

CRR-G-032-B

Guideline for the Application for Acceptance for New Light Rail Works or New Light Rail Rolling Stock

Guidance for CRR Inspectors and Railway Organisations

Issue	Prepared by	Reviewed by	Approved by	Date
B	Mary Molloy	Ruth Baldwin	Brian Higginson	07.09.2020

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1 Introduction

This document intends to give guidance according to RSA 2005 and supporting explanation on the Irish legal provisions around the Application for Acceptance (AFA) for:

- ‘New Light Rail Works’ in accordance with RSA 2005 (section 42),
- ‘New Light Rail Rolling Stock’ in accordance with RSA 2005 (section 43).

This guideline is based on the requirements of the Railway Safety Act 2005 (RSA). The main aspects covered are:

- the establishment of a project level SMS,
- the establishment of a project level Application Specific Safety Case, and
- the generation of documented evidence to demonstrate the safety level of the project.

2 Abbreviations and Definitions

2.1 Abbreviations

Term / Abbreviation	Meaning
AFA	Application for Acceptance
Applicant	The Railway Organisation applying for AFA
ASPSC	Application Specific Project Safety Case
CCO	Command, Control and Signalling, Onboard
CCT	Command, Control and Signalling, Trackside
CMS	Competency Management System
CRR	Commission for Railway Regulation
CSM	Common Safety Method
EU	European Union
FMECA	Failure Modes, Effects and Criticality Analysis
GASC	Generic Application Safety Case
GPSC	Generic Product Safety Case
HR	Hazard Record
IA	Independent Assessor according to RSA 2005 (Providing an Independent Assessment Report on the full scope of the project safety management activities)

Term / Abbreviation	Meaning
INF	Infrastructure
IPR	Independent Professional Review, providing independent assessment reporting on certain parameters within the scope of a project, in accordance with RSC Guidelines.
ISA	Independent Safety Assessment, providing Assessor reporting as defined in EN50126/EN50126-2/EN50128/50129
NDT	Non-destructive Testing
NRSA	New Rolling Stock Assessment
NWA	New Works Assessment
NSA	National Safety Authority
PHA	Project Hazard Analysis
QMS	Quality Management System
RO	A metro, tramway or other light rail system (RSA as amended)
RSA	Railway Safety Act 2005 as amended (amendments SI 61 of 2008, SI 444 of 2013, SI 258 of 2014)
RSC	Commission for Railway Regulation and NSA in Ireland (formerly the Railway Safety Commission)
RST	Rolling Stock
SC	Safety Case as per EN50126)
SCM	Safety and Compliance Matrix
SMS	Safety Management System
SP	Safety Plan
Technical File	Documented evidence of all compliance and safety requirements
V&V	Verification and Validation as defined by EN 50126-1/-2, EN50128, EN50129. This may include activities of Testing and Commissioning.

2.2 Definitions

2.2.1 Light Rail

The term '**Light Rail**' shall be understood to include:

- Tram,

- Tram-Train,
- Metro,
- People Mover,
- Funiculars,
- Similar guided transport systems,

irrespective of whether the alignment is on-street, segregated, underground, elevated, shared with other railways, in densely populated areas, in suburban areas, in rural areas.

Notes:

The overall design and operational concepts are what distinguishes 'Light Rail' from 'Heavy Rail'. The differentiation is not based on individual technical topics as e.g. track gauge or max. axle load.

It is also not essential that light rail vehicles operate with steel wheels on steel track or that the propulsion system is installed in the vehicles.

For the avoidance of doubt: In (EU) 2016/798 (RSD) 'Light Rail' is more restrictively defined as "an urban and/or suburban rail transport system with a crashworthiness of C-III or C-IV (in accordance with EN 15227:2011) and a maximum strength of vehicle of 800 kN (longitudinal compressive force in coupling area); light rail systems may have their own right of way or share it with road traffic and usually do not exchange vehicles with long-distance passenger or freight traffic".

The same EU document also states "This Directive shall not apply to: (a) metros; (b) trams and light rail vehicles, and infrastructure used exclusively by those vehicles" which implies, that Tram and Metro are different from Light Rail.

The referenced standard EN 15227:2011 defines however the classes C-III to be for Tram-Trains, peri-urban Tram and C-IV to be for Tramway vehicles implying that these are Light Rail.

In summary the definition of light rail is open to interpretation based on current definitions.

2.2.2 Works

The RSA term '**Works**' shall be understood to include any fixed installations of a Light Rail System (i.e. infrastructure, traction energy supply, trackside command control and signalling equipment) as well as all related provisions for operation, maintenance and eventual decommissioning.

2.2.3 Rolling Stock

The RSA term '**Rolling Stock**' shall be understood to include any guided mobile equipment of a Light Rail System (i.e. LRV rolling stock, onboard command control and signalling equipment) as well as all related provisions for operation, maintenance and eventual decommissioning.

Notes:

In relation to terms used in the European Heavy Rail legislation, the RSA term 'Works' is equivalent to EU term 'Fixed Installations' and the RSA term 'Rolling Stock' is equivalent to EU term 'Vehicles'.

For the avoidance of doubt: The RSA2005 term 'Rolling Stock' is not equivalent to the EU term 'Rolling Stock'.

2.2.4 New

The RSA term '**New**' shall be understood to include:

- any new Rolling Stock
- any material alterations to already existing Rolling Stock
- any Rolling Stock which may have been in prior use but was not previously operated on the railway infrastructure of the relevant Light Rail system
- any material changes to Works of operational significance (including, for the avoidance of doubt, railway lines or additions to existing railway lines, bridges and structures, stations or other buildings required to operate or maintain railways, level crossings and signalling systems). This includes temporary changes while construction or modification of works is ongoing.

2.2.5 Parameters

A Light Rail System shall primarily be segregated into Light Rail Works and Light Rail Rolling Stock and on secondary level into a respective set of Parameters. (Figure 1, below)

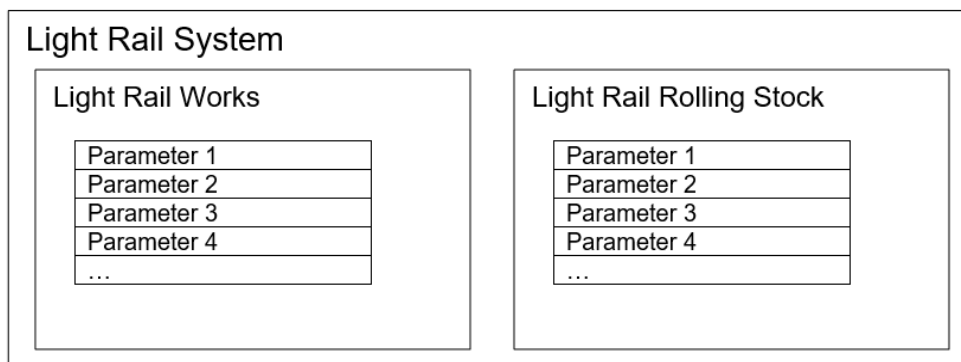


Figure 1 - Light Rail Parameters

The Guidelines CRR-G-016 and CRR-G-033 contain generic listings of those Parameters which the CRR considers of generic relevance to Light Rail projects.

These generic listings have been generated through consideration of current legislation, good industry practice and expert knowledge and aim to cover most Parameters of typical Light Rail Systems.

As generic documents they can never ensure full coverage of all relevant or necessary parameters for any possible Light Rail System element and variation. As part of applying a project level SMS a Railway Organisation shall:

- add further relevant parameters,
- make more detailed definitions of Parameters

as necessary in order to obtain the project specific list of Parameters.

Note: The CRR welcomes any proposal for continuous improvement of the generic Parameter listings.

3 References

RSA	Railway Safety Act 2005 + related amendments
EN 50126-1	Railway applications – The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 1: Basic requirements and generic process
EN 50126-2	Railway applications – The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS)- Part 2: Guide to the application of EN 50126-1 for Safety
EN 50128	Railway applications- Communications, signalling and processing systems – Software for railway control and protection systems
EN 50129	Railway applications – Communication, signalling and processing systems – Safety related electronic systems for signalling
(EU) 2016/798	Directive of the European Parliament and of the Council of 11 May 2016 on railway safety
(EU) 402/2013	Commission Implementing Regulation of 30 April 2013 on a common safety method for risk evaluation and assessment
ISO 17020	Conformity assessment – General criteria for the operation of various types of bodies performing inspection
ISO 17021	Conformity assessment - Requirements for bodies providing audit and certification of management systems (ISO 17021)
ISO 17025	General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025)
ISO 9001	Quality management systems - Requirements (ISO 9001)
CRR-G016	Guideline for Application for Acceptance of New Light Rail Rolling Stock
CRR-G-033	Guideline for Application for Acceptance of New Light Rail Works

Unless date or version of a referenced document is specified, the last available version/ amendment/ correction/ etc. at the time of sending an application to CRR shall be used.

4 Application for Acceptance (AFA) - Cases

According to RSA, a Railway Organisation may only commence:

- Case 1. The construction, installation or assembly of New Works, or
- Case 2. The operation of New Light Rail Works, or
- Case 3. The operation of New Light Rail Rolling Stock

after the CRR has accepted:

- in Case 1: the project level Safety Plan and Hazard Record,
- in Cases 2: and 3, the project level Application Specific Safety Case.

5 AFA and accompanying Documented Evidence

Each AFA shall be provided in writing in English language to the CRR. It shall be accompanied by the project specific documented evidence in English as indicated in section **Error! Reference source not found.**

The project level Safety Plan, Hazard Record or Application Specific Safety Case, as appropriate, are core documented evidence to accompany the AFA.

These core evidences shall be accompanied by further supporting documented evidence to demonstrate.

- the systematic and complete application of **all project level SMS methods**,
- the systematic and complete achievement of **all project results/ deliverables** generated through these project level SMS methods
- report(s) of the IPR(s)
- report(s) of the IA
- report(s) of the ISA

Note: The combination of all documented evidence is the 'Safety Assessment' or 'New Works Assessment' or 'New Rolling Stock Assessment' as indicated in RSA 2005.

All documented evidence shall be prepared and systematically sorted by the Railway Organisation in a format which permits an efficient external review.

Note: The RO may for the establishment of the documented evidence be supported by external suppliers, contractors and independent conformity assessment bodies.

Before submitting any application to the CRR, the applicant must perform a 'self-assessment' on the completeness and correctness of the application and the related Application Specific Safety Case documentation. This 'self-assessment' shall be documented and become attached to the submitted documentation.

6 Project level SMS Methods – Good industry practice

The project level Safety Plan, Hazard Record or Application Specific Safety Case, as appropriate, and their further supporting documentation, shall demonstrate that the project has applied all project level SMS methods as required by current good industry standards and applicable legislation.

The CRR considers, that good industry practice for project level SMS Methods is currently defined by:

- EN50126, EN50128, EN50129.
- CSM 402/2013 (as amended).

Note: The content of CSM 402/2013 is considered to represent good industry practice also for Light Rail, despite it not being specifically written for Light Rail projects.

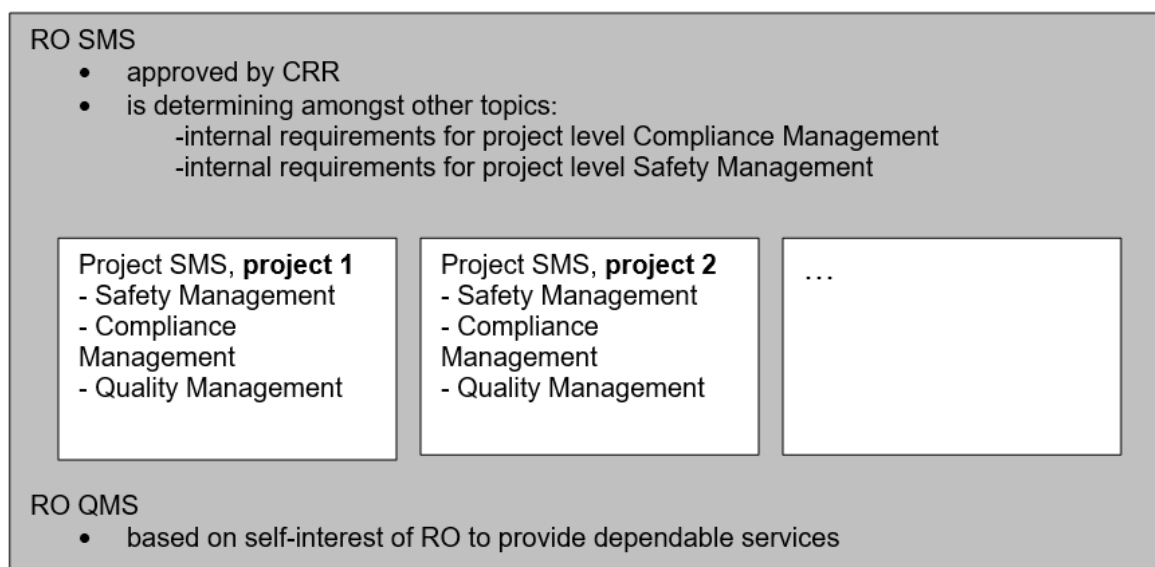
The CRR will review the application of project level SMS methods within a project against the aforementioned good industry practice. The Annexes to this CRR Guideline (CRR-G-032) provide further details on this aspect.

The project level Safety Plan, Hazard Record or Application Specific Safety Case, as appropriate, and their further supporting documentation, shall demonstrate that the project has applied all project level SMS methods to current good industry standards.

6.1 Project level SMS within RO SMS

At AFA stages 4, 5 and 6 (see section 9) the project level SMS needs to cover all SMS methods as required by this Guideline and also as required by the RO SMS. For this reason, the project level SMS at the preceding AFA stages should follow the same requirements/ methods.

In addition to project level Safety Management, it is also required to perform project level Compliance and Quality Management. In order to avoid multiple and divergent approaches, unnecessary duplication of work and potential contradictions between requirements, it is good industry practice, to integrate CMS and QMS into the SMS at project level. This integrated approach is aiming to ensure a 'full requirements' capture.



The purpose of the project level SMS is to reduce human error that could affect safety, compliance or quality throughout the lifecycle, and thus minimise the residual risk of safety-related systematic faults. It shall also ensure that all activities are in full compliance with all Irish or European legal requirements.

6.2 Main Activities of project level SMS

The CRR requires that the following main activities should be performed through the systematic application of the project level SMS.

General Project Management Activities

- G1 based on technical and geographical project scope the correct AFA Case must be initiated,
- G2 a competent project organisation must be established,
- G3 all affected Parameters and their Interfaces to the Light Rail System must be identified.

Compliance Activities

- C1 all relevant compliance requirements must be systematically and comprehensively identified,
- C2 compliance measures must be implemented,
- C3 compliance measures must be evidenced and assessed,
- C4 corrective actions must be taken if non-compliance is found.

Safety Management Activities

- S1 a project level Safety Plan shall establish a competent Project Organisation, life cycle phases for the project level SMS and the SMS activities for the various phases of the Project Life Cycles
- S2 all relevant hazards and related risks must be systematically and comprehensively identified and evaluated,
- S3 safety requirements must be derived from the risk evaluation,
- S4 safety measures must be implemented,
- S5 safety measures must be verified and validated, independently assessed, evidenced and monitored,
- S6 corrective actions must be taken if non-compliance is found,
- S7 residual risk must be assessed and found to be acceptable for safe light rail operation,
- S8 a hazard record must document close out of hazard and risk related activities,
- S9 a project level Application Specific Safety Case must summarise the project related SMS activities, demonstrate full verification and validation and define any application conditions

6.3 RO duties

ROs are the primary duty holders to ensure railway safety.

They may be supported by:

- contractual partners (Maintenance-Workshops, Suppliers, etc.) supporting their activities. In this case ROs remain fully responsible and must ensure that they make suitable contractual

arrangements and exercise suitable supervision of their contractors in order to extend their responsibilities onto their contractual partners.

- competent Experts/Organisations performing an independent activity of assessment or supervision (e.g. ISA, V&V, NSA, IA, IPR) in order to evaluate or supervise the effectiveness of the activities of the RO and their contractors. In principle, the RO must define the required scope and suitable level of independence and competence of such Experts/Organisations. This must reflect the level of criticality of the activities and must also consider current industry standards such as EN 50126-50129 and ISO 17020, 17021 and 17025. In a number of cases however legal provisions or RSC guidance require certain minimum levels of independence or competence (e.g. IA, IPR)

6.4 Relationship between Compliance Management and Safety Management

Compliance requirements are mainly derived from legislation in the areas of:

- Safety,
- Health,
- Environmental Protection,
- Technical Compatibility,
- Reliability and Availability.

Due to the inherent relationship of the requirements for Safety, Health and Environmental Protection and to a lesser degree Technical Compatibility, Reliability and Availability to any Safety Management activities, it is the case that a large overlap exists between the Compliance activities and Safety Management activities.

6.5 Activity G1 – Initiation of AFA process

Depending on the project scope, the applicant must apply for the correct AFA Case.

The required AFA Case shall be identified within the SP.

Please note, that only a project level Application Specific Safety Case may be used to receive Acceptance at AFA Stages 4;5;6.

6.6 Activity G2 – Establishment of competent project organisation

The information on roles and responsibilities, staff competence and project organisation shall be supplied within the SP. This must include at least a Project Manager and a Project Safety Manager (based on individual competence and complexity of Project, both tasks can be performed by the same person). Other roles are defined within these guidelines. All applications for AFA should in principle be done by a certified RO which can avail of an SMS. In the stages 1 to 3, it is however acceptable, that the Approval process is managed/ prepared by a representative (e.g. the Supplier). For the Stages 4 to 6 an Application to test/operate in a life Light Rail environment can only be granted to a certified RO with an established SMS.

6.7 Activity G3 – identification of all affected Subsystems and their Parameters

6.7.1 Interfaces between Parameters or to external parties

Interfaces between Parameters and interfaces to external systems or parties must be systematically identified. These interfaces must be managed within all Parameters affected.

6.7.2 Documentation

A list of project related Subsystems and Parameters must be created and referenced within the SP. If more affected Parameters are identified during the course of the project, these must be added.

Note: Preparation and maintaining of a SCM according to Annex 4 is considered to satisfy this task.

6.8 Activity C1 – identification of compliance requirements

Based on:

- the project scope,
- the required type of AFA,
- the affected Parameters,
- the affected Interfaces and,
- the project timeline and schedule,

all compliance requirements must be identified.

The scrutiny shall cover at least CRR and any applicable EU legislation (e.g. the New Approach Legislative Framework). The CRR will be able to provide guidance on current compliance requirements.

For each Parameter (including Interfaces) identified under activity G3 the relevant Compliance Requirements shall be systematically listed.

It is highly recommended to organise this list according to the CRR lists of Parameters. This list should be the starting point of a project level Safety- & Compliance-Matrix (see Annex 4).

6.9 Activity C2 – Implementation of compliance measures

The project must be designed and implemented in a way that enables compliance with all Compliance Requirements to be achieved. The RO must ensure this by their own activities as well as by the activities of their suppliers/ contractors.

6.10 Activity C3 – Evidencing and assessing of compliance measures

Evidence of Compliance must be documented, presenting all functional-, technical-descriptions, design drawings and part lists, simulations, calculations, test procedures, test results, material certificates, etc. as relevant for the assessment of compliance.

The evidence must be self-explanatory and understandable for an expert in the area.

The compliance for all requirements must be assessed.

Any assessment process shall follow ISO EN 17020, any auditing of management systems shall follow ISO EN 17021 any testing activities shall follow ISO EN17025 and any Certification Process shall follow ISO EN 17065.

In order to ensure completeness of the supplied evidence against the Compliance Requirements, the evidence shall be referenced within the Project Safety- & Compliance-Matrix (see Annex 4).

6.11 Activity C4 - Corrective action on non-compliance

If any non-compliance is found during the course of the project, corrective action must be taken until compliance is achieved.

6.12 Activity S1 – Safety Plan

The Safety Plan shall describe the Project SMS, project organisation, processes and activities that will be employed in the project development and how the Project Safety Case will provide documented evidence on the safety of the project. Each project must provide at least one Project Safety Manager. The SP and the Project SMS shall meet the requirements of EN 50126-50129, in co-ordination with those requirements derived from a certified RO SMS. The extension of the Project SMS to Sub-contractors, Suppliers and other parties involved with any safety related activity in the project must be managed by the Project Safety Manager. This may include subcontracting of certain SMS activities or interfacing with the sub-contractors or suppliers own SMS activities.

The SP shall be developed in accordance with Annex 1 of this Guidance, and updated for each stage as necessary

6.13 Activity S2 – PHA, Hazard Record, Risk Evaluation

Using the list of project related Subsystems, Parameters (and associated Interfaces) (Activity G3) as an initial starting point, all relevant Hazards and related Risks must be systematically and comprehensively identified and evaluated.

Further hazard identification shall be informed by expert workshops, checklists, experience from similar projects, FMECA, or other suitable tools until all conceivable hazards have been considered.

This shall be documented within the Project Hazard Record. The Hazard Record shall meet the requirements of EN 50126-50129, in connection with those requirements derived from a certified RO SMS (see Annex 2).

6.14 Activity S3 – Safety Requirements Specification

Based on hazards and the proposed safety measures to control these hazards within the Hazard Record, the Safety Requirements Specification shall be established. Care must be taken in order to coordinate this activity with activity C1 on the identification of compliance requirements. Contradictions between Safety and Compliance Requirements are not acceptable and must be resolved.

The Safety Requirements Specification shall be documented. This should be done within the Project Safety- & Compliance-Matrix Annex 4).

6.15 Activity S4 – Implementation of Safety Measures

The project change must be designed and implemented in a way which enables compliance with all Safety Requirements to be achieved. The RO must ensure this compliance by their own activities as well as by the activities of their contractors / suppliers.

6.16 Activity S5 – Independent Assessment, Safety Evidence and ongoing Monitoring

The RO must invite competent Experts/Organisations to perform an independent activity of assessment or supervision (e.g. ISA, V&V, NSA, IA, IPR, self-monitoring/auditing by RO) in order to

evaluate or supervise the effectiveness of the applied safety measures and the activities of the RO and their contractors /suppliers.

In principle, the RO may define the required scope and suitable level of independence of such Experts/Organisations. This shall reflect the level of criticality of the activities and current industry standards such as EN 50126-50129. In a number of cases however legal provisions or CRR guidance require certain minimum levels of independence or competence. The independent assessment must in all cases be evidenced by an assessment report.

Any assessment process shall follow ISO EN 17020, any auditing activities ISO EN 17021 any testing activities shall follow ISO EN17025 and any Certification Process shall follow ISO EN 17065. Where applicable, other requirements shall be met (e.g. RSA).

Safety Evidence must be documented in the form of a Technical File, presenting all functional-, technical-descriptions, design drawings and part lists, simulations, calculations, test procedures, test results, material certificates, etc. as relevant for the assessment.

Evidence to be provided in the format of a logical and systematic document-controlled suite of documentary evidence. The evidence must be self-explanatory and understandable for an expert in the area.

The RO must indicate the intended activities to monitor the safety behaviour of the change. This shall be documented within the SP and Safety Case.

6.17 Activity S6 - Corrective action on non-compliance

If any non-compliance with Safety Requirements is found, corrective action must be taken until compliance is achieved.

6.18 Activity S7 – Acceptance of residual risk

After implementing and independent assessment of a safety measure the RO must evaluate the residual risk of the related hazards. This must be done in line with the risk acceptance principles of a certified/authorised RO SMS and principles of EN 50126, and RSA. The residual risk must be acceptable for light rail operation.

This must be documented within the Hazard Record. (see Annex 2)

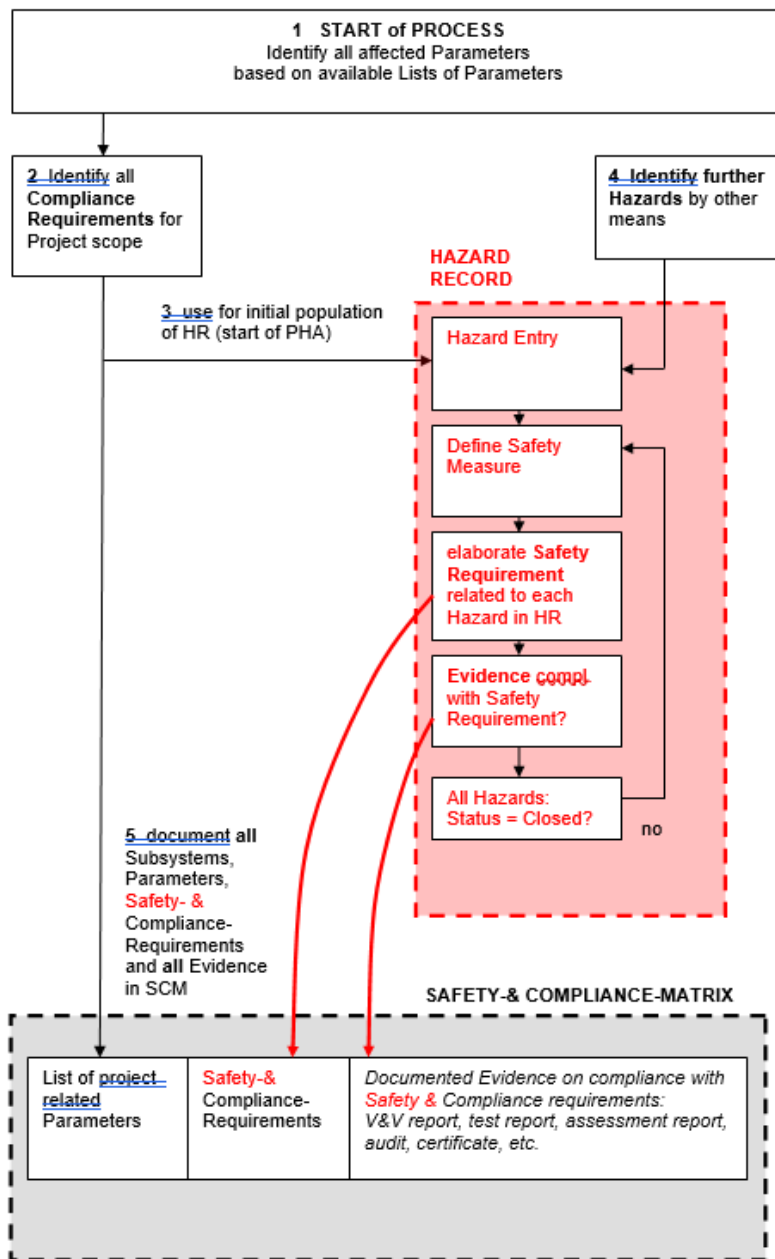
6.19 Activity S8 – Hazard Record

A project related Hazard Record must be prepared in line with the principles of EN 50126-50129.

This must demonstrate an evaluation of all residual risks to be acceptable for safe railway operation. Any Application Conditions must be identified, documented and applied.

The Hazard Record must comply with Annex 2 to this CRR Guidance.

Graphical explanation of Interfacing between Hazard Record and Safety and Compliance Matrix



6.20 Activity S9 – project level Application Specific Safety Case

A project level Application Specific Safety Case must be prepared in line with the principles of EN 50126-50129. The project level Application Specific Safety Case must summarise the project level SMS activities.

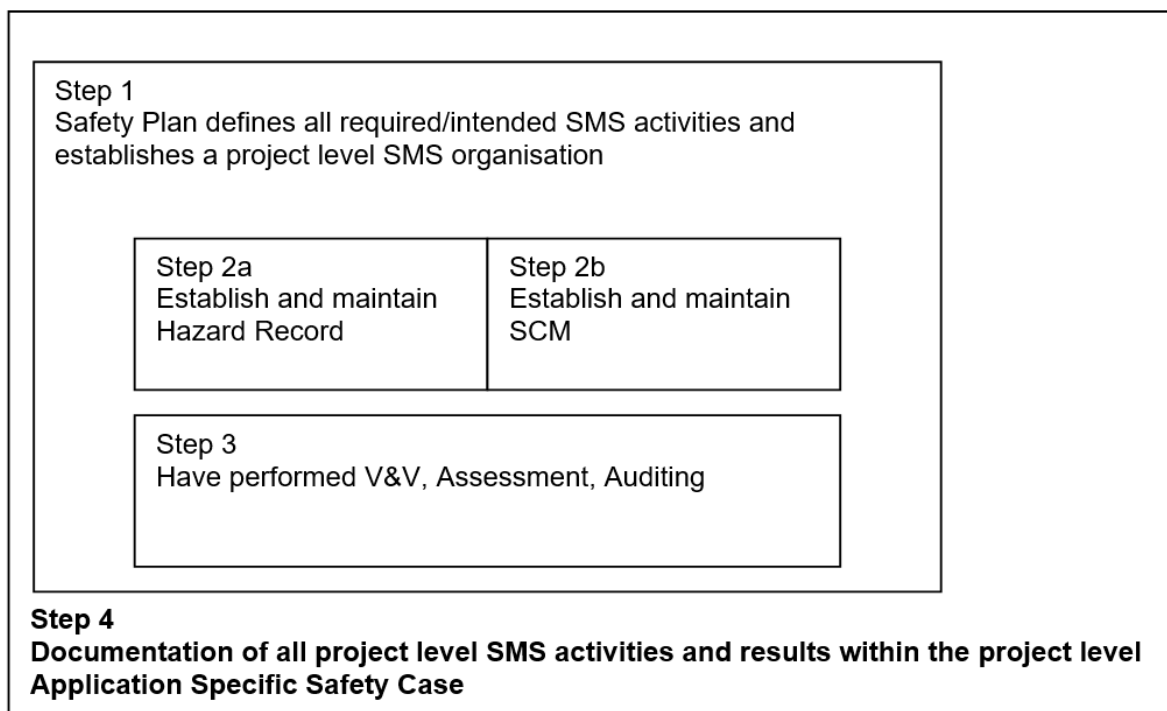
The project level Application Specific Safety Case may be based on a staggered approach of Generic Product Safety Case, Generic Application Safety Case and project level Application Specific Safety Case.

Note: Whether GPSC or GASC are used or not usually depends on the degree of expected further use of the Generic Product or its Generic Application in further projects.

For any operation (including test and interim operation) on the Light Rail System project level Application Specific Safety Case is required.

Each project level Application Specific Safety Case must comply with Annex 3 of this Guideline.

RSA Reg 42 and 43 require the preparation of a project level Application Specific Safety Case of New Works (NWA) or a project level Application Specific Safety Case of New Rolling Stock (NRSA). An Application Specific Project Safety Case developed in accordance with EN 50126-50129 and with this Guidance is considered to satisfy this requirement.



Relationship between Safety Plan, Hazard Record, Safety-& Compliance-Matrix, V&V/Assessment/Audit-Reporting and Safety Case.

7 Testing, V&V

The CRR expects the project to apply the methodologies given in CRR Guideline for the Application for Acceptance for New Light Rail Works (CRR-G-033) or New Light Rail Rolling Stock (CRR-G-016).

It is a fundamental safety management principle that, in order to validate any safety related design calculations, simulations and assumptions, V&V and type testing should be performed. Safety related type testing shall be performed under the scope of accreditation to ISO 17025. Safety related V&V shall be performed as defined in EN 50126-1/8/9. Any deviation from these principles should be justified.

Routine testing should cover a suitable subset of the type testing scope in order to demonstrate that a series production item complies with the core parameters of the design.

All tests shall be of repeatable nature and be covered by retrievable test reports. A test report shall include (but is not limited to):

- identification of the tested item and description of its parameters,
- the method of testing,
- description of environmental parameters,
- all results of testing,
- any deviations from the test method,
- the determination of conformity made from these results,
- all information needed to understand and interpret the report.

This information shall be reported correctly, accurately, and clearly.

Type and routine testing should follow legislative requirements as well as current best industry practice where appropriate.

8 Project Results/ Deliverables

The project level **SMS methods** shall be applied as appropriate to all project Parameters. This shall be covered by objective evidence.

The systematic and complete achievement of all project **results/ deliverables** shall also be evidenced through objective documented evidence.

The CRR will review the project results/ deliverables against the range of Parameters for Light Rail Works or Light Rail Rolling Stock as contained in CRR-G-016 and CRR-G-033 and against good industry practice and legislative requirements for these Parameters.

9 AFA Stages

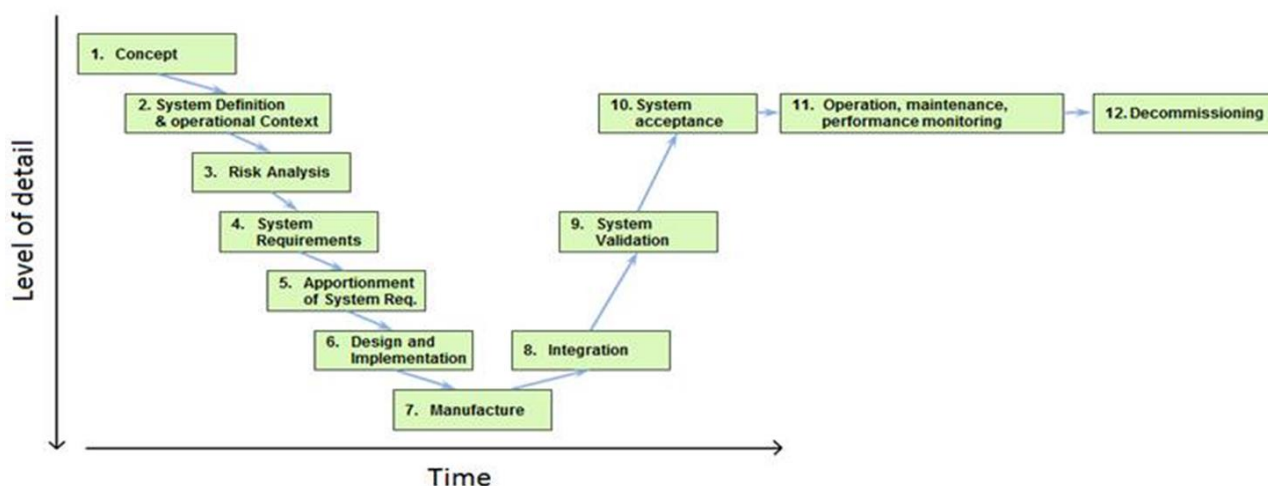
In order to align the level of development of the project's documentation, which will develop over time, with the required Acceptance by the CRR, 6 AFA Stages have been defined.

It is expected that the project's documentation will develop further from stage to stage, covering eventually all stages and the full scope of a project.

Please Note: To avoid loss of time or remedial work at the later project stages, it is highly recommended that the Applicant engages in regular project-progress meetings with the CRR and provide draft submissions of selected content of the Safety Assessment documentation to inform these meetings.

The Application must be provided to the CRR in a staged approach as indicated in section **Error! Reference source not found.**

The project level SMS methods require amongst other elements a systematic live cycle approach for performing the intended SMS activities during the project timeline. In order to match these live cycle activities the CRR offers also staggered AFA Stages as indicated in section **Error! Reference source not found.** Certain stages may be combined subject to agreement with the CRR.



System Life Cycle Phases to EN 50126-1

9.1 Table of AFA Stages

AFA Stage	Typical activities at project level	Core Document to be submitted with AFA (content always appropriate to the level of AFA Stage)
1 Concept	After performing general concept studies or feasibility studies and prior to requesting tenders.	- SP
2 Preliminary Design	After evaluation of tenders and preliminary decision on functional and technical design and prior to awarding a contract for execution of building/ manufacturing work.	- SP - HR - SCM
3 Detailed Design	After awarding a contract for execution of work, after detailed overall design has been elaborated and prior to production/ building.	- SP - HR - SCM
4 Testing	After production (construction, including, in particular, civil-engineering activities, manufacturing, constituent assembly and overall adjustment) and prior to any Testing in the live Railway System.	- SP - HR - SCM - ASPSC for Testing Stage - IA Report (if applicable) - IPR Report(s) (if applicable) - ISA Report(s) (if applicable)
5 Interim Operation	After principal completion of project specific safety assessment activities (incl. final testing), prior to full close out of open issues and prior to interim operation.	- SP - HR - SCM - ASPSC for Interim Operation - IA Report (if applicable) - IPR Report(s) (if applicable) - ISA Report(s) (if applicable)
6 Operation	After full completion of project specific safety assessment activities and prior to operation.	- SP - HR - SCM - ASPSC for Interim Operation - IA Report (if applicable) - IPR Report(s) (if applicable) - ISA Report(s) (if applicable)

10 Report(s) of the IPR(s)

For those Parameters for which the CRR Guidelines CRR-G-016 or CRR-G-033 require the involvement of an Independent Professional Reviewer, or where a Railway Organisation considers it necessary for other Parameters, the Railway Organisation shall employ at their expense one or more IPRs.

The IPR(s):

- shall be proposed by the Railway Organisation to the CRR,
- shall be acceptable to the CRR,
- shall hold an accreditation as Type A Third Party Inspection Body to ISO17020 in connection with the accredited competence to prepare inspections on a range of relevant standards across the technology used in the specified Parameters in a New Light Rail Works or New Light Rail Rolling Stock project,
- shall prepare inspection report(s) on the basis of the aforementioned accreditations on
 - the level of safety and
 - the level of compliance of the New Light Rail Works or New Light Rail Rolling Stock projects with the requirements defined on project level.

11 Report(s) of the IA

Where the CRR directs a Railway Organisation to do so (according to RSA), or where a Railway Organisation considers it necessary, the Railway Organisation shall employ at their expense an Independent Assessor to support and complement the CRR's review activities.

The IA:

- shall be proposed by the Railway Organisation to the CRR,
- shall be acceptable to the CRR,
- shall hold an accreditation as Type A Third Party Inspection Body to ISO17020 in connection with the accredited competence to prepare inspections on the project level SMS methods (at least EN50126, EN50128, EN50129) as well as inspections on a range of relevant standards across the technology used in a New Light Rail Works or New Light Rail Rolling Stock project,
- shall prepare an inspection report on the basis of the aforementioned accreditations on the level of safety of the New Light Rail Works or New Light Rail Rolling Stock project.

12 Report(s) of the ISA(s)

Where the project level SMS employs the standards EN 50126-1; 50128; 50129 an Independent Safety Assessor (ISA) is required to evaluate the correct application of the project level SMS activities.

The ISA(s):

- shall be acceptable to the Railway Organisation,
- shall fulfil the respective requirements for competence and independence as defined by EN 50126-1; 50128; 50129. This may be evidenced by an accreditation as Type A Third Party Inspection Body to ISO17020 in connection with the accredited competence to prepare inspections on EN 50126-1; 50128; 50129,
- shall prepare inspection report(s) on the basis of the aforementioned standards on the level of compliance of the New Light Rail Works or New Light Rail Rolling Stock project with the requirements of EN 50126-1; 50128; 50129.

13 CRR review of AFA

As a general principle the Railway Organisation has the duty to ensure the safety and compliance of their Light Rail System including any project activities on New Light Rail Works or New Light Rail Rolling Stock. The CRR review or a subsequent acceptance of an AFA will not relieve the applicant from any aspects of this duty.

The CRR review will evaluate the completeness and validity of an AFA by identifying documented objective evidence on

- whether the Applicant has been actively applying their duty to manage safety through the systematic application of a project level SMS,
- whether the results of this are contained within the documented evidence that accompany the AFA,
- whether these results can be considered to demonstrate the safety of any Parameters of the Light Rail System, which were affected by a project.

As Basis for their Review the CRR will use the RSA, associated Guidance and current good industry practice.

Upon receipt of an Application for an AFA Stage, the CRR will review the Application for completeness.

This CRR review will typically be performed by spot-checking of the submitted documented evidence. The focus of the sample-checking will be based on the potential of risk and known accident or incidents associated with similar technology/ procedures.

If this initial spot-check does not permit a conclusive judgement, the CRR may enlarge the spot-check, request more or updated documentation or may perform audits on the project level SMS.

If it is not possible for the CRR by these activities, to reach the understanding that the applicant has provided a complete and valid application, the CRR must render the submitted application inadequate and the CRR will hand back the application documents to the applicant. The same applies if an application includes falsified evidence.

14 Acceptance by CRR

An Acceptance will be communicated by the CRR to the Railway Organisation as a '**Letter of Acceptance**'. An Acceptance may contain conditions. The CRR may issue Letters of Acceptance of two variants:

- Acceptance of New Light Rail Works according to RSA
- Acceptance of New Light Rail Rolling Stock according to RSA

An Acceptance cannot be provided by the CRR, where the CRR after their review of the AFA concludes, that the documented evidence accompanying the AFA is not adequate or that it does not provide reasonable assurance on the safety of the intended project activity.

15 Further Clarification

Further clarification on these Guidelines can be sought from the CRR.

Annex I - Checklist for evaluation of a Project Safety Plan (SP)

1 Introduction

This checklist will be employed by the CRR when evaluating a Project Safety Plan in association with AFA Projects according to 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 AFA stage the Applicant must provide the current Project Safety Plan. *Note: Due to the evolving project SMS during AFA stages 1, 2, and 3 it is expected that the SP is updated accordingly. For AFA 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 be prepared by the RO (or a representative on behalf of the RO) under the scope of a RO SMS which has been approved by the CRR in accordance with the RSA 2005.

The Safety Plan must comply with current industry best practice. The application of EN 50126-1, EN 50126-2, EN 50128, EN 50129 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 AFA must arrange for an internal (or external) review of each Safety Plan revision against this Checklist by an expert in the field of SMS. This review must cover the completeness and content of the Safety Plan.

4 CRR evaluation of Project Safety Plan

The CRR must evaluate the Project for which the applicant is applying for AFA against the requirements of the RSA. The Project Safety Plan will be used by the CRR as one element to form an opinion, whether all requirements relating to AFA have been satisfied.

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

The provision of a Project Safety Plan is 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 or the requirements of a certified RO SMS.

Note2: The list may include reference to the SMS of a particular RO where these have provided the related information for reference.

5 Checklist for Safety Plan

No.	Section	Requirement	Reference
0	Document Control	<p>>Provide title, document identification number, revision, revision history, author, organisation and signatures.</p> <p>>Provide list of referenced documents.</p> <p>(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.)</p>	<p>- RSC-CL-001</p> <p>- Yellow Book, Volume 2, Appendix B.2</p>
1	Introduction		
1.1	Project introduction	Provide high level introduction to Project.	
1.2	Type of AFA sought	<p>Define Type of AFA sought at this project acc. to CRR-G-032, i.e.:</p> <ul style="list-style-type: none"> - RSA-AFA-NW - RSA-AFA-NRS 	- CRR-G-032
1.3	Level of Safety Case to be elaborated	<p>Describe the intended approach to delivering the project Safety Case(s). –</p> <p>Possible approaches include:</p> <ul style="list-style-type: none"> - 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) <p>The Applicant should consider whether a product might be re-used on future projects and will therefore benefit in delivering a GASC or GPSC. (Example: use of standardised “building blocks” within CCO/CCT, to minimise re-assessment at each future project at ASPSC level.)</p> <p>(Only the ASPSC level will be able to support an AFA for stage 4 or 5 or 6.)</p>	
1.4	Related Phase of Project Life-Cycle	Identify Phase(s) of Project Lifecycle and CRR AFA Stage(s) to which this Safety Plan revision is related.	
1.5	Identify Type of AFA Project.	<ul style="list-style-type: none"> -New build/ -Upgrade / -Renewal 	
2	Description of the Change	<p>Note 1: Provide appropriate detail to identify significant aspects, including boundaries and interfaces between the Change and the Railway System.</p> <p>Note 2: ‘Change’ means all Subsystems and Parameters (including their interfaces) affected by the AFA Project.</p>	
2.1	Definition/ Identification of Change	<p>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, chainage, version numbers, modification status, etc.</p> <p>(This should follow the typical industry approaches, used for precisely identifying products/ equipment/ installations/ etc.)</p>	

No.	Section	Requirement	Reference
2.2	Scope of Change	<p>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.</p> <p>(This can often be abbreviated, if supporting descriptive references are available as e.g. tender-specifications, contract-specifications, product descriptions, etc.)</p>	<p>- EN 50126-1, Section 6.2.3.4, b. - CRR-G-032</p>
2.3	Subsystems and Parameters (incl. Interfaces) affected by Change	<p>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 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.</p> <p>All Parameters shall be systematically listed to enable ease of referencing and assessment.</p> <p>(They shall be listed within the Project specific Safety- & Compliance- Matrix.)</p>	
2.4	Functional/ Technical Description of Change	<p>Provide information on objectives, purposes and functions / technical design solutions for all Subsystems, Parameters (incl. their Interfaces).</p> <p>(May be done by referencing appropriate Functional/ Technical descriptive Documentation/ Drawings/ Calculations/ Simulations/ etc. within a Project specific Safety- & Compliance- Matrix.)</p>	<p>- EN 50126-1, Section 6.2.3.4, c; - EN 50126-2; - Section 2.1.2; (- for information: Yellow Book, Chapter 14)</p>
2.5	Interface Description of Change	<p>Define system boundaries, and physical and functional interfaces.</p> <p>Note: This must cover also the interface to the RO Safety Management Systems and all related internal and external interfaces.</p> <p>(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.)</p>	
2.6	Environmental Conditions of Change	<p>Define environmental conditions relating to design and operation of the Change.</p> <p>(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.)</p>	- Yellow Book, Chapter 14.
3	Project Organisation		
3.1	Roles and Responsibilities, Organisational chart	<p>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.</p>	<p>- EN 50126-1, Section 6.2.3.4, d and o; - EN 50126-1, Sections 3.26, 3.40 and 5.3.5;</p>

No.	Section	Requirement	Reference
3.2	Personnel independence in tasks	<p>Ensure and demonstrate that an appropriate degree of (personnel) independence is provided for any review, V&V, auditing, assessment, etc. tasks.</p> <p>(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.)</p> <p>(This may be done in connection the organisational chart developed under 3.1 above.)</p>	<ul style="list-style-type: none"> - EN 17020; - EN 50126-1; - EN 50126-2; - EN 50128, Fig. 5; - EN 50129, Fig. 6; - RSA 2005; - Yellow Book, Chapter 13.
3.3	Project Documentation Management	<p>Define a project related documentation management process. This must include a documentation retention policy.</p> <p>All documentation relating to AFA 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.</p> <p>(You may refer to existing RO document management systems, that are suitable for this task.)</p>	- Yellow Book, Chapter 12;
4	Project Quality Management System	<p>Note1: <i>If no formal QMS is established, the Project must otherwise ensure that the activities below are performed in a consistent manner.</i></p> <p>Note2: <i>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.</i></p>	- EN 50126-1, Section 6.2.3.4, b.
4.1	Project QMS Provisions	<p>The Project QMS provisions must enable Design/ Manufacturing/ Series Production/ Commissioning/ Operations and Maintenance of the Change.</p> <p>(Refer to employed QM-Manual(s) and any QMS-Certification(s). Include information relating to relevant suppliers.)</p>	<ul style="list-style-type: none"> - EN 50126-1, Section 5.2; - CRR-G-032.
4.2	Project QMS Procedures	Define QMS procedures as relevant for the AFA Project on following tasks:	EN 50129 5.2
4.2.1		<ul style="list-style-type: none"> - Management of project organisational structure (Roles and Responsibilities, Organisational chart) <p>(This may be provided in connection with item 3.1.)</p>	
4.2.2		<ul style="list-style-type: none"> - Management of Project requirements specification (at least Compliance requirements/ Safety requirements). <p>(This may be done in connection with the SCM.)</p>	
4.2.3		<ul style="list-style-type: none"> - Management of design V&V, type testing, inspection, design reviews, Assessment, auditing, etc. 	

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No.	Section	Requirement	Reference
4.2.4		<p>- Management of procurement, supplier qualifications, supplier monitoring.</p> <p>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.</p> <p>(You may refer to existing procurement policies and procedures and relevant supplier selection criteria or refer to relevant sections of procurement contracts / specifications.</p> <p>Refer to auditing/monitoring arrangements that will be implemented for suppliers of Safety- or Compliance related goods and services)</p>	- Yellow Book, Chapter 8.
4.2.5		- Manufacturing/ installation/ commissioning	
4.2.6		- Series Inspection and testing	
4.2.7		- Product identification/ traceability/ configuration management/ change control (HW& SW)	
4.2.8		- Handling/ storage/ packaging/ delivery (where related to Safety/ Compliance)	
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 ISO9712 as baseline	
4.3.2		- Provide project related organisation of certified Welding Engineer, Welding Supervision, 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 specific 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 requirements for any other safety related bonding provisions (other than welding)	
4.5.1		- Identify any Training/ Certification/ Product Inspection requirements	
4.6	QMS Auditing	Plan auditing of all Project QMS activities as defined above.	

No.	Section	Requirement	Reference
5	Project Safety Management System	<p>Note 1: Provide appropriate detail to identify significant aspects, including interfaces and boundaries.</p> <p>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.</p> <p>Note.3: 'Change' means the Subsystems and Parameters including their Interfaces affected by the AFA Project.</p>	
5.1	Policy and Strategy to achieve safety	<p>Refer to the policy and strategy as defined at a generic level by a certified RO SMS and adopt for Project. Define on project-by-project basis a suite of appropriate references for the performance of SMS activities.</p> <p>(List i.e. the applicable standards, legislation, SMS provisions, industry practice / guidelines etc. that will be adopted to achieve safety.)</p>	<ul style="list-style-type: none"> - 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); - Railway Safety Act 2005; - CRR Guidelines; (- for information: Yellow Book, Chapter 11).
5.2	Level of Significance	<p>Provide judgement on Significance of Change.</p> <p>(Any project that requires AFA is automatically deemed Significant. In this case further analysis / judgment on Significance is not deemed necessary.)</p>	
5.3	Project Life-Cycle	<p>Define project life-cycle phases and show the relationship with basic life-cycle approach to EN 50126, AFA stages to CRR-G-032, and stages required by an applicable certified RO SMS.</p>	- EN 50126-1, Section 5.2;
5.4	Project Schedule	<p>Provide Project Schedule, referencing AFA stages.</p>	
5.5	Intended Service Life of Change	<p>Define Intended Service Life of Change.</p>	
5.6	Safety tasks	<p>Describe the system life-cycle related safety tasks to be undertaken within each lifecycle phase along with any relationships between them.</p> <p>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.</p> <p>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.</p> <p>Justify the adequacy of tasks chosen for the application under consideration.</p> <p>(You may refer to the Safety Case, HR or other documentation where the actual application and output of the safety tasks performed has/shall be documented.)</p>	- EN 50126-1, Sections 3.41 (+Fig.9), 5.2, 5.3.4 and 6 (incl.6.2.3.4, d);
5.7	System Requirements Specification	<p>Refer to documentation providing System Requirements Specification (at least Safety- & Compliance-Requirements)</p> <p>(You may refer to SCM which brings together all Safety- & Compliance-Requirements, from all the listed sources.)</p>	
5.7.1		- Tender Specification	
5.7.2		- Contract Specification	
5.7.3		- Legislative Requirements	
5.7.4		- Network Access/Compatibility Requirements	
5.7.5		- Other sources (best practice, state of art, etc.)	

No.	Section	Requirement	Reference
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)	
5.9	Hazard identification and analysis	Define approaches for hazard identification (e.g. creative, empirical and/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.	- Yellow Book (7 stage process).
5.9.1		-Structured approach: Use CRR 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.)	- Yellow Book, Appendix C.
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;
5.11	Risk tolerability criteria	Define risk tolerability criteria. Provide any risk matrix, qualitative/ quantitative to be employed.	- EN 50126-2, Table 5 THR/SIL relationship; - Yellow Book, Chapter 17; - PD R009-004 for additional information.
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, IPR, IA, 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.

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No.	Section	Requirement	Reference
5.13	System Design Evidence	<p>Provide reference to the suite of design evidence that will be generated.</p> <p>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.</p> <p>The suite of evidence must be systematically organised to enable easy referencing and retrieving of the information contained.</p> <p>(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.)</p>	- EN 50126-1, Fig. 9, Section 6.6.
5.14	Verification and Validation Plan	<p>Describe plan to verify and validate all Safety and Compliance related Subsystem- and Parameter-Functions, their combinations and internal and external interfaces.</p> <p>(This may be incorporated within the Project Safety- & Compliance- Matrix.)</p>	- EN 50126-1, Fig.9, Fig. 10 and Fig. 11, and Section 6.9; - Yellow Book, Chapters 11, 12 and 18,
5.15	Safety & Compliance Assessment Plan	<p>Plan for assessment of realisation of Safety- and Compliance-Requirements (tools to EN 50126-1, Annex B).</p> <p>The overall assessment planning may include the assessment in parts to be performed and documented in Reports by V&V, ISA, IPR, IA, Review Project Safety Management Review, Internal Project Review,.</p> <p>(These Reports or relevant sections thereof may be referenced within the Project Safety- & Compliance-Matrix.) V, ISA, IPR, IA, Project Safety Management Review, Internal Project Review)</p> <p>(These Reports or relevant sections thereof may be referenced within the Project Safety- & Compliance-Matrix.)</p>	- EN 50126-1, Sections 6.9 and 6.10, and Fig. 10; - Yellow Book, Chapters 13 and 18;
5.16	Safety & Compliance Audit Plan	<p>Define audit plan for compliance of the management process with the Safety Plan.</p> <p>(The overall auditing plan may include auditing in parts performed and documented in Reports by ISA, IPR, IA, Project Safety Manager Review, Internal Project Review.)</p>	- EN 50126-1, Section 6.12; - EN 50128; - EN 50129; - Yellow Book, Chapter 13.
5.17	Safety & Compliance Monitoring Plan	<p>Define monitoring process and plan to analyse Operation and Maintenance performance to ensure that realized Safety & Compliance is in conformance with requirements.</p> <p>(Refer to the applicable provisions of a certified RO SMS that are applicable to the subsystems under assessment, or any new provisions that must be developed to cover the scope of the project.)</p>	- EN 50126-1, Section 6.11, Phases B, A.
5.18	Provisions for SIL Assessment	<p>Perform pre-planning of activities for setting and assessing SIL.</p> <p>(This will predominantly relate to functions of the Change which are containing safety-critical electronic/ software elements.)</p>	- EN 50129, Annex E, in combination with - EN 50126; - EN 50128.
5.19	Safety Approval Process	<p>Identify the process for Safety Approval of Change to the Railway System.</p> <p>(Refer to type of AFA and safety approval processes of the certified RO SMS.)</p>	- EN 50126-1, Section 6.10; - EN 50129; - CRR-G-032; - RSA 2005

No.	Section	Requirement	Reference
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;
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 CRR-G-032-Annex1 (2). Further updating shall be done as required.)	- CRR 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 CRR AFA 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; Generic Application Safety Case and/ or Application Specific Project Safety Case.) (Note: Only an ASPSC will lead to AFA.)	- EN 50126-1; - EN 50126-2; - EN 50129; - RSA 2005; - Yellow Book, Chapter 18.
6.1.4		- Documentation evidencing achievement of Safety and Compliance Requirements. Define the process to prepare and manage these. (refer to section 4 above where applicable). (This may be referenced within the Project Safety- & Compliance Matrix.)	
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: Tram Type xyz, Manufacturer Build No., Serial Number of onboard ATP-Rack: xyz/ Platform Lift on Platform 1, Station xyz, Serial Number: xyz/ Substation Location: abc, Serial number of Transformer: xyz)	- EN 50126, Fig.9;
6.3	Configuration Management for Safety related Intangible products/ Electronic components/ Software	Define configuration management process at least for all 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.

No.	Section	Requirement	Reference
7	Technical Project Safety Reporting on Safety Qualification Testing		
7.1	Requirements for Safety Qualification Testing	<p>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.</p> <p>In all cases test procedures and test reports shall be elaborated. These shall in principle follow EN17025.</p> <p>(This may be referenced within the Safety- & Compliance-Matrix)</p>	EN17025
7.1.2	Assurance of correct Operation	<p>Define the testing process(es) to be applied for assurance of correct Operation of safety and compliance related functions.</p> <p>(Shall typically be included in Type-/ Series-/ Commissioning Testing.)</p>	
7.1.3	Effects of faults on Operation	<p>Define the testing process(es) to be applied for Effects of faults on Operation of safety and compliance related functions.</p> <p>(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.)</p>	
7.1.4	Operation with external influences	<p>Define the testing process(es) to be applied for operation of safety and compliance related functions under effects of external influences.</p> <p>(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)</p>	
7.2	Safety- and Compliance-Related Application Conditions	<p>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.</p> <p>(This may refer to sections of the project SCM or HR</p>	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		

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No.	Section	Requirement	Reference
8.1	Related Safety Cases	<p>Provide references to other Safety Cases on which the Project Safety Case depends (existing / accepted Safety cases and safety cases that will be developed)</p> <p>Describe where the interrelationship with any related Safety Cases will be documented.</p> <p>Assess compliance between Project Safety Plan and other related Safety Management Activities/ other Safety Cases.</p>	<p>- EN 50126-1, Sections 3.41 (+Fig.9), 5.2, 5.3.4 and 6 (incl.6.2.3.4, d);</p> <p>- EN 50126-1, Sections 6.9 and 6.10, and Fig. 10;</p> <p>- Yellow Book, Chapters 13 and 18.</p>
8.2	Application Conditions from related Safety Cases	<p>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.</p> <p>Describe where compliance with any related Safety cases will be documented.</p>	
9	Conclusion	<p>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 AFA.</p>	

Annex II - Checklist for evaluation of a Project Hazard Record (HR)

1 Introduction

This checklist will be employed by the CRR when evaluating a Project Hazard Record (HR) in association with AFA Projects according to RSA. A Hazard Record shall document and evidence the systematic identification of Hazards and the analysis and suitable mitigation and their associated Risks. This shall provide a clear justification major argument within the Application Specific Project Safety Case on the achievement of an appropriate level of safety.

In order to avoid repetition, documentary evidence is expected to be annexed or referenced to a Hazard Record. Any such Annexes and References shall be considered to be part of the Hazard Record.

2 Elaboration of a Project HR

Any Project HR 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 HR must be prepared by the RO (or a representative on behalf of the RO) under the scope of a RO SMS which has been approved by the CRR in accordance with the RSA 2005. *Note: This is notwithstanding the need to have all relevant stakeholders participate in workshops to identify and evaluate hazards.*

The HR must comply with current best practice. The application of EN 50126-1, EN 50126-2, EN 50128, EN 50129 is considered to represent current best practice.

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

3 Internal Review Report

The applicant for AFA must arrange for an internal (or external) review of each HR revision against this Checklist by an expert in the field of SMS. This review must cover completeness and plausibility of content of the Hazard Record.

4 CRR evaluation of Project HR

The CRR must evaluate the Project for which the applicant is applying for an AFA against the requirements of the RSA. The Project HR will be used by the CRR as one element to form an opinion, whether all requirements relating to AFA have been satisfied.

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

The provision of a Project HR 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, or the requirements of a certified RO SMS.*

***Note2:** The list may include reference to the SMS of a particular RO where these have provided the related information for reference.*

***Note3:** It is expected that the Hazard Record is maintained throughout the life of the asset. This may be fulfilled after AFA by the management of any open or ongoing hazards (and related Application Conditions) through a certified SMS of a RO. While the Hazard Record remains a live document throughout the Project Life-Cycle, for each stage of the AFA Application process, the Hazard Record shall be brought to conclusion as relevant for that stage. A formal version of the Project HR shall be issued as part of the AFA application for stages 2,3,4,5,6.*

***Note4:** All hazard identification, mitigation and risk evaluation shall reflect the **design operating state** of the part of the rail system under assessment. This must include all **permitted degraded operational modes**, all **foreseeable degraded modes** as well as all **interfaces within the affected part and to other parts of the rail system**.*

***Note5:** The hazard record shall be used as one source for Safety Requirements (EN50126-2 (5.3.2.3)).*

***Note6:** The hazard identification may be done by using checklists, workshops, lessons learnt, accident and incident information, expert knowledge or other means. In any case (for legal compliance) all parameters identified by law, regulations and guidelines must be considered as minimum.*

5 Checklist for Hazard Record

No.	Section	Requirement	Reference
0	Document Control	<p>>Provide title, document identification number, revision, revision history, author, organisation and signatures.</p> <p>>Provide list of referenced documents.</p> <p>(It is highly recommended to assign each referenced document a unique identifier to be used throughout the Project Hazard Record (and ideally throughout any other Project documentation). The Project may decide to keep a List of References as a separate document.)</p>	<p>- Yellow Book, Volume 2, Appendix B.2</p>
1	Introduction		
1.1	Hazard Record Introduction	<p>>Describe the aim and purpose of the Project Hazard Record.</p> <p>>Make reference to the project scope (asset/organisation, etc).</p> <p>>Refer to the current project lifecycle phase.</p>	<p>- EN50126 clause 6.3.3.3 (a);</p> <p>- Yellow Book, Volume 2, Appendix B.2</p>
1.2	Relationship with safety requirements specification	Refer to the Safety Requirements Specification if applicable or explain where the safety requirements are defined in this Hazard Record (see 4.17 below).	- Yellow Book, Volume 2, Appendix B.2
1.3	Hazard Record management process	Define the process for managing the Hazard Record, such as who may modify it and the approval process for each new entry.	- Yellow Book, Volume 2, Appendix B.2
1.4	Legislation and Standards	List legislation and standards applicable to this Hazard Record.	How broad is this process/ product?
1.5	Personnel involved in Hazard Identification	<p>Information of personnel involved in hazard identification and risk assessment, including their positions/competencies.</p> <p>(You may refer to the SP or also to records of attendance / participation in hazard identification workshops / exercises, to include the name, organisation / area of competence and role)</p>	6.3.3.3 (o);
2	Hazard Entries (optional)	<i>Where useful, for example in more complex projects with a complex arrangement of suppliers or multiple departments, provide separate list(s) of entries to record proposed hazards prior to their analysis. The list shall include as minimum the following information:</i>	
2.1		unique identifier (per entry)	
2.2		date of entry	
2.3		description of issue	
2.4		origin	

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No.	Section	Requirement	Reference
2.5		analysis (e.g. hazard raised, identified as duplicate or other outcome)	
3	Risk matrix and Risk Acceptability Criteria	<i>Provide any Risk Matrices and Risk Acceptability Criteria used for this Hazard Record.</i>	
4	Hazard Record Matrix	<i>Provide matrix containing hazard data. The matrix shall include as minimum the following information:</i>	6.3.3.3
4.1		unique identifier for each hazard	
4.2		origin of hazard i.e. the person, organisation or hazard workshop that identified the hazard (this may be incorporated in the unique identifier)	
4.3		grouping of hazards (this may be incorporated in the unique identifier) (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.)	
4.4		hazard description (a brief description of the hazard which should include the system functions or interfaces affected and their states that represent the hazard; this shall cover the intended operating state, any permitted degraded operating state, any interfaces and any influencing environmental conditions)	
4.5		consequence (It is sufficient to identify the consequence associated with the highest risk identified for this hazard. For clarification and further information, other consequences may also be listed.)	
4.6		Risk Acceptance Principle (e.g. according to CSM-RA 352/2009 or EN50126):	
4.6.1		1-full and un-derogated compliance code of practice	
4.6.2		2-comparison with a similar reference system which shall be fully documented and in principle be still approvable	
4.6.3		3a-qualitative risk evaluation (based on a certified RO SMS)	
4.6.4		3b-quantitative risk evaluation (based on a certified RO SMS)	
4.7		initial likelihood (likelihood of consequence before additional safety measures)	
4.8		initial severity (severity of consequence before additional safety measures)	
4.9		initial risk (risk derived from likelihood and severity before additional safety measures, in line with risk matrix and risk acceptability criteria as defined above) (Note: where Codes of Practice or Reference	

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No.	Section	Requirement	Reference
		Systems are used as the Risk Acceptance Principle estimation of likelihood and severity is not required.)	
4.10		Safety measures (which shall relate to the intended operating state, any permitted degraded operating state and any influencing environmental conditions. Record any assumptions made) (Current safety measures and Additional safety measures)	
4.11		residual likelihood (likelihood of consequence after additional safety measures)	
4.12		residual severity (severity of consequence after additional safety measures)	
4.13		residual risk (risk derived from likelihood and severity after additional safety measures, in line with risk matrix and risk acceptability criteria as defined above) (Note: where Codes of Practice or Reference Systems are used as the Risk Acceptance Principle estimation of likelihood and severity is not required.)	
4.14		risk owner (project participant, responsible for managing this risk)	
4.15		Status of Risk	
4.16		notes (which may include agreements reached, open actions, etc.)	
4.17		safety requirements (these are typically derived from the chosen safety measures) (SRs to be listed in relation to hazards or given by reference to a separate document)	
4.18		reference documents (this shall refer to evidence related to safety measures – e.g. drawings, calculations, test procedures, test reports, V&V evidence, independent assessment, evidence relating to comparability with Reference Systems, etc.) (this may be incorporated into separate columns as appropriate) (Where code of practice is employed, this may reference to an appropriate entry within the SCM to document full close out.)	

Annex III - Checklist for evaluation of a Project Safety Case (SC)

1 Introduction

This checklist will be employed by the CRR when evaluating Project Safety Cases in association with AFA Projects according to 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. 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 AFA 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 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 Application Specific Project Safety Case must have been prepared by the RO under the scope of a RO SMS which has been approved by the CRR in accordance with the RSA 2005.

The Safety Case must comply with current best practice. The application of EN 50126-1, EN 50126-2, EN 50128, EN 50129 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 Report

The applicant for AFA must arrange for an internal (or external) review of each Safety Case revision against this Checklist by an expert in the field of SMS. This review must cover completeness and plausibility of content of the Safety Case.

4 CRR evaluation of Application Specific Project Safety Case

The CRR must evaluate the Project for which the applicant is applying for an AFA against the requirements of the RSA. The Application Specific Project Safety Case will be used by the CRR as significant element to form an opinion, whether all requirements relating to AFA have been satisfied.

The attached list contains the minimum set of requirements. Any RO may decide to elaborate on these, if their SMS requires more or higher requirements. Where an RO 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, or the requirements of a certified RO SMS.

Note2: The list may include reference to the SMS of a particular RO where these have provided the related information for reference.

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 or intended activities).

5 Checklist for Safety Case

No	Section	Requirement	References
0	Document Control	<p>>Provide title, document identification number, revision, revision history, author, organisation and signatures.</p> <p>>Provide list of referenced documents.</p> <p>(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.)</p>	<p>- RSC-CL-001</p> <p>- Yellow Book, Volume 2, Appendix B.2</p>
1	Introduction		
1.1	Project introduction	Provide high level introduction to Project.	
1.2	Type of AFA sought	<p>Define Type of AFA sought at this project acc. to CRR-G-032, i.e.</p> <ul style="list-style-type: none"> - RSA-AFA-NW - RSA-AFA-NRS 	- CRR-G-009
1.3	Level of Safety Case	<p>Describe the level of Safety Case(s) presented –</p> <p>Possible levels include:</p> <ul style="list-style-type: none"> - 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) <p>(Only the ASPSC level will be able to support an AFA.)</p>	
1.4	Related Phase of Project Life-Cycle	Identify Phase of Project Lifecycle and CRR AFA Stage to which this Safety Case revision is related.	
1.5	Identify Type of AFA Project.	<ul style="list-style-type: none"> -New build/ -Upgrade / -Renewal 	
2	Description of the Change	<p>Note 1: Provide appropriate detail to identify significant aspects, including boundaries and interfaces between the Change and the Railway System.</p> <p>Note 2: ‘Change’ means all Subsystems and Parameters (including their interfaces) affected by the AFA Project.</p>	

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No	Section	Requirement	References
2.1	Definition/ Identification of Change	<p>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, chainage, version numbers, modification status, etc.</p> <p>(This should follow the typical industry approaches, used for precisely identifying products/ equipment/ installations/ etc.)</p> <p>(You may refer to the current SP.)</p>	
2.2	Scope of Change	<p>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.</p> <p>(This can often be abbreviated, if supporting descriptive references are available as e.g. tender-specifications, contract-specifications, product descriptions, etc.)</p> <p>(You may refer to the current SP.)</p>	<p>- EN 50126-1, Section 6.2.3.4, b.</p> <p>- CRR-G-032</p>
2.3	Subsystems and Parameters (incl. Interfaces) affected by Change	<p>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.</p> <p>All Parameters shall be systematically listed to enable ease of referencing and assessment.</p> <p>(They shall be listed within the Project specific Safety- & Compliance- Matrix.)</p>	
2.4	Functional/ Technical Description of Change	<p>Provide information on objectives, purposes and functions / technical design solutions for all Subsystems, Parameters (incl. their Interfaces).</p> <p>(May be done by referencing appropriate Functional/ Technical descriptive Documentation/ Drawings/ Calculations/ Simulations/ etc. within a Project specific Safety- & Compliance- Matrix.)</p>	<p>- EN 50126-1, Section 6.2.3.4, c;</p> <p>- EN 50126-2; Section 2.1.2;</p> <p>- Yellow Book, Chapter 14.</p>

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No	Section	Requirement	References
2.5	Interface Description of Change	<p>Define system boundaries, and physical and functional interfaces.</p> <p>Note: This must cover also the interface to the RO Safety Management Systems and all related internal and external interfaces.</p> <p>(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.)</p>	
2.6	Environmental Conditions of Change	<p>Define environmental conditions relating to design and operation of the Change.</p> <p>(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.)</p>	- Yellow Book, Chapter 14.
3	Project Organisation		
3.1	Roles and Responsibilities, Organisational chart	<p>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.</p> <p>(You may refer to the current SP.)</p>	<p>- EN 50126-1, Section 6.2.3.4, d and o;</p> <p>- EN 50126-1, Sections 3.26, 3.40 and 5.3.5;</p>
3.2	Personnel independence in tasks	<p>Ensure and demonstrate that an appropriate degree of (personnel) independence is provided for any review, V&V, auditing, assessment, etc. tasks.</p> <p>(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.)</p> <p>(This may be done in connection the organisational chart developed under 3.1 above.)</p> <p>(You may refer to the current SP.)</p>	<p>- EN 17020;</p> <p>- EN 50126-1;</p> <p>- EN 50126-2;</p> <p>- EN 50128, Fig. 5;</p> <p>- EN 50129, Fig. 6;</p> <p>- RSA 2005;</p> <p>- Yellow Book, Chapter 13.</p>

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No	Section	Requirement	References
3.4	Documentation Management	<p>Define a project related documentation management process. This must include a documentation retention policy.</p> <p>All documentation relating to AFA 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.</p> <p>(You may refer to existing RO document management systems, that are suitable for this task.)</p>	- Yellow Book, Chapter 12;
4	Project Quality Management Report	<p>Note1: <i>If no formal QMS is established, the Project must otherwise ensure that the activities below are performed in a consistent manner.</i></p> <p>Note2: <i>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.</i></p> <p>Note 3: <i>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.</i></p>	- EN 50126-1, Section 6.2.3.4, b.
4.1	Project QMS Provisions	<p>The Project QMS provisions must enable Design/ Manufacturing/ Series Production/ Commissioning/ Operations and Maintenance of the Change.</p> <p>(Refer to employed QM-Manual(s) and any QMS-Certification(s). Include information relating to relevant suppliers.)</p>	- EN 50126-1, Section 5.2; - CRR-G-032; - Yellow Book, Chapter 10.
4.2	Project QMS Procedures	Identify employed QMS procedures as relevant for the AFA Project on following tasks:	EN 50129 5.2
4.2.1		<ul style="list-style-type: none"> Management of project organisational structure (Roles and Responsibilities, Organisational chart) <p>(This may be provided in connection with item 3.1.)</p>	

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No	Section	Requirement	References
4.2.2		<ul style="list-style-type: none"> Management of Project requirements specification (at least Compliance requirements/ Safety requirements). <p>(This may be done in connection with the SCM.)</p>	
4.2.3		<ul style="list-style-type: none"> Management of design V&V, type testing, inspection, design reviews, Assessment, auditing, etc. 	
4.2.4		<ul style="list-style-type: none"> Management of procurement, supplier qualifications, supplier monitoring. <p>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.</p> <p>(You may refer to existing procurement policies and procedures and relevant supplier selection criteria or refer to relevant sections of procurement contracts / specifications.</p> <p>Refer to auditing/monitoring arrangements that will be implemented for suppliers of Safety- or Compliance related goods and services)</p>	- Yellow Book, Chapter 8.
4.2.5		<ul style="list-style-type: none"> Manufacturing/ installation/ commissioning 	
4.2.6		<ul style="list-style-type: none"> Series Inspection and testing 	
4.2.7		<ul style="list-style-type: none"> Product identification/ traceability/ configuration management/ change control (HW& SW) 	
4.2.8		<ul style="list-style-type: none"> Handling/ storage/ packaging/ delivery (where related to Safety/ Compliance) 	
4.2.9		<ul style="list-style-type: none"> Non-conformance handling and corrective actions 	
4.2.10		<ul style="list-style-type: none"> 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		<ul style="list-style-type: none"> Employment of EN 15085 family and ISO9712 as baseline 	

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No	Section	Requirement	References
4.3.2		<ul style="list-style-type: none"> • Provide project related organisation of certified Welding Engineer, Welding Supervision, Welders, NDT-Expert and NDT-Technicians. 	
4.3.3		<ul style="list-style-type: none"> • Document that welding design has been documented and authorised by certified Welding Engineer and manufactured by certified welders. 	
4.3.4		<ul style="list-style-type: none"> • 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		<ul style="list-style-type: none"> • Document specific baseline standard(s) for any welding or NDT performed as part of the project. 	
4.4.2		<ul style="list-style-type: none"> • 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 achievement of requirements for any other safety related bonding provisions (other than welding)	
4.5.1		<ul style="list-style-type: none"> • Document any Training/ Certification/ Product Inspection requirements 	
4.6	QMS Auditing	Document auditing of all Project QMS activities as defined above.	
5	Project Safety Management Report	<p>Note 1: Provide appropriate detail to identify significant aspects, including interfaces and boundaries.</p> <p>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.</p> <p>Note.3: 'Change' means the Subsystems and Parameters including their Interfaces affected by the AFA Project.</p>	

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No	Section	Requirement	References
5.1	Policy and Strategy to achieve safety	<p>Refer to the policy and strategy as defined at a generic level by a certified/authorised RO SMS and adopt for Project. Define on project-by-project basis a suite of appropriate references for the performance of SMS activities.</p> <p>(List i.e. the applicable standards, legislation, SMS provisions, industry practice / guidelines etc adopted to achieve safety)</p> <p>(You may refer to the current SP.)</p>	<p>- 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);</p> <p>- Railway Safety Act 2005; - CRR Guidelines; (- for information: Yellow Book, Chapter 11).</p>
5.2	Level of Significance	<p>Provide judgement on Significance of Change.</p> <p>(Any project that requires AFA is automatically deemed Significant. In this case `further analysis / judgment on Significance is not deemed necessary.)</p> <p>(You may refer to the current SP.)</p>	
5.3	Project Life-Cycle	<p>Define project life-cycle phases and show the relationship with basic life-cycle approach to EN 50126 and AFA stages to RSC-G-009, and stages required by an applicable certified/authorised RU/IM SMS.</p> <p>(You may refer to the current SP.)</p>	- EN 50126-1, Section 5.2;
5.4	Project Schedule	Provide Project Schedule, referencing AFA stages.	
5.5	Intended Service Life of Change	Define Intended Service Life of Change.	

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No	Section	Requirement	References
5.6	Safety tasks	<p>Describe the system life-cycle related safety tasks undertaken within each lifecycle phase along with any relationships between them.</p> <p>Describe the range of safety tasks and tools actually employed for each life-cycle phase.</p> <p>Justify the adequacy of tasks chosen for the application under consideration.</p> <p>(You may refer to the HR or other documentation where the actual application and output of the safety tasks performed has been documented.)</p>	- EN 50126-1, Sections 3.41 (+Fig.9), 5.2, 5.3.4 and 6 (incl.6.2.3.4, d);
5.7	System Requirements Specification	<p>Refer to documentation providing System Requirements Specification (at least Safety- & Compliance-Requirements)</p> <p>(You may refer to SCM which brings together all Safety- & Compliance-Requirements, from all the listed sources.)</p>	
5.7.1		<ul style="list-style-type: none"> • Tender Specification 	
5.7.2		<ul style="list-style-type: none"> • Contract Specification 	
5.7.3		<ul style="list-style-type: none"> • Legislative Requirements 	
5.7.4		<ul style="list-style-type: none"> • Network Access/ Compatibility Requirements 	
5.7.5		<ul style="list-style-type: none"> • Other sources (best practice, state of art, etc.) 	
5.8	Combined Project Safety and Compliance Requirements Specification	<p>Describe how Safety Requirements and Compliance Requirements were identified by the Project.</p> <p>Refer to Combined Project Safety and Compliance Requirements Specification in SCM.</p>	
5.9	Hazard identification and analysis	<p>Provide approaches used for hazard identification (e.g. creative, empirical and/ or structured).</p> <p>Note: Make use of past experience and lessons learnt or known incidents/accidents at similar systems nationally and internationally.</p> <p>Identify for each approach of hazard identification and analyses the process and format followed.</p>	- Yellow Book (7 stage process).

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No	Section	Requirement	References
5.9.1		<p>-Structured approach: Reference CRR Parameter Lists and other structured checklists for identification of safety related functions and associated hazards.</p> <p>(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.)</p>	- Yellow Book, Appendix C.
5.9.2		<p>-Empirical approach: Reference Lessons Learned/ past experience/ published accident reports for identification of hazards.</p> <p>(Detailed information on this may be incorporated within the Hazard Record.)</p>	- EN 50126-1, Fig. 9, Stage 2;
5.9.3		<p>-Creative approach: Reference Expert workshops for identification of hazards.</p> <p>(Detailed information on this may be incorporated within the Hazard Record.)</p>	-
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, Section 4.6;
5.11	Risk tolerability criteria	<p>Provide risk tolerability criteria. Provide any employed risk matrix, qualitative and/ or quantitative.</p> <p>(This may be incorporated within the current SP and/or the current Hazard Record.)</p>	<p>- EN 50126-2, Table 5 THR/SIL relationship;</p> <p>- Yellow Book, Chapter 17;</p> <p>- PD R009-004 for additional information.</p>
5.12	Project Safety- & Compliance- Requirements Review	<p>Provide reports on assessment for adequacy of Safety- & Compliance- Requirements during the whole lifecycle of the system.</p> <p>(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, Project Safety Management Review, Internal Project Review,)</p> <p>(These Reports or relevant sections thereof may be referenced within the Project Safety- & Compliance- Matrix.)</p>	<p>- EN 50126-1, Fig.9, Sections 2 and 6, Fig 10 and Fig. 11;</p> <p>- Yellow Book, Chapter 17.</p>

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No	Section	Requirement	References
5.13	System Design Evidence	<p>Provide reference to suite of generated design evidence.</p> <p>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.</p> <p>The suite of evidence must be systematically organised to enable easy referencing and retrieving of the information contained.</p> <p>(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.)</p>	
5.14	Verification and Validation	<p>Evidence V&V of all Safety and Compliance related Subsystem- and Parameter-Functions, their combinations and internal and external interfaces.</p> <p>(This may be incorporated within the Project Safety- & Compliance- Matrix.)</p>	<p>- EN 50126-1, Fig.9, Fig. 10 and Fig. 11, and Section 6.9;</p> <p>- Yellow Book, Chapters 11, 12 and 18,</p>
5.15	Safety Assessment, Compliance Assessment	<p>Document assessment of realisation of Safety- and Compliance-Requirements (tools to EN 50126-1, Annex B).</p> <p>(The overall assessment may include assessment in parts be performed and documented in Reports by V&V, ISA, IPR, IA, Project Safety Manager Review, and Internal Project Review.)</p> <p>(These Reports or relevant sections thereof may be referenced within the Project Safety- & Compliance- Matrix.)</p>	<p>- EN 50126-1, Sections 6.9 and 6.10, and Fig. 10;</p> <p>- Yellow Book, Chapters 13 and 18;</p>
5.16	Safety Audit	<p>Document Auditing undertaken for compliance of the management process against the Audit Plan.</p> <p>(This may reference auditing in parts be performed and documented in Reports by ISA, IPR, IA, Project Safety Manager Review, Internal Project Review.)</p>	<p>- EN 50126-1, Section 6.12;</p> <p>- EN 50128;</p> <p>- EN 50129;</p> <p>- Yellow Book, Chapter 13.</p>

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No	Section	Requirement	References
5.17	Safety & Compliance Monitoring Plan	<p>Define monitoring process and plan to analyse Operation and Maintenance performance to ensure that realized Safety & Compliance is in conformance with requirements.</p> <p>(Refer to the applicable provisions of a certified RO SMS that are applicable to the subsystems under assessment, or any new provisions that had been developed.)</p>	- EN 50126-1, Section 6.11, Phases B, A.
5.18	Provisions for SIL Assessment	<p>Document activities for setting and assessing SIL.</p> <p>This will predominantly relate to functions of the Change which are containing safety-critical electronic/ software elements.</p> <p>(This may be incorporated within the Project Safety- & Compliance- Matrix.)</p>	<p>- EN 50129, Annex E, in combination with</p> <p>- EN 50126;</p> <p>- EN 50128.</p>
5.19	Safety Approval Process of Change	<p>Identify the process for Safety Approval of Change to the Railway System.</p> <p>Refer to type of AFA and safety approval processes of the certified RO SMS.</p>	<p>- EN 50126-1, Section 6.10;</p> <p>- EN 50129;</p> <p>- RSC-G-009;</p> <p>- RSA 2005</p>
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, Fig. 9;
6.1.1		<p>- Project Safety Plan</p> <p>Refer to current version of Project Safety Plan.</p> <p>(To include all aspects of RSC-G-009-Annex1. Shall have been updated at least in accordance with CRR-G-032-Annex1 (2). Further updating as required.)</p>	- CRR Guidance;

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No	Section	Requirement	References
6.1.2		<p>- Project Hazard Record</p> <p>Refer to current version of Project Hazard Record.</p> <p>(To include all aspects of CRR-G-032-Annex2. Shall have been updated for the current Project stage.)</p>	
6.1.3		<p>- Supporting Safety Cases</p> <p>(Generic Product Safety Case; Generic Application Safety Case and or other applicable safety cases).</p>	
6.1.4		<p>- Documented Evidence of achievement of Safety and Compliance Requirements</p> <p>Systematic documentation evidencing achievement of Safety and Compliance Requirements. Identify the process to manage these.</p> <p>(This may be referenced within the Project Safety- & Compliance Matrix)</p>	
6.2	Configuration Management for Safety related Tangible Products/ Hardware	<p>Identify at least all safety related tangible products/ hardware for which configuration management must be established. (Type-ID, Version, Serial Numbers, etc.)</p> <p>This shall include all items which over the lifetime of the product may require traceability or batch identification. Typical industry provisions shall apply.</p>	- EN 50126, Fig.9;
6.3	Configuration Management for Safety related Intangible products/ Electronic components/ Software	<p>Define configuration management process at least for all safety related intangible products/ Electronic components or Software (Type, Version, etc.)</p> <p>Shall include all items which over the lifetime of the product may require traceability or identification. Typical industry provisions shall apply.</p>	- EN 50128.

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No	Section	Requirement	References
7	Technical Project Safety Report on Safety Qualification Testing		
7.1	Requirements for Safety Qualification Testing	<p>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.</p> <p>In all cases test procedures and test reports shall be provided. These shall in principle follow EN17025.</p> <p>(This may be referenced within the Safety- & Compliance-Matrix)</p>	EN17025
7.1.2	Assurance of correct Operation	<p>Documented evidence of correct operation of all safety and compliance related functions.</p> <p>(Typically performed as part of Type-/ Series-/ Commissioning Testing)</p>	
7.1.3	Effects of faults on Operation	<p>Documented evidence of acceptable reaction of safety and compliance related functions under simulated fault conditions.</p> <p>(Typically performed as part of Type-/ Series-/ Commissioning Testing)</p>	
7.1.4	Operation with external influences	<p>Documented evidence of acceptable reaction of safety and compliance related functions under environmental limit conditions and safe degradation under out of range conditions.</p> <p>(Typically performed as part of Type-/ Series-/ Commissioning Testing)</p>	
7.2	Safety- and Compliance-Related Application Conditions	<p>Identify all Safety- and Compliance-Related Application Conditions, as derived from the Safety- and Compliance-Requirements and the Hazard Record.</p> <p>(This may refer to the relevant sections of the Project HR and/or SCM.)</p>	
7.2.1	Operations	Identify Application Conditions for Operation.	
7.2.2	Maintenance	Identify Application Conditions for Maintenance.	

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No	Section	Requirement	References
7.2.3	Decommissioning and Disposal	Identify Application Conditions for Decommissioning and Disposal.	
8	Related Safety Cases		
8.1	Related Safety Cases	<p>Provide references and document compliance with any other Safety Cases on which this Project Safety Case depends.</p> <p>Document the interrelationship with any related Safety Cases.</p> <p>Document achieved compliance between Project Safety Plan and other related Safety Management Activities/ other Safety Cases.</p>	- EN 50126-1, Sections 3.41 (+Fig.9), 5.2, 5.3.4 and 6 (incl.6.2.3.4, d);
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 AFA and meets all relevant Safety and Compliance Requirements, subject to fulfilment of the specified Application Conditions.	

Annex IV - Template of a Project Safety & Compliance Matrix (SCM)

1 Introduction

This Template will be employed by the CRR when evaluating a Project Safety & Compliance Matrix (SCM) in association with AFA Projects according to r RSA for Light Rail. The Project Safety & Compliance Matrix shall summarise all Safety Requirements and all Compliance Requirements relating to a project in a structured format. In order to avoid repetition, documentary evidence may be annexed or referenced to a SCM. Any such Annexes and References shall be considered to be part of the SCM.

2 Elaboration of a Project SCM

Any Project SCM shall follow the structure provided below and shall include all columns listed. If any Matrix-Cell is not relevant for a given project, that Cell shall be marked as not relevant for this Project (in the Sample done by “n.a. “).

The Project SCM must have been prepared by the RO (or a representative on behalf of the RO) under the scope of a RO SMS which has been approved by the CRR in accordance with RSA2005.

The Project SCM must include Safety and Compliance Requirements for all project related Subsystems and Parameters listed in the relevant CRR Guidance on Parameters relating to the affected Subsystems, and also any additional affected Parameters identified during the course of the project.

The SCM combines references to a variety of relevant Project SMS documentation as defined by various chapters of EN 50126-1, EN 50126-2, EN 50128, EN 50129.

Each element entered into the SCM shall detail any constraints, dependencies, assumptions and caveats.

3 Internal Review Report

The applicant for AFA must arrange for an internal (or external) review of the SCM against this Template by an expert in the field of SMS. This review must cover completeness and plausibility of content of the SCM and must be documented in a report which must be provided to the CRR with the SCM.

4 CRR evaluation of Project SCM

The CRR must evaluate the Project for which the applicant is applying for an AFA against the requirements of Regulation 42&43 of RSA. The Project SCM will be used by the CRR as one element to form an opinion, whether all requirements relating to AFA have been satisfied.

The attached list contains the minimum set of information to be provided. Any RO may decide to elaborate on these, if their SMS defines more or higher requirements. (This is typically expected to be the case for complex Projects relating to signalling technology.) Where an RO decides to elaborate, on these requirements, the main chapter headings of the checklist should be retained.

The provision of a Project SCM to this template is 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, or the requirements of a certified/ authorised RO SMS.*

Note2: *The Hazard Record shall be used as a source for Safety Requirements (EN50126-2 (5.3.2.3)). It is expected that the Project SMS ensures that any Safety Requirements derived by the Project Hazard Record is carried forward into the SCM throughout the Project lifecycle.*

Note3: *Other Safety- and Compliance Requirements may be identified by using checklists, workshops, lessons learnt, accident and incident information, expert knowledge or other means. In any case (for legal compliance) all requirements identified by law and regulations (e.g. EC directives, or CRR guidance) must be considered as minimum.*

Note4: *The SCM shall reflect Safety- and Compliance-Requirements for the **design operating state** of the part of the light rail system to which it relates, all **permitted degraded operational modes**, all **foreseeable degraded modes** as well as all **interfaces within the affected part and to other parts of the rail system**.*

5 Checklist for Project Safety-& Compliance-Matrix

The following column headings in the SCM shall be understood to have the meaning stated below. Other column headings are considered self-explanatory.

Column heading	Meaning / requirement
Identification of Subsystems / Parameters	List for each subsystem the affected Parameters. Include all affected Subsystem Parameters from the relevant CRR Guidance on Parameters and any additional affected Parameters as identified throughout the project.
Safety- & Compliance- Req. Specification	List Standards (quoting the specific clause / sections) from which requirements relevant to the parameter have been derived and/or: List Hazard Record entries from which Safety Requirements relevant to the parameter have been derived.
Specification of Scope/ Method/ Classification to be applied	Where the quoted Standard specifies different requirements for different applications/classifications/options, the classification relevant to the project scope must be listed. For example, gauge, fire classification of rolling stock.

6 Template SCM

Identification of Subsystem / Parameters	Safety- & Compliance - Req. Specification **	Specification of Scope/ Method/ Classification	Derogations to initial Requirements	Technical/ Functional Description	Drawings/ Parts lists/ Calculation/ Simulation	Test Procedures / V&V Requirements	Test Report/ V&V Report	Assessment / Audit performed by	Assessment / Audit Report supporting AFA	Application Conditions for Operation	Application Conditions for Maintenance	Application Conditions for De-commissioning and Disposal
Subsystem INF												
Parameter 1	From Hazard Record abc	n.a.	n.a.	Tech Des 115	Drw Q5+Q6	P2	TR2	IPR	IPR Report xxx	n.a.	n.a.	> To be developed by last IM operator
Parameter 2	EN 11223	Fire Cat B	n.a.	Tech Des 116 +Func Des 416	Drw Q2	n.a.	n.a.	IPR	IPR Report xxx	n.a.	n.a.	n.a.
Parameter 3	UIC 123	n.a.	n.a.	n.a.	Drw Q2	P5	TR5	IPR	IPR Report	>max. axle load for INF line section is 16t	> use RO-Standard xyz for maintenance tolerances	n.a.
Parameter ...	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Subsystem OPE												
Parameter 1	RO Rule Book cl.xyz	n.a.	n.a.	RB 2012	n.a.	n.a.	n.a.	IPR	IPR Report xxx	RO RB 2012	n.a.	n.a.
Parameter 3	Hazard Record cl. xyz	n.a.	n.a.	Ops instruction 007	n.a.	P9	TR9	RO (self-assessment)	Report 1	RO RB 2012+ Ops instr. 007	n.a.	> fluorescent tubes to be treated as special waste

Explanatory Note: The SCM-Cells shall in principle be completely filled. However, if on a specific Project a Matrix-Cell is 'not relevant for this Project' it shall be marked accordingly (in the Sample done by "n.a."). Empty Cells shall be considered as being 'incomplete, information outstanding'.

** Compliance Requirements are e.g. derived from CRR Guidelines/Standards and Safety Requirements are derived e.g. from the project Hazard Record or Standards.
CRR-G-032-A-Annex4 (SCM)