# Guideline 3: MAINTENANCE

2020 / rev. 01

English

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# 1 Introduction

The aim of this guideline is to define the specificities of the maintenance business required to comply with the requirements of IRIS Certification® rev. 03 system. It guides and supports the user in preparatory work for the implementation of the ISO/TS 22163 requirements with a focus on maintenance.

The guideline describes all key topics or names their references, which might be worked on for a successful implementation of the IRIS Certification® rev. 03 system in a maintenance organization. The focus is on the ISO/TS 22163 requirements and the assessment methodology with key elements like knock-out criteria as well as the activities declared as mandatory, which are to be prepared in advance.

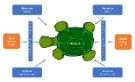
The details on

- the technical requirements can be found in the ISO/TS 22163 "Railway applications – Quality management system – Business management system requirements for rail organizations: ISO 9001:2015 and particular requirements for application in the rail sector".
- the certification process and the assessment methodology can be found in the IRIS Certification® Conformity assessment.

The guideline structure is following the ISO high level structure to support and enhance the understanding of the user. It can be used in conjunction with the ISO/TS 22163. The content concentrates on the ISO/TS 22163 clauses, where rail maintenance specifics are identified, or where explanation is needed.

In the annex, the user finds a comparison of existing regional maintenance regulations, such as Regulation (EU) 2019/779 [4] for the European system of certification for Entities in Charge of Maintenance (ECMs) with the IRIS Certification® rev. 03 system.

To emphasize the key areas a maintenance organization may focus on, the related mandatory requirements on Knock-out, process, Key Performance Indicators and retained documented information, which are assessed every year during a third-party audit, and in this document highlighted with following symbols for better visualization:

| **Knock-out requirement** | **Process** | **Mandatory process for performance evaluation** | **Key Performance Indicators** | **Retained documented information** |
|---|---|---|---|---|
|  |  |  |  |  |
| Always applicable | Mandatory | Mandatory turtle | Mandatory | Mandatory |
| Can be put as not applicable | Recommended | - | Recommended | Recommended |

The ISO/TS 22163 is a basic standard for the rail maintenance activity as well as other rail activities (manufacturing, design and development).

Maintenance in the rail sector is necessary in order to guarantee the safety, availability and comfort of the customer. It also enhances the products during their lifetime.

Maintenance activities are performed either by railway operators, system integrators, equipment manufacturers or by private maintainers.

Maintenance within the IRIS Certification® rev. 03 system, is an IRIS activity, which covers fleet maintenance, refurbishment and component overhaul/repairs. It may include maintenance (for new built: manufacturing) and/or design activities on track (infrastructure) and on board (rolling stock) systems.

The guideline content is a recommendation based on good practices from the rail sector experts and methods and is not subject to be audited by any third-party audit as a mandatory requirement.

# 2 Normative references

| | |
|---|---|
| ISO/TS 22163 | "Railway applications – Quality management system – Business management system requirements for rail organizations: ISO 9001:2015 and particular requirements for application in the rail sector" |
| IRIS Certification® Conformity assessment | Rules for achieving and maintaining IRIS Certification® recognition |

# 3 Terms and definitions

## 3.1 Terms and definitions for the rail sector

| | |
|---|---|
| Corrective Maintenance | maintenance carried out after fault recognition and intended to put an item into a state in which it can perform a required function<br>*[SOURCE: EN 13306:2010, 7.5]* |
| Keeper | natural or legal person that, being the owner of a vehicle or having the right to use it, exploits the vehicle as a means of transport and is registered as such in a vehicle register.<br>*[SOURCE: Interoperability Directive (EU) 2016/797, 2 (21)]* |
| Improvement | combination of all technical, administrative and managerial actions, intended to ameliorate the reliability and/or the maintainability and/or the safety of an item, without changing the original function<br>*[SOURCE: EN 13306:2010, 8.12]*<br>Supplementary: Improvements cover a combination of all the actions taken to increase functional reliability without changing function but applying new technology. |

| | |
|---|---|
| Inspection | examination for conformity by measuring, observing, or testing the relevant characteristics of an item.<br>*[SOURCE: EN 13306:2010, 8.1]* |
| Line Replaceable Unit (LRU) | a modular component that is designed to be replaced quickly at an operating location. The exchange of an LRU does not require any special aids. |
| Modernisation | technical restoration to remedy defects or to increase the standard of technology. In order to identify existing defects, a preliminary investigation should be carried out to determine the cause of the damage, the symptoms and the proposed measures. |
| Overhaul | comprehensive set of preventive maintenance actions carried out, in order to maintain the required level of performance of an item<br>*[SOURCE: EN 13306:2010, 8.6]* |
| Preventive Maintenance | maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or the degradation of the functioning of an item<br>*[SOURCE: EN 13306:2010, 7.1]*<br>NOTE An item could be an "entity treated", "equipment", "component", etc. |
| Repair | physical action taken to restore the required function of a faulty item.<br>*[SOURCE: EN 13306:2010, 8.10]*<br>Supplemental: Measures taken to restore the original operational state of components and systems. |
| Store Replaceable Unit (SRU) | Store Replaceable Unit - is a modular component designed to be replaced by a technician at a workshop or a depot. The exchange may require special equipment or aids. |
| Subject of Maintenance | a subject of maintenance can be rolling stock or wayside equipment. |
| Turtle | the Turtle diagram is a tool to visually display process characteristics and other high-level information to assist in the effective execution and improvement of business processes.<br>*[SOURCE:* IRIS Certification® Conformity assessment:2020, Appendix 5*]* |

## 3.2 Abbreviations

The abbreviations given in ISO/TS 22163 apply for the purpose of this document

| | |
|---|---|
| EPPPS | Externally Provided Process, Product and Services |
| FAI | First Article Inspection |
| FMEA | Failure Mode and Effects Analysis |
| FMECA | Failure Mode, Effects and Criticality Analysis |
| FRACAS | Failure Reporting Analysis and Corrective Action System |
| IRQB | The International Rail Quality Board |
| KPI | Key Performance Indicator |
| LCC | Life Cycle Costing |
| OEM | Original Equipment Manufacturer |
| RAMS | Reliability, Availability, Maintainability, Safety |
| RQMS | Rail Quality Management System containing safety issues as well *[Ref. ISO/TS 22163]* |

# 4 Context of the organization

## 4.1 Understanding the organization and its context

A maintenance organization describes clearly how it is organized, taken into consideration if it is a standalone organization or belonging to a corporation. Furthermore, it includes interaction with the market, competitors, main customers, product portfolio, expectation from the market, legal requirements, etc.

As per ISO/TS 22163 requirement, management reviews (see clause 9.3) have to take place regularly to ensure the understanding of issues influencing the organization and its context.

## 4.2 Understanding the needs and expectation of interested parties

A maintenance organization performs an analysis of its stakeholders to understand their needs and expectations towards its RQMS. It considers customers, external/internal providers, employees, management, regulatory bodies, etc. This stakeholder analysis is reviewed and updated periodically.

Expectations of interested parties can be identified in the following areas:

- Employee: internal communication (achievement of goals, bonus), training opportunities, career opportunities, etc.
- Customer: communication, zero defect, on time delivery rate, documented information, etc.

- Regulatory body: on time annual reporting, communication in case of serious accident, claims, etc.

# 5 Leadership

## 5.1 Leadership and commitment

### 5.1.1 General

Main focus of this area is the commitment and leadership of the top management in respect to the quality management system towards planned and unplanned maintenance activities. Top management should include in their planning human resources, infrastructure, logistics, materials for a certain percentage of additional works and/or deferred work.

### 5.1.2 Customer focus

In order to guarantee the safety, availability and comfort of the customer, the maintenance organization should focus on understanding and communicating customer requirements to all levels of the organization. By having a two-way communication, customer feedback and satisfaction should be enhanced, collected and acted upon.

Customer's requirements should also be understood in terms of the product life cycle. For example: mileage expectations of a wheel set.

Customer focus can be demonstrated at different levels (e.g. ranging from operational maintenance activities to account management at executive level).

## 5.2 Policy

The maintenance activity should be integrated in the company policy. Safety targets should be in correlation with the policy.

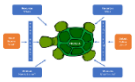
## 5.3 Organizational roles, responsibilities and authorities

Responsibility and competence of process owners is coherent and compatible with the given role and delegation evidences in a written form, e.g. assignment or job description are defined and maintained as documented information.

The different actors and their duties in the maintenance process are:

- The **vehicle/infrastructure equipment manufacturer** is responsible for the initial maintenance plan,
- The **keeper** of the fleet is responsible for ensuring that the vehicle is in a safe state for operation,
- The **operator** is responsible for the safe operation of the product and ensures the availability of the product for maintenance,
- The **maintainer** is responsible for performing the maintenance activities according to customer requirements, including maintenance execution and failure reporting,
- The **external provider** (operator, system integrator, equipment manufacturer, distributor) is responsible for providing products or services by fulfilling the contractual requirements.

### 5.3.1 Organizational roles, responsibilities and authorities – Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | - | - | - | Mandatory |

Refer to ISO/TS 22163. No further explanations are needed in this guideline.

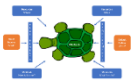
# 6 Planning

## 6.1 Actions to address risks and opportunities

Risks and opportunities may be understood at different levels, e.g. business and technical. At business level a SWOT analysis may be used and at technical level an FMEA or FMECA may be used to identify risks. It is recommended to link the FMEA and FMECA as an input to the FAI to determine criteria and to use a multi-disciplinary approach when assessing risks and when feasible involve customers.

One risk assessment method can be the process FMEA as a minimum per product family. Relevant to the scope of maintenance and agreements with customer (e.g. administration, packaging, transportation, cleaning, disassembly, etc.).

### 6.1.3 Actions to address risks and opportunities – Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| Always applicable | Mandatory | - | - | Mandatory |

Refer to ISO/TS 22163. No further explanations are needed in this guideline.

### 6.1.4 Contingency planning

Contingency planning is dedicated to preparing the organization for any kind of maintenance interruption. The following can be considered in maintenance activities:

- information technology,
- infrastructure interruptions,
- labour shortage,
- key production equipment,
- facility supply issues,
- transportation

Through the maintenance specificities, special attention may be given to the human resources management through an adequate succession planning to avoid lack of competences in key maintenance processes.

Due to potential localization of equipment, the organization may implement actions to ensure the continuity of the maintenance at own location or at any maintenance workshop.

More details can be found in ISO 22301 [3] Business continuity management.

### 6.2.3 Safety objectives

The organization should define safety objectives e.g. zero incident in correlation with manufactured products, in relation to mileage, environmental aspects, derailments.

## 6.3 Planning of changes

By planning of changes impacting the business management systems, the documentation of the existing situation is crucial to start any further planning.

The organization should have a risk management approach to manage changes in the maintenance file including maintenance plans, equipment, processes, organization staffing or interfaces. The decision for change is taken by knowing all consequences for the customer and the maintainer. The full supply chain is generally involved when a design change is validated.

Depending on the type of change, e.g. obsolescence, system upgrade, the applicable as built and validation file is the basis for analysis of a change request. It is key that the file is up to date.

The change should be validated according to the defined process in the business management system to keep the safe operational state of the product / system.

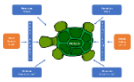
# 7 Support

## 7.1 Resources

Resources form a key cornerstone in a maintenance organization, including people and infrastructure. Top management commitment and leadership as specified in clause 5 of the ISO/TS 22163 need to be ensured especially for maintenance resources.

Risk analysis results should be considered to establish the risk provisions.

#### 7.1.1.1 General - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| - | Mandatory | - | - | Mandatory |

Refer to ISO/TS 22163. No further explanations are needed in this guideline.

### 7.1.2 People

Due to the maintenance business specificities, a contingency and succession planning for key people might be implemented and maintained to ensure the continuity of the business (see clause 6.1.4).

Key roles for continuous operations and business critical activities are to be identified and included in the contingency planning.

### 7.1.3 Infrastructure

The meaning of infrastructure in this clause also include the facility at which maintenance activities are performed - or in case of mobile teams - the equipment and tools needed to perform the maintenance activities. There is also an option where external maintenance staff is using the customer's infrastructure or facilities.

The driver for selecting maintenance location and the infrastructure of the facility to be used is the content of the maintenance plan.

All infrastructure, including facilities and equipment, are adapted, qualified, validated and maintained in order to be in line with the requirements of the maintenance plan.

### 7.1.4 Environment for the operation of processes

In addition to the environment determined in ISO/TS 22163 requirements, the maintenance activities may frequently be carried out at customer's sites or operator's premises where specific safety rules apply. Site conditions and rules are to be reviewed (e.g. in joint risk assessment), clearly communicated and understood before starting work offsite. Personnel needs to be trained regarding the risks and site rules.

### 7.1.5 Monitoring and measuring resources

The acceptance criteria of measurement/control tools have to be defined and a responsible person appointed within the organization who is authorized to release calibrated tools.

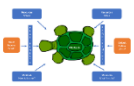
If equipment is found unfit for its purpose, then a risk assessment should be carried out.

More details about requirements for measurement systems can be found in the ISO 10012 [1].

#### 7.1.5.2 Measurement traceability

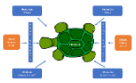
The organization should ensure the measurement traceability (traceability of all measurement) by considering the maintenance records, which may have a link to the respective measurement equipment in case of failure detection on the measurement equipment.

#### 7.1.5.3 Monitoring and measuring resources - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| - | Mandatory | - | - | Mandatory |

Refer to ISO/TS 22163. No further explanations are needed in this guideline.

### 7.1.6 Organizational knowledge - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | Recommended | - | - | - |

To avoid people dependency, organizational knowledge needs to be shared or transferred via documents and electronic tools (organised by topic) to enable feedback and passing on the lessons learnt.

Intellectual property should be protected. In case intellectual property is owned by other parties (e.g. contractor developed training materials), some sharing restrictions should be considered.

Organizational knowledge is constantly developing from Design to original manufacturing, from comparable projects, lessons learnt from maintenance works and field service, or in general from return of experience from operation, customer satisfaction, etc., throughout the life of products. As this organizational knowledge develops, the maintenance plan should be modified.

This organizational knowledge specific to products should be communicated and shared with the OEM respectively (see clause 8.3.3).

This knowledge may permit greater availability of the products, costs efficiency and optimization of the maintenance tasks.

## 7.2 Competence

Maintenance activities requiring special/specific qualifications and competences are identified by the organization. The execution of maintenance activities needs the allocation of staff with the appropriate competence(s), e.g. skills matrix.

Competence management should be supported by a training plan to ensure the updates of skills/qualifications as required. Refresher training (especially for safety-related tasks) or practical exam could be ways to keep awareness and up to date skills, especially for operators managing special processes to keep up to date knowledge and sufficient level of awareness of risks identified.

A focus is put on qualifications on special processes and activities with expiry dates (e.g. welding, bonding, non-destructive testing). These qualifications are to be followed up and recurring trainings are to be organized before authorizations expire.

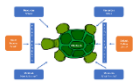
The IRQB Guideline 6: Special processes [10] contains further details regarding required competences.

Authorizations are necessary to carry out some tasks after specific trainings are provided (e.g. electrical, lifting, special processes, etc.). Therefore, qualification/authorisation could be visualized using skill matrices, or adequate electronic tools.

The organization ensures that the teams have the needed competences on maintenance activities as such. Shared knowledge in a team should be fostered to avoid unique knowledge.

Therefore, competence management should apply to all staff (including to temporary workers or in case of delegation of tasks/outsourcing) within the organization.

### 7.2.1 Competence - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| Always applicable | Mandatory | - | - | Mandatory |

Refer to ISO/TS 22163. No further explanations are needed in this guideline.

## 7.3 Awareness

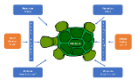
Raising awareness within the organization requires the implementation of soft skills and tools.

Examples of

- soft skills could be communication training
- tools could be 8D training, quality circle and employee town hall meeting

Field service, customer complaint, accidents, internal failure information, audit result should be used as training inputs to raise awareness of employees.

## 7.4 Communication

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | Recommended | - | - | - |

The organization should put in place communication strategies with all relevant stakeholders.

Efficient maintenance management requires good communication and a reliable exchange of information between all involved parties. An exchange of information should be organized in a regular basis and as required for the status update of the maintenance activities between the maintenance manager within the maintenance organization. This would focus on the exchange of information about operational, organizational and technical topics of maintenance, such as

- new or changed maintenance orders,
- new or changed regulations,
- new or changed maintenance documents,
- information about the qualification of the personnel,
- information about operations (changes, faults, accidents, suspected serial defects),
- information about executed maintenance work (maintenance orders, releases to service, usage restrictions, defects),

- technical, operational, organizational changes,
- changes in subcontracting (contractors, activities, equipment, training),
- internal audit reports,
- status of safety objectives.

This could also serve as a basis for the Management Review.

The heads of the maintenance are responsible for providing their respective organizations with maintenance-related information in a reliable, timely, comprehensible and easily accessible form before the application. It is suggested to implement a communication matrix.

An external exchange of information with owners, railway operators and railway infrastructure operators about the status of the maintenance should take place on a regular basis.

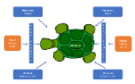
## 7.5 Documented information

### 7.5.1 General

Maintenance documented information (former documents and records) is allocated under the subject of maintenance. It should be possible to retrieve the history of the maintenance carried out on the subject of maintenance.

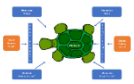
The responsibilities for managing documented information is defined, including clear interfaces, based on the contractual requirements e.g. technical library.

#### 7.5.3.2

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | - | - | - | Mandatory |

Refer to ISO/TS 22163. No further explanations are needed in this guideline.

#### 7.5.3.3 Control of documented information - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | Mandatory | - | - | Mandatory |

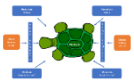
Refer to ISO/TS 22163. No further explanations are needed in this guideline.

# 8 Operation

## 8.1 Operational planning and control

The organization considers that maintenance may need to be carried out at multiple locations to meet customer requirements. Therefore, the activities at these multiple locations need to be planned and integrated to deliver the customer requirements. The processes should also consider the possibility of corrective activities being required in addition to the planned, preventive maintenance. The acceptance criteria following completion of the maintenance activities should be agreed with the customer and transferred into the maintenance plan.

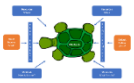
### 8.1.1 Planning for the outsourcing or transfer of processes

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | Mandatory | - | - | Mandatory |

The process considers what controls are necessary to ensure that its requirements are met, e.g. risk assessment, possibly jointly with the outsourcing company, passing down relevant customer requirements, defining roles and responsibilities, whether a FAI is to take place, how the outsourced work will be supervised and monitored, defining maintenance documented information to be produced and retained. Activities that may be outsourced could include cleaning, special testing services and overhaul of OEM systems.

Even when outsourcing the organization is still responsible for quality and product safety.

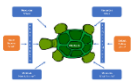
### 8.1.2 Tender management

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | - | Mandatory | Recommended | Mandatory |

The requirements defined in the clause 8.1.2 Tender management from the ISO/TS 22163 and the related parts of the IRIS Certification® Conformity assessment are applicable for maintenance organizations.

Maintenance activities cover fleet maintenance, refurbishment and component overhaul/repairs. Therefore, depending on its maintenance activities the maintenance organization implements the appropriate activities to ensure that the tender requirements from ISO/TS 22163 are fulfilled according to the organization characteristics.

### 8.1.3 Project management

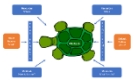
| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| Always applicable | Mandatory | Mandatory | Recommended | Mandatory |

The requirements defined in the clause 8.1.3 Project management from the ISO/TS 22163 and the related parts of the IRIS Certification® Conformity assessment are applicable to maintenance organizations.

The organization defines and documents which maintenance activities have to be handled as projects with milestones and stage gates (e.g. refurbishment). When using a gate review process, the criteria for passing to the next stage should be pre-defined.

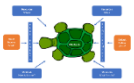
More details about guidance for project management can be found in the ISO 21500 [2].

#### 8.1.3.4 Project cost management

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| - | - | - | Mandatory | - |

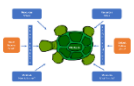
Refer to ISO/TS 22163. No further explanations are needed in this guideline.

#### 8.1.3.8 Project risk and opportunity management

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| - | - | - | - | Mandatory |

Refer to ISO/TS 22163. No further explanations are needed in this guideline.

### 8.1.4 Configuration management

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| Always applicable | Mandatory | - | - | Mandatory |

A proper configuration management allows an organization to have control over the status and version of hardware (e.g. bill of materials, spare parts, drawings) and software that are required to be

supplied or installed in a system or rolling stock. This is important when changes are required due to, for example, obsolescence.

For example, for vehicles:

- the vehicle configuration is handed over by the manufacturer to the maintenance provider
- the configuration list is part of the vehicle file
- a configuration list is created from the system at the time of delivery of a new vehicle
- this vehicle-related configuration list is archived in the vehicle file for each vehicle in the configuration folder
- the configuration of the vehicle should be maintained from the start of operations.

Additionally, the software configuration of the vehicle and subsystems is included and maintained in the vehicle configuration list e.g.:

- software version of the vehicle
- Automatic Train Protection software version
- cab radio software version
- juridical Recording Unit software version.

In this configuration list, the vehicle configuration as well as the software versions of the vehicle and the subsystems are requested.

The procurement and archiving of the vehicle configuration is the responsibility of the maintenance organization.

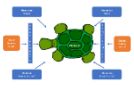
A risk assessment is required to assess the implications of installing any alternative hardware or software.

The configuration management process helps to keep situations under control where different versions of similar material/software are installed.

A typical maintenance requirement may be updating and maintaining the technical configuration and technical library and software during the life cycle of the material and rolling stock. This requires a process to be in place to ensure that all updates and changes are captured in the technical library.

Detailed information can be found in the IRQB Guideline 8: Configuration and change management [12].

### 8.1.5 Change management

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| Always applicable | Mandatory | - | - | Mandatory |

The change management process ensures that all planned or required changes such as changes in the maintenance organization, changes required by the customer, those required by component obsolescence, availability or reliability improvements, changes in laws and standards are assessed and if approved, implemented in a controlled way.

Where there is a related contract, the change process is closely aligned so that the implications on maintenance of the products/systems changes can be fully assessed.

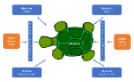
The impact of the change on maintenance activities (and OEM production if applicable) should be analysed (risk assessment) and the implementation organized adequately. Triggers for change might be technical, organizational and operational.

Depending on the criticality of the change or product/system, a rather simple or complex verification/validation process should be used. The validation is a pre-requisite for the final release and implementation of the change.

Detailed information can be found in the IRQB Guideline 8: Configuration and change management [12].

## 8.2 Requirements for products and services

### 8.2.1 Customer communication

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | - | - | Recommended | - |

For all maintenance contracts, a communication plan should be defined including the definition of responsible persons for communicating with the customer and who are the customer contacts in certain situations.

There may be different points of contact for different situations, e.g. for operational matters, engineering matters and for formal correspondence. SPOC may be a good practice. The communication may include an escalation process for the resolution of problems. Such a communication plan will help prevent misinformation and delays.

For maintenance contracts, it is recommended to have a 24 hour “on-call” plan for the communication and resolution of urgent issues that may affect customer operations e.g. concessions.

### 8.2.2 Determining the requirements related to products and services

The maintenance organization should identify the requirements from the maintenance contracts, taken in consideration

- Mandatory standards,
- Specific customer requirements,
- Customer’s operational requirements,

which may not be explicitly specified.

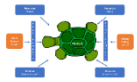
For example, the customer, if an operator, may have certain availability and reliability requirements (customer's operational requirements) that have to be achieved. Therefore, the organization designs a suitable maintenance product or service that allows those requirements to be met by e.g. ensuring that a certain number of systems are available.

Customer requirements may also include RAMS and LCC commitments and, for example, managing obsolescence.

### 8.2.3 Review of requirements related to products and services

When carrying out a review of the maintenance requirements, the version of the maintenance manual, overhaul specification and/or relevant drawings is agreed with the customer and with any relevant external provider before starting the work.

#### 8.2.3.2 Review of requirements related to product and services

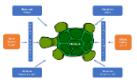
| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | - | - | - | Mandatory |

Refer to ISO/TS 22163. No further explanations are needed in this guideline.

### 8.2.4 Changes to requirements for products and services

When changes to the requirements are reviewed and approved (see clause 8.1.5), it is important that changes are documented and communicated in writing to all those involved in the supply chain. Including at the locations where some or all of the maintenance is being carried out.

### 8.2.5 Requirements for products and services - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| Always applicable | Mandatory | Mandatory | Mandatory | - |

The organization ensures that the requirements for its maintenance products or services are clearly defined and understood, that risks are assessed, and it has the ability to comply when either:

- designing or developing a product or service,
- responding to a product or service tender,
- executing a product or service contract for the product or service.

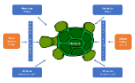
It may also be appropriate to include all the confirmed contract requirements in a contract management plan/database, which will include the descriptions of the requirements, timescales and the person responsible for the fulfilment of the requirements. This can then be reviewed on a regular basis with deviations recorded and correction action planned.

If appropriate, maintenance requirements can be defined in a maintenance plan, which may include the following information:

- list of safety related parts and related actions,
- frequency or periodicity table,
- verifications and check-ups,
- documental references (maintenance or product drawings, RAMS analysis, standards),
- required specific tooling and means,
- breakdown by equipment and functions (incl. localization and amounts),
- description of the actions (general tasks),
- constraints for procurement and storage of spare parts,
- estimated lead time versus resources.

## 8.3 Design and development of products and services

### 8.3.1 General

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | Mandatory | Mandatory | Mandatory | - |

The organization defines and documents, which maintenance activities should be handled as design and development activities.

Note that maintenance engineering is not considered as a design and development activity even though modernisation usually does include some design and development activity.

Within the IRIS Certification® rev. 03 system, Design and development is an IRIS activity, which could be certified stand alone. Therefore, the maintenance organization defines if it is within its scope.

When designing and developing a maintenance product or service, the organization takes the following factors into account as early as possible in the design and development process

- accessibility and ease of maintenance,
- ease dismounting and re-installation,
- intervention time for maintenance plan,
- tooling and infrastructure required,
- required competency of maintainers and operators,
- targeted Life Cycle Cost (wear parts, maintenance plan),
- obsolescence issues,
- safe maintenance operations,
- return of experience from operations,

- being able to test the product or service in its operational environment,
- environmental considerations (e.g. recycling, chemical safety, dangerous goods).

Additionally, the design authority should be clearly defined at an early stage for safety related decisions.

If the organization is introducing new technologies such as a new maintenance technique or process — e.g. automated inspection — the organization should perform a process FMEA before the implementation.

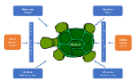
### 8.3.3 Design and development inputs

Examples of inputs to the design and development of maintenance products and services may be LCC and/or RAMS, field operational requirements and return of experience.

In case a maintenance organization has only the IRIS activity maintenance (not Design and development) the interfaces (remote functions, manufacturer) should be considered and documented.

## 8.4 Control of externally provided processes, products and services (EPPPS)

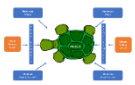
### 8.4.1 General

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | Mandatory | - | - | Mandatory |

In case of corporations, where certain activities are performed by internal functions (e.g. qualification of sub-suppliers may be done by the central department) not belonging to the maintenance organization, these activities have to be considered by the maintenance organization and documented respectively, including all interfaces.

The full EPPPS process is reflected and fulfilling the respective requirements of the ISO/TS 22163.

#### 8.4.1.1 General - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| Always applicable | Mandatory | Mandatory | - | Mandatory |

When making use of contractors or external providers for safety related products and services, the organization has processes in place to verify at the time of selection that contractors, subcontractors and external providers are competent.

Contractors, subcontractors and external providers should have a business management system that is documented and adequate for maintenance business.

The organization has processes to monitor the awareness of external providers and contractors of risks they may introduce to the organization´s operation.

As a minimum, the basic principles for this process is clearly defined, known and allocated in the contract between the contracting parties: responsibilities and tasks relating to railway safety issues, obligations relating to the transfer of relevant information between both parties and the tracea bility of safety related documents.

### 8.4.2 Type and extend of control

If subcontracting maintenance activities associated with safety related products and services, attention should be given to ensuring that the organization has processes to verify that the subcontractor is competent to perform the relevant maintenance activities.

Examples of safety related products and services can include maintenance, upgrade, overhaul, refurbishment and spares supply for the following parts:

- bogies,
- braking systems,
- coupling systems,
- door control systems,
- signalling systems,
- components installed in freight wagons used for the transportation of dangerous goods.

### 8.4.3 Information for external providers

The organization should ensure that its subcontractors' activities are managed so that the organization's objectives can be achieved and its commitments to customers fulfilled. The organization should therefore have a suitable:

- requirements management system,
- review system,
- control system

to ensure that relevant maintenance requirements from its customer are passed down to the subcontractor.

Relevant maintenance requirements could include overhaul specifications, drawings, technical library obligations, LCC and RAMS, obsolescence management, protection and segregation of customer material and/or tooling.

### 8.4.4 Supply chain management

Where the external provider is required to provide products and services to support the organization's maintenance activities, e.g. supply of spare parts or overhauled systems, the organization should ensure that there is flexibility in the delivery schedule to meet requirements for corrective or unplanned work.

For example, the external provider may need to urgently provide spare parts or repair the system due to an accident in operation. The organization may require the external provider to vary the planned delivery schedule on a regular periodic basis.

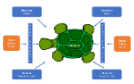
## 8.5 Production and service provision

### 8.5.1 Control of production and service provision

Maintenance organization describes in its process what needs to be done (e.g. as described in the maintenance plan) and the competencies and facilities needed.

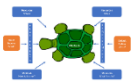
For a maintenance organization, the process might reflect that the product or service provision may take place at facilities owned by the customer or third parties and that it may need to control property (e.g. trains, systems, components) owned by the customer or operator.

#### 8.5.1.1 Control of production and service provision - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| - | Mandatory | Mandatory | - | - |

Refer to ISO/TS 22163. No further explanations are needed in this guideline.

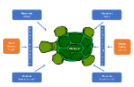
#### 8.5.1.2 Special processes

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| Always applicable | Mandatory | - | - | Mandatory |

Special processes are often used in maintenance activities. Therefore, the special process itself and also the qualification of the respective personnel needs to be managed. See clause 7.2 Competence.

For more information check IRQB Guideline 6: Special processes [10].

### 8.5.2 Identification and traceability

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| - | - | - | - | Mandatory |

The organization should have suitable methods/systems for identification (e.g. QR code, RFID) and traceability (avoid mixing up different components within a batch).

Customer requirements regarding identification and traceability may include the need to keep certain material separate (e.g. work sampling of welding parts, property belonging to customers). There may also be a need to retain certain material for inspection after overhaul or repair. Traceability requirements should be carefully controlled and managed during the long term maintenance contract.

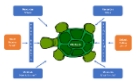
### 8.5.3 Property belonging to customers or external providers

If the maintenance product or service provision includes the use of customer or third-party property (e.g. vehicles, spare parts, depot facilities) then the organization should be able to document the traceability of such property up to the point of return or re-delivery. Care should be taken to ensure that such property is properly protected, segregated and cannot be used unless authorized.

### 8.5.4 Preservation

The organization should have documented specifications for the preservation of its materials and components. Preservation may include for example holding parts for inspection after repair or overhaul, preserving accident damaged components for investigation, overhaul of sensitive components or systems in a clean air room.

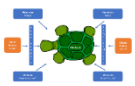
### 8.5.5 Post-delivery activities

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | Mandatory | - | - | - |

In a maintenance setting, examples of these activities may include ongoing requirements to maintain a technical library, warranty commitments, ongoing spare parts supply, FRACAS, accident repairs, technical support, asset disposal and archive of maintenance records.

It is recommended that clear points of contact are communicated for these activities.

### 8.5.6 Control of changes

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | - | - | - | Mandatory |

In a maintenance environment, the control of changes is important for many reasons (e.g. change of equipment, procedures, organization, staffing, interfaces and configuration to ensure clear traceability of change) and it is therefore recommended that the organization demonstrates it has a process to document the review, approval and implementation of changes (see clause 8.1.5).

It should be ensured that certain changes (e.g. safety relevant products, operationally/technically critical changes) might be approved with the FAI also by the manufacturer of the system being maintained, upgraded or refurbished.

### 8.5.7 Production scheduling

In the scope of the maintenance business, the maintenance activities are defined in the maintenance plan. It defines the maintenance work packages/activities and the time required.

Based on the maintenance plan materials, resources, competences and facilities' requirements are defined.

In cases of organizations performing manufacturing and maintenance activities, the production schedule could be composed of manufacturing and maintenance activities.

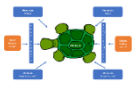
Due to the nature of maintenance activities, unplanned corrective maintenance may be required and there should be consideration of this aspect in the plan.

The organization should review its schedule constantly for possible bottlenecks and other risks that may affect the ability to meet customer requirements, e.g. lack of spare parts, equipment, resources.

Stakeholders may expect a KPI for monitoring production capacity utilization that should be implemented according to the clause 9.1.1.1.

Application software or planning tool may be helpful in improving this process by identifying the critical path and to implement changes in customer requirements as they may occur in time.

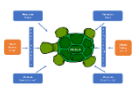
## 8.6 Release of products and services

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | - | - | - | Mandatory |

The organization should have a method/system to check, that the performed maintenance tasks are in accordance with the maintenance orders and to issue a documented notice (including any possible faults or defects regarding safety) to the customer. The handover of the product/system after maintenance and the verification that the product/system is able to re-enter into service should be agreed with the customer.

Responsibility for validating that the maintenance work has satisfactorily been completed is clearly defined.

## 8.7 Control of nonconforming outputs

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | - | - | Mandatory | Mandatory |

The organization controls the identification and resolution of non-conforming outputs in the provision of its maintenance activities.

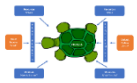
When an organization is carrying out maintenance on a product/system, it may be the case that the customer is prepared to accept a defect or agree to defer maintenance action when safety is not affected. This is sometimes referred to giving a concession.

In such cases the organization may have a documented process (see clause 8.7.3) for identifying and communicating the requirements for a concession as well as recording the decision and when the concession expires.

The organization also ensures that it plans the correction of the non-conformance in cooperation with the customer.

The organization should use an application software to record all non-conformities and concessions to ensure that follow-up actions are completed on time and there is a record of return of experience.

## 8.8 RAMS / LCC

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| Can be put as not applicable | Mandatory | - | - | Mandatory |

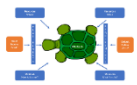
The organization calculates the RAMS/LCC objectives throughout the product life cycle; collect, share and analyse the data and act to correct any deviation. This is particularly important for organizations carrying out maintenance activities as RAMS/LCC may be a contractual commitment over a long period of time.

Where the organization is not responsible for maintaining the product, then it can plan for the collection and reporting of actual RAMS/LCC data from operations.

People responsible for RAMS/LCC have competences in failure reporting system such as FRACAS.

Detailed information can be found in the IRQB Guideline 4: RAMS/LCC [8].

## 8.9 First Article Inspection (FAI)

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| Can be put as not applicable | Mandatory | - | Recommended | Mandatory |

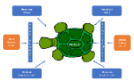
Refer to risk analysis such as FMEA. It is expected that the actions from FMEA are closed before starting FAI. Consider verification of applicable special processes.

The organization should consider using its FAI process during its maintenance activities in case of:

- change of external maintenance provider,

- change of maintenance location or external provider,
- before maintenance resumes after suspension for a specified time,
- start of maintenance activity for a new customer,
- change of maintenance activity or relevant equipment,
- after first upgrade or refurbishment,
- change of product/system in case of substitute product/system (e.g. obsolescence)

## 8.10 Obsolescence management

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | Mandatory | - | - | - |

The risk of obsolescence is high during a long lifetime of a maintained product/system. Therefore, obsolescence needs to be managed.

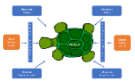
The organization identifies, as early as possible, the potential sources of obsolescence of the product to be maintained, develop mitigation actions, assign responsibility and define the budget.

The organization can obtain commitments from its external provider to adopt the same approach and includes a review of their obsolescence plan in the regular external provider meetings. This is to be included within an obsolescence management plan as part of an overall obsolescence strategy.

The maintenance organization should also ensure that it reviews and understands any obsolescence requirements contained in the contract.

Detailed information can be found in the IRQB Guideline 5: Obsolescence [9].

## 8.11 Innovation management

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | Recommended | - | - | - |

The process describes how and when the organization systematically reviews its own external environment and the external environment of its customers and stakeholders, how it identifies ideas to address any identified opportunities and threats, how the ideas are prioritized and developed, who are the key stakeholders and how they will be involved in the innovation process.

In case certain aspects of innovations are not carried out by the maintenance organization, interfaces (remote functions, manufacturer) are considered and documented.

Examples of innovations in maintenance may include new maintenance services or techniques, appointment of new suppliers, new tooling, changes to maintenance practices, provision of data.

# 9 Performance evaluation

## 9.1 Monitoring, measurement, analysis and evaluation

Reliability and availability should to be tracked, if applicable. This applies to new or refurbished product/systems.

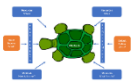
Performance evaluation should also focus on the fulfilment of:

- the safety objectives,
- on time delivery of maintained products and systems,
- the effectiveness of risk management,
- the performance of subcontractors,
- the generation of empirical data from operations and maintenance.

Maintenance-related empirical data from operations can be generated from the information of railway operators and infrastructure operations and empirical data from maintenance is derived from reports of internal maintenance providers.

The performance evaluation is set up in line with the maintenance contract and tuned with business processes such as budgeting.

#### 9.1.1.1 General - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| - | - | - | Mandatory | - |

Goals, targets and KPIs are defined and deployed in the organization.

There should be a good mix of KPIs that are used to prove compliance and to steer the organization.

### 9.1.2 Customer satisfaction

Customer satisfaction should be measured considering the contribution of interested parties for maintenance business based on the stakeholder analysis (see clause 4.2).

The collector of customer satisfaction data should ensure the transfer of information to departments or organizations involved in maintenance.

#### 9.1.3.1 Analysis and evaluation - Supplemental

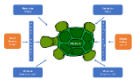
The organization should have methods/systems to regularly collect and analyse relevant safety data, including the handling of accidents, faults, near-accidents and other hazardous events in the context of maintenance of products/systems; and is part of the work safety instructions provided to every

employee periodically. The effectiveness of risk control arrangements should be regularly reviewed and updated.

The organization should have methods/systems to collect and share field experience data, especially with the manufacturer.

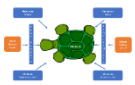
## 9.2 Internal audit

### 9.2.3 Internal audit - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | Mandatory | - | Recommended | Mandatory |

When defining the necessary skills of auditors (see clause 7.2), in addition to the basic requirements, the country specific regulatory requirements, maintenance specifics (products, services) and special processes (see also IRQB Guideline 6: Special Processes [10]) should also be considered.

## 9.3 Management review

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |   |  |
| - | - | - | - | Mandatory |

The management of the organization is to be informed about maintenance activities and the results of those activities in the management review.

## 9.4 Process reviews

Systematic application of process reviews as specified in the ISO/TS 22163 requires attention also in maintenance organizations, involving the stakeholders and customer representatives.

# 10 Improvements

## 10.1 General

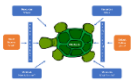
Potential sources of improvement and methods for a maintenance organization could be based on:

- performance of the process (use process reviews, e.g. performance evaluation),

- implementation of new safety developments by observing the recommendations of the national safety authority and the national investigation authority and investigations of the industry or internal investigations,
- elimination of any detected deficiencies,
- leveraging of findings from internal and external audits,
- use of information about investigations and causes of accidents, faults, near-accidents and other hazardous events, as required by other standards,
- reports/information from other relevant sources, such as general and specialist media, are consulted and considered,
- participation in specialist conferences,
- results of employee engagement

See IRQB Guideline 7: Problem solving [11]

### 10.2.3 Nonconformity and corrective action - Supplemental

| Knock-out requirement | Process | Mandatory process for performance evaluation | Key Performance Indicators | Retained documented information |
|---|---|---|---|---|
|  |  |  |  |  |
| - | Mandatory | - | - | Mandatory |

Refer to ISO/TS 22163. No further explanations are needed in this guideline.

# Bibliography


[1] ISO 10012 Measurement management systems — Requirements for measurement processes and measuring equipment (ISO 10012:2003)

[2] ISO 21500 Guidance on Project Management

[3] ISO 22301 Business continuity management

[4] Regulation (EU) 2019/779 Laying down detailed provisions on a system of certification of entities in charge of maintenance of vehicles pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 445/2011

[5] EN 13306 Maintenance – Maintenance terminology

[6] IRQB Guideline 1: Key Performance Indicators

[7] IRQB Guideline 2: First Article Inspection

[8] IRQB Guideline 4: RAMS/LCC

[9] IRQB Guideline 5: Obsolescence

[10] IRQB Guideline 6: Special processes

[11] IRQB Guideline 7: Problem solving

[12] IRQB Guideline 8: Configuration and change management

# ANNEX 1

The below listed Terms and Definitions are not used explicitly in this guideline. They are complementary and help for the understanding in maintenance organizations and support standardization.

## Terms and definitions for the rail sector

| | |
|---|---|
| Maintenance | The ISO/TS 22163, defines maintenance as the combination of all technical and administrative actions, including supervision actions, intended to retain a Product in or restore it to a state in which it can perform a required function. (ISO/TS 22163 clause 3.1.23). |
| Predetermined Maintenance | preventive maintenance carried out in accordance with established intervals of time or number of units of use but without previous condition investigation [5] 7.2 |
| Condition Based Maintenance | preventive maintenance which include a combination of condition monitoring and/or inspection and/or testing, analysis and the ensuing maintenance actions [5] 7.3 |
| Predictive Maintenance | condition based maintenance carried out following a forecast derived from repeated analysis or known characteristics and evaluation of the significant parameters of the degradation of the item [5] 7.4 |
| Deferred Corrective Maintenance | corrective maintenance which is not immediately carried out after a fault detection but is delayed in accordance with given rules [5] 7.6 |
| Immediate Corrective Maintenance | corrective maintenance that is carried out without delay after a fault has been detected to avoid unacceptable consequences [5] 7.7<br>In IRIS sometimes called as “Containment Maintenance” |
| Temporary Repair | physical action taken to allow a faulty item to perform its required function for a limited time interval and until a repair is carried out [5] 8.11 |
| Accidental Repair | Repair of an item that has been damaged in case of an accident |
| Modification | combination of all technical, administrative and managerial actions intended to change one or more functions of an item [5] 8.13<br>Supplementary: “Retrofitting”: Newer, more modern systems. Mechanical, electrical and design modifications. Simple system upgrades. |
| Rebuilding / Refurbishment | Rebuilding: action following the dismantling of an item and the repair or replacement of those sub-items, that are approaching the end of their useful life and/or should be regularly replaced [5] 8.14<br>Supplementary: Refurbishment: Quality-assured renovation and repair of items (components and vehicles) to an as-built state so that they can be put to further use – without changing function. |

## Abbreviations

| | |
|---|---|
| RU | Railway Undertaking/Railway Operator: Entity responsible for the operation of railway vehicles |
| IM | Infrastructure Manager – Entity responsible for operation of a railway infrastructure |
| PDCA | Plan – Do – Check – Act |
| QDC | Quality Deficiency Cost |
| RAM | Reliability, Availability, Maintainability |

# ANNEX 2

Maintenance Management Systems may be regulated different worldwide. There are existing regional maintenance regulations, such as Regulation (EU) 2019/779 [4] for the European system of certification for Entities in Charge of Maintenance (ECMs), which is used in this Annex as an example for a comparison with the IRIS Certification® rev. 03 system.

For a better understanding of the comparison following clarification should be made:

A. Responsibility for safety
B. Main functions of the Maintenance Management System

## A. Responsibility for safety

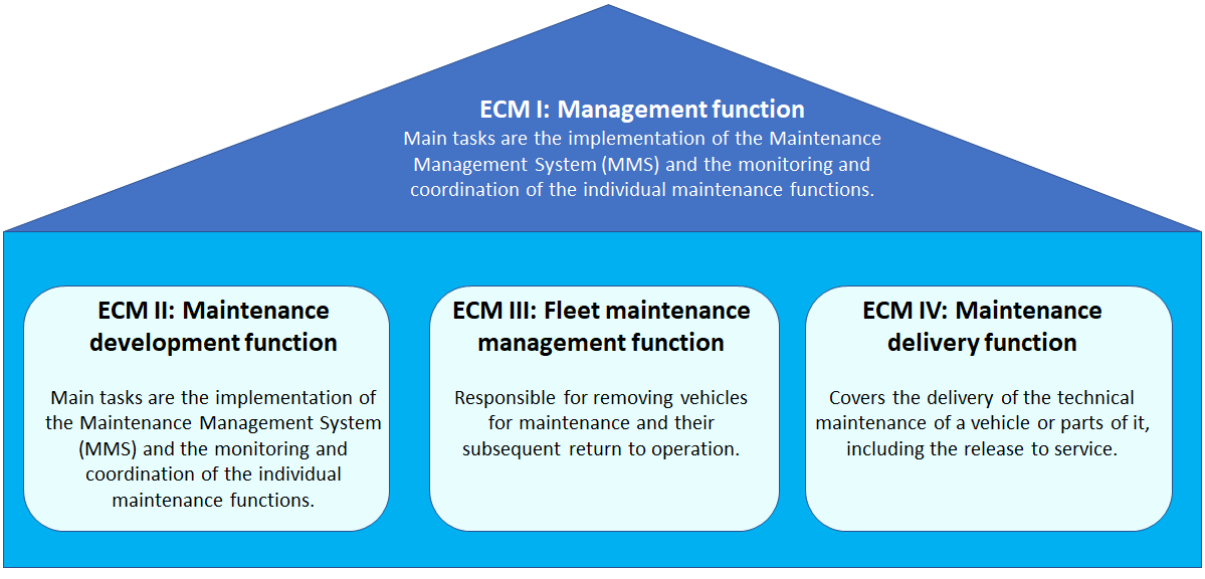
The opening of national rail transport markets to cross-border competition necessitated more standardization of safety requirements.

Each of the stakeholders now bears it share of responsibility for rail transport safety.

| | |
|---|---|
| RU / Operator | Responsible for safe operation<br>(transport of people and goods) |
| Keeper | Responsible for the overall safe condition of the vehicle<br>Is registered as the keeper in the National Vehicle Register |
| Maintenance provider | Responsible for the safe operational state of the vehicle |

## B. Main functions of the Maintenance Management System

Regulation (EU) 2019/779 [4] defines the functions and their corresponding requirements that a Maintenance Management System (MMS) has to cover.



# C. Comparison Regulation (EU) 2019/779 [4] with the IRIS Certification® rev. 03 system

| | | | ISO / TS 22163 | | | | |
|---|---|---|---|---|---|---|---|
| Nr. | ANNEX II TO REGULATION (EU) 2019/779 | | ISO 9001 requirements | Rail specific requirements | Clause number | Legal requirements | Remarks |
| | I | Requirements and assessment criteria for the management function | | | | | |
| | 1 | Leadership | | | | | |
| | | **Leadership** — commitment to the development and implementation of the maintenance system of the organisation and to the continuous improvement of its effectiveness | | | | | Description |
| | | The organisation shall have procedures for: | | | | | |
| 1 | (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; | x | | 5.2.1 | | |
| 2 | (b) | ensuring that safety targets are established, in line with the legal framework and consistent with an organisation's type, extent and relevant risks; | | x | 6.2.3 | | |
| 3 | (c) | assessing its overall safety performance in relation to its corporate safety targets; | x | x | 6.2.1 / 6.2.2 6.2.3 / 9.1.3.1 | | |
| 4 | (d) | developing plans and procedures for reaching its safety targets; | | x | 9.1.3.1 | | |
| 5 | (e) | ensuring that the resources needed to perform all processes are available to comply with the requirements of this Annex; | x | | 4.4.1 d) | | |
| 6 | (f) | identifying and managing the impact of other management activities on the maintenance system; | x | | 4.1 / 4.2 | | |
| 7 | (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; | x | | 5.1.1 g) / 9.3 | | |
| 8 | (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. | | x | 5.3.1 | | |
| | 2 | Risk management | | | | | |
| | | **Risk management** — 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 | | (x) | (6.1.3) | x | CSM 402/2013 to be applied |
| 9 | 2.1 | The organisation shall have procedures and arrangements in place to recognise the need and commitment to collaborate with keepers, railway undertakings, infrastructure managers, designers and manufacturers of vehicles and components or other interested parties. | x | | 6.1 / 5.1 | | Link to specific stakeholders |
| 10 | 2.2 | The organisation shall have risk management procedures to manage changes in the maintenance file, including maintenance plans, equipment, procedures, organisation, staffing or interfaces, and to apply the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798. | | (x) | 6.1.3 | x | CSM 402/2013 to be applied |
| 11 | 2.3 | When assessing risk, an organisation shall 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/EEC1. | | | | x | Link to HSE legislations |
| | 3 | Monitoring | | | | | |
| | | **Monitoring** — a structured approach to ensure that risk control measures are in place, working correctly and achieving the organisation's objectives | | | | | Description |
| | 3.1 | The organisation shall have a procedure to regularly collect, monitor and analyse relevant safety data, including: | x | | 9.1 | | ECM required safety data |
| 12 | (a) | (a) the performance of relevant processes; | x | | 9.1 | | |
| 13 | (b) | (b) the results of processes (including all contracted services and products); | x | | 9.1 | | |
| 14 | (c) | (c) the effectiveness of risk control arrangements; | x | | 9.1 | | |
| 15 | (d) | (d) information on experience, malfunctions, defects and repairs arising from day-to-day operation and maintenance. | | x | 9.1.3.1 | | |
| 16 | 3.2 | The organisation shall 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 shall have an internal auditing system which is independent, impartial and acts in a transparent way. This system shall have procedures in place to: | x | x | 9.2.1 9.2.2 **9.2.3** 9.4 | | |
| 17 | (a) | develop an internal audit plan, which may be revised depending on the results of previous audits and monitoring of performance; | | x | **9.2.3.1** | | |
| 18 | (b) | analyse and evaluate the results of the audits; | x | | 9.2.2 a) + d) | | |
| 19 | (c) | propose and implement specific corrective measures or actions; | x | | 9.2.2 e) | | |
| 20 | (d) | verify the effectiveness of previous measures or actions. | x | | 10.2.1 d) | | |
| 21 | 3.4 | The procedures mentioned in points 3.1, 3.2 and 3.3 of this Section shall comply with the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 and to the methods for assessing the safety level and the safety performance of railway operators at national and Union level as adopted pursuant to point (d) of Article 6(1) of that Directive. | | | | x | CSM 402/2013 to be applied |

| Nr. | | ANNEX II<br>TO REGULATION (EU) 2019/779 | ISO / TS 22163<br>ISO 9001 requirements | Rail specific requirements | Clause number | Legal requirements | Remarks |
|---|---|---|---|---|---|---|---|
| | **4** | **Continuous improvement** | | | | | |
| | | **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 | x | | 10 | | Description |
| | | The organisation shall have procedures to ensure that: | | | | | |
| 22 | (a) | identified shortcomings are rectified; | x | | 10.2 | | |
| 23 | (b) | new safety developments are implemented; | x | x | 8.2.4 / 8.2.5 | | Based on the product |
| 24 | (c) | internal audit findings are used to bring about improvement in the system; | x | x | 9.2.3 / 10.1 | | |
| 25 | (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; | x | | 10.2<br>10.3 | | |
| 26 | (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; | | | | x | COR: Common Occurance Reporting<br>SAIT: Safety Alert IT Tool |
| 27 | (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; | | | | x | |
| 28 | (g) | relevant reports or information from railway undertakings/infrastructure managers, keepers or other relevant sources are considered and taken into account. | | | | | |
| | **5** | **Structure and responsibility** | | | | | |
| | | **Structure and responsibility** — a structured approach to define the responsibilities of individuals and teams for secure delivery of the organisation's safety objectives | | | | | Description |
| 29 | 5.1 | The organisation shall have procedures to allocate responsibilities for all relevant processes throughout the organisation. | | x | 5.3.1<br>5.3.2 | | |
| 30 | 5.2 | The organisation shall 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. Those include the procedures indicated in point 2.1 above between the organisation and the keepers and, where appropriate, railway undertakings and infrastructure managers. | | x | 5.3.1<br>5.3.2 | | |
| 31 | 5.3 | The organisation shall 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 shall be coherent and compatible with the given role, and delegations shall be in writing. | | x | 5.3.1 | | |
| 32 | 5.4 | The organisation shall have procedures to ensure the coordination of activities related to relevant processes across the organisation. | | x | 5.3.1 | | |
| 33 | 5.5 | The organisation shall have procedures to hold those with a role in the management of safety accountable for their performance. | | x | 5.3.1 | | |
| | **6** | **Compentence management** | | | | | |
| | | **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 | | | | | Description |
| | 6.1 | The organisation shall set up a competence management system providing for: | | | | | |
| 34 | (a) | the identification of posts with responsibility for performing within the system all the processes necessary for compliance with the requirements of this Annex; | x | | 7.2 | | |
| 35 | (b) | the identification of posts involving safety tasks; | x | | 7.2 / 5.3 | | |
| 36 | (c) | the allocation of staff with the appropriate competence to relevant tasks. | x | x | 7.2.1 i) / 5.3 | | |
| | 6.2 | Within the organisation's competence management system, there shall be procedures to manage the competence of staff, including at least: | | | | | ECM asked for specifical physical fitness |
| 37 | (a) | identification of the knowledge, skills and experience required for safety-related tasks as appropriate for the responsibilities; | x | x | 7.2 / 7.2.1 b) | | |
| 38 | (b) | selection principles, including basic educational level, mental aptitude and physical fitness; | x | | 7.2 b) | | |
| 39 | (c) | initial training and qualification or certification of acquired competence and skills; | x | x | 7.2.1 c) +d)<br>7.2 | | |
| 40 | (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; | x | x | 7.3 / 7.3.1 | | |
| 41 | (e) | ongoing training and periodical updating of existing knowledge and skills; | | x | 7.2.1 | | |
| 42 | (f) | periodic checks of competence, mental aptitude and physical fitness where appropriate; | x | x | 7.2 c)<br>7.2.1 f) | | |
| 43 | (g) | special measures in the case of accidents/incidents or long absences from work, as required. | | x | 7.2.1 i) | | |

| | | | ISO / TS 22163 | | | | |
|---|---|---|---|---|---|---|---|
| Nr. | ANNEX II TO REGULATION (EU) 2019/779 | | ISO 9001 requirements | Rail specific requirements | Clause number | Legal requirements | Remarks |
| | 7 | **Information** | | | | | |
| | | **Information** — a structured approach to ensure that important information is available to those making judgments and decisions at all levels of the organisation | | | | | Description |
| 44 | 7.1 | The organisation shall 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, keepers and designers or manufacturers of vehicles or components, or both, when appropriate, 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. | x | | 7.4 | | |
| | 7.2 | To ensure an adequate exchange of information, the organisation shall have procedures for: | | | | | |
| 45 | (a) | the receipt and processing of specific information; | x | | 7.4 | | |
| 46 | (b) | the identification, generation and dissemination of specific information; | x | | 7.4 | | |
| 47 | (c) | making available reliable and up-to-date information. | x | | 7.4 | | |
| | 7.3 | The organisation shall have procedures to ensure that key operational information is: | | | | | |
| 48 | (a) | relevant and valid; | x | x | 7.5.2<br>7.5.3<br>7.5.3.3 | | partially, ISO/TS related to documented information |
| 49 | (b) | accurate; | x | x | 7.5.2<br>7.5.3<br>7.5.3.3 | | |
| 50 | (c) | complete; | x | x | 7.5.2<br>7.5.3<br>7.5.3.3 | | |
| 51 | (d) | appropriately updated; | x | x | 7.5.2<br>7.5.3<br>7.5.3.3 | | |
| 52 | (e) | verified; | x | x | 7.5.2<br>7.5.3<br>7.5.3.3 | | |
| 53 | (f) | consistent and easy to understand (including the language used); | x | x | 7.5.2<br>7.5.3<br>7.5.3.3 | | |
| 54 | (g) | made known to staff in accordance with their responsibilities, before it is applied; | x | | 7.5.3.2 | | |
| 55 | (h) | easily accessible to staff, with copies provided to them where required. | x | | 7.5.3.2 | | |
| | 7.4 | The requirements set out in points 7.1, 7.2 and 7.3 apply in particular to the following operational information: | x | x | 7.5 | | Most of the points are covered by 7.5. To be checked in details, due to different stakeholders and information flow |
| 56 | (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; | | | | x | |
| 57 | (b) | maintenance documentation; | | | | | |
| 58 | (c) | information on support provided to keepers and, where appropriate, to other parties, including railway undertakings/infrastructure managers; | | | | | |
| 59 | (d) | information on the qualification of staff and subsequent supervision during maintenance development; | | | | | |
| 60 | (e) | information on operations (including mileage, type and extent of activities, incidents or accidents) and requests of railway undertakings, keepers and infrastructure managers; | | | | | |
| 61 | (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; | | | | | |
| 62 | (g) | release to service and return to operation; | | | | | |
| 63 | (h) | maintenance orders; | | | | | |
| 64 | (i) | technical information to be provided to railway undertakings/infrastructure managers and keepers for maintenance instructions; | | | | | |
| 65 | (j) | emergency information concerning situations where the safe state of running is impaired, which may consist of: | | | | | |
| 66 | (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 shall also be shared with all involved parties; | | | | | |
| 67 | (ii) | urgent information on safety-related issues identified during maintenance, such as deficiencies detected in a component common to several categories or series of vehicles; | | | | | |
| 68 | (k) | all relevant information or data needed to submit the annual maintenance report to the certification body and to the relevant customers (including keepers), whereby this report shall also be made available upon request to national safety authorities. | | | | | |
| | 8 | **Documentation** | | | | | |
| | | **Documentation** — a structured approach to ensure the traceability of all relevant information | | | | | Description |
| 69 | 8.1 | The organisation shall have adequate procedures in place to ensure that all relevant processes are duly documented. | | x | 7.5.3.3 | | |
| | 8.2 | The organisation shall have adequate procedures in place to: | | | | | |
| 70 | (a) | regularly monitor and update all relevant documentation; | | x | 7.5.3.3 | | |
| 71 | (b) | format, generate, distribute and verify changes to all relevant documentation; | | x | 7.5.3.3 | | |
| 72 | (c) | receive, collect and archive all relevant documentation. | | x | 7.5.3.3 | | |

| | | | ISO / TS 22163 | | | | |
|---|---|---|---|---|---|---|---|
| **Nr.** | **ANNEX II TO REGULATION (EU) 2019/779** | | **ISO 9001 requirements** | **Rail specific requirements** | **Clause number** | **Legal requirements** | **Remarks** |
| | **9** | **Contracting activities** | | | | | |
| | | **Contracting activities** — a structured approach to ensure that subcontracted activities are managed appropriately in order for the organisation's objectives to be achieved | | | | | Description |
| 73 | 9.1 | The organisation shall have procedures in place to ensure that safety-related products and services are identified. | x | x | 8.2.2 / 8.5.2 / 8.5.2.1 | | |
| | 9.2 | When making use of contractors or suppliers, or both, for safety-related products and services, the organisation shall have procedures in place to verify at the time of selection that: | | | | | |
| 74 | (a) | contractors, subcontractors and suppliers are competent; | | x | 8.4.1.1.2 | | |
| 75 | (b) | contractors, subcontractors and suppliers have a maintenance and management system that is adequate and documented. | | x | 8.4.1.1.2 | | |
| 76 | 9.3 | The organisation shall have a procedure to define the requirements that such contractors and suppliers have to meet. | | x | 8.4.1.1 | | |
| 77 | 9.4 | The organisation shall have procedures to monitor the awareness of suppliers and/or contractors of risks they entail to the organisation's operations. | x | x | 8.4.3 / 8.4.3.1 | | |
| 78 | 9.5 | When the maintenance or 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). | x | x | 8.4.2 / 8.4.2.3 | | |
| | 9.6 | At least the basic principles for the following processes shall be clearly defined, known and allocated in the contract between the contracting parties: | | | | | |
| 79 | (a) | responsibilities and tasks relating to railway safety issues; | x | | 8.4.3 | | |
| 80 | (b) | obligations relating to the transfer of relevant information between both parties; | x | x | 8.4.3<br>8.4.3.1 | | |
| 81 | (c) | the traceability of safety-related documents. | | x | 8.4.3.1 | | |
| | **II.** | **Requirements and assessment criteria for the maintenance development function** | | | | | |
| | 1 | The organisation shall have a procedure to identify and manage: | | | | | All identification of safety is not explicit covered in ISO/TS 22163 |
| 82 | (a) | all maintenance activities affecting safety; | | | | | |
| 83 | (b) | all safety-critical components. | | | | | |
| | 2 | The organisation shall have procedures to guarantee conformity with the essential requirements for interoperability, including updates throughout the lifecycle, by: | | | | | |
| 84 | (a) | ensuring compliance with the specifications related to the basic parameters for interoperability as set out in the relevant technical specifications for interoperability (TSIs); | | | | x | |
| 85 | (b) | verifying in all circumstances the consistency of the maintenance file with the authorisation related to the vehicle (including any national safety requirements), including the conformity to the technical file and the type of records as in the European Register of Authorised Types of Vehicles (ERATV); | | | | x | |
| 86 | (c) | managing any substitution in the framework of maintenance; | | x | 8.1.5 | | |
| 87 | (d) | identifying the need for risk assessment of the potential impact of the change in question on the safety of the railway system, by application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798; | | | | x | |
| 88 | (e) | managing the configuration of all technical changes affecting the system integrity of the vehicle. | | x | 8.1.4 | | |
| 89 | 3 | The organisation shall have a procedure to design and support the implementation of maintenance facilities, equipment and tools specifically developed and required for maintenance delivery. The organisation shall 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. | x | | 7.1.3 / 7.1.4 | | |
| | 4 | When vehicles start operations, the organisation shall have procedures to: | | | | | |
| 90 | (a) | obtain access to the recommendations for maintenance of the initial documentation and to collect sufficient information on planned operations; | x | | 8.2.3.1 | x | Not covered: to collect sufficient information on planned operations |
| 91 | (b) | analyse those recommendations for maintenance of the initial documentation and to provide, by application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798, the first maintenance file, also taking into account the information contained in any associated guarantees; | x | x | 8.3 | x | Risk analysis according CSM 402/2013 is not covered |
| 92 | (c) | ensure that the implementation of the first maintenance file is done accordingly. | x | x | 8.4 | | The interface from ECM II to ECM IV is according to EPPPS |

| Nr. | | ANNEX II<br>TO REGULATION (EU) 2019/779 | ISO / TS 22163<br>ISO 9001 requirements | Rail specific requirements | Clause number | Legal requirements | Remarks |
|---|---|---|---|---|---|---|---|
| | 5 | To keep the maintenance file updated throughout the lifecycle of a vehicle, the organisation shall have procedures to: | | | | | |
| 93 | (a) | collect at least the relevant information in relation to: | x | | 6.3 / 8.8 / 8.2.1 | | It covers the principles. However not the specific requirements. |
| 94 | (i) | the type and extent of operations effectively performed, including, but not limited to accidents, serious accidents and incidents, as defined in Directive (EU) 2016/798; | | | | x | |
| 95 | (ii) | the detected failures on components; | | | | | |
| 96 | (iii) | the type and extent of operations planned; | | | | | |
| 97 | (iv) | the maintenance effectively performed. | | | | | |
| 98 | (b) | define the need for updates, taking into account the limit values for interoperability; | x | | 8.2.3 / 8.2.4 | | |
| 99 | (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 performed by application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798; | | x | 8.1.5 | x | CSM 402/2013 |
| 100 | (d) | ensure that the implementation of changes is done accordingly; | | x | 8.1.5 | | The interface from ECM II to ECM IV is according to EPPPS |
| 101 | (e) | monitor the effectiveness of the changes through a process in consistency with the methods for assessing the safety level and the safety performance of railway operators at national and Union level as adopted pursuant to point (d) of Article 6(1) of Directive (EU) 2016/798. | | x | 8.1.5 | x | CSM for monitoring 1078/2012 |
| | 6 | When the competence management process is applied to the maintenance development function, at least the following activities affecting safety shall be taken into account: | | | | | |
| 102 | (a) | application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 for assessment of changes of the maintenance file; | x | x | 7.2 | x | It covers with special requirements of CSM 402/2013 |
| 103 | (b) | engineering disciplines required for managing the establishment and the changes of the maintenance file and the development, assessment, validation and approval of substitutions in the framework of maintenance; | x | x | 7.2 / 7.2.1 | | |
| 104 | (c) | maintenance activities on safety-critical components; | | | | | |
| 105 | (d) | joining techniques (including welding and bonding); | | x | 8.5.1.2 | | |
| 106 | (e) | non-destructive testing. | | x | 8.5.1.2 | | |
| | 7 | When the documentation process is applied to the maintenance development function, the traceability of at least the following elements needs to be guaranteed: | | | | | |
| 107 | (a) | the documentation relating to the development, assessment, validation and approval of a substitution in the framework of maintenance; | x | x | 7.5 / 7.5.3.2 / 7.5.3.3 | | |
| 108 | (b) | the configuration of vehicles, including, but not limited to, safety-critical components and on-board software modifications; | x | x | 7.5 / 7.5.3.2 / 7.5.3.3 | | |
| 109 | (c) | records of the maintenance performed; | x | x | 7.5 / 7.5.3.2 / 7.5.3.3 | | |
| 110 | (d) | results of studies concerning return on experience; | x | x | 7.5 / 7.5.3.2 / 7.5.3.3 | | |
| 111 | (e) | all the successive versions of the maintenance file, including risk assessment; | x | x | 7.5 / 7.5.3.2 / 7.5.3.3 | | |
| 112 | (f) | reports on the competence and supervision of maintenance delivery and fleet maintenance management; | x | x | 7.5 / 7.5.3.2 / 7.5.3.3 | | |
| 113 | (g) | technical information to be provided to support keepers, railway undertakings and infrastructure managers. | x | x | 7.5 / 7.5.3.2 / 7.5.3.3 | | |
| | III. | **Requirements and assessment criteria for the fleet maintenance management function** | | | | | |
| 114 | 1 | The organisation shall 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. | | x | 8.1.2<br>8.4.1.1 | | The interface from ECM III to ECM IV is according to EPPPS |
| 115 | 2 | The organisation shall have a procedure for the composition of the work package and for the issue and release of the maintenance order. | x | x | 8.1.2<br>8.1.3.2 / 8.2.2 | | |
| 116 | 3 | The organisation shall have a procedure to send vehicles for maintenance in due time. | | x | 8.1.3.3 | | |
| 117 | 4 | The organisation shall have a procedure to manage the removal of vehicles from operation for maintenance or when safe operation is impaired or when needs of maintenance affect the normal operation. | | | | | |
| 118 | 5 | The organisation shall have a procedure to define the necessary verification measures applied to the maintenance delivered and the release to service of the vehicles. | | x | 8.4.2.2 | | |
| 119 | 6 | The organisation shall have a procedure to issue a notice of return to operation, including the definition of restrictions of use to ensure the safe running by taking into account the release to service documentation. | | x | 8.6.1 | | |
| 120 | 7 | When the competence management process is applied to the fleet maintenance management function, at least the return to operation shall be taken into account including defining the restriction of use. | x | x | 7.2 | | |

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| | 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: | | | | | |
| 121 | (a) | applicable rules and technical specifications; | x | x | 7.4 / 8.4.3 / 8.4.3.1 | | |
| 122 | (b) | the maintenance plan for each vehicle; | x | x | 7.4 / 8.4.3 / 8.4.3.1 | | |
| 123 | (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; | x | x | 7.4 / 8.4.3 / 8.4.3.1 | | |
| 124 | (d) | a list of materials, including a sufficiently detailed description of their use and the necessary health and safety information; | x | x | 7.4 / 8.4.3 / 8.4.3.1 | | |
| 125 | (e) | a dossier that defines the specifications for activities affecting safety and contains intervention and in-use restrictions for components; | x | x | 7.4 / 8.4.3 / 8.4.3.1 | | |
| 126 | (f) | a list of components or systems subject to legal requirements and a list of those requirements (including brake reservoirs and tanks for the transport of dangerous goods); | x | x | 7.4 / 8.4.3 / 8.4.3.1 | x | |
| 127 | (g) | application of the common safety methods related to the risk evaluation and assessment methods as adopted pursuant to point (a) of Article 6(1) of Directive (EU) 2016/798 for assessing changes affecting the fleet maintenance management function. | x | x | 7.4 / 8.4.3 / 8.4.3.1 | x | |
| 128 | 9 | When the information process is applied to the fleet maintenance management function, interested parties shall be at least informed of the return to operation, including restrictions on use relevant to users (railway undertakings and infrastructure managers). | x | | 7.4 / 8.2.1 | | |
| | 10 | When the documentation process is applied to the fleet maintenance management function, at least the following elements need to be recorded: | | | | | |
| 129 | (a) | maintenance orders; | x | x | 7.5.3.2 / 7.5.3.3 | | |
| 130 | (b) | return to operation, including restrictions on use relevant to railway undertakings and infrastructure managers. | x | x | 7.5.3.2 / 7.5.3.3 | | |
| | IV. | **Requirements and assessment criteria for the maintenance delivery function** | | | | | |
| | 1 | The organisation shall have procedures to: | | | | | |
| 131 | (a) | check the completeness and appropriateness of the information delivered by the fleet maintenance management function in relation to the activities ordered; | | x | 8.4.2.2 | | |
| 132 | (b) | verify the use of the required, relevant maintenance documents and other standards applicable to the delivery of maintenance services in accordance with maintenance orders; | x | | 8.2.3.1 | | |
| 133 | (c) | 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). | x | x | 7.1.6 / 7.1.6.1 | | |
| | 2 | The organisation shall have procedures to ensure that: | | | | | |
| 134 | (a) | components (including spare parts) and materials are used as specified in the maintenance orders and supplier documentation; | x | | 8.5.1 | | |
| 135 | (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; | x | x | 8.5.3 / 8.5.3.1 / 8.5.4 / 8.5.4.1 | | |
| 136 | (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. | x | x | 8.1 / 8.4.2.1 | x | |
| | 3 | The organisation shall 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: | | | | | |
| 137 | (a) | the safe delivery of maintenance, including the health and safety of maintenance staff; | x | x | 8.5.1.3 7.1.3 / 7.1.4 | x | Link to HSE legislations |
| 138 | (b) | ergonomics and health protection, also including the interfaces between users and information technology systems or diagnostic equipment. | x | x | 8.5.1.3 7.1.3 / 7.1.4 | x | Link to HSE legislations |
| | 4 | Where necessary to ensure valid results, the organisation shall have procedures to ensure that its measuring equipment is: | | | | | |
| 139 | (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 shall be recorded; | x | x | 7.1.5.2 / 7.1.5.3 | | |
| 140 | (b) | adjusted or re-adjusted as necessary; | x | | 7.1.5.1 b) | | |
| 141 | (c) | identified to enable the calibration status to be determined; | x | | 7.1.5.2 b) | | |
| 142 | (d) | safeguarded from adjustments that would invalidate the measurement result; | x | | 7.1.5.2 c) | | |
| 143 | (e) | protected from damage and deterioration during handling, maintenance and storage. | x | | 7.1.5.2 c) / 7.3 c) | | ECM ask for specific actions to ensure the right handling |

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| 144 | 5 | The organisation shall have procedures to ensure that all facilities, equipment and tools are correctly used, calibrated, preserved and maintained in accordance with documented procedures. | x | x | 7.1.3 / 7.1.5.3 / 8.5.1.3 | | |
| 145 | 6 | The organisation shall have procedures to check that performed tasks are in accordance with the maintenance orders and to issue the notice of release to service. The notice of release to service shall include all information that is useful to define restrictions of use. | | x | 8.6.1 | | |
| 146 | 7 | When the risk assessment process (in particular points 2.2 and 2.3 of Section I) is applied to the maintenance delivery function, the working environment shall include not only the workshops where maintenance is done but also the tracks outside the workshop buildings and all places where maintenance activities are performed. | x | | 7.1.4 | x | CSM 402/2013<br>Link to HSE legislations |
| | 8 | When the competence management process is applied to the maintenance delivery function, at least the following activities affecting safety where appropriate shall be taken into account: | | | | | |
| 147 | (a) | joining techniques (including welding and bonding); | | x | 8.5.1.2 | | |
| 148 | (b) | non-destructive testing; | | x | 8.5.1.2 | | |
| 149 | (c) | final vehicle testing and release to service; | x | x | 7.2 / 8.6 / 8.6.1 | | |
| 150 | (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.; | x | | 7.2 | | |
| 151 | (e) | maintenance activities on safety-critical components; | x | | 7.2 | | |
| 152 | (f) | maintenance activities on control-command and signalisation systems; | x | | 7.2 | | |
| 153 | (g) | maintenance activities on door control systems; | x | | 7.2 | | |
| 154 | (h) | other identified specialist areas affecting safety. | x | | 7.2 | | |
| | 9 | When the information process is applied to the maintenance delivery function, at least the following elements shall be provided to the fleet maintenance management and maintenance development functions: | | | | | |
| 155 | (a) | works performed in accordance with the maintenance orders; | x | | 7.4 / 8.4.3 | | |
| 156 | (b) | any possible fault or defect regarding safety which is identified by the organisation; | x | | 7.4 / 8.4.3 | | |
| 157 | (c) | the release to service. | x | | 7.4 / 8.6 | | |
| | 10 | When the documentation process is applied to the maintenance delivery function, at least the following elements shall be recorded for the maintenance activities affecting safety, as referred to in point 1(a) of Section II: | | | | | |
| 158 | (a) | clear identification of all facilities, equipment and tools; | x | x | 7.1.3 / 7.5 / 7.5.3.2 / 7.5.3.3 | | General requirements. Documented information in single clauses of ISO/TS |
| 159 | (b) | all maintenance works performed, including personnel, tools, equipment, spare parts and materials used and taking into account: | x | x | 7.1.1 / 7.5 / 7.5.3.2 / 7.5.3.3 | | |
| 160 | (i) | relevant national rules where the organisation is established; | x | x | 7.5 | x | |
| 161 | (ii) | requirements laid down in the maintenance orders, including requirements regarding records; | x | x | 7.5 / 7.5.3.2 / 7.5.3.3 | | |
| 162 | (iii) | final testing and the decision regarding the release to service; | x | x | 7.5 | | |
| 163 | (c) | the control measures required by maintenance orders and the release to service; | x | | 7.5 / 8.6 | | |
| 164 | (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 shall be confirmed prior to initial use and reconfirmed as necessary; | x | x | 7.5 / 7.1.5.3 | | |
| 165 | (e) | the validity of the previous measuring results when a measuring instrument is found not to conform to requirements. | x | x | 7.5 / 7.1.5.3 d) | | |

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