ERJU SYSTEM PILLAR

Quality Management Plan

Quality Management Plan

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Abstract	This quality management plan describes the general quality management approach for the System Pillar.
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1 Preamble

1.1 Purpose

QMP Purpose
The purpose of this SPPR-7890 - Quality Management Plan is to ensure that the deliverables resulting from activities of the System Pillar meet high-quality standards.
Quality assurance is provided through systematic quality reviews, while quality control is implemented through a combination of these reviews and corrective measures. Additionally, the plan aims to minimize human errors throughout the System Pillar's lifecycle, thereby reducing the risk of systematic faults.
This assurance is provided through a systematic process that contains

- a clear definition of all associated roles and responsibilities
- review activities and quality control activities.
  The plan establishes a feedback loop within the System Pillar to maintain and enhance quality.
- quality metrics

Quality management covers not only the result but also the path taken to achieve it. **Quality Assurance (QA) is involved in all stage of (system) development**.

The plan is not designed as a guide for users to produce quality artefacts but rather as a framework for evaluating the quality of outputs from the System Pillar. **[**SPPR-11574 **]**

1.2 Intended audience

Intended audience of QMP
This plan is intended primarily for use by the SPPR-10391 - Quality Manager of each and every System Pillar Tasks/Domains to assess whether the artefacts produced are of good quality.
For only the quality review wokflow/templates, jump to the **Appendix**.
The plan is authored and maintained by the SPPR-10390 - Lead Quality Manager . **[**SPPR-11576 **]**

1.3 Document Context

Context of QMP
This Quality Management Plan is applicable within the scope of the System Pillar for the entire lifecycle of the system development, as required by SPPR-2681 - [EN 50126-1:2017] . It focuses on evaluating the results against controlling documents and requirements, ensuring that all work products adhere to the defined stages of their lifecycle as described in relevant process documents and standards. **[**SPPR-11575 **]**

1.4 Glossary

1.4.1 Terms

Term	Status	Definition
SPPR-7767 - Quality attribute	Open	Quality attribute is a realized non-functional requirement used to evaluate the performance of a system Referenced by: SPPR-11575
SPPR-11696 - Quality	Open	Within the scope of the System Pillar, quality is the act of assuring compliance to established procedures, standards, requirements, rules and/or guidelines. In essence, it is the act of complying with the workflow decided and established by EET with support and feedbacks from System/Pillar tasks/ domains. As a result, the term quality by itself holds no significance within the scope of this plan; it gains meaning only when associated with governing conventions and procedures. Referenced by: SPPR-11575

1.4.2 Abbreviations

2 Quality Management Framework

2.1 Quality Objectives

See SPPR-8570 - Purpose

2.2 Quality Policy

See SPPR-3391 - [1] Europe's Rail Joint Undertaking Governance and Process Handbook v2.6 (December 2023)

2.3 Applicable Standards

See SPPR-8573 - Norms, Standards and Requirements

3 Quality Management System

3.1 Defining Quality

Quality
Within the scope of the System Pillar, quality is the act of assuring compliance to established procedures, standards, requirements, rules and/or guidelines. In essence, it is the act of complying with the workflow decided and established by EET with support and feedbacks from System/Pillar tasks/domains. As a result, the term quality by itself holds no significance within the scope of this plan; it gains meaning only when associated with governing conventions and procedures.

3.2 Design and Development Planning

The System Pillar or individual domains are responsible for maintaining a design and development process appropriate enough to ensure provision of the work products. The level of detail in these design processes is not of importance to the quality management plan. The design and development process documents will be used by the quality management team to control and approve the design work products. Therefore, the design and development process document should, at the least, cover the following topics.

It is imperative that the following points accompany diligent recording since the recordings provide evidence during a quality audit.

Quality Requirement	Coverage
A standard process to capture the nature, duration, severity and/or complexity of the **activities (tasks)**.	For example, Polarion's Kanban board could satisfy this condition.
Means to capture and/or provide **regular updates on the work**.	For example, scheduled weekly update meetings in which progress updates are either captured in a tool like Polarion or provided either verbally or visually can satisfy this condition.
Clear documentation of the required verification and validation activities and their outcome.	In the particular context of System Pillar, Verification and Validation still needs to be defined.
The number and type of resources – internal, external, FTE, mirror group and so on – needed for the work to be performed.	This point is covered by Core Group and the Systems Engineering Management Plan - 01 Main
The need for involvement of any stakeholders in the work process.	This point is covered by processes and roles defined in Systems Engineering Management Plan - 01 Main
Means to record, either directly or indirectly, applicable statutory and regulatory requirements and standards.	This point is covered by the References Usage Guidelines

Other planning, development and closing phase activities such as scheduling, budgeting, handing-off, terminating, ... are managed at Core Group level. Conflict resolution is defined in the escalation process as described in "Escalation of topic to SP Steering Group" in SPPR-3391 - [1] Europe's Rail Joint Undertaking Governance and Process Handbook v2.6 (December 2023) . **[**SPPR-11716 **]**

3.3 Control of Design

The System Pillar needs a defined control of design to ensure the deliverables are checked continually against their progress, standards, regulations and requirements. The controls are intended to reduce the risk of mistakes while developing the content and to ensure the processes are followed correctly. The System Engineering Management Plan (main document) contains an excellent overview of the relevant processes for the System Pillar. This iterative, phased approach of controlling the design is a primary quality management requirement.
The Systems Engineering Management Plan - 01 Main acts as the primary controller of the design activities performed within the System Pillar. The annexes of the SEMP act as secondary controllers of the activities performed within the System Pillar, specific to each domain or working group. The following table contains a rudimentary mapping of the controller and controlled for reference.

Controller	Controlled
SPPROCESS/10 SEMP V 01_01/SEMP Systems Engineering Management Plan : 714939	by all EET members
SPPROCESS/10 SEMP V 01_01/ Requirements Management Plan : 714939	by the SPPR-10728 - Lead Requirements Manager by coordinating the REQ-F team.
SPPROCESS/10 SEMP V 01_01/System Pillar MBSE Methodology Handbook : 714939	by the SPPR-11088 - Model Manager by coordinating the MOD-F team
Configuration Management Plan	by the SPPR-10396 - Lead Configuration Manager by coordination the team of SPPR-10397 - Configuration Managers
This plan	by the SPPR-10390 - Lead Quality Managerby coordinating the team of SPPR-10391 - Quality Managers

[SPPR-11747 **]**

This quality management plan does not concern itself with the rules contained within the controller documents. It only verifies if the rules are being followed. It is the responsibility of the controller document to accurately capture the applicable standards, regulations and requirements. The validity of such standards and regulations is beyond the scope of this quality management plan.
In cases where a suitable controller document cannot be identified, one must be created by the domain responsible for the work. The document must then be approved by the quality manager and domain lead(s).
The quality manager, or the person responsible for evaluating the quality of a work product, must elicit quality targets from the controller documents. They must be familiar with the controller document and produce a list of quality targets – the criteria on which the work will be judged – which must then be discussed and agreed upon with the task assignee and relevant leads. In addition to the control

parameters identified from the controller document, the following design and development control points should be incorporated and validated, at the least.

- The results to be achieved are clear and documented.
- Regular reviews of the work against its requirements are conducted and recorded.
- Verification and validation activities are conducted as per the technical plans, and all results and decisions are recorded.

[SPPR-11746 **]**

4 Quality Roles and Responsibilities

4.1 Quality Managers roles

The role of the Quality Manager in System Pillar will be filled by one SPPR-10390 - Lead Quality Manager supported by a group of SPPR-10391 - Quality Manager (one per task/domain).

Lead Quality Manager
This role is attached to Systemp Pillar Engineering Environment Team (EET):

- *as identified in System Pillar SEMP*
- *as allocated in All SEMP Allocation Roles*

SPPR-10390 - Lead Quality Manager is a single person responsible for all quality related matters in the System Pillar.
will represent System Pillar in all internal and external exchanges in matters of quality assurance, control and management. CENELEC standards assign the responsibility for establishing a quality management system to the Project Manager.
In this context it is expected that the SPPR-10390 - Lead Quality Manager will be independent from the System Pillar domains but be part of the same organisation. Therefore, the Quality Manager will most likely be depicted outside the project team, reflecting the independence needed. This role ensures that relevant strategies and methodologies for quality management are applied. The Quality Manager is the quality management representative for both internal and external stakeholders.

Her/His major responsibilities are:

- Responsible for creation, implementation and maintenance of the Quality Management Plan .
- Responsible for definition and reporting of quality objectives in alignment with System Pillar targets.
- Responsible for quality awareness.
- Build and animate the Qhality Management Functional team (QM-F)
  He/She must request all task/domains Leads to nominate AT LEAST ONE SPPR-10391 - Quality Manager , each - one acting as the official point of contact and the other deputizing for them in case of absence.

Note: Currently, there are no quality audits or gate reviews defined in the context of the System Pillar.

The SPPR-10390 - Lead Quality Manager should have access to all projects and plans on Polarion. If this is not possible, this quality management plan must justify the reason behind this restriction and propose a workaround.
In cases where access is restricted by design or chance, the lead of the working group under which the task falls should provide all required documents to the quality manager. SPPR-10390 - Lead Quality Manager may comment on the quality aspect of any work item.

SPPR-10390 - Lead Quality Manager has the power to appoint Task/Domains SPPR-10391 - Quality Manager as needed, within other rules governing the System Pillar.
The SPPR-10390 - Lead Quality Manager always has the final say and is responsible for ensuring quality within the System Pillar.
The SPPR-10390 - Lead Quality Manager may request a new SPPR-10391 - Quality Manager on reasonable grounds. In such cases, the SP management team must be informed.

Note: See All SEMP Allocation Roles for allocation of roles to people.

Abbreviation	LQM
ID	SPPR-10390

Quality Manager
This role is attached to Systemp Pillar tasks/Domains

- as identified in System Pillar SEMP
- as allocated in All SEMP Allocation Roles

Ideally one person for and from each domain/group within the System Pillar, responsible for all local quality related matters. For example, EET would have one SQM overseeing all Work Packages.
They report to the SPPR-10390 - Lead Quality Manager and, under normal conditions, have the same powers as the PQM but local to their domain/group.
This is not a new role. Any member from a working group may act as its quality representative - a point of contact. Even the work package lead/domain lead could act as SQM.

In cases of ambiguity, no clear path definition or unclear situations within the Quality Management Plan , the quality manager is authorized to decide the best course of action.
The Quality Manager is the single point of contact within his/her task/domain.
The Quality Managers are coordinated by the SPPR-10390 - Lead Quality Manager
The Quality Manager signature, as a mark of approval, is needed for all deliverables generated by/within his/her Task/Domain. Under normal conditions, they have access to all documents in their Task/Domain and can comment on the quality aspect of any work item.

The SPPR-10391 - Quality Manager can be anyone from the domain but not the domain lead.
The SPPR-10391 - Quality Manager is not accountable for quality within their domain. They only serve as the quality point-of-contact for the domain, and more importantly, assist the PQM in performing technical quality checks within the domain.

Abbreviation	QM
ID	SPPR-10391

Each System Pillar member must respect and work according to the Quality Management Plan. The Core Group has the overall responsibility for the successful execution of the project including compliance to the Quality Management System and compliance to the System Pillar targets. **[**SPPR-11432 **]**

Within the System Pillar's quality management system, the following roles and responsibilities have been defined:

4.2 System Pillar Tasks/Domains teams

Other roles and project organisation are described in Systems Engineering Management Plan - 01 Main

Roles are allocated in All SEMP Allocation Roles

4.3 External stakeholders

See Systems Engineering Management Plan - Annex MG Mirror Group Guideline

5 Quality Planning

5.1 Quality Planning Process

5.2 Integration with Other Plans

Other plans
Please remind that:

- The Systems Engineering Management Plan - 01 Main is the entry point to all plans, process and tools. Such processes are key to ensuring robust quality assurance; a quality management plan without these supporting processes and plans cannot ensure good quality
- Tthe list of documents, the links between them and applicable templates are available in Systems Engineering Management Plan - Annex L List of System Pillar Deliverables

[SPPR-11573 **]**

5.3 Quality Milestones and Reviews

Quality Milestones are driven by:

- System Pillar delivery planning (as explained in Configuration Management Plan)
- Intermediate steps (sometimes called sprints) managed internally by each task/domain

The goal of planning quality activities is of to review and control frequently and incrementally.
[SPPR-11577 **]**

6 Quality Assurance Activities

Quality Assyrance Activities
As there is no need so far, even if processes are defined for System Pillar, there is no process assurance, nor compliance audits activities defined. **[**SPPR-11578 **]**

7 Quality Control

7.1 Verification and Validation

There is currently no Verification and Validation activities defined for the specific context of System Pillar. Only quality reviews are foreseen (see below). **[**SPPR-11757 **]**

7.2 Review of deliverable documents

Checklists have been defined at specific steps of the review and approval process. The document review and approval process is described in Configuration Management Plan - Annex C Document Management Plan, Review and Approval Process **[**SPPR-11756 **]**

7.3 Inspection Procedures

There is no process inspection defined in the context of System Pillar. as it is not required. **[**SPPR-11758 **]**

7.4 Quality reviews

7.4.1 Process

As inspired by Plan-Do-Check-Act (PDCA), the review process is split into 3 major phases:

1. Plan
2. Perform the Quality Review
3. Record observations

Those 3 phases and the expected information has been implemented in the template that shall be used for the Quality Reviews: SP_QMCT-Generic Quality Checklist
Note that this process has been tailored for TrafficCS context in SPP-7712 - Perform EET Quality Check Review for: Local operation of trackside assets

The above phases generally apply to productions internal to the System Pillar. In cases where services, products or processes from external sources are involved, the scope of this plan reduces to only cover the validation of the sourced service. As a result, the secondary quality manager is only required to prove, through documented evidence, that the sourced service or product provides results as expected based on the requirements shared with the external organization.

When does Quality Review take place?
The Quality Review may be requested by Task/Domain leads, SPPR-10391 - Quality Manager Work Package leads when most appropriate, i.e. as early as possible but only when content is mature and stable.
All the content included in System Pillar delivarables published in status "Released" shall be Quality-Reviewed before the delivery of the SPPR-9932 - System Pillar Release .

Who is in charge?
The SPPR-10390 - Lead Quality Manager may sometimes delegate the work of conducting certain reviews to SPPR-10391 - Quality Manager . However, these reviews are technical quality reviews that primarily deal with technical processes, standards, SEMP Annexes and so on established within the System
SPPR-10390 - Lead Quality Manager must be notified of all reviews and shall ensure that the SPPR-10391 - Quality Manager is providing satisfactory evidence of quality assurance of the technical work.
For example. say there is a need to review the Work Product of a model integration or Capella-Polarion bridge strategy and they do not have a working knowledge of Capella and used add-ons. In such situations, the review will be performed by the SPPR-10390 - Lead Quality Manager . On the contrary, the technical quality audit covering topics such as "is any Systems Engineering Management Plan - Annex M1 Capella Model Element Rules violated?" can be better judged by the SPPR-10391 - Quality Manager who is from the respective Task/Domain. **[**SPPR-11780 **]**

7.4.2 Quality Review - Design Approval

A primary responsibility of the System Pillar is the creation of model-based system architecture definitions – designs, in simpler terms. The design review analyses a design to ensure that it meets the requirements and is feasible to implement. It is an integral part of the development process, as it can help identify and correct problems early on before they become costly. A design review aims to identify potential issues, validate design choices, provide feedback for improvement, and ensure that the design aligns with the desired objectives and specifications. This process helps mitigate risks, optimise the design, and enhance the project’s overall success. A design review is a formal evaluation process in which a design, typically of a product or system, is examined to assess its effectiveness, feasibility, and adherence to requirements. It involves analysing the design’s functionality, aesthetics, safety, manufacturability, and overall quality. In the System Pillar the approval process is used for the design reviews.

The SEMP contains rules and recommendations that directly govern the design process. This, therefore, becomes the controller document for the design and review process. The quality management of a design must hence ensure that the work product adheres to the guidelines and directives included in the SEMP and its respective annexes.

The first step in the quality management process governing design review and approval is to follow the SEMP work product review process discussed in the previous section. In addition, the following general

quality management review should be followed. In case of any overlap between the workflow recommended by this document and the SEMP review processes, SEMP documents take precedence.

7.4.3 Quality Review - Safety Aspects

The Performance, Reliability, Accessibility, Maintainability and Safety (PRAMS) domain is the premier authority over design and operational safety rules and measurements. It is their responsibility to ensure that safety, an emergent property in practical situations, is considered beyond reasonable doubt. This quality management plan only covers the process documents in place that govern the PRAMS domain. In situations where external products, services or processes are sourced, it is the responsibility of both the PRAMS domain and the domain which sourced these services to ensure that the external organization is aware of System Pillar (quality) requirements. Therefore, it is imperative that both the domains,

- Clearly communicate all requirements in writing with signed acknowledgment from all parties that the requirements are unambiguously understood by all.
- Clearly document and communicate the validation activities that will be performed on reception of the product or service. In System-of-Systems (SoS) applications, it is also important to validate the product in both local and global environments, i.e., test the component itself and its interactions when the entire system is “executed”.
- Clearly document and communicate any System Pillar SEMP or quality management rules, methods or requirements that must be followed by the external organization.
- Clearly document and agree on technical control and monitoring of the provided product or service, including regularly scheduled update meetings.
- **Internally**, within the involved System Pillar domains, discuss if the external organization is following the expected rules, processes or guidelines. If not, it is the responsibility of the task leads to report it to the domain leads. It is important to identify and control inconsistencies as early as possible.

Secondary quality managers from both domains, together or turn-by-turn, must plan regular checks into the collaboration and document their observations. Any inconsistency or cause for serious concern must be reported to the domain lead(s). **[**SPPR-11786 **]**

7.5 Post Review

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Post-review activities are as important as review activities.
SPPR-10697 - Task/Domain Lead Railways and SPPR-10707 - Task/Domain Lead Suppliers are accountable for prioritizing and following up the tasks, change requests, ... identified during the Quality Review.
SPPR-10697 - Task/Domain Lead Railways , SPPR-10707 - Task/Domain Lead Suppliers, SPPR-10390 - Lead Quality Manager or SPPR-10391 - Quality Manager of the Task/Domain in charge of the quality-reviewed work product, may qualify identified issues as non-conformities. In such cases, root-cause analysis is needed. See 7.6 - Non-Conformance Management

Factors triggering use of non-conformities are, among others:

- cost/delay of rework needed to solve the issue
- high, non anticipated PRAMS-S impact on current or other interacting systems
- recurrent issue

[SPPR-11785]

7.5.1 Closure of the Quality Review

To close a Quality Review, the person in charge of the review shall:

1. check that the report is complete, i.e. all parts of the template filled, all observations present, any non-conformity/ies is/are present in the report
2. change to waiting the status of the Polarion task related to this activity
3. notify end of Quality Review to
    a. the author(s) of the reviewed work product
    b. Task/Domain Leads and the SPPR-10391 - Quality Manager of the Task/Domain owner of the reviewed work product.
    c. SPPR-10390 - Lead Quality Manager
4. the identification of one or more nonconformities

[SPPR-11797]

7.6 Non-Conformance Management

Nonconformity in ISO 9001 is failure to meet a requirement. It can occur during an activity or a process. A nonconformity must lead to a root-cause analysis.
Nonconformities within the System Pillar can be categorised into two types.

1. Major – The nonconformity impacts cost, schedule and/or scope of work. An escalation may be necessary.
2. Minor – The nonconformity can be corrected with the same resources and within the original budget and schedule.

Regardless of its type, the detection of a nonconformity is crucial for continuous improvement of processes within the System Pillar. Therefore, nonconformities must be handled in the following manner.

1. Recognize and define the problem
2. Contain the problem
3. Determine its root-cause
4. Take appropriate action(s) to prevent it from recurring.

Step 1 happens during the Quality Review. Steps 2 to 4 form a major part of quality control.

The following chart can be used to determine the origin point of error.
Note: The chart is only an example. The Appendix contains all applicable templates for the System Pillar.

Problem/ Nonconformity:							
Date:							
Origin Point	**Standard**	**Process**	**Requirement**	**Human**	**External**	**Technical**	**Other (add text)**
	No applicable standard	No SEMP process defined	Requirement ambiguous	Misunderstood requirement	Supplier misunderstood requirement		

	No System Pillar guidelines	Process ambiguous	Multiple requirements for same artefact	Not aware of requirement	Supplier not aware of requirement		
	Standard not accessible	Process not accessible	No requirement exists	Unfamiliar with environment			
				Not enough time			
				Not aware of applicable SEMP process			
				Misunderstood applicable processes			

Depending on the outcome of the root-cause analysis, the corrective action will vary. Broadly, the corrective measures can be categorized as,

- **Local fix**
  A local fix is a one-time fix specific to the artefact under scrutiny. The appropriate processes and requirements exist, and no change to methods is required.
- **Global fix**
  A global fix requires the modification of a SEMP process or System Pillar requirements to ensure that such a nonconformity does not arise again in the future.

In certain cases, depending on the level of the nonconformity, a **working group** may be created, representing the concerned departments, to conduct a root cause analysis. Working group may be led by one of the task/domain Lead or by the SPPR-10391 - Quality Manager . This person will be the **Non-conformity Owner**.
There are different quality catalysts to support the analysis e.g. the Fishbone diagram, Pareto chart, FMEA, 5-Whys.

The resulting action plan will contain the necessary instructions to develop and implement the corrective actions related to the identified problems. **The most important step while creating the action plan is to ensure the elimination of the root cause and not only of the consequences** of the issues.
The Non-conformity Owner has the responsibility to properly set up the action plan. Within the action plan

the following content must be determined.

- Required actions
- Necessary resources for implementation
- Responsibilities
- Target dates

The final step in dealing with non-conformities is taking appropriate action to prevent its reoccurence in the future. This involves the following.

1. Identify the overseeing quality manager - secondary or primary. This is important because this manager will be a part of all the tasks concerning the corrective action in a "monitoring" role.
2. Identify individuals and create an ad-hoc working group.
3. The working group must produce a plan which must be signed off by both the overseeing quality manager and the domain lead(s) involved.
    a. The plan may involve improvements to the original work as applicable. For example, if the corrective action is on a requirement text, there is no scope for additional improvement.
4. The plan must also include required resources and estimated time.
5. The corrective action must be tested, with the test results approved by both the overseeing quality manager and involved domain lead(s).
6. The action must be rolled out to the System Pillar as applicable.
7. The post-review actions report must include the plan and the test results.

[SPPR-11784 **]**

8 Tools and Methods

See Systems Engineering Management Plan - 01 Main **[**SPPR-11791 **]**

9 Documentation and Configuration Management

9.1 Document Control

See *SPPROCESS/SEMP Annexes/SEMP Process 0945-Review and Approval Process : 714939* **[**SPPR-11792 **]**

9.2 Change Management

See Configuration Management Plan and Configuration Management Plan - Annex B Change Control Management Process **[**SPPR-11789 **]**

9.3 Interface with Configuration Management Plan

See chapter SPPR-7585 - Configuration Verification & Audits of the *SPPROCESS/10 SEMP V 01_01/ Configuration Management Plan : 714939* **[**SPPR-11790 **]**

10 Training and Competence

Training requirements are managed globally at EET level in Systems Engineering Management Plan - 01 Main .
There is no competence assessment defined in System Pillar. Nomination of experts is defined at

Europe's Rail level (See SPPR-3391 - [1] Europe’s Rail Joint Undertaking Governance and Process Handbook v2.6 (December 2023)) **[**SPPR-11788 **]**

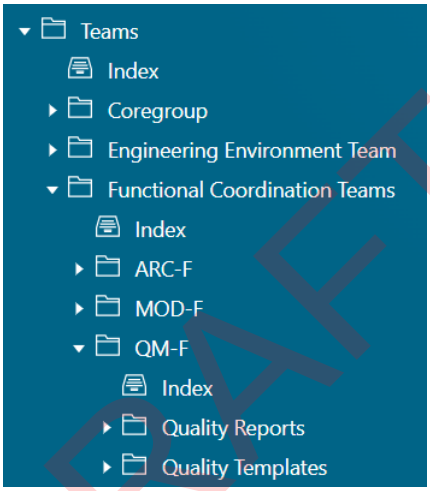
11 Continuous Improvement

Continuous exchanges (through e.g. functional teams meetings) help gathering improvements tasks.
In addiition, any task/domain may also request EET to clarify, define, design helper scripts and reports for a method and/or tool aspect (e.g. managing Application Conditions). **[**SPPR-11787 **]**

12 Quality Records and Reporting

12.1 Quality Artefacts

Quality Management Repository organisation
All working files or live documents must be created and/or referenced from the **QM-F** space in **SP-Public** Polarion project.

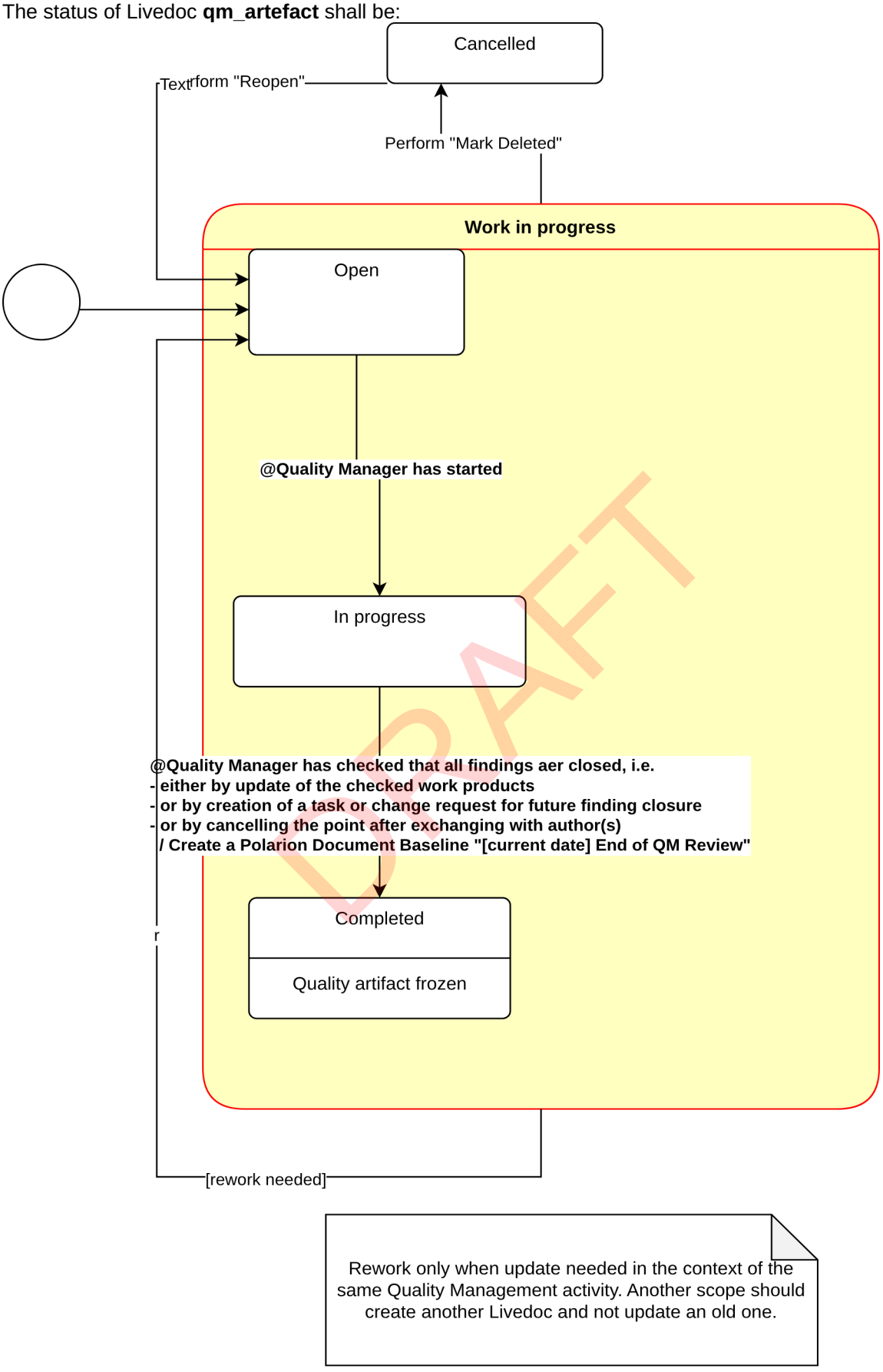


[SPPR-11690 **]**

Each Quality Management artefact shall be a Polarion Livedoc.
The following rules shall be followed:.

1. The name of the **Quality Management reports**:
    a. must be prefixed with "**SP_QMR-**", where SP means System Pillar and QMR means Quality Management Review.
    b. must contain 5 words or less between the prefix and suffix, both non-inclusive.
    c. must have the suffix "**-[domain name]**". For example, *SP_QMR-EET* or *SP_QMR-WP2 Quality Review-EET*
2. The name of the **Quality Management checklist and templates** must be prefixed with "**SP_QMCT-**", where SP means System Pillar, QMR means Quality Management Review and CT Checklist and Template.
3. The name of the **other Quality Management artefacts** must be prefixed with "**SP_QM-**", where SP means System Pillar and QM means Quality Management.
4. The **Quality Management reports** must use the type **qm_artefact** (see below) . Other Quality Management artefacts shall use the type **generic**.
5. All Quality Management artefacts, especially the quality reviews, must be diligently recorded.
6. The SPPR-10390 - Lead Quality Manager is accountable for the management of the QM-F Polarion space.

The status of Livedoc **qm_artefact** shall be:



Note that, in the context of the System Pillar, there are no audit logs to be recorded. **[**SPPR-11689 **]**

12.2 Quality Management repository

At the end of every working quarter of the System Pillar year, the review artefacts produced within that quarter must be baselined and added to a Polarion collection.
The collection must follow the naming scheme of **SP_QM-[*quarter and year*]-Artefacts**, where SP means System Pillar and QM means Quality Management. For example, *SP_QM-Q32024-Artefacts*.
In the absence of any quality management-specific guidelines, the general configuration management rules apply. **[**SPPR-11691 **]**

13 Appendix

13.1 Templates

13.1.1 Review of deliverable documents

Document workflow as well as mandatory review and approval process are explained in *SPPROCESS/ SEMP Annexes/SEMP Process 0945-Review and Approval Process : 714939* **[**SPPR-11425 **]**

13.1.2 Quality Reviews

For Quality Reviewsn the template is SP_QMCT-Generic Quality Checklist

13.2 Norms, Standards and Requirements

SPPROCESS/10 SEMP V 01_01/SEMP Annex Related Standards and Norms : 714939

Document ID	Dated	Title	link (informative)
CSM-RA (EU) 402/2013 ☐ SPPR-8746	30.04. 2013	Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009	
(EU) 2015/1136 ☐ SPPR-8747	13.07. 2015	Commission Implementing Regulation (EU) 2015/1136 of 13 July 2015 amending Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment	
TSI CCS (EU) 2016/919 ☐ SPPR-8749	27.05. 2016	Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the control-command and signalling subsystems of the rail system in the European Union	
(EU) 2019/776 ☐ SPPR-8748	16.05. 2019	Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU as regards the alignment with Directive (EU) 2016/797 of the European Parliament and of the Council and the implementation of specific objectives set out in Commission Delegated Decision (EU) 2017/1474	
(EU) 2020/387 ☐ SPPR-8751	09.03. 2020	Commission Implementing Regulation (EU) 2020/387 of 9 March 2020 amending Regulations (EU) No 321/2013, (EU) No 1302/2014 and (EU) 2016/919 as regards the extension of the area of use and transition phases	

Document ID	Dated	Title	link (informative)
(EU) 2020/420 SPPR-8750	16.03. 2020	Commission Implementing Regulation (EU) 2020/420 of 16 March 2020 correcting the German language version of Regulation (EU) 2016/919 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union	
COR (EU 2016/919 OJ L 279 SPPR-8752	15.10. 2016	Corrigendum to Commission Regulation (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union (OJ L 158, 15.6.2016)	
EN ISO 9001 SPPR-2665 - [ISO/IEC TR 90005-2008]	2015-09	Quality management systems - Requirements	
EN 50126-1 SPPR-2681 - [EN 50126-1:2017]	2017-10	Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 1: Generic RAMS Process	
EN 50126-2 SPPR-2680 - [EN 50126-2]	2017-10	Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) - Part 2: Systems Approach to Safety	
EN 50128 SPPR-2699 - [EN 50128]	2011-06	Railway applications - Communications, signalling and processing systems - Software for railway control and protection systems	
EN 50128/AC SPPR-2699 - [EN 50128]	2014-02	Railway applications - Communications, signalling and processing systems - Software for railway control and protection systems	
EN 50128/A1 SPPR-2699 - [EN 50128]	2020-02	Railway applications - Communication, signalling and processing systems - Software for railway control and protection systems	

Document ID	Dated	Title	link (informative)
EN 50128/A2 SPPR-2699 - [EN 50128]	2020-07	Railway applications - Communication, signalling and processing systems - Software for railway control and protection systems	
EN 50129 SPPR-2682 - [EN 50129]	2019-06	Railway applications - Communication, signalling and processing systems - Safety-related communication in transmission systems	

13.3 Covered topics

The quality management plan for the System Pillar must cover the following topics and provide necessary information on the same, as applicable.

- **Human Resources** – The human resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.
- **Infrastructure** – The provision and maintenance of an infrastructure necessary for the operation of the quality management plan.
- **Intangibles** – This includes anything that cannot be directly measured or quantified. For example, a work-conducive environment such as an unbiased demographic, psychological factors, physical factors such as temperature, noise and so on.
- **Baselines and Standards** – Suitable baseline parameters and general status-quo related information that is easily accessible to the involved parties. For example, these could be the international standards that apply to the work product.
  Note 1: When no suitable standards exist, a System Pillar internal document that contains expected verification and validation data, and other guidelines, must be maintained.
  Note 2: Deliverable baselining is covered by the SEMP Configuration Management Plan.
- **Knowledge Management** – This includes diligently recording the lessons learned and making it available for future work, ensuring that knowledge is not siloed or inaccessible, planning for future work and addressing changing needs or trends, ensuring that there is no single point of failure when it comes to dissipation of knowledge within the System Pillar community and so on. For example, planning and being prepared in advance for a future in which an active expert leaves the System Pillar.
- **Competence** – This is a human resource topic that specifically focuses on the skillset of individuals. The quality management plan must have a checklist in place that can easily identify and ensure that persons are competent on the basis of appropriate education, training and/or experience. As and when required, suitable training must be provided.
- **Communication** – The quality management plan is also responsible for including information on who will communicate with whom, when, and how on topics involving quality control.
- **Documentation** – The quality management plan should include documentation templates – in line with governing standards, if applicable – for quality reporting. This also covers document classification, distribution, storage and preservation, version control and disposition.
- **Awareness** – Probably the most important topic of all, this ensures that all members of the System Pillar are aware of all process documents. They must be able to retrieve a process document on demand with little to no dependence on any other individual

[SPPR-11793 **]**

14 Overview of main changes between versions

Not Applicable (Rationale: firt official version)

15 Open points: Issues and tasks for this document

15.1 Open or in progress

15.1.1 WIP - FOR FUTURE USAGE IF REQUESTED - Quality Audits

Process audits ensure adherence to the guidelines defined in this document. Regular audits must be scheduled to check if best practices, as defined in this document, are actually being implemented or followed by individual teams. A process audit evaluates whether a process and its resources are being managed effectively and accurately. It also helps determine if specific business objectives are being achieved. A process audit is collaborative and focuses on facilitating agile workflows. It checks the performance of how the work is done in accordance with the System Pillar processes. It does not primary check the content of the process. But the process results could be used as measurement. Any domain or team member can make a request towards the Quality Manager to perform a process audit in a certain process area based on defined processes in the corresponding project plan. This request leads to an alignment between the System Pillar member and the Quality Manager, if the process audit should be scheduled. Nevertheless, the Quality Manager is empowered to schedule any process audit based on personal discretion. Minimum requirement for this scheduled process audit is the announcement 3 months ahead. If a process audit has been agreed, it shall be planned accordingly. The Quality Manager is responsible for the overall planning. A group of participants shall be aligned and invited as well as an individual questionnaire to be created by the auditor in preparation to the audit. This questionnaire serves as a guideline for the auditor and is not to be shared in advance. The audit itself is led by PQM supported by an experienced auditor. Results of the process audit shall be documented, and the traffic light principle shall be used for overall assessment. The overall conclusion should be agreed between the process responsible within the System Pillar and the Quality Manager. Agreed action items, if any, shall be monitored and followed up by the team that has originally requested the audit. The sign-off of action items shall be presented to the Quality Manager upon request.
The auditor checklist, at the least, should contain the following items.

- Business objective - This must cover at least the need for the work performed from the point-of-view of the business, which in this case is System Pillar. This need can sometimes be nested, and it is the responsibility of the auditor to trace upwards until a linked business objective can be reached. If not, then the audit can be deemed “failed” and the escalation path should be followed.
- The controller document - The auditor must be aware of the controller documents.
- Global standards applicable to the System Pillar and the work under consideration.
- Local standards- SEMP documents in most cases that are applicable to the work under scrutiny.
- Responsibility of the System Pillar task.
- Responsibility of the domain.
- Responsibility of the work package.

A local audit – by the System Pillar Primary Quality Manager – is recommended to be conducted every six months. A global audit, by an experienced auditor outside the System Pillar, is recommended to be conducted at least once every year.
Escalation broadly covers the identification of nonconformities and the way in which they are dealt. The previous sections cover the steps involved in performing quality checks and identifying nonconformities. This section covers with the formalities involved in dealing with the nonconformities.
It is already established that nonconformities are of two types – major and minor. Both these conformities may be addressed by either a local fix or a global fix. The quality control that involves this addressing

follows the generation of a post-review actions report which contains escalation guidelines. The template in the Appendix contains the guidelines covering the steps between the identification of a nonconformity and its fixing.
The quality management plan covers escalations as part of quality checks performed to assess the quality of either a in-progress work product or a finished work product. Since this quality plan does not cover the initiation or planning phases, the escalation types considered in this document cover only those that happen in-progress or post work. Any nonconformity identified between 1% of the work and 99% of the work product, both inclusive, is a mid-work escalation; any nonconformity identified after 100% of the work product is done is a post-work escalation. Post-work escalations usually occur during final review gates or audits.
[SPPR-11795 **]**

15.2 WIP - FOR FUTURE USAGE IF REQUIRED - Quality Gates

Currently, SP works in an Agile way by iterative sprints based on subset of capabilities.
In this context, as not all Task/Domain are coordinated, usage of Gate Review is not suitable. Instead:
- checks are included in these sprints for early review (see quality reviews above).
- configuration checks are already specified in Configuration Management Plan - Annex A System Pillar Release Creation Process .
The proposed content below is kept in case Way of Working changes in System Pillar in the future.

Quality gates are essentially review milestones for deliverables produced within the System Pillar. Given the structure of the System Pillar, a single review plan cannot be generalised for all domains and working groups simply because the nature of work is different from one domain to another. Therefore, the review plan should be tailored to each domain or group. The following gates are generic, and ideally apply to the entire System Pillar regardless of the type and nature of the deliverable.

- Kick-off review: The secondary quality manager should ensure that the kick-off plan for every planned activity in their domain contains information regarding applicable standards and guidelines, the requirement(s) or business need that led to the initiation of this work, required resources, estimated work-output date, regularly scheduled update meetings (may be a part of an existing regular update meeting) and required accesses at the least. The kick-off review gate requires no additional work from the domain lead(s) or task assignees. It is the responsibility of the secondary quality manager to record the review outcome in the domain's local quality management folder in Polarion.
- Midway review: It is the responsibility of the secondary quality manager to keep track of estimated dates for all activities and conduct a review of the progress. A week's notice must be given to the domain lead(s) and task assignees. The quality manager must ensure that the work done so far is in compliance with applicable System Pillar processes. They are also required to check if the domain lead and task assignee are sufficiently aware of the applicable standards and processes. The manager also needs to verify, with the help of the domain lead(s), the validity of the work against its requirements or business needs. The conformity or nonconformity, along with review notes, must be documented in the local quality management repository. If escalation or quality control is needed, the suitable escalation path must be selected.
- Final review: The general quality review process described in the sections above applies to this quality gate.
- Ad-hoc reviews: Depending on the task and its internal milestones, the secondary quality manager may schedule additional quality review meetings. The process would be similar to that of a midway review.

All review gates will include **configuration management checks**.
Final reviews are part of all work in the System Pillar, and the general processes described in this plan

apply to this gate by default.

The following items will be considered towards creating a standard quality gate template.

- Scheduling of quality gates.
- Standard agenda used for structuring the quality gate meeting.
- Questionnaire prepared individually for each quality gate.
- Group of participants to be invited individually for each quality gate.
- Metric for assessing the result of a quality gate.
- General procedure and treatment of identified nonconformities.
- Reporting of results and quality gate conclusion.

This quality gate template may be the standard quality review template referenced earlier in the plan.
[SPPR-11794 **]**

15.3 Done

Quality Management Plan contains obsolete content and does not explain quality checks that are performed on TrafficCS content.
Document should be updated and link to it from RMP and Modelling Handbook to be completed in those documents

Status	Waiting
Assignee(s)	ANTOONS Gilles
ID	SPPR-11131