



CRR-G-009-G

Guidance on

**Application for Authorisation and
Application for Acceptance**

**for
Heavy Rail
Fixed Installations and Vehicles**

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Contents

1	Introduction	3
2	Glossary and Definitions	5
2.1	Glossary	5
2.2	Definitions.....	8
3	References.....	12
4	Authorisation Cases.....	15
4.1	General Information on all Authorisation Cases	15
4.2	Authorisation Cases related to the European Interoperability Directive (IOD) for Fixed Installations.....	16
4.3	Authorisation Cases related to the European Interoperability Directive (IOD) for Vehicles	17
4.4	Authorisation Cases related to the Irish Railway Safety Act (RSA) for Fixed Installations	20
4.5	Authorisation Cases related to the Irish Railway Safety Act (RSA) for a Series of Vehicles	21
5	Compliance and Safety Management within authorisation projects.....	22
5.1	SMS of Applicants	22
5.2	Project SMS.....	22
5.3	Requirements for Compliance activities within Project SMS	23
5.4	Requirements for Safety Management activities within Project SMS	24
5.5	Main Activities relating to Compliance and Safety Management	24
5.6	RU/IM duties.....	25
5.7	Relationship between Compliance Management activities and Safety Management activities.....	26
5.8	Activity G1 – Initiation of Authorisation/Acceptance process.....	26
5.9	Activity G2 – Establishment of competent project organisation	26
5.10	Activity G3 – identification of all affected Subsystems and their Parameters	27
5.11	Activity C1 – identification of compliance requirements	28
5.12	Activity C2 – Implementation of compliance measures.....	28
5.13	Activity C3 – compliance measures must be verified and validated, independently assessed, evidenced and monitored.....	28
5.14	Activity C4 - Corrective action on non-compliance.....	29
5.15	Activity S1 – Safety Plan	29
5.16	Activity S2 – PHA, Hazard Record, Risk Evaluation	29
5.17	Activity S3 – Safety Requirements Specification	29
5.18	Activity S4 – Implementation of Safety Measures.....	30
5.19	Activity S5 – Independent Assessment, Safety Evidence and ongoing Monitoring	30
5.20	Activity S6 - Corrective action on non-compliance.....	31
5.21	Activity S7 – Acceptance of residual risk	31
5.22	Activity S8 – Hazard Record.....	31
5.23	Activity S9 – Project Safety Case	31
6	Non-Application of TSIs and NRs	34
6.1	Non-Application of TSIs	34
6.2	Non-Application of IE NRs	34
7	Applying for Authorisation Cases.....	36
7.1	General Requirements for any Authorisation Case	36
7.2	Specific Requirements for Applications for Fixed Installations	38
7.3	Specific Requirements for Applications for Vehicles	43
8	CRR Review of Applications	48
9	Complaints and Appeals	50
10	Further Clarification.....	50

1 Introduction

This document gives guidance and explanation on the European and the Irish legal requirements for authorisation of heavy rail equipment/ acceptance of an Application Specific Project Safety Case for such equipment.

This guideline is primarily based on the requirements of the Railway Safety Act 2005 (as amended), the Interoperability Directive (EU) 2016/797 (as amended) and Commission Implementing Regulation (EU) 2018/545. As far as relevant, also the Railway Safety Directive (EU) 2016/798 (as amended) has been considered. This guideline gives effect to IOD Art 18(3) and (EU) 2018/545 7(6). As a general principle: both sets of legislation are applicable in Ireland, but in any scope where the European legislation applies in most cases the national Irish legislation ceases to be applicable in parts or fully. This avoids duplication of authorisation activities.

Note: European and Irish legislation use different vocabulary in relation to authorisation/acceptance. The term authorisation is used in European context and the term acceptance is used in Irish context.

The following authorisation cases are described in this document:

Authorisation Cases related to the European Interoperability Directive (IOD):

for Fixed Installations:

- **Authorisation to Place in Service (APIS) of Fixed Installations** (IOD Art 18);

for Vehicle Types (with an associated combination of Variant(s)+Version(s)+Area(s) of use):

- **First Authorisation** for Placing on the Market (APOM) of a Vehicle Type for a first associated combination of Variant(s)+Version(s)+Area(s) of use (IOD Art 24(1) with IOD Art 21 with (EU) 2018/545 14(1.a));
- **Renewal** of Authorisation for Placing on the Market (APOM) of an **already authorised Vehicle Type** with the same associated combination of Variant(s)+Version(s)+Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.b));
- **New Authorisation** for Placing on the Market (APOM) of an **already authorised Vehicle Type** with a changed associated combination of Variant(s)+Version(s)+Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.d))
- **Extended Area of Use Authorisation** for Placing on the Market (APOM) of an **already authorised Vehicle Type** with the same associated combination of Variant(s)+Version(s) and extended associated Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.c))
- **Temporary Conditional First Authorisation** for Placing on the Market (APOM) of a Vehicle Type for a first associated combination of Variant(s)+Version(s)+Area(s) of use (IOD Art 24(1) with IOD Art 21 with (EU) 2018/545 14(1.a) **and** with (EU) 2018/545 46(6));
- **Temporary Conditional New Authorisation** for Placing on the Market (APOM) of an **already authorised Vehicle Type** with a changed associated combination of Variant(s)+Version(s)+Area(s) of use (IOD 24(3) with IOD Art 21 with (EU) 2018/545 14(1.d) **and** with (EU) 2018/545 46(6))
- **Temporary Conditional Extended Area of Use Authorisation** for Placing on the Market (APOM) of an **already authorised Vehicle Type** with the same associated combination of Variant(s)+Version(s) and extended associated Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.c) **and** with (EU) 2018/545 46(6))

Note: The above is aimed at a Vehicle Type authorisation. Each physical Vehicle requires one of the below authorisations in addition.

for individual Vehicles in conformity to an authorised Vehicle Type (with an associated combination of Variant(s)+Version(s)+Area(s) of use):

- **Temporary Conditional Authorisation** in conformity to an authorised Vehicle Type for Placing on the Market (APOM) of a **Vehicle** with its associated combination of Variant+Version+Area(s) of use (IOD Art 25(1) with IOD Art 21 with (EU) 2018/545 14(1.e) **and** with (EU) 2018/545 46(6))

- **Authorisation** in conformity to an authorised Vehicle Type for Placing on the Market (APOM) of a **Vehicle** with its associated combination of Variant+Version+Area(s) of use (IOD Art 25(1) with IOD Art 21 with (EU) 2018/545 14(1.e))

Other options for individual Vehicle Authorisation for a first Vehicle of Type+Variant:

- **First Authorisation** for Placing on the Market (APOM) of a Vehicle for a first associated combination of Type+Variant(s)+Version(s)+Area(s) of use (IOD Art 24(1) with IOD Art 21 with (EU) 2018/545 14(1.a));
- **New Authorisation** for Placing on the Market (APOM) of an **already authorised Vehicle** with a changed associated combination of Type+Variant(s)+Version(s)+Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.d))
- **Extended Area of Use Authorisation** for Placing on the Market (APOM) of an **already authorised Vehicle** with the same associated combination of Type+Variant(s)+Version(s) and extended associated Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.c))
- **Temporary Conditional First Authorisation** for Placing on the Market (APOM) of a Vehicle for a first associated combination of Type+Variant(s)+Version(s)+Area(s) of use (IOD Art 24(1) with IOD Art 21 with (EU) 2018/545 14(1.a) **and** with (EU) 2018/545 46(6));
- **Temporary Conditional New Authorisation** for Placing on the Market (APOM) of an **already authorised Vehicle** with a changed associated combination of Type+Variant(s)+Version(s)+Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.d) **and** with (EU) 2018/545 46(6))
- **Temporary Conditional Extended Area of Use Authorisation** for Placing on the Market (APOM) of an **already authorised Vehicle** with the same associated combination of Type+Variant(s)+Version(s) and extended associated Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.c) **and** with (EU) 2018/545 46(6))

Authorisation Cases related to the Irish Railway Safety Act (RSA)

for Fixed Installations:

- **Acceptance of an ASPSC for Commencement of construction, installation or assembly** of Fixed Installations (RSA 42 (1)+(8));
- **Temporary Acceptance of an ASPSC** for conditional placing in **test service of Fixed Installations** (RSA 42 (1)+(5))
- **Temporary Acceptance of an ASPSC** for conditional placing in service of **Fixed Installations** (RSA 42 (1)+(5))
- **Acceptance of an ASPSC** for placing in service of **Fixed Installations** (RSA 42 (1)+(5))

for a Series of Vehicles:

- **Temporary Acceptance of an ASPSC** for conditional placing in **test service of Series of Vehicles** with the associated Type+Variant(s)+Version(s)+Area(s) of use (RSA 43 (1)+(7))
- **Acceptance of an ASPSC** for placing in service of **Series of Vehicles** with the associated Type+Variant(s)+Version(s)+Area(s) of use (RSA 43 (1)+(7))

This guideline in conjunction with its annexes also describes an approach for

- the establishment of a project level safety & compliance management system (SCMS),
- the establishment of a project level Application Specific Safety Case (ASPSC), and
- the generation of documented evidence to demonstrate the safety level of the project:
 - a project safety & compliance management plan,
 - a hazard record,
 - a safety & compliance matrix and
 - a safety case & demonstration of compliance.

Note: Applicants may choose an alternative approach for the SCMS but must demonstrate in that case, that the alternative approach will result in conformance with the applicable requirements in a systematic and assessable format.

2 Glossary and Definitions

2.1 Glossary

Term / Abbreviation	Meaning
APIS	Authorisation for Placing in Service Note: now only applies to authorisations of fixed installations under IOD.
ANMOC	Acceptable National Means of Compliance, refer to IOD Art2(34)
APOM	Authorisation for Placing on the Market
Applicant	The organisation applying for APIS or APOM
Area of Use	A network or networks within a Member State or a group of Member States in which a vehicle is intended to be used. <i>Note: At the time of drafting this guideline the name of the one Area of Use in the State is the 'Republic of Ireland Railway Network Area of Use.'</i>
ASPSC	Application Specific Project Safety Case
Authorising Entity	Entity that issues a Vehicle related authorisation under IOD (may be ERA or the CRR)
Blue Guide	The 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01)
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
AsBo	Assessment Body to CSM 402/2013, providing CSM-RE Safety Assessment Report, providing Report on conformity of Requirements Capture Process with (EU) 2018/545
DeBo	Designated Body
EC	European Commission
EC Technical File	Documented evidence demonstrating compliance with any applicable TSI requirement
ENE	Energy
Essential Requirements	Refer to IOD Annex III
Fixed Installation	Composed of the structural railway subsystems: CCT, ENE, INF
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). The IA shall be accredited under ISO 17020 Typ A as independent inspection body for those technical scopes which are contained in an authorisation project. Where in an authorisation project the CRR requires the appointment of an IA (or where an Applicant considers the introduction beneficial), the Applicant shall propose an IA to the CRR. The CRR shall determine if the IA is acceptable for that authorisation project.
IM	Authorised Infrastructure Manager to RSD
INF	Infrastructure
IOD	Directive (EU) 2016/797 (recast of Directive 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.

Term / Abbreviation	Meaning
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.
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
NR	National Rule
OSS	One-Stop-Shop
OPE	Functional Subsystem Operation and traffic management
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
Proposer	As defined CSM 402/2013 Art 3(11)
Rail System	See section 2.2
Railway Undertaking	as defined in the IOD
RFU	Recommendation for Use regarding TSIs, issued by NB RAIL the Coordination group of Notified Bodies. see NB-Rail homepage (http://circa.europa.eu/irc/nbg/nbrail/info/data/en/information/nbrail/RFU.htm)
RSA	Irish Railway Safety Act 2005, including Amendments
RSC	Railway Safety Commission (Irish NSA)
RSD	Directive (EU) 2016/798 (recast of Directive 2004/49/EC) Railway Safety Directive, including Amendments
RST	Rolling Stock
RO	Railway Organisation (Please refer to SI 476 2020 6 (2))
RU	Railway Undertaking
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.
Vehicle	Composed of the structural railway Subsystems: CCO, RST Refer also to section 2.2.

Term / Abbreviation	Meaning
Voluntary Standard	EC vocabulary: Standard or part thereof proposed by EC by ERA (in the form of lists 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 Alternative Solutions defined of his/her own choice. The Voluntary Standards or the related Alternative Solutions used to demonstrate compliance must be declared in the EC Technical File.

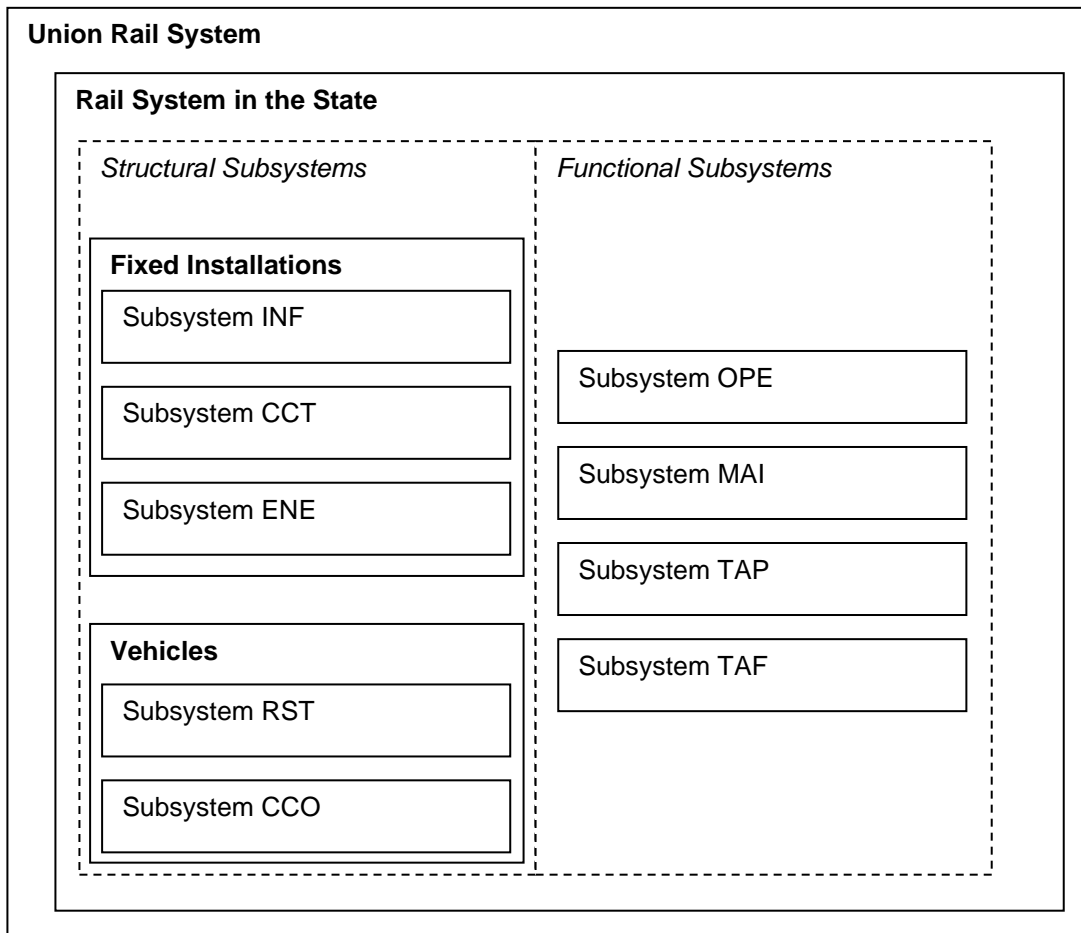
2.2 Definitions

2.2.1 Union Rail System

means the combination of the areas listed in IOD Annex II. The Union Rail System is composed of defined subsystems.

2.2.2 Subsystems

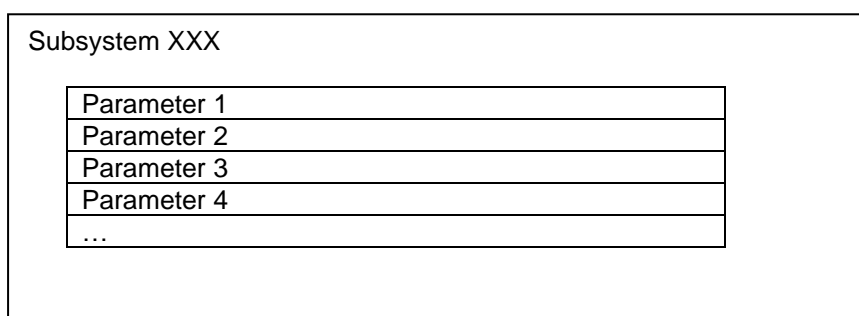
means the structural or functional parts of the Union rail system, as set out in IOD Annex II. The subsystems comprising the Union Rail System are broken down as follows:



It must be noted that during an authorisation project the Structural Subsystem is the actual Product, e.g. the 'infrastructure between mile-points a and b', a 'locomotive with the serial number xyz'.

2.2.3 Parameters

All sub-systems are composed of parameters.



The CRR provides lists of parameters for Subsystems in

- CRR-G-015 on RST and CCO with associated aspects of OPE, MAI, TAF, TAP,
- CRR-G-020 on CCT with associated aspects of OPE, MAI, TAF, TAP,
- CRR-G-024 on INF with associated aspects of OPE, MAI, TAF, TAP and
- CRR-G-026 on ENE with associated aspects of OPE, MAI, TAF, TAP.

Within a given project activity, any Parameter may be relevant for an Authorisation or not, depending on whether it is part of the Change (changed itself or impacted by a change of other Parameters).

Even though the aforementioned lists of parameters are intended to be as complete as possible, they may not necessarily contain every conceivable solution. Any Applicant must also investigate if due to new design solutions and new organisational/ operational concepts additional Parameters must be added to the project specific list of Parameters.

2.2.4 Change

Any modification of a subsystem of the heavy rail Union Rail System is according to CSM 402/2013 defined as a 'Change'. Changes include, but are not limited to, the addition of new elements or the modification of existing elements (the latter may be a renewal, upgrade, partial removal or replacement, etc. of an existing element).

The Change must in all cases include the actually modified elements and every impact of the modified elements on any non-modified elements.

For Changes a large set of requirements apply (e.g. legal, contractual,...). These requirements may equally aim at:

1. equipment
2. properties
3. methods/ processes to be applied by the stakeholders during design/ production/ validation/ authorisation/ operation/ maintenance/ disposal.

In all cases it is the duty of a Proposer for a Change to identify, apply and validate conformance with all these requirements. In most cases the Proposer will for the execution of this duty co-operate with suppliers, contractual partners, operators, maintainers, competent external experts, independent validation experts, etc. as necessary to achieve conformity.

In the case of Changes to existing Vehicles, the requirements of (EU) 2018/545 Art15 also apply. Depending on the extent of a Change to Vehicle, a new Vehicle Type, a new Variant and/or a new Version are created.

Note: Not every Change requires an authorisation.

It is the duty of the proposer for a Change to determine whether the extent of a Change requires an authorisation or not. Additionality of smaller Changes since the last authorisation must be considered.

According to the related legal requirements, the proposer must retain the documentation on its decision and on the internal safety management activities for the Change. This may be inspected through CRR supervision activities at a later time and if found to be incomplete or implausible will lead to enforcement actions.

Change proposers may wish to refer to RSA2005, (EU) 2018/545, RSD, CSM402 for more detailed background on this topic.

2.2.5 Vehicle

'vehicle' means a railway vehicle suitable for circulation on wheels on railway lines, with or without traction; a vehicle is composed of one or more structural and functional subsystems; (Article 2 of Directive (EU) 2016/797)

A Vehicle consists of the subsystems RST and CCO.

The individual vehicles within the Union Rail System can be individually identified by their European or Third Country Vehicle Number. Each individual Vehicle is usually associated to one Type+Variant+Version+Area of Use. Where an adaptable vehicle design is present (e.g. at Multi Purpose OTMs) several Variants and/ or Versions may be possible. Where a vehicle design has demonstrated the necessary conformity, it may have several Areas of Use.

2.2.6 Vehicle Type

A vehicle type defining the basic design characteristics of the vehicle as covered by a type or design examination certificate described in the relevant verification module'. (Article 2 of Directive (EU) 2016/797)

A Vehicle Type is further defined by its associated Variant(s)+Version(s)+Area(s) of use. The concept of vehicle type applies to the vehicle design as a whole, not to a specific subsystem. A vehicle may contain just the subsystem RST (e.g. a freight wagon) or the subsystems RST and CCO (e.g. a locomotive with radio and on-board signalling system). In the latter case, the characteristics of a vehicle type are the combination of the characteristics of its subsystems.

For any given vehicle type there can only be one **holder of the vehicle type authorisation**.

Only that holder has the right to define additional Versions to an authorised Vehicle Type.

Only that holder has the right to apply for authorisation of an individual Vehicle based on conformity to that authorised Vehicle Type. The holder of the vehicle type authorisation is responsible for the configuration management for the vehicle type.

However, two series of the same identical design may have different holders of the authorisations to place their vehicles (of their series) on the market which necessitates them to each apply for their own authorisation of Vehicle Type. The two series may, as requested by the applicants, be authorised with two different Vehicle Type designations, or with the same Vehicle Type designation, but two different Variant designations.

2.2.7 Variant of a Vehicle Type

'Variant' of a vehicle type is defined as 'an option for the configuration of a vehicle type that is established during a first authorisation of the vehicle type in accordance with Article 24(1) or changes within an existing vehicle type during its life cycle that require a new authorisation of the vehicle type in accordance with Articles 24(1) and 21(12) of Directive (EU) 2016/797'. (Article 2 of Regulation (EU) 2018/545)

Several Variants may be applied for during one authorisation project.

Where no Variant designation is defined in an application, the CRR will assign a Variant designation, e.g. "01".

In order to add a new Variant to an already authorised Vehicle Type, an authorisation is required.

A Variant may have been caused by a:

- Change of the design (e.g. compatibility to a different predefined formation),
- Change of the realisation method (i.e. manufactured under different manufacturing processes and quality management systems)
- Change of the applicant,
- Change of the Areas of use.

Note: As subsequently conformity to Vehicle Type may be applied for any of the authorised combinations of Vehicle Type+Variant, this concept may be used to establish a set of options for configuration by the applicant.

2.2.8 Version of a Vehicle Type

'Version' of a vehicle type is defined as 'an option for the configuration of a vehicle type or type variant or changes within an existing type or type variant during its life cycle, created to reflect changes to the basic design characteristics that do not require a new authorisation of the vehicle type in accordance with Articles 24(1) and 21(12) of Directive (EU) 2016/797. (Article 2 of Regulation (EU) 2018/545)

One or several Versions may be presented with an application for authorisation. These Versions will only be used to document a baseline on the Vehicle Type or individual Vehicle authorisation and do not limit the subsequent introduction of additional Versions as Changes under the full internal control of the holder of the Vehicle Type Authorisation.

Where no Version designation is defined in an application, the CRR will assign a Version designation, e.g. "01".

Versions may also be introduced at any time as a Change to already authorised Vehicle Type+Variant(s). The holder of the Vehicle Type Authorisation for a proposed Version Change must check, whether the intended Change does through its scope/extent/effects require by European or Irish legislation the application for an authorisation as a different Type or Variant.

Only if such an authorisation is not required, the Holder of the Vehicle Type Authorisation for a proposed Version Change may proceed to identify, apply and validate requirements for the Change under its internal control and may associate the Variant under its own responsibility to the authorised Vehicle Type in the Technical Documentation associated with the EC Declaration.

Otherwise the intended Version has become a new Type or Variant and accordingly an authorisation must be applied for.

2.2.9 Series of Vehicles

A number of fully identical vehicles.

Vehicles of the same type but different variants are not a series because they are not identical. Vehicles of the same type but different versions are not a series because they are not identical.

It follows therefore that a series of vehicles must have been produced to the same design type (including a specific version/variant combination) in the same manufacturing process.

2.2.10 Differences between APIS/ APOM/ PIS/ Acceptance

<p>Step1: Design, Production, Validation and Independent Assessment of a Structural Subsystem (including the internal safe and compliant integration of that Structural Subsystem)</p>	<p>Step2: <u>Placing in Service (PIS):</u> Safe and compliant integration of a Structural Subsystem with neighboring Structural Subsystems and associated Functional Subsystems (incl. the compatibility within an Area of use)</p>	<p>Step3: Safe and compliant operation (including maintenance) of a Structural Subsystem and associated Functional Subsystems while interfacing with neighbouring Structural Subsystems</p>
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APOM to IOD requires an Applicant to gain Authorisation for the Activities of Step1 before Placing a Subsystem in a Vehicle on the Market.

Note: Steps2 & 3 for Subsystems of Vehicles are under EU legislation required to be performed under RU internal self-control while applying its internal SMS (refer to RSD).

APIS to IOD requires an Applicant, who in this context shall be a RU in the State, to gain Authorisation for the Activities of Steps 1 and 2 before Placing a Fixed Installation in Service.

Note: Step 3 for Subsystems of Fixed Installations is under EU legislation required to be performed under IM internal self-control while applying its internal SMS (refer to RSD).

Acceptance to RSA requires an Applicant to seek Acceptance for an associated ASPSC that covers the activities of Steps 1 and 2. The Applicant shall in this context for

- Subsystems in a Vehicle be a RU that has been certified for the intended form of operation on the Rail System of the State (e.g. testing, passenger, freight),
- Subsystems in a Fixed Installation be an authorised IM in the State.

Note: Step 3 for Subsystems of Fixed Installations is required under EU legislation to be performed by the RU or IM through self-assessment while applying its internal SMS (refer to RSD).

3 References

(EC) 1907/2006	REGULATION (EC) NO 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
2007/59/EC	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
2007/756/EC	COMMISSION DECISION of 9 November 2007 adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC (2007/756/EC)
768/2008/EC	DECISION No 768/2008/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC
2008/110/EC	Directive 2008/110/EC of the European Parliament and of the Council of 16 December 2008 amending Directive 2004/49/EC on safety on the Community's railways
2009/131/EC	Commission Directive 2009/131/EC of 16 October 2009 amending Annex VII to Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community
2009/965/EC	Commission Decision of 30 November 2009 on 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
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 (2010/713/EU)
(EU) 201/2011	COMMISSION REGULATION (EU) NO 201/2011 of 1 March 2011 on the model of declaration of conformity to an authorised type of railway vehicle
2011/18/EU	Commission Directive 2011/18/EU of 1 March 2011 amending Annexes II, V and VI to Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community
2011/107/EU	Commission Decision of 10 February 2011 amending Decision 2007/756/EC adopting a common specification of the national vehicle register
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
2011/217/EU	Commission Recommendation of 29 March 2011 on the authorisation for the placing in service of structural subsystems and vehicles under Directive 2008/57/EC of the European Parliament and of the Council
2011/633/EU	Commission Implementing Decision of 15 September 2011 on the common specifications of the register of railway infrastructure
2011/665/EU	COMMISSION IMPLEMENTING DECISION of 4 October 2011 on the European register of authorised types of railway vehicles (2011/665/EU)
(EU) 321/2013	COMMISSION REGULATION (EU) No 321/2013 of 13 March 2013 concerning the technical specification for interoperability relating to the subsystem 'rolling stock — freight wagons' of the rail system in the European Union and repealing Decision 2006/861/EC
(EU) 402/2013	COMMISSION IMPLEMENTING REGULATION on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009
2014/30/EU	DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)
(EU) 1302/2014	COMMISSION REGULATION (EU) No 1302/2014 of 18 November 2014 concerning a technical specification for interoperability relating to the 'rolling stock — locomotives and passenger rolling stock' subsystem of the rail system in the European Union

(EU) 2015/995	COMMISSION REGULATION (EU) 2015/995 of 8 June 2015 amending Decision 2012/757/EU concerning the technical specification for interoperability relating to the 'operation and traffic management' subsystem of the rail system in the European Union
(EU) 2015/2299	Commission Implementing Decision (EU) 2015/2299 of 17 November 2015 amending Decision 2009/965/EC as regards an updated list of parameters to be used for classifying national rules
(EU) 2016/796	REGULATION (EU) 2016/796 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004
(EU) 2016/797	DIRECTIVE (EU) 2016/797 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on the interoperability of the rail system within the European Union (recast)
(EU) 2016/798	DIRECTIVE (EU) 2016/798 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 May 2016 on railway safety (recast)
(EU) 2016/919	COMMISSION REGULATION (EU) 2016/919 of 27 May 2016 on the technical specification for interoperability relating to the 'control-command and signalling' subsystems of the rail system in the European Union
(EU) 2016/1628	REGULATION (EU) 2016/1628 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC
2016/C 272/01	COMMISSION NOTICE The 'Blue Guide' on the implementation of EU products rules 2016 (2016/C 272/01)
(EU) 2018/545	COMMISSION IMPLEMENTING REGULATION (EU) 2018/545 of 4 April 2018 on establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council
(EU) 2018/761	COMMISSION DELEGATED REGULATION (EU) 2018/761 of 16 February 2018 establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012
(EU) 2018/762	COMMISSION DELEGATED REGULATION (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010
(EU) 2019/250	COMMISSION IMPLEMENTING REGULATION (EU) 2019/250 of 12 February 2019 on the templates for 'EC' declarations and certificates for railway interoperability constituents and subsystems, on the model of declaration of conformity to an authorised railway vehicle type and on the 'EC' verification procedures for subsystems in accordance with Directive (EU) 2016/797 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 201/2011
(EU) 2019/773	COMMISSION IMPLEMENTING REGULATION (EU) 2019/773 of 16 May 2019 on the technical specification for interoperability relating to the operation and traffic management subsystem of the rail system within the European Union and repealing Decision 2012/757/EU
(EU) 2020/424	COMMISSION IMPLEMENTING REGULATION (EU) 2020/424 of 19 March 2020 on submitting information to the Commission as regards non-application of technical specifications for interoperability in accordance with Directive (EU) 2016/797
TSI	<i>Note: References to TSIs are not provided here, as they are in constant evolution. Please use search function of ERA homepage to identify TSIs and ensure to use the applicable version and any applicable amendments of the TSIs. (http://www.era.europa.eu/Search/Advanced-Search/Pages/home.aspx)</i>
ERA TSI Guidance	<i>Note: References to ERA TSI Guidance documents are not provided here, as they are in constant evolution. Please use search function of ERA homepage to identify TSIs and their associated ERA Guidance. (http://www.era.europa.eu/Search/Advanced-Search/Pages/home.aspx)</i>
ERA G PA-VA	Guidelines for the practical arrangements for the vehicle authorisation process, V1.0, 10/09/2018, ISBN 978-92-9205-436-6

ERA-PRG-005/02_374	Catalogue of examples - Examples for the practical arrangements for the vehicle authorisation process
RSA 2005	Railway Safety Act 2005 + related amendments
S.I. 61 of 2008	EUROPEAN COMMUNITIES (RAILWAY SAFETY) REGULATIONS 2008
S.I. 70 of 2011	EUROPEAN COMMUNITIES (RAILWAY SAFETY) REGULATIONS 2011
S.I. 419 of 2011	EUROPEAN COMMUNITIES (INTEROPERABILITY OF THE RAIL SYSTEM) REGULATIONS 2011 (4 August 2011)
S.I. 444 of 2013	EUROPEAN UNION (RAILWAY SAFETY) REGULATIONS 2013
S.I. 476 of 2020	S.I. No. 476 of 2020 EUROPEAN UNION (RAILWAY SAFETY) REGULATIONS 2020
S.I. 477 of 2020	S.I. No. 477 of 2020 EUROPEAN UNION (INTEROPERABILITY OF THE RAIL SYSTEM) REGULATIONS 2020
ISO 9000:2015	ISO 9000:2015 Quality management systems -- Fundamentals and vocabulary
ISO 9001:2015	ISO 9001:2015 Quality management systems -- Requirements
ISO 17000:2004	ISO/IEC 17000:2004 Conformity assessment -- Vocabulary and general principles
ISO 17020	Conformity assessment – General criteria for the operation of various types of bodies performing inspection
ISO 17021-1	Conformity assessment - Requirements for bodies providing audit and certification of management systems
ISO 17025	General requirements for the competence of testing and calibration laboratories
ISO 17065	Conformity assessment – Requirements for bodies certifying products, processes and services
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

4 Authorisation Cases

4.1 General Information on all Authorisation Cases

A number of legislative requirements will demand the Proposer of a Change to obtain an authorisation for the Change or the acceptance of the associated ASPSC from the affected authorities such as CRR or from ERA. In this case the Proposer of a Change becomes the 'Applicant'.

An individual legal requirement may provide limitations on who may be an applicant for a certain authorisation case.

For each of the authorisation cases the legal basis (e.g. IOD or RSA) is provided (in brackets).

Depending on the nature of the Change and depending on options/ conditions chosen by the applicant (where these are contained within the legislative requirements), different parts /principles/ options from legislation will become applicable.

It is therefore important for any applicant to identify the correct authorisation case(s) for their project. It is possible, that several parallel options of authorisation cases are available to choose from. It is also possible that several authorisation cases must be combined and performed in parallel or in a prescribed succession.

This section provides information on the different authorisation cases for heavy rail.

4.1.1 The geographical and technical scope of authorisation cases under IOD is the Union Rail System, with the following exceptions (S.I. 2020/477):

- (a) metros;
- (b) trams and light rail vehicles, and infrastructure used exclusively by those vehicles;
- (c) networks that are functionally separate from the rest of the railway system and intended only for the operation of local, urban or suburban passenger services, as well as undertakings operating solely on those networks.
- (d) privately owned railway infrastructure, including sidings, used by its owner or by an operator for the purpose of their respective freight activities or for the transport of persons for non-commercial purposes, and vehicles used exclusively on such infrastructure;
- (e) infrastructure and vehicles reserved for a strictly local, historical or touristic use;
- (f) light rail infrastructure occasionally used by heavy rail vehicles under the operational conditions of the light rail system, where it is necessary for the purposes of connectivity of those vehicles only;
- (g) vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit to be effected on a confined and limited section of heavy rail infrastructure for connectivity purposes only, and
- (h) the electric traction energy supply system of the Dublin suburban passenger service,

IOD authorisation is only possible when the intended design stage of the equipment has been met and can therefore not be issued for testing or time limited conditional operation.

4.1.2 The geographical and technical scope of authorisation cases under RSA is the Rail System in the State.

This scope includes any parameters and Subsystems unless they are covered in an APIS/ APOM issued under IOD in connection with S.I. 2020/477.

For the avoidance of doubt: The RSA scope includes all (parts of) heavy rail Subsystems that are excluded from the scope of the IOD as listed above.

This scope also covers certain conditional cases for acceptance of ASPSCs

- for testing of Vehicles or Fixed Installations within an active railway,
- before commencement of work at Fixed Installations or for time limited conditional operation of Fixed Installations.

This document provides the CRR guidance for these Authorisations in respect of heavy rail (For light rail authorisation refer to CRR-G-032.).

Note: IOD Annex I does not include depots for conventional lines intended for passenger service in its scope. There is a mention of depots but only in the context of interconnecting lines between high-speed and conventional networks. Therefore, authorisation for placing in service of rolling stock maintenance depots is not currently required for the network in the State.

4.1.3 Conditions during Authorisation/ Acceptance

It is expected that the Applicant designs a Subsystem for certain nominal and permitted degraded operational conditions. (In IOD this topic is termed 'conditions and limits of use'). These must be stated in the documented evidence which accompanies an application for Authorisation/ Acceptance.

Where during an independent assessment of a Subsystem additional conditions are discovered, they must be added by the Applicant to the mentioned documented evidence.

The Authorising Entity may need to place additional conditions on an Authorisation/Acceptance to ensure that compliance with the requirements will be maintained. Timebound conditions may in this context only be used at a Temporary Acceptance to RSA. This shall be based on a plausible corrective action plan submitted by the Applicant.

4.2 Authorisation Cases related to the European Interoperability Directive (IOD) for Fixed Installations

4.2.1 Authorisation to Place in Service (APIS) of Fixed Installations (to IOD Art 18);

Material Changes to the CCT, ENE and INF and the associated OPE, MAI, TAF, TAP subsystems shall be placed in service only if they are designed, constructed and installed, validated and independently assessed in such a way as to meet the Essential Requirements, and they have been granted authorisation by the CRR.

Material Changes in this context include

- Introduction of new Fixed Installations,
- Modification of existing Fixed Installations (incl. renewal or upgrade)
- Removal or partial removal of existing Installations where this causes a change to the remaining Fixed Installations.

that have the potential to affect the safety or other Essential Requirements, including, for the avoidance of doubt, railway lines or additions to existing railway lines, bridges and structures, stations or other buildings required to operate or maintain railways, level crossings and signalling systems. The CRR may be consulted by an Applicant in order to obtain an opinion on whether a project is a material Change.

In each authorisation project the applicant shall provide to the CRR a:

Communication to CRR on a Change to Fixed Installation which will require IOD Authorisation

Where a project includes ERTMS aspects, the applicant shall additionally apply to ERA for:

ERA approval for Tenders of trackside ERTMS projects (to IOD Art 19)

and may apply to CRR for:

CRR opinion for Tenders of trackside ERTMS projects (to IOD Art 19 (3))

Notes:

Small Maintenance activities and such activities which merely reinstate the original design/ performance properties are usually not material Changes. Large scale maintenance activities and those which alter the original design/ performance properties such as renewal or upgrading may require authorisation. It is the proposer's responsibility to determine, if an authorisation is required.

Even for projects which aim for an IOD authorisation, applicants also need to make earlier applications under RSA according to the authorisation cases in sections:

- 4.4.1
- 4.4.2
- 4.4.3

4.3 Authorisation Cases related to the European Interoperability Directive (IOD) for Vehicles

IOD Articles 24&25 with Article 21 in connection with (EU) 2018/545 14 and 15 define several authorisation cases from which the applicant must chose the appropriate case(s), and in some situations of the applicability of several cases and apply them in the correct sequence.

4.3.1 Vehicle Type Authorisations

4.3.1.1 First Authorisation for Placing on the Market (APOM) of a Vehicle Type for a first associated combination of Variant(s)+Version(s)+Area(s) of use (to IOD Art 24(1) with IOD Art 21 with (EU) 2018/545 14(1.a))

Where an applicant has been able to demonstrate, that a Vehicle Type and its associated combination of Variant(s)+Version(s)+Area(s) of use conforms with the applicable requirements, a first authorisation can be issued for that combination of Vehicle Type+Variant(s)+Version(s)+Area(s) of use.

In addition to the Vehicle Type authorisation, each individual physical Vehicle requires additional Authorisation. Refer to sections 4.3.2 and 4.3.3.

4.3.1.2 Renewal of Authorisation for Placing on the Market (APOM) of an already authorised Vehicle Type with the same associated combination of Variant(s)+Version(s)+Area(s) of use (to IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.b))

Where the applicable legal requirements have been changed but the Applicant has been able to demonstrate that the already authorised Vehicle Type and its associated combination of Variant(s)+Version(s)+Area(s) of use also conforms with the changed requirements, a renewal of the authorisation can be issued.

Note: Where the Vehicle Type requires a Change, to become compliant with the changed legal requirements, the authorisation case 4.3.1.3 must be used.

4.3.1.3 New Authorisation for Placing on the Market (APOM) of an already authorised Vehicle Type with a changed associated combination of Variant(s)+Version(s)+Area(s) of use (to IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.d))

A new authorisation is required in the following cases: Where the Applicant has

- made Changes to an already authorised vehicle type that meet the criteria set out in IOD Art 21(12) (e.g. to satisfy amended legislative requirements that required a design Change),
- created a new Vehicle Type or Variant based on an already authorised vehicle type/variant, pursuant to (EU) 2018/545 Art15,
- when the applicant that is proposing the Change is not the original holder of the vehicle type authorisation

Through the new Vehicle Type authorisation, a different entity can become the Applicant and subsequently the holder of the Vehicle Type authorisation for the new Vehicle Type. The new holder of the Vehicle Type authorisation will have the responsibility for the entire new Vehicle Type and its ongoing configuration management.

Where the Applicant has been able to demonstrate that the new (=after the design Change) Vehicle Type and its associated combination of Variant(s)+Version(s)+Area(s) of use also conforms with the changed requirements, a new authorisation can be issued.

4.3.1.4 Extended Area of Use Authorisation for Placing on the Market (APOM) of an already authorised Vehicle Type with the same associated combination of Variant(s)+Version(s) and extended associated Area(s) of use (to IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.c))

Where the Applicant has been able to demonstrate that the already authorised Vehicle Type and its associated combination of Variant(s)+Version(s) also conforms with the applicable requirements of an additional Area of use, an Extended Area of Use Authorisation can be issued.

Note: Where the Vehicle Type requires a Change, to become compliant with the extended Area of use requirements, the authorisation case 4.3.1.3 must be used.

4.3.1.5 Temporary Conditional First Authorisation for Placing on the Market (APOM) of a Vehicle Type for a first associated combination of Variant(s)+Version(s)+Area(s) of use (to IOD Art 24(1) with IOD Art 21 with (EU) 2018/545 14(1.a) and with (EU) 2018/545 46(6))

Temporary conditional equivalent for authorisation case 4.3.1.1.

In addition to the Vehicle Type authorisation, each individual physical Vehicle requires additional Authorisation. Refer to sections 4.3.2 and 4.3.3.

4.3.1.6 Temporary Conditional New Authorisation for Placing on the Market (APOM) of an already authorised Vehicle Type with a changed associated combination of Variant(s)+Version(s)+Area(s) of use (to IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.d) and with (EU) 2018/545 46(6))

Temporary conditional equivalent for authorisation case 4.3.1.3.

4.3.1.7 Temporary Conditional Extended Area of Use Authorisation for Placing on the Market (APOM) of an already authorised Vehicle Type with the same associated combination of Variant(s)+Version(s) and extended associated Area(s) of use (to IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.c) and with (EU) 2018/545 46(6))

Temporary conditional equivalent for authorisation case 4.3.1.4

4.3.2 Conformity to Vehicle Type Authorisations

Where the Applicant has been able to validate that a physical Vehicle conforms to an already authorised Vehicle Type and its associated combination of Variant(s)+Version(s)+Area(s) of use, the Applicant may declare this and apply for an Authorisation in conformity to an authorised Vehicle Type.

The applicant may only declare the conformity of a given physical vehicle (or a group of Vehicles) to an authorised vehicle type, after that vehicle (the group of Vehicles) has been completed and has been validated (by serial or commissioning testing). Thus, conformity to type can only become authorised after these activities have been completed.

Due to this, it is not possible to apply for an authorisation in conformity to a Vehicle Type in advance of a planned production of a vehicle or a series of vehicles.

4.3.2.1 Temporary Conditional Authorisation in conformity to an authorised Vehicle Type for Placing on the Market (APOM) of a Vehicle with its associated combination of

Variant+Version+Area(s) of use (IOD Art 25(1) with IOD Art 21 with (EU) 2018/545 14(1.e))

This is the associated case for the authorisation cases:

- 4.3.1.5
- 4.3.1.6
- 4.3.1.7

4.3.2.2 Authorisation in conformity to an authorised Vehicle Type for Placing on the Market (APOM) of a Vehicle with its associated combination of Variant+Version+Area(s) of use (to IOD Art 25(1) with IOD Art 21 with (EU) 2018/545 14(1.e))

This is the associated case for the authorisation cases:

- 4.3.1.1
- 4.3.1.2
- 4.3.1.3
- 4.3.1.4

4.3.3 Other options for individual Vehicle Authorisation for a first Vehicle of Type+Variant

Instead of Authorisation in Conformity to the authorised Vehicle Type (Section 4.3.2) the Applicant may request a Vehicle authorisation together with the Vehicle Type authorisation case.

In the case of a Renewal Authorisation for a Vehicle Type, this option does not apply.

This option applies exclusively to the first vehicle of an authorised combination of Type+Variant and for that vehicle's actual combination of Version+Area(s) of use. (to IOD 21 with (EU) 2018/545 14(1.a+c+d)).

Note: In this situation, it is clear that the vehicle is in conformity with the Vehicle Type so no declaration of conformity to type is required for that first vehicle. All other subsequent vehicles of that vehicle type will need to use authorisation case 4.3.2.

4.3.3.1 First Authorisation for Placing on the Market (APOM) of a Vehicle for a first associated combination of Type+Variant(s)+Version(s)+Area(s) of use (to IOD Art 24(1) with IOD Art 21 with (EU) 2018/545 14(1.a))

This is the alternative option for authorising one physical Vehicle in parallel with authorisation case 4.3.1.1.

4.3.3.2 New Authorisation for Placing on the Market (APOM) of an already authorised Vehicle with a changed associated combination of Type+Variant(s)+Version(s)+Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.d))

This is the alternative option for authorising one physical Vehicle in parallel with authorisation case 4.3.1.3.

4.3.3.3 Extended Area of Use Authorisation for Placing on the Market (APOM) of an already authorised Vehicle with the same associated combination of Type+Variant(s)+Version(s) and extended associated Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.c))

This is the alternative option for authorising one physical Vehicle in parallel with authorisation case 4.3.1.4.

4.3.3.4 Temporary Conditional First Authorisation for Placing on the Market (APOM) of a Vehicle for a first associated combination of Type+Variant(s)+Version(s)+Area(s) of use (to IOD Art 24(1) with IOD Art 21 with (EU) 2018/545 14(1.a) and with (EU) 2018/545 46(6))

This is the alternative option for authorising one physical Vehicle in parallel with authorisation case 4.3.1.5.

4.3.3.5 Temporary Conditional New Authorisation for Placing on the Market (APOM) of an already authorised Vehicle with a changed associated combination of Type+Variant(s)+Version(s)+Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.d) and with (EU) 2018/545 46(6))

This is the alternative option for authorising one physical Vehicle in parallel with authorisation case 4.3.1.6.

4.3.3.6 Temporary Conditional Extended Area of Use Authorisation for Placing on the Market (APOM) of an already authorised Vehicle with the same associated combination of Type+Variant(s)+Version(s) and extended associated Area(s) of use (IOD Art 24(3) with IOD Art 21 with (EU) 2018/545 14(1.c) and with (EU) 2018/545 46(6))

This is the alternative option for authorising one physical Vehicle in parallel with authorisation case 4.3.1.7.

4.4 Authorisation Cases related to the Irish Railway Safety Act (RSA) for Fixed Installations

To avoid confusion the term 'New Works' from RSA in this guideline is replaced by and deemed to be equivalent to 'Fixed Installation'.

An applicant shall obtain the consent of the CRR before bringing into operation fixed installations (RSA 2005 42(1), (5), (8) and (15)).

Note: According to section 4.1 the electric traction energy supply system of the Dublin suburban passenger service is within the scope of RSA Acceptance and not in the scope of IOD APIS.

The authorisation cases in this section apply to Material Changes of Fixed Installations. Material Changes in this context include

- Introduction of new Fixed Installations,
- Modification of existing Fixed Installations (incl. renewal or upgrade)
- Removal or partial removal of existing Fixed Installations where this causes a change to the remaining Fixed Installations,

that have the potential to affect the safety or other compliance requirements, including, for the avoidance of doubt, railway lines or additions to existing railway lines, bridges and structures, stations or other buildings required to operate or maintain railways, level crossings and signalling systems. The CRR may be consulted by an Applicant in order to obtain an opinion on whether an intended Change is a Material Change.

In each authorisation project the applicant shall provide a:

Communication to CRR on a Change to Fixed Installation which will require IOD Authorisation

Note: Small Maintenance activities and such activities which merely re-instate the original design/ performance properties are usually not Material Changes. Large scale maintenance activities and those which alter the original design/ performance properties may as renewal or upgrading require authorisation.

4.4.1 Acceptance of an ASPSC for Commencement of construction, installation or assembly of Fixed Installations (to RSA 42 (1)+(8))

Applicants for intended Material Changes of Fixed Installations must apply to the CRR for an Acceptance of an ASPSC prior to the commencement of construction, installation or assembly. The Applicant must demonstrate through the ASPSC the safety and conformity of an intended construction, installation or assembly of Fixed Installations. That Applicant may then apply for the Acceptance of that ASPSC.

4.4.2 Temporary Acceptance of an ASPSC for conditional placing in test service of Fixed Installations (for RSA 42 (1)+(5))

Where the Applicant has been able to evidence through an ASPSC the safety and conformity of an intended test activity within the active Rail System in The State, that Applicant may apply for the Acceptance of the ASPSC.

4.4.3 Temporary Acceptance of an ASPSC for conditional placing in service of Fixed Installations (to RSA 42 (1)+(5))

Where the Applicant has been able to evidence through an ASPSC the safety and conformity of an intended temporary and conditional placing in service of Fixed Installations, that Applicant may apply for the Acceptance of the ASPSC.

4.4.4 Acceptance of an ASPSC for placing in service of Fixed Installations (RSA 42 (1)+(5))

Where the Applicant has been able to evidence through an ASPSC the safety and conformity of an intended placing in service of Fixed Installations, that Applicant may apply for the Acceptance of the ASPSC.

4.5 Authorisation Cases related to the Irish Railway Safety Act (RSA) for a Series of Vehicles

To avoid confusion the term 'New Rolling Stock' from RSA is in this guideline is replaced by and deemed to be equivalent to 'Series of Vehicles'.

A Series may be one or more identical physical Vehicle(s). In order to ensure compatibility with the concept of Vehicle Type to IOD, a Series shall be defined through Type+Variant(s)+Version(s)+Area(s) of Use.

An applicant shall obtain the consent of the CRR before bringing into operation a Series of Vehicles (RSA 2005 43(1) and (7)).

Note: According to section 4.1.1(h) the electric traction energy supply system of the Dublin suburban passenger service is within the scope of RSA Acceptance and not in the scope of IOD APOM.

The authorisation cases in this section apply to Material Changes of a Series of Vehicles. Material Changes in this context include

- Introduction of new Vehicle Type+Version+Variant+Area of Use,
- Modification of existing Vehicles (incl. renewal or upgrade)
- Removal or partial removal of existing Vehicle equipment where this causes a change to the remaining Vehicle equipment,

that have the potential to affect the safety or other compliance requirements. The CRR may be consulted by an Applicant in order to obtain an opinion on whether an intended Change is a Material Change.

Note: Small Maintenance activities and such activities which merely re-instate the original design/ performance properties are usually not Material Changes. Large scale maintenance activities and those which alter the original design/ performance properties may as renewal or upgrading require authorisation.

4.5.1 Temporary Acceptance of an ASPSC for conditional placing in test service of a Series of Vehicles (to RSA 43 (1)+(7))

Where the Applicant has been able to evidence through an ASPSC the safety and conformity of an intended test activity within the active Rail System in The State, that Applicant may apply for the Acceptance of the ASPSC.

4.5.2 Temporary Acceptance of an ASPSC for conditional placing in service of a Series of Vehicles (to RSA 43 (1)+(7))

Where the Applicant has been able to evidence through an ASPSC the safety and conformity of an intended conditional placing in service of a Series of Vehicles in the State, that Applicant may apply for the Acceptance of the ASPSC.

4.5.3 Acceptance of an ASPSC for placing in service of Series of Vehicles (to RSA 43 (1)+(7))

Where the Applicant has been able to evidence through an ASPSC the safety and conformity of an intended placing in service of a Series of Vehicles in the State, that Applicant may apply for the Acceptance of the ASPSC.

5 Compliance and Safety Management within authorisation projects

5.1 SMS of Applicants

European as well as Irish legal provisions require RUs/IMs as duty holders to ensure the safety of their activities, (RSD Art.4(3) in combination with (EU) 402/2013, RSD Art.9 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 ERA/ NSA(s) and fully comply with this SMS at all times. This SMS must include processes for the safe management of Change projects. These processes are called the Project SMS.

For Applicants which are not RUs or IMs they shall have a formal means of managing safety by virtue of an Project SMS even if it is not certified or authorised (RSD Art.4(4) in combination with IOD, (EU) 402/2013, (EU) 2018/545). This often consists of processes that are embedded in the Applicant's QMS.

In the following, the terms 'Applicant' / 'RU(acting as an Applicant)' / 'IM(acting as an Applicant)' are simplified to 'Applicant' in order to increase readability.

The relevant legal requirements shall be identified by the Applicant through the application of RSD, RSA, (EU) 402/2013 and CSM 2018/762 and can at large be separated into:

- Compliance management activities and
- Safety management activities.

All Applicants are obliged through

- RSD Art4(3.c+d) and Art4(4) as 'other actors' or 'contractors' (to RUs/IMs)
- IOD Annex III (refer to 'essential requirements' Safety, Protection of Health, Protection of Environment)
- (EU) 2018/545 (refer to 'requirements capture') with CSM(EU) 402/2013

to manage safety and other relevant compliance activities on the level of the authorisation project.

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

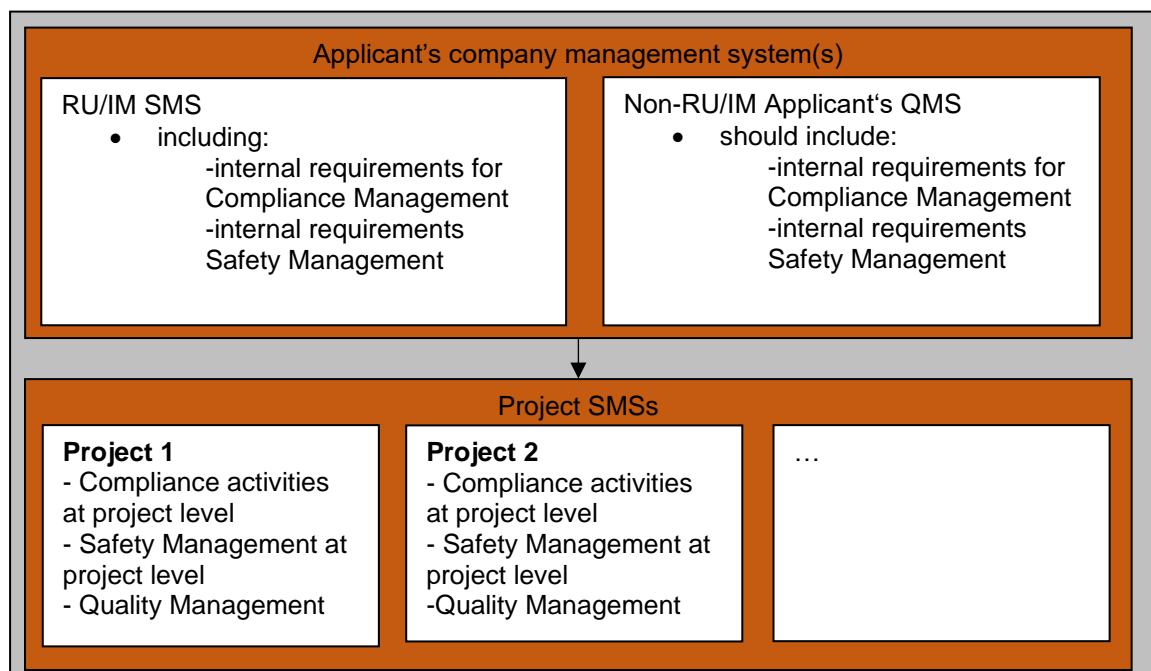
- *allocation of trained/ experienced experts in safety management activities,*
- *allocation of trained/ experienced experts in the technology of the relevant Subsystem(s),*
- *allocation of realistic timeslots for PIS/ APIS/APOM/Acceptance activities within the project schedule.*

5.2 Project SMS

Any project which introduces a Change must establish a Project 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 to 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 (EU) 402/2013.



For activities connected to **APIS** (see section 2.2) of a Change to Subsystems in the case of **Fixed Installations**, the Applicant's Project SMS must ensure in co-ordination with the IM's SMS (of that IM which performs the PIS) that all relevant legal requirements relating to that project are identified and fulfilled.

For activities connected to **Acceptance** (see section 2.2) of a Change to Subsystems in the case of **Fixed Installations**:

The Applicant for Acceptance must be the IM that performs the PIS. That IM must ensure through its SMS and Project SMS that all relevant legal requirements relating to that project are identified and fulfilled.

For activities connected to **Acceptance** (see section 2.2) of a Change to Subsystems in the case of **Vehicles**:

The Applicant for Acceptance must be the RU that performs the PIS. That RU must ensure through its SMS and Project SMS that all relevant legal requirements relating to that project are identified and fulfilled.

Note: For activities connected to PIS (see section 2.2) of a Change to Subsystems in the case of Vehicles, the RU that performs the PIS must employ its SMS and Project SMS in co-ordination with the results of the Applicant's Project SMS activities, to ensure that all relevant legal requirements relating to that project are identified and satisfied.

This activity is not subject to direct external authorisation.

5.3 Requirements for Compliance activities within Project SMS

Overview of requirements:

The Applicant must apply to the relevant Authorising Entity and receive the Authorisation/Acceptance before a Change to a Subsystem may be Placed in Service/On the Market. (IOD Art 18+20)

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 Art 18+20+Annex III; Blue Guide; RSA).

The Applicant must demonstrate evidence that a Change to a Subsystem is technically compatible with the Railway System in the State. (IOD Art 18+20+Annex III)

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(1(d)) and 6(1) of RSD).

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 Art 15(2))

The RU/IM when acting as Applicant 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 2018/762 Annex I 1.1(d) + Annex II 1.1(d))

In Summary:

The Project SMS must ensure compliance with all applicable requirements derived from IOD, TSIs, Mandatory and Voluntary Standards, NRs, RSD, RSA, CSMs, TDD, other EU Legislation, the EU Blue Guide, other National Legislation, etc.

5.4 Requirements for Safety Management activities within Project SMS

The Project SMS must ensure that risks are managed in line with the requirements derived from IOD, RSD, RSA, (EU) 402/2013, EU 2018/762, and other applicable legislation. It is further considered to be good industry practice to apply EN50126-1/-2, EN50128, EN50129, EN50159-1/-2 when establishing the project SMS.

The Applicant must demonstrate evidence that a Change to a 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 Articles (18+20) +Annex III; Blue Guide; RSA).

The Project SMS must include all requirements of CSM (EU) 402/2013, as amended.

The Applicant must demonstrate evidence that a Change to a 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(1(d)) and 6(1) of RSD. (IOD Art 18+20).

In Summary:

The Applicant's Project SMS must ensure effective Risk and Safety Management in accordance with (EU 2018/762, RSD, RSA, IOD Art18+20+Annex III and CSM (EU) 402/2013.

5.5 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 Authorisation Case(s) must be initiated in the right sequence,
- G2 a competent project organisation must be established,
- G3 all affected Subsystems and Parameters and their Interfaces to the Union Rail System must be identified.

Compliance Activities

- C1 all relevant compliance requirements must be systematically and comprehensively identified,
- C2 compliance measures must be implemented,
- C3 compliance measures must be verified and validated, independently assessed, evidenced and monitored,
- 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

Note: for APOM, applicants must establish a Requirements Capture process. This process overlaps with activities C1-C4 but must follow a specific process. Further guidance for this process is described in Annex 5.

5.6 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. 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 criticality of the activities and must also consider current industry standards such as EN 50126-50129 and ISO 17020, 17021 and 17025. In a number of cases however legal provisions, standards or CRR guidelines require certain minimum levels of independence or competence (e.g. NoBo, DeBo, IA, ISA)

Note that independent assessment, supervision activities or CRR activities do not relieve RU/IMs or their contractual partners 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.

- After authorisation to place on the market and during placing in service of Vehicles, an Area of use compatibility check (which replaces the previous concept of route compatibility) must be performed by the RU. This involves checking values for the vehicle against the parameters defined in TSI OPE Appendix D1. Compatibility of Area of use, with the network statement and route book must also be checked. Any tests which have been performed for the authorisation for the Area of use should not be repeated. This checking is done under the RU and is part of the PIS process of the RU and not part of the authorisation process which is performed by the Applicant.

5.7 Relationship between Compliance Management activities and Safety Management activities

As introduced above, the main compliance requirements are 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 Management activities and the Safety Management activities.

Further: the application of Project SMS activities under CSM (EU) 402/2013 must not lead to requirements contradictory to those laid down in the relevant TSIs which are mandatory (CSM (EU) 402/2013/ Art2(3)).

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

Note: Should an Applicant wish to retain separation between the two activities, it must ensure that no contradiction between the elements is created. An Applicant desiring to do so should seek more specific guidance from the CRR before and during the authorisation project activities.

5.8 Activity G1 – Initiation of Authorisation/Acceptance process

Depending on the project scope, the applicant must apply for the correct Authorisation/Acceptance Case.

The required Authorisation Case(s) shall be identified.

Please note, that only an ASPSC may be used to receive Authorisation/Acceptance.

5.9 Activity G2 – Establishment of competent project organisation

The information on roles and responsibilities, staff competence and project organisation shall be supplied. 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.

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

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 – Railway 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 application case must use the structure of Subsystems 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.

The Applicant must systematically identify all Subsystems and all Parameters affected by the envisaged project.

Parameters

All Parameters related to the project scope must be identified and managed by the Applicant through the Project SMS.

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.

Documentation

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

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

5.11 **Activity C1 – identification of compliance requirements**

Based on

- the project scope,
- the required type of Authorisation/Acceptance,
- the nature of affected Sub Systems,
- the affected Parameters,
- the affected Interfaces,
- the project timeline and schedule and
- any non-applications sought and granted,

all compliance requirements must be identified using a method as indicated in IOD together with (EU) 2018/545 and (EU) 402/2013.

The scrutiny shall cover at least TSIs, Mandatory and Voluntary Standards, NRs. IOD, RSD, RSA, CSMs, New Legislative Framework Regulations, New Approach Directives, Blue Guide, TOs, TDs, RFUs and the Implementation Act for Vehicle Authorisation. Due to the constant evolution of the EU legislative requirements, this list cannot be exhaustive. The CRR may 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 CRR list of Parameters. This list should be the starting point of a Project Safety- & Compliance-Matrix (see Annex 4).

Requirements Capture for APOM Projects

Regulation (EU) 2018/545 requires-the applicant to capture how they managed their requirements capture process. An approach for and description of the requirements capture process is provided in Annex 5

5.12 **Activity C2 – Implementation of compliance measures**

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

5.13 **Activity C3 – compliance measures must be verified and validated, independently assessed, evidenced and monitored**

Evidence of Compliance must be documented by the Applicant 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/APOM/Acceptance like those on application of CSM (EU) 402/2013.

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

The compliance for all requirements must be assessed, reported (and, in some cases, certified) by NoBo, DeBo, ISA, IA, V&V, CSM-AB, self-assessment by RU/IM/Applicant, etc. as far as required.

Assessment must deliver in each case evidence in the format of an assessment report, which may need to be accompanied by a Certificate or Declaration or Assessment Files (e.g. NoBo, DeBo File) in some cases. A Certificate or Declaration without accompanying assessment report will not be acceptable.

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

Any assessment process shall follow EN 17020 Type A (with exception of CSM-AB activities which may be to Type A or B or C), any auditing of processes or management systems shall follow EN 17021 any testing activities shall follow EN17025 and any Certification activities shall follow EN 17065. Where applicable other requirements shall also 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 Annex 4).

The Applicant must indicate the intended activities to monitor the compliance behaviour of the change. This shall be documented within the SP and Safety Case (see Annexes 1 and 3).

5.14 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.

5.15 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, EN50128, and EN 50129, CSM (EU) 402/2013 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 Project SMS activities.

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

5.16 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 (EU) 402/2013 in connection with those requirements derived from a certified/authorised RU/IM SMS (see Annex 2).

5.17 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 (EU) 402/2013 Art2(2))

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

5.18 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 Applicant must ensure this compliance by its own activities as well as by the activities of its contractors / suppliers.

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

The Applicant 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 Applicant) in order to evaluate or supervise the effectiveness of the activities of the Applicant and their contractors /suppliers.

In principle the Applicant may define the required scope and suitable level of independence of such Experts/Organisations. This shall reflect the level of criticality of the activities and current industry standards such as EN 50126-50129.

In a number of cases however legal provisions or CRR guidance require certain minimum levels of independence or competence (e.g. NoBo, IE DeBo, IA, CSM-AB).

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

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

Any assessment process shall follow EN 17020 Type A (with exception of CSM-AB activities which may be to Type A or B or C), any auditing activities EN 17021 any testing activities shall follow EN17025 and any Certification activities shall follow EN 17065. Where applicable, other requirements shall also 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 Applicant must indicate the intended activities to monitor the safety behaviour of the change. This shall be documented within the SP and Safety Case.

Where there is a requirement for an IE DeBo assessment (e.g. by a TSI, NR or by CRR), or where an Applicant considers the involvement of an IE DeBo beneficial, the Applicant shall employ at their expense one or more IE DeBos. The IE DeBos:

- shall hold a valid recognition by CRR for the assessment scope in question and while performing the assessment,

- shall prepare inspection/ audit report(s), IE DeBo Certificates and associated IE DeBo Files on the basis of the aforementioned recognition

Where there is a requirement for an IA, or where an Applicant considers its involvement beneficial, the Applicant shall employ at their expense an IA to support and complement the CRR's review activities. The IA:

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

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

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

5.20 **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.

5.21 **Activity S7 – Acceptance of residual risk**

After implementation and after independent assessment of a safety measure the Applicant 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 the principles of EN 50126, CSM (EU) 402/2013, RSD and RSA. The residual risk must be acceptable for railway operation by the eventual RU/IM.

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

5.22 **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 (EU) 402/2013.

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

An approach for the Hazard Record is provided in Annex 2 to this CRR Guidance.

5.23 **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 (EU) 402/2013. The project safety case must summarise the project related SMS activities.

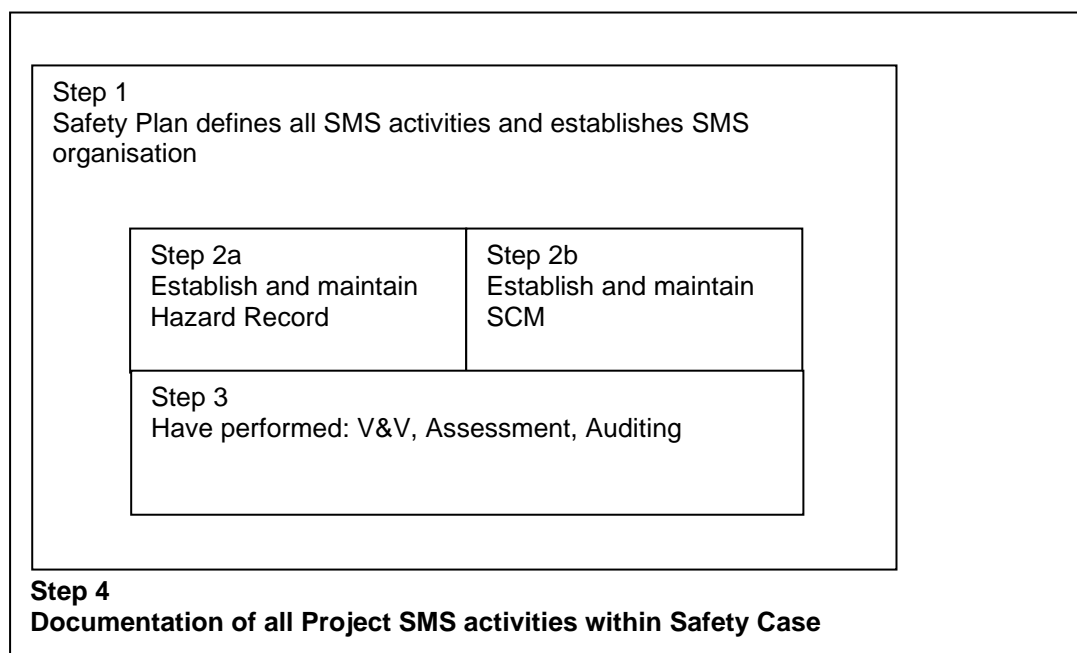
The Project Safety Case may be based on a staggered approach of Generic Product Safety Case, Generic Application Safety Case and Application Specific Project Safety Case.

Note: Whether GPSC or GASC are used usually depends on the degree of expected further use of the Generic Product or its Generic Application in further projects.

For any operation (including time limited conditional test or interim operation) on the live Railway System in the State an ASPSC is required.

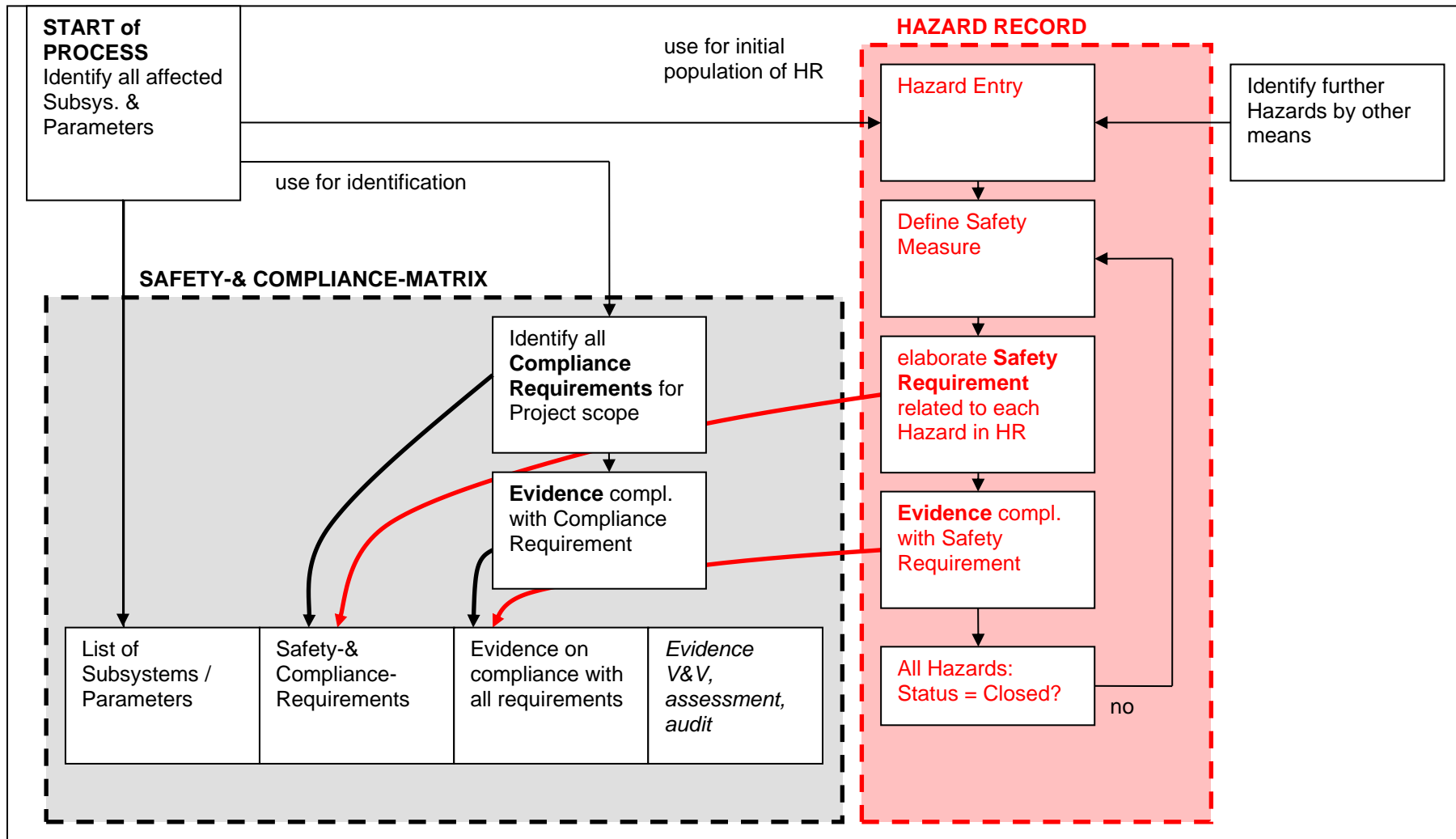
An approach for the development of a Safety Case is provided in Annex 3.

RSA 42 and 43 require the preparation of a Safety Assessment of New Works (NWA) or a Safety Assessment of New Rolling Stock (NRS). An ASPSC developed in accordance with EN 50126-50129 and CSM (EU) 402/2013 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 with management of safety – and compliance requirements.



Graphical Explanation of SMS activities on management with Safety- and Compliance Requirements

6 Non-Application of TSIs and NRs

For applications under the IOD any applicant must comply with relevant TSIs and IE NRs unless the Applicant provides a suitable justification for the non-application of TSIs or national rules.

6.1 Non-Application of TSIs

The non-application of (parts of) TSIs may be allowed by the European Commission on the basis of IOD 7.

When an Applicant requests a non-application for an authorisation Project, the applicant has to prepare the file mentioned in IOD Art 7 in accordance with 2020/424 and SI 2020/477 and provide this file to the CRR.

Amongst other required information, this file shall indicate the (parts of) TSIs not to be applied, the alternative provisions to be applied and the measures to monitor their implementation.

- According to IOD Art 13(2.b) the Applicant shall propose as alternative provisions a suitable set of Irish National Rules (IE NRs). The selected set of IE NRs must satisfy the essential requirements as defined in IOD Annex III.
- According to IOD Annex IV(3.1) in combination with IOD Art.15(8) the Applicant shall propose as measures to monitor the implementation of the IE NRs one (or more) IE DeBo(s) which is competent for the scope of the project.

The CRR will review any request using the checklist in Annex VI.

The CRR will communicate this file to the European Commission as required by IOD Art 7.

In the cases of IOD Art 7(1.a+b),(6),(7) where no reply from the European Commission is required/ received, the CRR shall determine whether the non-application can be granted. The CRR shall consider whether the application of the alternative provisions will likely result in:

- at least the same level of safety,
- at least the same level of protection of health,
- at least the same level of protection of the environment and
- an equivalent level of fulfilment of the other Essential Requirements of the IOD.

In the cases of IOD Art 7(1.c+d+e) an answer on the request for non-application is expected from the European Commission. Pending the answer from the European Commission the provisions of IOD Art 7(6) apply.

Where an Applicant wishes to list its project(s) according to IOD Art 7(2), they shall provide such information within 10 months after the commencement of applicability of a new TSI/ revised TSI/ a TSI amendment.

6.2 Non-Application of IE NRs

An Applicant may request from the CRR a non-application of (parts of) IE NRs according to the following cases (for compatibility, taken mutatis mutandis from IOD Art 7(1.a-c):

- (a) For a proposed Change of a Subsystem which is at an advanced stage of development or which is already the subject of a contract in the course of performance on the date when the IE NR(s) concerned became applicable.
- (b) Where, following an accident or a natural disaster, the conditions for the rapid restoration of the network do not economically or technically allow for partial or total application of the relevant IE NRs, in which case the non-application of the IE NRs shall be limited to the period before the restoration of the network;

- (c) For any proposed Change of a Subsystem, when the application of the IE NR(s) concerned would compromise the economic viability of the project and/or the compatibility of the Rail System in the State, for example in relation to the loading gauge, track gauge, space between tracks or electrification voltage;

In these cases the Applicant may propose to the CRR either:

- 1) to apply the superseded version of an IE NR (instead of the current version of that IE NR) that was applicable at the time when the Subsystem became developed to an advanced stage or became the subject of a contract in the course of performance, where this will result in:
 - at least the same level of safety,
 - at least the same level of protection of health,
 - at least the same level of protection of the environment and
 - an equivalent level of fulfilment of the other Essential Requirements of the IOD.
- 2) where no previous version of the IE NR exists, or where the previous version of IE NR does not satisfy sub-clause 1) above, or where case (b) applies, to apply an alternative provision that will result in:
 - at least the same level of safety,
 - at least the same level of protection of health,
 - at least the same level of protection of the environment and
 - an equivalent level of fulfilment of the other Essential Requirements of the IOD.

The Applicant shall prepare a file using the principles of 2020/424.

The CRR shall determine, based on the requirements of this clause 6.2, whether the non-application file is complete and plausible. Where this is the case, the CRR may grant the non-application and the related alternative provisions, where this is not the case, the CRR shall hand the request back to the Applicant and state the reasons.

7 Applying for Authorisation Cases

7.1 General Requirements for any Authorisation Case

7.1.1 Stages

The project timeline is divided into six Stages which must be performed in successive order.

7.1.2 Suitability of Content of each Submission

Before submitting any application to the CRR, the Applicant in execution of their duties must perform a self-assessment on the completeness and correctness of the application and the related project specific Safety Case documentation.

Evidence of this self-assessment must be made in the form of a checklist and submitted with the application.

Where the CRR finds that a submission is defective in this regard (e.g. not complete, not consistent, content not plausible) it may return the submission to the Applicant together with stating the reasons.

7.1.3 Associated Communications/ Documented Evidence

Any Application or Communication/ Documented Evidence to CRR shall be in the English language.

Table A below identifies for each Authorisation Case further associated communications or documented evidence.

All associated communication or documented evidence must be created/ up-dated/ still be applicable for the Stage where it is indicated.

Overview on the Associated Communications/ Documented Evidence:

Communications/ Documented Evidence	Requirements for Content	To be created by
Application Letter	Cover Letter for an Application for an Authorisation Case. To include at least the legal identity of the Applicant, identification of the Fixed Installation / Vehicle, a list of contents for this submission, signature(s) of authorised representative(s). Refer also to IOD, RSA, (EU) 2018/545 as relevant.	Applicant
Application for a Pre-Engagement Opinion	Refer to (EU) 2018/545 7(3) + 22 and other sections.	Applicant
Communication Letter	Letter to communicate an intended RSA Authorisation Case to the CRR. In order to obtain a statement of the CRR on the plausibility of the approach chosen by the applicant. To include at least the legal identity of the Applicant, identification of the Fixed Installation / Vehicle, a list of contents for this	Applicant

	submission, signature(s) of authorised representative(s).	
Pre-Engagement File	Refer to (EU) 2018/545 22 and other sections.	Applicant
Request letter	Request for either ERA and optional CRR opinion for Tenders of trackside ERTMS projects. Refer to IOD Art 19 (3).	Applicant
SP (Safety & Compliance Management Plan)	Refer to Annex 1	Applicant
HR (Hazard Record)	Refer to Annex 2 and Annex 5	Applicant
SCM (Safety & Compliance Matrix)	Refer to Annex 4 and Annex 5	Applicant
ASPSC (Application Specific Project Safety Case)	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. Refer to Annex 3	Applicant
CSM-AB Safety Assessment Report	Refer to (EU) 402/2013 with EN 17020	CSM-AB (AsBo)
CSM-AB Report on Requirements Capture (only for Vehicle projects)	Refer to (EU) 2018/545 in connection with (EU) 402/2013.	CSM-AB (AsBo)
EC Declaration of Verification	Refer to IOD, TSIs, (EU) 2018/545, (EU) 2019/250 as relevant	Applicant
National Declaration of Verification	Refer to IOD, TSIs, (EU) 2018/545, (EU) 2019/250 as relevant	Applicant
Combined Technical File	Refer to IOD, TSIs, (EU) 2018/545, (EU) 2019/250 as relevant	Applicant
EC Certification (with Report(s) and NoBo File(s))	Refer to IOD, TSIs, (EU) 2018/545, (EU) 2019/250, RFU-STR-001, RFU-STR-011 as relevant. Where requested by the Applicant, the NoBo shall issue an Intermediate Statement of Verification (ISV) to cover certain stages of the EC verification procedure or certain parts of the subsystem.	NoBo
IE DeBo Certification (with Report(s) and IE DeBo File(s))	Refer to IOD, TSIs, (EU) 2018/545, (EU) 2019/250, RFU-STR-001, RFU-STR-011 as relevant (replace IE NR for TSI and IE DeBo for NoBo as relevant). Where a Parameter List of the CRR (refer to section 2.2) requires so, an IE DeBo Certificate (with associated Report and File) shall be submitted.	IE DeBo
Declaration of Conformity to an Authorised Vehicle Type	Refer to IOD, (EU) 2018/545, (EU) 2019/250 10+Annex VI.	Applicant
IA (to RSA) Report	Refer to RSA, ISO 17020.	IA

Table A

7.1.4 Submissions to the CRR

Any submission containing an application (including the relevant attachments, refer to IOD, to TSIs, to (EU)2019/250, to ERA guidance, etc. as applicable) should be made sufficiently in advance of when the Applicant requires authorisation/ acceptance.

The Applicant should take into account the time frames specified in Article 34 of Commission Implementing Regulation (EU) 2018/545 and Article 18 of IOD, for Vehicles and Fixed Installations respectively.

It is recommended to add an additional time allowance to respect the complexity of a project and to allow for correction of any inconsistencies which may be present in an application.

The time frame for review of the application may be extended

- if it is found during the check of completeness of the application that there is information missing or
- if a justified doubt is raised (and it is duly recorded in agreement with the applicant to extend the timeframe).

If the CRR is the chosen Authorising Entity, then Applicants may provide draft versions of applications to the CRR prior to submitting applications through the OSS.

7.1.5 ERTMS trackside Tender applications

The Applicant shall submit any ERTMS trackside Tender applications to ERA through the OSS.

7.2 Specific Requirements for Applications for Fixed Installations

It is typical, that both, IOD and RSA related Authorisation Cases may be required by the applicant in a project.

Applicants should be aware of the differences between IOD and RSA:

7.2.1 Who may be the Applicant?

According to IOD Art 2(22), the Applicant may for IOD authorisation cases be an RU, an IM or any other person or legal entity, such as a manufacturer, an owner or a keeper. For the purpose of IOD Art 15, the 'Applicant' means a contracting entity or a manufacturer, or its authorised representatives. For the purpose of Article 19, the 'applicant' means a natural or legal person requesting the Agency's decision for the approval of the technical solutions envisaged for the ERTMS trackside equipment projects.

For RSA authorisation cases the Applicant may be an RO. As that RO must under RSA 42 with 39 have an SMS for its activities, it is clear that only those ROs that have an SMS which covers Changes to and operation of Fixed Installations may be considered in the context of RSA 42. (These ROs can be seen as equivalent to IMs according to IOD/ RSD.)

In the case of Fixed Installations it is also required, that the Applicant closely co-operates with the eventual IM in the State that will operate the Fixed Installation in order to fulfil their joint obligations of Project SMS and IM SMS (refer to section 5).

Note: In this context it may greatly reduce management effort and interfacing between stakeholders (and thus business risk), when the Applicant is the eventual IM to operate the Fixed Installation.

7.2.2 Request for ERA approval for Tenders of ERTMS projects

In the case of trackside control-command and signalling subsystems involving

- European Train Control System (ETCS) and/or
- Global System for Mobile Communications — Railway (GSM-R) equipment,

the positive decision of the Agency issued in accordance with IOD Art 19; and, in the case of a change to the draft tender specifications or to the description of the envisaged technical solutions that

occurred after the positive decision, the compliance with the result of the procedure referred to in Article 30(2) of Regulation (EU) 2016/796.

7.2.3 Abbreviations used in Table B

Within the table the following abbreviations are used.

- (M) = document submission is mandatory.
- (MA) = document submission is mandatory and an Acceptable National Means of Compliance (ANMOC) is provided in this guideline. The ANMOC indicates an acceptable national method/ format/ content of the expected document. The indicated content is mandatory. The applicant may use an alternative method/ format, as long as
 - at least the same content is contained in a systematic and traceable structure,
 - the same overall result/ effect is generated.
- (R) = document submission is recommended

Table B of Stages relating to authorisation projects for Fixed Installations

Stage	Submissions on project scope where IOD applies	Submissions on project scope where RSA applies	Note	Typical activities at project level	Documents to be submitted where IOD applies	Documents to be submitted where RSA applies
1 Concept	For any project: Communication to CRR on a Change to Fixed Installation which will require Authorisation		At this stage the CRR requires a communication of the Applicant on the nature of the project.	After performing general concept studies or feasibility studies and prior to requesting tenders.	<ul style="list-style-type: none"> - Communication letter (M) - SP (MA) 	<ul style="list-style-type: none"> - Communication letter (M) - SP (MA)
1.a	Where the Change includes ERTMS aspects: Request for: ERA approval for Tenders of trackside ERTMS projects (to IOD Art 19) Optional: Request for: CRR opinion for Tenders of trackside ERTMS projects (to IOD Art 19 (3))	n.a.			<ul style="list-style-type: none"> - Request letter (M) 	n.a.
2 Preliminary Design	For any project: Communication to CRR on a Change to Fixed Installation which will require Authorisation		At this stage the CRR requires a communication of the Applicant on the status of the project.	After evaluation of tenders and preliminary decision on functional and technical design and prior to awarding a contract for execution of any work.	<ul style="list-style-type: none"> - Communication letter (M) - SP (MA) - HR (MA) - SCM (MA) 	<ul style="list-style-type: none"> - Communication letter (M) - SP (MA) - HR (MA) - SCM (MA)
3 Overall (detailed) Design	For any project: Authorisation case 4.4.1		This RSA Acceptance is required for any project in the State.	After awarding a contract for execution of work, after detailed overall design has been elaborated and prior to production/ building.	<ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) 	
4 Testing	For any project: Authorisation case 4.4.2		This RSA Acceptance is required for any project in the State.	Prior to any Testing in the live Railway System in the State.	<ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) 	

					<ul style="list-style-type: none"> - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M where Change is significant, otherwise R) - EC Certification (=ISV) (with Report and NoBo File) (R) - IE DeBo Certification (=ISV) (with Report and IE DeBo File) for this Stage (M) - IA (to RSA) Report (if applicable) (M) 		
5 Interim Operation	For any project: Authorisation case 4.4.3		This RSA Acceptance is required for any project where Testing in the live Railway System in the State is required.	After principal completion of project specific assessment activities (incl. final testing), prior to full close out of open issues.	<ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M where Change is significant, otherwise R) - EC Certification (=ISV) (with Report and NoBo File) (R) - IE DeBo Certification (=ISV) (with Report and IE DeBo File) as far as available (R) - IA (to RSA) Report (if applicable) (M) 		
6 Operation	Authorisation case 4.2.1	Authorisation case 4.4.4		After full completion of project specific assessment activities as required by national and EU legal provisions	<table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top; width: 50%;"> <ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M where Change is significant, otherwise R) </td> <td style="vertical-align: top; width: 50%;"> <ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M where Change is significant, otherwise R) - IE DeBo Certification (with Report) </td> </tr> </table>	<ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M where Change is significant, otherwise R) 	<ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M where Change is significant, otherwise R) - IE DeBo Certification (with Report)
<ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M where Change is significant, otherwise R) 	<ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M where Change is significant, otherwise R) - IE DeBo Certification (with Report) 						

					<ul style="list-style-type: none"> - EC Declaration of Verification (M) - National Declaration of Verification (M) - Combined Technical File (M) - EC Certification (with Report and NoBo File) (M) - IE DeBo Certification (with Report and IE DeBo File) (M) - IA (to RSA) Report (if applicable) (M) 	<ul style="list-style-type: none"> and IE DeBo File) (M) IA (to RSA) Report (if applicable) (M)
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Table B

Note: For Fixed Installations the submissions stages 1 to 3 can be combined upon a proposal of the Applicant and the agreement of the CRR.

7.3 Specific Requirements for Applications for Vehicles

In a project, it is possible, that only IOD or RSA related Authorisation Cases may be applicable, however it is typical, that a combination of both, IOD and RSA related Authorisation Cases may be required by the applicant (e.g. testing under RSA and final authorisation under IOD).

Applicants should be aware of the differences between IOD and RSA:

7.3.1 Who may be the Applicant?

According to IOD Art 2(22), the Applicant may for IOD authorisation cases be an RU, an IM or any other person or legal entity, such as a manufacturer, an owner or a keeper. For the purpose of IOD Art 15, the 'Applicant' means a contracting entity or a manufacturer, or its authorised representatives.

For Vehicle Authorisations in conformity to a Vehicle Type, the Applicant may be only the Holder of the related Vehicle Type authorisation.

For RSA authorisation cases the Applicant may be an RO. As that RO must under RSA 43 with 39 have an SMS for its activities, it is clear that only those ROs that have an SMS which covers Changes to and operation of Vehicles may be considered in the context of RSA 43. (These ROs can be seen as equivalent to RUs according to IOD/ RSD.)

In the case of Vehicles for IOD authorisation cases it is not mandatory, that the Applicant co-operates with the eventual RU (that will operate the Vehicle in the State) before performing PIS. If however after authorisation at the subsequent stage of PIS a non-compatibility between Applicant's Project SMS and RU SMS is discovered, PIS of the Vehicle may become impossible.

For RSA authorisation cases it is required that the RU intending to operate the Vehicle is the Applicant (in fulfilment of their joint obligations under Project SMS and RU SMS (refer to section 5)).

Note: In this context it may greatly reduce management effort and interfacing between stakeholders (and thus business risk), when the Applicant is the eventual RU to operate the Vehicle.

7.3.2 Requirements-Capture

According to (EU) 2018/545 the Applicant may employ one of two options for Requirements-Capture:

- The standardised methodology for the process for the requirements capture taken from (EU) 402/2013 Annex I and adapted to also capture non-safety requirements **and** provision of a positive CSM-AB Report on Requirements Capture, or
- A non-standardised methodology for the process for the requirements capture. In this case the Authorising Entity shall be presented by the Applicant with a concise report of the Applicant, on that non-standardised approach and how it has created equivalent results to the standardised methodology for the process of the requirements capture taken from (EU) 402/2013 Annex I and adapted to also capture non-safety requirements.

Note: It is important to note, that the standardised method can be assessed by the AsBo step by step together with the developing project (and feedback can be obtained and acted upon), whereas the non-standardised method can only be assessed by the CRR at the end of the project (and feedback at this late time in the project timeline may present a significant project risk).

7.3.3 Pre-Engagement Application

Where an Applicant intends later to apply for an IOD Authorisation Case for Vehicles, that Applicant may in accordance with (EU) 2018/545 22 apply at the Authorising Entity for a Pre-Engagement Opinion on a Pre-Engagement Baseline. All related requirements of (EU) 2018/545 shall be adhered to.

The Application shall be accompanied by the Pre-Engagement File.

Note: Pre-Engagement is not an Authorisation Case. It is a formalised communication for certain information between the Applicant and the Authorising Entity before an IOD Application is made. The

resulting 'Pre-Engagement Baseline' may be referred to for a maximum of 84 Months but it is subject to required modifications to (EU) 2018/545 Art24(4).

7.3.4 OSS

Any IOD Authorisation Case or any Pre-Engagement must be performed via the One Stop Shop (OSS)(ERA web based interface).

The applicant shall submit their application using the template for the application in Annex XVII of ERA's Guidelines for the Practical Arrangements for Vehicle Authorisation, available on [ERA's website](#). This template is intended to cover the requirements of Annex I of Regulation (EU) 2018/(EU) 2018/545 for the applicant's submission. The application shall include a mapping table indicating where the various aspects of the applicant's file are located.

7.3.5 Abbreviations used in Table C

Within the table the following abbreviations are used.

- (M) = document submission is mandatory.
- (MA) = document submission is mandatory and an Acceptable National Means of Compliance (ANMOC) is provided in this guideline. The ANMOC indicates an acceptable national method/ format/ content of the expected document. The indicated content is mandatory. The applicant may use an alternative method/ format, as long as
 - at least the same content is contained in a systematic and traceable structure,
 - the same overall result/ effect is generated.
- (R) = document submission is recommended

Table C of Stages relating to authorisation projects for Vehicles

Stage	Submissions on project scope where IOD applies	Submissions on project scope where RSA applies	Note	typical activities at project level	Documents to be submitted where IOD applies	Documents to be submitted where RSA applies
1 Concept	Optional: Application for a Pre-engagement Opinion ((EU) 2018/545 7(3) and 22)	Recommended: Communication to CRR on a Change to a Vehicle which will require RSA Acceptance	CRR recommends at this Stage a communication from the Applicant on the nature of the project.	After performing general concept studies or feasibility studies and prior to requesting tenders.	where this option is used: - Application for a Pre-engagement (M) - Pre-Engagement File (M)	- Communication letter (R) - SP for Concept Stage (R)
2 Preliminary Design		Recommended: Communication to CRR on a Change to a Vehicle which will require RSA Acceptance	CRR recommends at this Stage a communication from the Applicant on the status of the project.	After evaluation of tenders and preliminary decision on functional and technical design and prior to awarding a contract for execution of any work.		- Communication letter (R) - SP (R) - HR (R) - SCM (R)
3 Overall (detailed) Design		Required: Communication to CRR on a Change to a Vehicle which will require RSA Acceptance	CRR recommends at this Stage a communication from the Applicant on the status of the project.	After awarding a contract for execution of work, after detailed overall design has been elaborated and prior to production/ building.		- Communication letter (R) - SP (R) - HR (R) - SCM (R)
4 Testing	For any project: Authorisation case 4.5.1		This RSA Acceptance is required for any project where Testing in the live Railway System in the State is required.	Prior to any Testing in the live Railway System in the State.	- Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M) - CSM-AB Report on Requirements Capture (M, where used) - EC Certification (=ISV) (with Report and NoBo File) (R) - IE DeBo Certification (=ISV) (with Report and IE DeBo File) for this Stage (M) - IA (to RSA) Report (if applicable) (M)	
5 Interim Operation	Application for either authorisation case:	Authorisation case 4.5.2		After principal completion of project specific assessment	- Application Letter (M)	- Application Letter (M)

	4.3.1.5 4.3.1.6 4.3.1.7 & 4.3.3.4 4.3.3.5 4.3.3.6			activities (incl. final testing), prior to full close out of open issues.	<ul style="list-style-type: none"> - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M) - CSM-AB Report on Requirements Capture (M, where used) - EC Certification (=ISV) (with Report and NoBo File) (R) - IE DeBo Certification (=ISV) (with Report and IE DeBo File) for this Stage (M) - IA (to RSA) Report (if applicable) (M) 	<ul style="list-style-type: none"> - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - CSM-AB Safety Assessment Report (M) - CSM-AB Report on Requirements Capture (M, where used) - IE DeBo Certification (=ISV) (with Report and IE DeBo File) for this Stage (M) - IA (to RSA) Report (if applicable) (M)
5a	Authorisation Case: 4.3.2.1	n.a.			<ul style="list-style-type: none"> - Application Letter (M) - Declaration of Conformity to an Authorised Vehicle Type (M) 	n.a.
6 Operation	Application for either authorisation case: 4.3.1.1 4.3.1.2 4.3.1.3 4.3.1.4 & 4.3.3.1	Authorisation case: 4.5.3		After full completion of project specific assessment activities as required by national and EU legal provisions	<ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) 	<ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA)

	4.3.3.2 4.3.3.3				<ul style="list-style-type: none"> - CSM-AB Safety Assessment Report (M) - CSM-AB Report on Requirements Capture (M, where used) - EC Declaration of Verification (M) - National Declaration of Verification (M) - Combined Technical File (M) - EC Certification (with Report and NoBo File) (M) - IE DeBo Certification (with Report and IE DeBo File) (M) - IA (to RSA) Report (if applicable) (M) 	<ul style="list-style-type: none"> - CSM-AB Safety Assessment Report (M) - IE DeBo Certification (with Report and IE DeBo File) (M) - IA (to RSA) Report (if applicable) (M)
6a	Authorisation Case: 4.3.2.2	n.a.			<ul style="list-style-type: none"> - Application Letter (M) - Declaration of Conformity to an Authorised Vehicle Type (M) 	- n.a.

Table C

8 CRR Review of Applications

8.1 General

Note: The CRR will consider as an ANMOC for the methods and results of the Project SMS (SP; HR; CSM; ASPSC) the Section 5 and the Annexes to this guidance.

The CRR will consider as an ANMOC for the methods and results of the of the Requirements Capture process the requirements of (EC) 402/2013 Annex I in combination with the Section 5 and the Annexes to this guidance.

Upon receipt of an Application the CRR will assess the Application for plausibility and completeness (either directly to the CRR or in case of IOD APOM applications through OSS).

Where this is acceptable, the CRR will proceed to the review of the content.

In doing so, the CRR must consider whether the applicant has demonstrated that the applicable requirements of IOD, (EU) 402/2013, RSA and/or (EU) 2018/545 have been complied with.

This will typically be performed by sampling of the submitted documentation. If this does not permit a conclusive judgement, the CRR shall enlarge the sample size, request more or updated documentation or may perform audits on the Project SMS. The CRR will amend the depth of its analysis based on the quality of documentation sampled, confidence gained in the diligence of the Applicant, the complexity of the project and the risk associated with project.

If it is not possible for the CRR by these activities, to reach the understanding that the Applicant has provided a complete and valid application, the CRR must render the submitted application inadequate and the CRR will hand back the Application to the applicant. The same applies, if the Application includes falsified evidence. In that case the CRR may also be required to take legal action.

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

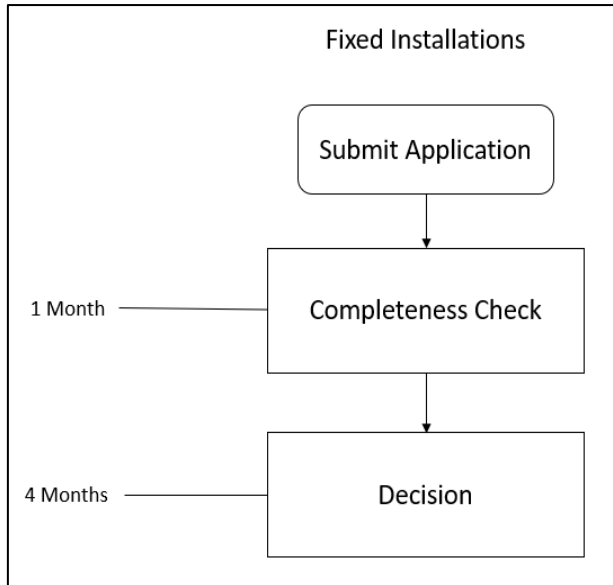
When a stage 6 APIS/Acceptance is issued by the CRR APIS/Acceptance team a copy is sent to the CRR Supervision team.

For IOD APOM the applicant will be notified of the decision via the OSS.

8.2 Fixed Installations IOD and RSA

For fixed installation APIS or for Acceptance within one month of receipt of the applicant's request, the CRR will inform the applicant that their application file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof.

The CRR will take its decision (on an Application), within four months of receipt of all relevant information. This timeframe is applicable to Fixed Installations under the scope of IOD or RSA only.



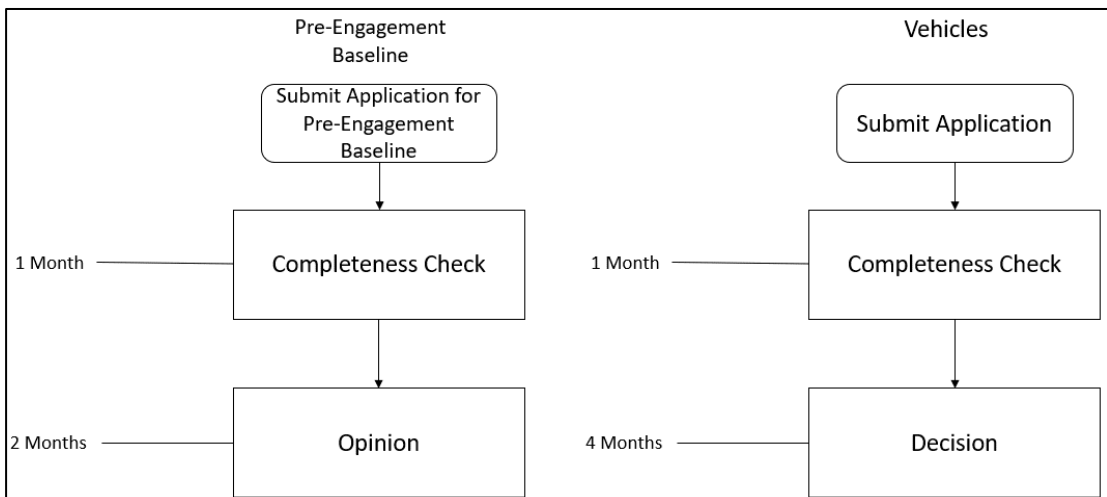
Timeframes for Fixed Installations under IOD or RSA

8.3 Vehicles IOD

For the pre-engagement application for IOD APOM, the authorising entity and, when applicable for the area of use, the CRR shall inform the applicant on the completeness or otherwise of the file submitted within one month from receiving the submission.

Where an applicant applies for pre-engagement (via OSS), two months after it has been acknowledged that the file is complete the authorising entity will issue an Opinion on the Pre-engagement baseline.

For IOD Vehicles/Vehicle Type/ Variant APOM authorisations (via OSS) the CRR will take its decision within four months, except for the case of authorisation in conformity to type. In the latter case the CRR will make a decision within one month.



Timeframes for Vehicle APOM under IOD

9 Fees and Charges

Fees and charges by the CRR are levied in accordance with the Railway Safety Act 2005, as amended.

Fees and charges by ERA will be in accordance with (EU) 2018/764.

10 Complaints and Appeals

In the case of a decision refusing an APOM/APIS/Acceptance the CRR will provide a written response to the applicant with justification.

The applicant may, within one month of receipt of the negative decision, submit an appeal that the CRR review its decision. The appeal must be accompanied by a justification.

The CRR will respond to such a request for review within two months from the date of receipt to confirm or reverse its decision.

If the applicant still has an issue with the CRR's decision, they can make a complaint to the CRR directly or alternatively make an appeal to the ERA's board of appeals. The applicant may study Regulation (EU) 2018/545 and Regulation (EU) 2016/798 to gain information on the appeals procedure.

Appeals on decisions made by the CRR and any formal complaints can be made directly to the CRR through the CRR complaints and appeals procedure (CRR-P-010). This procedure is available on the CRR website.

Where ERA is the Authorising Entity the applicant must also use the ERA's board of appeals.

11 Further Clarification

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