

ECM certification
Application guide including explanations
ECM certification scheme

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Change Control

Version No	Changed Section	Date	Description of Change
1.0	All new	28/10/2011	This documents is based on ECM certification scheme draft 0.5 and results from consultation

Table of content:

- A. Preliminaries
- B. Guidelines

A. Preliminaries

This document contains the guidelines to be used by certification bodies when assessing ECM and applicants for separate maintenance functions in conformity with the ECM Regulation

[Additional comments explaining this application guide further are presented in blue throughout the document.](#)

B. Application guide

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1. Introduction

This document aims at providing to the Certification bodies the necessary common rules to certify against the specified requirements of the Commission Regulation (EU) 445/2011 of 10/05/2011 on a system of certification of the entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 (ECM regulation).

The principles on which the ECM certification scheme is based are described in the article 7 and annex III of the ECM Regulation.

The article 7 has not been judged as sufficient by European Co-Operation for Accreditation (EA) to get assurance that the certification will be performed on the same way within the European Union and will fully reflect the needs of the market, in particular the equivalence of certificates..

Therefore this document has been developed as part of the sectoral accreditation scheme related to ECM certification

Limits:

- This document addresses only freight wagons as stated in the ECM Regulation.
- This document addresses the ECM certification and provides general rules for the certification of separate maintenance functions. Separate self-supporting documents will be dedicated specifically to maintenance workshops, maintenance development and fleet maintenance management.

[The documents related to maintenance development and fleet maintenance management will be developed for beginning of 2012. The document related to certification of maintenance workshops is the maintenance workshop certification scheme.](#)

The newcomers Entities in charge of Maintenance (ECMs) that have the maintenance procedures/system in place but have not yet worked (could not present any evidence on the application of procedures) are also considered in this document

2. REFERENCE DOCUMENTS AND DEFINITIONS

2.1. Reference documents

2.1.1. Legal texts

1) **Safety Directive**

means the Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification and all amendments. It includes of course all the amendments published until the date of this document.

2) **ECM regulation**

means the Regulation 445/2011 of 10/05/2011 on a system of certification of the entity in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 (ECM regulation).

3) **Regulation n° 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 339/93.

4) **Commission Regulation (EC) n° 352/2009** of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council.

5) **Interoperability Directive**

means the Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (Recast).

2.1.2. Other reference documents

- 1) **EN 45011:1998** General requirements for bodies operating product certification systems (ISO/IEC Guide 65:1996)
- 2) **EN ISO/IEC 17007:2009** Conformity assessment -- Guidance for drafting normative documents suitable for use for conformity assessment
- 3) **EN ISO/IEC 17021:2011** Conformity assessment -- Requirements for bodies providing audit and certification of management systems
- 4) **EN ISO/IEC 17050-1:2010** Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements
- 5) **EN ISO/IEC 17050-2:2004** Conformity assessment -- Supplier's declaration of conformity -- Part 2: Supporting documentation
- 6) **IAF MD 1:2007** Certification of Multiple Sites Based on Sampling
- 7) **IAF MD 2:2007** Transfer of Accredited Certification of Management Systems
- 8) **IAF MD 5: 2009** Duration of QMS and EMS Audits

2.2. Definitions

The definitions of the Safety Directive and ECM regulation are applicable.
The definitions of ISO 9000:2005 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

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 **audit evidence** and evaluating it objectively to determine the extent to which **audit criteria** are fulfilled

(in French: Processus systématique, indépendant et documenté en vue d'obtenir des preuves d'audit et de les évaluer de manière objective pour déterminer dans quelle mesure les critères d'audit sont satisfaits)

NOTE 1 Internal audits, sometimes called first-party audits, are conducted by, or on behalf of, the **organization** itself for management review and other internal purposes, and may form the basis for an organization's declaration of **conformity**. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

NOTE 2 External audits include those generally termed second- and third-party audits. Second-party audits are conducted by parties having an interest in the organization, such as **customers**, or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations, such as those providing certification/registration of conformity to ISO 9001 or ISO 14001.

NOTE 3 When two or more **management systems** are audited together, this is termed a combined audit.

NOTE 4 When two or more auditing organizations cooperate to audit a single **auditee**, this is termed a joint audit

(ISO)

(d) Certification committee

means the Committee established by the certification body for delivering an opinion on which the certification decision is taken by the certification body.

(ERA)

(e) Certification decision

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

NOTE A certification scheme can utilize some or all of these types of certification decisions.

(ISO)

(f) Certification scheme

According to ISO, certification scheme means certification system related to specified products, to which the same specified requirements, specific rules and procedures apply. According to EN 45011:1998, products must be understood as manufactured products, services or processes.

(g) Certification scheme owner

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

NOTE The certification scheme owner can be the certification body itself, a governmental authority or other.

(ISO)

For certifications of ECM, separate maintenance functions including maintenance workshops according to the ECM Regulation, ERA is the scheme owner.

(h) Certification system

Rules, procedures, and management for carrying out certification.

(ISO)

(i) Conformity assessment system

Rules, procedures and management for carrying out conformity assessment
NOTE Conformity assessment systems may be operated at international, regional, national or sub-national level.
(ISO)

(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
(ISO)

(k) 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 amendments)

(l) 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)

(m) 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)

(n) 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.

(o) European Railway Agency (ERA)

means the European Institution providing the EU Member States and the Commission with technical assistance in the fields of railway safety and interoperability.
ERA is established and ruled by the Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European Railway Agency (including all amendments)

(p) Evaluation

Selection and determination function activities in the certification process as described in ISO/IEC 17000:2004

(q) Freight wagon

means a non-self-propelled vehicle designed for the purpose of transporting freight or other materials to be used for activities such as construction or infrastructure maintenance (ECM regulation)
(ECM Regulation)

(r) Independent safety assessment body (ISA)

Means the body mentioned in the article 6(1) of the Commission regulation 352/2009.

(s) 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)

(t) 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)

(u) Justification

Rationale establishing that no adverse impact on the competence, consistency and impartiality of the certification body's operation of the certification scheme has resulted.
(ISO)

(v) 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 33 of the Interoperability directive 2008/57;
(Safety Directive)

(w) 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 en route.
- 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.

Generally the first level of maintenance is not performed by maintenance staff but by drivers and/or operational staff. Sometimes first level may be subcontracted to ECMs but in that case will remain under the control and thus the responsibility of RUs/IMs.

Therefore level 1 should not be taken into account.

The levels of maintenance are usually combined 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 includes 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 includes level 4 and level 5.

(x) 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 (ECM regulation).
(ECM Regulation)

(y) Multi-site Organisation

A multi-site organisation is defined as an organization having an identified central function (hereafter referred to as a central office – but not necessarily the headquarters of the organization) at which certain activities are planned, controlled or managed and a network of local offices or branches (sites) at which such activities are fully or partially carried out.
(ISO-IAF)

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

(aa) Object of conformity assessment

Any particular material, product (including services), installation, process, system, person or body to which conformity assessment is applied
(ISO)

(bb) OTIF

Means the Intergovernmental Organisation for International Carriage by Rail

(cc) Process

Set of interrelated or interacting activities which transforms inputs into outputs.

(ISO)

(dd) Product

Result of a process.

NOTE 1 Four generic product categories are noted in ISO 9000:2005: services (e.g. transport); software (e.g. computer program, dictionary); hardware (e.g. engine, mechanical part); processed materials (e.g. lubricant).

Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed material depends on the dominant element.

NOTE 2 Products include results of natural processes such as growth of plants and formation of other natural resources.

(ISO)

(ee) Separate Maintenance function

refers to entities performing limited scope of maintenance activities as considered in the ECM Regulation (in particular article 8 and annex I) (ECM regulation)

(ff) Service

Result of at least one activity necessarily performed at the interface between the supplier and the customer and is generally intangible.

(ISO)

(gg) Scope of certification

Range or characteristics of products, processes or services covered by certification. The scope of certification generally includes;

- the product(s), process(es) or service(s),
- the applicable certification system/scheme, and
- the standard(s) and other normative document(s) (including date of publication) to which the product(s), process(es) or service(s) has been judged to comply.

(ISO)

(hh) 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)

(ii) Surveillance

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

(ISO)

(jj) Temporary Site

A temporary site is one set up by an organisation in order to perform specific work or a service for a finite period of time and which will not become a permanent site.

(ISO)

(kk) Type of vehicle

means a vehicle type defining the basic design characteristics of the vehicle as covered by a single type examination certificate

(Interoperability Directive 2008/57)

(ll) Wheelset

means a unit composed of an axle, two complete wheels, brake discs if equipped, and two complete axle boxes

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

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
ERA	European Railway Agency (scheme owner)
GCU	General Contract of Use
IAF	International Accreditation Forum
(IAF) MD	Mandatory document of IAF
IM	Infrastructure Manager
ISA	Independent Safety Assessment Body
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

3. Certification scheme for ECM certification

The European Railway Agency is the scheme owner in consistency with the rules of EA

The scheme owner is the entity who requests for a sectoral accreditation scheme against the EA rules.
According to the article 13(2a.) of regulation n° 765/2008, the European Commission should be the scheme owner.
In relation to the ECM regulation, ERA has proposed to be the scheme owner on behalf of the European Commission, which has been accepted.

As stated in article 13(2a), ERA shall address scheme proposals to the EU Commission (DG MOVE) for peer evaluation by relevant Committees (at least RISC- Railway Interoperability and Safety Committee).

3.1. Purpose and type of ECM certification

According to the art 1(2) of the ECM regulation, *the purpose of the system of is to provide evidence that an entity in charge of maintenance has established its maintenance system and can meet requirements laid down in this Regulation to ensure the safe state of running of any freight wagon for which it is in charge of maintenance.*
The art 7(1) of the ECM regulation points out that *certification shall be based on an assessment of the **ability** of the entity in charge of maintenance to meet the relevant requirements in Annex III and to apply them consistently.*

The stakeholders pointed out three main risks that must be kept under control to create and develop trust among stakeholders and in particular between Railway Undertakings, keepers and ECMs.
They may be summarised as following:

- The ECM should have a maintenance system based on processes compliant with the articles 5(2) to 5(5) and the annex III of the ECM Regulation. A system based on processes provides assurance that the activities of ECMs are performed in a structured way.
- The engineering and technical tasks must be performed by competent persons
- The analysis and decisions leading to outputs of processes must be relevant to assure safety.
-

Stakeholders pointed out that a management system certification according EN ISO 17021:2011 is necessary but not sufficient to develop trust between ECMs and RUs.

Management system certification

This section describes the principles of management system certification following the ISO approach.

Objective and limit of a management system certification

A management system is a set of interacting or interdependent management processes.

A management system certification aims at providing assurance that an organisation put in place a management system that **makes it able** to comply with other interested parties' specified requirements.

For instance

- 1) A quality management system certification against ISO 9001:2008 aims at providing assurance that an organisation **is able** to consistently provide products that meet customer and legal requirements (ISO 9001:2008 section 1.1.). But ISO 9001:2008 does not establish absolute requirements for quality performance. The performance is required by the customer.
- 2) An environmental management system certification against ISO 14001:2004 aims at providing assurance that an organisation **is able** to develop and implement a policy and objectives which take into account legal requirements and other requirements to which the organisation subscribes, i.e. requirements issued by other interested parties, and information about significant environmental aspects (ISO 14001:2004 section 1). But ISO 14001:2004 does not establish absolute requirements for environmental performance. The performance is required by interested parties and authorities.

It means that the management system certification provides a positive evaluation on the ability of the organisation to comply with other interested parties' specified requirements but the experience shows that it doesn't provide, in all cases, sufficient guarantee on the level of performance achieved or the degree of compliance with these specified requirements.

In other words the organisation is capable to comply with the specified requirements but the level of compliance itself is not guaranteed because not enough evaluated. .

It would mean that a management system certification of an ECM aims at providing assurance that the ECM put in place a management system that **makes it able** to ensure that the wagons are in a safe state of running by means of a maintenance system but without any sufficient guarantee on achieving a specified safety performance level.

In other words, safety performance is not guaranteed, because not evaluated.

How is the assessment of a management system carried out?

The assessment is performed against assessment requirements including assessment criteria.

These requirements may be contained in an international standard (e.g. ISO 9001:2008, ISO 14001:2008) or in a legal text (e.g. CSM Conformity assessment)

The assessment requirements address processes and/or procedures that must be implemented by the applicant to certification. The applicant has the responsibility to ensure the conformity between its processes and procedures and the assessment requirements. The assessment body is responsible to perform the assessment against the assessment requirements and additional specified rules for assessment (if any) and to take a decision regarding the conformity of the applicant's management system with the assessment requirements.

There should not be any confusion between the assessment requirements and the other parties' specified requirements mentioned above.

The assessment of the management system against the assessment requirement is composed of:

- The assessment of the conformity of the management system documentation against the relevant assessment requirements (the document review).
- The evaluation, through an on-site assessment, of the implementation of the applicant's processes and procedures. Two aspects are considered:
 - The evaluation of the dissemination and the real use of the processes and procedures by the relevant staff in daily working activities. The evaluation is based on evidences.
 - The effectiveness of the applicant's processes and procedures is also evaluated through the outputs of internal auditing, management review, policy, performance objectives, performance targets, performance monitoring, operational controls.

But it doesn't mean that the provided evidences are analysed to verify if the outputs of each process are consistent with the inputs. For instance there is no analysis of consistency of the content of approved changes mentioned in II.5(c) with the need for updates identified according to II.5(b). This analysis is outside the scope of a management system certification.

It is clear that for ECM certification the requirements and assessment criteria that are listed in the annex III of Commission Regulation (EU) N° 445/201 (the ECM regulation) shall be used.

To facilitate the understanding, consider the requirement II.5. of the annex III of the maintenance development function.

"5. *To keep the maintenance file updated throughout the lifecycle of a freight wagon, the organisation must have procedures to:*

- (a) *collect at least the relevant information in relation to:*
 - (i) *the type and extent of operations effectively performed, including, but not limited to, operational incidents with a potential to affect the safety integrity of the freight wagon;*
 - (ii) *the type and extent of operations planned;*
 - (iii) *the maintenance effectively performed;*
- (b) *define the need for updates, taking into account the limit values for interoperability;*
- (c) *make proposals for and approve changes and their implementation, with a view to a decision based on clear criteria, taking into account the findings from risk assessment;*
- (d) *ensure that the implementation of changes is done correctly."*

The assessment of the management system of the ECM against this requirement is composed of:

- The assessment of the conformity of the ECM relevant procedures with this requirement II.5. It means the demonstration that the ECM has defined (organisational) procedures that comply with this requirement II.5.
- The assessment of the real use of these ECM relevant procedures by relevant ECM staff by means of evidences showing that the procedures are really applied.
- The effectiveness of the ECM's processes and procedures is also evaluated through the outputs of internal auditing, management review, policy, performance objectives, performance targets, performance monitoring, operational controls applicable to this requirement II.5.

But it doesn't mean that the provided evidences are analysed to verify if the outputs of processes are consistent with the inputs. For instance there is no analysis of consistency of the content of approved changes mentioned in II.5(c) with the need for updates identified according to II.5(b). This analysis is outside the scope of a management system certification.

Remark: the full assurance on the compliance with the specified requirements is difficult to reach in practical because assessments never cover all the details completely as they are limited by availability of resources and cost. This is why professionals prefer to speak about 'providing reasonable assurance' rather than about 'providing assurance'

To conclude, the management system certification according to the ISO approach provides assurance that the organisation has a management that makes it able to meet requirements but not that the requirements on outcomes are sufficiently met.

The railway stakeholders have a long experience with management system certifications based on the ISO approach, in particular quality management certifications based on the ISO 9000 series, because most of them have included these in their qualification schemes addressed to their contractors. But they consider, by experience, that these management system certifications based on ISO approach are insufficient to create and maintain trust with their contractors. Therefore most of the railway stakeholders complete their demands related to management system certifications with additional assessments (inspections):

- on the processes put in place by their contractors to design and manufacture products; or
- directly on the outputs of their contractors' processes (it includes inspections on product/services delivered by the contractors).

Some railway stakeholders address the problem on a different way: They require a maturity performance regarding the management systems of their contractors.

ERA is convinced that when a management system is mature enough and that all processes are working in a very efficient way (including e.g. the internal audit process), a management system certification can provide sufficient assurance that the outputs of processes correspond to the expected results. Therefore additional assessments on outputs of processes or final products delivered by contractors become useless.

The problem for ECM certification is that there is no certitude that the maintenance systems of ECMs are mature enough to assure trust between Railway stakeholders because the concept of ECMs separated from Railway undertakings and relevant certifications are new for railway stakeholders. Most of the railway stakeholders themselves are convinced that the maintenance systems of ECMs are not mature enough. Therefore ERA considers that it is too early now to limit the ECM certification to a management system certification.

As mentioned earlier, most of the railway stakeholders are used to imposing assessments (inspections) on processes or outputs of processes to their contractors. In particular they have concerns on availability of sufficient technical and engineering competences and on the relevance between inputs and outputs of processes put in place by the ECMs.

Therefore ERA proposes to combine a management system assessment based on ISO approach to an assessment (inspections) related to the availability of technical and engineering competences and to the relevance between inputs and outputs of processes.

Nevertheless ERA is convinced that further reflections on development of the maturity of maintenance systems and on migration to a management system certification for ECMs have to be done in short delay. Those reflections should be the base for a revision of the ECM certification scheme within two or three years, time that seems necessary for the development of trust between railway stakeholders and in particular between railway undertakings, keepers and ECMs. ERA will lead those reflections and the further revision.

The ECM certification aims at supporting the creation and development of trust between stakeholders in particular between RUs and ECMs by facilitating the control of the risks identified here above.

It means in practical that the ECM certification aims to provide assurance that the arrangements put in place makes the ECM able to maintain wagons registered in the NVRs for which it is in charge in order to ensure that wagons are in a safe state of running by assuring:

- 1) That the management of maintenance activities and exchange of information is done through procedures for which:
 - a. the conformity against the articles 5(2), 5(3), 5(4) and 5(5) and the annex III of the ECM Regulation has been assessed; and
 - b. the effectiveness has been assessed.
- 2) That the maintenance of wagons is carried out in such a way that the wagons are in conformity with legislation in force, in particular safety and interoperability rules and rules related to transport of dangerous goods when appropriate.
- 3) The availability of the engineering and technical competences necessary to maintain freight wagons.
- 4) The coherence between the outputs and inputs of processes related to maintenance development, fleet maintenance management and maintenance delivery.

Therefore the ECM certification is a process certification for which the conformity assessment is composed of two parts:

- 1) An assessment of the maintenance system covering the point 1) here above; and
- 2) Inspections on a set of selected processes of the maintenance system (selected in maintenance development, fleet maintenance management and maintenance delivery), covering points 2), 3) and 4) here above..

3.2. Certification process

3.2.1. Principles

The ECM certification as defined in the preceding section shall be structured as:

- Formal application to the Certification Body (3.2.2.2.)
- Review of the application (3.2.2.2.)
- Initial assessment (or pre-award assessment) (3.2.2.3.)
- Delivery of certificate (3.2.2.4.)
- Surveillance activities during the validity period (3.2.2.5.)
- Recertification process (3.2.2.6.)

Additional necessary principles are added for:

- Multi-sites assessment (3.2.3.1.)
- Used language (3.2.3.2.)
- Assessment time (3.2.3.3.)
- Changes in the maintenance system (3.2.3.4.)
- Access and traceability of reports (3.2.3.5.)
- Conditions on revocation and suspension of certificate (3.2.3.6.)
- Existing certification (3.2.3.7.)
- Certification decision identification number (3.2.3.8.)
- Use of certificate (3.2.3.9.)
- Transfer of certificate (3.2.3.10.)

This structure is compliant with the art 7 of the ECM regulation and with the common good practices in the certification domain such as the section 9 of ISO 17021:2011 ([or section 8 of future ISO 17065:2012](#))

The inspections on selected processes are introduced in the initial assessment and in the surveillance activities.

Therefore the initial assessment is composed of the initial audit related to the assessment of the maintenance system and initial inspections on selected processes.

The surveillance activities combine the surveillance related to assessment of the maintenance system and the surveillance inspections on selected processes.

In case of multi-sites assessment, the rules related to certification of Multiple Sites based on sampling (IAF MD 1:2007) are applicable without prejudice to following rules

The certification shall be performed against the requirements defined in the ECM regulation, in particular the articles 5(2) to 5(5), the article 7 and the annex III

The assessment process is composed on two parts:

Part 1: Assessment of the maintenance system

The maintenance system is considered in its globality. Therefore the assessment is based on the management system assessment approach. This leads to a certification process compliant with the section 9 of EN ISO17021:2011.

Part 2: Inspections on selected processes

The inspections shall be performed against the principles defined here below.

The inspections do not cover all the procedures of the annex III of the ECM regulation for economic reasons. A selection has been made taking into account the criticality of procedures regarding safety from a RU point of view.

The inspections cover the main procedures leading to:

- the setting up and continuous update of the maintenance file (maintenance development);
- the issue of maintenance orders, removals from operation and return to operation (fleet maintenance management); and
- the respect of maintenance orders and the issue of release to service (in maintenance delivery)

RUs must be provided with assurance that ECMs fulfil their duty as stated in the art 14a(3) of the Safety Directive.

The selection of procedures was validated through the consultation of Recognised Bodies (sector associations CER, UNIFE and UIP mainly).

Therefore the inspections cover the processes put in place by the ECM that are relevant to the following requirements of annex III of ECM Regulation:

- Maintenance development:
 - Conformity with Interoperability rules (II.2. of annex III of ECM regulation)
 - Establishment of maintenance file (II.4. of annex III of ECM regulation)
 - Update of maintenance file (II.5. of annex III of ECM regulation)
- Fleet maintenance management:
 - Issue of maintenance orders and removal from service (III.2, III.3 and III.4 of annex III of ECM Regulation)
 - Issue of return to operation (III.6. of annex III of ECM regulation)
- Maintenance delivery
 - Issue of working instructions from maintenance orders (IV.1. of annex III of ECM regulation)
 - Issue of release to service including control of coherence between maintenance works performed and maintenance orders. (IV. 6. Of annex III of ECM regulation)

The inspections focus also on activities affecting safety as stated in the ECM regulation:

- Activities affecting safety identified by the ECM (maintenance development, II.1. of annex III of ECM Regulation)
- Joining techniques
- Non-Destructive Tests (NDTs)
- Maintenance of braking system
- Maintenance of wheelsets, running gear and draw gear

Wheelsets include: axles, wheels, brake discs when equipped and complete axle boxes

Running gear is the set of interrelated elements that carry and guide the wagon unit and transmit braking forces where so required. It includes bogie frame, all attached equipments, body to bogie connections, bogie and suspension (such as the components quoted in the PrEN 16235).

Draw gear considers also separate buffers if equipped.

- When appropriate maintenance of tanks and other specific equipments related to transport of dangerous goods

Tank wagons

Other specific equipments related to transport of dangerous goods mean here equipments aiming at loading/unloading tank wagons such as valves and assuring safety such as devices used to measure internal pressures and specific discharge valves, ...

Other wagons specialised in transport of dangerous goods:

Other specific equipments related to transport of dangerous goods mean containment equipments of dangerous goods that are fixed on the wagon, equipments aiming at loading/unloading tank wagons such as valves and assuring safety such as devices used to measure internal pressures and specific discharge valves, ...

Flat wagons used for intermodal transport of road trailers and semi-trailers, containers and swap bodies are not considered as wagons specialised in transport of dangerous goods if not otherwise mentioned.

- Coordination of maintenance at the level of the wagon

These activities affecting safety are issued from annex III of ECM Regulation

The inspections aim to assess

- the existing competences related to selected processes
- the coherence between the inputs and the outputs of selected processes

3.2.2 Process

Assessments and certifications shall be carried on without prejudice to the article 7 of the ECM regulation.

The following process is the process for the certification of ECM by accredited certification bodies against the requirements of the ECM Regulation.
All actions taken by certification bodies shall be compliant with the article 7 of the ECM Regulation.

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<u>3.2.2.1. Assessment rules</u>	
<p>The assessment shall be in conformity with the section 9 of ISO 17021:2011.</p>	<p>The structure of the section 9 of EN ISO 17021:2011 is kept for inspections to assure consistency between part 1 and part 2. The inspections are composed of review of documents provided by the ECM and on-site inspections.</p> <p>These on-site inspections may be on-site observations of staff of the ECM at work or interviews of staff of the ECM.</p>
<u>3.2.2.2. Formal application and review of application</u>	
<u>Content of the formal application</u>	
<p>The ECM applies for certification by providing the following documents:</p> <ul style="list-style-type: none"> • The form in the annex IV of the ECM regulation. • The necessary information in consistency with art 9.2.1. of ISO 17021:2011 <p>This information contains at least:</p> <ul style="list-style-type: none"> • Information on wagons: <ul style="list-style-type: none"> ○ Structured information on wagons for which the ECM is in charge. The structure is based on types. In case no type has been defined, the structure is based on the design of the wagons. The complete list of wagons may also be provided. For all wagons, list of applicable rules is provided. <p><u>Type of wagon</u> The type is defined in the interoperability directive and subsequent legislation. For existing wagons a formal type in conformity with the Interoperability directive may be not defined. See relevant EU legislation and guidelines regarding type.</p> <p><u>Applicable rules:</u> It includes the legal rules: International rules such as RID or European Union rules or national rules such as the national rules supporting specific cases and open points of TSIs. Any other agreed rules according to contracts with customers of ECM (in many cases the keeper). For instance sector agreed rules or rules related to maintenance defined in private contracts such as the GCU. The customer may also impose by contract with ECM international, national or industry standards related to maintenance such as international standards (e.g.EN 15313, EN 473 or 15085), national standards (e.g. DIN 27000 series) or industry standards (e.g.VPI rules)</p> <ul style="list-style-type: none"> ○ Structured information on wagons intended or planned to be maintained in the forthcoming years. The structure is based on types. In case no type has been defined, the structure is based on the design of the wagons. For all wagons, list of applicable rules is provided. 	

Part 1: Assessment of the maintenance system

Part 2: Inspections on selected processes

- For wagons transporting dangerous goods:
List of classes of dangerous goods transportable or approved to be transported with list of applicable rules). These lists help the certification body to define in detail the scope of the assessment related to conformity with applicable rules.

It includes legal rules such as RID, environmental protection rules, occupational health and safety rules, any additional sector agreed rules or specific rules imposed by customers of ECM.

- Description of the organisational structure of the ECM. It provides the necessary information to the certification body on the complexity of the organisational structure. The description takes into account:
 - Appropriate organigrams of the ECM organisation.
 - A description of its structure that includes the external entities performing maintenance activities for the ECM.

These external entities may be contracted by the ECM or imposed by contracts with keepers (e.g. organisation of maintenance delivery in GCU).

- For the external entities the ECM shall indicate if they are:
 - directly qualified by the ECM; and/or

The ECM must get assurance that the external entities are competent and capable to provide the maintenance services ordered to them by the ECM.

The ECM develops qualification schemes to assess the competence and capability of external entities. The schemes include also the surveillance performed by the ECM on outcomes provided by the external site.

There are also different tools that may be used by the ECM to qualify the external entities:

- The ECM may assess external entities against its own assessment rules.
- The ECM may impose third party certification or third party assessments on:
 - management system of the external site (such as management system certification international standards ISO 9001:2008 or industry standard IRIS); and/or
 - capabilities of external sites (such as VPI certification based on inspections); and/or
 - capabilities of individual persons (such as certification of welders or NDT technician).

When relying on third party certifications or third party assessments, The ECM should keep in mind the three main risks mentioned in section 3.1 of this document.

In general the qualification schemes developed by ECM are composed of ECM proper assessment and third party certification(s).

- third party certified or assessed against:
 - the ECM Regulation; and/or
 - management system certification international, national or industry standards; and/or
 - international, national or industry standards regarding capabilities of organisations or capabilities of individual workers.

- The ECM shall provide basic information on its organisation relevant to its size and complexity

Information such as:

- number of permanent staff for each internal sites or attributed to each maintenance function (maintenance development, fleet maintenance management, maintenance delivery, management function);
- turnover
- number, size and activities of the different sites internal and external;
- geographical extent of its activities.

The ECM is recommended to reflect on the most appropriate relevant information to permit to the certification body to define its necessary resources and propose the most appropriate (man) assessment days

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<ul style="list-style-type: none"> • Structured description of the processes put in place by the ECM and how they comply with the requirements for certification of the annex III of the ECM regulation. The ECM may provide a table for a better understanding of relations between its processes and the requirements stated in the annex III of the ECM regulation. • Information on the maintenance policy relevant to the Annex III I.1.(a) of the ECM Regulation. The information may include a maintenance policy statement. <p style="text-align: center;"><u>Application review</u></p> <p>When reviewing the application, the certification body shall apply the section 9.2.2. of ISO 17021:2011 and the art 7(2) of the ECM regulation.</p> <p>Based on the application documents the certification body shall determine the scope (parameters) of the assessment and shall request the necessary detailed documentation to perform the assessment. The requested documents may include records, previous assessment reports and templates of forms defined in the procedures and used by the ECM. The documents may be provided in electronic format.</p>	
<p><u>3.2.2.3. Initial assessment</u></p> <p>The initial assessment shall be composed of an initial audit of the maintenance system and an initial inspection.</p> <p>The initial assessment shall be composed of two stages as described here below.</p> <p>The initial assessment shall be conducted by an assessment team composed of an audit team and an inspection team. Individual assessor may work simultaneously on audit of the maintenance system and on inspection.</p> <p>The assessment team shall have access to all necessary documents of the ECM and to ECM staff.</p> <p>The assessment team shall determine the initial assessment program, the necessary resources (competencies and quantity) and the duration of the assessment (number of assessment days) and takes the necessary arrangements with the ECM.</p> <p>When the assessment team notifies to the ECM that he considers that he has received all the necessary documents to perform the assessment, the period of 4 months to deliver the ECM certificate as stated in the article 7(3) of the ECM Regulation starts.</p>	
<p><u>Initial audit</u></p> <p>The initial audit of the maintenance system shall be conducted as described in the section 9.2.3. of ISO 17021:2011.</p>	<p><u>Initial inspection</u></p> <p>The initial inspection is applicable in initial assessment stage 2</p>
<p><u>3.2.2.3.1. Initial assessment stage 1</u></p> <p>The initial assessment stage 1 is composed only of the initial assessment stage 1 audit of the maintenance system.</p>	
<p><u>Initial audit stage 1</u></p> <p>The audit consists in an examination of the relevancy of the documents to the requirements for certification</p>	

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<p>as stated in the ECM regulation 445/2011. The audit team shall audit that all the procedures put in place by the ECM in its maintenance system are in conformity with the requirements of annex III of the ECM regulation 445/2011 and are established, documented and reviewed regularly. The art 9.2.3.1. of ISO 17021:2011 is applied.</p> <p>The procedures put in place by the ECM include all supporting documents such as working instructions, forms, templates, ...</p> <p>The examination shall take into account the size, nature and complexity of the organisation, and the objectives and scope of the audit.</p> <p>In some situations, this examination may be deferred until the on-site activities start, if this is not detrimental to the effectiveness of the conduct of the audit. In other situations, a preliminary site visit may be conducted to obtain a suitable overview of available information.</p> <p>If the documentation is found to be inadequate, the assessment team leader should inform the ECM. A decision should be made as to whether the audit should be continued or suspended until documentation concerns are resolved.</p> <p>A single document presented by the ECM may address one or more procedures of annex III of the ECM regulation. A single requirement of annex III of the ECM regulation may be covered by more than one document presented by the ECM¹.</p> <p>The audit team may request additional documents to perform its tasks if he has previously justified doubts on the compliance with requirements of annex III of the ECM Regulation.</p> <p>The audit team may request to interview staff members.</p>	
<p><u>3.2.2.3.2. Initial assessment stage 2</u></p> <p>In a multi-site assessment and for each maintenance function, the assessment team shall perform assessment in at least one site for each category defined in section 3.2.3.1. of this document.</p> <p>The initial assessment stage 2 is composed of an initial assessment stage 2 audit and initial assessment stage 2 inspections.</p>	
<p style="text-align: center;"><u>Initial assessment stage 2 audit</u></p> <p>The audit team shall audit that the procedures put in place by the ECM are known and duly used by the staff (management, specialists, and all workers) on a permanent base.</p> <p>It includes the procedures put in place to comply with Regulation 352/2009.</p>	<p style="text-align: center;"><u>Initial assessment stage 2 inspections</u></p> <p>The stage 2 inspections shall be composed of :</p> <ul style="list-style-type: none"> • Inspections on existing competences • Inspections on coherence between inputs and outputs of the selected processes defined in section 3.2.2.1.

¹ See 4.2.1 note 1 of ISO 9001:2008

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>	
<p>The procedures put in place by the ECM include all supporting documents such as working instructions, forms, templates, ...</p> <p>The certification body shall perform a risk assessment to target the audit activities in function of the initial audit stage 1 findings and public information on railway safety.</p> <p>The public information means here the information easily accessible to certification bodies. This information should ideally be provided by ERA and NSAs as NSAs should have the widest and more detailed view on risks of railway system.</p> <p>The co-operation framework put in place by ERA according to article 6 of the ECM Regulation shall aim to compile this public information on railway safety.</p> <p>The audit shall be done at least by interviewing selected staff members and by controlling that the correct internal documents (forms, check-lists, risk assessment log books, internal review documents,...) are effectively used and correctly filled according to the procedures put in place by the ECM.</p> <p>The release to service and the return to operation documentation shall be covered by the audits.</p> <p>The audit team shall evaluate also that the extent of internal documents is appropriate to the size and the extent of activities of the ECM.</p> <p>For all functions, the audit team shall assess the effectiveness of the procedures put in place by the ECM through the analysis of the applicable outputs of internal auditing, management review, policy, performance objectives, performance targets, performance monitoring and operational controls.</p>	<p><u>Inspections on existing competences related to selected processes</u></p> <p>The inspection team evaluates the appropriateness of the competences in place against the activities performed by the ECM in particular regarding:</p> <ul style="list-style-type: none"> - The access to appropriate competent persons involved in the technical and engineering activities (technical experts). <p>Competent persons may be in-house or external.</p> <ul style="list-style-type: none"> - The competence of coordination staff to understand the key elements of technical and engineering activities (generalist manager, staff responsible for integration at the level of complete wagons). <p>The inspection team verifies that involved persons have sufficient knowledge, workload and experience relatively to their respective scope of activities. The inspection is based on:</p> <ul style="list-style-type: none"> • evidences provided by the ECM <p>Evidences such as CV, continuous training, participation in seminars of conferences, internal evaluation documents.</p> <p>Legal rules on protection of personal data shall be applied by the inspection team and the ECM.</p> <ul style="list-style-type: none"> • interviews of staffs; and • on-site observation of staff . <p>For supporting harmonisation in the EU, it is recommended that relevant international standards or any other international commonly used good practices such as industry standards are used by the inspection team to justify their experts' judgements.</p> <p>Even if the inspection team should refer to relevant international standards and any other international commonly used good practises, it is not mandatory to ECM to comply with them except when required by the legislation. However the equivalence of used</p>	<p><u>Inspections on coherence between inputs and outputs of selected processes</u></p> <p>The inspections shall be based on:</p> <ul style="list-style-type: none"> • sampling of dossiers ; • interviews of staffs; and • on-site inspection . <p>It is recommended that the coherence is analysed on the base of existing standards and other international commonly used good practises.</p> <p>A list of standards and other international commonly used good practises will be established and updated when necessary through the cooperation put in place by ERA according to article 6 of the ECM Regulation</p> <p>Nevertheless the application by the ECM of standards and other good practises listed is not mandatory.</p>

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>	
	<p>methods or practice should be demonstrated. The ECM should manage the competences against the risks for safety in any case.</p> <p>A list of relevant international standards and other international commonly used good practises will be established and updated when necessary through the cooperation put in place by ERA according to article 6 of the ECM Regulation</p> <p>This list does not replace the ECM's responsibility to maintain his own list of standards and commonly used good practises he has decided to use.</p>	
<u>Specificities for maintenance development</u>		
<p>In addition:</p> <ol style="list-style-type: none"> 1) The audit team shall verify that the ECM is aware of the legal requirements related or impacting maintenance and considers them in the maintenance development activities. 2) For each level of maintenance (light and heavy), for each scope category of wagons (tank wagons, other wagons specialised in transport of dangerous goods and remaining wagons as stated in ECM regulation annex IV and V) , the audit team shall choose several dossiers related to establishment and update of maintenance files. The choice will be based on the extent of maintenance activities. The areas having an important impact on safety shall be audited in priority. They include: <ul style="list-style-type: none"> • Activities affecting safety defined by the ECM (maintenance development, II.1. of annex III of ECM Regulation) • Joining techniques • Non-Destructive Tests (NDTs) • Maintenance of braking system • Maintenance of wheelsets, running gear running gear and draw gear • When appropriate maintenance of tanks and other specific equipments related to transport of dangerous goods • Coordination of maintenance at the level of the entire wagon • Any other activities considered as relevant by the audit team in regards of public information on safety as mentioned here above <p>The audit team shall verify that the maintenance development procedures put in place by the ECM are duly applied by relevant staff.</p>	<p><u>Inspections on existing competences</u></p> <p>The inspection team verifies that:</p> <ol style="list-style-type: none"> 1) for section II.2 of Annex III of ECM Regulation 445/2011: The relevant staffs involved in the verification know the European legislation (Railway Interoperability directives, relevant TSIs) and any other documents considering the interoperability of the wagons (guidelines, various public documents of ERA or EU Commission such as guidelines or Commission recommendations). 2) For sections II.4. and II.5. of annex III of ECM regulation 445/2011: The relevant staffs has knowledge of applicable legal rules and has engineering knowledge relevant to activities affecting safety meaning activities identified by the ECM according to annex III of ECM regulation 445/2011, II.1. ,joining techniques, NDTs, maintenance of wheelsets, running gear and draw gear, maintenance of braking system and coordination of maintenance at the level of wagon.. 3) Dangerous goods: tank and associated 	<p><u>Inspections on coherence between inputs and outputs of selected processes</u></p> <p>The inspection team assesses the coherence of the maintenance file established by the ECM with the information the ECM has received from users.</p> <p>The main users are keepers and Railway Undertakings.</p> <p>In particular the certification body assesses that the maintenance file established by the ECM is coherent with:</p> <ul style="list-style-type: none"> • The information contained in the relevant TSI (there is a need for the ECM to identify the relevant TSIs and related documents such as guidelines) • Limit values applicable to the vehicle according to the verified design and to the placing in service documents. • Operational data received (mileage, pattern of services,...) • Any other information received or owned by the ECM • Performance required by the customers of ECM (reliability, availability, cost)

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>	
<p>The audit team shall assess the effectiveness of the maintenance development procedures put in place by the ECM through the analysis of the applicable outputs of internal auditing, management review, policy, performance objectives, performance targets, performance monitoring and operational controls.</p>	<p>equipments, specific equipments related to dangerous goods. The relevant staffs know the European legislation (Dangerous goods directives, relevant regulations such as RID) and any other documents considering the safety of transport of dangerous goods (guidelines, various public documents of EU Commission such as guidelines or DVs). The relevant staffs have a sufficient engineering knowledge of the technologies used.</p> <p>4) For all activities here above, the technical and engineering documentation and the documentation related to legislation in use present at ECM premises are sufficient and appropriate to the extent of activities.</p> <p>The interviews and on-site observations are based on samples of dossiers of establishment or updates of maintenance files.</p>	<ul style="list-style-type: none"> • Results of ECM's risk assessments • Complaints <p>To do so, the inspection team checks that:</p> <ul style="list-style-type: none"> - The ECM has systematically identified the relevant inputs related to interoperability <p>For instance, relevant essential requirements of the interoperability directive 2008/57, the relevant specifications (TSIs), the eventual specific information contained in the verification documents provided by NoBos and designated bodies, the design limit values and other relevant information contained in the technical documentation provided to the ECM, When applicable the specific requirements in the authorisation(s) of placing in service, and the applicable national rules are also considered.</p> <p>National rules may be relevant to specific cases defined in applicable TSIs or to open points in applicable TSIs.</p> <ul style="list-style-type: none"> - The other inputs identified by the ECM are relevant and exhaustive - Risk assessment methods and results justify the decisions taken for the establishment or update of the maintenance file (if there is intervention of independent safety assessment body (ISA), check only that the ISA is competent and the presence of a report in conformity with art 7 of Regulation 352/2009. - The parts of maintenance file non-compliant with interoperability requirements are formally identified and rejected by the ECM whenever TSIs are applicable - There is monitoring made by the ECM about the correct implementation in fleet maintenance management and maintenance delivery and the outputs of monitoring are effectively used as input for II.5. of Annex III of the ECM Regulation (continuous improvement) <p>The checking covers the activities affecting safety:</p> <ul style="list-style-type: none"> ○ Activities affecting safety defined by the ECM (maintenance development, II.1. of annex III) ○ Joining techniques

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>	
		<ul style="list-style-type: none"> ○ NDTs ○ Maintenance of braking system ○ Maintenance of wheelsets running gear running gear and draw gear ○ When appropriate maintenance of tanks and other specific equipments related to transport of dangerous goods ○ Coordination of maintenance at the level of the wagon <p>Specifically for the following activities affecting safety, the certification body checks that:</p> <ul style="list-style-type: none"> - For joining: <ul style="list-style-type: none"> ○ The relevant part of the dossier is in consistency with the international standards (welding) or any other international good practices. ○ The working rules in the maintenance file are sufficiently detailed and understandable by competent welders (meaning welders qualified against international standards) and by welding management of maintenance delivery <p>For other joining techniques: same checks when appropriate. For innovative solutions like gluing, international standards or good practices may be missing. In that case risk assessment performed by the ECM is taken into account.</p> <p>For NDTs:</p> <ul style="list-style-type: none"> ○ the relevant part of the dossier is in conformity with the international standards or any other international good practices. ○ The NDT including the decision criteria are defined in function of failure risks and convenient for the defects expected. Technology and decision

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>	
		<p>criteria must be clearly formalised.</p> <ul style="list-style-type: none"> ○ The working rules including decision criteria in the maintenance file are sufficiently detailed and understandable by competent technicians (meaning technicians qualified against international standards) and by relevant management of maintenance delivery <p>- For Tank and associated equipments Specific equipments dangerous good when appropriate:</p> <ul style="list-style-type: none"> ○ The ECM has identified exhaustively the relevant inputs, i.e. rules (e.g. RID, directive on transport of dangerous goods), international standards and other international commonly used good practices ○ The relevant inputs previously identified by the ECM are relevant and exhaustive ○ Risk assessment methods and results justifies the decisions taken for the establishment of the maintenance file ○ The parts of maintenance file non-compliant with dangerous goods rules are formally identified and rejected ○ There are verifications made by the ECM about the correct implementation in maintenance fleet management and delivery of the maintenance file and these verifications are used as input when applying II.5. of Annex Iii of the ECM

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>	
		<p>regulation.</p> <p>The checks shall be made on sampling of dossiers of establishment or update of the maintenance file.</p>
<u>Specificities for fleet maintenance management</u>		
<p>In addition:</p> <ol style="list-style-type: none"> 1) The audit team shall verify that the ECM is aware of the legal requirements related or impacting maintenance and considers them in the fleet maintenance management activities 2) For different levels of maintenance and scope categories of wagons (tank wagons, other wagons specialised in transport of dangerous goods and remaining wagons as stated in ECM regulation annex IV and V), the audit team shall choose several wagons for which maintenance has been ordered. The choice will be based on the extent of the maintenances activities and the characteristics of the fleet maintained. The areas having an important impact on safety shall be audited in priority. They include: <ul style="list-style-type: none"> • Activities affecting safety defined by the ECM (maintenance development, II.1. of annex III of ECM Regulation) • Joining techniques • Non-Destructive Tests (NDTs) • Maintenance of braking system • Maintenance of wheelsets, running gear and draw gear • When appropriate maintenance of tanks and other specific equipments related to transport of dangerous goods • Coordination of maintenance at the level of the wagon • Any other activities considered as relevant by the audit team in regards of public information on safety as mentioned here above <p>The audit team has the responsibility to define the amount of dossiers to be assessed. All levels of maintenance must be considered in the assessment.</p> <p>The audit team shall verify that the fleet maintenance management procedures put in place by the ECM are duly applied by relevant staff. In particular the audit team shall concentrate its assessment on the documents and information exchanged with maintenance delivery (such as maintenance orders and release to service) and with external interested parties (such as claims and return to operation).</p> <p>The audit team shall assess the effectiveness of the fleet maintenance management procedures put in place by the ECM through the analysis of the applicable outputs of internal auditing, management review, policy, performance objectives, performance targets, performance monitoring and operational controls.</p>	<p><u>Inspections on existing competences related to selected processes</u></p> <p>NA</p>	<p><u>Inspections on coherence between inputs and outputs of selected processes</u></p> <p>The assessment is based on a sampling of dossiers.</p> <p>The inspection team shall check that the periodicity of maintenance activities defined in the maintenance file is respected in the maintenance orders and in the removals from service.</p> <p>The inspection team shall check the coherence between the return to operation and the maintenance orders, the maintenance file, the releases to services received from maintenance delivery and when existing the additional final testing performed by the fleet Maintenance Management itself. It includes:</p> <ul style="list-style-type: none"> - Validation of releases to service against maintenance orders and planned maintenance operation in maintenance file. - File content, logging, conservation - Determination of restrictions <ul style="list-style-type: none"> - Transmission of restrictions to users: <p>According to contractual arrangements. But keepers and RUs must be considered.</p> <p>There may be no direct contact between RUs and ECMs, contacts are made then through intermediate entities (for instance keepers).</p> <p>The contractual arrangement between the ECM and the intermediate entity must be</p>

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>	
		<p>considered by the inspection team during its assessment.</p> <ul style="list-style-type: none"> - Transmission of other information such as maintenance problems, improper operation, ... to relevant entities <p>In application of article 5(5) of the ECM Regulation: <i>“All contracting parties shall exchange information on safety-related malfunctions, accidents, incidents, near-misses and other dangerous occurrences as well as on any possible restriction on the use of freight wagons.”</i></p> <p>To conclude, a judgment on functioning and effectiveness of information circulation should be given by assessment team</p> <p>As the Return to Operation notification may be considered as ECM self-assessment of the maintenance performed, the requirements of EN ISO/IEC 17050-1 should be used by the certification body in its assessment provided the document demonstrating global compliance have been completed as required by EN ISO/IEC 17050-2.</p>
<u>Specificities for maintenance delivery</u>		
<p>In addition:</p> <ol style="list-style-type: none"> 1) The audit team shall verify that the ECM is aware of the legal requirements related to maintenance or impacting its industrial activities (including health and safety legal rules and environmental rules) and considers them in the maintenance delivery activities. 2) For each level of maintenance (light and heavy), for each scope category of wagons (tank wagons, other wagons specialised in transport of dangerous goods and remaining wagons as stated in ECM regulation annex IV and V), the audit team shall choose several wagons and components maintained in the audited location. The areas having an important impact on safety shall be audited in priority. They include: <ul style="list-style-type: none"> • Activities affecting safety defined by the ECM (maintenance development, II.1. of annex III of ECM Regulation) • Joining techniques • Non-Destructive Tests (NDTs) • Maintenance of braking system 	<p><u>Inspections on existing competences related to selected processes</u></p> <p>The inspection team verifies that:</p> <ol style="list-style-type: none"> 1) For maintenance activities related to activities affecting safety: activities identified by the ECM according to annex III, II.1. of ECM regulation: Joining techniques, NDTs, maintenance of wheelsets, running gear and draw gear, maintenance of braking system and coordination of maintenance at the level of wagon: The relevant technical staff and local management staff have sufficient technical knowledge in regards of the extent of maintenance orders requirements. 	<p><u>Inspections on coherence between inputs and outputs of selected processes</u></p> <p>The inspection team creates a supporting checklist identifying relevant parts of the ordered maintenance requirements</p> <p>The certification body shall assess the working instructions, measuring procedures and control procedures (for instance control of technical works, performed by local management) and any other technical document are coherent with the maintenance orders received and the state of the art.</p>

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>	
<ul style="list-style-type: none"> • Maintenance of wheelsets, running gear and draw gear • When appropriate maintenance of tanks and other specific equipments related to transport of dangerous goods • Coordination of maintenance at the level of the wagon • Any other activities considered as relevant by the audit team in regards of public information on safety as mentioned here above <p>The audit team shall verify that the maintenance delivery procedures put in place by the ECM are duly applied by relevant staff. The audit team shall also verify the presence and the use of the facilities, tools and measuring tools (including their maintenance and calibration) required from maintenance orders.</p> <p>The audit team shall assess the effectiveness of the maintenance delivery procedures put in place by the ECM through the analysis of the applicable outputs of internal auditing, management review, policy, performance objectives, performance targets, performance monitoring and operational controls.</p> <p>The audit teams shall verify that the maintenance orders (got from fleet maintenance management) are duly considered in local documents such as work instructions, work procedures and measuring procedures available to interested staff. The audit team shall verify that these local documents are duly applied by relevant staff.</p> <p>If the assessments (verifications) are successful then the maintenance delivery audited premises will be presumed to be competent for the maintenance of the relevant scope category of wagons for the relevant level of maintenance.</p> <p>E.g. Location A, level light (line) maintenance, tank wagons If the assessments (verifications) are successful for one or more tank wagons maintained in the location A according to the relevant light (line) maintenance orders then the maintenance workshop shall be considered as competent to maintain tank wagons in the location A at the level of light maintenance.</p> <p>If the (assessment) verifications are not successful then the audit team shall perform quick checks on additional wagons to confirm or not the first results. No successful quick checks shall lead to a critical non-conformity. If the quick checks are successful for at least one wagon the auditor will perform in depth verification. In cases of success of in-depth verification, non-conformity is issued. In case in-depth verification is not successful, a critical non-conformity is issued.</p> <p>Remark: For mobile team, one successful audit in one place where maintenance activities are performed is sufficient to provide a reasonable assurance on its capability. The audit must nevertheless cover the extent of activities attributed to the mobile team by the ECM.</p>	<p>2) Dangerous goods: tank and associated equipments, specific equipments dangerous goods. The local management staffs know the applicable legislation European legislation (Dangerous goods directives, relevant regulations such as RID) and any other documents considering the safety of transport of dangerous goods (guidelines, various public documents of EU Commission such as guidelines or DVs). The relevant technical staff and local management staff have sufficient competences with the technologies used in regards of the extent of maintenance orders requirements.</p> <p>3) For all activities here above, the technical documentation present in premises is sufficient and appropriate to the extent of maintenance delivery activities.</p> <p>Prior to the assessment the inspection team shall analyse the maintenance orders to derive maintenance orders common requirements on competences the maintenance delivery must have. He will agree with the ECM on these common requirements and shall base his assessment on them.</p>	<p>The inspection team shall assess that the results of application of relevant working instructions, measuring procedures and control procedures are relevant to requirements of maintenance orders.</p> <p>This inspection shall consist of :</p> <p>a) verifying that the technical state of the safety related parts of the wagons, after the application of these instructions and procedures, is in conformity with the maintenance orders,</p> <p>b) and/or observing the execution of the maintenance operations while they are carried out in application of these instructions and procedures (the inspection team shall accompany the selected staff in their activities</p> <p>The inspection team shall assess that the releases to service are coherent with the maintenance performed, the final testing performed and the maintenance ordered. He will also assess that the release to service is transmitted to relevant fleet maintenance managers.</p> <p>The assessment shall be done through sampling based on:</p> <ul style="list-style-type: none"> - Maintenance activities The samples shall address the activities affecting safety: joining techniques, NDTs, maintenance of braking system, maintenance of wheelsets, running gear and draw gear, when appropriate equipments specific to transport of dangerous goods, and the integration of maintenance activities at the level of the wagon. - Level of maintenance (light and heavy) - Scope category of wagons ((tank wagons, other wagons specialised in transport of dangerous goods and remaining wagons as stated in ECM regulation annex IV and V)
<u>Specificities for exchange of information</u>		

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<p>For information the ECM has to receive from users of vehicles according to art 5 of the ECM regulation, the audit team shall assess that the ECM has:</p> <ul style="list-style-type: none"> • Defined a list of information that must be requested • Contracts with users. In these contracts there must be arrangements on <ul style="list-style-type: none"> ○ Which information has to be received ○ How, in which format, in which delay ○ Contractual arrangements to provide assurance to the ECM to receive effectively the requested information. ○ Arrangements regarding claims when information is not received • Evidences of information effectively received • Evidences on release to service • Analysis of information received for improvement of the exchange of information and in particular to improve the list mentioned here above in the first bullet. <p>For information the ECM has to provide to users according to art 5 of the ECM regulation 445/2011, the audit team shall assess that the ECM has</p> <ul style="list-style-type: none"> • List of information to provide • Contracts with keepers or direct contracts with RUs. In these contracts there must be arrangements on <ul style="list-style-type: none"> ○ Which information have to be provided ○ How, in which format, in which delay ○ Contractual arrangements to provide assurance to the RUs/keeper regarding the effective provision of information. ○ Arrangements regarding analysis of claims when information is not provided • Evidences of information effectively provided • Evidences on return to operation • Analysis of information provided for improvement of the exchange of information and in particular to improve the list mentioned above. <p>This assessment shall be done through samples of information exchanged and review of contracts.</p>	
<p><u>3.2.2.4. Delivery of certificate</u></p> <p><u>3.2.2.4.1. Initial report</u></p> <p>The assessment team shall issue an initial assessment report that will be the basic input for the decision. The initial assessment report is composed of the initial audit report and the initial inspection report. The assessment report shall contain at least the following common points:</p> <ul style="list-style-type: none"> • the list of the assessment team members with their scope of activity; • the identification data of the ECM after verification of 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 (management, maintenance development, fleet maintenance management or maintenance delivery); • the scope of the assessment • the assessment program • the assessment synthesis – List of requirements examined for each site and non-conformities • the assessment conclusions (justification on certification decision) 	

Part 1: Assessment of the maintenance system

Part 2: Inspections on selected processes

The assessment team has access to any initial and surveillance assessment reports of contractors (maintenance workshops, other maintenance providers performing separate maintenance functions) when they are certified under this scheme.

The assessment team has access to all reports related to other certifications of the ECM that were taken account in the initial assessment.

When the assessment team agreed with ECMs to take into account existing certifications prior to the initial assessment, the assessment team has access to all reports of the other involved certification bodies. Other certifications may be based on international standards such as ISO 9001:2008 or industry standards such as IRIS.

The draft initial assessment report will be delivered to the ECM within 2 weeks after the end of the initial assessment

Non-conformities:

For each non-conformity, the certification body shall indicate the origin, the detailed causes and the risks for safety linked to the non-conformity. The ECM has to address his remedial action plan to the assessment team within 15 working days after receiving the draft initial report. The remedial action plan includes the measures intended on how and within which period the non-conformities will be closed out.

A Critical non-conformity is A Non-conformity leading:

- Either to a risk about safety, interoperability or environment due to the maintained wagons
- Or to a risk about capacity of management system to keep the level of performance of operations.
- Or **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))

Notes:

- 1) A non-conformity can be technical or organisational
- 2) The cooperation between certification bodies as stated in article 6 of the ECM Regulation will aim to develop and precise critical non-conformities

A non-critical non-conformity is a non-conformity without direct impact:

- On safety, interoperability or environment due to the maintained vehicles
- Or on the immediate capacity of maintenance system to keep the level of performance of operations

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

The details on conformity treatment of non-conformities are defined in annex 1.

Composition of the initial audit report

The section 9.2.4. Of the ISO 17021:2011 related to initial audit conclusions is applicable.

The initial audit report shall contain at least:

- List of sites audited
- List of procedures audited for each site
- Sampling methodology used
- List of documents used in the audit. All documents used must be referenced
- Audit findings and results
- Number of critical non-conformities
- Number of non-critical non-conformities

Composition of the initial inspection report

By extension of the concept of non-conformity:

A critical non-conformity means, for inspections, missing or insufficient competences or insufficient coherence that may not be solved within a 6 months period

6 month is the period to implement the action plan aiming to remove the non-critical non-conformities or critical non-conformities in initial assessment as described in section 5 of annex I of this document.

Nevertheless for insufficient competences or insufficient coherence, there could be a necessity of more than 6 months period to remove effectively the insufficiency.

For instance when welders are not sufficiently skilled, recruiting or training and qualifying them may take more than 6 months.

It is important that the ECM takes the actions aiming at solving the non-conformity and controlling the

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<ul style="list-style-type: none"> • Number of points for which a clarification is necessary • Non-conformities; corrective measures intended to be taken by the ECM and opinion of the audit team regarding the appropriateness and the time required for these measures • Evaluation of the level of safety including specific points that may lead to unsafe situation. • The proposal of the audit team regarding the decision 	<p>related risks. Even if it could take more than 6 months to remove completely the non-conformity, the risks must be under control within 6 months.</p> <p>For instance for welders not sufficiently skilled, the action plan could consider the following actions: training and qualification programs and additional controls of works performed by the welders such as control by a recognised specialist in welding.</p> <p>The ECM has to respect the time allowed according to section 5 of annex I of this document to put in place the actions to train and qualifying welders and organise additional controls to ensure the control of risks. But availability of appropriate qualified welders may take additional time to allowed time according to section 5 of annex I of this document.</p> <p>To conclude: when the effective removal of non-conformity exceeds 6 months, the non-conformity is considered as critical by the certification body and the risks related to this non-conformity must be under control within the allowed time compliant with section 5 of this document.</p> <p><u>A non-critical non-conformity</u> means, for inspections, missing or insufficient competences or insufficient coherence that may be solved within a 6 months period.</p> <p>The initial inspection report shall contain at least:</p> <ul style="list-style-type: none"> • List of sites inspected • List of inspections made for each site • Sampling methodology used • Inspections findings • Number of critical non-conformities • Number of non-critical non-conformities • Number of points for which a clarification is necessary • Non-conformities: <ul style="list-style-type: none"> ○ corrective measures intended to be taken by the ECM and opinion of the inspection team regarding the appropriateness and the time required for these measures ○ For coherence between inputs and outputs of selected processes, explanation on lack of coherence <ul style="list-style-type: none"> • The proposal of the inspection team regarding the decision

3.2.2.4.2. Decision

The decision is taken by the certification body upon the opinion of the **Certification Committee**.

The **Certification Committee** bases his opinion on the assessment reports provided by the assessment team.

No member of the assessment team may take part to the Certification Committee and vice-versa.

The certification body shall identify each certificate delivered in conformity with the section 3.2.3.8. of this document

An ECM certificate shall be valid for a period up to 5 years except for newcomer ECMs for which specific rules defined in section 3.2.4. of this document are applied

Part 1: Assessment of the maintenance system

Part 2: Inspections on selected processes

There are two types of newcomers:

- 1) Newcomers who have never been providing ECM services because they are not certified against the ECM regulation. These newcomers can only provide the documentation related to the establishment of the procedures in conformity with the annex III of the ECM Regulation. It is hardly possible for them to produce sufficient documents to judge on the implementation and daily use of their maintenance system.
- 2) Newcomers who have a long experience in providing ECM services but who have never been certified. These newcomers have procedures in place and may provide sufficient documents related to the implementation and daily use of their maintenance system.

The second category is not considered by the specific rules for newcomers defined in section 3.2.4.

Conditions to certification relative to non-conformities:

Certification can only be awarded if:

- Every critical non-conformity has been successfully solved.
- Actions to solve non-critical non-conformities have been planned in a way and delay accepted by the certification body.

The relevant information on the appeal process must be transmitted to the ECM with the decision. The appeal shall suspend the decision but NSAs must be informed by the certification body on its decision and on the appeal.

The appeal decision after investigation shall take place within 2 months.

3.2.2.5. Surveillance

3.2.2.5.1. Assessment

The principles defined in sections 3.2.2.3 of this document are applicable except that all permanent sites have to be audited at least once a year during the validity period of the certificate.

The article 7(4) of the ECM Regulation indicates validity up to 5 years.

In this ECM certification scheme, only two validity periods are envisaged:

- 5 years
- 1 year for newcomers in the conditions of section 3.2.4 of this document.

There are no reasons to consider intermediate validity periods because the assessment is composed of an initial assessment and surveillance activities meaning that the ECM remains under the assessment of the certification body during the whole validity period of 5 years. In case of finding non-conformities during this validity period, suspension, limitation of scope or revocation of the certificate may be pronounced by the certification body.

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

Surveillance assessment may be composed :

- On-site assessment (audits + inspections); and/or
- Examination of documents provided by the ECM for instance by exchange of mails or e-mails

It is not required to the assessment team to only perform on-site assessment in the surveillance. Part of the surveillance assessment may also be limited to examination of documents provided by the ECM.

- The non-conformities identified in the initial assessment and in any other preceding surveillance activities
- The annual report provided by the ECM compliant with the section I(7.4.k) of the annex III of the ECM Regulation.

The purpose of the report would be to provide the certification body with information which could be used to support the definition of the scope, the depth and the extent of surveillance assessment.

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<p>The annual report has then an impact on the necessary competences to meet within the assessment team.</p> <p>An annual report, as described here below, could reasonably be expected to be an output of the ECM management function and could be used also for internal purposes such as management review.</p> <ul style="list-style-type: none"> - The appropriate actions put in place by the certification body to check claims according to articles 5 (7) and 9 of the ECM regulation. <p>The annual report provided by the ECM contains at least:</p> <ul style="list-style-type: none"> - Explanations and justification on how non-conformities have been undertaken and/or solved - Information on volume of maintenance carried out during the prevailing period - Changes related to: <ul style="list-style-type: none"> - Legal ownership of the company - Organisation (procedures in place) - Vehicles for which the ECM is in charge of maintenance - Sites and contractors including processes and equipments <ul style="list-style-type: none"> It includes changes on internal/external activities related to the three maintenance functions: maintenance development, fleet maintenance management and maintenance delivery. - Contractual arrangements with users <ul style="list-style-type: none"> It includes mainly the keepers. It covers also the exchange of data - Maintenance system including the ECM management functions and the three maintenance functions - Defects and failures including information exchanged against article 5(5) of the ECM regulation. - Internal audit reports - NSA and other authorities enforcement actions/investigations including claims according to article 9 of the ECM Regulation - Competence management. <p>The ECM has to add to the annual report all information he considers relevant for the assessment team.</p> <p>The ECM address the report in due time before the planned surveillance assessment upon an agreement with the certification body</p> <p>It is reasonable to consider a period of one month before planned surveillance for addressing annual reports to the certification body who will distribute them to the relevant assessment team.</p>	
<p>The surveillance activities are a combination of activities stated in the sections 9.3. of ISO 17021:2011</p> <p>The surveillance activities consist mainly in on-site audits but a supplementary assessment of the documentation of the maintenance system cannot be excluded if audit findings show that the processes put in place by the ECM and their effectiveness may be not consistent with the annex III of the ECM regulation.</p>	<p>The surveillance activities consist in on-site inspections and examination of documents provided by the ECM. The principles described for initial inspections in this document are applicable.</p>
<p><u>3.2.2.5.2. Report</u></p>	

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<p>The assessment team shall issue a surveillance report. The surveillance report is composed of the surveillance audit report and the surveillance inspection report.</p> <p>The assessment team may have access to any initial and surveillance reports of contractors (maintenance workshops, other maintenance providers) when they are certified under this scheme.</p> <p>For each non-conformity, the certification body shall indicate the origin, the detailed causes and the risks linked to the non-conformity. The ECM has to address his remedial action plan within 15 working days after receiving the draft surveillance report. The remedial action plan includes the measures intended on how and within which period the non-conformities will be closed out.</p> <p>The draft surveillance report will be delivered to the ECM within 15 working days after the end of the surveillance assessment.</p> <p>The details on conformity treatment of non-conformities are defined in annex 1.</p>	
<p>The initial audit report shall contain at least:</p> <ul style="list-style-type: none"> • List of sites audited • List of procedures audited for each site • Sampling methodology used • List of documents used in the audit. All documents used must be referenced • Audit findings and results • Number of critical non-conformities • Number of non-critical non-conformities • Number of points for which a clarification is necessary • Non-conformities; corrective measures intended to be taken by the ECM and opinion of the audit team regarding the appropriateness and the time required for these measures • Evaluation of the level of safety including specific points that may lead to unsafe situation. • The proposal of the audit team regarding the decision 	<p>By extension of the concept of non-conformity: <u>A critical non-conformity</u> means, for inspections, missing or insufficient competences or insufficient coherence that may not be solved within a 6 months period</p> <p><u>A non-critical non-conformity</u> means, for inspections, missing or insufficient competences or insufficient coherence that may be solved within a 6 months period.</p> <p>The initial inspection report shall contain at least:</p> <ul style="list-style-type: none"> • List of sites inspected • List of inspections made for each site • Sampling methodology used • Inspections findings • Number of critical non-conformities • Number of non-critical non-conformities • Number of points for which a clarification is necessary • Non-conformities: <ul style="list-style-type: none"> ○ corrective measures intended to be taken by the ECM and opinion of the inspection team regarding the appropriateness and the time required for these measures ○ For coherence between inputs and outputs of selected processes, explanation on lack of coherence • The proposal of the inspection team regarding the decision
<p style="text-align: center;"><u>3.2.2.5.3. Decision</u></p> <p>For any non-conformity discovered during surveillance, resolution of non-conformity shall be implemented in a time allowed conform to annex 1 of this document.</p> <p>In case of proposal of revocation, limitation of the scope of certificate or suspension of certificate in the surveillance report, the certification body shall take its decision within two weeks upon the opinion of the Certification Committee.</p> <p>Suspension of certificate means “temporary revocation”. The certification body may decide limited period suspension or condition-based suspension. Both are subject to the certification body’s decision to be removed. Revocation is definitive. This is done in application of article 7(7) of the ECM Regulation.</p> <p>The Certification Committee bases his opinion on the assessment reports provided by the assessment team.</p>	

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<p>No member of the assessment team may take part to the Certification Committee and vice-versa.</p> <p>The relevant information on the appeal process must be transmitted to the ECM with the decision. The appeal shall suspend the decision but NSAs must be informed by the certification body on its decision and on the appeal. The appeal decision after investigation shall take place within 2 months.</p> <p>In case of revocation, limitation of scope of certificate or suspension, the certification body shall identify its decision in conformity with the section 3.2.3.8. of this document.</p>	
<p><u>3.2.2.6. Recertification process</u></p>	
<p>The ECM Certificate shall be renewed after application and full re-assessment against the ECM regulation, its guidelines and this document.</p> <p>The reports of the preceding period of validity shall be considered by the certification body to set-up his assessment.</p> <p>The assessment shall be performed in accordance with section 9.4. of ISO 17021:2011 except the provisions related to on-site assessments.</p>	

3.2.3. General points

The following sections take care of the multi-site aspect that will be encountered when certifying many ECMs, the languages used in the assessment and indication on assessment time.

3.2.3.1. Multi-site assessment

The maintenance activities may be performed on several sites. These sites may be internal or external to the ECM.

External sites may be certified against the ECM Regulation (separate maintenance functions including maintenance workshops). Also the internal sites may also be certified against the ECM regulation, independently of the ECM.

Because of the multiplicity of sites, 4 main categories of sites have been defined, as shown in the following table

For all categories of sites, the assessment team shall assess the ability of the ECM to:

- keep the outcome of maintenance provided by each sites under control (control of conformity of product/services provided by internal/external sites with ECM requirements); and
- assure the coordination of all maintenance activities, including the exchange of information,

	Certified against ECM Regulation	Not certified against ECM Regulation
Internal sites	<p>Principle: The certificate of the internal site provides assurance to the ECM that the internal site is <u>competent</u>.</p> <p>Therefore the assessment team shall focus its assessment on the ability of the ECM to</p> <ul style="list-style-type: none"> ○ Assure that the internal site certificate is relevant to the maintenance activities that are performed 	<p>This site shall be assessed by the certification body when assessing the whole ECM.</p> <p>Therefore the assessment team shall focus its assessment on the conformity of the internal site with the annex III of the ECM regulation.</p>
External sites	<p>Principle: The certificate of the external site provides assurance to the ECM that the external site is <u>competent</u>.</p>	<p>Principle: the assessment team should normally not be in position to perform assessment on external sites unless it has been previously</p>

	<p>Therefore the assessment team shall focus its assessment on the ability of the ECM to</p> <ul style="list-style-type: none"> ○ Assure that the external site certificate is relevant to the outsourced maintenance activities. 	<p>arranged with the ECM and the external site.</p> <p>Therefore the assessment team shall focus its assessment on the ability of the ECM to:</p> <ul style="list-style-type: none"> ○ assure maintenance activities are done by <u>competent</u> external sites by assuring that the external site complies with the requirements of annex III of ECM Regulation. <p>The assessment team may accompany the ECM staff when they perform qualification visits at the external site(s). In that case the assessment team shall observe how the ECM staffs performs the qualification activities (including identification of non-conformities with ECM requirements addressed to the external site, reporting, decision making and follow-up of these non-conformities by the ECM). .</p> <p>The assessment team should be competent in the area of activities of the external site to be capable to identify non-conformities with ECM requirements addressed to this external site. In such a situation the assessment team is capable to judge on the capability of the ECM to qualify and keep under control the external site.</p>
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3.2.3.2. Used language

The assessment 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.

This section applies to all steps of the assessment

3.2.3.3. Assessment time

The Initial assessment cannot impair the 4 month delay stated in the ECM regulation to deliver certificates. The certification body shall establish a balance between initial assessment and surveillance when he detected risks for safety. He will apply the principles of proportionality

The principle to be followed is that there must be a common agreement between the ECM and the certification body.

The certification body must ensure that the assessment time is sufficient. In case the certification body considers that no agreement on assessment time may be achieved, he is free to refuse the contract.

The assessment time shall be based on size and complexity of the ECM.

No final agreement has been reached on the question of necessary assessment time.
Assessment time is characterised by the number of necessary man-days to perform the assessment.

Nevertheless the number of man-days for inspections has to remain sufficiently limited to limit additional costs while keeping the assessment effective. The following information is given for supporting the certification bodies and ECMs when defining and negotiating number of man-days. This information will be revised as implementation of ECM Regulation will go on and sufficient return on experience will be available. Revision will take place within the cooperation of the certification bodies stated in article 6 of the ECM Regulation.

The certification body should apply the principle of proportionality between the necessary human resources for initial assessment and surveillance and risks for safety.

The certification body and the ECM have to reach an agreement on what is fair number of man-days respectively for initial assessment and surveillance with the ECM's right to appeal against unfair number of man-days or right to choose another certification body. The certification body has the right to refuse to perform the assessment and to deliver the certificate if an agreement on fair man-days could not be achieved.

The following rules give an indication on the minimum assessment man-days to be considered for a 5 years' certification. Nevertheless It remains the responsibility of the certification body to define the assessment man-days he needs.

Part 1: maintenance system assessment

The IAF MD 5:2009 shall be applied. The annex B of IAF MD 5:2009 should be the reference for calculation as it takes into account size and complexity of the organisation.

Complexity

An ECM shall be considered as an organisation with a MEDIUM complexity when performing all functions in internal. In case of outsourcing to organisations certified against the separate maintenance function certification defined in the article 8 and annex I of ECM Regulation, the complexity may be considered LOW.

The certification body may also consider the variety of types of wagons maintained in its evaluation of the complexity.

Size

There could be difficulties to consider the size of the organisation when only taking into account the number of persons involved. In some cases persons may work not only for maintenance services of an organisation but also for other activities.

For instance keepers' competence management may provide services to the keeper's ECM part of organisation and for other keeper's commercial part of the organisation.

Other information as turnover of maintenance activities and number of wagons maintained may also provide base for calculating the size of the company.

Reduction of assessment man-days could be envisaged when the ECM has got other certifications. The certification body shall justify any reduction based on a gap analysis with the requirements from the ECM regulation and from this document. Gap analysis should not be acceptable when the certification body has no assurance on competence of assessors or no access to requirements and assessment reports related to the other certifications.

Other certifications may be ISO 2001:2008 or IRIS or national certifications such as certification of maintenance workshops in Spain and the Netherlands.

Part 2: inspections on selected processes

Similar to part 1, reduction of assessment man-days could be envisaged when the ECM has got other certifications. The certification body shall justify any reduction based on a gap analysis with the requirements from the ECM regulation and from this document. A gap analysis is not acceptable when the certification body has no assurance on the competence of assessors or no access to requirements and assessment reports related to the other certifications.

Other certifications that could be considered: VPI certifications for maintenance workshops.

1) Maintenance development and fleet maintenance management

It is supposed that maintenance development and fleet maintenance management are performed on the same site of the organisation.

The assessment on activities affecting safety necessitates high skilled specialised professionals. The high number of inspections days takes care of the difficulty to find individual experts capable to assess together two or more categories of activities affecting safety. In case there is a need of high number of experts, the number of man-days invoiced may be significantly higher than the total man-days required in the table. This aspect will be strongly analysed at the level of cooperation of certification bodies according to the article 6 of the ECM Regulation.

Inspections days when all activities affecting safety are performed internally	Initial inspections (Man-days)	Surveillance inspections (Man-days/year)
Without dangerous goods	2 to 3	1 to 1.5
With dangerous goods	3 to 4	1 to 1.5

The figures of the table shall be considered for one site. If the activities are spread on more than one site, the certification body shall adapt the number of days

The variation of figures depends on the complexity.

The complexity is function on the variety of types of wagons maintained and marginally on the size of the fleet maintained (turnover).

The complexity of technologies involved on vehicles should not be considered for wagons but are more relevant for locomotives and passenger carriages. Nevertheless, when facing special wagons, the certification body should take care of this issue.

A reduction could be envisaged depending on activities affecting safety outsourced to organisations certified against the separate maintenance function certification defined in the ECM Regulation.

2) Maintenance delivery

As here above, the assessment on activities affecting safety necessitates high skilled specialised professionals. The high number of inspections days takes care of the difficulty to find individual experts capable to assess together two or more categories of activities affecting safety. In case there is a need of high number of experts, the number of man-days invoiced may be higher than the total man-days required in the table. . This aspect will be strongly analysed at the level of cooperation of certification bodies according to the article 6 of the ECM Regulation.

Inspections days when all activities affecting safety are performed internally (for one site)	Initial inspections (Man-days)	Surveillance inspections (Man-days/year)
Without dangerous goods	2 to 3	1 to 1.5
With dangerous goods	3 to 4	1 to 1.5

The figures of the table shall be considered for one site. The variation of figures depends on the size of the site and complexity of maintenance technical tasks performed.

The size is function of the number of persons performing maintenance of wagons on the site and the number of wagons maintained each year (turnover).

The complexity is function on the levels of maintenance effectively performed. Site performing maintenance light maintenance is less complex than site performing heavy maintenance that is itself less complex than site performing both light and heavy maintenance together. Complexity depends also on the variety of types of wagons maintained.

A reduction should be envisaged depending on activities affecting safety outsourced to organisations certified against the certification of maintenance workshops defined in the ECM Regulation.

A reduction should be envisaged if the inspections on maintenance delivery may be easily coupled to inspections on maintenance development.

A reduction should be envisaged for small sites performing only a limited number of basic maintenance tasks related to light maintenance

3.2.3.4. Changes in the maintenance system

The certification body shall consider changes mentioned in the annual report (see section 3.2.2.5.1 of this document) and any other changes notified to him through a preliminary dossier addressed by the ECM.in consistency with the section 8.6.3. of ISO 17021:2011 at the latest one month before the next surveillance assessment planned.

In case the changes might have a significant impact on the certification of the ECM, the ECM has to inform the certification body immediately.

The certification body shall immediately assess the impact and evaluate the need of immediate surveillance actions.

Guidelines on the significance of changes will be developed under the cooperation of certification bodies stated in article 6 of the ECM regulation.

The certification body shall apply the sections 9.5.1. and 9.5.2. of ISO 17021:2011.

Maintenance system

A preliminary dossier shall be addressed to the certification body This dossier shall contain:

- information on changes in the organisation, in the procedures, in staff, equipments that have an influence on the maintenance system.
- Information on changes of the scope of the certificate.

Existing competences

A list of changes with reference to the information of the initial application, as defined in section 3.2.2.2. that occurred during the last period before surveillance is addressed to the certification body prior to surveillance inspection. Changes are related to activities under the scope of inspections (see above in section 3.1 of this document)

The inspection team shall then make the appropriate assessment to get assurance that the existing competences remain sufficient.

3.2.3.5. Access and traceability of reports

Reports mean any initial assessment and surveillance reports addressed by the certification body to the ECM.

The reports are properties 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. By that way the certification body shall have access to the full dossier before proceeding to the renewal of certification (recertification).

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

[NSAs have the right to get copies of reports when the NSAs perform activities relevant to applicable legislation, in particular the article 16 of the Safety Directive.](#)

The section 9.9. of ISO 17021:2011 shall be applied, in particular the section 9.9.3. related to confidentiality

Languages of reports

All reports will be written in the language(s) agreed between the certification body and the ECM.

For commercial purposes (better communication with customers), the ECM may request by contract to the Certification body to translate the reports in English and/or French and/or German.

3.2.3.6. Conditions on revocation, limitation of scope and suspension of certificate

Non-observance of the preconditions for certification may lead to certification being revoked or suspended (= 'temporary revoked') or the scope of the certificate might be limited by the Certification Body. If the certificate is revoked, it loses its validity.

The following criteria for revoking or suspending the certificate or limiting the scope of the certificate shall be taken into account:

- **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 improved / solved non-conformities after recurrent audits and inspections + corrective measure's list
 - Repeated failure to apply corrective measures as determined by the certification body
 - Persistent insufficiency in existing competences or coherence. Non-critical non-conformity related to inspections not solved within 6 months shall be considered as persistent.
 - Critical non-conformity
- **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

The section 9.6 of ISO 17021:2011 shall be applied.

3.2.3.7. Existing certification

This section applies when the ECM 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 of maintenance workshops as in Spain and in The Netherlands.

Only the third party certifications for which the certification body performing ECM certification may get assurance on the competence of the third party assessment bodies or assessors can be taken into account.

The certification body performing ECM certification gets assurance on the competence of the third party assessment bodies when:

- For Part 1 of the ECM Certification Scheme
The third party assessment body has an organisation corresponding to an accreditation against EN ISO/IEC 17021:2006 or 2011.
- For Part 2 of the ECM Certification Scheme
About inspections, the third party assessment body has an organisation corresponding to an accreditation against EN ISO/IEC 17020:2004 (independence should not be necessary type A) and refers to the relevant requirements (inspection) of the ECM regulation, particularly for the qualification of the inspectors.

The certification body shall make a documented gap analysis and then may adapt the assessment taking into account:

- The scope of the existing certifications
- The scope of certificates relevant to these existing certifications
- The content of all assessment reports and any relevant documents provided to the ECM by the certification body who delivered the existing third parties certificate. The ECM shall provide them to the certification body in charge of ECM certification.

Documents on comparison between ECM certification and industry certifications or national existing certifications will be provided and will be updated when necessary. These documents will be validated at the level of the cooperation framework that will be to be put in place according to the article 6 of the ECM Regulation.

3.2.3.8. Certification decision identification number

The Certification body shall identify each decision on certification, i.e. delivery, revocation, limitation of scope or suspension of certificates, in conformity with the European Identification Number (EIN)

The EIN 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 amendments)

Structure of EIN

For facilitating the implementation of ECM certification, the structure of EIN to identify ECM certificates (including separate maintenance function certificates and maintenance workshop certificate) 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.

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

- 31 for ECM certification
- 32 for certification of maintenance workshops
- 33 for certification of separate maintenance functions

'cd' = counter that identifies the accredited certification body. This code is previously provided by the accreditation body. From '01' to '99'

'ef' = year when the decision on certification is taken by the certification body (delivery, revocation, suspension, limitation of scope). Example 2011: 'ef' = '11'

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

Example:

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

3.2.3.9. Use of certificate

The certificate shall be used for communication to third parties by the ECM only with the mention of the list of sites covered.

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

3.2.3.10. Transfer of certificate

When the certification body loses his accreditation, the relevant rules of IAF shall be applied.

When the ECM decides to change the Certification Body, the applicable rules of IAFMD 2:2007 shall be applied.

The transfer is the recognition of a certification issued by one accredited certification body by another accredited certification body.

The IAF MD2:2007 provides the normative rules for transferring a certification while maintaining its integrity.

The transfer process is based on a documented review by the accepting certification body prior to accept the transfer.

The review, called pre-transfer review, consists mainly on a document review and a visit to the ECM performed by the accepting certification body.

The pre-transfer review covers the following aspects:

- Confirmation that the certified activities of the ECM fall into the scope of accredited activities of the accepting certification body
- The reasons for seeking a transfer
- Verification that the ECM has a valid certificate
- An evaluation of the last assessment reports
- The treatment of complaints and non-conformities.

3.2.4. Application of certification scheme to newcomer ECM

For newcomer ECM who have not been registered as ECM in the NVRs before 31 May 2013 and therefore cannot provide evidences on the effective implementation of their maintenance system, the following certification process shall be applied.

There are two types of newcomers:

- 1) Newcomers who have never been providing ECM services because they are not certified against the ECM regulation. These newcomers can only provide the documentation related to the establishment of the procedures in conformity with the annex III of the ECM Regulation. It is hardly possible for them to produce sufficient documents to judge on the implementation and daily use of their maintenance system.
- 2) Newcomers who have a long experience in providing ECM services but who have never been certified. These newcomers have procedures in place and may provide sufficient documents related to the implementation and daily use of their maintenance system.

The first category could not support the full certification process described in this document because no assessment on implementation of the procedures may be performed by the certification body in absence of evidences concerning the part 1 assessment but also the part 2 assessment, i.e. the inspections on selected processes. Therefore a specific scheme is developed in section 3.2.4 of this document.

The second category is not considered by the specific rules for newcomers defined in this document.

The assessment shall be limited to the maintenance system

The section 3.2.2.1 (Assessment rules) of this document shall be applied except the rules related to inspections.

The section 3.2.2.2 (formal application and review of the application) of this document shall be applied.

The section 3.2.2.3 (initial assessment) of this document shall be limited to the initial audit stage 1 as described in section 3.2.3.3.1. of this document

The section 3.2.2.4 of this document shall be applied except for the rules related to inspections but the validity of the certificate shall be limited to 1 year.

The section 3.2.2.5 and 3.2.2.6 shall not be applied. It means that the certificate delivered to a newcomer ECM cannot be renewed (no recertification possible).

Before the end of the validity of the certificate, the ECM shall apply for an ECM certification that will be performed following the full process defined in section 3.2.2 of this document.

The results of all assessments performed during the one year validity of the certificate of the newcomer ECM should be taken into account by the certification body when assessing the ECM against the full process to avoid any unnecessary redundancy or duplication.

The certification body shall clearly mention the validity of 1 year on the ECM certificate with the mention 'newcomer ECM –application of ECM certification scheme section 3.2.4.'

4. Certification scheme for separate maintenance functions

The article 8 and the annex I of the ECM Regulation are applicable.

The certification process described in the sections 3.2.2 and 3.2.3 shall be applied only to maintenance functions for which an entity makes a formal application.

It means that an applicant willing to be certified as ECM and willing that its maintenance delivery sites are certified as maintenance workshops, has to apply for ECM certification AND to certification of maintenance workshops.

The maintenance function certified shall be clearly mentioned on the certificate with all clear indications covering the activities effectively performed and assessed to avoid misinterpretation.

The assessment shall take into account the additional complexity related to applicants providing services to several clients including ECMs.

The applicant to certification of separate maintenance function is in general performing activities as contractor of several clients including ECMs. In its organisation the applicant has to take care of the specific requirements of its various clients. This adds an additional complexity in the consideration on activities affecting safety. The certification body has to reflect this aspect in its assessments.

The certificate for separate maintenance function may also be limited to maintenance of components of freight wagons upon request of the applicant.

ECM certification is related to complete wagons. There could not be an ECM certificate for an entity maintaining only components. In that case only separate maintenance function certification against article 8 and annex I of the ECM regulation may be envisaged.

The relevant templates in annex IV and V of the ECM Regulation shall be used by certification bodies.

Additional separated certification schemes based on this document will be developed to avoid interpretations.

Annex 1: Treatment of non-conformities

The decision to deliver or continue to subscribe the certification of an ECM or a separate function, when critical non-conformities (NCs) are found, shall follow conditions and rules below:

1. **Critical NCs:** the criticality of the non-conformity is defined under the responsibility of the assessment team, but exceptionally it can be re-qualified by the Certification Committee, in this case, the justifications of the decision are notified to the applicant and to the assessment team.
2. **Answers to the NCs, Action Plan :** for each NC, the applicant (ECM) shall set up an action plan which contains:
 - An analyse of the scope of the NC, precedence, services, customers concerned...
 - An analyse of the causes and the need to put in place correctives actions in order to avoid to reproduce this NC,
 - 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 15 working days after reception of the initial draft or surveillance draft report.
The evidences that the situation is under control are given in function of the performed analyse:
 - The evidence that the NC is corrected
 - If necessary, the process in order to avoid this situation
 - In this case, evidence that this process is implemented.
3. **Estimation of this action plan by the assessment team,** the assessment team:
 - Has to appreciate the relevancy of the analyses carried out.
 - Has to declare about the relevancy of actions and delays announced in order to have the situation under control (see below, implementation of the action plans, time allowed).
 - Has to examine the evidences of the actions annexed,
4. **If the applicant refuses a non-conformity :**
 - The applicant shall justify its refusal and why it disagrees.
 - If this disagreement concerns the findings of the NC, the applicant is not obliged to propose an action plan.
 - If the disagreement concerns the criticality or the consequences of the NC, the applicant shall propose an action plan.When the report is examined by the Certification Body, the Certification Committee shall take a justified position which is notified to the assessment team.
The need to set up an actions plan and the time allowed (possible) to transmit this plan to the Certification Body are specified if necessary.
The Certification Body can ask for a modification (content or time allowed).
5. **Implementation of the actions plan : time allowed**

The time allowed starts at the date of the closure of the current assessment, when the NC is presented and accepted or refused.
The actions plan shall be implemented in the 6 months after the closure meeting.
For critical NCs detected during surveillance activities, the maximum time allowed is reduced to 3 months.
For critical NCs detected in initial assessment, in assessment related to extension of the scope of the certificate or in complementary assessment, the maximum time allowed is 6 months after the closure meeting.
6. **Treatment of the NCs : verification**

Generally, implementation of an action plan and its efficiency, are verified during the next assessment on the site of the applicant.
The verification, in order to verify if the situation concerning critical NCs is under control, is anticipated. This verification, can also be anticipated in the case of certain non- critical NCs when in the conditions below:

 - **Critical NCs :** According to the nature of the NC and the choice of the Certification Body, this verification is performed by documentary examination or by an assessment on site.
In case of documentary examination, the evidences requested are transmitted to the Certification Body, no later than 15 working days after the deadline of the time allowed for implementing the actions plan. (It means 3 ½ months after the closure meeting of surveillance assessment or 6 ½ months in the case of initial assessment, assessment related to extension of the scope of the certificate, and complementary assessment).
If a verification by assessment on site is decided, this verification shall be scheduled in the 3 months after the closure meeting (6 months in the case of initial assessment, extension of the scope of the certification, and complementary assessment), and take place in the 3 months after, therefore maximum 6 month after the closure meeting (9 months in the case of initial assessment, extension of the certification, and complementary assessment).
If due to the applicant, the implementation of the actions decided in order to have the situation(s) under control cannot be observed in the time allowed, an unfavourable or conditionally decision is pronounced.
 - **Non-critical NCs :** The Certification Body can demand a particular monitoring of the implementation of actions plans following on non-critical NCs well identified, precisising the nature (type of verification, time allowed,...)
The persistency and/or the accumulation of non-critical NCs can lead the Certification Body to a treatment similar to critical NCs.

7. Certification decision : taking into account of the treatment of the NCs

7.1 Initial assessment and extension:

7.1.1 *Presence of critical NCs*

- a) A favourable decision can be decided only after the observation of the implementation of the actions in order to have the situation under control.
- b) So, as soon as a critical NC is expressed and if the noting of the implementation of the whole necessary actions in order to have the situation under control has not been achieved previously to the presentation of the assessment report, the decision is either conditionally unfavourable, until the implementation of these actions, or unfavourable.
- c) If a conditionally unfavourable decision is decided, a favourable decision can be decided subsequently, when the implementation of the concerned actions is observed.
- d) If an unfavourable decision is decided, it is a refusal of certification and a possible new application has to be requested.

7.1.2 *Lack of critical NCs*

A favourable decision can be decided if the time allowed for the implementation of the decided actions in order to have the observed situation under control are conform to time allowed in section 5 of this annex.

Equally a conditionally unfavourable decision or unfavourable can be decided. In this case, the provisions of the section 7.1.1 c) and d) of this annex are applied.

7.2 Surveillance assessment, additional, and re-evaluation:

7.2.1 *Presence of critical NCs:*

- a) A favourable decision can be decided, only after the observation of the implementation of the necessary actions in order to have the situation under control.
- b) So, as soon as a critical NC is expressed and if the noting of the implementation of the whole necessary actions in order to have the situation under control has not been achieved previously the presentation of the assessment report, the decision is either conditionally favourable, or conditionally unfavourable, until the implementation of these actions, or unfavourable.
The conditionally favourable decision can be decided, only if the time allowed for the implementation of decided actions in order to have the observed situation under control are conforms to those defines in section 5.
- c) If a conditionally unfavourable decision is decided, the certification of the ECM is suspended, the provisions of section 7.1.1.c) of this annex are applied.
- d) If an unfavourable decision is decided, the certification of the ECM is removed or the scope of the certificate is limited.

7.2.2 *Lack of critical NCs:*

A favourable decision can be decided if the time allowed for the implementation of the decided actions in order to have the observed situation under control are conform to time allowed in section 5.

A conditionally favourable decision or a conditionally unfavourable decision can be decided until the verification of the implementation of actions, or equally an unfavourable decision can be decided. In these cases, the provisions of the section 7.2.1c) and d) of this annex are applied.

7.3 Additional assessments:

7.3.1 *Presence of critical NCs*

- a) A favourable decision can be decided if the implementation of the decided actions in order to have the situation under control is observed. Owing to the fact that this assessment already results from a request of verification of decided actions, a conditionally favourable decision can't be decided until a new verification of actions.
- b) In the other cases, the decision is unfavourable.

It can be, only:

- Conditionally unfavourable until the verification of the implementation of the decided actions in order to have the situation(s) under control, or unfavourable, if the additional assessment results from a conditionally decision. In these cases the provisions of the sections 7.2.1c) and d) of this annex are respectively applied.
- Unfavourable if the additional assessment results from a conditionally unfavourable decision. In this case the certification of the ECM is refused or removed.

7.3.2 *Lack of critical NCs*

- a) A favourable decision can be decided only if the times allowed are conforms to section 5. A conditionally favourable decision can't be decided.

b) Equally, a conditionally unfavourable decision or an unfavourable decision can be decided, until the verification of the implementation of actions. The provisions of the section 7.3.1b) of this annex are applied.

Below, a nonconformity form, observations, correctives actions and decisions.

Audit Report N° : Certification or draft N° :		NON CONFORMITY (NC) N°		<input type="checkbox"/> NC – critical (major) <input type="checkbox"/> NC – non critical (minor)	
		And CORRECTIVE ACTIONS			
Applicant (ECM) : Site of the observation :		Date issued:			
ECM Regulation - Clause concerned: Concerns : <input type="checkbox"/> Dispositions <input type="checkbox"/> Implementation					
Non-conformity Description					
Established consequences : (conséquences avérées)					
Led Risks : (risqué induits)					
Assessor Name:		Date:		Assessor Signature:	
ECM Agreement : <input type="checkbox"/> YES <input type="checkbox"/> NO Comments (possible) :					
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 this NC:					
Decided action in order to have under control the observed situation:				Due date:	
ECM Representative Name:		Signature:		Current date:	
Relevance of the action plan estimation					
Relevance of the analyse of the scope of the NC and of the analyse of the causes <input type="checkbox"/> YES <input type="checkbox"/> NO Comments (possible)					
Relevance of the decided actions in order to have under control the observed situation : <input type="checkbox"/> YES <input type="checkbox"/> NO Time allowed (relevant) <input type="checkbox"/> YES <input type="checkbox"/> NO Comments (possible):					
Assessor Name:		date:		Signature:	

Evidences Examination – actions in order to have under control the situation (the report shall be completed)		
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 (possible):		
Assessor Name:	Date:	Signature:
Evidences Examination – actions in order to have under control the situation (this part is completed after the decision)		
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 (possible):		
The Certification Body:	Date:	Signature:
Verification of the efficiency of the actions and closing of the NC (next assessment)		
Respect of the action plan (consistency, time allowed): <input type="checkbox"/> YES <input type="checkbox"/> NO		
Evidence elements considered:		
Comments (possible):		
Efficiency of the actions implemented: <input type="checkbox"/> YES <input type="checkbox"/> NO		
Comments (possible):		
Closing of the NC: <input type="checkbox"/> NC CLOSED <input type="checkbox"/> NC NOT CLOSED <input type="checkbox"/>		New NC N°:
Assessor:	Date:	Signature: