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INTRODUCTION TO CSM-RA APPLICATION

RAIL BALTICA

GUIDANCE


CONFIDENTIAL

LIST OF SUCCESSIVE VERSIONS

Version	Date	Objet
1D	16.02.2022	First issue of the report – draft (reference EC_9644_0015_vD1)
1DB	08.07.2022	Updates following the meeting of 17.06.22 in Riga - draft
1	08.12.2022	Official issue

The latest version supersedes the previous.

VALIDATION

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1. Purpose.

This document is issued with the intention of summarizing the most relevant available texts related with Commission Implementing Regulation (EU) n° 402/2013, and to outline the expected tasks to be performed by the RB Rail risk management responsables.

Those conditions concern the design, construction, placing in service, upgrading, renewal, operation and maintenance of the parts of that system as well as the professional qualifications of, and health and safety conditions applying to, the staff who contribute to its operation and maintenance.

1.1. Reference documents.

The Regulatory context of the authorisation process is defined by the following Legal texts:

Reference	Legal Text
402/2013/EU	Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 “ CSM-RA regulation ” in this document.
2016/798/EU	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety “ Safety Directive ” in this document
2019/776/EU	Commission Implementing Regulation (EU) 2019/776 of 16 May 2019 amending Commission Regulations (EU) No 321/2013, (EU) No 1299/2014, (EU) No 1301/2014, (EU) No 1302/2014, (EU) No 1303/2014 and (EU) 2016/919 and Commission Implementing Decision 2011/665/EU as regards the alignment with Directive (EU) 2016/797 of the European Parliament and of the Council and the implementation of specific objectives set out in Commission Delegated Decision (EU) 2017/1474 (Text with EEA relevance.).

The regulation Annex I defines the process, the way it shall be performed and the definition of the different tasks to be performed. Any level safety manager shall know in detail and understand the content and requirements included in it.

Nevertheless, we list as well some documents containing specific guidance:

Reference	Text
ERA/GUI/01-2008/SAF	Guide for the application of the Commission Regulation on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of the Railway Safety Directive.
Guide010	Guide à l’usage des demandeurs d’autorisation de mise en service d’installations fixes sur le système ferroviaire interopérable
UK Guide	Common Safety Method for Risk Evaluation and Assessment Guidance on the application of Commission Regulation (EU) 402/2013

The first document, issued by the European Railways Agency does not contain any legally binding advice. *It contains explanatory information of potential use to all actors(1) whose activities may have an impact on the safety of railway systems and who directly or indirectly need to apply the CSM*

Regulation. It may serve as a clarification tool without however dictating in any manner compulsory procedures to be followed and without establishing any legally binding practice. The guide provides explanations on the provisions contained in the CSM Regulation and should be helpful for the understanding of the approaches and rules described therein. Actors may continue to use their own existing methods for the compliance with the CSM Regulation.

The other two documents have been issued by French and British agencies and are also very useful to understand how to apply the Regulation.

2. Risk Management Process.

1.2. Definition of the process.

The risk management process is defined in Annex 1 Ch 2 of the CSM-RA Regulation. We introduce here a summary of the process:

The risk management process is a harmonized process based on four steps:

1. Definition of the evaluated system (purpose, functionalities, scope, interfaces, environment, existing security measures, hypotheses, etc.);
2. Systematic identification of hazards and risks, associated safety measures and the resulting safety requirements ;
3. Demonstration of the system's compliance with the identified safety requirements;
4. Management of all identified hazards and associated safety measures.

With regard to the management of the risk management process, it should be noted that the risks introduced by suppliers and all kind of contractors, including their subcontractors, are also to be managed.

The risk acceptability of the evaluated system is assessed according to the following risk acceptance principles used alone or combining them:

- the application of Codes of Practice ;
- comparison with similar reference system(s);
- explicit risk estimation (qualitative or quantitative).

It shall be demonstrated in the risk assessment that the chosen risk acceptance principle is applied correctly and used consistently.

In order to control a hazard, a safety measure may be transferred to another actor in agreement with the latter. The hazard remains recorded in the hazard log of the entity transferring it and can only be considered controlled when the risk assessment of these hazards is carried out by the other actor and the solution is approved by all the actors concerned (see Annex I Article 4.2. of the CSM Regulation).

The Hazard Log ensures the traceability of the risk management process throughout the design, construction, testing and commissioning of the project. After the authorization to place in service, the Infrastructure Manager continues to update the Hazard Log as an integral part of its risk management process, throughout the life cycle of the system. (Annex I- Article 4.1.1. of the CSM Regulation).

This risk management process is subject to assessment by an independent assessment body. The report produced by the assessment body shall in particular, include its assessment of the relevance and completeness of the safety analysis.

Finally, on the grounds of the safety assessment report submitted by the assessment body, the proposer shall produce a statement that all identified hazards and associated risks are controlled so as to be maintained at an acceptable level. (see Article 16 of the CSM Regulation).

1.3. Evidence from the application of the risk management process.

As requested in Annex 1 Ch 5 of the CSM Regulation, the risk management process is to be documented by the proposer "in such a way that all the necessary evidence showing the suitability of both the application of the risk management process and of its results are accessible to an assessment body."

In the same Ch 5 requests the proposer to include at least the following in the documentation:

- A description of the organisation and the experts appointed to carry out the risk assessment process;
- Results of the different phases of the risk assessment and a list of all the necessary safety requirements to be fulfilled in order to control the risk to an acceptable level;
- Evidence of compliance with all the necessary safety requirements;
- All assumptions relevant for system integration, operation or maintenance, which were made during system definition, design and risk assessment.

In order to illustrate how this documentation can be structured taking in account the fact that the process shall be iterative, the French regulation requires this evidence to be delivered in three steps:

- Safety Definition Report.
- Preliminary Safety Case.
- Safety Case.

Through this reports and documents, the proposer describes how it is guaranteed the compliance with railway safety regulations and to ensures the coverage of the risks identified through the live cycle of the project including the operation and maintenance phases of the system or subsystem. The purpose is to enable the AsBo and the NSA to assess whether the overall level of safety of the rail system has been maintained, or in case of a new project, the defined overall level of safety.

1.3.1. Safety Definition Report.

The SDR is transmitted from the initial phase of the project.

It presents the project, the proposers organisation and describes the main technical and functional characteristics of the project and in particular for ERTMS projects, the list of functions planned to be

implemented. It identifies the main safety issues and mentions the TSIs and national rules applicable by the applicant in the subsequent phases of the project.

This report must also present the provisional project schedule and specify the work considered to be preparatory and therefore not requiring the prior approval of the DPS to be undertaken.

1.3.2. Preliminary Safety Case.

It is transmitted at the end of the design phase and before the installation phase.

The construction work within the scope of the PSC can only be undertaken after approval of this document.

When the project involves several phases, it might be requested by the NSA or the AsBo that this document would be delivered for each stage.

It mainly presents:

- the description of the safety management envisaged on the project (safety management plan , organizational charts describing the organization, etc.) ;
- a description of the design elements and the principles of implementation of the system or subsystems intended to be operated ;
- the list of TSIs and national rules applied as well as any derogations envisaged;
- the detailed planning of all phases of the project;
- the works envisaged and the special conditions for carrying out the works to ensure the safety of the lines operated;
- the procedures for taking into account the opinions of the EPSF and the DGSCGC issued at the DDS stage;
- the programme of tests and tests planned to be carried out;
- a description of the operating procedures and maintenance principles envisaged, including minimum operating conditions;
- the description of the risk analysis process: the organisation of the different actors, the methods used;
- risk analyses : risk identification, associated explicit hedging measures, identification of exported constraints and conceded entities, etc.
- the Hazard Log in its final form: the risks must be closed at the design level (i.e. the design coverage measures have been amortized);

As part of the risk analysis process presented in the PSC, and in order to issue an approval, it is necessary that the risks identified in the Hazard log be closed at the design level.

1.3.3. Safety Case .

It will prove that:

- the work was carried out in accordance with the PSC and the requirements of the AsBo or the NSA.
- any deviations from the previously approved PSC were managed by ensuring the safety of the project;

- the requirements are well taken into account:
- the planned operation and maintenance of the system or subsystem ensures that the level of security of the systems is maintained throughout their lifetime ;
- all risk coverage identified during the risk management process is effectively implemented (the applicant must be able to provide explicit proof of each hedging measure);
- the exported constraints are amortized (i.e. accepted and implemented) by the receiving entity.

As part of the risk analysis process presented in the SC, and in order to issue the Application to place in service, it is necessary that:

- the risks identified in the SC are closed ;
- the evidence is provided or referenced in the SC ;

1.4. NoBo vs AsBo assessment and Safe integration

The essential requirements of interoperability (NoBo) are

- Safety,
- Reliability and Availability,
- Health,
- Environmental Protection,
- Technical compatibility, and
- Accessibility.

Nevertheless, the sole compliance of a design or a project with TSI(s) and NNTR does not ensure safety is fully covered as outlined in the precedent chapter. For that sake, the Safety Directive 2016/798 requires the application of the Reg. 403/2013 on CSM-RA in order to ensure a project manages safely the changes when these changes are found significant.

The compliance with TSI(s) will ensure compliance with the essential requirements to the extent they are covered by the basic requirements listed in §2.2., but not all identified risks triggered by a safety significant change or a new project. Designated Bodies will assess the Notified National Technical Rules, theoretically to ensure compliance with aspects of the essential requirements not covered in TSI(s). In the practice, this doesn't happen yet.

On the other hand, when applying CSM-RA the proposer is entitled to apply the methodology and demonstrate that all risks are controlled, while the assessment body (sometimes called the ISA) check the correct application and the suitability of the results.

The range of this synergy would depend of the nature of the change, the amount of National Rules verified by the DeBo and in which way TSI(s) basic requirements application are able to prove that a number of risks are controlled.

This way, the CSM-RA and AsBo assessment at subsystem level should cover the whole scope of the change, where the NoBo and DeBo outputs will be useful for the proposer to prove that some risks are covered. Other risks not covered by these two missions would be proven to be covered by one of the three risk acceptance principles defined in the Reg. 402/2013.

Therefore, not only at overall level, but at subsystem level CSM-RA must also be applied to demonstrate safety is fully controlled.

Finally, safe integration is a part of the CSM-RA process performed at overall or subsystem level. At this level the proposer will need to prove that all safety requirements exported among subsystems

have been properly transferred and endorsed by receivers, and that shared risks are controlled by the relevant subsystems.

The proposer needs to prove as well that (a) SRAC(s) and requirements exported to system level are controlled, (b) system level risks are controlled, and (c) the safety integration with operation and maintenance has been successfully performed.

In order to assess the essential requirement of safety and the safe integration of the railway system, CERTIFER refers to 2014/897/UE recommendation, CSM-RA regulation and CENELEC standards.

CERTIFER would support Rail Baltica and coordinate with any other assessment body or notified body to ensure that the interfaces for each of the assessed subsystems are understood and covered by the relevant assessments and certifications.

3. AsBo assessment process.

The AsBo performs the assessment basically through documentary review of the risk management process evidence, and presential or on-line audits.

Both methodologies in any case are performed in the frame of the independent safety assessment of the risk management process performed by RB Rail and its sub contractors. CERTIFER would like to remind that this process does not comprise a conformity assessment of the railway system as a product: the AsBo scope is to assess a process.

CERTIFER is providing in this chapter some practical information to ease the assessment process.

1.5. Documentary review.

When performing documentary review, Open Item Lists (OILs) are created to record questions and observations raised by the assessors. These OILs are sent back to the risk managers owners of the evidence assessed, so they could answer to the assessor questions. These answers could involve sending new or updated information, clarifications, or proposal of other kind of actions to be performed to close the remarks.

An OIL contains mainly the following information: Item #, Assessor ID, Opening date, Reference of the related document, Status, Assessor question, RB Rail AS answer, Answering date.

The statuses for items are: open, closed, or closed SRMD. Closed SRMD (Sous réserve de Modifications Documentaires in French – Subject to document amendment) means that the remark would be closed on the basis of a future update or delivery of a document as described or proposed in a previous answer. In any case, it would be up to the assessor to agree the closure of the remark once received the document agreed as mentioned.

OILs are working documents, retracing the whole evaluation, the final version of which is annexed to the Assessment Report.

The closure of all remarks issued on a package of documents as evidence of application of the CSM-RA process means that the assessor has enough information to issue a safety report. This status does not imply by any means an “approval” of any design, since this is not the objective of an AsBo assessment.

Roles and responsibilities for OILs	
Position	Roles and responsibilities
Project Leader / Deputy Project Leader	<ul style="list-style-type: none"> ▪ Forward OILs to RB Rail AS by approving OILs contents
Lead System Assessor	<ul style="list-style-type: none"> ▪ Review, comment and approve OILs prepared by Assessors ▪ Open and answer items at System-level and Subsystem level
Lead Safety Assessor	<ul style="list-style-type: none"> ▪ Open and answer items related to the safety management
Assessors	<ul style="list-style-type: none"> ▪ Open and answer items related to the safety management within his/her field of expertise

1.6. Audits.

As mentioned, the AsBo assessment is performed as well through audits, usually requested by the Assessors, accordingly with the Inception Report and the future assessment plan strategy.

The object of the audit could involve any of the activities to be performed by Rail Baltica Risk Managers at system or subsystem level, up to the 402/2013 Regulation (overall safety organization, quality organization and management, safety requirements management, implementation of the CSM-RA at any level, etc.).

This safety documentation transmittal shall be compliant with “RB RAIL Deliverables Information traceability quality requirements for AsBo/NoBo” Instruction (RB0007-SEA-INS-QA-Z-00001).

Whenever an audit will be agreed (location, participants, scope, date, etc.), the assessors will provide an audit plan for the auditee to prepare the audit (availability of people, documents, presentations or any kind of information).

The audit plan will be similar to the one included as Annex.

After the audit, the Assessors will deliver an audit report, as described in the audit plan below.

ANNEX 1 AUDIT PLAN

1. Reference documents

Standards and European regulations:

- The Directive (EU) 2016/798 of the European parliament and of the council of 11 May 2016 on railway safety
- The Commission Implementing Regulation (EU) N° 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009, modified by the Commission Implementing Regulation (EU) 2015/1136 of 13 July 2015;
- NF EN ISO 9001: Quality Management System: Requirements, 2015;
- NF EN ISO 19011: Guidelines for quality and/or environmental management systems audit, 2018;
- NF EN ISO/CEI 17021: Conformity assessment – Requirements for bodies providing audit and certification of management systems, 2015.
- EN 50126: "Railway applications – The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS)", 1999
- EN 50128: "Railway Applications – Communications, Signalling and Processing Systems – Software for Railway Control and Protections Systems ", 2011
- EN 50129: "Railway Applications – Communication, Signalling and Processing Systems – Safety Related Electronic Systems for Signalling ", 2003

1.6.1. Other Documents :

- Chapter 7 of CERTIFER's AsBo inception report, referenced EC_9867_0010 version 2.
- Explanatory Note on the roles and responsibilities of the ASBO. RFU 1.

2. Field of the audit

The safety audit described in this plan is part of the business recorded under the reference EC_9867 and presented in chapter 7 of CERTIFER's AsBo inception report.

The purpose of this audit is to assess if the Safety and Quality Management System implemented is effectively and correctly applied for the design and construction of RB Rail railways system.

This is covered by Regulation 402/2013, as developed in RFU 1:

RFU 1 The AsBo needs the following information:	Regulation 402/2013
(1) the complete system definition of the change as required in paragraph § 2.1.2 in Annex I of Regulation 402/2013, including the interfaces with other sub-systems and other actors impacted by the change through those interfaces;	Art. 6(2)(a), § 1.1.6, § 1.2.1 & § 2.1.2 in Annex I
(2) the description of the proposer's (and sub-contractors, if any) safety and quality processes in place for managing the change, including in particular their risk assessment and risk management planning;	Art. 6(2)(b), § 1.1.6 & § 1.1.2 in Annex I
(3) the description of the organisation (1), the project management and the risk management. This requires the proposer's description of the roles of all involved actors (including the sub-contractors [if any] and those impacted through the interfaces [see section § 3(b)(1) above]) and of the competencies of the experts appointed for carrying out the risk management process for the change.	Art. 6(2)(b), § 1.1.6, § 1.1.2, § 1.2.3, § 1.2.4, & § 5.2(a) in Annex I

Note: The conformity of the system/sub-systems to the safety requirements will not be determined during this audit, which purpose is only to assess the capacity of the quality system to minimise human errors in each step of the lifecycle of the system, the capacity of the organization implemented to ensure the safety of the design.

⁽¹⁾ The term organisation refers here to the proposer's (project) organisation, including the safety and quality processes and assigned resources and responsibilities, actually put in place by the proposer for managing the development, the risk assessment and risk management of the significant change under assessment. It does not refer to the overall organisation of the proposer's company. Where the CENELEC 50126, 50128, 50657 and 50129 standards are used as Codes of Practice for controlling the identified hazards, the project organisation is expected to describe how the compliance with the CENELEC Safety Integrity Levels, and the associated levels of independency of project development activities, is achieved for the hazards and risks arising from the change under assessment. By virtue of point § 3.3 in Annex I of Regulation 402/2013, the ASBO is required to independently assess whether the project organisation matches with the applicable Safety Integrity Levels.

3. Reference for the audit

This audit follows the strategy set in chapter 7 of the AsBo Inception report where it is planned an initial audit of RB Rail AS Quality and Safety Management System (§ 7.5.1):

The main scope of this audit would be to perform a first high-level assessment to cover among other aspects:

- How RB Rail AS has planned to apply CSM-RA methodology at system level and perform the safe integration and system level (organization, key personnel, resources, etc.),
- How RB Rail AS previews to liaise the high-level safety CSM-RA with CSM-RA methodology performed by subsystem contractors (hazards transfers, SRAC(s), safety targets, etc.),
- Quality procedures at system level and to be applied by design and construction contractors.
- What is the Risk Acceptance Principle strategy previewed to mitigate risks at system and subsystem level. Within this task, CERTIFER assessors would gain knowledge and provide an opinion on the reference(s) systems(s) or/and CoP framework (Design Guidelines) applied by RB Rail AS within its CSM-RA strategy.

This audit will cover the initial safety activities at Global Project-level.

As per ERA document 'Clarification Note on Safe Integration' (ERA 1209/063 V 1.0), the AsBo assessment shall cover:

- the overall organisation, management and coordination by RB Rail AS of the development, risk assessment and risk management at the levels of both the railway system and the different contributing subsystems,
- the relevance and completeness of the risk assessment and risk management for the railway system as a whole,
- the level of safety for the railway system as a whole,
- the allocation by RB Rail AS of the system functional, technical and safety requirements to the different contributing parts of the railway system, i.e.:
 - the functions, requirements and hazards/risks to be managed directly by RB Rail AS at the level of the railway system,
 - the functions, requirements and hazards/risks allocated to every contributing sub-system and to be managed by subsystems contractors (those in charge of safety management).
- every stakeholder correctly understands the hazards/risks, functional, technical and safety requirements under their responsibility of control (i.e. RB Rail AS and all concerned stakeholders),
- the methods and resources deployed for demonstrating the compliance with the functional, technical and safety requirements:
 - Deployed by RB Rail AS for the system requirements that are not allocated to any contributing sub-system.
 - Deployed by INFRASTRUCTURE and ENERGY Contractors (in charge of safety management). For the whole trackside CCS, CERTIFER will cross-accept the safety assessment report of the sub- system AsBo under the conditions of the Commission Implementing Regulation (EU) 402/2013.

- Deployed by RB Rail AS for the coordination and consolidation of the results imported from those sub-contractors, including the conclusions from the safety assessment reports of the respective AsBos of the contributing sub-systems. This includes the independent assessment of the following:
 - the allocation of functional, technical and safety requirements to the contributing sub- systems
 - the demonstration of the appropriate risk control of every hazard/risk that is exported to the system by the risk assessment and risk management of the different sub-systems. This can be done by either complying with the exported safety related application conditions/ constraints (SRACs) or by defining other risk control measures that make the risk acceptable.

Likewise, regarding System Safe Integration the Inception report reads (§ 7.5.4):

Safe integration consists in evaluating the overall consistency of the risk management and the system- level safety.

Safe integration at system level is assumed to be carried out by RB Rail AS.

Safe integration assessment is carried out both at subsystem- and at railway-system levels, within operational and maintenance concept.

Safe integration at system-level needs shall be performed all along the project's cycle, dealing with system-level hazards, interfaces among subsystems, transfer of hazards, SRAC(s), etc.

Before any Operating Section is placed into service, RB Rail AS' safety organisation will need to manage hazards and ensure that those that were transferred to other subsystems are closed. Also, hazards at system-level, the transfer of Safety-Related Application Conditions (SRACs) to Operations & Maintenance, etc... will need to be processed the same.

CERTIFER will assess all those processes before any Operating Section is placed into service.

Likewise, this WP covers CERTIFER's assessment of the safe integration that shall be performed at subsystem-level by the Contractors in charge of each WP(s) CSM-RA process, taking into account their safety related interfaces with RB Rail AS system-level safety organization and as well eventual safety interfaces among other WP Contractors when needed.

To do so, CERTIFER will assess the following:

- Requirements allocated to subsystem from the system,
- Requirements imported from other subsystems within the WP or other WP(s),
- Export of requirements to system (SRAC(s)) and to other subsystems within the WP or WP through shared interfaces.

CERTIFER will perform the following audits:

- Remote audits every four months to assess the high-level RB Rail AS safety management organization.
- 2 on-site audits at integration testing stage per Operating Section.

Previously to this audit, and to place its grounds, Certifer has assessed the set of RAMS management documents issued by RB Rail to the date. After a second loop of remarks and answers, many items remain open. Most of them are directly related with the planned scope of the initial audit and the safe integration audits as described above.

Open remarks in OIL EC_9867_0100 will be brought up during the audit when relevant to further discuss them.

4. Members of the audit team

- Lead assessor Risk Management:
- Safety Integration Assessor:
- Lead Assessor Generic Railway System:
- Key Technical Expert O&M:
- Project Manager:

5. Mission of the audit team

CERTIFER's service is to perform an investigation to provide a judgement, based evidence, of the suitability of the infrastructure subsystem under assessment to fulfil its safety requirements.

During this audit, the audit team will:

- Examine and verify the structure, policies, processes, procedures, records and associated documents of the applicant, applied to the project subject of the service of assessment body assigned to CERTIFER.
- Confirm compliance with all the requirements applicable to the scope of the missions of CERTIFER for the Project.
- Confirm that the processes and procedures are implemented and maintained effectively, so that the management system can be trusted.

6. On-site Audit

6.1. Place

6.2. Date

6.3. Planning

This planning can be changed during the audit, according to the availability of the people to meet or the issues to be discussed.

Date/Time/ Duration/Place Paris Time Riga Time	Audit Topic	Attendees
Opening Meeting		
Date: Time:	<u>Opening Meeting</u> <ul style="list-style-type: none"> • Audit presentation by the AsBo • Presentation of all audit participants 	RB Rail CERTIFER

Technical Session 1 Project Organization and System Safety Management		
Date: Time: Place: RB Rail presentations: 45min. AsBo questions and discussion: 45 min	<u>Project organization and schedule</u> RB Rail organization for the design and construction of the railways system departments, overall organization chart, stakeholders, responsibilities, etc)	RB Rail CERTIFER
	<u>System Safety Management</u> <ul style="list-style-type: none"> • Safety management of the project: safety organization, safety activities, independence of roles and responsibilities and live cycle of the process. • Analysis and management of safety risks regarding the system (application of the Common Safety Method). • Safety objectives applicable to the project. • Involvement of the design teams in the risk management of the Project, in particular, in the production of the Preliminary Risk Analysis. 	

Technical Session 2 Safety Requirements Management, Integration and Interface Management		
Date: Time: Place: RB Rail presentation: 40 min. AsBo questions and discussion: 35 min	<u>Requirements Management.</u> <ul style="list-style-type: none"> • Identification, review and management of safety requirements (at railways overall system level). • Identification and management of the mitigations measures to be implemented during the project. • Hazard Management System, management of Hazard Log database, hazard review group, hazard identification workshops, controls implementation, etc.` • Hazard and other logs and linkage • Requirement verification and validation 	RB Rail CERTIFER
	<u>System Integration and Interfaces</u> <ul style="list-style-type: none"> • Management of system interfaces - external and internal Interface Control Documents 	

Audit Team Meeting and Closing Meeting		
Date:	<u>Audit Team internal meeting</u> Discussion on conclusions and issue of remarks	RB Rail
Time:		
Place: Teams	<u>Closing Meeting</u> Presentation of conclusions and remarks.	CERTIFER
Internal meeting: 45 min.		
Closing meeting: 45 min		

6.4. Method

The audit on site will be based on the harmonized standard ISO 9001.

The questions raised during the documentary audit will be discussed in order to define their final status in the report.

The elements above-mentioned in the planning will be considered **where the activities take place and at the storage locations of the corresponding records.** In that way, the auditors will be allowed to interview the participants and inspect the records by sampling.

The audit report will indicate, for each reviewed element of the planning, the documents that had been checked, then, it will attest of the existence of sufficient and relevant records, to demonstrate that each applicable requirement has been properly addressed in the frame of the concerned project.

7. Deviations classification

The identified deviations are classified in three categories:

Non-conformity (NC): If the answer given does not match with the requirement or matches in a very insufficient way, in case it's a fundamental requirement (such as safety) that may induce a risk (important or/and imminent). Non-conformities must be handled in order to authorize the delivery of a positive safety assessment report.

Remarks (R): If the answer given is not fully satisfactory but is not deemed as a non-conformity in terms of "criticality". A remark will not enable CERTIFER to issue a positive safety assessment report unless a corrective action is carried out. However, several remarks raised on one unique subject can prevent the delivery of a positive safety report.

Area of concern (AC): It deals with potential areas of improvement for which CERTIFER will not require a short-term concrete response. However, those subjects could be reconsidered later to check their actual seriousness.

In addition, the following statements can be used in the report, if necessary:

Very positive point (PF): The treatment of a requirement is more satisfactory than the common level, for instance the means or the methods applied to the project particularly deemed effective or efficient.

Point to be clarified (PC): The wording of the treatment of a requirement doesn't allow the auditor to make an opinion about its conformity (issues concerning the understanding of the requirement). That point should be clarified by CERTIFER in an internal way (by the Sectoral Committee which is concerned).

8. Following

The found deviations, if any, will be shared at the closing meeting with the applicant, but will be classified afterwards between the auditors involved in this mission, and then registered in a report. The draft report will be transmitted to the audited entity within 15 working days after the audit. For the non-conformities and remarks, an OIL will be created to follow-up their closure.