Railway Safety Commission

# RSC-G-009-E
# Guideline for the Process of Authorisation for Placing in Service of Railway Sub Systems

**Guidance for RSC Inspectors, Railway Undertakings/ Infrastructure Managers and Applicants for APIS**

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

**Contents**

# 1 Introduction

This Guideline is intended to give guidance and explanation on the related Irish and European legal provisions for the Authorisation to Place in Service (PIS) of **New and Altered (Upgraded/Renewed) Railway Infrastructure, Control Command and Signalling Equipment, Energy Supply Equipment and Rolling Stock**. It cannot replace additional self study of the applicable legal documentation.

This guideline is based on the requirements of Railway Safety Act 2005, Interoperability Directive 2008/57/EC and Railway Safety Directive 2004/49/EC.

This guideline is applicable to all parts of the Heavy Rail Network in the State.

This guideline and its associated annexes are National Technical Rules relevant for the Authorisation Process relating to 2008/57/EC (Art 15):
- assessing the technical compatibility of subsystems with the system into which they are being integrated,
- assessing the safe integration of subsystems in accordance with Articles 4(3) and 6(3) of Directive 2004/49/EC.
- checking, before subsystems are placed in service, that they comply, where applicable, with the relevant TSI provisions on operation and maintenance.

# 2 Abbreviations and Definitions

| **Term / Abbreviation** | **Meaning** |
|---|---|
| APIS | Authorisation for Placing in Service (by RSC) |
| Applicant | The organisation applying for APIS by the RSC. |
| ASPSC | **Application Specific** Project Safety Case |
| Blue Guide | Guide to the Implementation of Directives Based on New Approach and Global Approach, New Legislative Framework (Regulation (EC) No 764/2008, 765/2008, 768/2008) |
| CCO | Command, Control and Signalling, Onboard |
| CCS | Command, Control and Signalling |
| CCT | Command, Control and Signalling, Trackside |
| Combined Technical File | Combination of EC Technical File and National Technical File |
| CSM-AB | Assessment Body to CSM 352/2009, providing CSM-AB-Report |
| DeBo | Designated Body |
| EC | European Commission |
| EC Technical File | Documented evidence demonstrating compliance with any applicable TSI requirement |
| ENE | Energy |
| 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) |
| IM | Authorised Infrastructure Manager to RSD |
| INF | Infrastructure |
| IOD | 2008/57/EC Interoperability Directive, including Amendments |
| 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 EN50126-1/EN50126-2/EN50128/50129 |
| ISV | Intermediate Statement of Verification: NoBo Certification covering only parts or stages of the NoBo assessment process. |
| Mandatory Standard | EC vocabulary: Standard or part thereof and its revision as referenced in a TSI. The use of this Standard and this Revision is mandatory under IOD. |

| Term / Abbreviation | Meaning |
|---|---|
| Module | EC vocabulary: Assessment Procedure as defined and permitted in a TSI in combination with 2010/713/EU. |
| National Technical File | Documented evidence demonstrating compliance with national requirements |
| New Legislative Framework | EC Regulations regulating compliance requirements for certain technical areas (including Railway Interoperability). Consisting of 764/2008, 765/2008, 768/2008. (http://ec.europa.eu/enterprise/policies/single-market-goods/documents/new-legislative-framework/index_en.htm) |
| NoBo | Notified Body |
| NSA | National Safety Authority |
| NSR | National Safety Rule (Safety Rule applicable to all RU/IM in Ireland) |
| NTR | National Technical Rule (applicable in all cases where no TSI is applicable, or where a NTR defines specific characteristics for technical compatibility and safe integration of subsystems with the Railway System in the State.) |
| PIS | Placing in Service (by RU/IM), after APIS has been granted and after all RU/IM SMS activities relating to this project are concluded |
| Railway Undertaking to RSA | Railway Undertaking to RSA, organisation performing tasks of RU or IM |
| RFU | Recommendation for Use regarding TSIs, issued by **NB RAIL** the Coordination group of Notified Bodies 2008/57EC. see NB-Rail homepage (http://circa.europa.eu/irc/nbg/nbrail/info/data/en/information/nbrail/RFU.htm) |
| RSA | Railway Safety Act 2005, including Amendments |
| RSC | Railway Safety Commission (Irish NSA) |
| RSD | 2004/49/EC Railway Safety Directive, including Amendments |
| RST | Rolling Stock |
| RU | Certified Railway Undertaking to RSD |
| RU/IM | In the interest of readability in this Guidance the term RU/IM shall include RU or IM (to RSD) or Railway Undertaking (to RSA) as relevant. Likewise the term SMS shall include SMS (to RSD) or Safety Case (to RSA) as relevant. |
| TAF | Telematic Applications Freight |
| TAP | Telematic Applications Passengers |
| TD | ERA Technical Document may be called up by a TSI or other EU legislation to further define certain requirements. Use search function of ERA homepage to find TDs (http://www.era.europa.eu/Search/Advanced-Search/Pages/home.aspx) |
| TO | ERA Technical Opinion, may provide additional clarification on certain parameters of a TSI. See ERA homepage (http://www.era.europa.eu/Core-Activities/Interoperability/Pages/INT-TO.aspx) |
| SC | Safety Case, (where this term is used, it is understood to have meaning from EN50126, and not the meaning of a 'Railway Undertaking Safety Case' as defined by RSA (which is equivalent to an SMS to RSD). |
| SCM | Safety and Compliance Matrix |
| SP | Safety Plan |
| Subsystem | Predefined sub-element of the Rail System, see IOD, Annex II |
| V&V | Verification and Validation as defined by EN 50126-1/-2, EN50128, EN50129. This may include activities of Testing and Commissioning. |
| Voluntary Standard | EC vocabulary: Standard or part thereof proposed by ERA or EC (in the form of Harmonised Standards) in relation to IOD. The application allows a direct presumption of conformity with the essential requirements of the IOD. The applicant can choose whether or not to apply voluntary standards. However, if the applicant chooses not to apply a voluntary standard, he/she has the obligation to prove that the subsystem/IC is in conformity with essential requirements by the use of other defined means of his own choice. The Voluntary Standards or the related other defined means used to demonstrate compliance must be declared in the EC Technical File. |

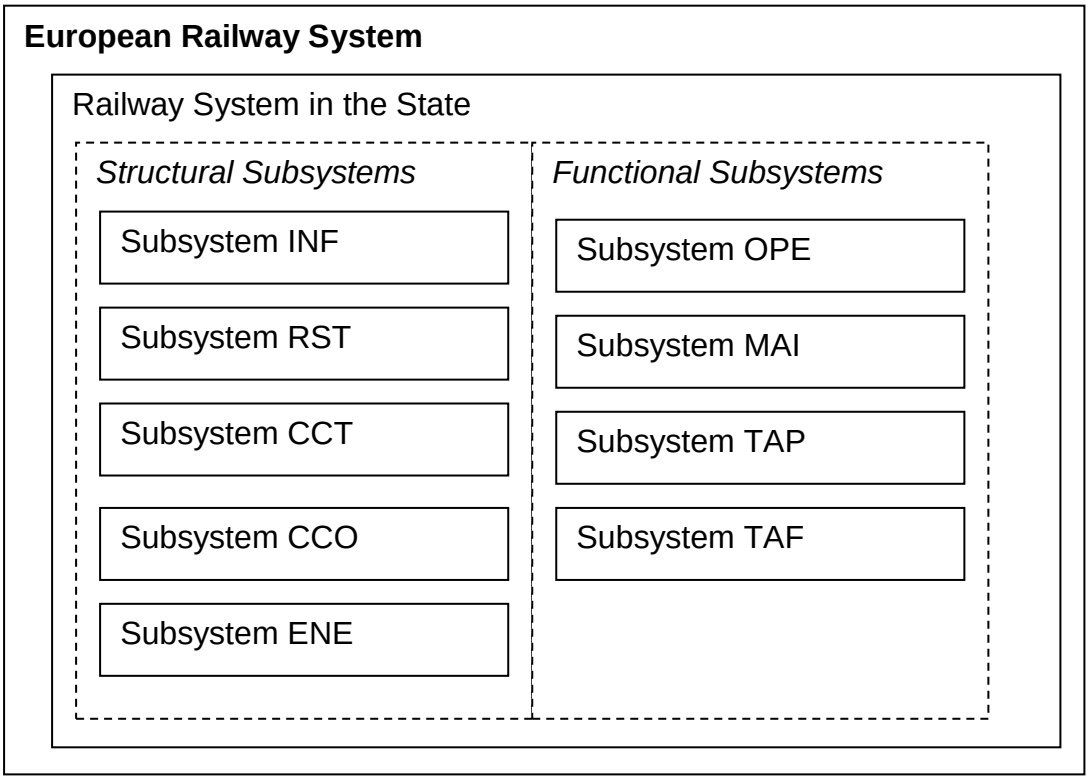
# 3 References

| | |
|---|---|
| TDD | DIRECTIVE 2007/59/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community |
| IOD | DIRECTIVE 2008/57/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 June 2008 on the interoperability of the rail system within the Community + related amendments |
| RSD | DIRECTIVE 2004/49/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004(Railway Safety Directive) + related amendments |
| CSM 352/2009 | COMMISSION REGULATION (EC) no 352/2009 of 24 April 2009 (CSM RE&A) |
| 2007/756/EC | COMMISSION DECISION of 9th November 2007 (2007/756/EC) (National Vehicle Register) + related amendments |
| 2008/110/EC | (amendment to RSD) |
| 2009/131/EC | (amendment to IOD) |
| 2009/965/EC | COMMISSION DECISION of 30th November 2009 (RST reference document) |
| 2010/713/EU | COMMISSION DECISION of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council |
| 2011/18/EU | (amendment to IOD) |
| 2011/107/EU | (amendment to 2007/756/EC) |
| 2011/155/EU | COMMISSION DECISION of 9 March 2011 on the publication and management of the reference document referred to in Article 27(4) of Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community |
| 2011/633/EU | COMMISSION IMPLEMENTING DECISION of 17th September 2011 (2011/633/EU (RINF)) |
| 2011/665/EU | COMMISSION IMPLEMENTING DECISION of 4th October 2011 (2011/665/EU (ERATV)) |
| 2011/217/EU | COMMISSION RECOMMENDATION of 29th March 2011 (APIS Recommendation) |
| RSA 2005 | Railway Safety Act 2005 + related amendments |
| S.I. 419 of 2011 | EUROPEAN COMMUNITIES (INTEROPERABILITY OF THE RAIL SYSTEM) REGULATIONS 2011 (4 August 2011) |
| EU 201/2011 | COMMISSION REGULATION EU no 201/2011 of 1st March 2011 (conformity to authorised type of vehicle) |
| Blue Guide | Guide to the implementation of Directives based on the New Approach and the Global Approach, EC 2000 (can be found on: http://ec.europa.eu/enterprise/policies/single-market-goods/documents/blue-guide/index_en.htm) |
| 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 |
| 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/IEC 17021:2011) |
| ISO 17025 | General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005) |
| ISO 9001 | Quality management systems - Requirements (ISO 9001:2008) |
| **Note:** | References to TSI are not provided here, as they are in constant evolution. Please use search function of ERA homepage to find TSIs (http://www.era.europa.eu/Search/Advanced-Search/Pages/home.aspx) |

# 4 Definitions: Railway System, Subsystems, Parameters, Vehicle

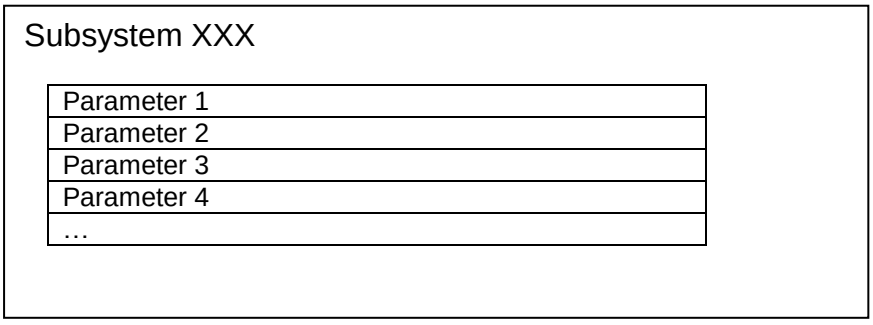
## 4.1 Railway System, Subsystems

Based on European legal provisions, the ‘European Rail System’ and therefore also the ‘Rail System in the State’ have been segmented into a number of predefined ‘Subsystems’. (ref. IOD, Annex II)




## 4.2 Parameters

Subsystems may be further broken down into Parameters.




The EU has only pre-defined a limited number of Parameters yet. See for example list of Parameters for Subsystem RST within 2009/965/EC.

A Parameter may be relevant for the Authorisation for Placing in Service (see below) or not. This is depending on whether the Parameter is safety related or whether legal definitions relate to this Parameter.

- *Example for a Parameter relevant for APIS due to being safety related: Emergency Braking distance of a new type of RST.*
- *Example for a Parameter relevant for APIS due to related legal provisions (in this case TSI PRM): Position of PRM carpark facilities at a new station.*
- *Example for a Parameter **not** relevant for APIS, as it is neither safety related or covered by legal provisions: Position of non-PRM carpark facilities at a new station.*

Where a Parameter is **relevant for APIS**, it is the intention of the RSC to identify this parameter and place it onto a Parameter List relating to RSC guidance on APIS. This shall support a common and equal approach within the State, until the EU provides complete Parameter lists.

The EU regulatory environment for railways is in constant evolution since a number of years. It is therefore possible that new parameters may be added to the RSC listings if new or updated legislation requires this. The Applicant at the start of a new project requiring APIS must consult with the RSC, to ensure the most up to date parameter listings are used by the project in developing the project safety documentation.

The RU/IM promoting the PIS Project must also investigate if due to new design solutions and new operational concepts additional Parameters must be added to the Project related Parameter list.

## 4.3 Vehicle

In addition to the above, the EU has defined the concept of a 'Vehicle'. The Vehicle is composed of all Structural Subsystems – and parameters thereof – which are integrated into a physical Vehicle. (IOD ch.V).

- *A typical case of a Vehicle is that of a locomotive which may consist of Parameters of Subsystem RST and CCO.*

# 5 Definitions: PIS and Variants of APIS

The current and applicable Irish and European legislation provides for a large number of variants relating to the concept of APIS. To give some clarity on the issue, this chapter lists the current existing variants of APIS.

## 5.1 PIS

According to IOD, RSA and RSD, RU/IMs must follow a controlled and regulated process, when Placing in Service (PIS) New or Modified Structural Subsystems.

*Note: Due to the large number of applicable national and European legal provisions, industry standards and associated internal procedures of RU/IMs, the PIS process may be considered complicated and work intensive by non-experts in the field. Experience has shown that this can be easily overcome by three typical professional project management activities:*

- *allocation of trained/ experienced experts in safety management activities,*
- *allocation of trained/ experienced experts in the technology of the relevant Subsystem,*
- *allocation of realistic timeslots for PIS/ APIS activities within the project schedule.*

## 5.2 IOD-APIS

One step of the process leading to PIS is to apply for the Authorisation for Placing in Service (APIS) of such structural Subsystems according to IOD to the RSC as relevant NSA for the Railway System in the State. Only after receiving such APIS, can the RU/IM Place the Structural Subsystem in Service. (IOD 15(1))

Based on legal provisions, an APIS must be applied for each Structural Subsystem separately.

- *Example: A new electrified and signalled Railway Line will typically require three separate APIS, for the Subsystems INF, ENE, CCT.*

It must be noted that the Structural Subsystem is the actual Product, e.g. the 'infrastructure between mileage a and b', a 'locomotive with the serial number xyz'.

This implies that even when a series of identical products shall be Placed in Service, in principle each Product must be subject to individual APIS and PIS.

However, the APIS for all products and Subsystems delivered within a project may be supported by one combined set of project documentation (SP, HR, SC and SCM).

## 5.3 IOD-APIS-TV

For 'Vehicles' the EU has made provisions for a 'simplified process'. (IOD ch. V)

Instead of separate APIS for those Subsystems composing of the Vehicle, an Authorisation for Placing in Service of a Type of Vehicle (APIS-TV) will be granted. (IOD Art 26(1+2))

- For the first Vehicle of a Type, the RSC will grant an Authorisation for Placing in Service of a Type of Vehicle (APIS-TV). The process leading to this is similar to that of IOD-APIS as introduced above.
- For the series production – i.e. Vehicle no2, vehicle no3, etc. – the Applicant may after scrutiny of each Vehicle declare the conformity of that individual Vehicle to the Authorised Type of Vehicle. For each Vehicle a separate 'Declaration of conformity to an Authorised Type of Vehicle' (DCATV) according to EU 201/2011 shall be prepared.
- If a vehicle differs from the Authorised Type, it will be required to apply for a separate IOD-APIS-TV. In such a case it is however expected that the previous evidence documentation can largely be re-used, as typically only for those aspects which are different, new documented evidence must be elaborated.

## 5.4 RSA-APIS-NW/ RSA-APIS-NRS

In order to avoid inconsistencies in the definition and handling of PIS projects, the previously applied concept of Letters of Acceptance of New Works Assessment or New Rolling Stock Assessment (RSA 42+43) will in future be termed:

- RSA-APIS-NW (Authorisation for Placing in Service of New Works according to RSA)
- RSA-APIS-NRS (Authorisation for Placing in Service of New Rolling Stock according to RSA)

The concept of Subsystems and Parameters shall also be applied to RSA-APIS projects.

## 5.5 Scope of APIS

5.5.1 The geographical and technical scope of **RSA-APIS-NW/RSA-APIS-NRS** is the **complete Railway System in the State**(RSA 42+43)., This includs all Subsystems and Parameters. For the avoidance of doubt also those parameters and sub-systems excluded to the scope of IOD-APIS/ IOD-APIS-TV listed in section 5.5.2 are also included.

5.5.2 The geographical and technical scope of **IOD-APIS/ IOD-APIS-TV** is the **European Railway System, with the following exceptions** (SI 419/2011 Reg3):

- metros, trams and other light rail systems,
- networks that are functionally separate from the rest of the rail system and intended only for the operation of local, urban or suburban passenger services, as well as Railway Undertakings operating solely on these networks,
- the electric traction energy supply system of the Dublin suburban passenger service, including alterations to and extension of the existing system,
- privately owned railway infrastructure and vehicles exclusively used on such infrastructure that exist solely for use by the owner for its own freight operations,
- infrastructure and vehicles reserved for a strictly local, historical or touristic use.
- mobile railway infrastructure construction and maintenance equipment (Based on a written application by an Applicant, the RSC may include mobile railway infrastructure construction and maintenance equipment into the scope of the IOD as provided for in IOD Annex I.)

- track access to terminals and main port facilities (including those serving or potentially serving more than one user) (IOD Art1(4))

Where an applicant seeks to Place in Service in the State any Structural Subsystems to which the IOD is applicable, the applicant must apply to the RSC for a combined APIS in order to comply with the requirements of both Irish (RSA) and European (IOD) law.

# 6 Compliance and Risk Management within PIS projects

## 6.1 SMS of RU/IMs

European as well as Irish legal provisions require RU/IMs as duty holders to ensure the safety of their activities. (RSD Art.4(3) in combination with RSD Art.6(3) and RSA Reg.36)

It is a legal obligation that RU/IMs install a structured SMS, have this SMS certified/authorised as suitable for operating safety related railway activities by an NSA and fully comply with this SMS at all times.

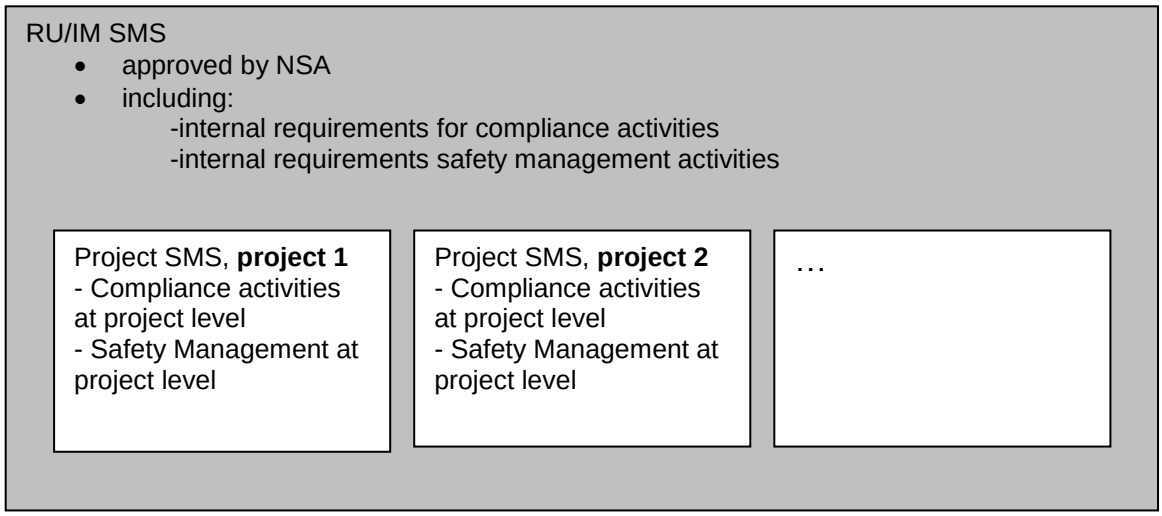
In relation to those activities of an RU/IM which are connected to PIS of New or Altered (Upgraded/Renewed) Subsystems, the RU/IM SMS must ensure that all relevant legal requirements relating to that project are identified and satisfied. These requirements may mainly be derived from RSD, RSA, EU 1158/2010 and EU 1169/2010 and can at large be separated into:

- Compliance activities and
- Safety management activities.

## 6.2 Project SMS

The typical format of managing PIS of New or Altered (Upgraded/Renewed) Subsystems is that of a project.

Any RU/IM project leading to PIS, must establish a Project SMS which mirrors all relevant SMS provisions of the surrounding RU/IM SMS.




The purpose of the Project SMS is to reduce the incidence of safety-related human errors throughout the life-cycle, and thus minimise the residual risk of safety-related systematic faults. It shall also ensure that all activities are in full compliance with all legal requirements.

If the Applicant is not an RU/IM according to RSD, it is highly recommended to seek close co-operation with that RU/IM that is envisaging to place the Subsystem in service (PIS), in order to be able to comply with all requirements of RSA, RSD, IOD and CSM 352/2009.

## 6.3 Requirements for Compliance activities within Project SMS

6.3.1 The Applicant must apply for APIS or APIS-TV to the RSC and receive this APIS **before** a new or modified Subsystem may be Placed in Service. (IOD 15(1))

6.3.2 The Applicant must demonstrate evidence that the new or modified Subsystem has been designed, constructed and installed in such a way as to meet the **'Essential Requirements**' of the IOD and any other applicable Irish and EU legal provisions. (IOD 15(1)+Annex III; Blue Guide; RSA).

6.3.3 The Applicant must demonstrate evidence that the new or modified Subsystem is **technically compatible** with the Railway System in the State. (IOD 15(1); EU 1158/2011 Annex III A)

6.3.4 The Applicant must demonstrate evidence that the new or modified Subsystem will be **safely integrated** into the Rail System in the State accordance with Articles 4(3) and 6(3) of Directive 2004/49/EC. (IOD 15(1))

6.3.5 The Applicant must demonstrate evidence that the new or modified Subsystem will comply, where applicable, with the **relevant TSI provisions on operation and maintenance**. (IOD 15(2))

6.3.6 The RU/IM must demonstrate that as part of the intended PIS all applicable **Technical standards, Operational and Maintenance standards and other Prescriptive Conditions** have been identified, implemented and monitored for compliance. (EU 1158/2011 Annex II L.1+ Annex III A; EU 1169/2011 Annex II L.1)

- *In Summary: The Project SMS must ensure compliance with all applicable requirements derived from TSIs, Mandatory and Voluntary Standards, NTRs and NSRs, IOD, RSD, RSA, CSMs, other New Approach Directives, the Blue Guide, etc.*

6.3.7 The RSC may also need to place conditions on an APIS to ensure that permanent compliance with the above mentioned requirements will be maintained.

6.3.8 In case of any under-fulfilment of these requirements, the RSC may have to deny APIS until full compliance is demonstrated, or may provide conditional APIS based on a plausible corrective action plan submitted by the applicant.

## 6.4 Requirements for Safety Management activities within Project SMS

6.4.1 The Project SMS must ensure that as part of the PIS Project risks are managed in line with the requirements derived from a certified/authorised RU/IM SMS.(RSD 4(3)+6(3)). Like the RU/IM SMS, also the Project SMS must comply with the relevant **requirements for SMS activities** as defined by RSD, RSA, EU 1158/2011, EU 1169/2011, CSM 352/2009. It is further considered to be good industry practice to apply EN50126-1/-2, EN50128, EN50129, EN50159-1/-2 when establishing the project SMS.

6.4.2 The Applicant must demonstrate evidence that the new or modified Subsystem has been designed, constructed and installed in such a way as to meet the **'Essential Requirements**' of the IOD and any other applicable Irish and EU legal provisions which relate to **Safety, protection of Health and Environment**. (IOD 15(1)+Annex III; Blue Guide; RSA).

6.4.3 The Project SMS must include all requirements of CSM 352/2009. The term '**Change**' includes in this context the PIS of new or modified Structural Subsystems. A Change which requires APIS, must according to CSM 352/2009 (whereas (9), third situation) be considered as '**Significant**'.

6.4.4 The Applicant must demonstrate evidence that the new or modified Subsystem will be **safely integrated** into the Rail System in the State and that **safety related provisions for operation and maintenance** have been established in accordance with Articles 4(3) and 6(3) of Directive 2004/49/EC. (IOD 15(1)+(2))

- *In Summary: The RU/IM SMS as well as the Project SMS must ensure effective Risk and Safety Management in accordance with EU 1158/2010, EU 1169/2010, RSD, RSA, IOD 15(1)+(2) and CSM 352/2009.*

## 6.5 Main Activities relating to Compliance and Safety Management

**For any Project the following activities must be performed:**

**General Project Management Activities**

G1 based on technical and geographical project scope the correct type of APIS/ APIS-TV process must be initiated,
G2 a competent project organisation must be established,
G3 all affected Subsystems and Parameters and their Interfaces to the Railway 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 Safety Plan shall establish a competent Project Organisation, life cycle phases for the Project SMS and SMS activities for the various phases of the Project Life Cycle
S2 all relevant Hazards and related Risks must be systematically and comprehensively identified and evaluated,
S3 Safety Requirements must be derived from the initial 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 railway operation,
S8 a hazard record must document close out of hazard and risk related activities,
S9 a project safety case must summarise the project related SMS activities and any application conditions

Upon completion and evidencing of the above mentioned activities an RU/IM may request an APIS for the project scope from the RSC. After receiving an APIS, the RU/IM may than Place the Structural Subsystems covered by the project into operation at their own discretion.

## 6.6 RU/IM duties

RUs and IMs are the primary duty holders to ensure railway safety. (See RSA, RSD)

All other stakeholders defined by EU and Irish legislation or SMS concepts are either:

- contractual partners to them (i.e. Keeper, ECM, Maintenance-Workshop, Supplier) supporting their activities. In this case RU/IMs 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, CSM-AB, NoBo, DeBo, IA) in order to evaluate or supervise the effectiveness of the activities of the RU/IM and their contractors. In principle the RU/IM must define the required scope and suitable level of independence and competence of such Experts/Organisations. This must reflect the level of critically 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. NoBo, DeBo, IA, IPR)

- *Note that independent assessment, supervision activities or RSC activities do not relieve RU/IMs from any of their duties, especially not from ensuring full compliance with law and regulations, performing constant self supervision and contractor supervision, reacting on critical developments, or being the duty holder for railway safety. In essence: the presence or not of such activities should ideally cause no change to the RU/IM activities in practical terms, as the RU/IM must based on internal measures, already ensure full compliance and risk management. (RSA 4(3))*

## 6.7 Relationship between Compliance and Safety Management elements

As introduced in cl. 6.3 above, the compliance requirements are mainly derived from the IOD. The IOD is a Directive in the framework of the "New Approach", and therefore defines compulsory 'Essential Requirements'. These are contained in IOD Annex III:

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

Due to the inherent relationship of the Essential Requirements Safety, Health and Environmental Protection and to a lesser degree Technical Compatibility, Reliability and Availability to any Safety Management activities, it becomes obvious that a large overlap exists between the Compliance activities and the Safety Management activities.

Further the application of SMS activities under CSM 352/2009 must not lead to requirements contradictory to those laid down in the relevant TSIs which are mandatory (CSM 352/2009 Art2(2)).

In order to avoid unnecessary duplication of work and potential contradictions between the need for compliance and the outcome of any safety management activities, it is highly recommended, that both elements are addressed as an integrated Project Safety Management Approach. This guidance assumes that the term Project SMS includes all activities relating to both Compliance and Safety Management.

- *Note: Should an RU/IM wish to retain separation between the two elements, it must ensure that no contradiction between the elements is created. An RU/IM desiring to do so should seek more specific advice from the RSC before and during the PIS project activities.*

# 7 PIS Project SMS Activities

All PIS project related SMS activities must be performed in line with the principles of a certified/authorised RU/IM SMS and the principles of EN 50126-50129 and CSM 352/2009.

## 7.1 Activity G1 – Initiation of APIS process

Depending on the project scope, the applicant must apply for either an RSA-APIS-NW or an RSA-APIS-NRS or a combined RSA-APIS-NW+IOD-APIS or RSA-APIS-NRS+IOD-APIS-TV approach.

The required APIS variant shall be identified within the SP.

Please note, that only an Application Specific Project Safety Case may be used to receive APIS.

## 7.2 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 by EU and Irish regulations.

## 7.3 Activity G3 – identification of all affected Subsystems and their Parameters

### 7.3.1 Sub Systems

RSA and IOD provide different definitions of the structural and functional subsystems of the Rail System. The following table provides clarification on equivalence.

| RSA – Rail System elements | Sub Systems of Rail System (IOD Annex II) |
|---|---|
| New Works | Structural Subsystem Infrastructure (INF) |
| | Structural Subsystem trackside Control Command and Signalling (CCT) |
| | Structural Subsystem Energy (ENE) |
| | Functional Subsystem Operation and Traffic Management (OPE) (requirements relating to INF, CCT, ENE) |
| | Functional Subsystem Maintenance (MAI) (requirements relating to INF, CCT, ENE) |
| | Functional Subsystem Telematics Applications for Passenger and Freight services (TAF/TAP) (requirements relating to INF, CCT, ENE) |
| New Rolling Stock | Structural Subsystem Rolling Stock (RST) |
| | Structural Subsystem onboard Control Command and Signalling (CCO) |
| | Functional Subsystem Operation and Traffic Management (OPE) (requirements relating to RST, CCO) |
| | Functional Subsystem Maintenance (MAI) (requirements relating to RST, CCO) |
| | Functional Subsystem Telematics Applications for Passenger and Freight services (TAF/TAP) (requirements relating to RST, CCO) |

To avoid inconsistencies in approach, the structure of any RSA-APIS application or combined RSA-IOD-APIS application must use the Sub System- structure indicated in the table above. In addition for Vehicles the IOD concept of ‘Vehicle’ is considered to be equivalent to the RSA concept of ‘New Rolling Stock’.

The term ‘new’ relating to RSA includes ‘new’ and ‘modified’ (‘renewed’ or ‘upgraded’) as defined by IOD.

Any APIS application must systematically identify all Subsystems and all Parameters affected by the envisaged project.

### 7.3.2 Parameters

The level of Subsystem is a high level grouping only and must for practical engineering work and for practical SMS activities be further elaborated into Parameters.

The RSC publishes separate guidance containing lists of Parameters, relating to each Subsystem. All Parameters related to the project scope must be identified and managed by the Project SMS.

| Sub Systems of Rail System (IOD Annex II) | RSC Guidance on Parameters |
|---|---|
| Structural Subsystem Infrastructure (INF) | RSC-G-024 |
| Structural Subsystem trackside Control Command and Signalling (CCT) | RSC-G-020 |
| Structural Subsystem Energy (ENE) | RSC-G-026 |
| Functional Subsystem Operation and Traffic Management (OPE) (requirements relating to INF, CCT, ENE) | RSC-G-024 |
| Functional Subsystem Maintenance (MAI) (requirements relating to INF, CCT, ENE) | RSC-G-024 |
| Functional Subsystem Telematics Applications for Passenger and Freight services (TAF/TAP) (requirements relating to INF, CCT, ENE) | RSC-G-TBD |
| Structural Subsystem Rolling Stock (RST) | RSC-G-015 |
| Structural Subsystem onboard Control Command and Signalling (CCO) | RSC-G-020 |
| Functional Subsystem Operation and Traffic Management (OPE) (requirements relating to RST, CCO) | RSC-G-015 |
| Functional Subsystem Maintenance (MAI) (requirements relating to RST, CCO) | RSC-G-015 |
| Functional Subsystem Telematics Applications for Passenger and Freight services (TAF/TAP) (requirements relating to RST, CCO) | RSC-G-TBD |

#### 7.3.3 Interfaces between Parameters or to external parties

Interfaces between Parameters or to external parties must be systematically identified and managed within all Parameters affected by that interface.

#### 7.3.4 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 of a SCM according to RSC-G-009 Annex 4 is considered to satisfy this task.*

## 7.4 Activity C1 – identification of compliance requirements

Based on

- the project scope,
- the required type of APIS,
- the nature of affected Sub Systems,
- the affected Parameters,
- the affected Interfaces,
- the project timeline and schedule and
- any Derogations sought and granted,

all compliance requirements must be identified.

The scrutiny shall cover at least TSIs, Mandatory and Voluntary Standards, NTRs and NSRs. IOD, RSD, RSA, CSMs, New Legislative Framework Regulations, New Approach Directives, Blue Guide, TOs, TDs, RFUs. Due to the constant evolution of the EU legislative requirements, this list cannot be exclusive. The RSC will be able to provide guidance on current compliance requirements.

For each Sub System, 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 RSC list of Parameters. This list should be the starting point of a Project Safety- & Compliance-Matrix (see RSC-G-009 Annex 4).

## 7.5 Activity C2 – Implementation of compliance measures

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

## 7.6 Activity C3 – Evidencing and assessing of compliance measures

Evidence of Compliance must be documented in the format of a Combined 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 of compliance.

Please note that the Combined Technical File must include the EC Technical File and the National Technical File and any further evidence relevant for APIS like those on application of CSM 352/2009.

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

The compliance for all requirements must be assessed and in some cases certified by NoBo, DeBo, ISA, IA, V&V, CSM-AB, self assessment by RU/IM, etc. as far as required. This shall in each case be evidenced by an assessment report, which may need to be accompanied by a Certificate or Declaration in some cases. A Certificate or Declaration without accompanying assessment report will not be acceptable.
Assessment reports, Certificates and Declarations shall be provided within the EC Technical File and National Technical File.

Any assessment process shall follow EN 17020, any auditing of management systems shall follow EN 17021 any testing activities shall follow EN17025 and any Certification Process shall follow EN 45011. Where applicable other requirements shall be respected (e.g. IOD, RFUs).

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 RSC-G-009 Annex 4).

## 7.7 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.

## 7.8 Activity S1 – Safety Plan

The Safety Plan shall describe the Project SMS, project organisation, processes and activities that will be employed in the development of the Project Safety Case. Each project must provide at least one Project Safety Manager. The SP and the Project SMS shall respect the requirements of EN 50126-50129, CSM 352/2009 in co-ordination with those requirements derived from a certified/authorised RU/IM 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

## 7.9 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-work-shops, 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 respect the requirements of EN 50126-50129, CSM 352/2009 in connection with those requirements derived from a certified/authorised RU/IM SMS (see RSC-G-009 Annex 2).

## 7.10 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. (refer to CSM 352/2009 Art2(2))

The Safety Requirements Specification shall be documented. This may be done within Project Safety- & Compliance-Matrix (see RSC-G-009 Annex 4).

## 7.11 Activity S4 – Implementation of Safety Measures

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

## 7.12 Activity S5 – Independent Assessment, Safety Evidence and ongoing Monitoring

The RU/IM must invite competent Experts/Organisations to perform an independent activity of assessment or supervision (e.g. ISA, V&V, NSA, CSM-AB, NoBo, DeBo, IA, self monitoring/auditing by RU/IM) in order evaluate or supervise the effectiveness of the activities of the RU/IM and their contractors /suppliers.

In principle the RU/IM may define the required scope and suitable level of independence of such Experts/Organisations. This shall reflect the level of critically of the activities and current industry standards such as EN 50126-50129. In a number of cases however legal provisions or RSC guidance require certain minimum levels of independence or competence (e.g. NoBo, DeBo, IA, IPR, CSM-AB).

The independent assessment must in all cases be evidenced by an assessment report, which may need to be accompanied by a Certificate or Declaration in some cases. (A Certificate or Declaration alone will not be acceptable.)

Assessment reports, Certificates and Declarations shall be provided within the combined EC Technical File and National Technical File.

Any assessment process shall follow EN 17020, any auditing activities EN 17021 any testing activities shall follow EN17025 and any Certification Process shall follow EN 45011. Where applicable, other requirements shall be respected (e.g. RSA, RSD, IOD, RFUs).

Safety Evidence must be documented in the form of a combined 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.

Please Note that this activity includes the EC Technical File and the National Technical File and further evidence.

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

## 7.13 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.

## 7.14 Activity S7 – Acceptance of residual risk

After implementing and independent assessment of a safety measure the RU/IM must evaluate the residual risk of the related hazard. This must be done in line with the risk acceptance principles of a certified/authorised RU/IM SMS and principles of EN 50126, CSM 352/2009, RSD and RSA. The residual risk must be acceptable for railway operation.

This must be documented within the Hazard Record. (see RSC-G-009 Annex 2)

## 7.15 Activity S8 – Hazard Record

A project related Hazard Record must be prepared in line with the principles of a certified/authorised RU/IM SMS and the principles of EN 50126-50129 and CSM 352/2009.

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 RSC Guidance.

## 7.16 Activity S9 – Project Safety Case

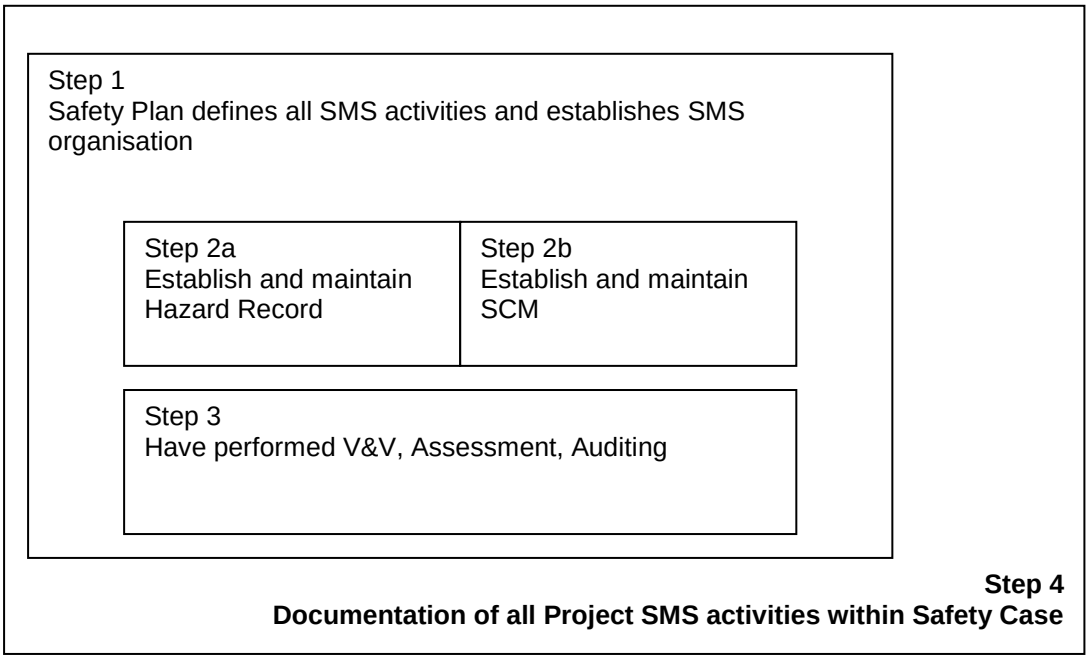
A project related Safety Case must be prepared in line with the principles of a certified/authorised RU/IM SMS and the principles of EN 50126-50129 and CSM 352/2009. The project safety case must summarise the project related SMS activities.

The Project Safety Case may be based on a staggered approach of Generic Product Safety Case, Generic Application Safety Case and Application Specific Project Safety Case. Whether GPSC or GASC are used is usually depending 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 life Railway System in the State an Application Specific Safety Case is required.

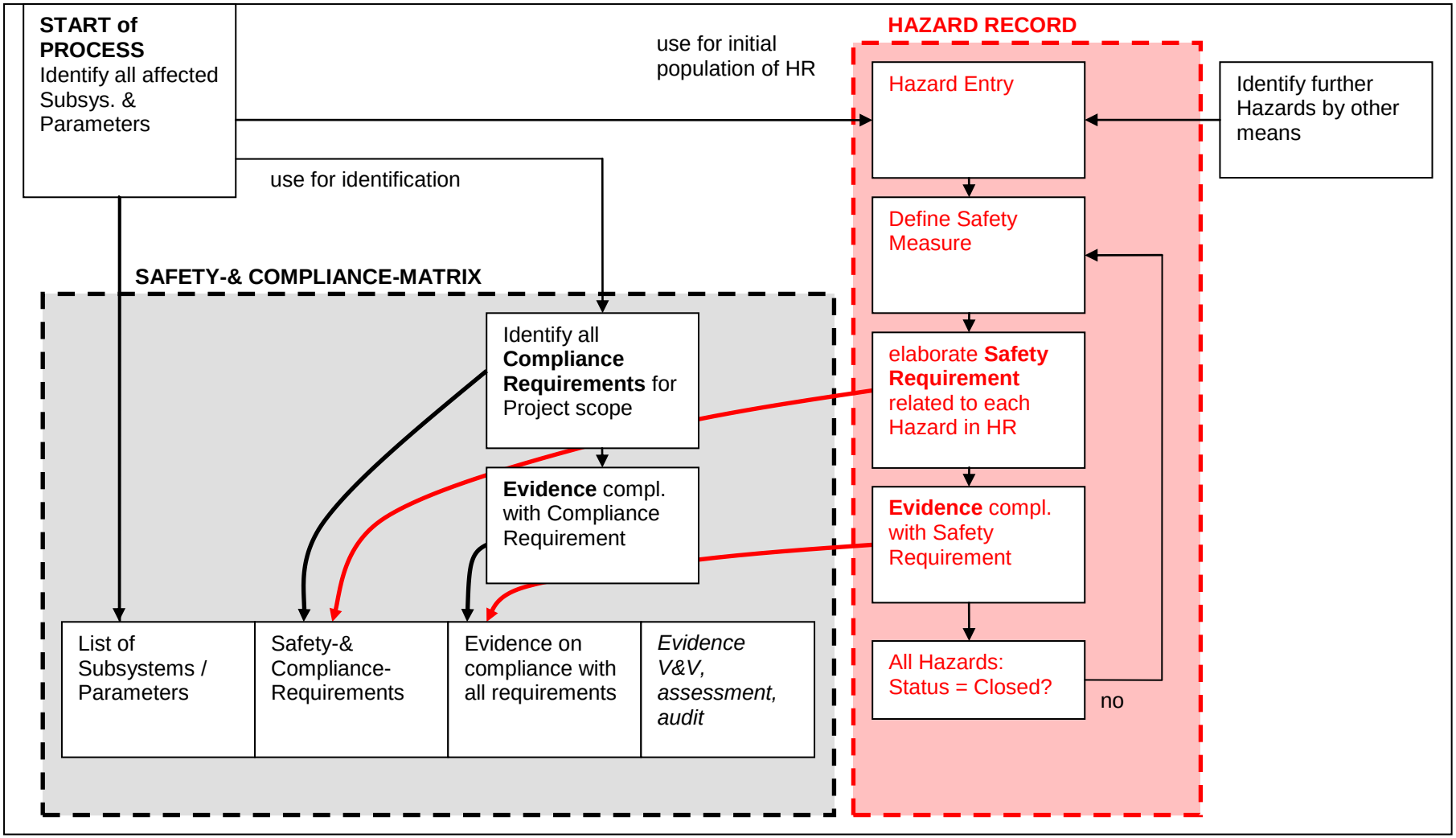
Each Safety Case must comply with RSC-G-009 Annex 3.

RSA Reg.42 and 43 require the preparation of a Safety Assessment of New Works (NWA) or a Safety Assessment of New Rolling Stock (NRSA). An Application Specific Project Safety Case developed in accordance with EN 50126-50129 and CSM 352/2009 and 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.

**Graphical explanation of SMS activities on management of safety – and compliance requirements.**



# 8 Application for APIS

### 8.1 Application for RSA-APIS-NW / RSA-APIS-NRS

The Applicant for this process may be a Railway Undertaking to RSA. This is the appropriate process where there are no applicable IOD requirements for the project for which APIS is sought. Main areas where RSA-APIS-NW or RSA-APIS-NRS is applicable are included in section 5.5.2.

For avoidance of doubt, “Railway Undertaking to RSA” includes organisations who are designated as RU or IM according to RSD.

Each application to the RSC must be provided in writing in English. It must be accompanied by the project specific SMS documentation in English. This must be developed further from stage to stage, covering eventually all stages and the full scope of the project.

Before submitting any application to the RSC, the applicant in execution of his or her duties must perform a self assessment on the correctness and completeness of the application and the related project specific Safety Case documentation. This must be documented and become attached to the submitted documentation.

In such cases as desired by the Applicant or requested by the RSC a conclusive Independent Assessor Report (according to RSA) – covering the full project scope – must accompany each application.

In such cases as desired by the Applicant or requested by the RSC a conclusive IPR on certain aspects of the project scope must accompany an application.

*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 RSC and provide draft submissions of selected content of the Safety Assessment documentation to inform these meetings.*

The project related safety management activities must result in an Application Specific Project Safety Case (and if used additionally, a Generic Product Safety Case and a Generic Product Application Safety Case) according to EN 50126- 50129.

In order to establish a common national rule in relation to risk evaluation, risk assessment and risk acceptability criteria, the respective procedures and requirements of CSM 352/2009 shall be used when developing a Project Safety Case for RSA-APIS.

If the applicant is obliged to maintain a certified/authorised SMS for Railway Operation (or ‘Safety Case’ for Railway Operation according to RSA) the relevant provisions of that SMS must also be complied with. Documented evidenced must be available in this regard.

The Application must be provided to the RSC in a staged approach as indicated in the table overleaf:

**Table of Stages relating to Application for RSA-APIS-NW / RSA-APIS-NRSRSA-APIS**

| Stage | NWA-Application | NRSA-Application | Typical activities at project level | Documents to be submitted |
|---|---|---|---|---|
| 1 Concept | NWA Application for Concept Stage | NRSA Application for Concept Stage | After performing general concept studies or feasibility studies and prior to requesting tenders. | - SP for Concept Stage |
| 2 Preliminary Design | (Optional, not mandatory for NWA: NWA Application for Preliminary Design Stage) | NRSA Application for Preliminary Design Stage | After evaluation of tenders and preliminary decision on functional and technical design and prior to awarding a contract for execution of any work. | - SP<br>- HR<br>- SCM |
| 3 Overall (detailed) Design | NWA Application for Overall Design Stage | NRSA Application for Overall Design Stage | After awarding a contract for execution of work, after detailed overall design has been elaborated and prior to production/ building. | - SP<br>- HR<br>- SCM |
| 4 Testing | NWA Application for Testing Stage<br><br>(if applicable) | NRSA Application for Testing Stage | 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<br>- HR<br>- SCM<br>- ASPSC for Testing Stage<br>- CSM-AB Report<br>- IA (to RSA) Report (if applicable)<br>- IPR report (if applicable) |
| 5 Interim Operation | (Optional, not mandatory for NWA: NWA Application for Interim Operation Stage) | (Optional, not mandatory for NRSA: NRSA Application for Interim Operation Stage) | 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<br>- HR<br>- SCM<br>- ASPSC for Interim Operation<br>- CSM-AB Report<br>- IA (to RSA) Report (if applicable)<br>- IPR report (if applicable) |
| 6 Operation | NWA Application for Operation Stage | NRSA Application for Operation Stage | After full completion of project specific safety assessment activities and prior to operation. | - SP<br>- HR<br>- SCM<br>- ASPSC<br>- CSM-AB Report<br>- IA (to RSA) Report (if applicable)<br>- IPR report (if applicable) |

### 8.2 Combined RSA-IOD-APIS

This is the appropriate process where there are any applicable IOD requirements for the project for which APIS is sought.

As part of assessing an Application for APIS the RSC will have to ensure that the requirements of 2008/57/EC Art 15 (1) and (2) are satisfied. These stipulate that subsystems may be authorised for placing in service only if they are designed, constructed and installed in such a way as to meet the essential requirements concerning them in relation to technical compatibility, safe integration into the Railway System and provisions for operations and maintenance. In particular, the RSC will need to evaluate before granting APIS:

- the technical compatibility of the change affected sub systems with the railway system into which they are being integrated (considering related TSI, NSR, NTR provisions, EC Declaration of Verification and National Declaration of Verification, Technical File and National Technical File, etc.),

- the safe integration of these subsystems in accordance with RSD Articles 4(3) and 6(3). These require the application of the related RU/IM SMS procedures and the CSM 352/2009 procedures to be performed by the RU/IM.

- That the subsystem complies, where applicable, with the relevant TSI provisions on operation and maintenance. This also requires the application of the RU/IM SMS procedures and the CSM 352/2009 procedures to be performed by the RU/IM.

The assessment will only be possible, if the applicant provides the related evidence to the RSC, i.e. EC Declaration of Verification and National Declaration of Verification, attached Technical Files and Project Safety Case resulting from the application of SMS and CSM 352/2009 documentation by the RU/IM envisaging PIS.

Each application must be provided to the RSC in writing in English. An application must be accompanied by the above mentioned documentation resulting from the application of IOD, RSA, RSD, RU/IM SMS and CSM 352/2009.

If one or more ISVs are prepared as part of the EC Certification, these may be used in the application for stages 4 and 5 as appropriate. An ISV is not sufficient to gain stage 6 APIS, for which an EC Certificate must be provided. As defined by IOD and associated legislation and guidance, an EC Certificate may refer to previously prepared ISVs. If this is used, all such ISVs become integral part of the EC Certification.

Before submitting an application to the RSC, the applicant in execution of his or her duties according to IOD in combination with SI 419/2011, RSD and CSM 352/2009 must perform a self assessment on the correctness and completeness of the application and the related Safety Case documentation. This must be documented and become attached to the submitted documentation.

This Process will require that various project aspects are submitted for assessment to a NoBo or a DeBo which has been designated for this purpose by the Republic of Ireland.

*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 RSC and provide draft submissions of selected content from the Risk Assessment documentation in order to inform these discussions.*

**National Rule: When an Applicant is obliged to apply for an RSA-APIS in combination with an IOD-APIS, the Applicant shall prepare an integrated approach which complies with the requirements relating to both aspects.**

The Application must be provided to the RSC in a staged approach as indicated in the table overleaf:

**Table of Stages relating to Application for Combined RSA-IOD-APIS**

| Stage | Application for APIS | Note | typical activities at project level | Documents to be submitted |
|---|---|---|---|---|
| 1 Concept | Application for Concept Stage | | After performing general concept studies or feasibility studies and prior to requesting tenders. | - SP for Concept Stage |
| 2 Preliminary Design | Application for Preliminary Design Stage | | After evaluation of tenders and preliminary decision on functional and technical design and prior to awarding a contract for execution of any work. | - SP<br>- HR<br>- SCM |
| 3 Overall (detailed) Design | Application for Overall Design Stage | | After awarding a contract for execution of work, after detailed overall design has been elaborated and prior to production/ building. | - SP<br>- HR<br>- SCM |
| 4 Testing | Application for Interim APIS for Testing<br><br>(if applicable) | APIS will in such cases be limited to the national Railway System | Prior to any Testing in the live Railway System. | - SP<br>- HR<br>- SCM<br>- ASPSC for Testing Stage<br>- CSM-AB Report<br>- EC Declaration of Verification<br>- National Declaration of Verification<br>- EC Certification as far as available<br>- National Certification as far as available<br>- Combined Technical File<br>- IA (to RSA) Report (if applicable)<br>- IPR report (if applicable) |
| 5 Interim Operation | (Optional, not mandatory: Application for APIS for Interim Operation Stage) | APIS will in such cases be limited to the national Railway System | After principal completion of project specific assessment activities (incl. final testing), prior to full close out of open issues. | - SP<br>- HR<br>- SCM<br>- ASPSC for Interim Operation<br>- CSM-AB Report<br>- EC Declaration of Verification<br>- National Declaration of Verification<br>- EC Certification as far as available<br>- National Certification as far as available<br>- Combined Technical File<br>- IA (to RSA) Report<br>- IPR report |
| 6 Operation | Application for APIS | | After full completion of project specific assessment activities as required by national and EU legal provisions | - SP<br>- HR<br>- SCM<br>- ASPSC<br>- CSM-AB Report<br>- EC Declaration of Verification<br>- National Declaration of Verification,<br>- EC Certification<br>- National Certification<br>- Combined Technical File<br>- IA (to RSA) Report (if applicable)<br>- IPR report (if applicable) |

# 9 RSC Assessment & APIS

Upon receipt of a complete and valid application for a stage, the RSC will assess the Application for plausibility and completeness. In doing so, the RSC must consider whether the applicant has demonstrated that the requirements of IOD, RSD, CSM, RSA. (especially IOD 15(1+2), RSD 4(3)+6(3), CSM 352/2009, RSA 42+43) have been complied with.

This will typically be performed by spot-checking of the submitted documentation. If this does not permit a conclusive judgement, the RSC may enlarge the spot-check, request more or updated documentation or may perform audits on the SMS which has been employed for the project.

If it is not possible for the RSC by these activities, to reach the understanding that the applicant has provided a complete and valid application, the RSC must render the submitted application inadequate and the RSC will hand back the application documents to the applicant.

The same applies, if the application includes falsified evidence. In that case the RSC may also be required to take legal action.

If it is possible for the RSC to reach the understanding that the applicant has provided a complete and valid submission, the RSC will issue a related APIS with or without associated conditions.

# 10 Further Clarification

Further clarification on these Guidelines and the APIS processes to IOD and RSA can be sought from the RSC.