

Engineering Inspection Plans For Entity in Charge of Maintenance Certificates

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1. Introduction

1.1 On 26 August 2011 the Railways and Other Guided Transport Systems (Safety) (Amendment) Regulations 2011 (the amending regulations) inserted regulation 18A into the Railways and Other Guided Transport Systems (Safety) Regulations 2006 (ROGS). Regulation 18A brings the changes made to the 2004 European Railway Safety Directive into force. It introduces the concept of an entity in charge of maintenance (“ECM”) to ROGS. Each vehicle (including passenger or freight) on the mainline railway in Great Britain has to have an ECM assigned to it and this ECM has to be identified in the National Vehicle Register (“NVR”). Each ECM has to also establish a maintenance system. Please see Chapter 8 of [“A Guide to ROGS”](#) for further information.

1.2 The revised European Railway Safety Directive requires that for freight wagons the ECM must obtain an ECM certificate from a certification body. ORR will act as a certification body for ECM’s for an initial period of two years. The ECM certificate provides evidence that an ECM has established a maintenance system, as set out in European Regulation 445/2011 (the ECM Regulation), which ensures that the freight wagons for which it is responsible are safe to operate. Once issued, an ECM certificate is valid throughout the European Union.

1.3 The ECM Regulation enables an ECM for freight wagons to apply for a certificate from 31 May 2012. All ECM’s for freight wagons must obtain an ECM certificate by 31 May 2013.

1.4 ORR has produced a guidance manual “Entities in Charge of Maintenance Certificate Assessment & Guidance Manual” for applicants which outlines the assessment process associated with obtaining an ECM certificate. This document should be read in conjunction with the guidance manual.

Engineering Inspection Plans

1.5 Engineering Inspection Plans (EIPs) have been developed primarily to achieve consistency for inspectors carrying out engineering inspections and allow for a targeted approach on these inspections. They also form an assessment tool as some evidence may be applicable to more than one clause of the criteria set out in Annex III of the ECM Regulation.

1.6 ORR has assigned EIPs against the clauses of the criteria in Annex III. A table setting out how the EIPs apply to Annex III can be found in Annex A of this document.

1.7 There are 11 EIPs; these are listed below.

- EIP 1: Maintenance & Overhaul Policy
- EIP 2: Competence incl. Selection, Recruitment and Training, Leadership & Competence of Managers

- EIP 3: Maintenance Planning incl. Classified Repairs and Modifications, Safe Systems & Permits to work, Wheel / Rail Interface issues
- EIP 4: Engineering & Organisational Change
- EIP 5: Contracts & Interfaces
- EIP 6: Standards, Procedures & Document Control
- EIP 7: Audit
- EIP 8: Procurement
- EIP 9: Risk Assessment
- EIP 10: Work Equipment
- EIP 11: Performance History

The Assessment Process

1.8 To obtain an ECM certificate, the assessment team will carry out a documentary review & inspections to satisfy themselves that the applicant is demonstrating compliance of the assessment criteria outlined in Annex III of the ECM Regulation 445/2011.

1.9 ORR expects the applicant to state how they believe they meet the requirements of the assessment criteria set out in Annex III of the regulation. The evidence should refer to company procedures and relevant industry standards where appropriate. Applicants can expect to be asked to provide copies of these documents at some stage during the assessment process.

Proportionality

1.10 ORR does not expect all applicants to have every example of evidence listed within an EIP. The assessment team will take into account, the size and nature of an applicant's activities when assessing the evidence provided.

Assessment Timescale

1.11 From receipt of submission of the ECM's application (and after all further information subsequently requested has been received), ORR will have four months in which to carry out assessment of the application and make a decision as to whether an ECM certificate is awarded to the applicant.

EIP summary documents

Annex A – Table listing EIPs clause by clause of criteria in Annex III of the ECM Regulation.

EIP 1: Maintenance and Overhaul Policy

Background

The maintenance (and overhaul policy) is the pivotal policy document, which sets out the management processes on how rail vehicle maintenance is controlled and managed. It is not compulsory, but if adopted, can provide a coherent plan for rail vehicle maintenance under the ECMs direct or third party control.

We are looking for;

- Leadership — *commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness*
- Structure and responsibility — *a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation's safety objectives*

Assignment objectives

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions.

In Particular the organisation must have procedures for:

- Establishing a maintenance policy appropriate to the organisation's type and extent of service and approved by the organisation's chief executive or his or her representative;
- Ensuring the availability of the resources needed to perform all processes to comply with the requirements of this Annex;
- Identifying and managing the impact of other management activities on the maintenance system;
- Ensuring that staff and staff representatives are adequately represented and consulted in defining, developing, monitoring and reviewing the safety aspects of all related processes that may involve staff.

The organisation must have procedures to allocate responsibilities for all relevant processes throughout the organisation.

The organisation must have procedures to clearly define safety-related areas of responsibility and the distribution of responsibilities to specific functions associated with them as well as their interfaces. These include the procedures indicated above between the organisation and the keepers and, where appropriate, transport undertakings and infrastructure managers.

The organisation must have procedures to ensure that staff with delegated responsibilities within the organisation has 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.

The organisation must have procedures to ensure the coordination of activities related to relevant processes across the organisation.

The organisation must have procedures to hold those with a role in the management of safety accountable for their performance.

Examples of evidence

- Shows a policy document and procedure including a statement or reference to the identification of the maintenance plan covered by the maintenance policy and its implementation on all relevant classes of rail vehicles.
- Shows a policy for change, development and implementing maintenance policies and plans.
- Shows a company profile, roles and responsibilities of all the principal organisations - Including an organisational organogram/tree.
- Identifies key roles Inc. Professional Head, job description/duties, delegation
- Shows a policy for setting out competence requirements of those personnel responsible for setting the maintenance policy.
- Shows a statement on the involvement of any third parties
- Shows a method of ensuring that the records of the maintenance of the rail vehicles are established, maintained and retrievable.
- Shows a policy for setting out maintenance facility requirements.
- Shows a policy for setting out regular internal (and where appropriate external) audits are undertaken to check the implementation and continuing effectiveness
- Can demonstrate compliance to national standards

Guidance

- GM/RT2004 - Rail Vehicle Maintenance

EIP 2: Competence

Background

Competence of staff making and implementing safety critical activities and decisions are a key element in maintaining safe traction and rolling stock.

We are looking for:

Leadership — commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness.

Competence management — a structured approach to ensure that employees have the competences required in order to achieve the organisation's objectives safely, effectively and efficiently in all circumstances.

Assignment objectives

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions.

In Particular the organisation must have procedures for:

- setting up a competence management system providing for:
- the identification of posts with responsibility for performing within the system all the processes necessary for compliance with the requirements of this Annex;
- the identification of posts involving safety tasks; and
- the allocation of staff with the appropriate competence to relevant tasks.

Within the organisation's competence management system, there must be procedures to manage the competence of staff, including at least:

- Identification of the knowledge, skills and experience required for safety-related tasks as appropriate for the responsibilities;
- Selection principles, including basic educational level, mental aptitude and physical fitness;
- Initial training and qualification or certification of acquired competence and skills;
- Assurance that all staff are aware of the relevance and importance of their activities and how they contribute to the achievement of safety objectives;

- On-going training and periodical updating of existing knowledge and skills;
- Periodic checks of competence, mental aptitude and physical fitness where appropriate;
- Special measures in the case of accidents/incidents or long absences from work, as required.

When the competence management process is applied to the maintenance development function, at least the following activities affecting safety must be taken into account:

- Assessment of the significance of changes for the maintenance file and proposed substitutions in the course of maintenance;
- Engineering disciplines required for managing the establishment and the changes of maintenance file and the development, assessment, validation and approval of substitutions in the course of maintenance;
- 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.

When the competence management process is applied to the maintenance delivery function, at least the following activities affecting safety must be taken into account:

- (a) joining techniques (including welding and bonding);
- (b) non-destructive testing;
- (c) final vehicle testing and release to service;
- (d) maintenance activities on brake systems, wheel sets and draw gear and maintenance activities on specific components of freight wagons for the transport of dangerous goods, such as tanks, valves, etc.;
- (e) other identified specialist areas affecting safety.

Examples of evidence

- Has the applicant determined and established the requirements for a competence management system (CMS)? Does it assess the competence and fitness by post profile and engineering function, engineering staff and managers who manage and/or influence safety critical activities, staff and contractors?
- Does the CMS deliver the 15 Principles set out in DEVELOPING AND MAINTAINING STAFF COMPETENCE - Railway Safety Publication 1
- Determine if the CMS has been implemented. Is the periodicity of re-assessment based upon the level of risk?
- Determine what medical fitness standards are required for safety critical work and if these are being applied.
- Determine if a training needs analysis is undertaken on a person-by-person basis or task by task basis, and that training and supervision is structured and delivered to underpin competence standards.
- Confirm if the applicant supports and maintains the CMS through continuous professional development or by training through recognised professional bodies, trade associations or other bodies.

- Determine if the applicant has determined a policy / procedure for managing sub-standard performance and restoring competence to satisfactory levels
- Demonstrate how changes in competence requirements resulting from engineering change, modifications, and schedule amendments are identified and implemented.
- Determine if the applicant has determined a policy / procedure for competence for specialised or non-routine activities including abnormal operation and/or out of course activities such as derailment offsite.
- Verify if the applicant exercises control over the contract by specifying the terms and conditions, relating to health and safety, and ensuring that contractor selection is undertaken using appropriate methods by proven competent staff against clear competence standards.
- Determine if the applicant has documented the safety critical systems to which the Competence Management System shall assess.

Guidance

- Regulations 24 and 25 of the Railways and Other Guided Transport Systems (Safety) Regulations 2006
- Developing and Maintaining Staff Competence - Railway Safety Publication 1.

EIP 3: Maintenance Planning

Background

The underpinning activities of ensuring safe plant and equipment in undertaking planned vehicle maintenance in a coordinated and controlled manner to ensure engineering integrity and assurance. Out of course maintenance repairs and modifications can have a dramatic effect on the safety if not properly managed.

Assignment objectives

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions.

In Particular the organisation must have procedures:

- to check the completeness and appropriateness of the information delivered by the fleet maintenance management function in relation to the activities ordered;
- to control the use of the required, relevant maintenance documents and other standards applicable to the delivery of maintenance services in accordance with maintenance orders;
- to ensure that all relevant maintenance specifications in the maintenance orders are available to all involved staff (e.g. they are contained in internal working instructions);
- to ensure that all relevant maintenance specifications, as defined in applicable regulations and specified standards contained in the maintenance orders, are available to all involved staff (e.g. they are contained in internal working instructions); and
- to check that the performed maintenance tasks are in accordance with the maintenance orders and to issue the notice to release to service that includes eventual restrictions of use.

When the risk assessment process is applied to the maintenance delivery function, 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.

When the information process is applied to the maintenance delivery function, at least the following elements must be provided to the fleet maintenance management and maintenance development functions:

- works performed in accordance with the maintenance orders;
- any possible fault or defect regarding safety which is identified by the organisation; and

- the release to service.

When the documentation process is applied to the maintenance delivery function, at least the following elements must be recorded:

- clear identification of all facilities, equipment and tools related to activities affecting safety;
- all maintenance works performed, including personnel, tools, equipment, spare parts and taking into account:
- relevant national rules where the organisation is established;
- requirements laid down in the maintenance orders, including requirements regarding records;
- final testing and decision regarding release to service;
- the control measures required by maintenance orders and the release to service;
- 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; and
- the validity of the previous measuring results when a measuring instrument is found not to conform to requirements.

The organisation must have a procedure to identify and manage all maintenance activities affecting safety and safety-critical components.

When vehicles start operations, the organisation must have procedures to:

- obtain the initial documentation and to collect sufficient information on planned operations;
- analyse the initial documentation and to provide the first maintenance file, also taking into account the obligations contained in any associated guarantees; and
- ensure that the implementation of the first maintenance file is done correctly.

To keep the maintenance file updated throughout the lifecycle of a vehicle, the organisation must have procedures to:

- collect at least the relevant information in relation to:
- 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 vehicle;
- the type and extent of operations planned;
- the maintenance effectively performed;
- define the need for updates, taking into account the limit values for interoperability;
- 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; and
- ensure that the implementation of changes is done correctly.

When the documentation process is applied to the maintenance development function, the traceability of at least the following elements needs to be guaranteed:

- the documentation relating to the development, assessment, validation and approval of a substitution in the course of maintenance;
- the configuration of vehicles, including, but not limited to, components related to safety;
- records of the maintenance performed;
- results of studies concerning return on experience;
- all the successive versions of the maintenance file, including risk assessment;
- reports on the competence and supervision of maintenance delivery and fleet maintenance management; and
- technical information to be provided to support keepers, transport undertakings and infrastructure managers.

The organisation must have a procedure to check the competence, availability and capability of the entity responsible for maintenance delivery before placing maintenance orders. This requires that the maintenance workshops are duly qualified to decide upon the requirements for technical competences in the maintenance delivery function.

The organisation must have a procedure for the composition of the work package and for the issue and release of the maintenance order.

The organisation must have a procedure to send vehicles for maintenance in due time.

The organisation must have a procedure to manage the removal of vehicles from operation for maintenance or when defects have been identified.

The organisation must have a procedure to define the necessary control measures applied to the maintenance delivered and the release to service of the vehicles.

The organisation must have a procedure to issue a notice to return to operation, taking into account the release to service documentation.

When the competence management (CM) process is applied to the fleet maintenance management function, at least the return to operation must be taken into account.

When the information process is applied to the fleet maintenance management function, at least the following elements need to be provided to the maintenance delivery function:

- applicable rules and technical specifications;
- the maintenance plan for each vehicle;
- a list of spare parts, including a sufficiently detailed technical description of each part to allow like-for-like replacement with the same guarantees;
- a list of materials, including a sufficiently detailed description of their use and the necessary health and safety information;
- a dossier that defines the specifications for activities affecting safety and contains intervention and in-use restrictions for components;

- 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); and
- all additional relevant information related to safety according to the risk assessment performed by the organisation.

When the information process is applied to the fleet maintenance management function, at least the return to operation, including restrictions on use relevant to users (transport undertakings and infrastructure managers), needs to be communicated to interested parties.

When the documentation process is applied to the fleet maintenance management function, at least the following elements need to be recorded:

- maintenance orders; and
- return to operation, including restrictions on use relevant to transport undertakings and infrastructure managers.

Examples of evidence

- Shows a maintenance plan for each vehicle exists including a sufficiently detailed a list of tasks and spare parts (with a description of each part to allow like-for-like replacement) so not as to compromise safety.
- Shows the maintenance plan limits are clear and unambiguous and are being controlled.
- Shows the adequacy of procedures to show how maintenance tasks are devised/monitored/supervised/assessed to confirm that tasks are being carried out correctly i.e. schedule or that tasks are correctly/feasibly described in the schedule.
- Shows how vehicles are removed from service and what processes are in place to allow vehicles back into service.
- If limitations are applied, how are they managed and controlled.
- Shows if the maintenance plan is certificated or verified by a third party and if so to what standard or process.
- Shows that the maintenance plan delivers suitable levels of safety performance.
- Shows for those vehicles that have been authorised that they meet the requirements of the relevant TSIs.
- For those vehicles subject with a Technical File, where the file is kept and how it is updated
- For those vehicles subject with a Technical File, what limitations are imposed and how they are being complied with.
- Shows that sufficient time is being allocated to the maintenance allocation in order to undertake essential safety checks and repairs.
- Show how maintenance responsibilities are being delegated and managed and how these being controlled are. How are derogations or non-conformities being managed.
- Shows how feedback on maintenance plans exist and how this gets incorporated into the review process, and how staff participates in such a scheme.

- Shows how engineering change (to the plan) is being properly controlled.
- Shows a procedure or system to ensure vehicle defects are identified, examined and follow up action is implemented.
- Shows how the deferral of safety critical work is controlled, and the robustness of the application through adequate management procedures.
- Shows how deferred work is identified as safety critical
- Shows how vehicle repairs are being carried out, tested and approved in accordance with established engineering good practise and documented processes.
- Shows how engineering best practise is being adopted, particularly using mechanical tools, fasteners, adhesives and greases.
- Shows how repairs are being carried out in a timely effective manner using good engineering practise techniques and methods.
- Shows how near misses due to engineering reasons are being investigated.
- Shows how the integrity of planned maintenance scheduling (paper/electronic databases) in accordance with exam philosophy to reflect best safety practise.
- Shows the effectiveness of the audit programme on maintenance planning
- Shows how exam documentation is being controlled by adequate management procedures.
- Shows how supervision of work in progress is being exercised and those safe systems of work are being developed and implemented.
- Shows how the level of mechanical integrity, the balance of staff (with sufficient knowledge and skill) and engineers with expert knowledge.
- Shows how the maintenance facilities support maintenance activities.
- Shows how the applicant has a management process for controlling modifications and repairs
- Shows how those modifications are being subject to peer review through scrutiny and engineering acceptance process.
- Shows that records are being kept
- Shows that drawings, documents, schedules are up to date as a consequence of a maintenance or repair procedure
- Shows how modifications and repairs are being implemented under a safe system of work and appropriate risk assessment to ensure that the effect of the repair modifications does not adversely affect safety.
- Shows how axles and bearings are being maintained in accordance with standards and rules and associated competencies are also being maintained
- Shows how wheel profile management is being utilised to best effect. Flange height/thickness/tread hollow wear etc.
- Shows how out of course repairs such as tyre turning, and activities for example axle box detection and wheel chex activations are being adequately managed.

- Shows how Non-Destructive Testing, is being carried in accordance with rules and standards according to best practise.
- Shows how classified and non-classified repairs including jointing techniques are being managed and controlled.
- Shows how wheel set damage is being identified, recorded, and appropriately actioned as to maintain safety of freight wagons.
- Shows how frame twist is being identified, recorded, and appropriately actioned as to maintain safety of freight wagons
- Shows how good practise in storing axle bearings and wheel sets is carried out to prevent damage to bearings.
- Shows level of 'intelligent' interrogation by Wheelchex, padview, treadview, roundchex, etc.

Guidance

- TN – 006 Issuing Certificates of Engineering Acceptance
- TN – 028 Minor Repairs
- GM/RC2515 Code of Practice - Engineering Development of Rail Vehicles
- GM/RT2000 Engineering Acceptance of Rail Vehicles
- GM/RT2004 Requirements for Rail Vehicle Maintenance
- RIS-2701-RST Certification Processes for NDT Operatives, Equipment and Facilities used for inspecting Rail Vehicles
- GMGN2646 Guidance on Axle Bearing Maintenance
- GE/RT8040 [Low Adhesion between the Wheel and the Rail - Managing the Risk](#)
- GM/RT2466 [Railway Wheel sets](#)

EIP 4: Engineering and Organisational Change

Background

Engineering and Organisational Changes documents how change particularly to safety critical services and systems are managed. Risks from change needs to be identified and thought through to ensure safety levels are not compromised.

Assignment objectives

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions.

In Particular the organisation must have procedures:

- to manage changes in equipment, procedures, organisation, staffing or interfaces, and to apply Commission Regulation (EC) No 352/2009 (the common safety method for risk evaluation and assessment);
- to manage any substitution in the course of maintenance in compliance with the requirements of the Directive 2008/57/EC (transposed in Great Britain as the Railways (Interoperability) Regulations 2011) and the relevant TSIs;
- to identify the need for risk assessment regarding the potential impact of the substitution in question on the safety of the railway system;
- to assess the significance of changes for the maintenance file and proposed substitutions in the course of maintenance;
- to identify documentation relating to the development, assessment, validation and approval of a substitution in the course of maintenance;
- to define the need for updates, taking into account the limit values for interoperability;
- to ensure that the implementation of changes is done correctly; and
- to ensure the configuration of vehicles, including, but not limited to, components related to safety.

Examples of evidence

- Change policy document and procedure including a statement on how change is identified and implemented on all relevant classes of vehicles and services.
- Defines change including what is significant and material.

- Shows an implementation strategy document on how change will be managed.
- Has a recognised or systematic process or approach that utilises standards or guidance.
- Determines the competence of those personnel responsible for setting and implementing change including involvement of any third parties.
- Has a policy for change, development and implementing maintenance policies and plans through Engineering change.
- Recognises changes to maintenance or facilities requirements, safe systems of work or risk assessments
- Recognises changes to internal (and where appropriate external) audits are undertaken to check the implementation and continuing effectiveness
- Recognises changes to procurement including handling, storage and transportation.
- Demonstrate that modifications and repairs are being implemented under a safe system of work and appropriate risk assessment to ensure that the effect of the repair modifications does not adversely affect safety.
- Demonstrate that records are being kept including but not exclusively safety/risk assessment, design information drawings, parts lists, implementation instructions special maintenance instructions operating instructions test reports
- Demonstrate that said documents such as drawings, documents, schedules are up to date as a consequence of an engineering change through MICE procedure

Guidance

- GM/RT2004 - Rail Vehicle Maintenance
- GM/RC2515 Code of Practice - Engineering Development of Rail Vehicles
- GM/RT2000 Engineering Acceptance of Rail Vehicles

EIP 5: Contracts and Interfaces

Background

Safety Critical train-borne components, sub-systems, vehicle systems and whole vehicles are often sub-contracted out to provide engineering and economic betterment. There is a necessity to check not only the individual but also sum of the components and functions carried out by contractors.

Contracting activities — a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation's objectives to be achieved

Assignment objectives

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions.

In Particular the organisation must have procedures in place:

- to ensure that safety related products and services are identified;
- that, when making use of contractors and/or suppliers for safety related products and services, the organisation has procedures in place to verify at the time of selection that:
 - (i) contractors, subcontractors and suppliers are competent; and
 - (ii) contractors, subcontractors and suppliers have a maintenance and management system that is adequate and documented.
- to define the requirements that such contractors and suppliers have to meet;
- to monitor the awareness of suppliers and/or contractors of risks they entail to the organisation's operations;
- that when the maintenance/management system of a contractor or supplier is certified, the monitoring process described in Section 3 – Monitoring in Annex A may be limited to the results of the contracted operational processes referred to in Section 3.1(b);
- that (at least) the basic principles for the following processes must be clearly defined, known and allocated in the contract between the contracting parties; and
- that responsibilities and tasks relating to railway safety issues, obligations relating to the transfer of relevant information between both parties and traceability of safety-related documents are identified.

Examples of evidence

- Has a policy document and procedure including how suitable service and contract organisations are identified and selected. Has a recognised or systematic process to show what processes are used.
- Defines what is a safety critical service or product
- Shows an implementation strategy on how the requirements of technical and safety, statutory and mandatory requirements are managed.
- Shows how the applicant exercises control over the contract by specifying the terms and conditions, relating to health and safety, and ensuring that contractor selection is undertaken using appropriate methods by proven competent staff against clear competence standards.
- Demonstrates that adequate assessment and monitoring activities are undertaken of contractors to ensure competence (and where appropriate fitness) of contractor staff. How are these competencies assessed?
- Demonstrate how safety performance targets are set and monitored for sub-contractors.
- Demonstrate how sub-contractors control and maintain their safety performance targets.
- Shows effective planning in place to show how risks have been identified, and how the applicant has made liaison arrangements to co-ordinate activities, such that the interfaces between tasks are properly taken into account, especially where risk controls need more than one party to fulfill part of the control function.
- Demonstrates effective liaison and contract review processes between all contractors, which might impact on each other, and for making changes in methods as a consequence.
- Demonstrate effective control of access by contractors to work areas and facilities
- Has a procedure for dealing with emergencies whilst work is being undertaken.
- Has procedures in place to preserve evidence that may be required as part of an investigation.
- Has a system or process to link the applicant and contractor risk assessments, and any changes in operation needed by either party in the light of specific tasks and risks.
- Has sufficient process to adequately monitor contractors when they start on site and communicating site roles and safety hazard information.
- Has procedures in place to eliminate or reduce risk not merely transfer it to contractors and that the applicant must show how they exercise control over the contract by specifying the terms and conditions, relating to health and safety, and ensuring that contractor selection is undertaken using appropriate methods by proven competent staff against clear competence standards.

Guidance

None specified.

EIP 6: Standards, Procedures and Document Control

Background

Industry and company standards, and other semi-quasi sources, along with other processes and procedures is core to engineering activities to ensure minimum standards are met, and best practise applied.

Assignment objective

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions.

In Particular the organisation must have procedures:

- that show a structured approach to ensure the traceability of all relevant information
- that show a structured approach to ensure that important information is available to those making judgments and decisions at all levels of the organisation
- to define reporting channels to ensure that, within the entity itself and in its dealings with other players, including infrastructure managers, railways undertakings and keepers, information on all relevant processes is duly exchanged and submitted to the person having the right role both within its own organisation and in other organisations, in a prompt and clear way.
- to ensure an adequate exchange of information, the organisation must have procedures for:
 - the receipt and processing of specific information;
 - the identification, generation and dissemination of specific information;
 - making available reliable and up-to-date information.
- to ensure that key operational information is:
 - relevant and valid;
 - accurate;
 - complete;
 - appropriately updated;
 - controlled;
 - consistent and easy to understand (including the language used);

- made known to staff before it is applied;
- easily accessible to staff, with copies provided to them where required.
- that checks of the accuracy and completeness of national vehicle registers regarding the identification (including means) and registration of the vehicles are maintained by the organisation;

For maintenance documentation:

- Information on support provided to keepers and, where appropriate, to other parties, including transport undertakings/infrastructure managers;
- Information on the qualification of staff and subsequent supervision during maintenance development;
- Information on operations (including mileage, type and extent of activities, incidents/accidents) and requests of transport undertakings, keepers and infrastructure managers;
- Records of maintenance performed, including information on deficiencies detected during inspections and corrective actions taken by transport undertakings or by infrastructure managers such as inspections and monitoring undertaken before the departure of the train or en route;
- Release to service and return to operation;

For maintenance orders;

- Technical information to be provided to transport undertakings/infrastructure managers and keepers for maintenance instructions;
- Emergency information concerning situations where the safe state of running is impaired, which may consist of:
 - (i) The imposition of restrictions of use or specific operating conditions for the vehicles maintained by the organisation or other vehicles of the same series even if maintained by other entities in charge of maintenance, whereby this information should also be shared with all involved parties;
 - (ii) Urgent information on safety-related issues identified during maintenance, such as deficiencies detected in a component common to several types or series of vehicles;
- All relevant information/data needed to submit the annual maintenance report to the certification body and to the relevant customers (including keepers), whereby this report must also be made available upon request to national safety authorities.

The organisation must have adequate procedures in place to ensure that all relevant processes are duly documented to:

- regularly monitor and update all relevant documentation;
- format, generate, distribute and control changes to all relevant documentation;
- receive, collect and archive all relevant documentation

Examples of evidence

- Has a method of developing and unifying of standards and processes to ensure risk is managed.

- Shows that a document control process is in place, which ensures there are recognised points of entry for all documents and standards. What records are retained of the review of documents and the impact on maintenance and overhaul specifications?
- Shows that a procedure exists that reviews all new and revised standards and documents by a competent person. How is the competence and authority of the reviewer deemed?
- Has a process which defines what prompts a review of documents and standards.
- Shows how maintenance documentation is verified that it is fit for purpose and completed in a controlled, timely and effective manner demonstrating unambiguous compliance to the associated standard.
- Shows that maintenance records are checked for accuracy, completeness and using current and up to date documents.
- Shows that information needed for maintenance is relevant and valid, and, easily accessible to staff. It is consistent and easy to understand made known to staff before it is applied, with copies provided to them where required.
- Shows a procedure, which ensures an auditable trail to ensure compliance to all applicable standards, and that any actions arising can be demonstrated to have been implemented.
- Shows that the applicant instigates and develops their own standards that promulgate engineering good practise based upon principles, and drives continuous improvement.
- Shows that any instructions and/or procedures developed from standards are promulgated to the end user by a document control process, which allows for the expedience of any urgent maintenance requirements.
- Shows a procedure exists for withdrawing superseded or cancelled documents.
- Shows that the applicant adequately manages contractors and interested parties to ensure that cascaded policies/procedures /standards are understood and applied.
- Shows they have a procedure setting out the method of storing and readily retrieving the documents upon request by appropriate authorities.
- Shows a policy for retention to ensure the traceability of all relevant information.

Guidance

None specified.

EIP 7: Audit

Background

Audit and Monitoring — a structured approach to ensure that risk control measures are in place, working correctly and achieving the organisation's objectives. How an ECM carries out internal and external critical assessments is a prime factor in good governance.

Assignment objectives

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions.

In Particular the organisation must have the following procedures:

- A periodic review of all processes, the organisation must have an internal auditing system which is independent, impartial and acts in a transparent way. This system must have procedures in place to:
 - (i) develop an internal audit plan, which can be revised depending on the results of previous audits and monitoring of performance;
 - (ii) analyse and evaluate the results of the audits;
 - (iii) propose and implement specific corrective measures/actions; and
 - (iv) verify the effectiveness of previous measures/actions.
- The organisation must have procedures to guarantee conformity with the essential requirements for interoperability, including updates throughout the lifecycle, by:
 - (i) ensuring compliance with the specifications related to the basic parameters for interoperability as set out in the relevant technical specifications for interoperability (TSIs);
 - (ii) verifying in all circumstances the consistency of the maintenance file with the authorisation of placing-in-service (including any national safety authority requirements), the declarations of conformity to TSIs, the declarations of verification, and the technical file;
 - (iii) managing any substitution in the course of maintenance in compliance with the requirements of the Directive 2008/57/EC (transposed in Great Britain as the Railways (Interoperability) Regulations 2011) and the relevant TSIs;
 - (iv) identifying the need for risk assessment regarding the potential impact of the substitution in question on the safety of the railway system;
 - (v) managing the configuration of all technical changes affecting the system integrity of the vehicle.

Examples of evidence

- Shows that they have a process which sets out the policy and strategy for audit.
- They have a mechanism to provide assurance that policies and standards are being adhered to and remain suitable to meet maintenance needs.
- Shows how topics are selected and managed through the audit process. Provision of clarity on the proportionality of audit in relation to risk.
- Shows that a method of measuring the risk gap of what is promulgated / practised through an audit process and to determine the value and weight they attach to the findings to ensure root causes of failure or weak processes and work practices are readily identified.
- Shows if the audit process identifies if the maintenance activities are being compromised by underperforming maintenance processes and facilities.
- Shows how contractor involvement in the applicant's audit process, and how the contractors own audit procedures will be discussed with the applicant. Shows there are arrangements in place to conduct surveillance of the suppliers.
- Shows how the results of audits are disseminated both to the applicant and to the contractor, and how follow up actions / timescales are managed.
- Shows how lessons are learnt from the audit, and ensuring corrections and recommendations for continuous improvement are closed out in a timely and effective manner.
- Shows the qualities, competence, training and professional qualifications of auditors (or audit services) to determine audit effectiveness.
- Shows if the audit process identifies if the maintenance activities are being compromised by underperforming maintenance processes and facilities.
- Shows overlap/integration with key business requirements including any accreditation to ISO9000/14000/18000 and HS(G)65 in achieving best practice.

Guidance

- GM/RT2450

EIP 8. Procurement

Assignment objectives

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions:

In Particular the organisation must have procedures for:

- components and materials are stored, handled and transported in a manner that prevents wear and damage and as specified in the maintenance orders and supplier documentation; and
- all components and materials, including those provided by the customer, comply with relevant national and international rules as well as with the requirements of relevant maintenance orders.

Examples of evidence

- Shows a procurement process or procedure including a statement on its implementation.
- Shows how risks are identified and managed through the procurement process.
- Shows documents on how safety critical suppliers and services are selected, evaluated and maintained.
- Shows a certificated quality and / or management system.
- Engages with a specialised body to establish assurance of the procurement process.
- Shows clarity in setting out specific requirements that suppliers are competent to pass requirements to their suppliers, and responsibility is maintained by the ECM.
- Shows documented evidence of supplier requirements that are sent to prospective suppliers that includes assessment of safety and quality management system, competence in product controls and record keeping.
- Shows how on-going standards and good practice are maintained and limits of their capabilities are not compromised.
- Shows procedure for storage, handling and transportation of materials.
- Can demonstrate on-going monitoring and supervision of suppliers and services.
- Can demonstrate facilities do not undermine wear and damage to components and materials.

- Can demonstrate components and materials meet relevant rules. Shows labelling and traceability (where required) is being maintained.

Guidance

- GMRT2470 Wheel set Supplier Qualification
- GMRT2450 Safety critical products & services

EIP 9: Risk Assessment

Background

Risk assessment — a structured approach to assess risks associated with the maintenance of vehicles, including those directly arising from operational processes and the activities of other organisations or persons, and to identify the appropriate risk control measures

Assignment scope

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions:

In Particular the organisation must have procedures:

- to analyse risks relevant to the extent of operations carried out by the organisation, including the risks arising from defects and construction non-conformities or malfunctions throughout the lifecycle;
- to develop and put in place risk control measures.
- to have procedures and arrangements in place to recognise the need and commitment to collaborate with keepers, transport undertakings, infrastructure managers, or other interested parties.
- to have risk assessment procedures to manage changes in equipment, procedures, organisation, staffing or interfaces, and to apply Commission Regulation (EC) No 352/2009 (the common safety method for risk evaluation and assessment).
- that, when assessing risk, an organisation must have 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 (primarily implemented in Great Britain by the Management of Health and Safety at Work Regulations 1999).
- that, when the risk assessment process is applied to the maintenance delivery function, 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.

Examples of evidence

- Has a policy or procedure in place setting out the strategy for risk assessment.
- Has a process in place that determines when to apply the CSM Regulations including what triggers significant technical changes.

- Has a systematic and structured process in place for identifying the major hazards associated with (on and where) maintenance activities are performed ensuring that suitable and sufficient risk assessments have been undertaken for each of the reasonably foreseeable hazards identified.
- Has a systematic and structured process in place for risk analyses to identify measures to control the risks arising from the hazards.
- Demonstrates the use of qualitative, semi-quantitative or quantitative methods to assess the overall risk associated with each hazardous and how these may change in degraded and emergency situations.
- Shows it has processes and mechanisms in place that defines and evaluates the system that is subjected to the risk assessment, including any assumptions which determine the limits for the risk assessment
- Provides clear and comprehensive documentary evidence of the methodologies, assumptions, data, judgements and interpretations used in the development of the risk assessment and the analysis of its results.
- Understands and uses standards and rules which are widely accepted in the railway sector. Also understands that evidence of in-service history alone is unlikely to prove that a high integrity system has an acceptable safety level.
- Shows on-going monitoring and compliance with the control measures identified in the risk assessment and that the periodic review of the risk assessments (or means of indicating when an early review is needed).
- Shows procedures in place to ensure that collaboration and sharing of the necessary information is passed to contractors and other interested persons from the risk assessment process. In that the risk is managed not simply transferred.
- Has a process or procedure in place identifying the safety and technical competencies needed.

Guidance

- ORR guidance on the application of the common safety method (CSM) on risk assessment and evaluation. September 2010
- RSSB Risk Modelling www.safetyriskmodel.co.uk
- Engineering Safety Management (The Yellow Book)
- EN50126:1999 Railway applications – (RAMS)
- ACOP - Management of Health and Safety at Work Regulations 1999

EIP 10: Work Equipment

Background

Has a structure in place to ensure work equipment and facilities support maintenance activities and plans.

Assignment objectives

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions.

In Particular the organisation must have procedures:

- to ensure that all facilities, equipment and tools are correctly used, calibrated, preserved and maintained in accordance with documented procedures;
- 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; and
- to determine, identify, provide, record and keep available suitable and adequate facilities, equipment and tools to enable it to deliver the maintenance services in accordance with maintenance orders and other applicable specifications, ensuring:
 - (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.
- To ensure valid results, and ensure that its measuring equipment is:
 - (a) calibrated or verified at specified intervals, or prior to use, against international, national or industrial measurement standards — where no such standards exist, the basis used for calibration or verification must be recorded;
 - (b) adjusted or re-adjusted as necessary;
 - (c) identified to enable the calibration status to be determined;
 - (d) has a safeguard from any adjustments that would invalidate the measurement result; and
 - (e) protected from damage and deterioration during handling, maintenance and storage.

- To ensure that all facilities, equipment and tools are correctly used, calibrated, preserved and maintained in accordance with documented procedures.

Examples of evidence

- Shows a policy for setting out maintenance facility requirements.
- Shows the extent of the activities taking place
- Shows the choice of tools and equipment are suitable for carrying out the task.
- Shows that tools and equipment are being stored, handled and maintained so not as to compromise both the health and safety of the staff or stock.
- Shows that tools and equipment provided by contractors and visitors working within the maintenance facility do not compromise either the health or safety of the staff or rolling stock.
- Has a list of calibrated equipment and shows a process that sets out what Measuring Instrumentation and test equipment is required.
- How calibration requirements are set and that these requirements are being maintained do not adversely affect safety.
- Shows what controls are in place to prevent use of equipment that is out of calibration
- Shows a process that the calibration of equipment is traceable to maintenance plans, individual tasks and staff to enable checking, validation or error correction. What procedures are in place to control non-conforming or defective pieces of equipment?
- Shows that adjustments, decisions or actions made from calibrated equipment are recorded.
- Shows that records are being kept, and these records are easily retrievable, and can be understood and acted upon where necessary.
- Shows that if lifting equipment is used, is it clearly identified that it is suitable for use.
- Shows any level of abuse/near misses through the misuse to equipment or facilities do not adversely affect safety.
- Shows any modifications and/or repairs being applied to equipment or facilities does not adversely affect safety.
- Shows the level of maintenance / reliability /availability of equipment and facilities do not adversely affect safety.

Guidance

None specified.

EIP 11: Performance history

Background

Understanding what our safety performance is, and how we can improve is a key element in maintaining safe traction and rolling stock.

Assignment Scope

To verify Annex III Requirements for the maintenance development function, fleet maintenance and maintenance delivery functions.

In Particular the organisation must have procedures:

- To ensure that safety targets are established, in line with the legal framework and consistent with an organisation's type, extent and relevant risks;
- To assess its overall safety performance in relation to its corporate safety targets;
- To develop plans and procedures for reaching its safety targets;
- To identify and managing the impact of other management activities on the maintenance system;
- To ensure that senior management is aware of the results of performance monitoring and audits and takes overall responsibility for the implementation of changes to the maintenance system;
- To ensure that staff and staff representatives are adequately represented and consulted in defining, developing, monitoring and reviewing the safety aspects of all related processes that may involve staff.

The organisation must have a procedure to regularly collect, monitor and analyse relevant safety data, including:

- the performance of relevant processes;
- the results of processes (including all contracted services and products);the effectiveness of risk control arrangements;
- information on experience, malfunctions, defects and repairs arising from day-to-day operation and maintenance.
- procedures to ensure that accidents, incidents, near-misses and other dangerous occurrences are reported, logged, investigated and analysed.

The organisation must have procedures to ensure that:

- identified shortcomings are rectified;
- new safety developments are implemented;
- internal audit findings are used to bring about improvement in the system;
- preventive or corrective actions are implemented, when needed, to ensure compliance of the railway system with standards and other requirements throughout the lifecycle of equipment and operations;
- relevant information relating to the investigation and causes of accidents, incidents, near-misses and other dangerous occurrences is used to learn and, where necessary, to adopt measures in order to improve the level of safety;
- relevant recommendations from the national safety authority, from the national investigation body and from industry or internal investigations are evaluated and implemented if appropriate; and
- relevant reports/information from transport undertakings/infrastructure managers and keepers or other relevant sources are considered and taken into account.

Examples of evidence

- Policy or procedure document which sets out how performance targets are identified and managed including a statement on its implementation on all relevant classes of rail vehicles.
- Identifies a standard to establish and set safety performance targets.
- Identifies a legal framework in which the safety performance target is set.
- Quantify performance history metrics and return of history to establish a level of risk.
- Policy or procedure document which sets out how the defect-reporting procedure captures data and from what sources including staff.
- Has a policy of recording, investigating and analysing accidents, incidents, near-misses and other dangerous occurrences data to identify trends and forecast safety improvements.
- Has a method of raising and disseminating safety performance information to other affected parties including national safety authorities
- Has a method of putting into place actions based upon immediate and holistic safety performance data.
- Policy or procedure on what safety related information is recorded including defects that give rise to urgent actions.
- Policy or procedure document which sets out to determine how effective procedures and policies are in achieving safety performance level targets for all relevant classes of rail vehicles.
- Evaluates and implements recommendations from formal bodies including RAIB.
- Evaluates and implements recommendations from other bodies including Railway Undertakings and Infrastructure Managers.
- Has assigned a safety performance target to a supplier or 'cat A' type items
- Identification of failure events for both in traffic and off vehicle repair

- Appraises risk control measures based upon safety performance data.
- Identifies a tolerance of carded and similar type events.
- Measures maintenance data compliance metrics including deferred work and actions relating to maintenance plans.
- Identifies who undertakes the review of targets and the process of intervention authority.
- Establishes a record and data retention policy.

Guidance

None specified.

Annex A – Table listing EIPs clause by clause of criteria in Annex III of the ECM Regulation

Annex III of ECM Regulation: I Management Functions Requirements & Assessment Criteria	Evidence required to meet criteria
<p>1. Leadership — <i>commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness</i></p>	
<p>The organisation must have procedures for: (a) establishing a maintenance policy appropriate to the organisation's type and extent of service and approved by the organisation's chief executive or his or her representative;</p>	EIP 1 – Maintenance & Overhaul Policy
<p>(b) ensuring that safety targets are established, in line with the legal framework and consistent with an organisation's type, extent and relevant risks;</p>	EIP 1 - Maintenance & Overhaul Policy EIP 11 - Performance History
<p>(c) assessing its overall safety performance in relation to its corporate safety targets;</p>	EIP 1 - Maintenance & Overhaul Policy EIP 11 - Performance History
<p>(d) developing plans and procedures for reaching its safety targets;</p>	EIP 1 - Maintenance & Overhaul Policy EIP 11 - Performance History
<p>(e) ensuring the availability of the resources needed to perform all processes to comply with the requirements of this Annex;</p>	EIP 3 – Maintenance Planning
<p>(f) identifying and managing the impact of other management activities on the maintenance system;</p>	EIP 1 - Maintenance & Overhaul Policy EIP 4 – Engineering & Organisational Change
<p>(g) ensuring that senior management is aware of the results of performance monitoring and audits and takes overall responsibility for the implementation of changes to the maintenance system;</p>	EIP 1 - Maintenance & Overhaul Policy EIP 7 – Audit
<p>(h) ensuring that staff and staff representatives are adequately represented and consulted in defining, developing, monitoring and reviewing the safety aspects of all related processes that may involve staff.</p>	EIP 1 - Maintenance & Overhaul Policy

2. Risk assessment — <i>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</i>	
2.1. The organisation must have procedures for:	
(a) analysing risks relevant to the extent of operations carried out by the organisation, including the risks arising from defects and construction non-conformities or malfunctions throughout the lifecycle;	EIP 4 - Engineering & Organisational Change
(b) evaluating the risks referred to in point (a);	EIP 9 – Risk Assessment
(c) developing and putting in place risk control measures.	EIP 9 - Risk Assessment
2.2. The organisation must have procedures and arrangements in place to recognise the need and commitment to collaborate with keepers, railway undertakings, infrastructure managers, or other interested parties.	EIP 1 - Maintenance & Overhaul Policy EIP 5 – Contracts & Interfaces EIP 6 – Standards, Procedures & Document Control
2.3. The organisation must have risk assessment procedures to manage changes in equipment, procedures, organisation, staffing or interfaces, and to apply Commission Regulation (EC) No 352/2009 (1).	EIP 4 – Engineering & Organisational Change EIP 9 – Risk Assessment
2.4. When assessing risk, an organisation must have 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 (2).	EIP 6 – Standards, Procedures & Document Control EIP 10 – Work Equipment

3. Monitoring — <i>a structured approach to ensure that risk control measures are in place, working correctly and achieving the organisation's objectives</i>	
3.1. The organisation must have a procedure to regularly collect, monitor and analyse relevant safety data, including:	
(a) the performance of relevant processes;	EIP 6 – Standards, Procedures & Document Control EIP 11 – Performance History
(b) the results of processes (including all contracted services and products)	EIP 5 – Contracts & Interfaces EIP 8 – Procurement
(c) the effectiveness of risk control arrangements;	EIP 7 - Audit EIP 9 – Risk Assessment
(d) information on experience, malfunctions, defects and repairs arising from day-to-day operation and maintenance.	EIP 11 - Performance History
3.2. The organisation must have procedures to ensure that accidents, incidents, near-misses and other dangerous occurrences are reported, logged, investigated and analysed.	EIP 11 – Performance History
3.3. For a periodic review of all processes, the organisation must have an internal auditing system which is independent, impartial and acts in a transparent way. This system must have procedures in place to:	
(a) develop an internal audit plan, which can be revised depending on the results of previous audits and monitoring of performance;	EIP 7 - Audit
(b) analyse and evaluate the results of the audits;	EIP 7 - Audit
(c) propose and implement specific corrective measures/actions;	EIP 7 - Audit
(d) verify the effectiveness of previous measures/actions.;	EIP 7 - Audit

4. Continuous improvement — <i>a structured approach to analyse the information gathered through regular monitoring, auditing, or other relevant sources and to use the results to learn and to adopt preventive or corrective measures in order to maintain or improve the level of safety</i>	
The organisation must have procedures to ensure that:	
(a) identified shortcomings are rectified;	EIP 7 - Audit
(b) new safety developments are implemented;	EIP 4 – Engineering & Organisational Change EIP 6 – Standards, Procedures & Document Control
(c) internal audit findings are used to bring about improvement in the system;	EIP 7 - Audit
(d) preventive or corrective actions are implemented, when needed, to ensure compliance of the railway system with standards and other requirements throughout the lifecycle of equipment and operations;	EIP 4 – Engineering & Organisational Change EIP 6 – Standards, Procedures & Document Control
(e) relevant information relating to the investigation and causes of accidents, incidents, near-misses and other dangerous occurrences is used to learn and, where necessary, to adopt measures in order to improve the level of safety;	EIP 11 – Performance History
(f) relevant recommendations from the national safety authority, from the national investigation body and from industry or internal investigations are evaluated and implemented if appropriate;	EIP 11 – Performance History
(g) relevant reports/information from railway undertakings/infrastructure managers and keepers or other relevant sources are considered and taken into account.	EIP 6 – Standards, Procedures & Document Control EIP 11 – Performance History

<p>5. Structure and responsibility — <i>a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation's safety objectives</i></p>	
<p>5.1. The organisation must have procedures to allocate responsibilities for all relevant processes throughout the organisation.</p>	<p>EIP 1 - Maintenance & Overhaul Policy</p>
<p>5.2. The organisation must have procedures to clearly define safety-related areas of responsibility and the distribution of responsibilities to specific functions associated with them as well as their interfaces. These include the procedures indicated above between the organisation and the keepers and, where appropriate, railway undertakings and infrastructure managers.</p>	<p>EIP 1 - Maintenance & Overhaul Policy Organisation EIP 5 – Contracts & Interfaces</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>EIP 1 - Maintenance & Overhaul Policy EIP 2 – Competence</p>
<p>5.4. The organisation must have procedures to ensure the coordination of activities related to relevant processes across the organisation.</p>	<p>EIP 1 - Maintenance & Overhaul Policy EIP 4 - Engineering & Organisational Change EIP 6 – Standards, Procedures & Document Control</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>	<p>EIP 1 - Maintenance & Overhaul Policy EIP 2 – Competence</p>

6. Competence management — a structured approach to ensure that employees have the competences required in order to achieve the organisation's objectives safely, effectively and efficiently in all circumstances	
6.1. The organisation must set up a competence management system providing for:	
(a) the identification of posts with responsibility for performing within the system all the processes necessary for compliance with the requirements of this Annex;	EIP 1 - Maintenance & Overhaul Policy EIP 2 – Competence Management
(b) the identification of posts involving safety tasks; EN L 122/32 Official Journal of the European Union 11.5.2011	EIP 1 - Maintenance & Overhaul Policy
(c) the allocation of staff with the appropriate competence to relevant tasks.	EIP 2 – Competence EIP 3 – Maintenance Planning
6.2. Within the organisation's competence management system, there must be procedures to manage the competence of staff, including at least:	
(a) identification of the knowledge, skills and experience required for safety-related tasks as appropriate for the responsibilities;	EIP 2 - Competence
(b) selection principles, including basic educational level, mental aptitude and physical fitness;	EIP 2 - Competence
(c) initial training and qualification or certification of acquired competence and skills;	EIP 2 - Competence
(d) assurance that all staff are aware of the relevance and importance of their activities and how they contribute to the achievement of safety objectives;	EIP 1 - Maintenance & Overhaul Policy EIP 2 - Competence
(e) ongoing training and periodical updating of existing knowledge and skills;	EIP 2 - Competence
(f) periodic checks of competence, mental aptitude and physical fitness where appropriate;	EIP 2 - Competence
(g) special measures in the case of accidents/incidents or long absences from work, as required.	EIP 2 - Competence

7. Information — <i>a structured approach to ensure that important information is available to those making judgments and decisions at all levels of the organisation</i>	
7.1. The organisation must have procedures to define reporting channels to ensure that, within the entity itself and in its dealings with other actors, including infrastructure managers, railways undertakings and keepers, information on all relevant processes is duly exchanged and submitted to the person having the right role both within its own organisation and in other organisations, in a prompt and clear way.	EIP 5 – Contracts & Interfaces EIP 11 – Performance History
7.2. To ensure an adequate exchange of information, the organisation must have procedures:	
(a) for the receipt and processing of specific information;	EIP 6 – Standards, Procedures & Document Control
(b) for the identification, generation and dissemination of specific information;	EIP 6 – Standards, Procedures & Document Control
(c) for making available reliable and up-to-date information	EIP 6 – Standards, Procedures & Document Control
7.3. The organisation must have procedures to ensure that key operational information is:	
(a) relevant and valid;	EIP 6 – Standards, Procedures & Document Control
(b) accurate;	EIP 6 – Standards, Procedures & Document Control
(c) complete;	EIP 6 – Standards, Procedures & Document Control
(d) appropriately updated;	EIP 6 – Standards, Procedures & Document Control
(e) controlled;	EIP 6 – Standards, Procedures & Document Control
(f) consistent and easy to understand (including the language used);	EIP 6 – Standards, Procedures & Document Control
(g) made known to staff before it is applied;	EIP 6 – Standards, Procedures & Document Control
(h) easily accessible to staff, with copies provided to them where required.	EIP 6 – Standards, Procedures & Document Control
7.4. The requirements set out in points 7.1, 7.2 and 7.3 apply in particular to the following operational information:	
(a) checks of the accuracy and completeness of national vehicle registers regarding the identification (including means) and registration of the freight wagons maintained by the organisation;	EIP 4 – Engineering & Organisational Change
(b) maintenance documentation;	EIP 4 – Engineering & Organisational Change EIP 6 – Standards, Procedures & Document Control
(c) information on support provided to keepers and, where appropriate, to other parties, including railway undertakings/infrastructure managers;	EIP 5 – Contracts & Interfaces
(d) information on the qualification of staff and subsequent supervision during maintenance development;	EIP 2 – Competence EIP 5 – Contracts & Interfaces
(e) information on operations (including mileage, type and extent of	EIP 5 – Contracts & Interfaces

activities, incidents/accidents) and requests of railway undertakings, keepers and infrastructure managers;	
(f) records of maintenance performed, including information on deficiencies detected during inspections and corrective actions taken by railway undertakings or by infrastructure managers such as inspections and monitoring undertaken before the departure of the train or en route;	EIP 1 – Maintenance & Overhaul Policy EIP 5 – Contracts & Interfaces EIP 6 – Standards, Procedures & Document Control
(g) release to service and return to operation;	EIP 11 – Performance History
(h) maintenance orders; EN 11.5.2011 Official Journal of the European Union L 122/33	EIP 3 – Maintenance Planning
(i) technical information to be provided to railway undertakings/infrastructure managers and keepers for maintenance instructions;	EIP 5 – Contracts & Interfaces
(j) emergency information concerning situations where the safe state of running is impaired, which may consist of:	EIP 5 - Contracts & Interfaces
(i) the imposition of restrictions of use or specific operating conditions for the freight wagons maintained by the organisation or other vehicles of the same series even if maintained by other entities in charge of maintenance, whereby this information should also be shared with all involved parties;	EIP 5 - Contracts & Interfaces
(ii) urgent information on safety-related issues identified during maintenance, such as deficiencies detected in a component common to several types or series of vehicles;	EIP 1 - Maintenance & Overhaul Policy EIP 5 - Contracts & Interfaces EIP 11 – Performance History
(k) all relevant information/data needed to submit the annual maintenance report to the certification body and to the relevant customers (including keepers), whereby this report must also be made available upon request to national safety authorities.	EIP 1 - Maintenance & Overhaul Policy EIP 5 - Contracts & Interfaces

8. Documentation — <i>a structured approach to ensure the traceability of all relevant information</i>	
8.1. The organisation must have adequate procedures in place to ensure that all relevant processes are duly documented.	EIP 1 - Maintenance & Overhaul Policy EIP 6 – Standards, Procedures & Document Control
8.2. The organisation must have adequate procedures in place to:	
(a) regularly monitor and update all relevant documentation;	EIP 6 – Standards, Procedures & Document Control
(b) format, generate, distribute and control changes to all relevant documentation;	EIP 6 – Standards, Procedures & Document Control
(c) receive, collect and archive all relevant documentation.	EIP 6 – Standards, Procedures & Document Control

9. Contracting activities — <i>a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation's objectives to be achieved</i>	
9.1. The organisation must have procedures in place to ensure that safety related products and services are identified.	EIP 1 - Maintenance & Overhaul Policy EIP 8 – Procurement
9.2. When making use of contractors and/or suppliers for safety related products and services, the organisation must have procedures in place to verify at the time of selection that:	
(a) contractors, subcontractors and suppliers are competent;	EIP 5 - Contracts & Interfaces EIP 8 – Procurement
(b) contractors, subcontractors and suppliers have a maintenance and management system that is adequate and documented.	EIP 5 - Contracts & Interfaces
9.3. The organisation must have a procedure to define the requirements that such contractors and suppliers have to meet.	EIP 5 - Contracts & Interfaces EIP 8 - Procurement
9.4. The organisation must have procedures to monitor the awareness of suppliers and/or contractors of risks they entail to the organisation's operations.	EIP 5 - Contracts & Interfaces EIP 7 - Audit
9.5. When the maintenance/management system of a contractor or supplier is certified, the monitoring process described in point 3 may be limited to the results of the contracted operational processes referred to in point 3.1(b).	EIP 5 - Contracts & Interfaces
9.6. At least the basic principles for the following processes must be clearly defined, known and allocated in the contract between the contracting parties:	
(a) responsibilities and tasks relating to railway safety issues;	EIP 1 - Maintenance & Overhaul Policy EIP 5 - Contracts & Interfaces EIP 6 – Standards, Procedures & Document Control
(b) obligations relating to the transfer of relevant information between both parties;	EIP 1 - Maintenance & Overhaul Policy EIP 5 - Contracts & Interfaces EIP 6 – Standards, Procedures & Document Control
(c) the traceability of safety-related documents.	EIP 1 - Maintenance & Overhaul Policy EIP 5 - Contracts & Interfaces EIP 6 – Standards, Procedures & Document Control

II Requirements and assessment criteria for the maintenance development function	Engineering Inspection Plans (EIP)
1. The organisation must have a procedure to identify and manage all maintenance activities affecting safety and safety- critical components	EIP 1 - Maintenance & Overhaul Policy EIP 2 – Competence EIP 4 – Engineering & Organisational Change EIP 5 - Contracts & Interfaces EIP 6 – Standards, Procedures & Document Control EIP 8 - Procurement
2. The organisation must have procedures to guarantee conformity with the essential requirements for interoperability, including updates throughout the lifecycle, by:	
(a) ensuring compliance with the specifications related to the basic parameters for interoperability as set out in the relevant technical specifications for interoperability (TSIs);	EIP 1 - Maintenance & Overhaul Policy EIP 4 – Engineering & Organisational Change EIP 6 – Standards, Procedures & Document Control
(b) verifying in all circumstances the consistency of the maintenance file with the authorisation of placing-in-service (including any national safety authority requirements), the declarations of conformity to TSIs, the declarations of verification, and the technical file; EN L 122/34 Official Journal of the European Union 11.5.2011	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control
(c) managing any substitution in the course of maintenance in compliance with the requirements of the Directive 2008/57/EC and the relevant TSIs;	EIP 4 - Engineering & Organisational Change
(d) identifying the need for risk assessment regarding the potential impact of the substitution in question on the safety of the railway system;	EIP 4 - Engineering & Organisational Change EIP 9 – Risk Assessment
(e) managing the configuration of all technical changes affecting the system integrity of the vehicle.	EIP 4 - Engineering & Organisational Change
3. 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.	EIP 1 - Maintenance & Overhaul Policy EIP 3 – Maintenance Planning EIP 10 – Work Equipment

4. When freight wagons start operations, the organisation must have procedures to:	
(a) obtain the initial documentation and to collect sufficient information on planned operations;	EIP 1 - Maintenance & Overhaul Policy EIP 4 - Engineering & Organisational Change
(b) analyse the initial documentation and to provide the first maintenance file, also taking into account the obligations contained in any associated guarantees;	EIP 3 - Maintenance Planning EIP 6 – Standards, Procedures & Document Control EIP 9 – Risk Assessment
(c) ensure that the implementation of the first maintenance file is done correctly.	EIP 6 – Standards, Procedures & Document Control
5. To keep the maintenance file updated throughout the lifecycle of a freight wagon, the organisation must have procedures to:	
(a) collect at least the relevant information in relation to:	
(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;	EIP 3 - Maintenance Planning EIP 5 – Contracts & Interfaces
(ii) the type and extent of operations planned;	EIP 3 - Maintenance Planning EIP 5 – Contracts & Interfaces
(iii) the maintenance effectively performed;	EIP 6 – Standards, Procedures & Document Control EIP 11 – Performance History
(b) define the need for updates, taking into account the limit values for interoperability;	EIP 3 - Maintenance Planning EIP 4 - Engineering & Organisational Change EIP 6 – Standards, Procedures & Document Control
(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;	EIP 9 – Risk Assessment
(d) ensure that the implementation of changes is done correctly.	EIP 3 - Maintenance Planning EIP 4 - Engineering & Organisational Change EIP 6 – Standards, Procedures & Document Control
6. When the competence management process is applied to the maintenance development function, at least the following activities affecting safety must be taken into account:	
(a) assessment of the significance of changes for the maintenance file and proposed substitutions in the course of maintenance;	EIP 4 - Engineering & Organisational Change
(b) engineering disciplines required for managing the establishment and the changes of maintenance file and the development, assessment, validation and approval of substitutions in the course	EIP 2 – Competence EIP 4 - Engineering & Organisational Change EIP 9 – Risk Assessment

of maintenance;	
(c) 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.	EIP 2 - Competence EIP 3 - Maintenance Planning EIP 5 – Contracts & Interfaces
7. When the documentation process is applied to the maintenance development function, the traceability of at least the following elements needs to be guaranteed:	
(a) the documentation relating to the development, assessment, validation and approval of a substitution in the course of maintenance;	EIP 4 - Engineering & Organisational Change
(b) the configuration of vehicles, including, but not limited to, components related to safety;	EIP 4 - Engineering & Organisational Change
(c) records of the maintenance performed;	EIP 3 – Maintenance Planning
(d) results of studies concerning return on experience;	EIP 6 – Standards, Procedures & Document Control
(e) all the successive versions of the maintenance file, including risk assessment;	EIP 4 - Engineering & Organisational Change EIP 6 – Standards, Procedures & Document Control EIP 7 - Audit
(f) reports on the competence and supervision of maintenance delivery and fleet maintenance management;	EIP 6 – Standards, Procedures & Document Control EIP 7 - Audit
(g) technical information to be provided to support keepers, railway undertakings and infrastructure managers. EN 11.5.2011 Official Journal of the European Union L 122/35	EIP 6 – Standards, Procedures & Document Control

III. Requirements and assessment criteria for the fleet maintenance management function	Engineering Inspection Plans (EIP)
1. The organisation must have a procedure to check the competence, availability and capability of the entity responsible for maintenance delivery before placing maintenance orders. This requires that the maintenance workshops are duly qualified to decide upon the requirements for technical competences in the maintenance delivery function.	EIP 2 – Competence EIP 5 – Contracts & Interfaces EIP 6 – Standards, Procedures & Document Control EIP 7 - Audit EIP 8 – Procurement
2. The organisation must have a procedure for the composition of the work package and for the issue and release of the maintenance order.	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control
3. The organisation must have a procedure to send freight wagons for maintenance in due time.	EIP 3 - Maintenance Planning
4. The organisation must have a procedure to manage the removal of freight wagons from operation for maintenance or when defects have been identified.	EIP 3 - Maintenance Planning
5. The organisation must have a procedure to define the necessary control measures applied to the maintenance delivered and the release to service of the freight wagons.	EIP 3 - Maintenance Planning
6. The organisation must have a procedure to issue a notice to return to operation, taking into account the release to service documentation.	EIP 3 - Maintenance Planning EIP 6 – Standards, Procedures & Document Control
7. When the competence management (CM) process is applied to the fleet maintenance management function, at least the return to operation must be taken into account.	EIP 2 – Competence
8. When the information process is applied to the fleet maintenance management function, at least the following elements need to be provided to the maintenance delivery function:	
(a) applicable rules and technical specifications;	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control
(b) the maintenance plan for each freight wagon;	EIP 3 - Maintenance Planning
(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;	EIP 3 - Maintenance Planning EIP 8 – Procurement

(d) a list of materials, including a sufficiently detailed description of their use and the necessary health and safety information;	EIP 3 - Maintenance Planning EIP 8 - Procurement
(e) a dossier that defines the specifications for activities affecting safety and contains intervention and in-use restrictions for components;	EIP 3 - Maintenance Planning EIP 8 - Procurement
(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);	EIP 6 – Standards, Procedures & Document Control EIP 8 - Procurement
(g) all additional relevant information related to safety according to the risk assessment performed by the organisation	EIP 9 - Risk Assessment
9. When the information process is applied to the fleet maintenance management function, at least the return to operation, including restrictions on use relevant to users (railway undertakings and infrastructure managers), needs to be communicated to interested parties.	EIP 6 – Standards, Procedures & Document Control
10. When the documentation process is applied to the fleet maintenance management function, at least the following elements need to be recorded:	
(a) maintenance orders;	EIP 3 - Maintenance Planning
(b) return to operation, including restrictions on use relevant to railway undertakings and infrastructure managers.	EIP 6 – Standards, Procedures & Document Control

IV. Requirements and assessment criteria for the maintenance delivery function	Engineering Inspection Plans (EIP)
1. The organisation must have procedures to:	
(a) check the completeness and appropriateness of the information delivered by the fleet maintenance management function in relation to the activities ordered;	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control
(b) control the use of the required, relevant maintenance documents and other standards applicable to the delivery of maintenance services in accordance with maintenance orders;	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control
(c) ensure that all relevant maintenance specifications in the maintenance orders are available to all involved staff (e.g. they are contained in internal working instructions);	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control
(d) ensure that all relevant maintenance specifications, as defined in applicable regulations and specified standards contained in the maintenance orders, are available to all involved staff (e.g. they are contained in internal working instructions).	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control
2. The organisation must have procedures to ensure that:	
(a) components (including spare parts) and materials are used as specified in the maintenance orders and supplier documentation;EN L 122/36 Official Journal of the European Union 11.5.2011	EIP 8 - Procurement
(b) components and materials are stored, handled and transported in a manner that prevents wear and damage and as specified in the maintenance orders and supplier documentation;	EIP 8 - Procurement
(c) all components and materials, including those provided by the customer, comply with relevant national and international rules as well as with the requirements of relevant maintenance orders.	EIP 8 - Procurement
3. The organisation must have procedures to determine, identify, provide, record and keep available suitable and adequate facilities, equipment and tools to enable it to deliver the maintenance services in accordance with maintenance orders and other applicable specifications, ensuring:	
(a) the safe delivery of maintenance, including the health and safety of maintenance staff;	EIP 3 - Maintenance Planning EIP 6 – Standards, Procedures & Document Control EIP 9 – Risk Assessment EIP 10 – Work Equipment

(b) ergonomics and health protection, also including the interfaces between users and information technology systems or diagnostic equipment.	EIP 6 – Standards, Procedures & Document Control EIP 9 – Risk Assessment EIP 10 – Work Equipment
4. Where necessary to ensure valid results, the organisation must have procedures to ensure that its measuring equipment is:	
(a) calibrated or verified at specified intervals, or prior to use, against international, national or industrial measurement standards — where no such standards exist, the basis used for calibration or verification must be recorded;	EIP 10 – Work Equipment
(b) adjusted or re-adjusted as necessary;	EIP 10 - Work Equipment
(c) identified to enable the calibration status to be determined;	EIP 10 - Work Equipment
(d) safeguarded from adjustments that would invalidate the measurement result;	EIP 10 - Work Equipment
(e) protected from damage and deterioration during handling, maintenance and storage.	EIP 10 - Work Equipment
5. The organisation must have procedures to ensure that all facilities, equipment and tools are correctly used, calibrated, preserved and maintained in accordance with documented procedures.	EIP 10 - Work Equipment
6. The organisation must have procedures to check that the performed maintenance tasks are in accordance with the maintenance orders and to issue the notice to release to service that includes eventual restrictions of use.	EIP 6 – Standards, Procedures & Document Control EIP 11 – Performance History
7. When the risk assessment process (in particular point 2.4 of section I) is applied to the maintenance delivery function, 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.	EIP 9 – Risk Assessment EIP 10 - Work Equipment
8. When the competence management process is applied to the maintenance delivery function, at least the following activities affecting safety must be taken into account:	
(a) joining techniques (including welding and bonding);	EIP 2 – Competence EIP 3 - Maintenance Planning
(b) non-destructive testing;	EIP 2 - Competence EIP 3 - Maintenance Planning
(c) final vehicle testing and release to service;	EIP 2 - Competence EIP 3 - Maintenance Planning

(d) maintenance activities on brake systems, wheel sets and draw gear and maintenance activities on specific components of freight wagons for the transport of dangerous goods, such as tanks, valves, etc.;	EIP 2 - Competence EIP 3 - Maintenance Planning
(e) other identified specialist areas affecting safety.	EIP 2 - Competence EIP 3 - Maintenance Planning
9. When the information process is applied to the maintenance delivery function, at least the following elements must be provided to the fleet maintenance management and maintenance development functions:	
(a) works performed in accordance with the maintenance orders;	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control EIP 11 – Performance History
(b) any possible fault or defect regarding safety which is identified by the organisation;	EIP 3 – Maintenance History EIP 6 – Standards, Procedures & Document Control EIP 11 – Performance History
(c) the release to service.	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control EIP 11 – Performance History
10. When the documentation process is applied to the maintenance delivery function, at least the following elements must be recorded:	
(a) clear identification of all facilities, equipment and tools related to activities affecting safety;	EIP 3 – Maintenance Planning EIP 11 – Performance History
(b) all maintenance works performed, including personnel, tools, equipment, spare parts and materials used and taking into account:	
(i) relevant national rules where the organisation is established;	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control
(ii) requirements laid down in the maintenance orders, including requirements regarding records;	EIP 3 – Maintenance Planning EIP 6 – Standards, Procedures & Document Control
(iii) final testing and decision regarding release to service;	EIP 3 - Maintenance Planning
(c) the control measures required by maintenance orders and the release to service;	EIP 3 - Maintenance Planning
(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;	EIP 3 – Maintenance Planning EIP 10 - Work Equipment

(e) the validity of the previous measuring results when a measuring instrument is found not to conform to requirements.

EIP 3 – Maintenance Planning
EIP 11 – Performance History

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