

CRR-G-009-H

Guidance on

Application for Authorisation and Application for Acceptance

for Heavy Rail Fixed Installations and Vehicles

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1 Introduction

This document gives guidance and explanation on the European and the Irish legal requirements for authorisation/acceptance of heavy rail 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).

The scope of this document is limited to the Republic of Ireland.

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

The following authorisation cases are described in this document:

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

- **Authorisation** for Placing in Service (APIS) of **Fixed Installations** (IOD Art 18);

Authorisation Cases related to the European Interoperability Directive (IOD) for **Vehicle Types** (with an associated combination of Variant(s)+Version(s)+Area(s) of use):

- **First Authorisation** for Vehicle Type Authorisation 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 Vehicle Type Authorisation 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 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** Vehicle Type Authorisation 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))

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):

- **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))

Under section 42 and 43 of the RSA the CRR grants acceptances of an Application Specific Safety Cases (ASPSC) for rolling stock and new works. The Acceptance Cases related to the Irish Railway Safety Act (RSA) are as follows:

for Fixed Installations:

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

for a Series of Vehicles:

- **Temporary Acceptance** 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** 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 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 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
Acceptance	Acceptance of an ASPSC by the CRR under Section 42 or 43 of a new works assessment or a new rolling stock assessment respectively.
APIS	Authorisation for Placing in Service <i>Note: now only applies to authorisations of fixed installations under IOD.</i>
APOM	Authorisation for Placing on the Market
Applicant	The organisation applying for Acceptance (RSA) or Authorisation (IOD)
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>
AsBo	Assessment Body to CSM 402/2013, providing Safety Assessment Report, providing Report on conformity of Requirements Capture Process with (EU) 2018/545
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

Term / Abbreviation	Meaning
CCS	Command, Control and Signalling
CCT	Command, Control and Signalling, Trackside
DeBo	Designated Body
DeBo-File	File, prepared by the DeBo, accompanying the EC Certificates, QMS Approvals and ISVs that were issued by the DeBo (IOD Annex IV 3.3). (RFU-STR-011 is relevant mutatis mutandis)
EC	European Commission
ENE	Energy
ERA	European Railway Agency
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 Type A as independent inspection body for those technical scopes which are contained in an acceptance project. Where in an acceptance 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 acceptance 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 CRR Guidelines.
ISA	Independent Safety Assessment, providing Assessor reporting as defined in EN50126-1/EN50126-2/EN50128/50129
ISV	Intermediate Statement of Verification: NoBo/IE-DeBo Certification covering only parts or stages of the NoBo/IE-DeBo assessment process.
MAI	Maintenance (Functional Subsystem of the Railway System See section 2.2
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: Conformity Assessment Procedure covering the design and production phases of a product. The TSI specify the Module to be used for conformity assessment for each parameter. The specific set of "modules" for Railway Subsystems are defined in Decision 2010/713/EU. Most railway specific modules require a third-party independent conformity assessment performed by NoBos and/or IE-DeBos.
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
NoBo-File	File, prepared by the NoBo, accompanying the EC Certificates, QMS Approvals and ISVs that were issued by the NoBo (IOD Annex IV 2.3.4). (See RFU-STR-011)
NR	National Rule
NSA	National Safety Authority
OPE	Functional Subsystem Operation and traffic management
OSS	One-Stop-Shop
PIS	Placing in Service (by RU/IM), after Authorisation/Acceptance 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)

Term / Abbreviation	Meaning
Rail System	See section 2.2
Railway Undertaking	as defined in the IOD
Requirements Capture	means the process of identification, assignment, implementation and validation of requirements performed by the applicant in order to ensure that relevant Union and national requirements are complied with. Requirements capture may be integrated in the product development processes. (Reg. 2018/545)
RFU	Recommendations for Use (RFUs) are prepared by the coordination group of the notified bodies (NB-Rail). The RFUs record questions, doubts or concerns about a specific TSI content or some aspects regarding its application together with a common solution/interpretation. RFUs are not intended to change the text of a TSI or any other European legislation but are proposed to provide a common understanding on relevant issues or parts of a legal text. The complete list of RFUs can be found on the NB-Rail website. See NB-Rail homepage (http://circa.europa.eu/irc/nbg/nbrail/info/data/en/information/nbrail/RFU.htm)
RO	Railway Organisation (Please refer to SI 476 2020 6 (2))
RSA	Irish Railway Safety Act 2005, including Amendments
RSD	Directive (EU) 2016/798 (recast of Directive 2004/49/EC) Railway Safety Directive, including Amendments
RST	Rolling Stock
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 Organisation (to RSA) as relevant.
SC	Safety Case, documented demonstration that the product (e.g. a system, subsystem or equipment) complies with the specified safety requirements (EN50126)
SCM	Safety and Compliance Matrix
SMS	Safety Management System, this guidance refers to both SMS (RSA) and SMS(RSD) as just SMS to aid readability.
SP	Safety Plan
Subsystem	The structural or functional parts of the Union rail system, as set out in Annex II; see IOD, Annex II
TAF	Telematic Applications Freight
TAP	Telematic Applications Passengers
TD	ERA Technical Document is a document issued by the Agency (ERA). It 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)
Technical File	File containing: Nobo-File, Debo-File, Design evidence documentation, Certificates Relating to other legislation of the Union, list of ICs and the AsBo safety assessment report (on the verification of the safe integration). This is prepared by the applicant and submitted with the EC declaration of verification (IOD Art. 15(4) & Annex IV 2.4) (See RFU-STR-011)
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)
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.

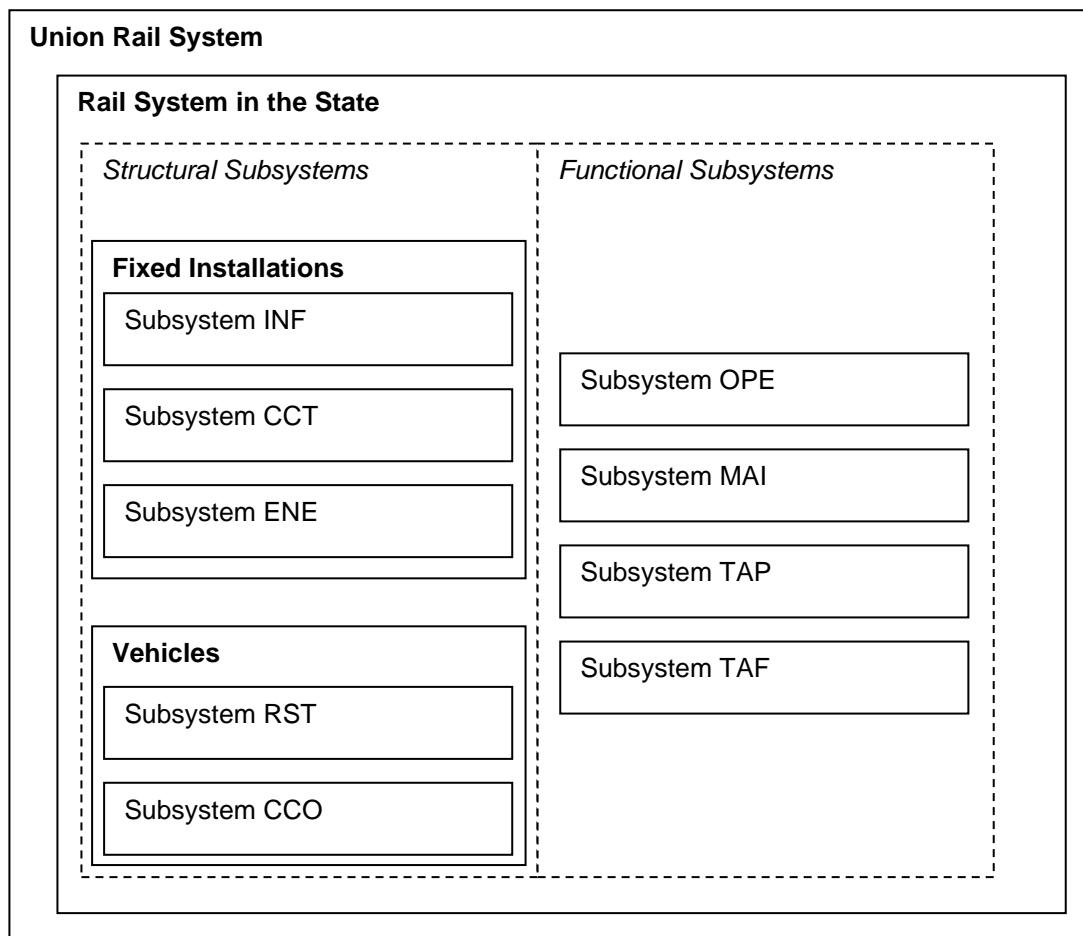
2.2 Definitions

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.

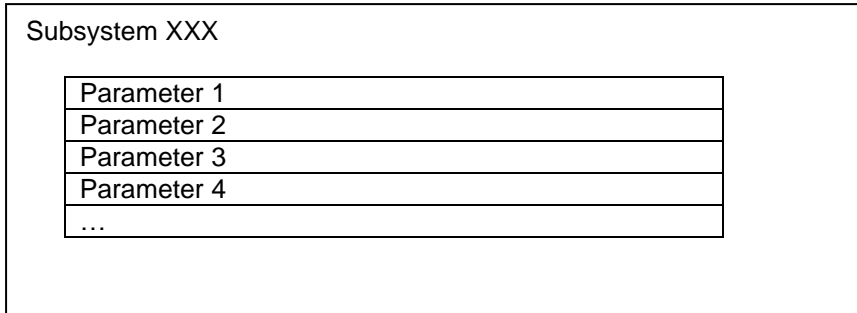
2.2.2 Subsystems

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:



2.2.3 Parameters

All sub-systems are composed of parameters. Some of the parameters for a railway subsystem will be defined in the relevant TSIs as 'basic parameters', but for all of the subsystems there exists parameters which compose the subsystem which are not listed as a 'basic parameter'.



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/Acceptance 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 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 management of the change should consider not only the elements within the scope of the change but also the effect on interfaces and the system as a whole.

For Changes a large set of requirements may apply (e.g. legal, contractual, among others). This is discussed further in section 5.

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 Art 15 and IOD Art 21(12) 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/acceptance. Changes which require an authorisation/acceptance are referred to as Material Changes throughout this document regardless of the legislative framework or authorisation/acceptance case applicable.

It is the duty of the proposer for a Change to determine whether the extent of a Change requires an authorisation/acceptance or not. Additionality of smaller Changes since the last authorisation/acceptance 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 may lead to enforcement actions.

Change proposers may wish to refer to RSA2005, (EU) 2018/545, RSD, IOD and 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.

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.

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 Version 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 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 requires an Applicant, who in this context shall be an IM 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

- Vehicles be an RU that has been certified for the intended form of operation on the Rail System of the State (e.g. testing, passenger, freight),
- Fixed Installations 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; as amended by (EU) 2015/1136
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
(EU) 2020/453	COMMISSION IMPLEMENTING DECISION (EU) 2020/453: Commission Implementing Decision (EU) 2020/453 of 27 March 2020 on the harmonised standards for railway products drafted in support of Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community
<i>TSI</i>	<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>
<i>ERA TSI Guidance</i>	<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 1209/063 V 1.0	Clarification Note on Safe Integration ERA 1209/063 V 1.0
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
RFU-STR-011	Content of NoBo File

4 Authorisation/Acceptance Cases

4.1 General Information on all Authorisation/Acceptance Cases

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

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

There are legal requirements on who may be an applicant for a certain authorisation/acceptance case, see section 7.12.

For each of the authorisation/acceptance cases described in this section 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/acceptance case(s) for their project.

It is possible, that several parallel options of authorisation/acceptance cases are available to choose from.

It is also possible that several authorisation/acceptance cases must be combined and performed in parallel or in a prescribed succession.

4.1.1 The geographical and technical scope of authorisation cases under IOD in Ireland

S.I. 477/2020 gives effect to the IOD((EU) 2016/797) and the scope of the IOD is established in Reg. 3 within the S.I. The following railway infrastructure is exempt from the Regulations of S.I. 477/2020 and by extension the IOD:

- (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.

Applicants must consider the technical and geographic scope when determining which authorisation/acceptance case is relevant to their project. The authorisation cases applicable under the different legislative frameworks are described in sections 4.2 to 4.5. Figures 1 (for vehicles) and 2 (for fixed installations) show the authorisation/acceptances cases and their respective section in this document. As shown, regardless of the applicable legislative framework for the final authorisation/acceptance, the acceptances for testing are granted with respect to the RSA.

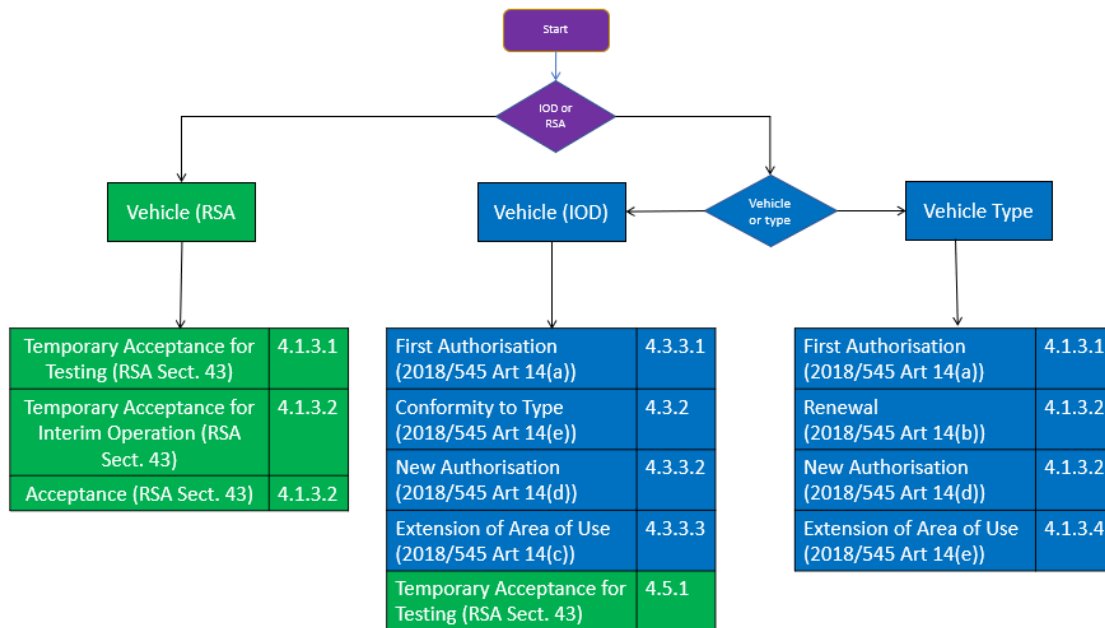


Figure 1-Flowchart for Vehicle Authorisation/Acceptance Cases

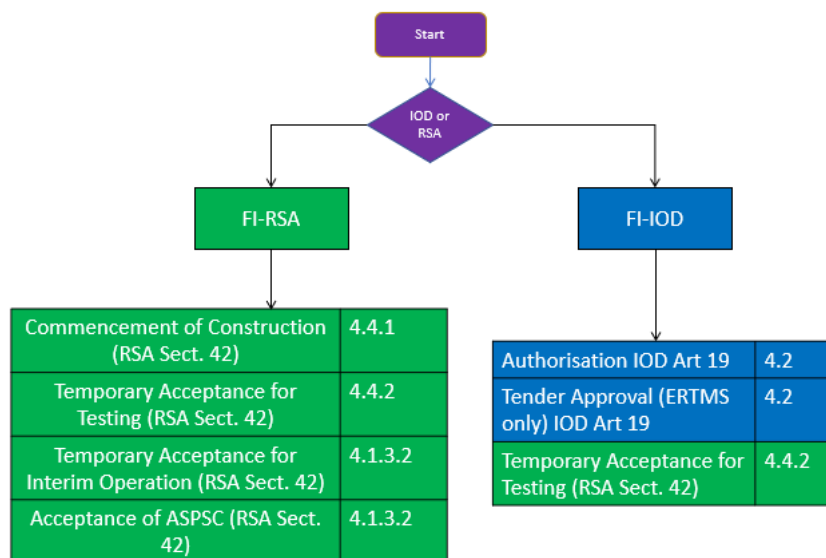


Figure 2-Flowchart for Fixed Installation Authorisation/Acceptance Cases

4.1.2 The geographical and technical scope of acceptance 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

- 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 acceptances in respect of heavy rail (For light rail acceptance 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 deemed necessary, they must be added by the Applicant to the mentioned documented evidence.

For Temporary Acceptance to RSA, the CRR may need to place additional conditions on an Acceptance to ensure that compliance with the requirements will be maintained. This shall be based on a plausible corrective action plan submitted by the Applicant.

For Authorisations to IOD, the Authorising Entity may add additional conditions to the conditions placed by the applicant. The applicant may request a review of these conditions ((EU) Reg. 2018/545 Art. 46(8) and if they are still unsatisfied, they may appeal these conditions under (EU) Reg. 2018/545 Art. 51, in a similar manner to how they would appeal a decision.

As per (EU) Reg. 2018/545 Art. 46(6)-time limited conditions may be placed on an authorisation, provided the applicant can submit a suitable estimate of compliance. However, these should be generally avoided.

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 (IOD Art 18 (1)+(2)).

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 the event of renewal or upgrading of existing subsystems, the applicant shall send a file describing the project to the CRR. The CRR, shall examine the file and shall decide whether a new authorisation for placing in service is needed, on the basis of the following criteria:

- (a) the overall safety level of the subsystem concerned may be adversely affected by the works envisaged;
- (b) it is required by the relevant TSIs;
- (c) it is required by the national implementation plan; or
- (d) changes are made to the values of the parameters on the basis of which the authorisation was already granted. The CRR shall take its decision within a predetermined, reasonable time, and, in any case, within four months of receipt of all relevant information.

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. This should be provided as part of the stage 1 submission, see Table B in section 7. For projects within the scope of the RSA this letter must be provided prior to commencement of construction, see section 4.7.1.

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))

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

4.4.1

4.4.2

4.4.3

Notes:

Maintenance activities and such activities which merely reinstate the original design/ performance properties are usually not Material Changes, see section 2.2.4. However, maintenance activities which alter the original design/ performance properties may require authorisation. It is the proposer's responsibility to determine if an authorisation is required.

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 Articles 14&15 define several authorisation cases from which the applicant must chose the appropriate case(s), and apply them in the correct sequence.

4.3.1 Vehicle Type Authorisations

4.3.1.1 **First Authorisation for 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 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 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.

Note: In case of changes to an already authorised vehicle type and/ or vehicle, the applicant for the new authorisation is responsible for the new design and the new vehicle type as a whole. However, the existing holder of the vehicle type authorisation is still responsible for the unchanged parts of the design and the new applicant is responsible for the changes it introduces and the interfaces with the unchanged parts of the design of the vehicle type.

4.3.1.4 Extended Area of Use Authorisation 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.

4.3.2 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))

Where the Applicant has been able to validate that a physical Vehicle or a series of Vehicles conforms to an already authorised Vehicle Type and its/their 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 (series 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.

Note: For conformity to type for a series of vehicles Applicants may submit one single application for the whole series, provided they meet the above criteria.

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.

4.4 Acceptance 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 acceptance 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 the CRR on a Change to Fixed Installation which will require Acceptance. This should be provided as part of the stage 1 submission, see Table B in section 7.

Note: Maintenance activities which merely re-instate the original design/ performance properties are usually not Material Changes, as per RSA 42(15). Maintenance activities which alter the original design/ performance properties may require acceptance.

4.4.1 Acceptance 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 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 Acceptance.

4.4.2 Temporary Acceptance for testing 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 fixed installation for testing within the active Rail System in the state, that Applicant may apply for the Acceptance.

4.4.3 Temporary Acceptance 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.

4.4.4 Acceptance 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.

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

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

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 Vehicle/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 acceptance cases in this section apply to Material Changes to Vehicle(s). Material Changes in this context include

- Introduction of new Vehicle Type+ Variant +Version +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: Maintenance activities and such activities which merely re-instate the original design/ performance properties are usually not Material Changes, as per RSA 43(14). Maintenance activities which alter the original design/ performance properties may require acceptance. Significant renewals may also require acceptance.

4.5.1 Temporary Acceptance 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.

4.5.2 Temporary Acceptance 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.

4.5.3 Acceptance 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.

5 Non-Application of TSIs and NRs

For applications under the IOD any applicant must comply with relevant TSIs and IE NRs unless the Applicant has applied for and has been granted Non-Application for the TSIs or national rules.

5.1 Non-Application of TSIs

The non-application of (parts of) TSIs may be allowed by the European Commission on the basis of IOD Art.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 Regulation (EU) 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 (see also IOD Art. 14 (1.c) & 45(2)) .

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.

5.2 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 to apply an alternative provision that will result in:

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

In cases where the IE NRs have been updated during the course of the project and complying with the new version of the IE NR has an impact on the viability of the project, then the applicant can use the same process to justify the application of the IE NR as they would use for an alternative provision and justify that using the superseded IE NR for the project meets criteria i to iv above. This may require additional measures beyond the measures in the superseded IE NR to ensure that the criteria above are met.

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

The CRR shall determine, based on the requirements of this clause 5.2, 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.

6 Applying for Authorisation/Acceptance Cases

6.1 General Requirements for any Authorisation /Acceptance Case

6.1.1 Stages

The project timeline is divided into six Stages (five stages for APOM and Authorisation of Vehicle Types) which must be performed in successive order. Certain stages may be combined or omitted.

6.1.2 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.

6.1.3 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/Acceptance Case further associated communications or documented evidence.

All associated communication or documented evidence must be created/ updated/ 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/Acceptance 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/Acceptance Case to the CRR. In order to obtain a statement of the CRR on the plausibility of the approach chosen by the applicant.	Applicant

	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).	
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
Safety 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
AsBo Safety Assessment Report	Refer to (EU) 402/2013 with EN 17020	AsBo
AsBo Report on Requirements Capture (only for Vehicle projects)	Refer to (EU) 2018/545 in connection with (EU) 402/2013.	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
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
IPR Report (RSA only)	Independent Professional Review, providing independent assessment reporting on certain parameters within the scope of a project, in accordance with CRR Guidelines.	IPR
IA (to RSA) Report	Refer to RSA, ISO 17020.	IA

Table A

6.1.4 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 sections 43 and 44 of RSA, 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.

6.1.5 ERTMS trackside Tender applications

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

6.2 Specific Requirements for Applications for Fixed Installations

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

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

6.2.1 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. Logically the applicant for Fixed Installations should be the IM. The applicant needs to provide documentary evidence of compliance with (EU) 402/2013 and (EU) 2018/762. The IM may also have other particular requirements.

For RSA acceptance cases the Applicant must 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 where the Applicant is not the IM, that the Applicant must closely cooperate 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.

6.2.2 Request for ERA approval for Tenders of ERTMS projects

For trackside control-command and signalling projects involving European Train Control System (ETCS) and/or Global System for Mobile Communications - Railway (GSM-R) equipment, the application must include the positive decision of the Agency issued in accordance with IOD Art.19. If a change to the draft tender specifications or to the description of the envisaged technical solutions has occurred after the positive decision, then the compliance with the result of the procedure referred to in Regulation (EU) 2016/796 Art. 30(2) must also be included.

6.2.3 Requirements Capture

Though not mandated for Fixed Installations the CRR recommends the use of the requirements capture process in applications. See also section 6.3.2 and Annex 5.

6.2.4 Abbreviations used in Table B

Within the table the following abbreviations are used.

- (M) = document submission is mandatory.
- (MA) = document submission is mandatory and the respective methods outlined in Annex 1-6 of this guidance are considered a suitable means of creating the documents. However, 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/acceptance projects for Fixed Installations

Stage	IOD Submissions	RSA Submissions	Note	Typical activities at project level	Documents for IOD Submissions	Documents for RSA Submissions
1 Concept	For any project: Communication to CRR on a Change to Fixed Installation which will require Authorisation /Acceptance		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.	- Communication letter (M) - SP (MA)	- 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.			- Request letter (M)	n.a.
2 Preliminary Design	For any project: Communication to CRR on a Change to Fixed Installation which will require Authorisation /Acceptance		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.	- Communication letter (M) - SP (MA) - HR (MA) - SCM (MA)	- Communication letter (M) - SP (MA) - HR (MA) - SCM (MA)
3 Overall (detailed) Design	For any project: Acceptance 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.	- Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) ASPSC for this Stage (MA)	
4 Testing	For any project: Acceptance 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.	- Application Letter (M) - SP (MA) - HR (MA) - SCM (MA)	- Application Letter (M) - SP (MA) - HR (MA) - SCM (MA)

				<ul style="list-style-type: none"> - ASPSC for this Stage (MA) - AsBo Safety Assessment Report (M where Change is significant, otherwise R) - EC Certification (=ISV) (with Report and NoBo File (R))and IE DeBo Certification (=ISV) (with Report and IE DeBo File) for this Stage(M unless an IPR Report is provided, see Note in sect. 5.18) - IA (to RSA) Report (M if applicable) 	<ul style="list-style-type: none"> - ASPSC for this Stage (MA) - AsBo Safety Assessment Report (M where Change is significant, otherwise R) - IE DeBo Certification (=ISV) (with Report and IE DeBo File) (M unless an IPR Report is provided, see Note in sect. 5.18) - IA (to RSA) Report (M if applicable)
5 Interim Operation	For any project: Acceptance 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) - AsBo 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) - AsBo Safety Assessment Report (M where Change is significant, otherwise R)

					<ul style="list-style-type: none"> - 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 (M if applicable) 	<ul style="list-style-type: none"> - IE DeBo Certification (=ISV) (with Report and IE DeBo File)(M unless an IPR Report is provided, see Note in sect. 5.18) - IA (to RSA) Report (M if applicable)
6 Operation	Authorisation case 4.2.1	Acceptance case 4.4.4		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) - AsBo Safety Assessment Report (M where Change is significant, otherwise R)EC Declaration of Verification (M) - National Declaration of Verification (M) - Technical File (M) - EC Certification (with Report and NoBo File) (M) - 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) - AsBo Safety Assessment Report (M where Change is significant, otherwise R) - IE DeBo Certification (=ISV) (with Report and IE DeBo File)(M) (an IPR Report will also suffice see Note in sect. 5.18) - File containing technical evidence(M if a DeBo file is not submitted.)

					and IE DeBo File) (M) - IA (to RSA) Report (M if applicable)	- IA (to RSA) Report (M if applicable)
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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.

6.3 Specific Requirements for Applications for Vehicles

In a project, it is possible, that only IOD or RSA related Authorisation/Acceptance Cases may be applicable, however it is typical, that a combination of both, IOD and RSA related Authorisation/Acceptance 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.

6.3.1 Who may be the Applicant?

According to IOD Art 2(22), the Applicant may for IOD vehicle 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 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 **Error! Reference source not found.**)).

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.

6.3.2 Requirements-Capture

The risk management process set out in Annex I to (EU) No 402/2013 shall be used by the applicant as the methodology for requirements capture as regards the essential requirement 'safety' related to the vehicle and subsystems as well as safe integration between subsystems for aspects not covered by the TSIs and the national rules.

For the management of other requirements 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 AsBo 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 by 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).

6.3.3 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).

6.3.4 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.

6.3.5 Abbreviations used in Table C

Within the table the following abbreviations are used.

- (M) = document submission is mandatory.
- (MA) = document submission is mandatory and the respective methods outlined in Annex I-IV of this guidance are considered a suitable means of creating the documents. However, 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/acceptance projects for Vehicles

Stage	IOD submissions	RSA Submissions	Note	typical activities at project level	Documents for IOD submissions	Documents for RSA submission
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) - AsBo Safety Assessment Report (M) AsBo Report on Requirements Capture (M, where used) - EC Certification (=ISV) (with Report and NoBo File (R)) and IE DeBo	- Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - AsBo Safety Assessment Report (M) AsBo Report on Requirements Capture (M, where used) - IE DeBo Certification (=ISV) (with Report and IE

					<p>Certification (=ISV) (with Report and IE DeBo File) for this Stage (M))(an IPR report may also suffice for this stage, see Note in sect. 5.18)</p> <p>- IA (to RSA) Report (M if applicable)</p>	<p>DeBo File)(M) (an IPR Report will also suffice see Note in sect. 5.18)</p> <p>- IA (to RSA) Report (M if applicable)</p>
5 Interim Operation	N/A	Acceptance case 4.5.2		After principal completion of project specific assessment activities (incl. final testing), prior to full close out of open issues.	- N/A	<ul style="list-style-type: none"> - Application Letter (M) - SP (MA) - HR (MA) - SCM (MA) - ASPSC for this Stage (MA) - AsBo Safety Assessment Report (M) - AsBo Report on Requirements Capture (M, where used) - IE DeBo Certification (=ISV) (with Report and IE DeBo File)(M) (an IPR Report will also suffice see Note in sect. 5.18) - IA (to RSA) Report (M if applicable)
6 Operation	Application for either authorisation case: 4.3.1.1 4.3.1.2 4.3.1.3 4.3.1.4 &	Acceptance 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)

	4.3.3.1 4.3.3.2 4.3.3.3				<ul style="list-style-type: none"> - AsBo Safety Assessment Report (M) - AsBo Report on Requirements Capture (M, where used) - EC Declaration of Verification (M) - National Declaration of Verification (M) - 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 (M if applicable) 	<ul style="list-style-type: none"> - AsBo Safety Assessment Report (M) - IE DeBo Certification (=ISV) (with Report and IE DeBo File)(M) (an IPR Report will also suffice see Note in sect. 5.18) - IA (to RSA) Report (M if applicable) File containing technical evidence (M if DeBo-File is not provided)
6a	Authorisation Case: Error! Reference source not found.	n.a.			<ul style="list-style-type: none"> - Application Letter (M) - Declaration of Conformity to an Authorised Vehicle Type (M) 	- n.a.

Table C

7 CRR Review of Applications

7.1 General

*Note: The CRR consider the methods (SP; HR; CSM; ASPSC) outlined in Section **Error! Reference source not found.** and the Annexes to this guidance as a suitable means of creating a Project SMS .*

*The CRR consider the requirements of (EC) 402/2013 Annex I in combination with Section **Error! Reference source not found.** and the Annexes to this guidance as a suitable means of performing the Requirements Capture process.*

Applications are submitted either directly to the CRR or in the case of APOM and Authorisations for Vehicle Type(s) through the OSS. Upon receipt of an Application the CRR will assess the Application for plausibility and completeness.

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

During the review 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 (RSA Sect. 42(2), 43(2) or IOD Art. 18 (7) + 21(7)). For APOM and Authorisations for Vehicle Types applications this process will be managed through the identification of issues in line with (EU) 2018/545 Art. 41. If the Application includes falsified evidence, the application will be immediately refused. 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/Acceptance/APOM/Authorisation for Vehicle Type 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.

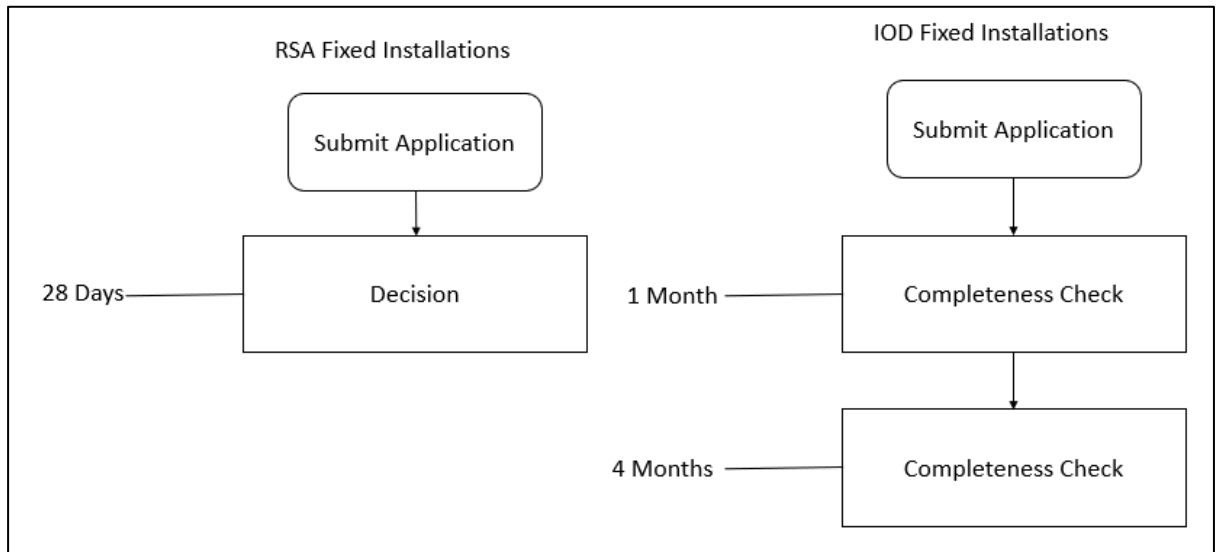
For APOM and Authorisations for Vehicle Type(s) the applicant will be notified of the decision via the OSS.

7.2 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.

The CRR will take its decision (on an Application), within four months of receipt of all relevant information for Fixed Installations under the scope of IOD. The CRR will take its decision (on

an Application), within 28 days of receipt of all relevant information for Fixed Installations under the scope of RSA.



Timeframes for Fixed Installations under IOD or RSA

7.3 Vehicles RSA

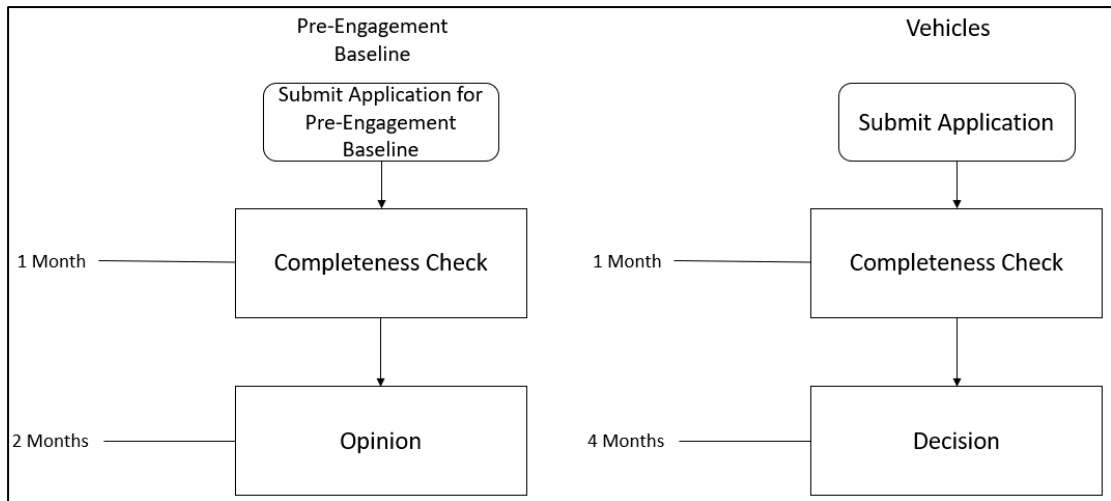
For Vehicle Acceptance (Case 4.5.1, 4.5.2 and 4.5.3.) the CRR will provide the applicant with a decision within 28 days, beginning on the date of receipt by the Commission of a new rolling stock assessment or a revised new rolling stock assessment or receipt of all information or clarifications requested by the CRR.

7.4 Vehicles IOD

For the pre-engagement application for APOM and Authorisations for Vehicle Type(s), 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 APOM and Authorisations for Vehicle Types and Variants (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 and Authorisation for Vehicle Types and Variants

8 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, as amended.

9 Complaints and Appeals

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

Appeals on decisions made by the CRR and any formal complaints can be made directly to the CRR through the CRR Representations 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.

10 Further Clarification

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