

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 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 notice<sup>1</sup> 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.

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<sup>1</sup> 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.