CRR-G-009-G-Annex3 v2.0(SC)
Checklist for evaluation of a **Project Safety Case**

Prepared by:	Aidan O'Sullivan
Reviewed by:	Mary Molloy
Authorised by:	Brian Higgisson
Issue date:	03 Feb 2021

AN COIMISIÚN UM RIALÁIL IARNRÓID
COMMISSION FOR RAILWAY REGULATION

1 Introduction

This checklist will be employed by the CRR when evaluating Project Safety Cases in association with PIS Projects according to IOD or RSA. A Safety Case shall document and evidence, that a suitable level of safety has been achieved by the Project, in order to perform Placing in Service or Placing on the Market. In order to avoid repetition, documentary evidence is expected to be annexed or referenced to a Safety Case. Any such Annexes and References shall be considered to be part of the Safety Case.

2 Elaboration of an Application Specific Project Safety Case

When applying for CRR stages 4, 5 or 6 the applicant must provide at least a current 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 should follow the structure provided below and should include all sections listed. If any section is not relevant for a given project, that section shall still be provided as headline and it should 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.

For APIS/Acceptance cases, the Project Safety Case must have been prepared under the scope of a certified/authorised RU/IM SMS under RSD and CSM 402/2013 or an 'RU-Safety Case' in accordance with RSA approved by the CRR. For APOM cases, it is preferable that the applicant engages with the RU/IM that will be operating the Vehicle/s and uses their certified/authorised SMS in developing the Project Safety Case (as part of the Project SMS).

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 402/2013 is considered to represent current best practice.

Each chapter of the Application Specific Project Safety Case has to be prepared, detailing any constraints, dependencies, assumptions and caveats.

3 Internal Review by Applicant

The applicant must arrange for an internal (or external) review of the Safety Case by an expert in the field of

SMS. This review must cover completeness and plausibility of content of the Safety Case, must be documented and must be provided to the CRR with the Safety Case. A checklist against all the clauses and sub-clauses in section 5 below would be an acceptable approach.

4 CRR evaluation of Application Specific Project Safety Case

The CRR must evaluate the Project (Change acc. to CSM 402/2013) for which the applicant is applying for an APIS/AFA/APOM against the against the requirements of IOD 18+ 20+21 RSD 4(1)+6(1), CSM 402/2013 and RSA.. The Application Specific Project Safety Case will be used by the CRR as one element to form an opinion, whether all requirements relating to APIS/APOM/Acceptance 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 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 be applicable, arising from the application of EN 50126-1, EN 50126-2, EN 50128, EN 50129, EN50159-1/-2, CSM 402/2013, IA VA 2018/545 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 Checklist.*

Note3: *Where the requirements to fulfil any item on the checklist are adequately detailed in the current version of the Project Safety Plan, and that Safety Plan contains current valid information pertaining to that requirement, it is sufficient to reference the relevant section of the current version of the Project Safety Plan, so as to avoid duplication. In such cases, the References must clearly state achievements of the Project (and not intended future activities).*

5 Checklist for Safety Case

No	Section	Requirement	References
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 Case (and ideally throughout any other Project documentation). The Project may decide to keep a List of References as a separate document.)	- CRR-CL-001
1	***Introduction***		
1.1	Project introduction	Provide high-level introduction to Project.	
1.2	Type of Application	Define Type of APIS/AFA/APOM sought at this project acc. to CRR-G- 009, i.e.: - RSA-AFA-NW - RSA-AFA-NRS - IOD-APIS - IOD-APOM (First Authorisation, New Authorisation, Renewal, Extended Area of Use, Conformity to type	- CRR-G-009 - IA VA 2018/545

No	Section	Requirement	References
1.3	Level of Safety Case	Describe the level of safety case presented – Possible levels 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) (Only the ASPSC level will be able to support an APIS/Apom/Acceptance.)	
1.4	Related Phase of Project Life-Cycle	Identify Phase of Project Lifecycle and CRR Stage to which this Safety Case revision is related.	
1.5	Identify Type of APIS/APOM/Acceptance	-New build/First Authorisation -Upgrade /New Authorisation/Extended Area of Use -Renewal Conformity to type	-IOD+TSIs -CRR-G-009 -IA VA 2018/545
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.*	
2.1	Definition/ Identification of Change	Precisely define/ identify the Subsystem or Parts thereof to which this Project Safety Case 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.) (You may refer to the current SP.)	
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.) (You may refer to the current SP.)	- EN 50126-1, - CRR-G-009
2.3	Subsystems and Parameters (incl. Interfaces) affected by Change	Identify 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 CRR 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.)	

No	Section	Requirement	References
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, - EN 50126-2; - CSM 402/2013, Annex 1 :2.1.2; -
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 Parameters which they are affecting.)	- CSM 402/2013, Annex 1: 2.1.2;
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 a Project specific Safety- & Compliance- Matrix. All Environmental Conditions shall be placed with all Parameters which they are affecting.)	
3	***Project Organisation***		
3.1	Roles and Responsibilities, Organisational chart	Define details, 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. (You may refer to the current SP.)	- EN 50126-1, - CSM 402/2013, Annex 1: 1.1.6
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.) (You may refer to the current SP.)	- EN 17020; - EN 50126-1; - EN 50126-2; - EN 50128, - EN 50129, - CSM 402/2013; - RSA 2005; -

No	Section	Requirement	References
3.4	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.)	
4	***Project Quality Management Report***	***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.* ***Note 3:*** *You may refer to current version of the SP. Describe and justify any deviations from the planned approach, Elaborate on any items that were not adequately defined in the SP. Document the output of the Quality management activities undertaken.*	- EN 50126-1,
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 50129, - CRR-G-009.
4.2	Project QMS Procedures	Identify employed QMS procedures as relevant for the PIS Project on following tasks:	EN 50129
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	References
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)	
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	Identify employed welding and related NDT provisions for Rolling Stock.	
4.3.1		• Employment of 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		• Document that welding design has been documented and authorised by certified Welding Engineer and manufactured by certified welders.	
4.3.4		• Document that any NDT has been defined by certified NDT-Expert and performed by certified NDT-Technician.	
4.4	Specific QMS provisions for welding of Subsystems other than Rolling Stock	Identify employed welding and related NDT for Subsystems other than Rolling Stock.:	
4.4.1		• Document baseline standard(s) for any welding or NDT performed as part of the project.	
4.4.2		• Document any Training/ Certification for Welding Engineers, Welders, NDT-Experts, NDT-Technicians participating at the Project	
4.5	Specific QMS provisions for other safety related bonding activities.	Identify any other safety related bonding provisions (other than welding)	
4.5.1		• Document any Training/ Certification requirements	
4.6	QMS Auditing	Document auditing of all Project QMS activities as defined above.	

No	Section	Requirement	References
5	***Project Safety Management Report***	***Note 1:*** *Provide appropriate detail to identify significant aspects, including interfaces and boundaries.* ***Note 2:*** *Provide high level information in the Safety Case. 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.*	
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 adopted to achieve safety) (You may refer to the current SP.)	- EN 50126-1, EN 50126-1 (in combination with EN 50126-2, EN 50128, EN 50129, EN 50159-1, EN 50159-2); - CSM 402/2013; - RSA 2005; - CRR Guidelines;
5.2	Level of Significance to CSM 402/2013	Provide judgement on CSM Significance. (You may refer to the current SP.)	-CSM 402/2013
5.3	Project Life-Cycle	Define project life-cycle phases and show the relationship with basic life-cycle approach to EN 50126 and project stages to CRR-G-009, and stages required by an applicable certified/authorised RU/IM SMS. (You may refer to the current SP.)	- EN 50126-1,
5.4	Project Schedule	Provide Project Schedule, referencing 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 undertaken within each lifecycle phase along with any relationships between them. Describe the range of safety tasks and tools actually employed for each life-cycle phase. Justify the adequacy of tasks chosen for the application under consideration. (You may refer to the HR or other documentation where the applicability and output of the safety tasks performed has been documented.)	- EN 50126-1,
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.)	

No	Section	Requirement	References
5.7.1		• Technical 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 were identified by the Project. Refer to Combined Project Safety and Compliance Requirements Specification in SCM. Note for IOD APOM projects this section should be written to cover the Requirements Capture process mandated by (EU) Reg. 2018/545	
5.9	Hazard identification and analysis	Provide approaches used 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. Identify for each approach of hazard identification and analyses the process and format followed.	- CSM 402/2013, Annex 1: 2.2;
5.9.1		Structured approach: Reference 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 CRR Subsystem Parameter Lists in order to enable efficient assessment of completeness.)	
5.9.2		Empirical approach: Reference Lessons Learned/ past experience/ published accident reports for identification of hazards. (Detailed information on this may be incorporated within the Hazard Record.)	- EN 50126-1, -EN 50126-2,
5.9.3		Creative approach: Reference Expert workshops for identification of hazards. (Detailed information on this may be incorporated within the Hazard Record.)	-
5.9.4		Refer to hazards in Project Hazard Record	
5.10	Risk assessment and on-going risk management	Identify performed risk assessment and risk management processes up to the current lifecycle phase of the project.	- EN 50126-1, - EN 50126-2 - CSM 402/2013, Annex 1, 2.3, 2.4 and 2.5.
5.11	Risk tolerability criteria	Provide risk tolerability criteria. Provide any employed risk matrix, qualitative or quantitative. (This may be incorporated within the current SP and/or the current Hazard Record.)	- EN 50126-2, - CSM 402/2009, Sections 2.5.4 and 2.5.6; - EN 50129:2018

No	Section	Requirement	References
5.12	Project Safety- & Compliance- Requirements Review	Provide reports on assessment for adequacy of Safety- & Compliance- Requirements during the whole lifecycle of the system. (The overall assessment for adequacy of Safety- & Compliance requirements may in parts to be performed and documented in Reports by V&V, ISA, IPR, 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,
5.13	System Design Evidence	Provide reference to suite of generated 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 systematically organised Project Safety- & Compliance- Matrix. The systematic order shall follow that of the CRR 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,
5.14	Verification and Validation	Evidence V&V of 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, - IOD.
5.15	Safety Assessment, Compliance Assessment	Document assessment of realisation of Safety- and Compliance-Requirements (tools to EN 50126-1, Annex B). (The overall assessment may include assessment in parts be performed and documented in Reports by V&V, ISA, IPR, IA, DeBo, NoBo, CSM-AB Review Project Safety Manager Review, and Internal Project Review.) (These Reports or relevant sections thereof may be referenced within the Project Safety- & Compliance- Matrix.)	- EN 50126-1, - IOD.
5.16	Safety Audit	Document Auditing undertaken for compliance of the management process against the Audit Plan. (This may reference auditing in parts be performed and documented in Reports by ISA, IPR, IA, DeBo, NoBo, CSM- AB Review Project Safety Manager Review, Internal Project Review.)	- EN 50126-1, - EN 50128; - EN 50129;

No	Section	Requirement	References
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.)	- EN 50126-1, - TSI Modules V/ CV
5.18	Provisions for SIL Assessment	Document activities for setting and assessing SIL. This will predominantly relate to functions of the Change which are containing safety-critical electronic/ software elements. (This may be incorporated within the Project Safety- & Compliance- Matrix.)	- EN 50129, in combination with - EN 50126; - EN 50128.
5.19	Safety Approval Process of Change	Identify the process for Safety Approval of Change to the Railway System. Refer to type of APIS/APOM/Acceptance and safety approval processes of the authorised/certified IM/RU SMS.	- EN 50126-1, - EN 50129; - CRR-G-009; - RSA 2005
6	***Safety related deliverables***	**Note:** Provide details of safety related deliverables for each lifecycle phase.	
6.1	SMS Documentation	The Project SMS must produce an Application Specific Project Safety Case and related documented objective evidence supporting the ASPSC This is expected to include as a minimum the following documentation:	- EN 50126-1, - EN 50126-2
6.1.1		- Project Safety Plan Refer to current version of Project Safety Plan. (To include all aspects of CRR-G-009-Annex1. Shall have been updated at least in accordance with CRR-G-009-Annex1 (2). Further updating as required.)	- CRR Guidance;
6.1.2		- Project Hazard Record Refer to current version of Project Hazard Record. (To include all aspects of CRR-G-009-Annex2. Shall have been updated for the current Project stage.)	
6.1.3		- Supporting Safety Cases (Generic Product Safety Case; or Generic Application Safety Case or other applicable safety cases).	
6.1.4		- Documented Evidence of achievement of Safety and Compliance Requirements Systematic documentation evidencing achievement of Safety and Compliance Requirements. Identify the process to manage these. In order to avoid duplication of work, this may be integrated with a Technical File mandated by IOD. (This may be referenced within the Project Safety- & Compliance Matrix)	-IOD+TSI EU Technical File+ National Technical File

No	Section	Requirement	References
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.	- EN 50126-1, - EN 50126-2
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.	- EN 50128.
7	***Technical Project Safety Report on Safety Qualification Testing***		
7.1	Requirements for Safety Qualification Testing	Provide Requirements for Safety Qualification Testing as 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 provided. These shall in principle follow EN17025. (This may be referenced within the Safety- & Compliance-Matrix)	TSI Modules V/CV EN 17025
7.1.1	Assurance of correct Operation	Documented evidence of correct operation of all safety and compliance related functions. (Typically performed as part of Type-/ Series-/ Commissioning Testing)	
7.1.2	Effects of faults on Operation	Documented evidence of acceptable reaction of safety and compliance related functions under simulated fault conditions. (Typically performed as part of Type-/ Series-/ Commissioning Testing)	
7.1.3	Operation with external influences	Documented evidence of 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	Identify all Safety- and Compliance-Related Application Conditions, as derived from the Safety- and Compliance-Requirements and the Hazard Record. (This may refer to the relevant sections of the Project HR and/or SCM.)	EN50129 section
7.2.1	Operations	Identify Application Conditions for Operation.	
7.2.2	Maintenance	Identify Application Conditions for Maintenance.	
7.2.3	Decommissioning and Disposal	Identify Application Conditions for Decommissioning and Disposal.	
8	***Related Safety Cases***		

No	Section	Requirement	References
8.1	Related Safety Cases	Provide references and document compliance with any other Safety Cases on which this Project Safety Case depends. Document the interrelationship with any related Safety Cases. Document achieved compliance between Project Safety Plan and other related Safety Management Activities/ other Safety Cases.	- EN 50126-1,
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 part shall summarise the evidence presented in the previous parts of the Safety Case, and argue based on the evidence provided, that the Change is adequately safe for PIS and meets all relevant Safety and Compliance Requirements, subject to fulfilment of the specified Application Conditions.	