RSC-G-009-E-Annex1 (SP)
Checklist for evaluation of a **Project Safety Plan**

Prepared by:	Maik Wuttke	31.08.2012
Reviewed by:	Mary Molloy	31.08.2012

1 Introduction

This checklist will be employed by the RSC when evaluating a Project Safety Plan in association with PIS Projects according to IOD or RSA. A Project Safety Plan shall document, that a suitable Safety Management System has been installed by the Project, in order to perform any activities leading to Placing in Service in a safe and controlled manner. In order to avoid repetition, documentary evidence may be annexed or referenced to a Safety Plan. Any such Annexes and References shall be considered to be part of the Safety Plan.

2 Elaboration of a Project Safety Plan

When applying for each APIS stage the Applicant must provide the current Project Safety Plan.

Note: Due to the evolving SMS during APIS stages 1, 2,and 3 it is expected that the SP is updated accordingly. For APIS stages 4, 5 and 6, if no revision of the Safety Plan has been necessary due to additional information or change in approach, the Applicant may refer to the most recent Project Safety Plan to be the current SP.

Any Project Safety Plan shall follow the structure provided below and shall include all sections listed. If any section is not relevant for a given project, that section shall still be provided as headline and it shall give a (brief) explanation why this chapter is not relevant.

Each Section shall provide relevant information addressing the Requirement and References given in the list.

The Project Safety Plan must have been prepared under the scope of a certified/ authorised RU/IM SMS under RSD and CSM 352/2009 or an 'RU-Safety Case' in accordance to RSA approved by the RSC.

The Safety Plan must comply with current industry best practice. The application of EN 50126-1, EN 50126-2, EN 50128, EN 50129 in association with CSM 352/2009 is considered to represent current best practice.

Each chapter of the Safety Plan has to be prepared, detailing any constraints, dependencies, assumptions and caveats.

3 Internal Review Report

The applicant for APIS must arrange for an internal (or external) review of the Safety Plan against this Checklist by an expert in the field of SMS. This review must cover completeness and plausibility of content of the Safety Plan, and must be documented in a report which must be provided to the RSC with the Safety Plan.

4 RSC evaluation of Project Safety Plan

The RSC must evaluate the Project (Change acc. to CSM 352/2009) for which the applicant is applying for APIS against the requirements of IOD 15(1+2), RSD 4(3)+6(3), CSM 352/2009 and RSA. The Project Safety Plan will be used by the RSC as one element to form an opinion, whether all requirements relating to APIS have been satisfied.

The attached list contains the minimum set of requirements. Any RU/IM may decide to elaborate on these, if their SMS requires more or higher requirements. Where an RU/IM decides to elaborate on these requirements, the main chapter headings of the checklist should be retained.

The provision of a Project Safety Plan is also considered to support the requirements of RSA 42+43 for providing a New Works Assessment or a New Rolling Stock Assessment.

Note1: In addition to this Checklist, other requirements may also be applicable, arising from the application of EN 50126-1, EN 50126-2, EN 50128, EN 50129, EN50159-1/-2, CSM 352/2009, or the requirements of a certified/ authorised RU/IM SMS.

Note2: The list may include reference to the SMS of particular RUs and IMs where these have provided the related information for reference. At any time RUs and IMs may come forward to have their reference information added, updated or erased within this list.

5 Checklist for Safety Plan

No.	Section	Requirement	Reference	IE SMS (RU &IM)
0	*Document Control*	>Provide title, document identification number, revision, revision history, author, organisation and signatures. >Provide list of referenced documents. (It is highly recommended to assign each referenced document a unique identifier to be used throughout the Project Safety Plan (and ideally throughout any other Project documentation). The Project may decide to keep a List of References as a separate document.)	- RSC-CL-001 - Yellow Book, Volume 2, Appendix B.2	
1	*Introduction*			
1.1	Project introduction	Provide high level introduction to Project.		
1.2	Type of APIS sought	Define Type of APIS sought at this project acc. to RSC-G-009, i.e.: - RSA-APIS-NW - RSA-APIS-NRS - IOD-APIS - IOD-APIS-TV - Combined RSA-APIS-NW+IOD-APIS - Combined RSA-APIS-NRS+IOD-APIS-TV	- RSC-G-009	

No.	Section	Requirement	Reference	IE SMS (RU &IM)
1.3	Level of Safety Case to be elaborated	Describe the intended approach to delivering the project Safety case. – Possible approaches include: - Application Specific Project Safety Case,(ASPSC) - ASPSC, supported by Generic Product Safety Case (GPSC) and / or Generic Application Safety Case (GASP) - GASC, supported by GPSC (for later use as basis of an ASPSC for future projects) The Applicant should consider whether a product might be re-used on future projects and related possible future benefits in delivering GASC or GPSC. (Example: use of standardised "building blocks" within CCO/CCT, to minimise re-assessment at each future project at ASPSC level.) (Only the ASPSC level will be able to support an APIS for stage 4 or 5 or 6.)		
1.4	Related Phase of Project Life-Cycle	Indentify Phase(s) of Project Lifecycle and RSC APIS Stage(s) to which this Safety Plan revision is related.		
1.5	Identify Type of APIS Project.	-New build/ -Upgrade / -Renewal	-IOD+TSIs	
2	*Description of the Change*	*Note 1: Provide appropriate detail to identify **significant** aspects, including **boundaries** and **interfaces between the Change and the Railway System**.* *Note 2: 'Change' means all Subsystems and Parameters (including their interfaces) affected by the PIS Project.*		IE-SMS-014 Clause 4.2.4.1
2.1	Definition/ Identification of Change	Precisely define/ identify the Subsystem or Parts thereof to which this Project Safety Plan refers, including (as relevant) unique type identification, positions on the network, chainages, version numbers, modification status, etc. (This should follow the typical industry approaches, used for precisely identifying products/ equipment/ installations/ etc.)		
2.2	Scope of Change	Define scope of Change (as caused by the project to the Railway System) in physical, functional, legal, etc. boundaries and define related interfaces to the Railway Network. Identify applicability of IOD, any TSIs or granted Derogations to TSIs. (This can often be abbreviated, if additional descriptive references are available as e.g. tender-specifications, contract-specifications, product descriptions, etc.)	- EN 50126-1, Section 6.2.3.4, b. - RSC-G-009	IE-SMS-014 Appendix 2

No.	Section	Requirement	Reference	IE SMS (RU &IM)
2.3	Subsystems and Parameters (incl. Interfaces) affected by Change	Identify and Manage systematically all Subsystems and all Parameters (including their interfaces) affected by the Change. This must at least include all affected Parameters, which are listed in RSC Guidance for the related Subsystems. If further Parameters are considered to be relevant by the project SMS experts, these must also be identified and added. All Parameters shall be systematically listed to enable ease of referencing and assessment. (They shall be listed within the Project specific Safety- & Compliance- Matrix.)		
2.4	Functional/ Technical Description of Change	Provide information on objectives, purposes and functions / technical design solutions for all Subsystems, Parameters (incl. their Interfaces). (May be done by referencing appropriate Functional/ Technical descriptive Documentation/ Drawings/ Calculations/ Simulations/ etc. within a Project specific Safety- & Compliance- Matrix.)	- EN 50126-1, Section 6.2.3.4,c; - EN 50126-2; - CSM 352/2009, Section 2.1.2; (- for information: Yellow Book, Chapter 14)	IE-SMS-014 Clauses 4.2.4.1.1 & 4.2.4.1.2
2.5	Interface Description of Change	Define system boundaries, and physical and functional interfaces. **Note:** This must cover also the interface to the RU/IM Safety Management Systems and all related internal and external interfaces. (May be done by referencing appropriate Functional/ Technical/ Organisational interfaces defined by descriptive Documentation/ Drawings/ Application Conditions/ etc. relating to Interfaces within the Project specific Safety- & Compliance- Matrix. All Interfaces shall be placed with all the Parameters which they are affecting.)	- CSM 352/2009, Section 2.1.2;	IE-SMS-014 Clause 4.2.4.1.3
2.6	Environmental Conditions of Change	Define environmental conditions relating to design and operation of the Change. (May be done by referencing appropriate Functional/ Technical descriptive Documentation/ Drawings/ Application Conditions/ etc. relating to environmental conditions within the Project specific Safety- & Compliance- Matrix. All Environmental Conditions shall be placed with the Parameters which they are affecting.)	- Yellow Book, Chapter 14.	IE-SMS-014 Clause 4.2.4.1.4
3	**Project Organisation**			
3.1	Roles and Responsibilities, Organisational chart	Define details of roles and responsibilities for all bodies undertaking SMS related tasks within the project lifecycle and their required and demonstrated competencies to perform those roles / undertake those tasks. Define relationships between bodies undertaking tasks.	- EN 50126-1, Section 6.2.3.4, d and o; - EN 50126-1, Sections 3.26, 3.40 and 5.35; - CSM 352/2009, Section 1.1.6	IE-SMS-014 Clause 4.2.5.4

No.	Section	Requirement	Reference	IE SMS (RU &IM)
3.2	Personnel independence in tasks	Ensure and demonstrate that an appropriate degree of (personnel) independence is provided for any review, V&V, auditing, assessment, etc. tasks. **(Note:** This shall generally be related with the extent of the risk and in any case it must comply with codes of practice, legal and statutory requirements.) (This may be done in connection the organisational chart developed under 3.1 above.)	- EN 17020; - EN 50126-1; - EN 50126-2; - EN 50128, Fig. 5; - EN 50129, Fig. 6; - CSM 352/2009; - RSA 2005; - Yellow Book, Chapter 13.	IE-SMS-014 Clauses 5.9 & 5.10
3.3	Project Documentation Management	Define a project related documentation management process. This must include a documentation retention policy. All documentation relating to PIS of the Change must be retained at least for the service live of the Change plus 5years (This shall support any re-introduction of equipment into service and any potential incident or accident investigations.) Any relevant documentation must be handed to a future owner, in case of transfer of ownership. Additional legal requirements for retention times may apply. (You may refer to existing RU/IM document management systems, which are suitable for this task.)	- Yellow Book, Chapter 12;	
4	*Project Quality Management System*	*Note1: If no formal QMS is established, the Project must otherwise ensure that the activities below are performed in a consistent manner.* *Note2: The Project QMS activities must enable the Project to design, manufacture and commission the change according to the Safety- and Compliance Requirements. In case of series production, the QMS must ensure that all produced items are identical to the approved Type.*	- EN 50126-1, Section 6.2.3.4, b.	IE-SMS-014 Appendix 2
4.1	Project QMS Provisions	The Project QMS provisions must enable Design/ Manufacturing/ Series Production/ Commissioning/ Operations and Maintenance of the Change. (Refer to employed QM-Manual(s) and any QMS-Certification(s). Include information relating to relevant suppliers.)	- EN 50126-1, Section 5.2; - RSC-G-009.	
4.2	Project QMS Procedures	Define QMS procedures as relevant for the PIS Project on following tasks:	EN 50129 5.2	
4.2.1		- Management of project organisational structure (Roles and Responsibilities, Organisational chart) (This may be provided in connection with item 3.1.)		
4.2.2		- Management of Project requirements specification (at least Compliance requirements/ Safety requirements)). (This may be done in connection with the SCM.).)		
4.2.3		- Management of design V&V, type testing, inspection, design reviews, Assessment, auditing, etc.		

No.	Section	Requirement	Reference	IE SMS (RU &IM)
4.2.4		- Management of procurement, supplier qualifications, supplier monitoring. Ensure and demonstrate that suppliers/ sub-contractors which participate at design, manufacture, commissioning, testing, operation and maintenance of any Safety- or Compliance- Project Parameters are identified from the stage of procurement, that their qualification is appropriate and that they are regularly monitored. (You may refer to existing procurement policies and procedures and relevant supplier selection criteria or refer to relevant sections of procurement contracts / specifications. Refer to auditing/monitoring arrangements that will be implemented for suppliers of Safety- or Compliance related goods and services)	- Yellow Book, Chapter 8.	IE-SMS-009 particularly Clause 4.2, IE-SMS-014 Clause 5.1.6
4.2.5		- Manufacturing/ installation/ commissioning		
4.2.6		- Series Inspection and testing		
4.2.7		- Product identification/ traceability/ configuration management/ change control		
4.2.8		- Handling/ storage/ packaging/ delivery		
4.2.9		- Non-conformance handling and corrective actions		
4.2.10		- Definition and management of application conditions for operation/ maintenance/ decommissioning/ disposal		
4.3	Specific QMS provisions for welding on Rolling Stock	Define welding and related NDT provisions for Rolling Stock:		
4.3.1		- Employ EN 15085 family and EN 473 as baseline		
4.3.2		- Provide project related organisation of certified Welding Engineer, Welders, NDT-Expert and NDT-Technicians.		
4.3.3		- Ensure that welding design is documented and authorised by certified Welding Engineer and manufactured by certified welders.		
4.3.4		- Ensure that any NDT is defined by certified NDT-Expert and performed by certified NDT-Technician.		
4.4	Specific QMS provisions for welding of Subsystems other than Rolling Stock	Define welding and related NDT provisions for Subsystems other than Rolling Stock:		
4.4.1		- Identify baseline standard(s) for any welding or NDT performed as part of the project.		
4.4.2		- Identify any Training/ Certification requirements for Welding Engineers, Welders, NDT-Experts, NDT-Technicians participating at the Project		
4.5	Specific QMS provisions for other safety related bonding activities	Define any other safety related bonding provisions (other than welding)		
4.5.1		- Identify any Training/ Certification requirements		
4.6	QMS Auditing	Plan auditing of all Project QMS activities as defined above.		

No.	Section	Requirement	Reference	IE SMS (RU &IM)
5	*Project Safety Management System*	*Note 1: Provide appropriate detail to identify significant aspects, including interfaces and boundaries.* *Note 2: Provide high level information in the Safety Plan. Large volumes of detailed evidence and supporting documentation need not be reproduced, provided precise references are given to such documents.* *Note.3: 'Change' means the Subsystems and Parameters including their Interfaces affected by the PIS Project.*		IE-SMS-014 Clause 4.2.4.1
5.1	Policy and Strategy to achieve safety	Refer to the policy and strategy as defined at a generic level by a certified/authorised RU/IM SMS and adopt for Project. Define on project-by-project basis a suite of appropriate references for the performance of SMS activities. (List i.e. the applicable standards, legislation, SMS provisions, industry practice / guidelines etc. that will be adopted to achieve safety.)	- EN 50126-1, Section 6.2.3.4,a; - EN 50126-1 (in combination with EN 50126-2, EN 50128, EN 50129, EN 50159-1, EN 50159-2); - CSM 352/2009; - Railway Safety Act 2005; - RSC Guidelines; (- for information: Yellow Book, Chapter 11).	IE-SMS-001
5.2	Level of Significance to CSM 352/2009	Provide judgement on CSM Significance. (Any project that requires APIS is automatically deemed Significant, in accordance with the CSM. In this case further analysis / judgment on Significance is not deemed necessary.)	-CSM 352/2009	IE-SMS-014
5.3	Project Life-Cycle	Define project life-cycle phases and show the relationship with basic life-cycle approach to EN 50126, APIS stages to RSC-G-009, and stages required by an applicable certified/authorised RU/IM SMS.	- EN 50126-1, Section 5.2;	IE-SMS-014 Clause 4.2.4.4 & Appendix 2
5.4	Project Schedule	Provide Project Schedule, referencing APIS stages.		
5.5	Intended Service Life of Change	Define Intended Service Life of Change.		
5.6	Safety tasks	Describe the system life-cycle related safety tasks to be undertaken within each lifecycle phase along with any relationships between them. In the Stage 1 and 2 SP, define the available range of safety tasks and tools to be considered for application per life-cycle phase. In subsequent revisions of the Safety Plan as the project progresses, you may state which safety tasks and tools have actually been employed for each previous life-cycle phase and state those intended to be employed in subsequent phases. . Justify the adequacy of tasks chosen for the application under consideration. (You may refer to the Safety Case, HR or other documentation where the applicability and output of the safety tasks performed has shall be documented.)	- EN 50126-1, Sections 3.41 (+Fig.9), 5.2, 5.3.4 and 6 (incl.6.2.3.4,d);	IE-SMS-014 Appendix 2
5.7	System Requirements Specification	Refer to documentation providing System Requirements Specification (at least Safety- & Compliance-Requirements) (You may refer to SCM which brings together all Safety- & Compliance-Requirements, from all the listed sources.)		
5.7.1		- Tender Specification		

No.	Section	Requirement	Reference	IE SMS (RU &IM)
5.7.2		- Contract Specification		
5.7.3		- Legislative Requirements		
5.7.4		- Network Access Requirements		
5.7.5		- Other sources (best practice, state of art, etc.)		
5.8	Combined Project Safety and Compliance Requirements Specification	Describe how Safety Requirements and Compliance Requirements must be identified by the Project. Establish Combined Project Safety and Compliance Requirements Specification. (Refer to Project Safety- & Compliance- Matrix)		IE-SMS-014 Clause 4.2.4.1.5
5.9	Hazard identification and analysis	Define approaches for hazard identification (e.g. creative, empirical or structured). **Note:** Make use of past experience and lessons learnt or known incidents/accidents at similar systems nationally and internationally. Define for each approach of hazard identification and analyses the process and format to be followed.	- CSM 352/2009, Section 2.2; - Yellow Book (7 stage process).	IE-SMS-014 Clause 5.1.1.1,
5.9.1		Structured approach: Use RSC Parameter Lists and other structured checklists for identification of safety related functions and associated hazards. (It is highly recommended that the Hazard Record should generally be structured following the systematic order of the RSC Subsystem Parameter Lists in order to enable efficient assessment of completeness.)	- Yellow Book, Appendix C.	IE-SMS-006
5.9.2		Empirical approach: Use Lessons Learned/ past experience/ published accident reports for identification of hazards.	- EN 50126-1, Fig. 9, Stage 2;	
5.9.3		Creative approach: Use Expert workshops for identification of hazards.		
5.9.4		Document hazards in Project Hazard Record		
5.10	Risk assessment and on-going risk management	Plan to perform and document risk assessment and risk management processes for the entire lifecycle of the Project.	- EN 50126-1, Section 4.6; - CSM 352/2009, Annex 1, Sections 2.3, 2.4 and 2.5.	IE-SMS-014 Clause 5
5.11	Risk tolerability criteria	Define risk tolerability criteria. Provide any risk matrix, qualitative or quantitative to be employed.	- EN 50126-2, Table 5 THR/SIL relationship; - CSM 352/2009, Sections 2.5.4 and 2.5.6; - Yellow Book, Chapter 17; - PD R009-004 for additional information.	IE-SMS-014 Clauses 5.1.7, 5.1.8, 5.2, 5.3, 5.4. & 5.5
5.12	Project Safety- & Compliance- Requirements Review Plan	Establish process for assessment of adequacy of Safety- & Compliance- Requirements during the whole lifecycle of the system. Identify assessment reports that will be provided during the whole lifecycle of the system. (The overall assessment planning may include the assessment in parts to be performed and documented in Reports by V&V, ISA, IPPR, IA, DeBo, NoBo, CSM-AB Review Project Safety Management Review, Internal Project Review,. (These Reports or relevant sections thereof may be referenced within the Project Safety- & Compliance- Matrix.)	- EN 50126-1, Fig.9, Sections 2 and 6, Fig 10 and Fig. 11; - Yellow Book, Chapter 17.	IE-SMS-014 Clauses 5.6.6 to 5.6.8 (Safety Validation Panel review and CSM-AB report may be considered as Project Safety Review activities.)

No.	Section	Requirement	Reference	IE SMS (RU &IM)
5.13	System Design Evidence	Provide reference to suite of design evidence that will be generated. This shall provide all functional/ technical descriptions, drawings and parts lists, calculations, simulations, test procedures, test reports, etc. which will be used to demonstrate achievement of the Safety and Compliance Requirements. The suite of evidence must be systematically organised to enable easy referencing and retrieving of the information contained. (It is highly recommended that this is done within a systematically organised Project Safety- & Compliance-Matrix. The systematic order shall follow that of the RSC lists for Subsystems and Parameters, as long as no systematic order is prescribed by the EU. This is to facilitate a co-ordinated approach within the State. If the EU Technical File or National Technical File shall be used for this purpose - avoiding duplication of work - they must comply with the same requirements.)	- EN 50126-1, Fig. 9, Section 6.6.	
5.14	Verification and Validation Plan	Describe plan to verify and validate all Safety and Compliance related Subsystem- and Parameter-Functions, their combinations and internal and external interfaces. (This may be incorporated within the Project Safety- & Compliance- Matrix.)	- EN 50126-1, Fig.9, Fig. 10 and Fig. 11, and Section 6.9; - Yellow Book, Chapters 11, 12 and 18, - IOD.	IE-SMS-014 Clauses 5.8 & 5.9
5.15	Safety & Compliance Assessment Plan	Plan for assessment of realisation of Safety- and Compliance-Requirements (tools to EN 50126-1, Annex B). The overall assessment planning may include the assessment in parts to be performed and documented in Reports by V&V, ISA, IPPR, IA, DeBo, NoBo, CSM-AB Review Project Safety Management Review, Internal Project Review,. (These Reports or relevant sections thereof may be referenced within the Project Safety- & Compliance-Matrix.)V, ISA, IPPR, IA, DeBo, NoBo, CSM-AB Review Project Safety Management Review, Internal Project Review,. (These Reports or relevant sections thereof may be referenced within the Project Safety- & Compliance-Matrix.)	- EN 50126-1, Sections 6.9 and 6.10, and Fig. 10; - Yellow Book, Chapters 13 and 18; - IOD.	IE-SMS-014 Clauses 5.9 & 5.10
5.16	Safety & Compliance Audit Plan	Define audit plan for compliance of the management process with the Safety Plan. (The overall auditing plan may include auditing in parts performed and documented in Reports by ISA, IPR, IA, DeBo, NoBo, CSM-AB Review Project Safety Manager Review, Internal Project Review.)	- EN 50126-1, Section 6.12; - EN 50128; - EN 50129; - Yellow Book, Chapter 13.	IE-SMS-014 Clauses 5.9 & 5.10

No.	Section	Requirement	Reference	IE SMS (RU &IM)
5.17	Safety & Compliance Monitoring Plan	Define monitoring process and plan to analyse Operation and Maintenance performance to ensure that realized Safety & Compliance is in conformance with requirements. (Note 1. Refer to the applicable provisions of an authorised/certified IM/RU SMS that are applicable to the subsystems under assessment, or any new provisions that must be developed.) (Note 2. The EU is currently drafting a CSM on Monitoring, which may regulate this issue more precisely.)	- EN 50126-1, Section 6.11, Phases B, A. - TSI Modules V/ CV	IE-SMS-001 Clauses 4.4.4, 4.4.5, 4.6
5.18	Provisions for SIL Assessment	Perform pre-planning of activities for setting and assessing SIL. (This will predominantly relate to functions of the Change which are containing safety-critical electronic/ software elements.)	- EN 50129, Annex E, in combination with - EN 50126; - EN 50128.	
5.19	Safety Approval Process	Identify the process for Safety Approval of Change to the Railway System. (Refer to type of APIS and safety approval processes of the authorised/certified IM/RU SMS.)	- EN 50126-1, Section 6.10; - EN 50129; - RSC-G-009; - RSA 2005	IE-SMS-014 Clause 5.12 & 5.13 for internal approval
6	**Safety related deliverables**	**Note:** Provide details of expected safety related deliverables for each lifecycle phase.		
6.1	SMS Documentation	The Project SMS must produce a Safety Case and related documented objective evidence supporting the safety case. This is expected to include as a minimum the following documentation:	- EN 50126, Fig. 9;	IE-SMS-014 Clause 5.11
6.1.1		- Project Safety Plan Define the process to prepare Project Safety Plan, define its contents and expected updating throughout the project lifecycle. (To include all aspects of this checklist. Shall be updated at least in accordance with RSC-G-009-Annex1 (2). Further updating shall be done as required.)	- RSC Guidance;	
6.1.2		- Project Hazard Record and update throughout the project lifecycle. Define the process to prepare Project Hazard Record, define its contents, and expected updating throughout the project lifecycle. (To be retained live throughout the life of the Change, to be updated at least for every stage of the RSC APIS process. Further updating shall be done as required – in principle everybody raising a new hazard shall be entitled to request updating of the Project Hazard Record.)		
6.1.3		- Project Safety Case(s) Define the process to prepare Project Safety Case(s), define its/their contents, and expected updating throughout the project lifecycle. (Generic Product Safety Case; or Generic Application Safety Case; or Application Specific Project Safety Case.) (**Note:** Only an ASPSC will lead to APIS.)	- EN 50126-1; - EN 50126-2; - EN 50129; - RSA 2005; - CSM 352/2009, Section 5; - Yellow Book, Chapter 18.	IE-SMS-014 Clause 5.11

No.	Section	Requirement	Reference	IE SMS (RU &IM)
6.1.4		- Documentation evidencing achievement of Safety and Compliance Requirements. Define the process to prepare and manage these. (refer to section 4 above if applicable). (This may be referenced within the Project Safety- & Compliance Matrix.)	-IOD+TSI EU Technical File+ National Technical File	
6.2	Configuration Management for Safety related Tangible Products/ Hardware	Identify at least all safety related tangible products/ hardware for which configuration management must be established. (Type-ID, Version, Serial Numbers, etc.) This shall include all items which over the lifetime of the product may require traceability or batch identification. Typical industry provisions shall apply. (Examples: EMU Type 8500, EMU Manufacturer Build No., Serial Number of onboard ATP-Rack: xyz/ Platform Lift on Platform 1, Pease Station, Serial Number: xyz/ Substation Location: abc, Serial number of Transformer: xyz)	- EN 50126, Fig.9;	IE-SMS-014 Clause 5.11
6.3	Configuration Management for Safety related Intangible products/ Electronic components/ Software	Define configuration management process at least for safety related intangible products/ Electronic components or Software (Type, Version, etc.) Shall include all items which over the lifetime of the product may require traceability or identification. Typical industry provisions shall apply. (Examples: SW version of on-board ATP-Rack: xyz,)	- EN 50128.	
7	***Technical Project Safety Reporting on Safety Qualification Testing***			
7.1	Requirements for Safety Qualification Testing	Requirements for Safety Qualification Testing shall be derived from the Safety- and Compliance Requirements-Specification and the Hazard Record. They shall include at least those Aspects listed below. In all cases test procedures and test reports shall be elaborated. These shall in principle follow EN17025. (This may be referenced within the Safety- & Compliance-Matrix)	TSI Modules V/CV EN17025	
7.1.2	Assurance of correct Operation	Define the testing process(es) to be applied for assurance of correct Operation of safety and compliance related functions. (Shall typically be included in Type-/ Series-/ Commissioning Testing.)		
7.1.3	Effects of faults on Operation	Define the testing process(es) to be applied for Effects of faults on Operation of safety and compliance related functions. (To generate documented evidence of acceptable reaction of safety and compliance related functions under simulated fault conditions. -Shall typically be performed as part of Type-/ Series-/ Commissioning Testing.)		

No.	Section	Requirement	Reference	IE SMS (RU &IM)
7.1.4	Operation with external influences	Define the testing process(es) to be applied for operation of safety and compliance related functions under effects of external influences. (Documented evidence shall be elaborated to demonstrate acceptable reaction of safety and compliance related functions under environmental limit conditions and safe degradation under out of range conditions. -Typically performed as part of Type-/ Series-/ Commissioning Testing)		
7.2	Safety- and Compliance-Related Application Conditions	Define how Safety- and Compliance-Related **Application Conditions** will be derived and reference where they will be documented. This shall include at least those listed below. (This may refer to sections of the project SCM or HR	EN50129 section 5.4(5)	
7.2.1	Operations	- Define how Safety- and Compliance-Related Application **Conditions for Operations**, will be derived and reference where they will be documented.		
7.2.2	Maintenance	- Define how Safety- and Compliance-Related Application **Conditions for Maintenance**, will be derived and reference where they will be documented.		
7.2.3	Decommissioning and Disposal	- Define how Safety- and Compliance-Related Application **Conditions for Decommissioning and Disposal**, will be derived and reference where they will be documented.		
8	**Related Safety Cases**			
8.1	Related Safety Cases	Provide references to other Safety Cases on which the Project Safety Case depends (existing / accepted Safety cases and safety cases that will be developed) Describe where the interrelationship with any related Safety Cases will be documented. Assess compliance between Project Safety Plan and other related Safety Management Activities/ other Safety Cases.	- EN 50126-1, Sections 3.41 (+Fig.9), 5.2, 5.3.4 and 6 (incl.6.2.3.4,d); - EN 50126-1, Sections 6.9 and 6.10, and Fig. 10; - Yellow Book, Chapters 13 and 18.	IE-SMS-014 Appendix 2
8.2	Application Conditions from related Safety Cases	Demonstrate that all the Safety- and Compliance-Related application conditions specified in each of the related existing / accepted Safety Cases are either fulfilled or will be carried forward into the Safety- and Compliance-Related application conditions of the Project Safety Case. Describe where compliance with any related Safety cases will be documented.		
9	**Conclusion**	This shall conclude and declare that the planned safety management activities as described in the Safety Plan are adequate activities for this Project SMS, the outcome of which will demonstrate the Change is adequately safe for PIS.		