

OTIF



**ORGANISATION INTERGOUVERNEMENTALE POUR
LES TRANSPORTS INTERNATIONAUX FERROVIAIRES**

**ZWISCHENSTAATLICHE ORGANISATION FÜR DEN
INTERNATIONALEN EISENBAHNVERKEHR**

**INTERGOVERNMENTAL ORGANISATION FOR INTER-
NATIONAL CARRIAGE BY RAIL**

**A 93-02/2.2009
30.11.2009**

Original : EN

Memorandum of Understanding

**establishing the basic principles of a common system of certification
of entities in charge of maintenance for freight wagons - with
Annexes A – F, which form an integral part of the memorandum**

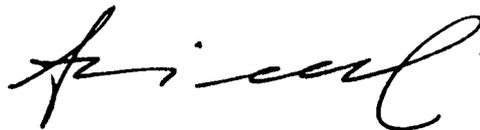
Important Note: Annex F contains specific provisions applicable to OTIF Member States signatories, which are not members of the European Union

The **Swiss Confederation**, Member State of the Organisation hereby accedes to this Memorandum of Understanding with the rights and obligations which it entails.

The Secretary General will inform the other Member States and the European Union of this accession and make it public on the web-site of the Organisation.

Done at Berne, 22 January 2010

For Switzerland:



Mr. Max Friedli

Director of the Federal Office of Transport
Federal Department of the Environment,
Transport, Energy and Communications

Memorandum of Understanding (MoU)

Establishing the basic principles
of a common system of certification of
entities in charge of maintenance
for freight wagons

Brussels, 14 May 2009

1. PREAMBLE

- (1) The entry into force of the new 1999 COTIF¹ Convention on 1st July 2006 has brought in new rules governing contracts for the use of vehicles. According to its CUV appendix², wagon keepers are no longer obliged to register their wagons with a railway undertaking. The former RIV³ Agreement between railway undertakings has ceased to apply and was partially replaced on the same date by a new private and voluntary agreement the General Contract of Use (GCU)⁴ between railway undertakings and wagon keepers whereby the latter are in charge of the maintenance of their wagons. In order to reflect these changes and to make easier the implementation of Article 10 of Directive (EC) No 2004/49 (hereinafter referred to as "Railway Safety Directive") on safety certification of railway undertakings, the European Commission (hereinafter referred to as "the Commission") adopted on 13 December 2006 a proposal of modification of that Directive. This amendment was adopted on 16 December 2008 under Directive 2008/110/EC⁵. This MoU is based on that amendment.
- (2) Before a vehicle is placed in service, according to the rules for authorising new vehicles and those relating to existing vehicles, or used on the network, an Entity in Charge of its Maintenance (hereinafter referred to as "ECM") will be a mandatory requirement and is to be identified in the National Vehicle Register. A railway undertaking, an infrastructure manager or a keeper could be such an ECM.
- (3) In accordance with the revised Railway Safety Directive and for freight wagons only, the ECM shall be certified in accordance with a system to be developed by the European Railway Agency (hereinafter referred to as "the Agency") and to be adopted by the Commission. Where this ECM is a railway undertaking (RU) or an infrastructure manager (IM), this certification should be included in the procedure for safety certification or authorisation. The certificate delivered to such entity would ensure that all applicable maintenance requirements are met for any freight wagon of which it is in charge. This certificate should be valid in the whole Community and should be delivered by a body able to audit the maintenance management system set up by such entities. As freight wagons are frequently used in international traffic and as an ECM may want to use workshops established in more than one Member State, the certification body should be able to perform its controls in the whole Community.

¹ Convention concerning International Carriage by Rail (COTIF)

² Uniform Rules concerning Contracts of Use of Vehicles

³ *Regolamento Internazionale Veicoli*

⁴ The GCU website: <http://www.gcuoffice.org/spip.php?article15>

⁵ Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways (Railway Safety Directive) (OJ L 345, 23.12.2008, p. 62)

- (4) The increasing opening of the railway traffic markets results in additional interfaces, in particular between the ECMs of freight wagons and the railways companies.
- (5) The stakeholders, as represented by ERFA⁶, CER⁷, UIC⁸ and UIP⁹ have repeatedly stated their substantial interest in a certification system for ECMs to be set up on a voluntary basis, with a view to the adoption of the certification system in accordance with Article 14a(5) of Directive 2004/49/EC. This possibility was discussed in the working group "role of the keeper" and considered to be a good solution for the transition period. This solution can be implemented by means of a Memorandum of understanding (MoU) between the appropriate authorities of the Member States of the European Union.
- (6) As railway traffic does not stop at the borders of the European Union, it would make sense, in anticipation of the intended revision of Appendix G (ATMF) of the COTIF 1999 and its adjustment to Community legislation, to extend such an agreement also to interested non EU Member States of OTIF¹⁰. This would accommodate the legitimate interest of the stakeholders in a use of freight wagons as generous as possible.

2. AGREEMENT:

The signatories conclude the following agreement:

2.1. Goal

2.1.1. Recognition:

This MoU aims at setting up a provisional voluntary system of certification of ECMs in the case of freight wagons. It establishes the principle of mutual recognition of certificates granted to ECMs.

2.1.2 Certification:

Any RU or IM, which is, as stated in its safety certificate, operating vehicles for which maintenance is carried out by an ECM certified according to this MoU, will be understood to satisfy all safety requirements concerning maintenance of those vehicles which may be imposed by any National Safety Authority (NSA) under a safety certificate or safety authorisation issued in compliance with Articles 10 or 11 of the Railway Safety Directive.

⁶ European Rail Freight Association

⁷ Community of European Railways Infrastructure Companies

⁸ International Union of Railways

⁹ International Union of Private Wagons

¹⁰ Intergovernmental Organisation for International Carriage by Rail

This is without prejudice to the responsibility, under Article 4 of the Railway Safety Directive, of railway undertakings and infrastructure managers for the safe operation of trains.

Such certification will not prevent the hauling RU or IM to do any necessary safety visual, auditory checks and measurements before starting a train. These checks are the last and most important safety means to detect any "non safe" events which may have happened during the previous trip of the vehicle or where a train preparation check has detected a lack of maintenance.

2.1.3 Common Understanding:

This MoU will support a common understanding of the role and tasks of the ECM and interfaces with other actors.

2.2. Role and tasks of the ECM

The ECM will ensure that vehicles are maintained in accordance with:

- a) the maintenance file of each vehicle;
- b) the requirements in force including maintenance rules and TSI provisions.

The ECM is responsible for following up the maintenance process and rules of a vehicle.

The tasks of the ECM and its interfaces with the actors are further developed in Annex B.

2.3. Certification of the ECM under this MoU

- 2.3.1. An ECM may be certified if it has implemented a system for maintenance which includes the requirements given by Annex B.
- 2.3.2. An ECM will be certified by a body fulfilling the requirements mentioned in Annex D.
- 2.3.3. The initial certification of the ECM and its ongoing inspection will comply with the criteria and procedures set out in Annex C. Use of the forms given in Annex E is recommended.
- 2.3.4. To obtain certification of its Maintenance System an ECM has to hold a civil liability insurance.
- 2.3.5. The cost of the certification and ongoing inspection procedure will be met by the ECMs.

2.4. Validity of certificates of an ECM

- 2.4.1. The ECM certification will be renewed at least every five years and it can be revoked by the issuing certification body, if the ECM does not fulfil the relevant requirements.
- 2.4.2. The ECM certificates granted under the provisions of this MoU will be valid throughout the Community.

2.5. Requirements for the certification bodies

- 2.5.1. The Certification Body (hereinafter referred to as “CB”) will fulfil the following minimum requirements, further detailed in Annex D:

- (a) The CB will be organisationally, functionally and in its decisions independent from railway undertakings, infrastructure managers, wagon keepers and ECMs and will not perform similar services.
- (b) The CB and the deployed personnel will have the required professional competence in particular regarding the organisation of the maintenance of freight wagons and the appropriate maintenance systems.
- (c) The CB will ensure that it makes its decisions impartially.
- (d) The CB will hold civil liability insurance, unless a member state is liable under a national legal provision.

- 2.5.2. Member states will implement an appropriate recognition or accreditation process. Both the accreditation and recognition process will be based on criteria of independence, competence and impartiality, such as the relevant European standards.

Competent authorities will publish an application form to be used by bodies which intend to act as CBs for ECMs or a list of detailed criteria to be recognised as competent to do so. The competent authorities have the right to undertake audits from time to time of the compliance with Annex B of the approval/recognition procedure.

A CB being assessed under paragraph 2.3.2 has a declaration of its competence on the basis of the relevant European standards, this will be considered by the Member state when assessing the body.

- 2.5.3. The Agency will consider the need to establish a CB Coordination Group and if appropriate, the Commission will mandate the Agency to organise such a group. Each body acting as certification body for ECMs and, where appropriate, the competent authorities will keep a list of the ECMs certified by them. These lists will be kept up-to-date and notified to the Agency to be published.
- 2.5.4. Each Member State will notify the Agency of the list of CBs. That notification will be done one year after the signature of this MoU for the first time and then in all cases of changes. The CBs have to notify to the Agency the ECMs they have

certified and also those, whose certification have been refused. The Agency will publish and keep up-to-date a consolidated list of ECM certification bodies.

2.6. International cooperation

2.6.1. Competent authorities of OTIF states which are not EU Member States will be able to sign this MoU. To this effect, the General Directorate for Energy and Transport of the Commission (DG TREN) will liaise with the OTIF Secretariat General in order to organise the signature by OTIF non EU Member States who would like to sign this MoU.

Due to differences between Community legislation and the COTIF 1999 convention, specific provisions applicable to non EU signatories are necessary and are detailed in Annex F.

2.7. Governance of this MoU

2.7.1. This agreement will be signed by the competent authorities of the EU Member States. It will apply in each Member State from the date of signature by the representative of that Member State and, where appropriate, when the Member State has taken the national measures needed to apply the MoU. The Member States notify this date to DG TREN.

2.7.2. DG TREN will publish it and keep up-to-date the lists of signatories and the date of the application in the Member States (Annex A).

2.7.3. The Agency will organise an exchange of experience between NSAs, under Article 6(5) of its Regulation (EC) No 881/2004 (Agency Regulation) and Article 17(4) of the Railway Safety Directive with a view to a uniform application of this MoU.

2.7.4. This agreement will lose its validity as soon as a certification system for ECMs adopted under Community legislation enters into force.

Done at Brussels, 14 May 2009

For Austria:

Dipl. Ing. Michael Walter
Railway and Interoperability Committee (RISC) Member
Ministry of Transport



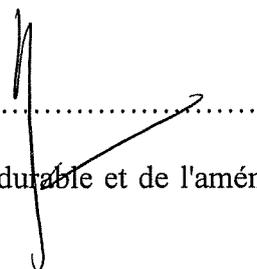
For Belgium:

Mr Pierre Forton
Directeur général Transport Terrestre
Service Public Fédéral Mobilité et Transports



For France:

Mr Denis Huneau
Ingénieur général des ponts et chaussées
Ministère de l'écologie, de l'énergie, du développement durable et de l'aménagement du territoire
(pour le Ministre, par délégation)



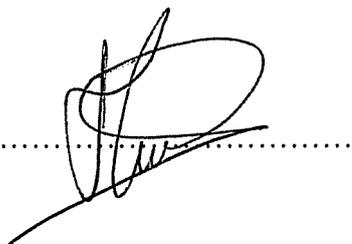
For Germany:

Mr Michael Harting
Deputy Director General of the Department "Railways"
Federal Ministry of Transport, Building and Urban Affairs



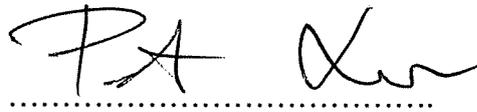
For Greece:

Mr. George Patris
Transport Attaché
Permanent Representation of Greece to the EU



For Hungary:

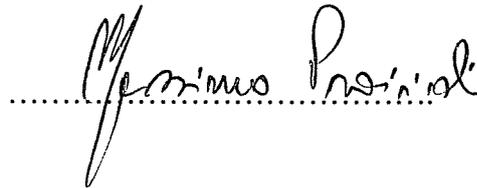
Mr. Péter Lányi
Deputy General Director
Ministry of Transport, Telecommunication and Energy



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For Italy:

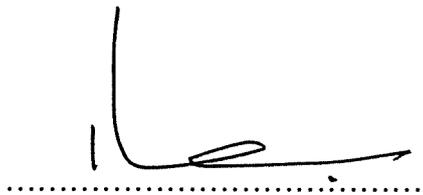
Mr. Massimo Provinciali
Direttore Generale
Ministero delle Infrastrutture e dei Trasporti



.....

For Luxemburg:

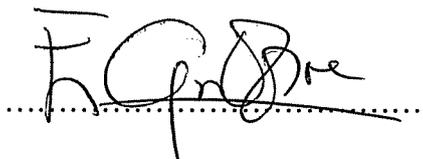
M. François Jaeger
Directeur Gestion Réseau
(pour le Gouvernement, par délégation)



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For The Netherlands:

Drs. E. Griffioen
Chief Inspector
National Safety Authority



.....

For Romania:

Dr. Marin Stancu
Deputy Director
Ministry of Transport and Infrastructure
Directorate for Infrastructure and Railway Transport



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List of Annexes:

- Annex A: List of EU Member States and OTIF non EU Member States applying this MoU
- Annex B: Requirements to the ECM for setting up its Maintenance System
- Annex C: Assessment Criteria and Procedures
- Annex C1 – Assessment Criteria
 - Annex C2 – Assessment Procedures
- Annex D: Accreditation and recognition of CB
- Annex E: Forms
- Annex E1 – Application form
 - Annex E2 – Certificate form
- Annex F: Specific provisions applicable to OTIF non EU signatories

Memorandum of Understanding

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for freight wagons

14 May 2009

ANNEX A

List of EU Member States applying this MoU
(including date of signature and date of
application)

List of OTIF non EU Member States applying
this MoU (including date of signature and
date of application)

Updated on 30.11.2009

EU Member States applying this MoU

EU Member State	Date of signature	Date of application
Austria	14.05.2009	
Belgium	14.05.2009	
France	14.05.2009	
Germany	14.05.2009	
Greece	14.05.2009	
Hungary	14.05.2009	
Italy	14.05.2009	
Luxemburg	14.05.2009	
The Netherlands	14.05.2009	
Romania	14.05.2009	

OTIF non EU Member States applying this MoU

OTIF non EU Member States	Date of signature	Date of application

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ANNEX B
Requirements to the ECM for setting up its
maintenance system

Reference documents

Ref.	Document Title	Document ref.
/1/	“SMS Assessment Criteria” published by the European Railway Agency	Version for NSA impact assessment from 31/05/2007
/2/	Document package “Safety Management System (SMS) and Vehicle Keeper Certification” drafted by UIC, UIP, ERFA, CER on behalf of the Commission Working Group “Role of the keeper”	15/01/2008
/3/	ERA Note: Safety Certification in the Railway System	Version 1.0 from 24/07/2007
/4/	MoU establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons	Version 1.0 from 13/10/2008
/5/	MoU – ECM Cert – Annex C1 (Assessment Criteria)	Version 1.0 from 13/10/2008

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1 Introduction

The herewith presented requirements are due to help an Entity in Charge of Maintenance (ECM) when setting up a maintenance system. They have no legal power; however, they aim to ensure compliance with the elements and assessment criteria proposed by the Agency for the ECM certification under the amendment of the Railway Safety Directive and during the transition period until new railway legislation is fully implemented in all Member States. The proposal is based on the structure and content of the maintenance system elements proposed by the Agency /5/ and the industry documents /2/.

The Agency recommends building the maintenance system as a process-oriented management system. This allows not only for integration with the safety management system (SMS) in case the ECM is also railway undertaking (RU) or infrastructure manager (IM), but as well with all other well-established management systems. The system needs to take into account the extent of operation and the company size of the ECM to avoid the system being bloated above the necessary level of complexity.

This Annex describes in total how the ECM fulfils its role and responsibilities and meets its obligations regarding maintenance, including overhauls, for the vehicles for which it is responsible so that they can be used by an RU in full accordance with its SMS as well as relevant standards and prescriptive conditions.

Generally speaking, the ECM has to ensure the following points to fulfil its role:

1. The ECM manages the maintenance files for every freight wagon for which it is/will be registered in the NVR as ECM and ensures its correct application.
2. The ECM ensures traceability of the maintenance operations done on every wagon in managing and keeping update the maintenance records of each individual vehicle.
3. The ECM analyses the return on experience, including data from operations and incidents or accidents, in order to update the maintenance file as appropriate (such as optimisation or restrictions decisions).
4. The ECM has to inform the carrying RU/IM of a wagon about any restrictions or specific operating conditions.

2 Maintenance System Elements

General Elements:

(taken from SMS requirements and elements and adapted to the ECM's maintenance system)

- A. Organisational aspects
- B. Document management
- C. Safety performance monitoring
- D. Supply of maintenance and material
- E. Use of contractors and suppliers
- F. Compliance with standards
- G. Staff competence
- H. Internal auditing

Specific Elements:

(additional to SMS requirements and elements)

- I. Maintenance procedures
- J. Monitoring of contractors

3 General Elements

A. ORGANISATIONAL ASPECTS

The ECM needs to compose a maintenance system manual, describing all organisational and technical procedures with direct or indirect safety impact on the railway system. It should also contain a description of the ECM's business activity and its organisational structure. Maintenance performance targets should be defined as well as the level of safety performance, to which both its management needs to commits itself. Traceability of the maintenance system processes and procedures should be taken into account when designing them.

Delegation of tasks and functions needs to be clearly stated.

A closed management cycle permitting continuous improvement should be visible in all processes and procedures, and for putting in place adequate measures to control and mitigate them.

The maintenance system manual should be reviewed on a regular basis and after any significant change or event.

The ECM needs to maintain the maintenance plans which ensure the required quality through periodic maintenance in order to meet the requirements laid down by the relevant regulations and the ECM's maintenance performance targets, to achieve safety and minimum vehicle failure¹.

B. DOCUMENT MANAGEMENT

The ECM needs to ensure that there are appropriate processes in place for the collation, receipt, processing and management of and secured access rights to all information relative to the management process for the maintenance and operational integrity of the rolling stock. It needs to be traceable and complete and shall include, but shall not be limited to:

- National vehicle register (NVR) and rolling stock register,
- Register of relevant maintenance workshops,
- Maintenance management information systems including records of all maintenance undertaken and maintenance due on rolling stock, which shall be subject to specified time periods for differing levels of archive storage,
- Other applicable software,
- Procedures for the receipt and processing of specific information relative to the operational integrity of rolling stock including, but not limited to operational and/or maintenance incidents with a potential to affect the safety integrity of his rolling stock,
- Procedures for the identification, generation and dissemination of specific information relative to the operational integrity of rolling stock including, but not limited to operational and/or maintenance incidents with a potential to affect the safety and integrity of rolling stock, and which are identified during any maintenance activity,
- Operational duty profiles of rolling stock for which the ECM is responsible. It may include tonne kilometres and total kilometres delivered by the carrying RU.

¹ See further explanations under point I

- A process to ensure reliable information is made available for RUs, in accordance with the relevant regulations.

In all processes it should be reflected that measures to control safety information are important to maintain and improve safety performance and also allow for corrective actions to be taken efficiently.

The ECM needs to define reporting channels to ensure that within its own organisation as well as with other organisations information is duly exchanged and submitted to the right person/role/function in a prompt and clear way.

The ECM should have an organisation able to manage and update, as soon as information is provided, the documents necessary to properly undertake the management of the maintenance of each vehicle. This should consider

- Applicable regulations,
- The maintenance plan for each type of vehicle,
- A list of spare parts, including a sufficiently detailed technical description of each part to allow replacement with an identical item having the same guarantees,
- A dossier defining the relevant safety/interoperability limits for components, which limits are not to be exceeded in operation,
- A list of components or systems which are subject to legal requirements, e.g. brake reservoirs, tanks for the transport of dangerous goods etc.,
- For each wagon, the history of the maintenance operations carried out on safety critical components, as well as the current applicable text, will be kept for a period at least equal to the useful life of the component but not less than the applicable statute of limitation.

C. SAFETY PERFORMANCE MONITORING

The ECM should implement urgent appropriate remedial actions to reduce the risk to an acceptable level. This should include fleet inspections and maintenance activity.

D. SUPPLY OF MAINTENANCE

To ensure that maintenance and material are delivered in required quality and that all necessary information is transferred from suppliers to the ECM and vice versa the ECM needs a structured system for the procurement of goods and contracted services. This system needs to comprise processes to

- derive maintenance requirements/standards/processes from safety and/or reliability data and from the assignment of rolling stock to their services, where appropriate;
- adjust/adapt maintenance intervals according to type and extent of service performed by the freight wagons, where appropriate;
- ensure that the responsibility for maintenance is clearly defined in the organisation, to identify the competencies for maintenance posts and to allocate appropriate levels of responsibility;
- to gather information on experience/feedback, maintenance malfunctions, defects and repairs and use it to learn and adopt corrective measures to improve the level of safety;

- identify, recognise and report risks linked to construction deficiencies/non-conformities or malfunctions and faulty functioning conditions throughout the lifecycle (even though fulfilling factory and other requirements and product approval and certification had been already granted);
- verify and control that performance and results of maintenance done comply with standards set by the ECM.

E. USE OF CONTRACTORS AND CONTROL OF SUPPLIERS

When the ECM makes use of (sub-)contractors procedures for procurement and contract management need to be established.

Regarding procurement the ECM should establish and maintain procedures for ensuring that purchased goods, services and products comply with specified railway safety requirements. These procedures need to ensure that:

- procurement documents contain adequately specified railway safety requirements;
- steps are taken to verify that the supplied goods or services, including those supplied from within the organisation, comply with railway safety requirements before they are accepted;
- where appropriate or specified, traceability of manufacture through batch or other identification is available.

Regarding contract management the ECM needs to ensure that its relevant procedures respect safety issues. Therefore tender or proposal invitation documents should be reviewed by the organisation to ensure that railway safety requirements are adequately defined and documented. Any conflict between the specified railway safety requirements and those contained in a tender or proposal should be resolved before a contract is awarded.

The capability of a potential contractor to comply with the specified safety requirements should be reviewed before a contract is awarded. Permission for the engagement of a subcontractor by the contractor both initially and during the course of a contract needs to be subject to a review of the capability of the proposed subcontractor to comply with the specified railway safety requirements.

F. COMPLIANCE WITH STANDARDS AND PRESCRIPTIVE CONDITIONS THROUGHOUT THE LIFECYCLE OF EQUIPMENT AND OPERATION

The maintenance system must ensure that all vehicles or components are in accordance with the requirements defined by the maintenance plan or relevant standards and prescriptive conditions, which are given by TSIs, national safety rules as defined in the Railway Safety Directive, operational and maintenance rules or authority decisions.

Therefore the ECM needs to establish processes to

- identify all necessary safety related requirements, relevant for the extent of operations and to ensure that they are updated and accordingly implemented;
- monitor implementation of all necessary safety related requirements;
- implement corrective actions, when needed, to ensure compliance of the railway system with standards and other prescriptive conditions throughout the lifecycle of equipment and operations;

- ensure that the right staff, procedures, specific documents, equipment and rolling stock is used for the purpose intended.

G. STAFF COMPETENCE

The required professional capabilities must be clearly defined and a record of the competence and training of those involved in the overall process shall be established and kept updated. Necessary knowledge, skills and aptitude (medical and psychological) of staff need to be refreshed/updated to retain the level required to safely perform each task.

The ECM needs to establish a competence management system ensuring

- the identification of posts that have responsibilities for taking operational decisions within the system;
- the identification of posts that perform safety-critical tasks;
- the allocation of staff with the appropriate competence to relevant tasks.

H. INTERNAL AUDITING

Internal audits need to be carried out by the ECM to ensure continuous improvement and the completeness of the management cycle. Therefore procedures should be established that allow for regular review of the internal procedures and the control of the (sub-)contractors' processes. The audits should follow the approach given by the industry standard /2/ as it is rather exhaustive regarding the qualification of auditors as well as the audit protocols.

Generally, to allow for sound review of the maintenance system as well as of the safety performance, the ECM should draw up, at least once year in a controlled manner, a summary of maintenance activities to review. This should include:

- Safety defect events and performance monitoring trends,
- Changes in personnel,
- Training or assessment of personnel,
- Periodic maintenance records,
- Overdue and projected periodic maintenance activities,
- Wheel bearing or axle incidents.

4 Specific Elements

I. MAINTENANCE PROCEDURES

The ECM has the information about the conditions in which the maintained vehicle and components are operating, such as kilometrage, climatic or landscaped environment. Taking into account the general maintenance specifications given by the manufacturer the ECM will define the limits of components in service in knowledge of those. It needs to ensure that the maintenance plan does not exceed those limits.

Every vehicle must be linked to a maintenance plan, which should

- be part of the maintenance file to each type of vehicle,
- at minimum comply with the requirements laid down in the rolling stock TSI as far as applicable,
- be a combination of preventive operations and based on results obtained from the safety performance monitoring,
- have rules in terms of document management that are established and written, particularly for the documentation given to the workshops
- have a justified periodicity and content on the basis of the SPM.

To be able to fulfil the maintenance plan requirements, it is necessary that the ECM

- observes the vehicles' operation in service and on feedback from maintenance operations or specific investigations by the safety performance monitoring;
- evaluates new types of vehicles or newly developed components through following a step by step progression by observing the vehicles in operation, by tests and programmed investigations to confirm the current maintenance rules or otherwise;
- takes into account the climatic conditions and the general conditions of use for the profile of the foreseen use;
- ensures the traceability of both construction and maintenance related documents: the people in charge of their conception (author and approver) must have their names and their qualifications clearly identified.

The ECM should have an organisation able to manage the maintenance and the operational integrity of the vehicles, by using a preventive maintenance programme. Therefore the ECM should be able to check

- that programmed deadlines have been properly respected;
- that there are no risks of exceeding the set deadlines;
- if there exists a risk of exceeding the set deadlines, it needs to have a procedure in place for contacting the relevant parties involved in the use of the vehicle(s) and even for further escalation measures, for example by contract, ensuring that the entities actually driving the vehicle are motivated to let it go for maintenance.

Conditioning is that the ECM must be able to manage and analyse all information linked to the operational behaviour of his vehicles, so as to be able to undertake any necessary corrective and/or preventive actions.

The ECM needs to ensure that the maintenance plan as such or related to individual types of vehicles is regularly reviewed. Therefore the ECM should maintain a list of his vehicles identifying vehicle type, maintenance plan and maintenance cycle. It should review the maintenance plan for suitability, during all types or levels of maintenance operations.

The ECM should have a maintenance review process to check regularly the suitability of the maintenance plan and to justify any change therein. The Maintenance Plans should be reviewed annually or after any of the following events:

- Analysis if safety performance monitoring shows unacceptable risk,
- Safety related change to the operational activities of the vehicles,
- Notification of risk found in vehicles of similar type,
- Any accident or incident caused by a vehicle's component failure or any known risk,
- Relevant alterations in applicable regulations and rules,
- Direct instruction from relevant bodies,
- Significant change to maintenance staff competency,
- Significant change to the maintenance facility,
- Change of maintenance contractor,
- Change in location of the maintenance facility.

Maintenance will be carried out by workshops, which therefore need to comply with certain conditions in order to contribute accordingly to the maintenance system of the ECM and its safety performance.

Where the ECM uses maintenance workshops, they should ensure their competence for example by following the management system given by the Agency's proposal for the certification of maintenance workshops² or – for the transitional period – national certification procedures, as far as they are applicable. Additionally, some basic requirements need to be ensured by the ECM:

- Maintenance rules in the maintenance plan are correctly applied and replaced components comply with the current regulations.
- All maintenance facilities should be assessed by the ECM or competent agents on a regular basis but not exceeding a one year interval. They will produce an assessment report which will be presented at the ECM's annual review meeting³.
- The criteria for assessment shall weigh suitability for purpose of the workshop against what work it is expected to be undertaken in the maintenance plans.
- In case of work controlled by an RU the ECM will rely on the safety certificate of the RU that the said RU also performs the foregoing and that a vehicle returned to service has automatically received the "approval for release into service".

J. MONITORING OF CONTRACTORS

To ensure a qualified relationship with (sub-)contractors the ECM needs to establish and maintain procedures for the selection, control and ongoing review of contractors and subcontractors for safety-related tasks, including the coordination of these activities across all parts of the organisation. The type and extent of control exercises needs to be dependent upon the type of service and, where appropriate, on the records of contractors' and subcontractors' previously demonstrated capabilities and safety performance.

² Preliminary draft of the final report and the recommendation version 1.1 of 1 October 2008 (available on the Agency Extranet, to be published on the Agency website during first half of 2009)

³ Confer Chapter H "Internal Auditing"

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ANNEX C1
Assessment Criteria

Reference documents

Ref.	Document Title	Document ref.
/1/	“SMS Assessment Criteria” published by the European Railway Agency	Version for NSA impact assessment from 31/05/2007
/2/	Document package “Safety Management System (SMS) and Vehicle Keeper Certification” drafted by UIC, UIP, ERFA, CER on behalf of the Commission Working Group “Role of the keeper”	15/01/2008
/3/	ERA Note: Safety Certification in the Railway System	Version 1.0 from 24/07/2007
/4/	MoU establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons	Version 1.0 from 13/10/2008

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1 Introduction

The Agency proposes to let the certification of the Entity in Charge of Maintenance (ECM) regarding its maintenance system follow the approach given by the Railway Safety Directive for the safety certification of railway undertakings (RUs) and the safety authorisation for infrastructure managers (IMs). Therefore basic elements, in the style of Annex III of the Railway Safety Directive, are given in chapter 2 of this document. In chapters 3 and 4 assessment criteria are allocated to these elements, introduced by an abstract/description giving some guidance on how to understand and in which framework to apply the criteria.

The criteria within chapter 3 are abstracted from the SMS Assessment Criteria, which are used by national safety authorities (NSAs) to assess the safety management system (SMS) of RUs and IMs, and adapted to the needs of an ECM. This allows for seamless integration of the implementation and assessment of the maintenance system in case an RU or IM including the activity of an ECM has already set up an SMS according to Article 9 and Annex III of the Railway Safety Directive. However, as they cover the necessary organisational aspects that any ECM must cover to fulfil its role and responsibilities, this also allows for a stand-alone maintenance system for an ECM. Chapter 4's criteria deal with technical maintenance matters not covered by the SMS Assessment Criteria, nevertheless important to follow and abstracted from the industry standard /2/.

The procedures, which should be applied by the Certification Bodies (CBs), are given in Annex C2.

2 Maintenance System Elements

General Elements, which can be fulfilled through the SMS or else need to be handled in the stand-alone maintenance system:

- A. Organisational aspects
- B. Document management
- C. Safety performance monitoring
- D. Supply of maintenance and material
- E. Use of contractors and suppliers
- F. Compliance with standards
- G. Staff competence
- H. Internal auditing

Specific Elements, which have to be fulfilled by any entity within the maintenance system additionally to the SMS or the general requirements above:

- I. Maintenance procedures
- J. Monitoring of contractors

3 Criteria for the General Elements (abstracted from the SMS Assessment Criteria)

The following criteria are taken from the Agency's "SMS Assessment Criteria", adapted to the ECM needs and refer to Article 9 and Annex III of the Railway Safety Directive.

A. ORGANISATIONAL ASPECTS

(cf. Annex III 1)

ABSTRACT/DESCRIPTION

- A.0. A maintenance system needs to be established by an ECM to ensure the safety management of its maintenance operations on a continuous basis. The ECM should be able to identify all risks associated with its activity and put in place adequate measures to control and mitigate them.

A maintenance system manual should describe all activities that have direct or indirect effects on safety and it should ensure traceability of the maintenance system processes. It should contain explanation of roles, responsibilities and delegations and how competence of staff and reasonable allocation of resources are made certain.

The maintenance system needs to enable the management to fulfil its commitment to improve safety by foreseeing the possibility of implementing preventive and corrective actions. It should therefore be based on processes following a management cycle model.

ASSESSMENT CRITERIA

- A.1. There is a description of type, extent and risk of the ECM's operation.
- A.2. The ECM has provided a description of the maintenance system structure showing the allocation of roles and responsibilities, which are clearly defined regarding their interfaces and their impact on safety.
- A.3. Those in the organisation with delegated responsibilities have the authority, competence and appropriate means to perform and fulfil their function as well as responsibility and competence should be coherent and compatible with the given role/task.
- A.4. The ECM has a document that describes all main maintenance system processes.
- A.5. Safety critical processes and tasks carried out by the ECM or suppliers/(sub-)contractors are listed and briefly described.
- A.6. All safety related processes and areas of responsibilities have identified and qualified posts, responsible for them throughout the whole operating cycle (i.e. on call duty, permanence and replacements).
- A.7. Regular monitoring of task performances is assured by the line management chain that must intervene if the tasks are not being properly performed.
- A.8. There are processes to allocate adequate resources to deliver the safety tasks.
- A.9. There are processes in place to ensure, where reasonably practicable, the continuous improvement of the maintenance system.

B. DOCUMENT MANAGEMENT

(cf. Annex III 2(f) + (g))

ABSTRACT/DESCRIPTION

- B.0. The exchange of relevant information is crucial within and among organisations. It is therefore important that defined reporting channels and interfaces exist to ensure that all information is conveyed to the right person/role/function in a prompt and clear way.

All necessary safety-related information needs to be traceable, documented, complete and available when required as measures to control safety information are important to maintain and improve safety performance and also to allow for corrective actions to be taken efficiently.

ASSESSMENT CRITERIA

- B.1. There are processes to ensure that all relevant maintenance information, including day-to-day operational information, is available to staff before they must enforce/apply it.
- B.2. There are adequate processes in place to ensure that all relevant safety information is accurate, complete, appropriately updated and duly documented.
- B.3. There are adequate processes in place to:
- format, generate, distribute and manage the control of changes to all relevant safety documentation;
 - receive, collect and store/archive all relevant documentation/information on paper or by other means/registration systems;
 - ensure that staff are formerly given all relevant and updated documentation and act upon it as necessary.
- B.4. It is ensured that there are adequate arrangements in place for sharing of information between railway organisations.

C. SAFETY PERFORMANCE MONITORING

(cf. Annex III 1)

ABSTRACT/DESCRIPTION

- C.0. Safety performance monitoring is a crucial tool for closing the management cycle for continuous improvement. However, the monitoring processes should combine the safety performance monitoring with that of the maintenance system processes itself to allow for preventive or corrective actions using all possible levers.

ASSESSMENT CRITERIA

- C.1. There are processes in place describing arrangements to monitor and analyse relevant safety data.
- C.2. There are processes in place describing how identified shortcomings are rectified.
- C.3. There are processes in place describing how new safety developments and/or lessons learnt are implemented.
- C.4. There are processes in place describing how internal audit findings are used for continuous improvement.

D. SUPPLY OF MAINTENANCE AND MATERIAL
(cf. Article 9(2))

ABSTRACT/DESCRIPTION

- D.0. The separation of activities or functions between the various players involved in the operation of the railway system has let risks arise and requires co-operation between the players. The maintenance system needs to ensure that these interface risks are addressed in a coherent way.

ASSESSMENT CRITERIA

- D.1. There are processes to derive maintenance requirements/standards/processes from safety and/or reliability data and from the assignment of rolling stock to their services, where appropriate.
- D.2. There are processes to adjust/adapt maintenance intervals according to type and extent of service performed by the ECM, where appropriate.
- D.3. There are processes to ensure that the responsibility for maintenance is clearly defined in the organisation, to identify the competencies for maintenance posts and to allocate appropriate levels of responsibility.
- D.4. There are processes to gather information on experience/feedback, maintenance malfunctions, defects and repairs and use it to learn and adopt corrective measures to improve the level of safety.
- D.5. There are processes to identify, recognise and report risks linked to construction deficiencies/non-conformities or malfunctions and faulty functioning conditions throughout the lifecycle (even though fulfilling factory and other requirements and product approval and certification had been already granted).
- D.6. There are processes to verify and control that performance and results of maintenance done either by the ECM or third parties, comply with standards set by the ECM.

E. USE OF CONTRACTORS AND CONTROL OF SUPPLIERS

(cf. Article 9(2))

ABSTRACT/DESCRIPTION

- E.0. In case maintenance – or parts of it – is contracted out risks will be imported. This requires that the maintenance system disposes of adequate control processes ensuring the selection of qualified (sub-)contractors and suppliers, the necessary exchange of information and traceable delegation of responsibilities.

ASSESSMENT CRITERIA

- E.1. There are processes to verify beforehand the competence of (sub-)contractors and suppliers.
- E.2. Responsibilities and tasks, relating to railway safety issues, are clearly defined, known and allocated between the contracting partners and among all other concerned parties.
- E.3. The ECM has a process to ensure traceability of relevant documents and contracts.
- E.4. There is a validation process to ensure that supplied and (sub-)contracted services meet required standards.
- E.5. There are processes in place to safeguard that safety tasks are conducted within the required schedule and according to required standards and criteria.
- E.6. There are processes in place to safeguard day-to-day management of safety tasks.

**F. COMPLIANCE WITH STANDARDS AND PRESCRIPTIVE CONDITIONS
THROUGHOUT THE LIFECYCLE OF EQUIPMENT AND OPERATION**
(cf. Annex III 2(c))

ABSTRACT/DESCRIPTION

- F.0. All safety related procedures and processes of the maintenance system must be designed to comply with the regulatory framework and must be updated to take into account any variation or addition. Therefore the system should enable to promptly recognise variations/additions in the relevant regulatory framework.

For maintenance processes, organisations must comply with all legal requirements and relevant specifications, standards and requirements throughout the entire life cycle of equipment and operations. Therefore the system must ensure the prompt identification, collection, listing and respective implementation of requirements for staff, equipment and procedures in relevant standards and prescriptive conditions.

Relevant standards and prescriptive conditions are TSIs, national safety rules as defined in the Railway Safety Directive, operational and maintenance rules or authority decisions.

ASSESSMENT CRITERIA

- F.1. There are processes in place to identify all necessary safety related requirements, relevant for the extent of operations carried out by the ECM and ensure that they are updated and accordingly implemented.
- F.2. There are processes in place to monitor implementation of all necessary safety related requirements.
- F.3. There are processes in place to implement corrective actions, when needed, to ensure compliance of the railway system with standards and other prescriptive conditions throughout the lifecycle of equipment and operations.
- F.4. There are processes in place to ensure that the right staff, procedures, specific documents, equipment and rolling stock is used for the purpose intended.
- F.5. There are processes in place to ensure that maintenance is carried out according to the relevant requirements.

G. STAFF COMPETENCE

(cf. Annex III 2(e))

ABSTRACT/DESCRIPTION

G.0. The maintenance system must ensure that all staff with safety-related responsibilities is competent to perform their tasks and that staff skills and knowledge are maintained in all circumstances.

This should be done by means of a competence management system, including selection principles, initial training and – if applicable – certification of acquired competence, ongoing training and periodical knowledge update and finally proficiency checks.

ASSESSMENT CRITERIA

G.1. The ECM has set up a competence management system providing for:

- the identification of posts that have responsibilities for taking operational decisions within the system;
- the identification of posts that perform safety-critical tasks;
- the allocation of staff with the appropriate competence to relevant tasks.

G.2. There are processes in place to ensure that the necessary knowledge, skills and aptitude (medical and psychological) of staff are refreshed/updated to retain the level required to safely perform each task.

H. INTERNAL AUDITING

(cf. Annex III 2(j))

ABSTRACT/DESCRIPTION

H.0. Internal auditing serves the purpose of reviewing and verifying the effectiveness of the maintenance system, i.e. if the processes and procedures described within the system ensure that the operations and services comply with relevant requirements.

The ECM should establish a calendar of internal audits to be carried out (audit planning). Staff in charge of carrying out internal auditing (auditors) must be competent and experienced in the field/matter they are assessing and also skilled and adequately prepared and trained to perform audits.

Audits should be carried out in an impartial and independent way: auditors should be independent from the organisational unit being audited and conflict of interest between the assessing and the assessed party should be avoided.

ASSESSMENT CRITERIA

H.1. There is an internal auditing system in place which is independent, impartial and acts in a transparent way.

H.2. The ECM has a schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance.

H.3. Audits are carried out by suitably competent persons.

H.4. Procedures and/or processes are in place to

- identify and select auditors,
- analyse and evaluate the results of the audits,
- propose and implement specific corrective measures/actions,
- verify the effectiveness of previous measures/actions.

H.5. Senior management is aware of the results of audits and take overall responsibility for implementation of changes to the maintenance system.

4 Criteria for the Specific Elements (not included in the SMS Assessment Criteria)

The Criteria in this chapter are derived from the standard developed by the industry /2/.

I. MAINTENANCE PROCEDURES

ABSTRACT/DESCRIPTION

- I.0. Crucial part of the maintenance system is the profound knowledge about all safety-critical components which require maintenance and may import risks to the railway system.

Important for the planning of maintenance is also to know under which conditions the maintained components are operating. They include among others the kilometrage, the environment (climate, landscape, etc.) and the sort of goods.

ASSESSMENT CRITERIA

- I.1. There are processes to identify all safety critical components relevant for the ECM's operations.
- I.2. The ECM has a maintenance plan available, which takes into account all safety relevant components as well as the products carried and the operating environment.

J. MONITORING OF CONTRACTORS

ABSTRACT/DESCRIPTION

- J.0. In addition to the explanations given under D and E the monitoring of (sub-)contractors needs to be addressed. It is necessary to verify that also the (sub-)contractor has understood his role in and contribution to railway safety.

In case of the use of (sub-)contractors, the safety performance of the ECM is not only relying on its own processes, but also on those of the supplier/(sub-)contractor. This requires specific monitoring processes in the maintenance system.

ASSESSMENT CRITERIA

- J.1. There are processes in place to monitor the suppliers'/(sub-)contractors' understanding of risks they import to the ECM's operations.
- J.2. There are processes in place to ensure that safety critical products and services are identified and qualified suppliers/(sub-)contractors are selected.
- J.3. There are processes in place to conduct surveillance of suppliers/(sub-)contractors regarding their safety performance.

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ANNEX C2
Assessment Procedures

Reference documents

Ref.	Document Title	Document ref.
/1/	“SMS Assessment Criteria” published by the European Railway Agency	Version for NSA impact assessment from 31/05/2007
/2/	Document package “Safety Management System (SMS) and Vehicle Keeper Certification” drafted by UIC, UIP, ERFA, CER on behalf of the Commission Working Group “Role of the keeper”	15/01/2008
/3/	ERA Note: Safety Certification in the Railway System	Version 1.0 from 24/07/2007
/4/	MoU establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons	Version 1.0 from 13/10/2008
/5/	MoU – ECM Cert – Annex C1 (Assessment Criteria)	Version 1.0 from 13/10/2008

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1 Introduction

The Agency proposes to let the certification of the Entity in Charge of Maintenance (ECM) regarding its maintenance system follow the approach given by the Railway Safety Directive for the safety certification of railway undertakings (RUs) and the safety authorisation for infrastructure managers (IMs). Therefore the assessment procedures follow those developed under the Common Safety Method (CSM) for Conformity Assessment.

The CSM approach for SMS assessment will introduce two steps in the certification procedure: Firstly the assessment for the initial granting of the safety certificate or safety authorisation, which will be mainly based on the written procedures described in the manual of the safety management system (SMS). The NSA will need to verify the quality and appropriateness of the procedures according to the type and extent of operations of a particular RU or IM.

Secondly – after having granted certificate or authorisation – inspections on the ground need to be carried out under Article 16(2)(e) of the Railway Safety Directive to monitor if what has been written in the manual is actually performed in the operational daily work. Audits may be one means for conducting inspections, however neither prescribed nor explicitly recommended as there might be other means appropriate for a particular situation.

It is recommended by the Agency to adopt this approach also for the certification of the ECM.

2 Granting a certificate

For the procedure of granting a certificate for the maintenance system of an ECM it is necessary to distinguish between those entities being in the same time RU or IM and therefore integrate their maintenance system in the SMS and those that need to have a stand-alone maintenance management system.

2.1 ECMs HAVING A STAND-ALONE MAINTENANCE SYSTEM

For ECMs that are not part of an RU or IM and therefore need a stand-alone maintenance system the assessment for granting the certificate should contain the subsequent steps:

- Receipt of the candidate's application using the ECM maintenance system certificate application form and including the maintenance system manual.
- The maintenance system manual should contain information about the internal organisation of the ECM (organisation chart; description of roles, responsibilities and functions; procedures for delegation from the executive management down to all levels of staff as well as a list of delegated functions).
- The maintenance system manual should contain basic descriptions of all procedures that handle safety-related activities. It should refer to underlying documents, in which organisational or operational details for the particular maintenance activities are given.
- Verification of the quality, appropriateness and comprehensiveness of the procedures described in the maintenance system manual by means of the complete list of ECM Assessment Criteria. Evidences should be given by the basic descriptions of the procedures in the manual accompanied by links or references to underlying documents, which should be consulted, if deemed necessary.
- The verification should be carried out by CB staff with suitable competence knowing the particularities of freight transport and the maintenance part of the railway system concerning vehicles.

- If necessary, follow up of lacks, weaknesses or open points detected within the maintenance system by inspections on the ground regarding these particular issues.
- Processing of the file within and communicating a decision four months after having received the application.
- The certificate can be granted for a period up to five years, depending on the Member States' implementation of Article 10(5) of the Railway Safety Directive.

2.2 ECMs WHICH ARE ALSO RUs/IMs

Generally speaking, the assessment of an ECM that is also an RU/IM should not differ from an ECM having a stand-alone maintenance system. The eight General Elements listed in the ECM Assessment Criteria will be already covered when assessing the SMS and therefore do not require assessment additional to that. Nevertheless, the abstracts/descriptions in the ECM Assessment Criteria need to be taken into account to ensure that no maintenance-related interpretation is missed. The Specific Elements need to be assessed in any case additionally as they are not covered by the SMS. Therefore the list of assessment procedures reads:

- Receipt of the candidate's application using the SMS certificate application form and including the information on the ECM activity or attaching the ECM maintenance system certificate application form.
- The SMS manual should reflect for all relevant procedures any additional items regarding the ECM activity.
- The SMS manual should contain additional chapters dealing with the specific requirements to the ECM activity.
- The contents of the SMS manual and the procedures for verification of the quality, appropriateness and comprehensiveness of the procedures described need to follow the approach given by the CSM on Conformity Assessment.
- Evidences should be given by the basic descriptions of the procedures in the manual accompanied by links or references to underlying documents, which should be consulted, if deemed necessary.
- The verification of the maintenance system parts within the SMS should be carried out by NSA staff with suitable competence knowing the particularities of freight transport and the maintenance part of the railway system concerning vehicles.
- If necessary, follow up of lacks, weaknesses or open points detected within the maintenance system by inspections on the ground regarding these particular issues.
- Processing of the file within and communicating a decision four months after having received the application under Article 12(1) of the Railway Safety Directive.
- The certificate, as tied to the safety certificate or safety authorisation, will have duration of up to five years, depending on the Member States' implementation of Article 10(5) of the Railway Safety Directive.

3 Follow-up Inspections

The limited period of four months for the initial assessment of the ECMs maintenance system does not leave enough time to carry out a comprehensive audit to ensure that what has been written in the manual is actually what is performed on the ground. This is one reason for inspections following the granting of the certificate. The other reason can be open points, weaknesses or a lack in the procedures which are detected during the assessment or even later during operations. They may require immediate action or leave the time for thorough planning of an inspection.

The nature of inspections on the ground depends on their circumstances and the possibility of planning. Both matters lead to a different level of detail. If planning of the inspection is possible it can be far more detailed than in case of a short notice¹ inspection steered by detected open points, weaknesses or a lack in the procedures during a late stage of the initial assessment or when at any time urgency requires immediate action.

It may also depend on the case who will carry out the inspection, if the CB and the NSA are not identical.

The different cases are:

- Planned inspections during the initial assessment on issues that the CB wants to check for every ECM, which therefore can be prepared in advance and will not prolong the four months period.
- Planned inspections during the initial assessment that are initiated by a detected open point, weakness or lack in the procedures at the beginning of the four months and where still is enough time to prepare the inspection without prolonging the four months period.
- Planned inspections during the period after having granted the certificate with the purpose to check the ECM's safety performance and whether what has been written in the maintenance system manual and underlying documents is actually performed on the ground and which are not initiated by any occurrence.
- Planned inspections during the period after having granted the certificate initiated by a detected open point, weakness or lack in the procedures with no short-term or severe impact on the safety performance and therefore leaving enough time for thorough planning.
- Planned inspections at any time after having requested changes or corrective measures in the maintenance system to ensure they have been implemented as intended.
- Short notice inspections at any time that are initiated by a detected open point, weakness or lack in the procedures with short-term or severe impact on the safety performance requiring immediate action.

For planned inspections the CB may deem an audit as appropriate means. In these cases it is recommended by the Agency that the audit planning and organisation should follow the documents given by the industry standard /2/ as they cover exhaustively the details which need to be looked at in particular for ECMs. Nevertheless, it needs to be stated that they still require revision of order, structure and partly content to fit into the ECM maintenance system framework proposed by the Agency.

¹ Short notice inspections may still allow for a few days of planning. However, the level of detail will still be less compared to planned inspections with some months or at least several weeks of forerun.

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ANNEX D
Accreditation and recognition of certification
bodies

Reference documents

Ref.	Document Title	Document ref.
/1/	“SMS Assessment Criteria” published by the European Railway Agency	Version for NSA impact assessment from 31/05/2007
/2/	Document package “Safety Management System (SMS) and Vehicle Keeper Certification” drafted by UIC, UIP, ERFA, CER on behalf of the Commission Working Group “Role of the keeper”	15/01/2008
/3/	ERA Note: Safety Certification in the Railway System	Version 1.0 from 24/07/2007
/4/	MoU establishing the basic principles of a common system of certification of entities in charge of maintenance for freight wagons	Version 1.0 from 13/10/2008
/5/	MoU – ECM Cert – Annex C1 (Assessment Criteria)	Version 1.0 from 13/10/2008
/6/	CMW preliminary draft final report	Version 1.1 from 01/10/2008

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1 Introduction

The herewith presented requirements are due to support the member states in the assessment of competences of certification bodies (CB) in the field of the certification of Entity in Charge of Maintenance (ECM). The requirements have no legal power; however, they aim to give an assurance that the certification body will be capable to assess the management system put in place by the ECM in conformity with the elements and assessment criteria proposed by the Agency for the ECM certification under the amendment of the Railway Safety Directive and during the transition period until new railway legislation is fully implemented in all Member States.

2 Assessment of the competence of the CB

The CB must be competent to certify ECM. This competence should be assessed by an independent body (third party assessment).

Each MS shall implement an assessment process of the competences of the CB. This process shall consider two phases:

- Assessing that the management system put in place makes the CB capable to perform certification activities.
- Assessing that the involved auditors have sufficient professional competences in the railway domain in general and in maintenance of freight wagons in particular.

The assessment of the management system does not prevent doubts on the competences of auditors as individuals.

The certification of ECM hasn't existed until today. The ECM role has only been played by former 'National' railway undertakings. Therefore there are today few people capable to set up an ECM and/or to assess it outside the relevant experts of the former 'National' railway undertakings.

As the success of a certification is also in the confidence that RU, IM, keepers or NSA may put on auditors, it is recommended considering the assessment of auditors' professional competences in the assessment process.

This approach has currently been developed for many certifications developed by industrial sectors such as IRIS¹ or CEFIC² quality system.

The assessment of competences shall be handled either by:

- the National Accreditation Body through an accreditation process (see section 3) or
- the NSA or another body designated by the MS through a transparent recognition process (see section 4).

¹ More information to be found under: <http://www.iris-rail.org/>

² More information to be found under: <http://www.cefic.org/>

A MS may decide to designate the NSA as CB regarding the certification of the entity in charge of maintenance. The section 5 of this document considers the case.

3 Accreditation process

3.1. Assessment of the management system of the CB

The accreditation will be undertaken by the National Accreditation Body.

The assessment shall be performed by applying relevant International Standards. CEN and ISO have developed such standards largely widespread in the industry in the European Community and abroad.

The Agency recommends that the certification body should be accredited against the EN ISO/IEC 17021:2006 *Conformity assessment - Requirements for bodies providing audit and certification of management systems*

This EN ISO/IEC 17021:2006 standard supersedes the EN 45012:1998 *General requirements for bodies operating assessment and certification/registration of quality systems* standard. It means that this old EN standard will not be anymore applied by accreditation bodies.

But as the EN ISO/IEC 17021:2006 is only 2 years old a lot of conformity assessment bodies already involved in various certification activities related to management systems are still accredited against the EN 45012:1998. When the validity period of their accreditation will expire they will have to apply for the EN ISO/IEC 17021:2006.

Consequently the Agency recommends accepting also certification bodies that are only accredited against EN 45012:1998.

The NoBo that have been accredited against the EN 45011:1998 *General requirements for bodies operating product certification systems* standard should also be presumed as capable to deliver certification to ECM. This presumption may be limited in time by the MS. In that case the transitional period shall be notified to the Agency by the MS.

3.2. Assessment of the professional competence of auditors

The requirements in the standards point out only that the CB has to consider in its organisation the fact that it has to work with competent auditors. The accreditation body will assess the conformity of the management system of the certification body against the requirements of relevant standards. Therefore the National Accreditation Body will not assess the professional competences of auditors themselves with whom the certification body is working or intends to work.

There is no international standard dedicated to the assessment of auditors of ECM management systems. Developing such standard will take time and will be counterproductive because the MoU aims to set up an ECM certification **in short delay** before the complete transposition of the new SD.

For this reason the following requirement has been defined:

The auditors shall demonstrate:

- Relevant technical qualification:
 - university degree in sciences, engineering or business management; or
 - equivalent qualification by experience (10 years); or
 - national equivalent grade (a list shall be provided by each MS who signs the MoU)
- Relevant experience in maintenance in general (5 to 8 years) such as in:
 - Design and update of maintenance file
 - Expertise in technical studies related to RST and/or maintenance
 - Production management in RST maintenance workshops
 - QMS in entity where maintenance is designed and/or executed
- Sufficient experience in RST maintenance or at least in maintenance in one of the following industrial sector:
 - Steel industry;
 - Automotive;
 - mechanical engineering;
 - electrical engineering, or
 - energy (production plants)

This requirement shall be considered by the National Accreditation body for audits related to:

- The sections 7.1 and 7.2 of the EN ISO/IEC 17021:2006
- The sections 2.2.2. and 2.2.3. of the EN 45012:1998
- The sections 5. And 9.3 of the EN 45011:1998

4 Recognition process

The NSA or the body designated by the MS will set up a recognition process compliant with the section 2 of this document.

4.1. Assessment of the management system of the CB

The ISO/IEC 17021:2006 *Conformity assessment - Requirements for bodies providing audit and certification of management systems* presents the good practise for the relevant area of activities.

Therefore the NSA or the body designated by the MS should take it into account when defining the recognition process

4.2. Assessment of the professional competence of auditors

The requirement regarding professional competences defined in the section 3.2 shall be taken into account in the recognition process by the NSA or the body designated by the MS.

5 The CB is the NSA

The NSA is presumed to be capable in terms of competence to certify the ECM in accordance with Art. 14a Par. 4 of the draft revised railway safety directive.

The internal service of the NSA that will perform ECM certification should consider the ISO/IEC 17021:2006 *Conformity assessment - Requirements for bodies providing audit and certification of management systems* when setting up its organisation.

The internal service of the NSA that will perform ECM certification shall take into account the requirement defined in the section 3.2. when performing audits.

Moreover NSA should be able to carry out the same tasks as certification bodies, this may mean in particular to make audits, inspections where activities of the ECM are located (where its staff and maintenance workshops used are located, where the wagons managed by the ECM are circulating). By then in order to be able to certify ECM and monitor its activities, when not only located in one MS, the NSA will have to cooperate with NSA or a CB in the other(s) country(ies).

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ANNEX E1
Application form



APPLICATION for a CERTIFICATE for the ECM MAINTENANCE SYSTEM

Application for Certificates confirming acceptance of the Maintenance System of an Entity in charge of Maintenance in conformity with the Memorandum of Understanding and its national implementation measures

Certification Body reference number

CERTIFICATION BODY CONTACT INFORMATION

- 1.1 Certification Body addressed for the request _____
- 1.2 Complete postal address (street, postal code, city, country) _____

APPLICANT INFORMATION

- 2.1 Legal denomination _____
- 2.2 Complete postal address (street, postal code, city, country) _____
- 2.3 Phone number _____ 2.4 Fax number _____
- 2.5 Email address _____ 2.6 Website _____
- 2.7 National registration number _____ 2.8 VAT No _____
- 2.9 Other information _____

Contact person information

- 3.1 Family name and first name _____
- 3.2 Complete postal address (street, postal code, city, country) _____
- 3.3 Phone number _____ 3.4 Fax number _____
- 3.5 Email address _____

APPLICATION DETAILS

This application is for a

- 4.1 new certificate 4.2 updated/amended certificate
- 4.3 renewed certificate 4.4 EU Identification Number of the previous Certificate _____

Operation's details

- Type of company
- 5.1 Keeper 5.2 Maintenance provider
- 5.3 Railway Undertaking / Infrastructure Manager Others (specify) _____
- Maintenance is
- 5.4 done with own means
- 5.5 contracted out
- 5.6 Service to begin in _____

Submitted documents

6.1 Maintenance system manual If RU/IM: included in the SMS Manual Yes/No

6.2 Others specify: _____

SIGNATURES

Applicant _____
(first name, family name)

Date _____

Signature _____

Certification Body:
Internal reference number

Certification Body:
Date application received

SPACE RESERVED FOR THE ADDRESSED
CERTIFICATION BODY

Memorandum of Understanding
establishing the basic principles
of a common system of certification of entities
in charge of maintenance
for freight wagons

14 May 2009

ANNEX E2
Certificate form



CERTIFICATE for the ENTITY in CHARGE of MAINTENANCE

confirming acceptance of the Maintenance System within the European Union in conformity
with the Memorandum of Understanding and its national implementation measures

EU IDENTIFICATION NUMBER XX-61-20yy-zzzz

1. CERTIFIED ENTITY in CHARGE of MAINTENANCE

Legal denomination:	Acronym:
National registration number:	VAT No:

2. CERTIFICATION BODY

Organisation:
Country:

3. CERTIFICATE INFORMATION

This is a <ul style="list-style-type: none"> - new certificate <input type="checkbox"/> - renewed certificate <input type="checkbox"/> - updated/amended certificate <input type="checkbox"/> 	EU Identification Number of the previous certificate:
Validity from: _____ to: _____	
Type of company: (keeper, maintenance supplier, railway undertaking, infrastructure manager, etc)	
Maintenance is	<ul style="list-style-type: none"> - done with own means <input type="checkbox"/> - contracted out <input type="checkbox"/>

4. APPLICABLE NATIONAL IMPLEMENTATION MEASURES

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5. ADDITIONAL INFORMATION

--

Date issued

--

Signature _____

Internal reference number

--

Certification Body's
stamp

--

Memorandum of Understanding
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ANNEX F
Specific provisions applicable to OTIF non EU
signatories

Note: This annex does not apply to OTIF non EU signatories which apply EU legislation as a result of their international agreements with the EU

1. Introduction

COTIF 1999 includes no provisions concerning mandatory safety certification of the RUs and IMs and their SMS systems for the maintenance of their own vehicles, but some non EU OTIF Member States have/plan national rules which requires safety certification in compliance with the Community regulations. For RUs and IMs which have no such safety certification, their ECM activities will therefore have to be certified in full in the same way as an ECM having a “stand alone” maintenance system; e.g. Annex B applies to them in full. When RUs/IMs are indicated in the Annexes it shall generally be understood as safety certified RUs/IMs. Also safety certified RUs will need an (additional) ECM certification concerning the maintenance of vehicles not belonging to the RU itself (commercial maintenance).

2. Terminology

The COTIF Convention uses another terminology than the Community legislation. The following “translation” table should be used when a non-EC OTIF Member State applies the MoU and its Annexes:

EC terminology	OTIF terminology
NSA (National Safety Authority)	The national authority competent for admission and/or supervision of railway vehicles
Railway Safety Directive	No parallel in OTIF; national rules apply
NVR (National Vehicle Register)	The vehicle register according to ATMF Article 13. A proposal to establish OTIF NVRs for the non-EC OTIF Member States has been adopted by the Committee of Technical Experts on 11-12 February 2009. The OTIF NVRs will for each registered vehicle include the same information as in the EC NVRs, including the related ECM.
TSI (Technical Specification for Interoperability)	Technical specification included in an Annex to APTU; if no applicable Annex, national rules apply
EU Identification Number	OTIF Identification number, same structure as EC

3. Detailed additional provisions related to OTIF

ad 2.4.2: The ECM certificates granted should be valid throughout the European Community and those other OTIF Member States which have signed this MoU.

ad 2.5.3: The certification bodies and the authorities in the non EU OTIF Member States shall notify their updated lists to the OTIF Secretary General (SG). The Agency and OTIF SG will cooperate and at the same time publish a combined, consolidated list of the certified ECMs.

ad 2.5.4: Non EU OTIF Member States shall notify to the OTIF SG. The Agency and the OTIF SG will cooperate and at the same time publish the combined, consolidated list of ECM certification bodies.

ad 2.7.1: Non EU OTIF Member States shall notify to the OTIF SG.

ad 2.7.2: DG TREN and the OTIF SG will at the same time publish the combined, consolidated list of signatories (Annex A) and the date of application in the Member States.

ad 2.7.3: The competent authorities in the non-EC OTIF Member States should participate in the exchange of experience.

ad 2.7.4: It is expected that COTIF 1999 is amended in order to include an ECM certification system which is identical or equivalent to the Community system. When the latter enters into force, this MoU should be reviewed in order to maintain mutual recognition of ECM certificates between EU and non EU Member States.
