

CRR-G-027-B

Guidance for CRR Inspectors, Railway Undertakings, Infrastructure Managers and Applicants for ECM Certification

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1 Introduction

This Document is intended to give guidance and explanation on the related European legal provisions for the Certification of ECMs. It cannot replace additional self-study of the applicable legal documentation.

According to article 14a of the Railway Safety Directive 2004/49/EC: “Each vehicle before it is placed in service or used on the network, shall have an entity in charge of maintenance assigned to it and this entity shall be registered in the NVR”. Further to this; “In the case of freight wagons, each ECM shall be certified by a body accredited or recognised”.

Accordingly in the case of freight wagons (Regulation 445/2011 applicable to freight and hauled OTMs) their ECMs must have been certified independently by an ECM Certification Body by 31.05.2013. For these ECMs the CRR is offering to perform the compulsory European ECM Certification Scheme.

All other ECMs must ensure by their own management activities, full compliance with the relevant EU legal provisions. In accordance with 2004/49/EC Articles 4.3 & 4.4 an ECM must in this regard closely cooperate with the RU(s) which are operating the maintained vehicles. For these ECMs the CRR is offering a National ECM Certification Scheme (ECM Attestation).

2 Abbreviations and Definitions

Term / Abbreviation	Meaning
Applicant	The organisation applying for ECM certification at the CRR.
Certification Committee	The Committee established by the certification body for delivering an opinion on which the certification decision is taken by the certification body.
CRR	Commission for Railway Regulation, formerly the Railway Safety Commission (Irish NSA)
CSM-AB	Assessment Body to CSM 352/2009, providing CSM-AB-Report
First Maintenance File	EU vocabulary: First operative revision of the Maintenance File. This is the First complete revision of the Maintenance File for a new type of vehicle based on which maintenance activities may be performed. An ECM must endorse/ produce this for any new vehicle type (445/2011, Annex III, (II) 4. (a) & (b)) (see chapter 5.1 below).
FMM	Fleet Maintenance Management function, see section 4.3
Focus Sheet	Listing of audit stage 2 priority auditing topics. This is a risk based approach to target the audit activities based on; the initial audit stage 1 findings and public information on railway safety.
IM	Authorised Infrastructure Manager to RSD
Initial Maintenance File	EU vocabulary: Initial revision of the Maintenance File for a new vehicle type, which the manufacturer is expected to provide in the Technical File. Based on this initial file the ECM Maintenance Development Function must develop a First Maintenance File (445/2011, Annex III, (II) 4. (a)) (see chapter 5.1 below).
IOD	2008/57/EC Interoperability Directive, including Amendments
Maintenance File	EU vocabulary (see chapter 5.1 below).
Mandatory Standard	EU vocabulary: Standard or part thereof and its revision as referenced in a TSI. The use of this Standard in this Revision is mandatory under IOD.
Module	EU vocabulary: Assessment Procedure as defined and permitted in a TSI in combination with 2010/713/EU.
NoBo	Notified Body
NSA	National Safety Authority
NSR	National Safety Rule (Safety Rule applicable to all RU/IM in the State)
NTR	National Technical Rule (applicable in the State in all cases where no TSI is applicable, or where a NTR defines specific characteristics for technical compatibility and safe integration of subsystems with the Irish railway network)
OTM	On Track Machine
PIS	Placing in Service (by RU/IM), after APIS has been granted and after all RU/IM SMS activities relating to this project are concluded
Railway Undertaking to RSA	Railway Undertaking to RSA, organisation performing tasks of RU or IM

Term / Abbreviation	Meaning
RFU	Recommendation for Use regarding TSIs, issued by NB RAIL the Coordination group of Notified Bodies 2008/57EC. See NB-Rail homepage (http://circa.europa.eu/irc/nbg/nbrail/info/data/en/information/nbrail/RFU.htm)
RSA	Railway Safety Act 2005, including Amendments
RSD	2004/49/EC Railway Safety Directive, including Amendments
RST	Rolling Stock
RU	Certified Railway Undertaking to RSD
RU/IM	In the interest of readability in this Guidance the term RU/IM shall include RU or IM (to RSD) or Railway Undertaking (to RSA) as relevant.
SC	Safety Case, (where this term is used, it is understood to have meaning of EN50126/128/129, and not the meaning of a 'Railway Undertaking Safety Case' as defined by RSA (which is equivalent to an SMS to RSD).
SCM	Safety and Compliance matrix
SMS	Safety Management System - The term SMS shall include SMS (to RSD) or Safety Case (to RSA) as relevant.
SP	Safety Plan
Subsystem	Legally defined sub-element of the Rail System, see IOD, Annex II
TAF	Telematic Applications Freight
TAP	Telematic Applications Passengers
TD	ERA Technical Document, may be called up by a TSI or other EU legislation to further define certain requirements. Use search function of ERA homepage to find TDs (http://www.era.europa.eu/Search/Advanced-Search/Pages/home.aspx)
Technical File	Documented evidence demonstrating compliance with national requirements. (See also RFU-STR-011.)
TO	ERA Technical Opinion, may provide additional clarification on certain parameters of a TSI. See ERA homepage (http://www.era.europa.eu/Core-Activities/Interoperability/Pages/INT-TO.aspx)
V&V	Verification and Validation as defined by EN 50126-1/-2, EN50128, EN50129. This may include activities of Testing and Commissioning.
Voluntary Standard	EU vocabulary: Standard or part thereof proposed by ERA or EU within the Official Journal of the EU in relation to IOD. Its application allows a direct presumption of conformity with the Essential Requirements of the IOD. The applicant can choose whether or not to apply a Voluntary Standard. However, if the applicant chooses not to apply a Voluntary Standard, he/she has the obligation to prove that the subsystem/IC is in conformity with Essential Requirements by the use of other defined means of his own choice. (The Voluntary Standards or the related other defined means used to demonstrate compliance must be declared in the EU Technical File.)

3 References

/2004/49/EC/	DIRECTIVE 2004/49/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) Amended by: /2008/110/EC/ and /2009/107/EC/
/2008/110/EC/	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)
/2011/291/EU/	COMMISSION DECISION of 26 April 2011 concerning a technical specification for interoperability relating to the rolling stock subsystem — 'Locomotives and passenger rolling stock' of the trans-European conventional rail system (2011/291/EU)
/2009/149/EC/	COMMISSION DIRECTIVE 2009/149/EC of 27 November 2009 amending Directive 2004/49/EC of the European Parliament and of the Council as regards Common Safety Indicators and common methods to calculate accident costs
/2008/57/EC/	DIRECTIVE 2008/57/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 June 2008 on the interoperability of the rail system within the Community, as amended by 2009/131/EC, 2011/18/EU
/321/2013/	COMMISSION REGULATION (EU) No 321/2013 of 13 March 2013 concerning the technical specification for interoperability relating to the subsystem 'rolling stock — freight wagons' of the rail system in the European Union and repealing Decision 2006/861/EC
/2007/756/EC/	Commission Decision on NVR 2007/756/EC , as amended by 2011/107/EU
/2011/665/EU/	COMMISSION Decision, 2011/665/EU, ERATV
/RSA2005/	Act Number 31 of 2005, RAILWAY SAFETY ACT 2005 , including Amendments
/SI61/2008/	S.I. No. 61 of 2008, EUROPEAN COMMUNITIES (RAILWAY SAFETY) REGULATIONS 2008
/SI70/2011/	S.I. No. 70 of 2011 EUROPEAN COMMUNITIES (RAILWAY SAFETY) REGULATIONS 2011
/445/2011/	COMMISSION REGULATION (EU) No 445/2011 of 10.05.2011 on a system of certification of entities in charge of maintenance for freight waggons and amending regulation (EC) No 653/2007
/ERA-GUI-09/	ECM Certification, Application Guide including explanations, ECM certification scheme, ERA-GUI-09-2011-SAF-ECM
/ERA-GUI-10/	ECM certification, Application guide with additional explanations, Sectorial Accreditation Scheme, ERA-GUI-10-2011-SAF-ECM
/ERA-GUI-11/	ECM certification, Application guide including explanations, Maintenance workshop certification scheme, ERA-GUI-11-2011-SAF-ECM
/ERA-GUI-100/	ERA GUI 100 2013 Guide for the application of the Art 14 (a) of the Safety Directive and Commission Regulation (EU) No 445/2011 on a system of certification of entities in charge of maintenance for freight wagons
/1078/2012/	COMMISSION REGULATION (EU) No 1078/2012 of 16 Nov 2012 , CSM Monitoring
/1077/2012/	COMMISSION REGULATION (EU) No 1077/2012 of 16 Nov 2012 , CSM Supervision
/EWT/	EUROPEAN WHEELSET TRACEABILITY (EWT) FOR FREIGHT WAGON AXLES
/EWT-guide/	EUROPEAN WHEELSET TRACEABILITY (EWT) IMPLEMENTATION GUIDE FOR FREIGHT WAGON AXLES
/EVIC/	EUROPEAN VISUAL INSPECTION CATALOGUE (EVIC) FOR FREIGHT WAGON AXLES
/EVIC-guide/	EUROPEAN VISUAL INSPECTION CATALOGUE (EVIC) IMPLEMENTATION GUIDE FOR FREIGHT WAGON AXLES

/GCU/	GENERAL CONTRACT OF USE FOR WAGONS GCU Edition dated 1 January 2013 (especially chapters 9/10/11)
/352/2009/	/352/2009/ has been replaced by /402/2013/
/402/2013/	REGULATION (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009
/EN 50126-1/	Railway applications – The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 1: Basic requirements and generic process
/EN 50126-2/	Railway applications – The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS),- Part 2: Guide to the application of EN 50126-1 for Safety
/EN 50128/	Railway applications- Communications, signalling and processing systems – Software for railway control and protection systems
/EN 50129/	Railway applications – Communication, signalling and processing systems – Safety related electronic systems for signalling
/ISO 17020/	Conformity assessment – General criteria for the operation of various types of bodies performing inspection
/ISO 17021/	Conformity assessment - Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021:2011) (ISO/IEC 17021:2015)
/ISO 17025/	General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)
/ISO 9001/	Quality management systems - Requirements (ISO 9001:2008) (ISO 9001:2015)
/19011:2011/	EN ISO 19011:2011 Guidelines for auditing management systems
Note:	References to TSIs are not provided here, as they are in constant evolution. Please use search function of ERA homepage to find relevant TSIs (http://www.era.europa.eu/Search/Advanced-Search/Pages/home.aspx)

4 Definitions: ECM functions

According to Section 4 of the Regulation 445/2011/EU, the maintenance system shall be composed of the following functions:

- a) the management function, which supervises and coordinates the maintenance functions referred to in points (b) to (d) and ensures the safe state of the freight wagon in the railway system;
- b) the maintenance development function, which is responsible for the management of the maintenance documentation, including the configuration management, based on design and operational data as well as on performance and return on experience;
- c) the fleet maintenance management function, which manages the freight wagon's removal for maintenance and its return to operation after maintenance; and
- d) the maintenance delivery function, which delivers the required technical maintenance of a freight wagon or parts of it, including the release to service documentation.

4.1 ECM Management Function

According to section 4.10 of ERA-GUI-100:

The Management Function a) shall supervise and coordinate the functions b), c), and d) of the ECM and ensure the **safe state of the vehicles**.

The Management Function has two main tasks:

- **Coordination** of the functions b, c and d, as defined in the article 4.1, allowing the organization to achieve the maintenance targets defined in the Maintenance System (e.g. in the Maintenance Policy);
- **Supervision** of the of the functions b, c and d, as defined in the article 4.1, granting the conformity against legislation and standards and allowing the organization to improve its Maintenance System.

The **safe state of vehicles** can be ensured through a suitable vehicle design in combination with the implementation and the continuous review and improvement of the Maintenance System.

The **coordination** activities shall be performed according to processes and procedures defined within the Maintenance System, those provisions shall take into account the use of contractors, the allocation of responsibilities, the management of competence of the staff, the definition of strategies and plans to define and to achieve the maintenance targets, etc.

The Management Function oversees the implementation of the Maintenance System by a systematic monitoring process, which shall be based on the CSM for Monitoring (Commission Regulation 1077/2012) to check the performances of the ECM in the field of maintenance and safety. As required, the Management Function creates the conditions to correct or to improve the Maintenance performances, defining and implementing changes in the Maintenance System. Those changes shall be managed according to the CSM for Risk Assessment.

A decision making process should be managed by the Management Function on the basis of the results of the assessments of shared and owned risks. The CSM for Risk Assessment shall be used to define the Risk Management Process used to identify and control those risks.

The management function is defined in the Commission Regulation 445/2011 in the Art. 4.1.a with further information provided in to section 4.10 of ERA-GUI-100.

4.2 ECM Maintenance Development Function

According to section 4.11 of ERA-GUI-100:

The maintenance development function covers the management of the maintenance file, including the configuration management, based on design and operational data as well as on required performance and return on experience for all vehicles managed by the ECM. This function is responsible for the distribution of these files and their updates to interested parties

It also ensures compliance with good industry practice, interoperability and the necessary establishment and continuous update of the maintenance file.

This function includes the technical management of non-scheduled maintenance e.g. casualty repairs and renewal within the scope of maintenance. Further tasks are the definition and approval of spare parts and suppliers or alteration of maintenance intervals or procedures.

Further information on the Maintenance Development Function can be found in section 4.11 of ERA-GUI-100.

4.3 ECM Fleet Maintenance Management Function

According to section 4.12 of /ERA-GUI-100/:

The Fleet Maintenance Management (FMM) function covers the removal from/return to operation before/after maintenance and the execution of contracts with ECM internal/external entities delivering maintenance.

Return to operation is only possible when maintenance operations are completed and the vehicles are back in a safe state of running. With regard to the exchange of information, the information on the completeness of maintenance activities performed on the vehicle must be received from maintenance delivery, this is done through the release to service. Release to service is the commitment of the maintenance delivery function that the maintenance activities ordered are completed.

This function means in particular the responsibility for:

- Assigning the maintenance instructions contained in the vehicles maintenance files through maintenance orders addressed to the maintenance delivery function.
- Collecting and transferring, to maintenance development, information on maintenance performed and operations performed, including at least defects, incidents, accidents, mileage.

FMM must control the availability of the maintenance delivery.

FMM will have the duty to ensure that maintenance orders are addressed only to duly qualified entities performing maintenance delivery.

FMM is responsible for declaring the wagon fit for purpose and fit for its return to operation after the maintenance work has been completed by the maintenance delivery. This return to operation is finally addressed to RUs generally through the keeper. Further FFM has to distribute all information received from maintenance delivery about limitations and restrictions for use.

Further information on the Fleet Maintenance Management Function can be found in section 4.12 of ERA-GUI-100.

4.4 ECM Maintenance Delivery Function

According to section 4.10 of ERA-GUI-100:

This function covers the provision of suitable workshop facilities, tools and competent staff for the practical execution of maintenance and inspection work. This function performs maintenance based on maintenance orders received and after any performed maintenance this function must update the Maintenance Records and provide these to the fleet maintenance management function.

Further information on the Maintenance Delivery Function can be found in section 4.13 of ERA-GUI-100.

5 Other Guidance and Definitions

5.1 Maintenance File

Maintenance on any vehicle may only be performed based on a current Maintenance File. This must have been authorised/ endorsed by that ECM associated with the vehicle in question. The Maintenance file shall contain all relevant safety related maintenance requirements and information. At the time of writing this guidance references for the contents of the maintenance file could be found in the following documents, however, please refer to the ERA website for updated information:

- TSI CR WAG 321/2013 (4.5) and
- TSI CR LOC/PAS 2011/291/EU (4.2.12.3)

The Maintenance File must be continuously updated (445/2011 Ann III (II) 5) if and as required.

For a new type of vehicle a First (revision of the) Maintenance File shall be developed by the ECM based on the Initial (revision of the) Maintenance File which is typically provided by the vehicle supplier.

Further information on the Maintenance File can be found in section 10 of ERA-GUI-100.

5.2 Maintenance Requirements

This Guide cannot provide a complete listing, however the following should be considered.

5.2.1 General Maintenance Requirements

The following should be considered by all ECMs:

- Annex III of 445/2011,
- Joining techniques (for welding see EN 15085),
- Non-Destructive Testing (NDT) (see ISO 9712),
- Maintenance of braking systems /ERA-GUI-09/,
- Maintenance of wheelsets, running gear and draw gear /ERA-GUI-09/,
- Health and Safety Legislation,
- EMC Directive,
- Simple Pressure Vessels Directive,
- Applicable TSIs,
- Applicable CSMs.

5.2.2 Freight and hauled OTM specific Maintenance Requirements

For maintenance of freight vehicles the following additional items should be considered as good industry practice:

- EWT European Wheelset Traceability for freight wagons
- EVIC European Visual Inspection Catalogue for freight axles
- GCU (especially those parts relating to planning and performance of maintenance)
- RID (Transport of Dangerous goods) if applicable

5.2.3 Other vehicle (Locos, Passenger Stock, OTMs, etc.) Maintenance Requirements

For maintenance of non-freight vehicles the following additional items should be considered at a minimum: electrical systems and circuits, fuel systems, safety related train control functions (door control, multiple unit operation, traction cut-off, emergency lighting, emergency braking, tail lights, electrical breakers, etc.), signalling systems, train radio, fire performance.

5.3 National Vehicle Register (NVR)

The ECM shall ensure that the NVR registration for all vehicles managed by the organisation is available and current.

The information shall be checked/ managed as follows:

- Validity of NVR registration and correctness of NVR data:

- When a vehicle is first managed by an ECM.
- After any change of vehicle owner, keeper or ECM.
- At least once every 12 Months to confirm that no changes are required.
- Directly after the ECM becomes aware about a data inconsistency.
- If any inconsistency or error or missing data is identified, this must be corrected immediately. The ECM must in this case immediately notify the NVR-Registration Entity of all related NVRs (CRR for the NVR in the Republic of Ireland), and the Owner, and the Keeper, and - if safety critical Information was altered also the RU(s) operating the vehicle.

5.4 ECM Annual Report

The purpose of the annual report from the perspective of the certification body is to provide a summary of the ECM activities and changes as listed below for the reported period. This is used to focus the surveillance audit and re-certification activities and in doing so makes these activities more efficient and effective saving time and resources for both the certification body and the ECM. The ECM annual report may also be used by the ECM for management review purposes.

If the ECM annual report fails to provide sufficient detail the CRR will identify to the ECM the areas requiring more detail.

In accordance with /ERA-GUI-09/ 3.2.2.5.1.:

- The ECM annual report shall contain at least:
 - 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;
 - 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 equipment (This shall include changes on the balance internal/external activities related to the three maintenance functions: maintenance development, fleet maintenance management and maintenance delivery.)
 - Contractual arrangements with users (This shall include mainly the keepers. It covers also the exchange of data)
 - Maintenance system including the ECM management functions and the three maintenance functions,
 - Defects and failures including information exchanged against article 5(5) of the ECM regulation.
 - Internal audit reports
 - NSA and other authorities enforcement actions/investigations including claims according to article 9 of the ECM Regulation
 - Competence management.
 - The ECM has to add to the annual report all information he considers relevant for the assessment team.
 - The ECM address the report in due time before the planned surveillance assessment upon an agreement with the certification body.

5.5 Authorisation for Placing Into Service (APIS)

The ECM must ensure full compliance of their maintenance activities with current Irish and European provisions on APIS. This is to ensure that any existing APIS requirements are not violated over time. For any major overhaul constituting 'Renewal' or 'Upgrading' as defined by IOD a new/altered APIS may be required.

Please refer to:

- /445/2011/ Annex III, (II) 2.
- /IOD/
- /RSD/ 4(3) & 6(3)
- /CRR-G-009/
- /RSA/

5.6 ECM Safety management activities

The ECM must as part of their own SMS activities and adopted to their task in principle follow the same requirements which have been set to RU SMS activities as defined by RSD, RSA, CSM 402/2013, EU 1158/2011, EU 1169/2011. It is further considered to be good industry practice to apply EN50126-1/-2, EN50128, EN50129, EN50159-1/-2.

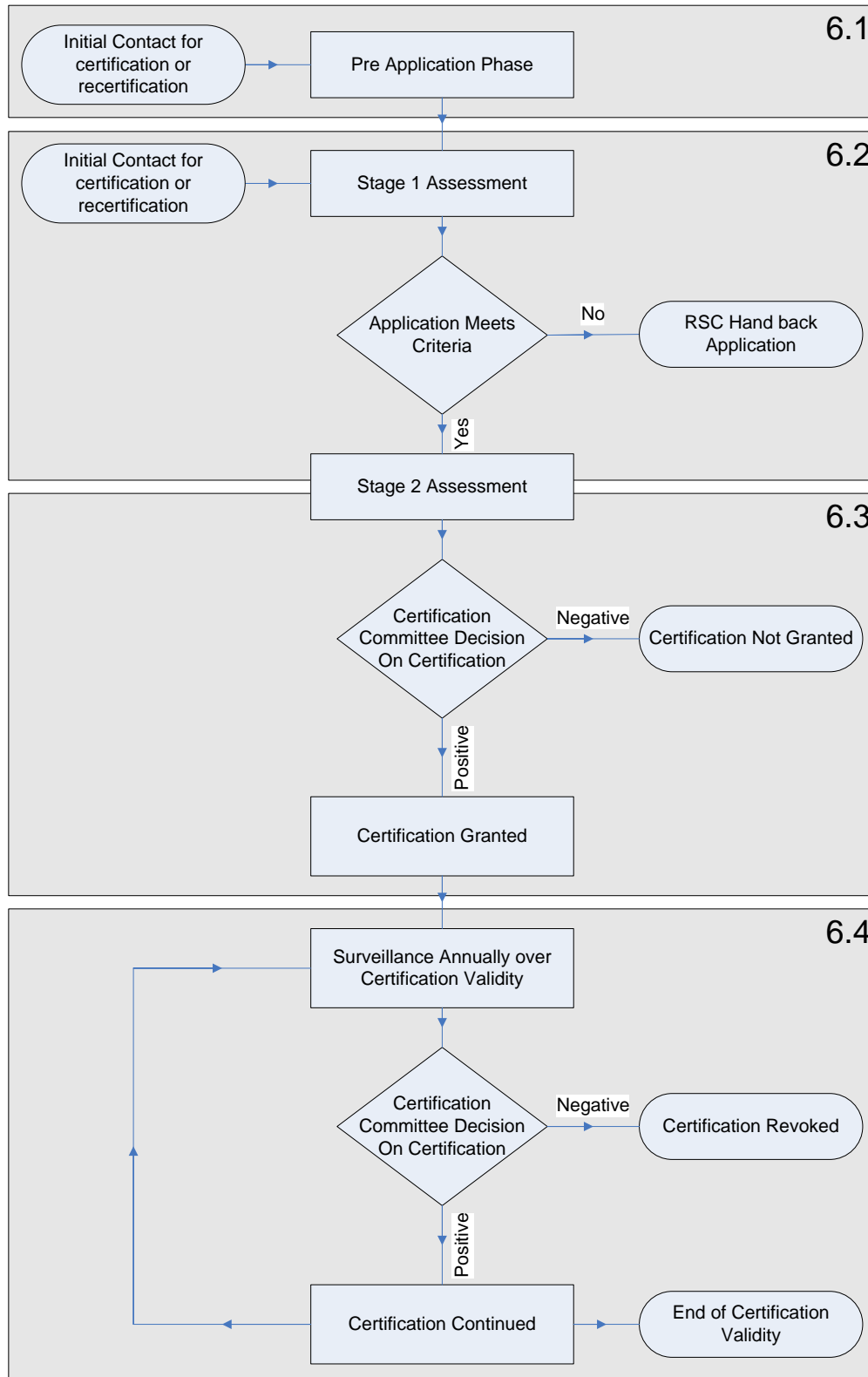
An RU as duty holder must ensure that risks are managed in line with the requirements derived from their certified/authorised RU/IM SMS (RSD 4(3)+6(3)). It is therefore important that any risk management activities performed by the ECM are specifically co-ordinated with that RU which will operate the vehicle.

The above referenced requirements mandate that all involved stakeholders cooperate in delivering the safety management activities. Organisational contractual arrangements in this regard must be documented.

6 Process for Certification as ECM

The CRR is offering the Certification as ECM to any Applicant within the State.

The overview of the CRRs ECM Certification scheme is shown in the Process map below. Each element of the process map is numbered with a reference to a section of this report which describes that element.



6.1 Pre-Application Phase

The applicant makes initial contact with the CRR and requests CRR for performing a pre-application phase prior to ECM certification services.

The CRR provides to the applicant the CRR ECM pre-application form (CRR-F-027), the pre-application checklist (CRR-CL-004) and the list of checklist supporting evidence form (CRR-F-028).

The applicant returns the pre-application form upon which a draft certification programme is developed by the CRR and agreed with the applicant with further communication employed as required.

The applicant completes the 'pre-application checklist' and 'list of checklist supporting evidence form' and return these to the CRR with all supporting documentation.

The CRR will assess the pre-application and may require additional activities to support this assessment, which may include; site visits, interviews with staff, meetings with staff and/or requests for additional documentation.

The CRR will provide a written response to the applicant on their submission. This may be supplemented with a meeting to discuss the feedback.

The applicant may at any time proceed to the application phase, however, it is advisable that the pre-application phase be completed first. Furthermore if the applicant has received negative results for a pre-application submission then this same submission will not be successful if submitted in the application phase.

6.2 Application Phase Stage 1

The applicant makes initial contact with the CRR and requests CRR ECM certification services (may not be required, if already engaged through the pre-application phase).

The CRR provides to the applicant the CRR ECM application form (CRR-F-027), the application checklist (CRR-CL-004) and the 'list of checklist supporting evidence form' (CRR-F-028).

The applicant provides all fully completed forms and checklists according to Annex IV of /445/2011/ to the CRR. These Form Sheets must be submitted with all supporting documentation on the Maintenance Management System. This includes all relevant information according to section 9.2.1. /ISO 17021/ and section 3.2.2.2. of /ERA-GUI-09/. If the applicant has already successfully engaged in the pre-application phase they should use the same application information from their successful pre-application submission (note; the same forms and checklist are used for pre-application and application and as such the check box for pre-application or application within the templates may simply be changed to use the same forms and checklist for both types of submission).

Upon receipt of a complete and valid Application, the CRR will assess the Application initially for plausibility and completeness. The CRR must consider whether the applicant has provided documented evidence against the requirements of 445/2011. This will typically be performed by spot checking of the submitted documentation. If this does not permit a conclusive judgement, the CRR may require additional activities to support this assessment, which may include; site visits, interviews with staff, meetings with staff and/or requests for additional documentation.

If it is not possible for the CRR by these activities, to reach the understanding that the applicant has provided a complete and valid application, the CRR must render the submitted application inadequate and the CRR will hand back the application documents to the applicant.

If the Application is found to be plausible and complete, the CRR will perform a Stage 1 Audit on the Maintenance Management System against the criteria. The CRR may require additional activities to support this assessment, which may include; site visits, interviews with staff, meetings with staff and/or requests for additional documentation.

As before - if it is not possible for the CRR by these activities, to reach the understanding that the applicant has provided a complete and valid application, the CRR must render the submitted application inadequate and the CRR will hand back the application documents to the applicant.

If the Application is found to be acceptable, the CRR will perform a Stage 2 Audit on the effectiveness of the applied Maintenance Management System.

If in the Application or during the Audit falsified evidence is provided the audit will be terminated.

6.3 Application Phase Stage 2

If in the Stage 1 Audit the Application is found to be acceptable, the CRR will perform a Stage 2 Audit on the effectiveness of the applied Maintenance Management System.

The CRR will develop and provide to the applicant a “Focus Sheet” which will outline areas of focus for the stage 2 audit and the basis of these focus areas. The focus areas will be determined by the CRR based on risk assessment which shall take into account at least outcomes and experience from the stage 1 assessment activities, and public information including information on accidents, incidents and previous shortcomings relevant to the applicant available from ERA and NSAs.

The CRR will develop and provide to the applicant an audit plan for the stage 2 audit. In producing this audit plan the CRR will attempt as far as is reasonable to facilitate the availability of the applicant’s staff and facilities. If the applicant fails to provide sufficient access to relevant documentation, staff and facilities required to perform the audit, the audit team may need to defer or stop the audit activities. The stage 2 audit will include at least interviews with relevant staff, sampling of evidence and on-site inspection.

Subsequent to the completion of the stage 2 audit activities the CRR audit team will produce a draft certification report and provide this to the applicant and to the certification committee. The applicant will provide an improvement plan for any identified non-conformities. See section 10 for guidance on non-conformities.

The CRR will then insert the improvement plan into the report or add it to the report as an appendix and will issue the report. The audit report will include the audit findings and a recommendation to the certification committee on whether to grant an ECM certificate.

The certification committee will decide based on the audit report whether to grant an ECM certificate. This certification committee decision may be further informed by meeting with the assessment and/or audit teams.

The certification committee decision on the issuance of a certificate will be communicated to the applicant in writing.

If the certification committee grants an ECM certificate to the applicant the certificate shall be issued to the applicant and a copy shall be uploaded to the European ERADIS database.

6.4 Surveillance Phase

According to the EU requirements, a Certificate may have a maximum validity of 5 years. During this time, at least annually the CRR will have to perform a Surveillance Audit. This shall provide objective evidence, on the ECMs ability to:

- practically apply its certified Maintenance Management System
- continuously update and improve on this system
- update the system where new legislation requires so

Prior to any Surveillance Audit the ECM must provide its annual report to the CRR as ECM-Certification Body. See section 5.4 for guidance on the ECM annual report.

The CRR will determine whether stage 1 audit activities are required based on the extent of changes made to the organisations maintenance management system. Minor changes may be assessed during stage 2 activities, however, major changes to the organisations maintenance management system may require more extensive stage 1 activities or may require a full stage 1 re-assessment.

The CRR will develop and provide to the applicant an audit plan for the stage 2 surveillance audit. In producing this audit plan the CRR will attempt as far as is reasonable to facilitate the availability of the applicant’s staff and facilities. If the applicant fails to provide sufficient access to relevant documentation, staff and facilities required to perform the audit the audit team may need to defer or stop the audit activities. The stage 2 audit will include at least interviews with relevant staff, sampling of evidence and on-site inspection.

Subsequent to the completion of the stage 2 audit activities the CRR audit team will produce a draft certification report and provide this to the applicant and to the certification committee. The applicant will provide an improvement plan for any identified non-conformities. See section 10 for guidance on non-conformities.

The CRR will then insert the improvement plan into the report or add it to the report as an appendix and will issue the report. The audit report will include the audit findings and a recommendation to the certification committee on whether to maintain the ECM certificate.

The certification committee will decide based on the audit report whether to maintain the ECM certificate. This certification committee decision may be further informed by meeting with the assessment and/or audit teams.

If the certification committee decision is to withdraw or place conditions/restrictions of a certificate this will be communicated to the applicant in writing.

7 Re-Certification of an ECM

ECM re-certification will be performed in line with section 6 with the addition that the ECM will provide the ECM annual report as part of the application as well as any other ECM historic documents or records that the certification body deems relevant.

8 Application as part of RU/IM SMS Certification/ Authorisation

If the applicant desires so, the assessment of fulfilment of ECM requirements to 445/2011 may be performed at the same time as certifying/ authorising an RU/IM SMS. In this case the CRR will issue a related Certificate according to 445/2011 Annex VI.

9 Application of CRR-Certification for non-freight ECM activities

The CRR offers a National ECM-Certification Scheme to certify non-freight ECM activities. This applies the same principles as defined in 445/2011. In the case that an application is made for voluntary ECM certification of non-freight wagons this will be performed using the same scheme with the following noted:

- Certification may be referred to as attestation of conformity pending further ERA advice
- All freight terminology and uses of the term wagon within the requirements will be interpreted as the most relevant alternative term. Such as;
 - Wagon will be interpreted to mean vehicle
- Where examples are given in the requirement that only include freight specific items the requirement will also include all other relevant items as applicable to the type of vehicle for which ECM activities are performed. Please see section 5.1.3 for further guidance.

10 Non-Conformities

Non-conformities may be identified during certification or during surveillance activities. Whenever a non-conformity is identified it is issued to the applicant/ECM via a non-conformity form CRR-F-030. When a non-conformity form is issued it will include:

- a reference to the certification/application,
- the specific activity through which the non-conformity was identified,
- the assessment/audit team members involved,
- the specific clause and location concerned, and
- a description of the non-conformity.

After a non-conformity is issued to the applicant/ECM they must state their agreement or otherwise with the finding via the non-conformity form to the CRR.

Once the non-conformity is agreed by the applicant/ECM they must provide an action plan via the non-conformity form to the CRR. An action plan:

- analyses and describes the issue with regard for the scope/extent and the root causes of the issue,
- presents a time bound plan on how the issue will be remedied.

An action plan must:

- analyse the scope of the non-conformity including;
 - the scope as identified during the audit and any other areas that may have be affected by the same or a similar issue,
 - what is affected, procedures, processes, other documents, implementation, etc.,
 - who and where: affected location, departments, and organisations.
- analyse the cause of the non-conformity including;
 - immediate causes,
 - root causes,
 - relevant contributing factors,
- describe a corrective action plan which;
 - fully explains how the non-conformity will be rectified,
 - fully explains how reoccurrence will be avoided,
 - makes reference to any documents which will be changed or developed in order to close the non-conformity,
 - provides a time line for completing these actions in compliance with the relevant ERA guidelines.

The issue may be caused by and/or may effect:

- Documentation/Processes/Procedures:
 - E.g. lack of documented process
 - E.g. ambiguity in process
 - E.g. incomplete process
 - E.g. process impossible to comply with
- Implementation:
 - E.g. process exists but staff did not know about process
 - E.g. process exists but staff did not follow process
 - E.g. process exists but staff could not follow process

When an action plan is provided to the CRR for a non-conformity, a written response will be provided to the applicant/ECM which will either accept or reject the action plan. If the action plan is rejected the reasons will be identified and described. Reasons for rejection of an action plan may be on the bases of incomplete analyses of the scope and/or causes, incomplete actions to completely close the non-conformity and/or a non-conforming due date. If the action plan is accepted the applicant/ECM must provide evidence to the CRR by the action plan due date to demonstrate that the action plan is complete and therefore the non-conformity has been resolved.

This Evidence must be sent as a complete package of evidence against each non-conformity. This package of evidence may be provided via hard or soft copy and must:

- clearly reference the related non-conformity,
- clearly describe how the non-conformity has been resolved,
- contain copies of all relevant procedures,
- contain samples/evidence of any relevant outputs.

When evidence that the non-conformity has been resolved is provided to the CRR a written response will be provided to the applicant/ECM to confirm that the evidence has been sufficient.

Verification is performed at the next onsite activity to re-confirm that the non-conformity has been completely resolved. This is typically performed during surveillance activities.

. If the non-conformity is found to be unresolved at the verification check and the due date for the non-conformity has passed this may result in conditions placed upon a certificate or revoking of a certificate.

11 Complaints Procedure

Complaints and appeals may be made to the CRR via the CRR Service Charter section of the CRR website: (<http://www.crr.ie/about/charter.html>).

12 Further Clarification

Further clarification on these Guidelines and the APIS processes to IOD and RSA can be sought from the CRR.