third parties certificate.

The ECM applicant shall provide all the documents to the Certification Body in charge of ECM certification.

3.4.5. Certification decision identification number

The Certification Body shall identify each decision on certification, i.e. award, renewal, amendment, suspension or revocation of certificates, in conformity with the European Identification Number (EIN).

Structure of EIN

For facilitating the implementation of ECM certification, the structure of EIN to identify ECM certificates (including outsourced maintenance function/s certificates) has been maintained, but the meaning of some codes has been changed as following.

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

The identification of the certificate includes the identification of the Certification Body.

'**XY**' = Country Code of the accreditation body or the recognition body or the NSA acting as certification body.

'**ab**' = type of documents (2 digits). Codes starting by 3 are reserved for maintenance:

- 31 for ECM certification
- 32 for certification of maintenance delivery function
- 33 for certification of outsourced maintenance function/s

'**cd**' = counter that identifies the accredited Certification Body. This code is previously provided by the accreditation body or the recognition body. From '01' to '99', '00' is reserved for the NSA acting as certification body.

'**ef**' = year when the decision on certification is taken by the Certification Body (award, revocation, suspension, modification of scope). Example 2011: 'ef' = '11'

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

Example:

FR/32/0212/0003: decision on certification ('0003') of separate maintenance workshop ('32') delivered by the Certification Body '02' accredited by the French Accreditation Body ('FR').

3.4.6. Use of certificate

The certificate shall be used for communication to third parties by the certified ECM only with the mention of the list of sites covered and indicating the scope and limitations of the certificate in detail.

The use of marks (on letters or commercial documents) is authorised only with the mention "scope communicated on request".

3.4.7. Transfer of certificate

The transfer of certificate happens when Certification Body loses his accreditation or when certified ECM decides to change Certification Body.

In both cases, the validity period of the ECM certificate is not impaired by transfer of the certificate under the surveillance of incoming Certification Body.

When the Certification Body loses his accreditation, the relevant rules of IAF may be applied.

When the ECM decides to change the Certification Body, the applicable rules of IAF MD 2:2017 may be applied.

3.4.8. Application of certification scheme to newcomers

For newcomer ECM who has not been registered as ECM in the NVRs before 16 June 2020 and therefore cannot provide evidences on the effective implementation of their maintenance system, the same certification process shall be applied.

The validity of newcomer certificate shall be limited to 1 year.

The same rules for newcomers apply also for certificates of outsourced maintenance functions as referred to in points (b), (c) and (d) of Article 14(3) of Safety Directive and specified in Art. 9 and 10 of ECM Regulation.

The certification body shall clearly mention the validity of 1 year on the certificate with the mention 'newcomer – application of ECM certification scheme section 3.4.8.'

3.4.9. Activity report of the Certification Body

According to Art. 6(7) of ECM Regulation, the certification bodies shall deliver an activity report to ERA. This report shall be delivered in electronic form every 3 years. The content of this report is defined in a separate document.

Annex 1: Definition and treatment of Non-Conformities

A Non-Conformity (NC) is the non-fulfilment of a requirement stated in the ECM Regulation.

Considering the criteria as in 3.3.4.4. and depending on its potential effects, the Non-Conformity may be classified as:

- **Critical**
- **Non-critical**

Critical Non-Conformity is a non-conformity leading to one of the following situations:

- risk of unsafe running vehicle operation
- risk about capacity of maintenance system to keep the level of performance of vehicle operations intended to meet requirements by keeper/railway undertaking

The risk of unsafe running vehicle operation is considered when potential/recurrent improper maintenance output may occur or has been found

- major incidents due to improper maintenance
- bad / low quality of the maintenance work (complaints to NSA, customer complaints (keepers, RUs))

or when the deficiencies on the processes might lead to uncontrolled output with potential unsafe effects on vehicle operation.

Non-critical Non-Conformity is a non-conformity without direct impact:

- on the safe running of the vehicles or
- on the planned capacity of maintenance management system to keep the level of performance of vehicle operations intended to meet requirements by keeper/railway undertaking

Note: repetitive or persistent non-critical Non-Conformity can induce a critical Non-Conformity.

In case any Non-Conformity is found, the assessment team is asked to evaluate if recovery actions for treatment of Non-Conformity are possible, realistic and credible within time allowed for decision.

This evaluation depends on the extent of non-compliance, the nature of Non-Conformities and the organisation of the management system.

In case assessment team has indicated that recovery actions for treatment of Non-Conformity are possible within time allowed for decision, the treatment of NC shall follow conditions, rules and time as below:

- **Action Plan:** for each NC, critical and non-critical, the applicant ECM (or the certified ECM in case of surveillance activities or re-certification) shall set up an action plan which contains:
 - An analysis of the scope of the NC, precedence, services, customers concerned.
 - An analysis of the causes and the need to put in place immediate correctives actions to remove the NC and in order to avoid to reproduce the NC in the future.
 - The decided actions in order to have under control the observed situation and the time allowed for the implementation.

This action plan shall be sent to the assessment team within 2 weeks after reception of the draft report (certification, surveillance or re-certification).

- **Estimation of action plan by the assessment team**

The assessment team shall verify the effectiveness of the action plan evaluating if the action plan is able to solve the NC and to take it under control also in future.

The evaluation of the action plan shall be recorded in the final report together with recommendation for Certification Committee.

- **Certification Body decision**

Once Certification Body receives final report and recommendation by Certification Committee with an Action Plan, it takes one of the following decisions within 2 weeks:

- Postpone its final decision (in case of first ECM certificate or re-certification)
- Suspend ECM certificate (in case of surveillance/re-certification)
- Confirm temporarily ECM certificate (in case of surveillance)

after verification of action plan. The Certification Body decision is notified to ECM and, in case of certificate suspended, to the Agency within 1 week.

- **Implementation of the action plan and time allowed for decision**

The ECM applicant (or certified ECM in case of surveillance activities and re-certification) is responsible for implementing the action plan and to solve the NC in the time allowed for decision.

The time allowed comprises also the estimation of action plan by the assessment team and any exchange of information between Certification Body and ECM to solve misunderstandings or deficiencies of documents and the verification by the Certification Body.

The Certification Body and the ECM shall take all the necessary agreements and arrangements to respect each other the following **time allowed for final decision**:

- a. In case of first certification: the limit of **4 months** to award with/without modification of the scope or refuse the ECM certification, according to Art. 7(5) of the ECM Regulation
- b. In case of surveillance/re-certification: a reasonable limit of **6 months** to revoke, confirm/renew with/without modification of the scope, confirm temporarily the ECM certification

- When critical NCs are detected, the maximum time allowed may be reduced to 3 months.

- **Verification of action plan by the assessment team**

The verification is performed by an assessment team to gain evidences on the implemented action plan (Non-Conformity is solved and situation under control also in future).

In case of critical NC and according to the nature of the NC, the Certification Body may charge the assessment team to perform the verification by documentary examination and/or by an assessment on-site.

The assessment team reports the results of the verification through an integration on the final report after gaining evidences that the situation is/is not under control by verifying:

- the objective evidence that the NC is solved/not solved
- where necessary, the process in order to avoid the NC in future has/has not been established
- In this case, evidence that this process is/is not implemented as established.

- **NOTE: If the applicant refuses a Non-Conformity:**

In case the ECM refuses to accept the Non-Conformity contained in the draft report, it shall justify its refusal of NC and why it disagrees addressing communication to Certification Body.

The Certification Committee shall take a justified and final recommendation for Certification Body by examination of assessment team reports and communication of refusal by ECM.

The final position of Certification Body is notified to the assessment team and the ECM.

Annex 2: Example of a Non-Conformity form

Certification/Surveillance/Re-certification Report N°:..... Certificate N°:.....			NON-CONFORMITY (NC) N°.			<input type="checkbox"/> NC – critical (major) <input type="checkbox"/> NC non-critical (minor)		
Applicant ECM or function (or certified ECM/certified function in case of surveillance activities/re-certification):..... Site of the observation : _____ Date issued: _____								
C E R T I F I C A T E D B Y E C M	ECM Regulation - Requirement concerned: Concerns: <input type="checkbox"/> Dispositions <input type="checkbox"/> Implementation							
	Non-conformity Description:							
	Causes/consequences:							
	Potential Risks:							
	Recovery Action possible within time allowed for decision: <input type="checkbox"/> YES <input type="checkbox"/> NO							
Assessor Name: _____			Date: _____			Assessor Signature: _____		
ECM Agreement : <input type="checkbox"/> YES <input type="checkbox"/> NO								
Comments:								
ECM Representative Name : _____			Date: _____			Signature: _____		
ACTION PLAN DECIDED								
Analyse of the scope of the NC (precedence, services, customers..):								
Analyse of the causes and need to put in place actions in order to avoid the reproduction of the NC:								
Decided action in order to have under control the observed situation:						Due date:		
ECM Representative Name:				Signature:		Current date:		
Estimation of the effectiveness of the action plan								
Relevance of the analysis of the scope of the NC and of the analysis of the causes <input type="checkbox"/> YES <input type="checkbox"/> NO								
Comments:								

R T B O D Y	Relevance of the decided actions in order to solve the NC and have under control the observed situation: <input type="checkbox"/> YES <input type="checkbox"/> NO Comments: Time allowed: Result of the estimation:		
	Assessor Name:	date:	Signature:
C E R T B O D Y	Action Plan documentary Verification – actions in order to have under control the situation		
	Documentation: evidences assessed <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA The documents assessed are acceptable <input type="checkbox"/> YES <input type="checkbox"/> NO Evidences acceptable in order to demonstrate that the situation is under control <input type="checkbox"/> YES <input type="checkbox"/> NO Documents assessed: Comments:		
Assessor Name:	Date:	Signature:	
C E R T B O D Y	Action Plan assessment on-site Verification – actions in order to have under control the situation		
	Documentation: evidences assessed <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA The documents assessed are acceptable <input type="checkbox"/> YES <input type="checkbox"/> NO Evidences acceptable in order to demonstrate that the situation is under control <input type="checkbox"/> YES <input type="checkbox"/> NO Documents assessed and evidences observed during assessment on-site : Comments:		
The Certification Body:	Date:	Signature:	
C E R T B O D Y	Final result on the NC		
	Respect of the action plan (consistency, time allowed): <input type="checkbox"/> YES <input type="checkbox"/> NO Documentary Evidences and findings during assessment on-site considered: Comments:		
Closing of the NC:	NC CLOSED <input type="checkbox"/> NC NOT CLOSED <input type="checkbox"/>	New NC N°:	
Proposal for Certification Committee decision:	Assessor:	Date:	Signature:

Annex 3: Flow charts of the certification process

