RSC-G-009D-Annex3 (SC) Checklist for evaluation of a **Project Safety Case**

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1 Introduction

This checklist will be employed by the RSC when evaluating Project Safety Cases in association with PIS Projects according to IOD or RSA.

2 Elaboration of an Application Specific Project Safety Case

When applying for APIS stages 4,5 or 6 the applicant must provide at least an Application Specific Project Safety Case.

Where a Generic Product Safety Case or a Generic Application Safety Case has been developed for products used at the Project, this may be referred to within the Application Specific Safety Case as appropriate in order to avoid repetitive work or assessments.

Any Project Safety Case 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 Requirements and References given in the list.

The Project Safety Case 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 Case must comply with current 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.

3 Internal Review Report

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

4 RSC evaluation of Application Specific Project Safety Case

The RSC must evaluate the Change for which the applicant has applied for an APIS against the requirements of IOD 15(1+2), RSD 4(3)+6(3), CSM 352/2009 and RSA. The Application Specific Project Safety Case will be used by the RSC 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.

The provision of an Application Specific Project Safety Case is also considered to satisfy 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 apply.*

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 been added, updated or erased within this Checklist.*

5 Checklist for Safety Case

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 acc. To RSC-G-009	- RSC-G-009	
1.3	Level of Safety Case to be elaborated	- **Generic Product** Safety Case; or - **Generic Application** Safety Case; or - **Application Specific Project** Safety Case. (Only the ASPSC level will be able to support an APIS.)		
1.4	Related Phase of Project Life-Cycle	Indentify Phase of Project Lifecycle and RSC APIS Stage to which this Safety Plan revision is related.		
1.5	Identify Type of PIS 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	Designation of Change	Precisely define the Subsystem or Parts thereoff to which this Project Safety Plan refers, including (as relevant) type designations, positions on the network, chainages, version numbers, modification status, etc.		

2.2	Scope of Change	Define scope of Change in physical, functional, legal, etc. boundaries and define related interfaces to the Railway Network. Identify applicability of any TSIs or granted Derogations to TSIs.	- EN 50126-1, Section 6.2.3.4, b. - RSC-G-009	IE-SMS-014 Appendix 2
2.3	Subsystems and Parameters (incl. Interfaces) affected by Change	Identify and Manage systematically all Subsystems and 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 other Parameters are considered to be relevant, these must also be identifed. These Parameters shall be systematcally listed to enable ease of referencing and assessment. (They should 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 System and all related internal and external interfaces. (May be done by referencing appropriate Functional/ Technical descriptive Documentation/ Drawings/ Application Conditions/ etc. relating to Interfaces within a Project specific Safety- & Compliance- Matrix. All Interfaces should be placed with 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 Interfaces within a Project specific Safety- & Compliance- Matrix. All Environmental Conditions should 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 bodies, roles, responsibilities, competencies undertaking tasks within the lifecycle and their relationships.	- 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

3.2	Personnel independence in tasks	Ensure and demonstrate that an appropriate degree of (personnel) independence is provided for all review, V&V, auditing and assessment 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.	- 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 acciden tinvestigations.) Any relevant documentation must be handed to a future owner of the Change, in case of transfer of ownership. (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 consitent 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/ Maintenance of the Change. (Refer to employed QM-Manual(s) and any QMS-Certification(s).)	- EN 50126-1, Section 5.2; - RSC-G-009.	
4.2	Project QMS Procedures	Identify employed 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)		
4.2.2		Management of Project requirements specification (at least Compliance requirements/ Safety requirements)).		
4.2.3		Management of design V&V, type testing, inspection, design reviews, Assessment, auditing, etc.		
4.2.4		Management of procurement, supplier qualifications, supplier monitoring. Ensure and demonstrate that suppliers/ sub-contractors which participate at design, manufacture, commissiong, testing, operation and mainatenance 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.	- 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 action		
4.2.10		Definition and management of application conditions for operation/ maintenance/ decommissioning/ disposal		
4.3	Specific QMS provisions for safety related bonding activities (welding, glueing, etc.)	Welding and related NDT provisions for RST:		
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 safety related bonding activities (welding, glueing, etc.)	Welding and related NDT for other Subsystems:		
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 safety related bonding activities (welding, glueing, etc.)	Any other safety related bonding.		
4.5.1		Identify any Training/ Certification requirements		
4.6	QMS Audit	Plan auditing of all Project QMS activities as defined above.		
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 included, 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.	- 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	Provide judgement on CSM Significance.	-CSM 352/2009	IE-SMS-014

	CSM 352/2009			
5.3	Project Life-Cycle	Define project life-cycle phases and show the relationship with basic life-cycle approach to EN 50126 and APIS stages to RSC-G-009.	- 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 the lifecycle phases along with any relationships between them. Make an initial definition of the available range of safety tasks and tools per life-cycle phase. Issue revisions of the Safety Plan in relation to the project progress. These shall state which safety tasks and tools have actually been employed for each life-cycle phase. Justify the adequacy of tasks chosen for the application under consideration.	- 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)		
5.7.1		□ Tender Specification		
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		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 ofthe RSC Subsystem Parameter Lists in order to enable efficient assessment of completeness.)	- Yellow Book, Appendix C.	IE-SMS-006
5.9.2		Use Lessons Learned/ past experience/ published accident reports for identification of hazards.	- EN 50126-1, Fig. 9, Stage 2;	
5.9.3		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 employed risk matrix, qualitative or quantitative.	- 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 of assessment of Safety- & Compliance- Requirements for adequacy during the whole lifecycle of the system. (The overall assessment planning may include this assessent in parts to be performed and documented in Reports by ISA, IA, DeBo, NoBo, CSM-AB Review Project Safety Manager Review, Internal Project Review, RU/IM Safety Validation Pannel.) (These Reports 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 Pannel review and CSM-AB report may be considered as Project Safety Review activities.)
5.13	System Design Evidence	Provide reference to suite of design evidence. This shall provide all functional/ technical descriptions, drawings and parts lists, calculations, simulations, test procedures, test reports, etc. which have been 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 systematicly organised Project Safety- & Compliance- Matrix. The systematic order shall follow that of the RSC checklists for Subsystems and Parameters, as long as no systematc order is prescribed by the EU. This is to vacilitate a co-ordinated approch 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 reqirements.)	- EN 50126-1, Fig. 9, Section 6.6.	
5.14	Verification and Validation Plan	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	Assess realisation of Safety- and Compliance- Requirements (tools to EN 50126-1, Annex B). (The overall assessment planning may include assessent in parts performed and documented in Reports by ISA, IA, DeBo, NoBo, CSM-AB Review Project Safety Manager Review, Internal Project Review.) (These Reports 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	Audit compliance of the management process with the Safety Plan. (The overall auditing plan may include assessent in parts performed and documented in Reports by ISA, 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
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 that the EU currently drafting a CSM on Monitoring, which may regulate this issue more precisely.)	- EN 50126-1, Section 6.11, Phases B, A.	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 related 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 of Change	Identify the process for Safety Approval of Change	- 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 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		This Project Safety Plan Define the process to prepare Project Safety Plan and its contents. (To be updated at least for each stage of RSC APIS process)	- RSC Guidance;	
6.1.2		Project Hazard Record Define the process to prepare Project Hazard Record and its contents. (To be retained live throughout the life of the Change, to be updated at least for every stage of the RSC APIS process.)		
6.1.3		Project Safety Case Define the process to prepare Project Safety Case(s) and its/their contents. (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
6.1.4		Documentation evidencing achievement of Safety and Compliance Requirements. Define the process to manage these. (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	Define configuration management process for Safety related tangible products/ hardware. (Type, Version, Serial Numbers, etc.)	- 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 for Safety related intangible products/ Electronic components/ Software (Type, Version, etc.)	- EN 50128.	
7	***Technical Project Safety Report 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 Requirements listed below. (This may be referenced within the Safety- & Compliance-Matrix)	TSI Moduls V/CV	
7.1.2	Assurance of correct Operation	Documented evidence of correct operation of all safety and compliance related functions. (Typically performed as Type-/ Series-/ Commissioning Testing)		
7.1.3	Effects of faults on Operation	Documented evidence of acceptable reaction of safety and compliance related functions under under simulated fault conditions. (Typically performed as part of Type-/ Series-/ Commissioning Testing)		
7.1.4	Operation with external influences	Documented evidence of acceptable reaction of safety and compliance related functions under environmental limit conditions/ under out of range conditions. (Typically performed as part of Type-/ Series-/ Commissioning Testing)		
7.2	Safety- and Compliance-Related Application Conditions	To include all Safety- and Compliance-Related Conditions, as derived from the Safety- and Compliance-Requirements and Hazard Record. (This may refer to the Project Safety- & Compliance-Matrix)		
7.2.1	Operations	Refer to Application Conditions for Operation.		
7.2.2	Maintenance	Refer to Application Conditions for Maintenance.		
7.2.3	Decommissioning and Disposal	Refer to Application Conditions for Decommissioning and Disposal.		
8	***Related Safety Cases***			
8.1	Related Safety Cases	Assess compliance between Project Safety Case 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 Safety Cases are either fulfilled in this Safety Case, or are carried forward into the Safety- and Compliance-Related application conditions of this Safety Case.		
9	***Conclusion***	This shall summarise the evidence presented in the previous parts of the Safety Case, and argue that the relevant Change is adequately safe fro PIS, subject to		

		compliance with the specified application conditions .		