

ECM certification

Application guide including explanations

Maintenance workshop certification scheme

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1.0	All new	21/10/2011	This documents is based on ECM certification scheme draft 0.5 and results from consultation

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- 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 maintenance workshops (MW) 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 MW certification scheme is based are described in the article 8 and annex I of the ECM Regulation. Meanwhile this scheme is compliant also with 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

[The ECM accreditation scheme includes accreditation of certification bodies performing certification of maintenance workshops in consistency with the ECM Regulation.](#)

Limit: This document addresses only freight wagons as stated in the ECM Regulation.

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.

(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 certification of maintenance workshops

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 (certification and accreditation) 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 certification of maintenance workshops

According to the art 1(2) of the ECM regulation, *the purpose of the system of certification is to provide evidence that the maintenance workshops have established their own maintenance system making them capable to maintain any freight wagon for which the ECMs have ordered maintenance activities.*

The art 7(1) of the ECM regulation points out that *certification shall be based on an assessment of the **ability** of the maintenance workshop to meet the relevant requirements in Annex III and to apply them consistently.*

The relevant requirements of annex III are limited to maintenance management and maintenance delivery.

The stakeholders pointed out three main risks that must be kept under control to create and develop trust among stakeholders. They may be summarised as following:

- The maintenance workshop 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. In other words the ECM is a “serious player” who can be trusted by partners and customers.

The type of certification chosen is the same as for the ECM certification scheme. See relevant document

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

It means in practical that the certification of maintenance workshops aims to provide assurance that the arrangements put in place makes the maintenance workshop able to maintain wagons registered in the NVRs for which it has received orders from ECMs, by assuring:

- 1) That the management of maintenance activities and exchange of information is done through procedures for which:
 - a. the conformity against the annex III of the ECM Regulation has been assessed; and
 - b. the effectiveness has been assessed.
- 2) That the maintenance workshops 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 delivery.

Therefore the certification of maintenance workshops 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 delivery function, 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 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 section IV of annex III of the ECM regulation for economic reasons. A selection has been made taking into account the criticality of procedures regarding safety from RU and ECM points of view.

The inspections cover the main procedures leading to the respect of maintenance orders and the issue of release to service

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 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 (stated in maintenance orders) and by the maintenance workshop.
- 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.

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 maintenance workshops 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 maintenance workshop and on-site inspections.</p> <p>These on-site inspections may be on-site observations of staff of the maintenance workshop at work or interviews of staff of the maintenance workshop.</p>
<u>3.2.2.2. Formal application and review of application</u>	
<u>Content of the formal application</u>	
<p>The maintenance workshop 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 which are usually maintained by the maintenance workshops. The structure is based on types. In case no type has been defined, the structure is based on the design of the wagons. <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>	

Part 1: Assessment of the maintenance system

Part 2: Inspections on selected processes

- 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.
- Structured information on components of freight wagons which are usually maintained by the maintenance workshop
- Structured information on components of freight wagons intended or planned to be maintained in the forthcoming years.
- 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, any additional sector agreed rules or specific rules imposed by customers of ECM.
- Description of the organisational structure of the maintenance workshop. 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 maintenance workshop organisation.
 - A description of its structure that includes the external entities performing maintenance activities for the maintenance workshop.

These external entities may be contracted by the maintenance workshop or imposed by contracts with ECMs or keepers (e.g. organisation of maintenance delivery in GCU).
 - For the external entities the maintenance workshop shall indicate if they are:
 - directly qualified by the maintenance workshop; and/or

The MW must get assurance that the external entities are competent and capable to provide the maintenance services ordered to them by the MW.
The MW develops qualification schemes to assess the competence and capability of external entities. The schemes include also the surveillance performed by the MW 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 MW may assess external entities against its own assessment rules.
 - The MW 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 MW should keep in mind the three main risks mentioned in section 3.1 of this document.

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

 - third party certified against the ECM Regulation and/or third party management system certified and/or third party certified against relevant standards (such as welding, NDTs) and/or third party certified against other industry standards..
- The maintenance workshop 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

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<p>- number, size and activities of the different sites internal and external; - geographical extent of its activities.</p> <p>The maintenance workshop 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</p> <ul style="list-style-type: none"> • Structured description of the processes put in place by the maintenance workshop and how they comply with the requirements for certification of the annex III of the ECM regulation. The maintenance workshop 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 maintenance workshop. 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 and staff of the maintenance workshop.</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 maintenance workshop.</p> <p>When the assessment team notifies to the maintenance workshop that he considers that he has received all the necessary documents to perform the assessment, the period of 4 months to deliver the 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>

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<u>3.2.2.3.1. Initial assessment stage 1</u>	
<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 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 maintenance workshop 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 maintenance workshop 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 maintenance workshop¹.</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>	
<u>3.2.2.3.2. Initial assessment stage 2</u>	
<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>	

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 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 maintenance workshop 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>The procedures put in place by the maintenance workshop include all supporting documents such as working instructions, forms, templates, ...</p> <p>The certification body shall develop 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 maintenance workshop.</p> <p>The release to service 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 maintenance workshop. The extent of activities includes also a maintenance workshop working for more than one ECM.</p> <p>The extent of activities includes complexity. Working for more than one ECM has as consequence that the maintenance workshop may have to deal with maintenance orders related to a greater number of different maintenance files than when working for one ECM. In particular different maintenance files issued by different ECMs may address vehicles of the same technical type. This complexity must be taken into account by the maintenance workshop but also by the certification body when performing its assessment.</p> <p>For the management function and the maintenance delivery function, the audit team shall assess the effectiveness of the procedures put in place by the maintenance workshop through the analysis of the applicable outputs of internal auditing, management review, policy, performance objectives, performance targets, performance monitoring and operational controls.</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. <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 maintenance workshop 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 or 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'</p>	<p style="text-align: center;"><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 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 maintenance workshop 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>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 the maintenance workshop to comply with them. The maintenance workshop should manage the competences against the risks for safety.</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 maintenance workshop's responsibility to maintain its own list of standards and commonly used good practises he has decided to use.</p>	
<u>Specificities for maintenance delivery</u>		
<p>In addition:</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • Activities affecting safety identified by the ECM and stated in maintenance orders • Activities affecting safety identified by maintenance workshop through risk assessment on maintenance orders received. • Joining techniques • Non Destructive Tests (NDTs) • Maintenance of braking system • Maintenance of wheelsets 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 maintenance workshop are duly applied by relevant staff.</p>	<p><u>Inspections on existing competences related to selected processes</u></p> <p>The inspection team verifies that:</p> <p>1) For maintenance activities related to activities affecting safety:</p> <ul style="list-style-type: none"> • activities affecting safety identified by the ECM and stated in maintenance orders; • activities identified by the maintenance workshop through risk assessment on maintenance orders received; • joining techniques; • NDTs; • maintenance of wheelsets and draw gear; • maintenance of braking system; and • coordination of maintenance at the level of wagon <p>The relevant technical staff and local management staff have sufficient technical knowledge in regards of the extent of maintenance orders requirements.</p> <p>2) Dangerous goods: tank and associated equipments, specific equipments dangerous goods. The local management staffs know the</p>	<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> <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 align="center"><u>Part 1: Assessment of the maintenance system</u></p>	<p align="center"><u>Part 2: Inspections on selected processes</u></p>	
<p>The audit team shall assess the effectiveness of the maintenance delivery procedures put in place by the maintenance workshop 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 team shall assess how the training and the competences of staff are managed when they work with documentation issued by different ECMs.</p> <p>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. The audit team shall assess how the maintenance workshop manages the complexity related to working for different ECMs.</p> <p>The audit teams shall verify that the maintenance orders are duly considered in local documents such as work instructions, work procedures and measuring procedures available to interested staff. The audit team shall assess how the ECM manages the documentation (maintenance orders and accompanying technical documentation) issued by the different ECMs to issue the local documents..</p> <p>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 workshop audited location 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 critical non-conformity If the quick checks are successful for at least one wagon the auditor will perform in depth verification. In cases of in-depth verification successful, non-conformity is issued. In case in-depth verification is not successful, 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 maintenance workshop.</p>	<p>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>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 maintenance workshop on these common requirements and shall base his assessment on them.</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 : <ul style="list-style-type: none"> • activities affecting safety identified by the ECM and stated in maintenance orders; • activities identified by the maintenance workshop through risk assessment on maintenance orders received; • joining techniques; • NDTs; • maintenance of wheelsets and draw gear; • maintenance of braking system; and • coordination of maintenance at the level of 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)
<p align="center"><u>Specificities for exchange of information</u></p>		
<p>For information the maintenance workshop has to receive from, the audit team shall assess that the maintenance workshop has:</p> <ul style="list-style-type: none"> • Defined a list of information that must be found in maintenance orders • Evidences of maintenance orders effectively received 		

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<ul style="list-style-type: none"> • Analysis of maintenance orders 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 maintenance workshop has to provide to ECMs, the audit team shall assess that the ECM has</p> <ul style="list-style-type: none"> • List of information to provide according to maintenance orders received • Arrangements regarding claims coming from ECMs • Evidences of information effectively provided including release to service • 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 maintenance orders.</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 maintenance workshop 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) <p>The assessment team has access to any initial and surveillance assessment reports of contractors when they are certified under this scheme. The assessment team has access to all reports related to other certifications of the maintenance workshop that were taken account in the initial assessment.</p> <p>When the assessment team agreed with the maintenance workshop 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.</p> <p>The draft initial assessment report will be delivered to the maintenance workshop within 2 weeks after the end of the initial assessment</p> <p><u>Non conformities:</u></p> <p>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 maintenance workshop 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.</p> <p>A Critical non-conformity is A Non-conformity leading:</p> <ul style="list-style-type: none"> • Either to a risk about safety, interoperability or environment due to the maintained wagons 	

<p align="center"><u>Part 1: Assessment of the maintenance system</u></p>	<p align="center"><u>Part 2: Inspections on selected processes</u></p>
<ul style="list-style-type: none"> • Or to a risk about capacity of management system to keep the level of performance of operations. • Or Recurrent improper maintenance output <ul style="list-style-type: none"> ○ major incidents due to (systematically) improper maintenance ○ Recurrent bad / low quality of the executed work (complaints to NSA, customer complaints (keepers, RUs)) <p>Notes:</p> <p>1) A non-conformity can be technical or organisational</p> <p>2) The cooperation between certification bodies as stated in article 6 of the ECM Regulation will aim to develop and precise critical non-conformities</p> <p>A non-critical non-conformity is a non-conformity without direct impact:</p> <ul style="list-style-type: none"> • 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 <p>Note: repetitive or persistent non-critical non-conformity can induce a critical non-conformity.</p> <p>The details on conformity treatment of non-conformities are defined in annex 1.</p>	
<p><u>Composition of the initial audit report</u></p> <p>The section 9.2.4. Of the ISO 17021:2011 related to initial audit conclusions is applicable.</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><u>Composition of the initial inspection report</u></p> <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>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 maintenance workshop takes the actions aiming at solving the non-conformity and controlling the 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. 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. The maintenance workshop 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>

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
	<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><u>3.2.2.4.2. Decision</u></p> <p>The decision is taken by the certification body upon the opinion of the Certification Committee.</p> <p>The Certification Committee bases his opinion on the assessment reports provided by the assessment team.</p> <p>No member of the assessment team may take part to the Certification Committee and vice-versa.</p> <p>The certification body shall identify each certificate delivered in conformity with the section 3.2.3.8. of this document</p> <p>A certificate of maintenance workshop shall be valid for a period up to 5 years</p> <p>Conditions to certification relative to non-conformities: Certification can only be awarded if:</p> <ul style="list-style-type: none"> • 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. <p>The relevant information on the appeal process must be transmitted to the maintenance workshop 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><u>3.2.2.5. Surveillance</u></p> <p><u>3.2.2.5.1. Assessment</u></p>	

Part 1: Assessment of the maintenance system

Part 2: Inspections on selected processes

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 during the validity period of the certificate.

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 MW 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 MW.

- The non-conformities identified in the initial assessment and in any other preceding surveillance activities
- The annual report provided by the maintenance workshop 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. The annual report has then an impact on the necessary competences to meet within the assessment team.

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.

- The appropriate actions put in place by the certification body to check claims according to articles 5 (7) and 9 of the ECM regulation.

The annual report provided by the maintenance workshop contains at least:

- 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:
 - 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
 - It includes changes on the balance internal/external activities.
 - Contractual arrangements with users
 - It includes mainly the ECMs. It covers also the exchange of data
 - Maintenance system including the management functions and the maintenance delivery function
 - Defects and failures including information exchanged.
 - Internal audit reports
 - NSA and other authorities enforcement actions/investigations including claims according to article 9 of the ECM Regulation
 - Competence management.

The maintenance workshop has to add to the annual report all information he considers relevant for the assessment team.

The maintenance workshop addresses the report in due time before the planned surveillance assessment upon an agreement with the certification body

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.

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<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 maintenance workshop 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 maintenance workshop. The principles described for initial inspections in this document are applicable.</p>
<p><u>3.2.2.5.2. Report</u></p> <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 maintenance workshop 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:</p> <p><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

<u>Part 1: Assessment of the maintenance system</u>	<u>Part 2: Inspections on selected processes</u>
<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> <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 maintenance workshop 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 style="text-align: center;"><u>3.2.2.6. Recertification process</u></p> <p>The 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 maintenance workshops, 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 maintenance workshop.
 External sites may be certified against the ECM Regulation.

Because of the multiplicity of sites, 2 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 maintenance workshop to:

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

	Certified against ECM Regulation	Not certified against ECM Regulation
External sites	<p>Principle: The certificate of the external site provides assurance to the maintenance workshop that the external site is <u>competent</u>.</p> <p>Therefore the assessment team shall focus its assessment on the ability of the maintenance workshop to</p> <ul style="list-style-type: none"> ○ Assure that the external site certificate is relevant to the outsourced maintenance activities. 	<p>Principle: the assessment team should normally not be in position to perform assessment on external sites unless it has been previously arranged with the maintenance workshop and the external site.</p> <p>Therefore the assessment team shall focus its assessment on the ability of the maintenance workshop 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 staff of the maintenance workshop when they perform qualification visits at the external site(s). In that case the assessment team shall observe how the staff of the maintenance workshop performs the qualification activities (including identification of non-conformities with requirements of the maintenance workshop addressed to the external site, reporting, decision making and follow-up of these non-conformities by the maintenance workshop). .</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 requirements addressed to this external site by the maintenance workshop. In such a situation the assessment team is capable to judge on the capability of the maintenance workshop to qualify and keep under control the external site.</p>

3.2.3.2. Used language

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

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 maintenance workshop 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 maintenance workshop.

[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 maintenance workshops 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 maintenance workshop have to reach an agreement on what is fair number of man-days respectively for initial assessment and surveillance with the maintenance workshop'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

A maintenance workshop shall be considered as an organisation with a LOW complexity. 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 the maintenance workshop but also for other activities.

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 maintenance workshop 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 maintenance workshop 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.

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 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 maintenance workshop, 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 maintenance workshop, the maintenance workshop 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 maintenance workshop.

The reports are properties of the certification body. The maintenance workshop has an unlimited right of use of the reports.

The reports shall be kept at least 6 years by the maintenance workshop 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 maintenance workshop 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 maintenance workshop.

For commercial purposes (better communication with customers), the maintenance workshop 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 (ECMs, 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 maintenance workshop has already got third party certifications such as:

- ISO certifications: EN ISO 9001:2008, EN 9100:2009, EN ISO 14001:2004, ...
- Industry certifications such as IRIS, RISAS or VPI,...
- National certifications: national certifications of maintenance workshops as in Spain and in The Netherlands.

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 maintenance workshop by the certification body who delivered the existing third parties certificate. The maintenance workshop shall provide them to the certification body in charge of certification of maintenance workshop.

[Documents on comparison between certification of maintenance workshop 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: 32 for certification of maintenance workshops

'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 maintenance workshop 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 maintenance workshop 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 maintenance workshop performed by the accepting certification body.

The pre-transfer review covers the following aspects:

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

Annex 1: Treatment of non-conformities

The decision to deliver or continue to subscribe the certification of a maintenance workshop, 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 (maintenance workshop) 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, precising 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 favourable decision can be decided only after the observation of the implementation of the actions in order to have the situation under control.
- 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.
- If a conditionally unfavourable decision is decided, a favourable decision can be decided subsequently, when the implementation of the concerned actions is observed.
- 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 favourable decision can be decided, only after the observation of the implementation of the necessary actions in order to have the situation under control.
- 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.
- If a conditionally unfavourable decision is decided, the certification of the maintenance workshop is suspended, the provisions of section 7.1.1.c) of this annex are applied.
- If an unfavourable decision is decided, the certification of the maintenance workshop is revoked 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 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.
- 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 maintenance workshop is refused or revoked.

7.3.2 Lack of critical NCs

- A favourable decision can be decided only if the times allowed are conforms to section 5. A conditionally favourable decision can't be decided.
- 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)
		And CORRECTIVE ACTIONS		<input type="checkbox"/> NC – non critical (minor)
Applicant (maintenance workshop) :		Date issued:		
Site of the observation :				
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:	
Maintenance workshop agreement : <input type="checkbox"/> YES <input type="checkbox"/> NO				
Comments (possible) :				
Maintenance workshop Representative Name :		Signature:		
Date:				
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:	
Maintenance workshop 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: CLOSED <input type="checkbox"/>	NC CLOSED <input type="checkbox"/> NC NOT	New NC N°:
Assessor:	Date:	Signature: