

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 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).