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 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

Contents

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.