



# RIS

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# Rail Industry Standard

## Freight Technical Committee Audit Protocol

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### Issue record

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### Superseded or replaced documents

This Rail Industry Standard does not supersede or replace any other Railway Group documents.

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### Part 1 Introduction

#### 1.1 Purpose of this document

- 1.1.1 This document is a standard for an audit protocol provided by the Freight Technical Committee (FTC), for the rail industry to use if they so choose to do so.
- 1.1.2 This document is of specific application to wagon Entities in Charge of Maintenance (ECMs) embraced by Commission Regulation number 445/2011 and provides Appendices as an audit protocol. This document can be used by ECMs for internal audit, for audit of their suppliers, or for others to audit ECMs.

#### 1.2 Application of this document

- 1.2.1 A member of RSSB may choose to adopt all or part of this document through internal procedures or contract conditions. Where this is the case the member of RSSB will specify the nature and extent of the application.
- 1.2.2 Therefore specific compliance requirements and dates have not been specified since these will be the subject of internal procedures or contract conditions.

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#### 1.4 The structure of this document

- 1.4.1 This document is set out as a series of requirements, in some cases followed by relevant guidance. The guidance is indicated by prefixing the paragraph number with the letter 'G'.

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#### 1.6 Approval and authorisation of this document

- 1.6.1 The content of this document was endorsed by the Freight Technical Committee on 27 November 2014.
- 1.6.2 The content of this document was approved by Rolling Stock Standards Committee on 16 January 2015.
- 1.6.3 This document was authorised by RSSB on 30 January 2015.

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### Part 2 Requirements for auditing

#### 2.1 Audit protocols

2.1.1 The 14 audit protocols prepared by the FTC are set out in Appendix A. They are:

- a) A.1 Management function.
- b) A.2 Maintenance development function.
- c) A.3 Fleet maintenance management function.
- d) A.4 Maintenance delivery function.
- e) A.5 Competence.
- f) A.6 Standards, procedures and document control.
- g) A.7 Contracts and interfaces.
- h) A.8 Engineering change.
- i) A.9 Risk assessment.
- j) A.10 Audit and compliance.
- k) A.11 Materials procurement and management.
- l) A.12 Site assessment.
- m) A.13 Vehicle condition audit.
- n) A.14 Holistic audit questions.

2.1.2 Each individual audit protocol shall be used as stipulated by the audit commissioner or as agreed between auditor and auditee, selecting the relevant protocols as appropriate. Clauses 2.1.3, 2.1.4 and 2.1.5 set out the purpose and scenarios under which the different protocols are to be used.

2.1.3 The first four audit protocols are for the four ECM functions as defined in EU Regulation 445/2011 on a system of certification of ECMs for freight wagons.

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G 2.1.3.1 The EU Regulation 445/2011 of 10 May 2011 on a system of certification of Entities in Charge of Maintenance (ECM) for freight wagons describes how companies can undertake the ECM management function and / or the maintenance development function and / or the fleet management function and / or the maintenance delivery function, or any combination of these.

G 2.1.3.2 It is possible, therefore, for only one of the first four protocols to be applicable to a specific company. In practice in GB the usual situations are for an ECM to cover all four functions, or for an ECM to cover the first three with maintenance delivery being contracted to a second company.

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2.1.4 The audit protocols A.5 to A.11 are topic-specific assessments of company processes and procedures. These protocols are able to be used alone or in conjunction with any of the four ECM function protocols in A.1 to A.4.

2.1.5 Protocols A.12 and A.13 are for physical site assessment of the facilities and 'product audit' of wagons. Appendix A.14 gives example questions to investigate relationships and communications across boundaries to establish that the ECM arrangements are holistically robust.

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### 2.2 Auditing

- 2.2.1 The auditor shall be suitably qualified, independent and experienced to make a valid judgement as to whether the auditee demonstrates knowledge, practices, processes, facilities, records, equipment and procedures to adequately comply with each of the questions asked.
- 2.2.2 The audit commissioner shall consider the size, scope and nature of the operation concerned and the level of safety risk involved to decide on the breadth and depth of the audit sample required. These criteria shall be specified to the auditor.
- 2.2.3 During the audit the auditor shall decide, for each audit question considered, whether the auditee has demonstrated adequate compliance taking account of the criteria specified by the audit commissioner.

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G 2.2.3.1 The auditor should continue to probe and ask questions, and seek evidence, until in their professional opinion they are able to decide compliance or otherwise.

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- 2.2.4 If adequate compliance has not been demonstrated the auditor shall either:

a) Stop the audit and inform the auditee, if the auditor decides that the non-compliance leads to an immediate unacceptable safety risk.

Or

b) Issue a Non-Conformance Report (NCR). The auditor shall decide whether the NCR is of a major or minor nature, and agree timescales for rectification.

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G 2.2.4.1 It is anticipated that if the auditor has to stop the audit, as shown in 2.2.4 a), consideration will be given to alerting the industry to the problem found by using the NIR-online system described in GE/RT8250.

G 2.2.4.2 The definitions of major and minor NCR are given in the 'Definitions' section.

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- 2.2.5 The auditor shall complete the NCR form shown in Appendix C for each non-compliance found.
- 2.2.6 The auditor shall issue an observation if they decide that the risk is acceptable but that improvements could or should still be made.
- 2.2.7 The auditor shall complete the observation form shown in Appendix D for each observation made.

### 2.3 Completion of audit

- 2.3.1 At the end of the audit the auditor and auditee shall have a close out meeting. If any NCRs are issued then a timescale to close each NCR shall be recorded.

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G 2.3.1.1 It is preferable for the timescale to be agreed at the meeting.

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- 2.3.2 The audit findings, including any observations of the auditor shall be made at the close out meeting.
- 2.3.3 The results of the audit shall be recorded and the auditor shall complete an audit summary sheet, as shown in Appendix B.

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2.3.4 The audit summary sheet shall be updated by the auditor when any major NCRs are closed out, and again when all the minor NCRs (if any) are closed out.

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G 2.3.4.1 The summary sheet should be made available on request to all railway industry companies represented at FTC with a legitimate interest in the outcomes of the audit.

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### Appendix A Audit Protocol Sheets

#### A.1 Management function

| Commission Regulation 445/2011 Annex III Requirement                                                                                                                   |                                                                                                                                                                                            | Possibly Evidenced By / Notes             | Evidence Considered | Compliant? |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|---------------------|------------|
| 1. Leadership — commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness. |                                                                                                                                                                                            |                                           |                     |            |
| 1.1 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;            | Maintenance Policy Document.              |                     |            |
| (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;                                                                  | Organisation Chart, job descriptions etc. |                     |            |
| (f)                                                                                                                                                                    | identifying and managing the impact of other management activities on the maintenance system;                                                                                              | Organisation Chart, job descriptions etc. |                     |            |
| (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; |                                           |                     |            |

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                              |                                                      |  |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|--|--|
| (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. <u>Risk assessment</u> — a structured approach to assess risk 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.                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                              |                                                      |  |  |
| 2.1 The organisation must have procedures for:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                              |                                                      |  |  |
| (a)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | analysing risk relevant to the extent of operations carried out by the organisation, including the risk arising from defects and construction non-conformities or malfunctions throughout the lifecycle;     | Procedures / sample risk assessments.                |  |  |
| (b)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | evaluating the risk 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, railway undertakings, infrastructure managers, or other interested parties.                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                              | Meetings / day-to-day communications.                |  |  |
| 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 which established a 'common safety method on risk evaluation and assessment' (CSM RA) . Commission Implementing Regulation (EU) No 402/2013 establishes a revised common safety method for risk evaluation and assessment. The revised CSM RA has been in force since 23 May 2013 (meaning it can be used from that date), and will apply from 21 May 2015 (meaning that it must be used from that date), at which time Commission Regulation (EC) No. 352/2009 is repealed. |                                                                                                                                                                                                              | Engineering and other change procedures.             |  |  |
| 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 EU Workplace Health and Safety Directive 89/391/EEC.                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                              | The Health and Safety at Work Act applies in the UK. |  |  |

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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|--|
| 3. <u>Monitoring</u> — 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, to apply Commission Regulation (EU) No 1078/2012 which establishes a common safety method for monitoring. This includes: |                                                                                                                                 | Safety defect reporting and monitoring procedures and processes. |  |
| (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.                                                         |                                                                                                                                 | Monitoring, investigation and NIR processes.                     |  |
| 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; | Audit procedure and plans.<br>Sample audits and follow-up.       |  |
| (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.                                                                        |                                                                  |  |

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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.

4.1 The organisation must have procedures to ensure that:

|     |                                                                                                                                                                                                                                      |                                                                             |  |  |
|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|--|--|
| (a) | identified shortcomings are rectified;                                                                                                                                                                                               |                                                                             |  |  |
| (b) | new developments that improve safety 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;                                | Process for Monitoring of Railway Group Standards, legislative changes etc. |  |  |
| (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; | NIR review.                                                                 |  |  |
| (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;                                         | Review of RAIB reports etc.<br>Internal investigations.                     |  |  |
| (g) | relevant reports / information from railway undertakings / infrastructure managers and keepers or other relevant sources are considered and taken into account.                                                                      |                                                                             |  |  |

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| 5. <u>Structure and responsibility</u> — <i>a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation's safety objectives.</i>                                                                                                                                                                                          |                                                                                                                                                                  |                                                              |  |  |
| 5.1 The organisation must have procedures to allocate responsibilities for all relevant processes throughout the organisation.                                                                                                                                                                                                                                                      |                                                                                                                                                                  | Procedures, job descriptions, competence management process. |  |  |
| 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. |                                                                                                                                                                  |                                                              |  |  |
| 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.                                                                                                                                                                                                                                           |                                                                                                                                                                  | Procedures.                                                  |  |  |
| 5.5 The organisation must have procedures to hold those with a role in the management of safety accountable for their performance.                                                                                                                                                                                                                                                  |                                                                                                                                                                  | Performance monitoring process.                              |  |  |
| 6. <u>Competence management</u> — <i>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.</i>                                                                                                                                                   |                                                                                                                                                                  |                                                              |  |  |
| 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; | Competence management procedure and processes.               |  |  |
| (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:                                                                                                                                                                                                                                         |                                                                                                                                                                  |                                                              |  |  |

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| (a)                                                                                                                                                                                                                                                                                                                                                                                                                            | identification of the knowledge, skills and experience required for safety-related tasks as appropriate for the responsibilities;                       | Competence management procedure and its application.<br><br>Drugs and alcohol and fatigue policies.<br><br>Human Resources processes. |  |  |
| (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)                                                                                                                                                                                                                                                                                                                                                                                                                            | ongoing 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. <u>Information</u> — 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. |                                                                                                                                                         | Do procedures and processes include requirements for information flow across boundaries with other organisations?                     |  |  |
| 7.2 To ensure an adequate exchange of information, the organisation must have procedures:                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                         |                                                                                                                                       |  |  |
| (a)                                                                                                                                                                                                                                                                                                                                                                                                                            | for the receipt and processing of specific information;                                                                                                 | Document control procedure etc.                                                                                                       |  |  |
| (b)                                                                                                                                                                                                                                                                                                                                                                                                                            | for the identification, generation and dissemination of specific information;                                                                           |                                                                                                                                       |  |  |
| (c)                                                                                                                                                                                                                                                                                                                                                                                                                            | for making available reliable and up-to-date information.                                                                                               |                                                                                                                                       |  |  |

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| 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 freight wagons maintained by the organisation;                                                                                         |  |  |  |
| (b)                                                                                                                   | maintenance documentation;                                                                                                                                                                                                                                                          |  |  |  |
| (c)                                                                                                                   | information on support provided to keepers and, where appropriate, to other parties, including railway 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 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; |  |  |  |
| (g)                                                                                                                   | release to service and return to operation;                                                                                                                                                                                                                                         |  |  |  |

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|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|--|--|
| (h)                                                                                                                                                                                   | maintenance orders;                                                                                                                                                                                                                                                                                            |                             |  |  |
| (i)                                                                                                                                                                                   | technical information to be provided to railway 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 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; |                             |  |  |
|                                                                                                                                                                                       | (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. <u>Documentation</u> — 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:                                                                                                                       |                                                                                                                                                                                                                                                                                                                | Document control procedure. |  |  |
| (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. <u>Contracting activities</u> — a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation's objectives to be achieved. |                                                                                                                                                                                                                                                                                                                |                             |  |  |

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|                                                                                                                                                                                                                                       |                                                                                                                     |                                                               |  |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--|--|
| 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;                                                            | Supplier approval and contract letting procedure / processes. |  |  |
| (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 risk 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;                                                       | Are these items covered in sample contract specifications?    |  |  |
| (b)                                                                                                                                                                                                                                   | obligations relating to the transfer of relevant information between both parties;                                  |                                                               |  |  |
| (c)                                                                                                                                                                                                                                   | the traceability of safety-related documents.                                                                       |                                                               |  |  |

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### A.2 Maintenance development function

| Commission Regulation 445/2011 Annex III Requirement                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                               | Possibly Evidenced By / Notes | Evidence Considered | Compliant? |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------|------------|
| 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 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 freight wagons start operations, the organisation must have procedures to:                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                               |                               |                     |            |

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| Commission Regulation 445/2011 Annex III Requirement                                                                                                                         |                                                                                                                                                                                         | Possibly Evidenced By / Notes | Evidence Considered | Compliant? |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|---------------------|------------|
| (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 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; |                               |                     |            |
|                                                                                                                                                                              | (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;              | Engineering change procedure. |                     |            |
| (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;                                                             |                               |                     |            |