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Guidance on the requirements in ROGS (regulation 18A) that relate to entities in charge of the maintenance of railway vehicles			
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1. Introduction

Purpose of this RSD Internal Guidance document (RIG)

- 1.1. The purpose of this RSD Internal Guidance document is to provide guidance to ORR inspectors on enforcement of regulation 18A of the [Railways and Other Guided Transport Systems \(Safety\) Regulations 2006](#) (“ROGS”), as amended;
- 1.2. This RIG draws on guidance provided by ORR in [A Guide to ROGS](#) and by the European Union Agency for Railways (“the Agency”) in its [Guide for the application of the Commission Regulation 445/2011 on a system of certification of entities in charge of maintenance of freight wagons](#). Although the Agency guidance is to support [Commission Regulation 445/2011](#) (“the ECM Regulation”) which currently only applies to ECMs of freight wagons, much of it is equally applicable to ECMs of other types of vehicle.
- 1.3. This RIG makes references to the following legislation, which are relevant to meeting the requirements of regulation 18A of ROGS:
 - [The Railways \(Interoperability\) Regulations 2011, as amended \[S.I. 3066/2011\]](#) (“RIR 2011”);
 - [The ECM Regulation](#);
 - [Commission Decision 2007/756/EC](#) (“the NVR Decision”), as amended by [Decision 2011/107/EC](#) and updated from time to time;
 - [Directive 2004/49/EC](#) (“the Railway Safety Directive”); and
 - [Health and Safety at Work etc. Act 1974](#).

Background

- 1.1. Regulation 18A of ROGS applies to all vehicles, including passenger rolling stock, freight wagons, on-track machines (OTMs), and locomotives. ROGS (as amended) defines a vehicle as:

“vehicle”—

 - (a) includes a mobile traction unit; and*
 - (b) in respect of the mainline railway, means a vehicle that runs on its own wheels on railway lines of a gauge of at least 350 millimetres, with or without traction, and is composed of one or more structural and functional subsystems or parts of such subsystems;”.*
- 1.2. Vehicles, such as OTMs, are not in the scope of regulation 18A if operating in engineering possessions. However, when they operate or are transported outside possessions they are in scope. (See also [“ECM Exempt”](#) in Section 3).

- 1.3. According to Regulation 18A of ROGS vehicles on the mainline railway in Great Britain must be assigned an ECM and the ECM must be identified in the National Vehicle Register (“NVR”) (See [Section 3](#) below). Each ECM must establish a maintenance system. An ECM responsible for freight wagons must also obtain an ECM certificate (See [Section 3](#) below). Please see [A Guide to ROGS](#) for further information.
- 1.4. Transport undertakings and infrastructure managers are still responsible for the safe operation of trains under their safety management systems. But under ROGS an ECM has to ensure that vehicles for which it has responsibility are maintained in a safe condition by means of a system of maintenance. (See [Section 4](#)).

2. Offences under regulation 18A of ROGS

- 2.1. Regulation 18A of ROGS extends the scope of offences under section 33(1)(c) of the [Health and Safety at Work etc Act 1974](#) to include an offence committed by:
 - a person who places in service or uses a vehicle without:
 - an ECM being assigned to it;
 - the ECM being registered in the National Vehicle Register; and
 - the ECM holding an ECM certificate if the vehicle is a freight wagon; and
 - an ECM that does not ensure that a vehicle it is responsible for has been maintained in a safe condition and is safe to run on the network.

3. The requirements of regulation 18A(1)

What the regulations say

- 3.1. Under regulation 18A(1), no person may place in service or use a vehicle on the mainline railway unless that vehicle has an ECM assigned to it, and that ECM is
 - a) registered in the NVR; and
 - b) holds an ECM certificate if the vehicle is a freight wagon*.

* The Agency is proposing to extend the ECM certification scheme to all vehicles. This is likely to result in ECMs of locomotives, passenger rolling stock, on-track plant/machines (operating outside engineering possessions) and all other vehicles on the mainline being required to obtain an ECM certificate. Our website <http://orr.gov.uk/rail/health-and-safety/health-and-safety-laws/rogs/entities-in-charge-of-maintenance> will be updated as soon as we become aware of the Agency’s decision.

- 3.2. The NVR is a database of vehicles authorised or operated in Great Britain under the RIR 2011. The Secretary of State has appointed a registration entity, Network Rail Infrastructure Ltd to maintain the NVR. The registration entity must ensure that the NVR conforms to the common specifications as set out in the Annex to the [NVR Decision](#).
- 3.3. An 'ECM certificate' is a certificate issued in accordance with the ECM Regulation to an ECM or a certificate recognised as being equivalent for those purposes in accordance with Article 12(3) to (7) of the ECM Regulation.

Who is responsible for assigning an ECM to a vehicle and registering it?

- 3.4. ORR regards the vehicle keeper as the registration holder for the purposes of the NVR, (unless other specific arrangements are made and explained to us). The registration holder is responsible for assigning an ECM and notifying the registration entity of its details. The registration entity will enter the details of the ECM on the NVR.
- 3.5. The Agency's guidance states that the registration holder (normally the keeper) has to:
 - select a competent ECM and contract with it. Sub-contractors, for example maintenance organisations, may be contracted by the registration holder of the ECM;
 - establish a working relationship with the ECM as required by the person or organisation that has ultimate control over the vehicle (e.g. by the owner);
 - ensure the information it provides to the registration entity is correct and, in the case of freight wagons, get assurance that the ECM holds a valid certificate (see paragraphs 4.16 - 4.18);
 - ensure that the vehicle is put at the disposal of the ECM to perform maintenance activities consistent with decisions concerning the Fleet Maintenance Management (see Annex A);
 - ensure where technical problems are detected, corrective action is taken by the ECM, for example through the contract with the ECM. [The transport undertaking will inform the registration holder, who in turn will inform the ECM unless otherwise decided by contract (e.g. the transport undertaking directly notifying the ECM)];
 - in the case of freight wagons, if the ECM certificate is suspended or revoked, take specific actions, for example notify another ECM to the registration entity;

- in the case of freight wagons, inform its commercial partners (i.e. the transport undertaking/infrastructure manager) of the suspension or revocation of an ECM certificate; and
 - specify any particular conditions of use of the vehicle (e.g. type of goods transported).
- 3.6. If the keeper is not the registration holder, it must still ensure that the vehicle is compliant with the legislation in force (as commercial partner of the transport undertaking) and therefore that the information on the NVR is correct.

What is the role of the transport undertaking in complying with regulation 18A(1)?

- 3.7. The transport undertaking has to ensure that each vehicle it uses has an ECM assigned to it and that it is registered in the NVR. A transport undertaking can check this for vehicles originating in Great Britain by accessing the GB NVR or Ravers 2 (see 3.12 below). Permission to access the NVR is granted by the registration entity. Contact details for the registration entity are as follows:

Address: Infrastructure Asset Data Management, Network Rail, The Quadrant: MK, Elder Gate, Milton Keynes MK9 1EN

Email: nvr@networkrail.co.uk

Phone: 01908 781346

- 3.8. If a transport undertaking finds a vehicle does not have an assigned and registered ECM, it should notify the registration holder and the registration entity.
- 3.9. The registration holder should then ensure that an ECM is assigned and registered.
- 3.10. Information on ECMs for vehicles originating in other EU Member States is available through the European Centralised Virtual Vehicle Register (“ECVVR”) which is accessible via the GB NVR. Transport Undertakings may wish to make enquiries with the relevant registration entity in other Member States about the respective NVR.
- 3.11. Transport undertakings must also ensure that the ECM for any freight wagon it uses holds an ECM certificate. Transport undertakings must also manage the operational risks of running trains in an unsafe state through their safety management systems. This includes arrangements to control risks relating to the supply of maintenance and material (regulation 5(1)(d) of ROGS).

The NVR and Ravers 2 (R2)

- 3.12. At the request of the rail industry, and to provide a practical solution, ECM information is also being made available through Ravers 2 (R2) which superseded the Rolling Stock Librar in November 2015. The

registration entity will provide relevant details by email to R2 which will show:

- Valid ECM
- ECM exempt
- No ECM assigned

3.13. ORR checks should be with the NVR and not on the RSL.

ECM Exempt

3.14. Vehicles are exempt from ECM requirements when they are excluded from the mainline railway requirements in ROGS (e.g. metro and heritage vehicles). These vehicles are not required to be on the NVR as they are excluded from the requirements of RIR11. As such, an ECM does not need to be assigned to these vehicles.

Transit moves on the mainline

3.15. Occasionally, 'ECM exempt' vehicles are required to be transported on the mainline railway. For example, hauled metro stock from a manufacturer to the functionally separate metro network or hauling a de-registered vehicle to a workshop to be dismantled. In these circumstances an ECM is not required even during transit, because these vehicles do not fall within the scope of the ECM requirements in ROGS. In these examples the locomotive hauling the metro stock is in scope so requires an ECM and the operator of the locomotive will be required to hold a safety certificate and manage the safety of the operation which will necessarily entail ensuring that the vehicles it is hauling are safe to be on the mainline.

Vehicles in storage

3.16. Occasionally, vehicles are withdrawn from service and/or removed from the register pending sale, re-leasing, modification etc. An ECM is not required for these vehicles because they are not in service or in use on the mainline railway, however, there is likely to be planned maintenance that must take place whilst the vehicle is in storage in order to ensure the vehicle's condition does not deteriorate. The transport undertaking and/or the ECM assigned to the vehicle when it returns to the mainline will be expected to ensure this planned maintenance has been carried out. For this reason, many owners, keepers and transport undertakings choose to voluntarily contract an ECM and keep the vehicle on the register whilst it is in storage.

What is the role of the ORR inspector in checking compliance with regulation 18A(1)?

3.17. ORR staff can check if a vehicle is assigned an ECM by contacting the registration entity (see 3.7). The registration holder should be contacted if a vehicle is found without an ECM.

3.18. A list of ECM certificates issued by all certification bodies can be found on the Agency's [ECM certificate database](#).

4. The requirements of regulations 18A(2) and 18A(3)

What the regulations say

4.1. Regulations 18A(2) and 18A(3) of ROGS, require an ECM to ensure that the vehicles for which it is responsible are safe to run on the mainline railway. This must be done through a system of maintenance (see below) in accordance with;

- the maintenance file (see below) for the vehicle,
- applicable maintenance rules; and
- applicable technical specifications for interoperability (TSIs)

What is a system of maintenance?

4.2. The ECM is responsible for developing a system of maintenance to manage and implement maintenance activities for the vehicles it is responsible for. ECMs can demonstrate compliance with regulations 18A(2) and (3) of ROGS by developing a system of maintenance along the lines of Annex III of European Commission Regulation 445/2011 (“the ECM Regulation”). The system described is for freight wagons, but it is equally applicable to other vehicles. Annex III of the ECM Regulation has been adapted for this RIG, (at Annex A) to make it applicable to all vehicles.

4.3. The ECM is responsible for coordinating and monitoring all maintenance activity with a vehicle or fleet of vehicles, including developing a maintenance file (see below). Certain maintenance tasks within the maintenance development, fleet maintenance management and maintenance delivery functions can be outsourced, in whole or in part. Regardless of the outsourcing arrangements in place, the ECM is responsible for the outcome of the maintenance activities it manages and must establish a system to monitor performance of those activities.

What is a maintenance file?

4.4. The maintenance file is a written file containing all the technical and management information necessary to determine the maintenance activities. It is a vital part of the maintenance arrangements and allows the ECM to demonstrate that it has suitable maintenance arrangements in place to make sure relevant rules and regulations are followed.

The development of the maintenance file

4.5. The maintenance file is developed based on whether a vehicle is authorised for placing in service under the [Railways \(Interoperability\) Regulations 2011 \[S.I. 3066/2011\]](#) (“RIR2011”) or not.

Vehicles authorised for placing in service

- 4.6. For vehicles authorised for placing in service, the maintenance file is developed from the technical file (see regulation 17(2)(a) of RIR 2011). The content of the technical file, with respect to maintenance information, is described in detail in the relevant TSI.
- 4.7. Interoperability does not cover all the technical characteristics of a vehicle. It covers the vehicle interface and compatibility requirements necessary to meet the essential requirements through applicable TSIs. Consequently, the ECM may require additional technical information. This is requested contractually between the applicant (for authorisation for placing in service) and the manufacturer of the vehicle.
- 4.8. For vehicles authorised for placing in service, the initial technical documentation informing the maintenance file, comprises:
- the initial maintenance documentation in the technical file; and
 - additional technical documentation requested contractually, including the relevant maintenance documentation.

Vehicles in service prior to the implementation of RIR2011

- 4.9. For vehicles placed in service prior to the implementation of RIR2011, the technical documentation to use in the maintenance file comprises:
- all technical information that is provided with the vehicles; and
 - additional technical documentation requested contractually, including the relevant maintenance documentation.
- 4.10. The maintenance file must also take into account the pattern of planned operations.

Content of the maintenance file

- 4.11. The maintenance file for each vehicle, or fleet of vehicles, contains all the information necessary to carry out maintenance. ERA guidance states that it is composed of the following four elements:
- i. general documentation
 - ii. maintenance design justification file
 - iii. maintenance description file
 - iv. configuration files
- 4.12. The information set out below in relation to these four elements should cover all the essential elements of the relevant maintenance schedule but not necessarily in the same form or sequence.

(i) General documentation

- 4.12.1. The general documentation is composed of:

drawings and description of the vehicle and its components;
any legal requirement concerning the maintenance of the vehicle;
drawing of systems (mechanical, electrical, pneumatic, hydraulic and control-circuit diagrams);
necessary calculations; and
additional on-board systems (description of the systems including description of functionality, specification of interfaces and data processing and protocols).

4.12.2. These may be updated by the ECM

(ii) Maintenance design justification file

4.12.3. The maintenance design justification file explains how maintenance activities are defined, designed and updated. It ensures that:

The vehicle's characteristics will be kept within permissible limits of use during its lifetime; and

The vehicle is safe for the planned patterns of operation

4.12.4. The maintenance design justification file provides information that determines the criteria for maintenance activities. It consists of:

precedents, principles and methods used to design the maintenance of the vehicle;

limits of the normal use of the vehicle (e.g. km/month, climatic limits, foreseen types of loads etc.) according to the planned pattern of operation;

relevant data used to design the maintenance and the origin of these data (e.g. return of experience);

tests, investigations and calculations carried out to design the maintenance

4.12.5. This file must be updated by the ECM to enable traceability of changes in maintenance.

(iii) Maintenance description file

4.12.6. The maintenance description file describes how maintenance activities have to be carried out. Maintenance activities include, among others:

inspection;

monitoring;

tests;

measurements;
replacements;
adjustments; and
repairs.

Maintenance activities are split in to:

preventive maintenance; scheduled and controlled;
corrective maintenance;
light and heavy maintenance

4.12.7. The maintenance description file should contain at least the following:

Component hierarchy and functional description. The hierarchy sets up the boundaries of the rolling stock by listing all the items belonging to the product structure of that rolling stock and using an appropriate number of discrete levels. The lowest item of the hierarchy must be a replaceable component;

Parts list which contains the technical and functional descriptions of the spare parts (replaceable units) and references from the spare part provider and manufacturer, in order to allow identification and procurement of the correct spare parts. The list must include all parts specified for changing on condition, or which may require replacement following electrical or mechanical malfunction, or which will foreseeable require replacement after accidental damage. Interoperability constituents must be indicated and referenced to their corresponding declaration of conformity.

A statement of the limit values for components which are not to be exceeded in service. The possibility of specifying operational restrictions in degraded mode (limit value reached) is permitted.

European legal obligations - where components or systems are subject to specific European legal obligations these obligations must be listed.

A maintenance plan i.e. the structured set of tasks to perform the maintenance including the activities, procedures and means. The set of tasks includes:

disassembly/assembly instructions drawings necessary for correct assembly/disassembly of replaceable parts;
maintenance criteria;

checks and tests in particular of safety relevant parts; these include visual inspection and non-destructive tests (where appropriate e.g. to detect deficiencies that may impair safety);

tools and materials required to undertake the task;

consumables required to undertake the task;

personal protective safety provision and equipment.

Necessary tests and procedures to be undertaken before release to service and return to operation.

(iv) Configuration files

4.12.8. The configuration files for each vehicle (parts list and bill of material) enables, in particular, traceability of maintenance activities throughout its lifecycle. They contain the records of maintenance performed. Traceability of maintenance records depends on their impact on safety and has to be compliant with applicable legislation.

4.12.9. Transport undertakings are required to describe their arrangements for safety through a safety management system (SMS), including arrangements to control risks relating to the supply of maintenance and materials (regulation 5(1)(d) of ROGS). A safety certificate held by a transport undertaking demonstrates that processes are in place to enable vehicle maintenance to be managed according to set standards and/or plans. ECMs, transport undertakings and infrastructure managers each have a role in managing risks arising from maintenance activities. Safety certificate and safety authorisation holders are subject to ORR inspections targeted at activities with the potential to give rise to serious risks, or where hazards appear to be less well controlled.

What is the role of the ORR inspector in checking compliance with regulations 18A(2) and 18A(3)?

4.13. Transport undertakings are required to describe their arrangements for safety through a safety management system (SMS), including arrangements to control risks relating to the supply of maintenance and materials (regulation 5(1)(d) of ROGS). A safety certificate held by a transport undertaking demonstrates that processes are in place to enable vehicle maintenance to be managed according to set standards and/or plans. ECMs, transport undertakings and infrastructure managers each have a role in managing risks arising from maintenance activities. Safety certificate and safety authorisation holders are subject to ORR inspections targeted at

activities with the potential to give rise to high risks, or where hazards appear to be less well-controlled.

- 4.14. ORR inspectors also have a role in checking that structural subsystems, for example those that go together to form rolling stock, are operated and maintained in accordance with the relevant essential requirements provided for in the respective TSIs and in compliance with the technical file of an authorised vehicle.
- 4.15. ORR inspectors may examine the maintenance system put in place by the ECM as part of the checks relating to the safety certificate or safety authorisation.

Maintenance of freight wagons

- 4.16. An ECM responsible for the maintenance of freight wagons has to demonstrate compliance with regulations 18A(2) and (3) of ROGS and obtain an ECM certificate from a certification body. A list of certification bodies can be found on the Agency website:
https://eradis.era.europa.eu/safety_docs/ecm/certBodies/default.aspx
- 4.17. An ORR inspector can rely on an ECM certificate as confirmation that an ECM responsible for freight wagons complies with regulations 18A(2) and 18A(3) of ROGS. It should not be necessary for inspectors to inspect certificate holders to check compliance with the regulations. If an ORR inspector has justified reason to doubt the ability of an ECM to meet the criteria, perhaps through intelligence or because they have inspected the company for compliance with other requirements in ROGS (e.g. safety certificate/authorisation), the inspector should liaise with the certification body that issued the certificate in the first instance. Unless it is an emergency, the inspector should not carry out additional inspections or raise findings against an ECM without liaising with the certification body.

Disagreements between certification bodies and NSAs

- 4.18. It is possible that differences of opinion will occur between ORR inspectors and certification bodies. For example, an ORR inspector may have a concern about an ECMs approach to complying with the requirements that the certification body has already accepted. It is important that in such circumstances the ORR inspector and certification body cooperate to mutually agree a course of action and not give the ECM conflicting instructions.

Certification bodies outside the UK

- 4.19. If an ORR inspector needs to raise a concern or liaise with a certification body that is outside the UK they can do so directly or via the National Safety Authority (NSA) of the Member State the certification body is accredited in. The Agency's [Certification Body database](#) can be used to identify the country the certification body is accredited in.

4.20. The Agency has a duty to facilitate cooperation between certification bodies in order to harmonise the approach to the assessment of ECMs. Disputes between certification bodies in different Member States should be escalated to the Agency.

What is the role of the certification body?

4.21. The certification body is responsible for verifying that an ECM complies with Regulations 18A(2) and 18A(3) and applies them consistently. An ECM Certificate will be issued by the certification body after an initial assessment has been carried out to verify that the ECM complies with the requirements and is capable of continuing to comply.

4.22. After issuing the ECM Certificate the certification body remains responsible for verifying that the ECM continues to comply with the requirements. The certification body may carry out additional audits or assessments ('surveillance' visits) and must investigate any allegations made by ORR inspectors, transport undertakings or anyone with justified reason to believe that the ECM does not comply with the requirements.

4.23. Certification bodies primarily issue certificates to ECMs of freight wagons but they may also issue certificates to ECMs of other vehicles if the ECM chooses to apply voluntarily or if the Agency extends the certification scheme to all vehicles (see [Section 3](#)).

ORR as a certification body

4.24. ORR was a certification body until 31st May 2018. All transport undertakings should have transferred to a new certification body and ORR inspectors are no longer carrying out inspections of ECMs to check compliance with Regulations 18A(2) and 18A(3).

What happens if a certification body ceases trading?

4.25. If a certification body ceases trading for whatever reason the certificates it issued do not automatically become invalid. ECMs that hold certificates issued by the certification body must transfer to a new certification body as soon as practicable and make arrangements for any programmed inspections/audits to be carried out on schedule.

What is the role of the transport undertaking in relation to regulations 18A(2) and 18A(3)?

4.26. All transport undertakings must manage the operational risks of running trains in an unsafe state. This is often achieved through pre-departure checks and monitoring en-route by operational staff (commonly referred to as first level maintenance).

4.27. An ECM for freight wagons with a certificate demonstrates an effective and efficient way of supporting the control of risks

associated with the supply of maintenance. This provides assurance to the transport undertaking that the ECM complies with regulations 18A(2) and 18A(3) of ROGS.

- 4.28. Transport undertakings must recognise this ECM certificate, but this does not remove their day-to-day responsibilities to operate safe trains (as set out in the safety management system).

The transfer of vehicles from one ECM to another

4.29. From time to time the maintenance of vehicles may be transferred from one ECM to another. The registration holder is responsible for updating the registration entity with the new ECM's details. The incoming ECM should request from the previous ECM all the necessary information regarding maintenance.

- 4.30. As far as possible, the incoming and outgoing ECMs should reach an agreement on what information will be transferred with the vehicle and this should include the following as a minimum:

For vehicles authorised for placing in service

- the latest maintenance documentation;
- reports from Notified Bodies ("NoBos");
- initial technical documentation;
- declarations of verifications and conformity to TSIs; and
- the authorisation for placing in service.

For existing vehicles

- the existing maintenance documentation;
- the existing homologation (i.e. engineering acceptance) certificates, or equivalent, including the possible limits of use; and
- all additional information requested by contract between both ECMs.

- 4.31. In cases of insolvency, it is possible that no information or insufficient information on maintenance is communicated to the new ECM. To ensure that at least safety-critical information is transferred with the vehicle, the registration holder may decide to request, by contract from the ECM, provisions related to the property of maintenance documentation (including any modification to it).

Action

(optional)

Note: Where the RIG relates to any potential enforcement action to be taken by an inspector, this section must include a clear steer as to what form that action should take.

Requirements for a system of maintenance

(Taken from Annex III of European Commission Regulation 445/2011 and adapted for the Rail Guidance Document on the ECM requirements in regulation 18A of ROGS)

The system of maintenance is composed of the following four functions:

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

(I) Requirements for the management function

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

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;
- (b) ensuring that safety targets are established, in line with the legal framework and consistent with an organisation's type, extent and relevant risks;
- (c) assessing its overall safety performance in relation to its corporate safety targets;
- (d) developing plans and procedures for reaching its safety targets;
- (e) ensuring the availability of the resources needed to perform all processes to comply with the requirements of this Annex;
- (f) identifying and managing the impact of other management activities on the maintenance system;
- (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;

- (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.
2. **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
- 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;
 - (b) evaluating the risks referred to in point (a);
 - (c) developing and putting in place risk control measures.
 - 2.2. The organisation must have procedures and arrangements in place to recognise the need and commitment to collaborate with keepers, transport undertakings, infrastructure managers, or other interested parties.
 - 2.3. The organisation must have risk assessment procedures to manage changes in equipment, procedures, organisation, staffing or interfaces, and to apply Commission Regulation (EU) No 402/2013 (as amended) (the common safety method for risk evaluation and 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 (primarily implemented in Great Britain by the Management of Health and Safety at Work Regulations 1999).
3. **Monitoring** — a structured approach to ensure that risk control measures are in place, working correctly and achieving the organisation's objectives
- 3.1. The organisation must have a procedure to regularly collect, monitor and analyse relevant safety data, including:
 - (a) the performance of relevant processes;
 - (b) the results of processes (including all contracted services and products);
 - (c) the effectiveness of risk control arrangements;
 - (d) information on experience, malfunctions, defects and repairs arising from day-to-day operation and maintenance.

- 3.2. The organisation must have procedures to ensure that accidents, incidents, near-misses and other dangerous occurrences are reported, logged, investigated and analysed.
- 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;
 - (b) analyse and evaluate the results of the audits;
 - (c) propose and implement specific corrective measures/actions;
 - (d) verify the effectiveness of previous measures/actions.
4. **Continuous improvement** — 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

The organisation must have procedures to ensure that:

 - (a) identified shortcomings are rectified;
 - (b) new safety developments are implemented;
 - (c) internal audit findings are used to bring about improvement in the system;
 - (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;
 - (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;
 - (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;
 - (g) relevant reports/information from transport undertakings/infrastructure managers and keepers or other relevant sources are considered and taken into account.
5. **Structure and responsibility** — a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation's safety objectives
 - 5.1. The organisation must have procedures to allocate responsibilities for all relevant processes throughout the organisation.

- 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, transport undertakings and infrastructure managers.
- 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.
- 5.4. The organisation must have procedures to ensure the coordination of activities related to relevant processes across the organisation.
- 5.5. The organisation must have procedures to hold those with a role in the management of safety accountable for their performance.
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;
 - (b) the identification of posts involving safety tasks;
 - (c) the allocation of staff with the appropriate competence to relevant tasks.
 - 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;
 - (b) selection principles, including basic educational level, mental aptitude and physical fitness;
 - (c) initial training and qualification or certification of acquired competence and skills;
 - (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;
 - (e) on-going training and periodical updating of existing knowledge and skills;

- (f) periodic checks of competence, mental aptitude and physical fitness where appropriate;
- (g) special measures in the case of accidents/incidents or long absences from work, as required.

7. **Information** — a structured approach to ensure that important information is available to those making judgments and decisions at all levels of the organisation

- 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.
- 7.2. To ensure an adequate exchange of information, the organisation must have procedures for:
 - (a) the receipt and processing of specific information;
 - (b) the identification, generation and dissemination of specific information;
 - (c) making available reliable and up-to-date information.
- 7.3. The organisation must have procedures to ensure that key operational information is:
 - (a) relevant and valid;
 - (b) accurate;
 - (c) complete;
 - (d) appropriately updated;
 - (e) controlled;
 - (f) consistent and easy to understand (including the language used);
 - (g) made known to staff before it is applied;
 - (h) easily accessible to staff, with copies provided to them where required.
- 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 vehicles maintained by the organisation;
 - (b) maintenance documentation;

- (c) information on support provided to keepers and, where appropriate, to other parties, including transport undertakings/infrastructure managers;
- (d) information on the qualification of staff and subsequent supervision during maintenance development;
- (e) information on operations (including mileage, type and extent of activities, incidents/accidents) and requests of transport undertakings, keepers and infrastructure managers;
- (f) 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;
- (g) release to service and return to operation;
- (h) maintenance orders;
- (i) technical information to be provided to transport undertakings/infrastructure managers and keepers for maintenance instructions;
- (j) 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;
- (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.

8. **Documentation** — a structured approach to ensure the traceability of all relevant information

- 8.1. The organisation must have adequate procedures in place to ensure that all relevant processes are duly documented.
- 8.2. The organisation must have adequate procedures in place to:
 - (a) regularly monitor and update all relevant documentation;
 - (b) format, generate, distribute and control changes to all relevant documentation;

- (c) receive, collect and archive all relevant documentation.
9. **Contracting** activities — a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation's objectives to be achieved
- 9.1. The organisation must have procedures in place to ensure that safety related products and services are identified.
 - 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;
 - (b) contractors, subcontractors and suppliers have a maintenance and management system that is adequate and documented.
 - 9.3. The organisation must have a procedure to define the requirements that such contractors and suppliers have to meet.
 - 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.
 - 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).
 - 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;
 - (b) obligations relating to the transfer of relevant information between both parties;
 - (c) the traceability of safety-related documents.

(II) Requirements for the maintenance development function

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

- (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;
 - (c) 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;
 - (d) identifying the need for risk assessment regarding the potential impact of the substitution in question on the safety of the railway system;
 - (e) managing the configuration of all technical changes affecting the system integrity of the vehicle.
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.
4. When vehicles start operations, the organisation must have procedures to:
- (a) obtain the initial documentation and to collect sufficient information on planned operations;
 - (b) analyse the initial documentation and to provide the first maintenance file, also taking into account the obligations contained in any associated guarantees;
 - (c) ensure that the implementation of the first maintenance file is done correctly.
5. To keep the maintenance file updated throughout the lifecycle of a vehicle, 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 vehicle;
 - (ii) the type and extent of operations planned;
 - (iii) the maintenance effectively performed;
 - (b) define the need for updates, taking into account the limit values for interoperability;
 - (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;
 - (d) ensure that the implementation of changes is done correctly.

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;
 - (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 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.
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;
 - (b) the configuration of vehicles, including, but not limited to, components related to safety;
 - (c) records of the maintenance performed;
 - (d) results of studies concerning return on experience;
 - (e) all the successive versions of the maintenance file, including risk assessment;
 - (f) reports on the competence and supervision of maintenance delivery and fleet maintenance management;
 - (g) technical information to be provided to support keepers, transport undertakings and infrastructure managers.

(III) Requirements for the fleet maintenance management function

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.
2. The organisation must have a procedure for the composition of the work package and for the issue and release of the maintenance order.
3. The organisation must have a procedure to send vehicles for maintenance in due time.

4. The organisation must have a procedure to manage the removal of vehicles from operation for maintenance or when defects have been identified.
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 vehicles.
6. The organisation must have a procedure to issue a notice to return to operation, taking into account the release to service documentation.
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.
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;
 - (b) the maintenance plan for each vehicle;
 - (c) a list of spare parts, including a sufficiently detailed technical description of each part to allow like-for-like replacement with the same guarantees;
 - (d) a list of materials, including a sufficiently detailed description of their use and the necessary health and safety information;
 - (e) a dossier that defines the specifications for activities affecting safety and contains intervention and in-use restrictions for components;
 - (f) a list of components or systems subject to legal requirements and a list of these requirements (including brake reservoirs and tanks for the transport of dangerous goods);
 - (g) all additional relevant information related to safety according to the risk assessment performed by the organisation.
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 (transport undertakings and infrastructure managers), needs to be communicated to interested parties.
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;
 - (b) return to operation, including restrictions on use relevant to transport undertakings and infrastructure managers.

(IV) Requirements for the maintenance delivery function

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;

- (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;
 - (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);
 - (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).
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;
 - (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;
 - (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.
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;
 - (b) ergonomics and health protection, also including the interfaces between users and information technology systems or diagnostic 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;
 - (b) adjusted or re-adjusted as necessary;
 - (c) identified to enable the calibration status to be determined;
 - (d) safeguarded from adjustments that would invalidate the measurement result;
 - (e) protected from damage and deterioration during handling, maintenance and storage.

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.
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.
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.
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);
 - (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.
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;
 - (b) any possible fault or defect regarding safety which is identified by the organisation;
 - (c) the release to service.
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;
 - (b) all maintenance works performed, including personnel, tools, equipment, spare parts and taking into account:
 - (i) relevant national rules where the organisation is established;
 - (ii) requirements laid down in the maintenance orders, including requirements regarding records;
 - (iii) final testing and decision regarding release to service;
 - (c) the control measures required by maintenance orders and the release to service;

- (d) the results of calibration and verification, whereby, for computer software used in the monitoring and measurement of specified requirements, the ability of the software to perform the desired task must be confirmed prior to initial use and reconfirmed as necessary; (e) the validity of the previous measuring results when a measuring instrument is found not to conform to requirements.