
Railway Industry Supplier Approval Scheme BRIEFING NOTE

Subject: Undertaking ECM certification based on a RISAS assessment

Advice to: Railway Industry Supplier Approval Bodies (RISABs)

Reference: Standard: RISAS/003 Issue: 4

Applies when: A RISAB, accredited under RISAS to deliver Service Product Groups S01 & S04, is contracted to undertake certification of an ECM or an organisation offering a service covered by ECM, leading to the issue of an ECM certificate.

Note's Purpose: To provide instruction and guidance to RISABs when undertaking a RISAS S01 or S04 assessment which is also intended to support certification of all or part of the applicant's organisation as an Entity in Charge of Maintenance under community regulation 445/2011/EC.

Note1 – a RISAB can only issue an ECM certificate if it is also accredited as an ECM certification body by UKAS.

Note 2 – Although this guidance is provided to assist RISABs when carrying a S01 / S04 assessment leading to the issue of an ECM certificate, in the event of misunderstanding or dispute, the ECM Regulations shall prevail, in particular the content of Annex III.

Background: RISAS 'Service' Product Groups S01 (Procurement of Vehicle Maintenance, Overhaul & Modification) and S04 (Delivery of Vehicle Maintenance, Overhaul & Modification) were developed in 2008 and were designed to be a 'good fit' for the requirements for ECM (based on the preliminary information of the latter scheme available at the time).

Discussion with UKAS in 2014, when preparing the proposal for a UK accreditation scheme for ECM certification bodies, confirmed that RISAS S01 / S04 assessments were a suitable basis for an ECM assessment and this approach was subsequently endorsed by DfT.

To support the introduction of the UK ECM certification scheme, this briefing note has therefore been prepared, based on a detailed comparison analysis of the requirements of ECM (as defined in 445/2011/EU and the ERA Guidance documents for the scheme) with the requirements of the RISAS Supplier Assessment Module outlined in RISAS/003 Part B.

The output from this analysis has been some detailed additions & clarifications to RISAS/003 together with specific, additional assessment criteria contained in the Appendix to this Briefing Note. By following the requirements of this briefing note therefore, a compliant ECM assessment will be undertaken, in conjunction with a RISAS S01 / S04 assessment of the same supplier.

1 Requirements for RISABs - Assessment

1.1 When agreeing the scope of a RISAS S01 or S04 assessment that is to cover ECM then the relevant ECM part or parts (as defined in Article 4 of the ECM Regs) shall be identified as follows:

ECM Part	Delivered by ECM	Sub-contracted	RISAS Module
I - Management	Mandatory	N/A (cannot be sub-contracted)	S01
II - Maintenance Development	Mandatory	Voluntary	S01
III - Fleet Maintenance Management	Mandatory	Voluntary	S01
IV - Maintenance Delivery	Mandatory	Voluntary	S04

1.2 When planning to undertake such an assessment, the attached Appendix shall be reviewed and all those requirements that match the relevant ECM part(s) (I to IV) shall be added to the prepared checklists to ensure full coverage of ECM requirements during the assessment.

2 Requirements for RISABs – Certification

2.1 A certificate issued in accordance with the ECM Regulations Annex IV is required in addition to any RISAS certificate issued.

2.2 Irrespective of any RISAS decision making process, an ECM certificate is valid for a maximum of five years, with surveillance on at least an annual basis.

3 Requirements for RISABs – Competence

3.1 RISAB Assessment team members should have an awareness / understanding of ECM Regulation 445/2011 and associated ERA guidance documents.

3.2 Make up of assessment teams should include the appropriate competency to cover maintenance of freight vehicles. This includes, when appropriate, maintenance of tanks and other specific equipment related to transport of dangerous goods (this includes knowledge of the European legislation (Dangerous goods directives and relevant regulations such as RID)).

4 References

Commission Regulation (EU) No. 445/2011 (10.5.2011) on a system of certification of entities in charge of maintenance for freight wagons

ERA-GUI-10-2011-SAF-ECM certification - Guide Sectoral Accreditation Scheme

ERA-GUI-09-2011-SAF-ECM certification - Guide ECM certification scheme

ERA-GUI-11-2011-SAF-ECM certification - Guide maintenance workshop certification scheme

5 Definitions

5.1 The main definitions of terms used in RISAS are contained in RISAS/001, Principles of RISAS.

Contact:

In the event of any queries on this Briefing Note, please contact:
John Barber at RSSB on 020 3142 5588,
or by e-mail to john.barber@rssb.co.uk

Signature/Name

J Barber
(Principal Assurance Engineer)

Appendix – Requirements arising from the ECM Scheme (as defined in the ECM Regulations 445/2011/EU and the ERA Guidance documents) to be addressed in addition to the RISAS Supplier Assessment Module outlined in RISAS/003 (issue 4)

RISAS/003 Reference	Subject area	ECM Reference	Additional Assessment Required
A.2.1.4	'Engineering Change' supplier	ECM Regs, Annex III.II.2(d)-(e) (Development Function (ECM Part II) issue only)	The requirements stated in this section of Annex III imply that to undertake the maintenance development function requires a supplier of 'Engineering Change' status. This should be clarified when considering the scope of assessment.
A.2.2.1 & 2.3.6	Preparation for assessment (documentation / information)	ERA Sectoral guide 3.2.2.3.1 – initial assessment stage 1	<p>The ECM scheme requires there to be: 'an examination of the relevancy of the documents to the requirements for certification as stated in the ECM regulation 445/2011. The audit team shall audit that all the procedures put in place by the ECM in its maintenance system are in conformity with the requirements of annex III of the ECM regulation 445/2011 and are established, documented and reviewed regularly.'</p> <p>The following clarification is given: 'In some situations, this examination may be deferred until the on-site activities start, if this is not detrimental to the effectiveness of the conduct of the audit. In other situations, a preliminary site visit may be conducted to obtain a suitable overview of available information.'</p> <p>RISABs should note that many of the requirements of ECM start with 'The organisation must have a procedure to...', hence identification and acceptance of procedural documentation is an important aspect of an ECM assessment. If the documentation is inadequate then a decision should be taken as to whether the full assessment should be undertaken or suspended until the documentation issues are resolved.</p>
A.2.2.4	Sub-supplier activity	ECM Regs, Article 4(3)&(4) (Management Function (ECM Part I) issue only)	The Regs permit the ECM to outsource any of the Part II, III or IV maintenance functions. Where the ECM relies heavily on outsourcing, then assessment of the ECM's procurement activities (including monitoring of performance) becomes a critical part of the assessment team and the RISAB should recognise this in the make-up of the assessment team (ref BN-007).
A.3.1.2	Interview with senior management	ECM Regs, Annex III.I.1	Interview with senior management should include reference to maintenance policy and safety targets.
A.4.4.1	Surveillance	ERA Sectoral guide 3.2.2.5.1 – Surveillance – Assessment	<p>The ECM Scheme is quite specific regarding the requirements for surveillance and, to support a certificate validity of 5 years, requires an annual surveillance audit. The minimum requirement is that all permanent sites have to be audited at least once during the validity period of the certificate. This can include the 'man in a van' scenario where associated with such a site.</p> <p>The scope of the surveillance activities should reflect the content of the annual report (see below).</p>

RISAS/003 Reference	Subject area	ECM Reference	Additional Assessment Required
A.4.4.1	Surveillance	ERA Sectoral guide 3.2.2.5.2 – Surveillance – Report	<p>As part of surveillance, the scheme requires an annual report to be provided by the ECM (or ECM provider). The minimum requirements for the report are:</p> <ul style="list-style-type: none"> - Explanations and justification on how non-conformities have been undertaken and/or solved - Information on volume of maintenance carried out during the prevailing period - Changes related to: <ul style="list-style-type: none"> • Legal ownership of the company • Organisation (procedures in place) • Vehicles for which the ECM is in charge of maintenance • Sites and contractors including processes and equipments • Contractual arrangements with users • Maintenance system including the ECM management functions and the three maintenance functions • Defects and failures <i>including information exchanged against article 5(5) of the ECM regulation*</i> • Internal audit reports • NSA and other authorities enforcement actions/investigations including claims according to article 9 of the ECM Regulation • Competence management. <p>(*currently (July 2015) subject of discussion at EU level as there is presently no means to do this)</p>
B.1(3)	Management organisation	ECM Regs, Annex III.1.5	<p>Assessment against B.1(3) should generally cover requirements of Annex III.1.5 but note the following:</p> <p>5.1. The organisation must have procedures to allocate responsibilities for all relevant processes throughout the organisation.</p> <p>5.3. The organisation must have procedures to ensure that staff with delegated responsibilities within the organisation have the authority, competence and appropriate resources to perform their functions. Responsibility and competence should be coherent and compatible with the given role, and delegation must be in writing.</p> <p>5.5. The organisation must have procedures to hold those with a role in the management of safety accountable for their performance.</p>
B.3(2)	Appropriate management procedures	ECM Regs, Annex III.III.3, 4 & 10(a)	<p>When assessing the fleet maintenance management function:</p> <p>‘The organisation must have a procedure to send freight wagons for maintenance in due time.</p> <p>‘The organisation must have a procedure to manage the removal of freight wagons from operation for maintenance or when defects have been identified.’</p> <p>‘Maintenance orders need to be recorded’</p>
B.3(4)	Compliance with specification(s)	ECM Regs, Annex III.II.2(a)-(c)	<p>When assessing the maintenance development function, this section of Annex III refers to conformity with the essential requirements of interoperability. However, this is only truly relevant for vehicles introduced since RIR2006. This should be clarified when considering the scope of assessment. By analogy, the equivalent requirements for a pre-RIR vehicle are described in GM/RT2004.</p>

RISAS/003 Reference	Subject area	ECM Reference	Additional Assessment Required
B.3(4)	Compliance with specification(s)	ECM Regs, Annex III.II.4(c)	When assessing the maintenance development function, this section of Annex III requires verification that the maintenance file produced has been correctly implemented: 'When freight wagons start operations, the organisation must have procedures to: (c) ensure that the implementation of the first maintenance file is done correctly.'
B.3(4)	Compliance with specification(s)	ECM Regs, Annex III.III.2	When assessing the fleet maintenance management function, 'The organisation must have a procedure for the composition of the work package and for the issue and release of the maintenance order'.
B.3(8)	Facilities, tools and equipment	ECM Regs, Annex III.II.3	When assessing the maintenance development function, the ECM Regs goes further in that it requires confirmation that the facilities, tools and equipment provided are actually being used as intended (on the vehicles).: 'The organisation must have a procedure to design and to support the implementation of maintenance facilities, equipment and tools specifically developed and required for maintenance delivery. The organisation must have a procedure to check that these facilities, equipment and tools are used, stored and maintained according to their maintenance schedule and in conformity with their maintenance requirements.' RISAS Briefing Note BN-001 may be useful in this regard.
B.3(8)	Facilities, tools and equipment	ECM Regs, Annex III.IV.3	When assessing the maintenance delivery function, the requirements are enhanced by requiring that tools and facilities must take into account: (a) the safe delivery of maintenance, including the health and safety of maintenance staff; (b) ergonomics and health protection, also including the interfaces between users and information technology systems or diagnostic equipment.
B.3(8)	Records of work completed	ECM Regs, Annex III.IV.10	When assessing the maintenance delivery function, at least the following elements must be <u>recorded</u> : (a) clear identification of all facilities, equipments and tools related to activities affecting safety;
B.4.2(1)	Required / available documentation	ECM Regs, Annex III.III.8	When assessing the fleet maintenance management function, the following documentation requirements are highlighted (over and above that which would naturally be covered as part of a RISAS assessment): (c) a list of spare parts, including a sufficiently detailed technical description of each part to allow like-for-like replacement with the same guarantees; (d) a list of materials, including a sufficiently detailed description of their use and the necessary health and safety information; (e) a dossier that defines the specifications for activities affecting safety and contains intervention and in-use restrictions for components; (f) a list of components or systems subject to legal requirements and a list of these requirements (including brake reservoirs and tanks for the transport of dangerous goods)

RISAS/003 Reference	Subject area	ECM Reference	Additional Assessment Required
B.5.1(1)	Risk management	ECM Regs, Annex III.1.2	Under the topics of 'Risk assessment', the requirement is for 'a structured approach to assess risks associated with the maintenance of freight wagons, including those directly arising from operational processes and the activities of other organisations or persons, and to identify the appropriate risk control measures' Whilst assessment against B.5.1(1) should generally cover this, there is a specific requirement for: '...procedures to take into account the need to determine, provide and sustain an appropriate working environment which conforms to Union and national legislation, in particular Council Directive 89/391/EEC.'
B.5.1(1)	Risk management	ECM Regs, Annex III.IV.7	When assessing the maintenance delivery function, risk management considerations for the working environment includes '...not only the workshops where maintenance is done but also the tracks outside the workshop buildings and all places where maintenance activities are performed'.
B.5.2(1)	Control of the Supply Chain – Supplier approval	ECM Regs, Article 8(1)	The 'presumption of conformity' principle outlined in B.5.2(1) is considered to be equivalent to the process explained in article 8(1) of the ECM Regs. See also guidance in A.2.2.4 above
B.5.1(3)	Records of work completed	ECM Regs, Annex III.IV.10	When assessing the maintenance delivery function, at least the following elements must be recorded: (d) the results of calibration and verification, whereby, for computer software used in the monitoring and measurement of specified requirements, the ability of the software to perform the desired task must be confirmed prior to initial use and reconfirmed as necessary; (e) the validity of the previous measuring results when a measuring instrument is found not to conform to requirements.
B.6.3	Feedback (information) to customers	ECM Regs, Annex III.I.7.4	As well as communication of information to customers, to cover the ECM requirements, assessment of this section also needs to consider: Communication with all stakeholders affected by the ECM, including vehicle keepers, railway undertakings and the infrastructure manager. With specific reference to freight wagons, information to be communicated includes: <ul style="list-style-type: none"> • information for the national vehicle register*; • information on operations (including mileage, type and extent of activities, incidents/accidents) • emergency information concerning situations where the safe state of running is impaired, which may consist of: <ul style="list-style-type: none"> (i) restrictions for use or specific operating conditions; (ii) urgent information on safety-related issues identified during maintenance • all relevant information/data for the annual surveillance report <p>(*in practice, updating data in RSL discharges this duty)</p>

RISAS/003 Reference	Subject area	ECM Reference	Additional Assessment Required
B.7	Management of competence	ECM Regs, Annex III.1.6.2g	Under Competence management there is an additional requirement to consider: '...special measures in the case of accidents/incidents or long absences from work, as required'.
B.7	Management of competence	ECM Regs, Annex III.II.6(c)	Competence requirements specific to freight vehicles are highlighted as: <ul style="list-style-type: none"> • joining techniques (including welding and bonding); • brake systems; • wheel sets and draw gear; • non-destructive testing techniques and • maintenance activities on specific components of freight wagons for the transport of dangerous goods such as tanks and valves.
B.7	Management of competence	ECM Regs, Annex III.III.7	When assessing the fleet maintenance management function, '...at least the return to operation must be taken into account.' (<i>when considering competence</i>)
B.8	Review and Development	ECM Regs, Annex III.II.5	To keep the maintenance file updated throughout the lifecycle of a freight wagon, the organisation must have procedures to: <p>(a) collect at least the relevant information in relation to:</p> <p>(i) the type and extent of operations effectively performed, including, but not limited to, operational incidents with a potential to affect the safety integrity of the freight wagon;</p> <p>(ii) the type and extent of operations planned;</p> <p>(iii) the maintenance effectively performed;</p> <p>(b) define the need for updates, taking into account the limit values for interoperability;</p> <p>(c) make proposals for and approve changes and their implementation, with a view to a decision based on clear criteria, taking into account the findings from risk assessment;</p> <p>(d) ensure that the implementation of changes is done correctly.</p>
B.8(2)	Records of work completed	ECM Regs, Annex III.IV.10	When assessing the maintenance delivery function, at least the following elements must be <u>recorded</u> : <p>(b) all maintenance works performed, including personnel, tools, equipment, spare parts and materials used and taking into account:</p> <p>(i) relevant national rules where the organisation is established;</p> <p>(ii) requirements laid down in the maintenance orders, including requirements regarding records;</p> <p>(iii) final testing and decision regarding release to service;</p> <p>(c) the control measures required by maintenance orders and the release to service;</p>
B.8(2)	Release to service documentation	ECM Regs, Annex III.III.6, 9 & 10(b)	When assessing the fleet maintenance management function: <p>The organisation must have a procedure to issue (<i>and record</i>) a notice to return to operation, taking into account the release to service documentation</p> <p>This procedure '... including restrictions on use relevant to users (railway undertakings and infrastructure managers), needs to be communicated to interested parties.'</p>