# 4. Paketti – mikä muuttuu?

3.5.2019

# Ohjelma

*8.30-9.00*    *Aamukahvi*

**9.00-9.05**    **Opening of the Seminar**
Railway Director Yrjö Mäkelä, Traficom

**9.05-9.20**    **ERA Academy**
Trainee Lorenzo Appressi, Executive office and Communication Unit, ERA

**9.20-10.00**    **Vehicle authorization – Basic principles 1**
Project Officer Jean-Francois Demoutiez, Planning and Approvals Delivery Unit, ERA

**10.00-10.40**    **Vehicle authorization – Basic principles 2**
Project Officer Kamil Pravdík, Railway Systems Unit, ERA

**10.40-11.00**    **Board of Appeal and ERA fees and charges**
Project Officer Jean–François Demoutiez, Planning and Approvals Delivery Unit, ERA

**11.00-11.15**    **An overview on the latest developments in the railway policy and legislation**
Senior Ministerial Advisor Risto Saari, Ministry of Transport and Communications

**11.15-11.30**    **Questions and answers**

*11.30-12.30*    *Lounas*

**12.30-12.40**    **Uusi sääntelykehys ja ohjeistus**
Johtava asiantuntija Une Tyynilä, Raideliikenteen esikunta, Traficom

**12.40-13.10**    **Markkinoillesaattamisluvan hakeminen**
Erityisasiantuntija Mauno Pajunen, Raideliikenteen infra -yksikkö, Traficom

**13.10-13.30**    **Markkinoillesaattamishakemuksen arviointi**
Tarkastaja Hannu Timperi, Raideliikenteen infra -yksikkö, Traficom

**13.30-13.40**    **Traficomilta haettavan markkinoillesaattamisluvan hinta ja muutoksenhakumahdollisuudet**
Johtava asiantuntija Une Tyynilä, Raideliikenteen esikunta, Traficom

**13.40-14.15**    **Mikä muuttuu ERTMS-ratalaitteiden hyväksynnöissä?**
Erityisasiantuntija Jukka Leino, Raideliikenteen infra -yksikkö, Traficom

**14.15-14.30**    **Kysymyksiä ja vastauksia**

*14.30-14.45*    *Kahvi*

**14.45-16.15**    **Keskitetyn palvelupisteen (One Stop Shop) käyttöopastus esimerkein**
Erityisasiantuntija Mauno Pajunen ja tarkastaja Hannu Timperi, Raideliikenteen infra -yksikkö, Traficom

# ERA Academy

Helsinki, 3rd May 2019

**Art. 39 of Regulation (EU) 2016/796** "Communication and dissemination"

"The Agency shall communicate to relevant stakeholders information relating to the Union framework of railway law and the development of standards and guidance in accordance with relevant communication and dissemination plans adopted by the Management board …"

Activity examples: **workshops**, **conferences** and **other dissemination events**

**Art. 43** "Assistance to MSs, candidate countries and stakeholders"

1. "At the request of the Commission, MSs, candidate countries or the networks referred to in Art. 38, the Agency shall engage in training and other appropriate activities concerning the application and explanation of railway safety and interoperability legislation and related products of the Agency such as registers, implementation guides and recommendations"

2. "The nature and extent of the activities referred to in paragraph 1, including the possible impact on resources, shall be decided by the Management board and included in the Agency programming document. The costs of such assistance shall be borne by the requesting parties unless otherwise agreed"

For whom are these activities?

- Railway undertakings, Infrastructure managers, Manufacturers
- National safety authorities, National investigation bodies
- Other applicants required by the NSAs
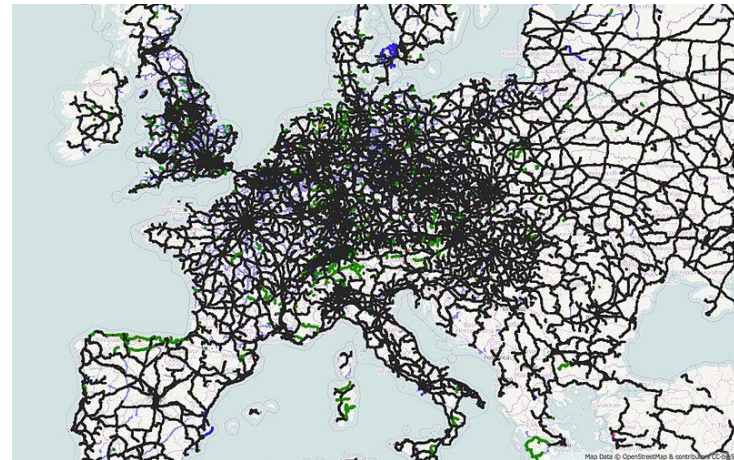
**WORK PACKAGE 1**. Establishing the ERA Academy

- Defining the **technical specifications** of the web tool

- Drafting the **ERA Academy concept** (strategic paper)

- Defining the open **Extranet page**

- Contact us at Academy@era.europa.eu
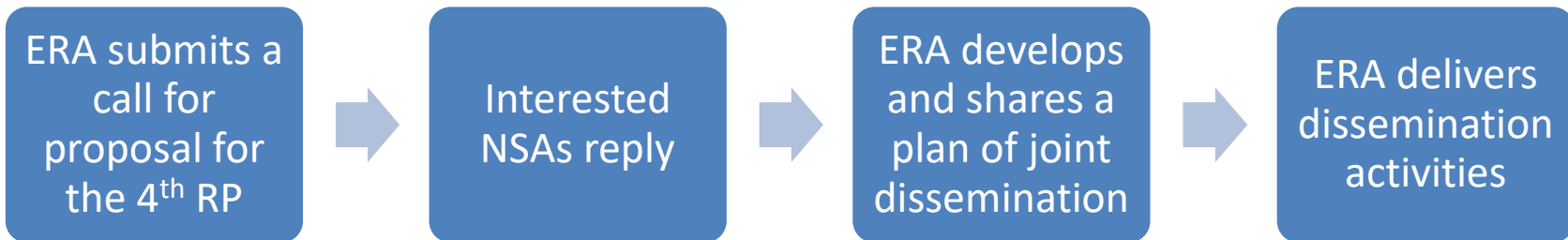
**WORK PACKAGE 2.** Developing dissemination material

ERA experts develop the **ERA Academy Library** containing dissemination and training materials packages

- Review and improve the quality of existing training materials
- Development of training videos to raise awareness on SSC, VA and ERTMS TA
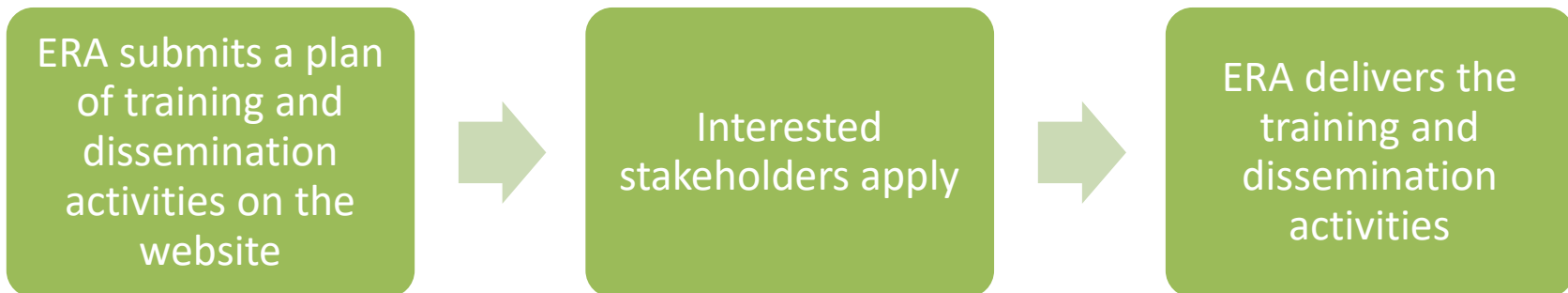- Next: risk assessment, transport of dangerous goods, safety culture, etc.

**WORK PACKAGE 3.** Delivering dissemination

**2019**

| ERA submits a call for proposal for the 4th RP | → | Interested NSAs reply | → | ERA develops and shares a plan of joint dissemination | → | ERA delivers dissemination activities |

**Forthcoming development**

| ERA submits a plan of training and dissemination activities on the website | → | Interested stakeholders apply | → | ERA delivers the training and dissemination activities |

The Agency is opting to recognise external experts:

1. To train the trainers (*Pool of Instructors*);

2. To organise and deliver training and dissemination activities on her behalf (*Recognised Training Organisms*, like training centres, Universities, etc.)

RTO

PoI

SCHOOL

/abc

NEVER STOP LEARNING!

# Dissemination activities in the context of the 4<sup>th</sup> RP. Planning
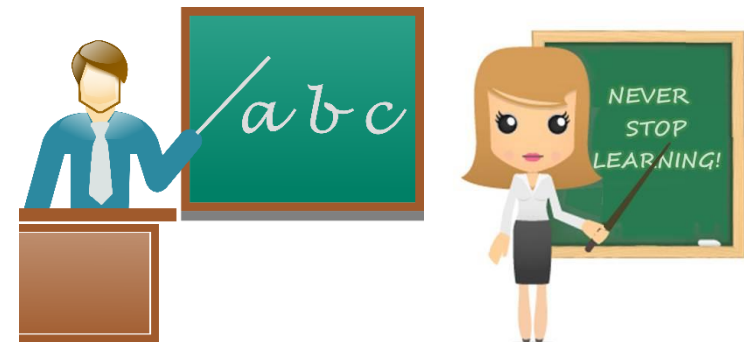
Dissemination activities in the context of the 4th RP. Planning

| Events type | Hosting organisation | Date | Place |
|---|---|---|---|
| Workshops on the technical pillar of the 4th RP | NSA FI | 02 – 03/05/2019 | Helsinki, Finland |
| | NSA HU | 04 – 05/06/2019 | Budapest, Hungary |
| | NSA PL | 18 – 19/06/2019 | Warsaw, Poland |
| | NSA IT | 10 – 11/09/2019 | Florence, Italy |
| | NSA HR | 23 – 24/09/2019 | Zagreb, Croatia |
| | NSA PT | 23 – 24/10/2019 | Lisbon, Portugal |
| | NSA DE | 29 – 30/10/2019 | Bonn, Germany |
| | NSA SE | 04 – 05/12/2019 | Stockholm/Örebo, Sweden |

"Training is expensive.

Without training is more expensive."

(Jawaharlal Nehru)

**EUROPEAN UNION AGENCY FOR RAILWAYS**

Making the railway system work better for society.

Follow us on  ERA_railways

Discover our job opportunities on **era.europa.eu**

# Presentation on vehicle authorisation
# in the framework of the 4th Railway Package

Kamil PRAVDIK, Jean – François DEMOUTIEZ

Helsinki, 3 May 2019

EUROPEAN
UNION
AGENCY
FOR RAILWAYS

# The legal framework

**1991**

**Council Directive 91/440/EEC**
Non discriminatory access to railway infrastructures

**1995**

**Council Directive 95/18/EC**
Licensing of railway undertaking

**1996**

**White paper**
A strategy for revitalising the Community's railways

**2001**

**1st railway package**
Open the international freight market, clarification of roles in the railway system, licensing of freight operators, policy for allocating capacity and fees

**2004**

**2nd railway package**

Interoperability Directive amended (covering TEN network), Safety Directive 2004/49/CE and Regulation 881/2004 (European Railway Agency created)

**2007**

**3rd railway package**

passenger rights better guaranteed, opening of the market for international railway services (from January 2010), European license for train drivers

**2008**

Interoperability Directive 2008/57/EC covering all the railway network
Directive 2008/110/EC amending the Safety Directive (ECMs introduced)

**2016**

**4th railway package (technical pillar)**

major revision of ERA regulation, Interoperability and Safety directives: new roles and responsibilities for ERA, single safety certificate and improved vehicle authorisation process

# The Vehicle (type) authorisation process - Applicable legislation and documents

## Directives

2016/797 - Interoperability directive
2016/798 - Safety directive

## Regulations

2016/796 - Agency regulation
2018/545 - Practical arrangements for the VA process
402/2013 - CSM for risk evaluation and assessment
250/2019 - EC declaration of verification
Draft - Classification of National Rules (2nd half 2019)

## Guidance

ERA-PRG-005/02_361 - Practical arrangements - VA process
ERA-PRG-005/02_374 - Catalogue of examples

## Agreements

Cooperation agreements between the Agency and the NSA

# The Vehicle (type) authorisation process – Document repository

## era.europa.eu



ERA > Applicants > Applications for vehicle (type) authorisation

### Legal framework

🔗 Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process

🔗 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 {...}

### Related guidance

📄 Practical arrangements for the vehicle authorisation process - Guidelines (5.72 MB)

📄 Practical arrangements for the vehicle authorisation process - Guidelines - Annex XVIII flowcharts (high-res) (1.89 MB)

📄 Practical arrangements for the vehicle authorisation process - Examples (170.19 KB)

📄 Clarification on authorisation of wagons in conformity with point 7.1.2 of the WAG TSI (211.47 KB)

### Related documents

📄 Overview of applicable legal framework (154.82 KB)

📄 OSS user guide for vehicle (type) authorisation applicants (1.58 MB)

### Related links

🔗 One-Stop Shop (OSS)

🔗 ERATV database

🔗 ERADIS database

🔗 Technical Specifications for Interoperability

🔗 National rules

🔗 Conformity Assessment

🔗 FAQ

# What's new?

NEWS

Vehicle to be used in 3 Member States

| 3rd railway package | 4th railway package | Vehicle type +variant & version |

MS 1 — First authorisation

MS 2 — Additional authorisation

MS 3 — Additional authorisation

ONE SINGLE AUTHORISATION

Authorisation for placing in service

Authorisation for placing on the market
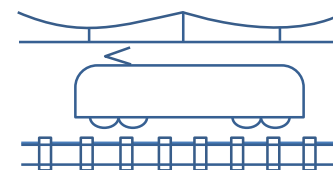
Vehicles

# The vehicle authorisation process in the context of railway operations

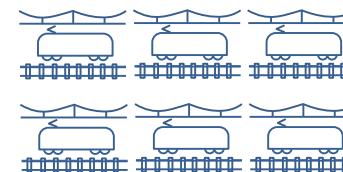| | | Activity | | >1 MS | Only 1 MS |
|---|---|---|---|---|---|
| 1 | Placing on the market of mobile subsystems | • Essential Requirements<br>• No need for authorisation of the mobile subsystem<br>• EC Declaration of Verification | | Applicant | |
| 2 | Vehicle authorisation for placing on the market / Vehicle type authorisation | • Technical compatibility of the subsystems within the vehicle<br>• Safe integration of the subsystems within the vehicle<br>• Technical compatibility of the vehicle with the network in the area of use | | Authorising entity<br><br>The Agency in collaboration with NSAs | The Agency or NSA (Applicant's choice) |
| | | | | One-Stop Shop | |
| 3 | Check before the use of authorized vehicle | Route compatibility on the basis of the Register of Infrastructure (RINF) and national rules | | Railway Undertaking | |
| 4 | Supervision | In case of non-compliance to essential requirements noticed during operation by Railway undertakings or ultimately by NSA and inducing safety risks (e.g. during supervision activities) authorisation can be <u>suspended, revoked or amended.</u> | | NSA(s) | |

The authorising entity depends on the area of use

- If the area of use = more than one Member State, then:
  - **The Agency is the authorising entity** and issues the vehicle authorisation for placing on the market and/or the vehicle type authorisation
  - The Agency collaborates with the concerned NSAs, the collaboration is structured in the cooperation agreements

- If Area of use = one Member State only, then:
  - **The applicant can choose** the Agency or the concerned NSA

In both cases the application is to be submitted through the One-Stop Shop (OSS)

# A single VA process

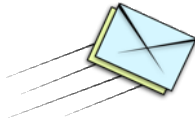**Stage 1** Preparation of the application

**Stage 2** Pre-engagement

**Stage 3** Conformity assessment

**Stage 4** Submitting the application

**Stage 5** Processing the application

**Stage 6** Final documentation

Suspension, revocation or amendment of an issued authorisation

**EU HARMONISED PROCESS**

**5 (+ 2) vehicle authorisation cases**

Case #

**First authorisation**

**1** — For a new vehicle type (including its variants and versions), and where applicable the first vehicle(s)

**New authorisation**

**2** — After a change (requiring an authorisation) of an already authorised vehicle type (including its variants and versions) and/or vehicle(s)

**Extended area of use**

**3** — For an already authorised vehicle type (including its variants and versions) and/or vehicle(s) in order to extend the area of use without a change of the design

**Renewed vehicle type authorisation**

**4** — For an already authorised type (including its variants and versions) in the event of a change to any relevant provisions in TSIs or national rules requiring the renewal of its authorisation

**Conformity to type**

**5** — For vehicles or series of vehicles conform to an already authorised and valid vehicle type (including its variants and versions)

Or combinations:
6. 'First authorisation + Conformity to type', or
7. 'New authorisation + extension of area of use

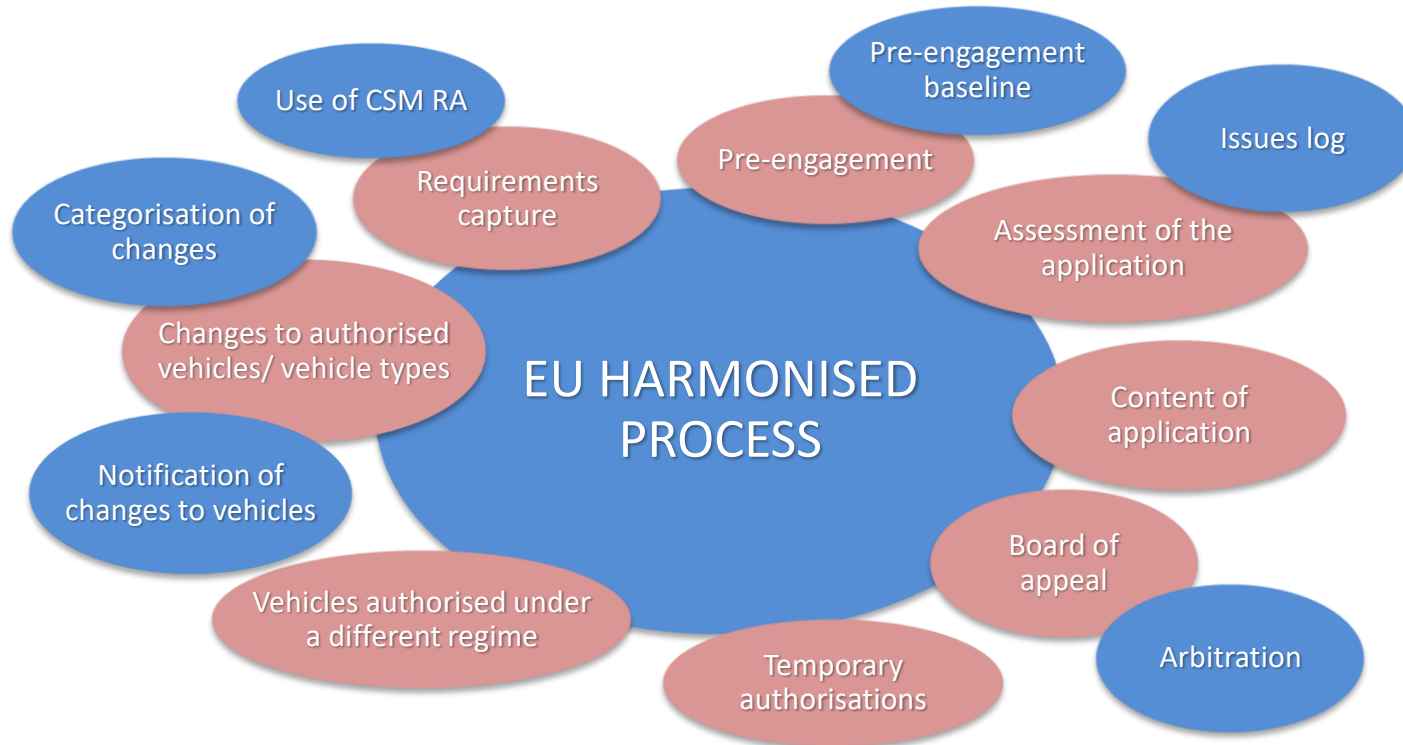Some key new/amended features of the VA process

EU HARMONISED PROCESS

Use of CSM RA
Requirements capture
Pre-engagement
Pre-engagement baseline
Issues log
Categorisation of changes
Assessment of the application
Changes to authorised vehicles/ vehicle types
Content of application
Notification of changes to vehicles
Board of appeal
Vehicles authorised under a different regime
Arbitration
Temporary authorisations

NEWS

# Type, variant & version

**Vehicle**
Railway vehicle suitable for circulation on wheels on railway lines, with or without traction; a vehicle is composed of one or more structural or functional subsystems

**Vehicle type**
Defines the basic design characteristics of vehicle(s), as covered by a type or design examination certificate described in the relevant verification module
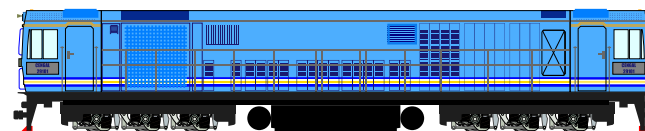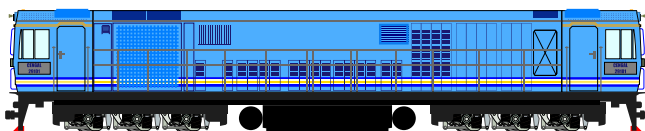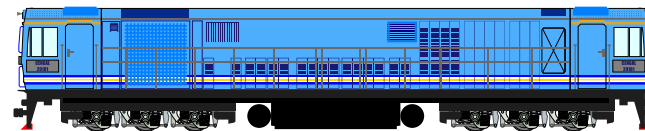
**Vehicle type version**
Option for the configuration of a vehicle type or vehicle type variant that **does not require** an authorisation

**Vehicle Type variant**
Option for the configuration of a vehicle type that **does require** an authorisation

# Vehicle type = concept identified in ERATV
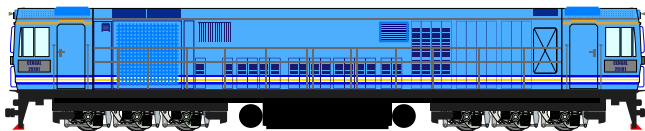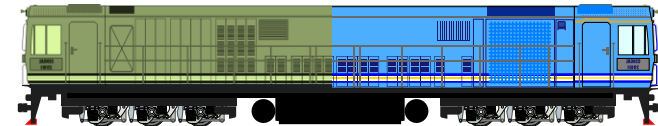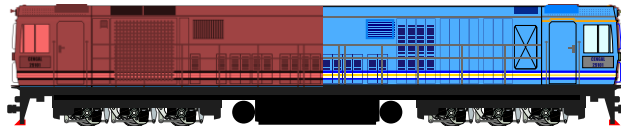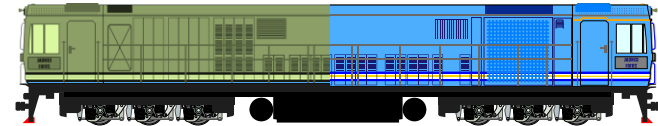


## All the vehicles conform to the same type

Type, variant & version – scenarios

Vehicle type = concept identified in ERATV

Vehicle variant A

Vehicle variant B
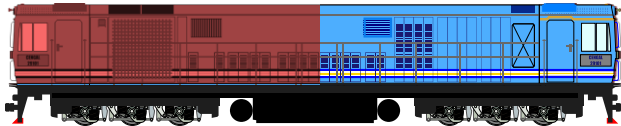
Vehicle variant A version 1

Vehicle variant A version 2

Slide 32
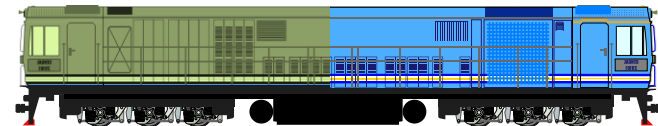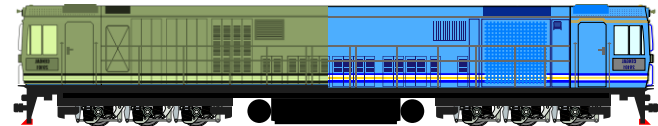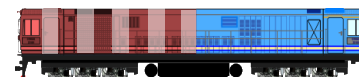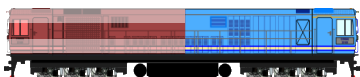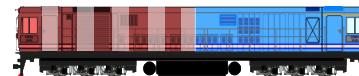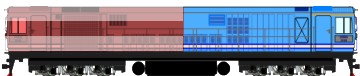
1.  The Vehicle 'type' identifies the design or 'concept' of the vehicle

2.  The vehicle 'type version' is an option for the configuration of a type, following changes in the basic design characteristics that do not require a new authorisation

3.  The vehicle 'type variant' is an option for a configuration of a type, established during first authorisation, or changes of an existing type that require a new authorisation

Vehicle type authorisation facilitates the authorisation of a number of vehicles of the same design in 'conformity to an authorised type' ("series")

Concepts of vehicle type *version* and *variant* aims at facilitating the authorisation process for 'platform' design ('variations' of a design)

# Vehicle type holder

1. Vehicles and vehicle types are composed of one or more subsystems

2. A mobile subsystem is placed on the market by the applicant for the subsystem without authorisation

3. The applicant for the mobile subsystem = contracting entity, manufacturer or its authorised representatives.

4. The applicant for the mobile subsystem issues an EC Declaration of Verification, EC DofV, that is accompanied by the technical file

5. The applicant for the mobile subsystem takes the responsibility:

   – for meeting the relevant requirements (Union law and national rules) (Article 15(2) of Directive (EU) 2016/797); and

   – to decide when a new EC DofV is required in the event of renewal or upgrading of the subsystem (Article 15(5) of Directive (EU) 2016/797).

1. The applicant for the vehicle type takes the responsibility for the vehicle type as a whole
   - There is no 'technical file' for the vehicle type

2. '**Holder of the vehicle type authorisation**' means the natural or legal person that has applied for and received the vehicle type authorisation

3. For a vehicle type, there can only be one holder (clear allocation of responsibilities).

4. The holder is responsible for the configuration management of the vehicle type. This to ensure that vehicles type keeps meeting essential requirements after authorisation

5. The role of the holder cannot be transferred / sold, unless if a company ceases to exist (to be treated as any other asset)

1. In case of a change of an authorised vehicle type where the new applicant becomes the holder:

   – The new holder is primarily responsible for the new design and the new vehicle type as a whole

   – Initial (previous) holder remains liable for the unchanged parts

   – New holder is responsible for the changes and the interfaces with the unchanged parts

2. In case of existing vehicles, the holder will be established:

   – According to ERATV registration (holder is already registered)

   – Only in case of changes, following article 15 (2018/545)

# Changes to vehicle (type)

Article 21(12) of Directive (EU) 2016/797 sets the scenarios in which a change to an authorised vehicle/vehicle type requires a new authorisation:

- Art. 21(12)(a): changes beyond the thresholds defined in the TSIs (basic design characteristics)

- Art. 21(12)(b): change has the potential to impact safety adversely (even if in the real implementation it does not)

- Art. 21(1)(c): it is required by the relevant TSIs (specific changes always require a new authorisation)

A change that does not require authorisation on the grounds of rules compliance, namely 21(12)(a) or (c), may still affect adversely safety, and may require a new authorisation.

The Regulation 2018/545 defines 4 categories of changes:

- Art 15(1)(a): the change does not introduce a deviation in the technical files accompanying the EC declaration(s) of verification

  *no changes in the design*

- Art 15(1)(b): change that introduces a deviation in the technical files but does not impact basic design characteristics nor triggers article 21(12) of Directive (EU) 2016/797:

  *change in the design that does not require a new authorisation*

- Art 15(1)(c): change that impacts basic design characteristics but does not trigger article 21(12) of Directive (EU) 2016/797 and does not require a new authorisation

  *change that needs to be reflected in ERATV, no need for a new authorisation*

- Art 15(1)(d): change that triggers article 21(12) and requires a new authorisation

  *change in the design that requires a new authorisation*

The entity managing the change does not have to be the holder of the vehicle type authorisation, hereafter the possible scenarios:

- **The holder** of the vehicle type authorisation is the entity managing the change :
    - Change according to 15(1)(a) or (b)    *no new authorisation*
    - Change according to 15(1)(c)    *no new authorisation (version)*
    - Change according to 15(1)(d)    *new authorisation (variant or type)*

- If the entity managing the change **it is not the holder** of the vehicle type authorisation :
    - Changes according to 15(1)(b),(c) or (d)    *new authorisation (type)*

- Only the elements of the design that are changed and their interfaces with the unmodified parts need to be assessed

ERATV

1. ERATV remains the repository of authorised vehicle types

2. Applications for authorisation shall contain the data to fill-in ERATV

3. Responsibilities regarding ERATV:
   – Authorising Entity for checking the consistency of the data, for completing ERATV and for the publication of the register
   – Applicant for the integrity (accuracy and technical relevance) of the data provided in the application
   – Holder of the vehicle type authorisation for providing the data to create a version and for integrity of the data

4. ERATV type authorisation must be valid in order to authorise vehicles in conformity with that type

5. Holder of the vehicle type authorisation shall inform the Authorising Entity in case a type authorisation is not anymore valid

# Basic Design Charateristics

NRs referred in TSIs
(specific cases, open
points)

Basic parameters

Vehicle design

Basic design characteristics

Reqs. from other standards,
manufacturer's procedures, etc.

Example of non-basic
design characteristics

TSI

Comfort
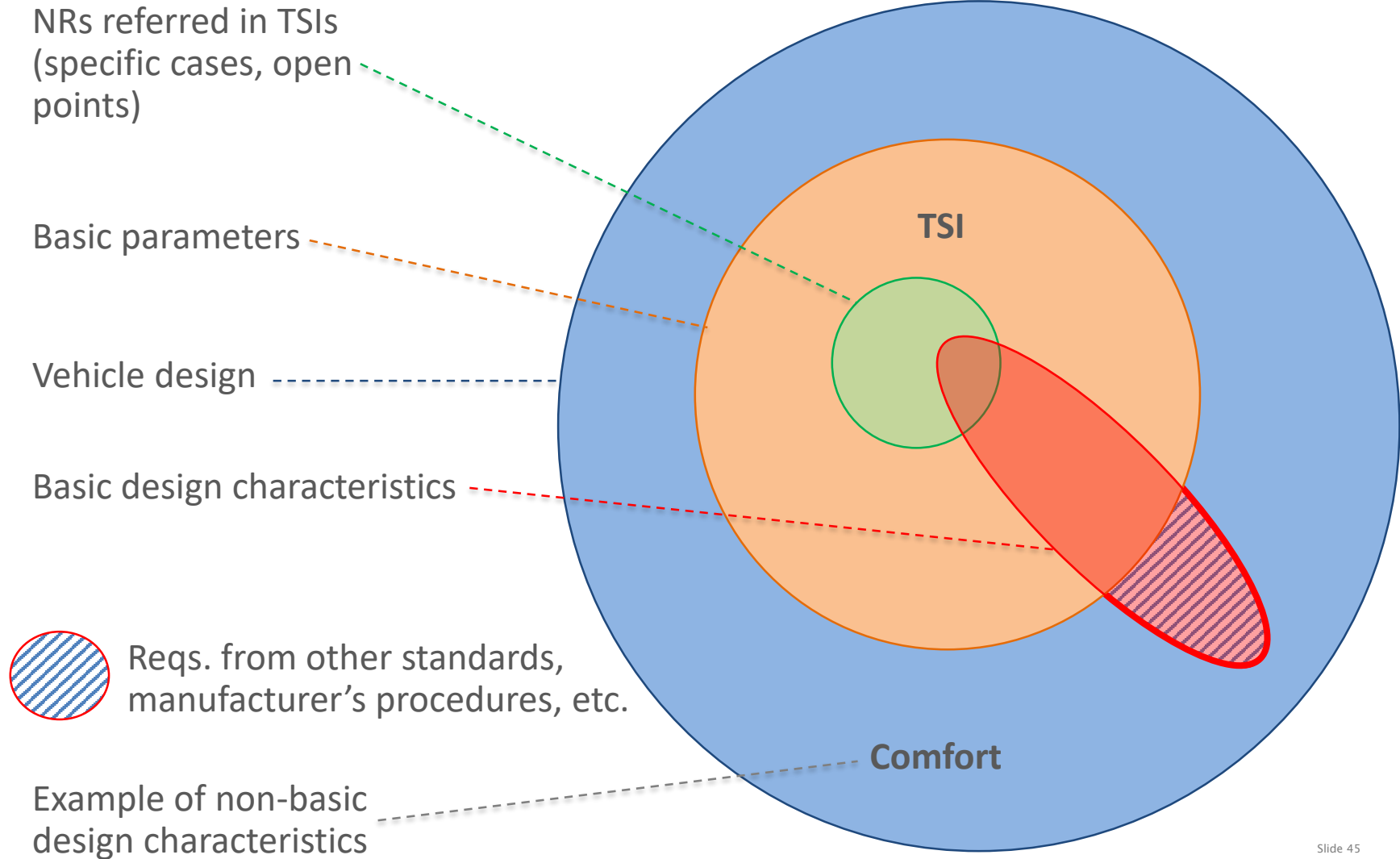
1. Article 48 (c) of Regulation 2018/545:

   – Type and/or design examination certificates -> chapters 7 of TSIs LOC&PAS, WAG & CCS (+changes that trigger 21(12)(a) of Directive 2016/797)

| 1. TSI clause | 2. Related bacis design characteristic(s) | 3. Change in the basic design characteristics triggering a new… | |
| --- | --- | --- | --- |
| | | 3. Changes impacting the basic design characteristics and not classified as 21(12)(a) of Directive (EU) 2016/797 | 4. Changes impacting the basic design characteristic and classified as 21(12)(a) of Directive (EU) 2016/797 |
| 4.2.2.2.3 End coupling | Type of end coupler | Change of the end coupler type | N/A |

   – Area of use of the vehicle

   – Conditions for use and other restrictions (issues authorisation)

   – Reference to declaration by the proposer referred to in article 3(11) of Regulation (EU) 402/2013

2. Annex II of (revised) ERATV decision

# Area of use

1. Authorisation case defined in Article 14(1)(c) of Regulation (EU) 2018/545

2. Change of the area of use of an authorised type without changes in the design (**without modifications**)

3. The checks to be performed shall be limited to the technical compatibility between the vehicle and the extended network

4. Checks already carried out at the first authorisation shall not be repeated

5. If the extension of the area of use covers networks in another MS, the Agency shall be the authorising entity.

6. Extension of the area of use could also apply within 1 MS (with more than one network). The applicant can choose the NSA or the Agency as Authorising Entity

1. The case of authorisation including **stations in neighbouring MSs** is not considered an extension of the area of use nor a case with an area of use covering more than 1 MS

2. In most cases, there is a need to **change the design** before extending the area of use:

- Combination of 2 authorisation cases in article 14(1) of Regulation (EU) 2018/545:
  - *New authorisation + extended area of use*
- Vehicles and/or vehicle types need to be authorised after the change in the MSs of the original area of use

- Then the changed vehicles and/or vehicle types authorisation is extended to new network(s)

- 1 single application combining both cases through OSS

- 1 common 1+4 month timeframe for both cases
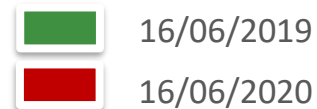
# Transitional period

**Some explanation :**
- Vehicle Authorisations: F°(Area of use)

- Different transposition dates in MS

- Some Applicants for Vehicle Authorisation need to follow two different regimes in parallel

- Transposition dates:



| | |
|---|---|
| 🟩 | 16/06/2019 |
| 🟥 | 16/06/2020 |

1. The OSS is accessible for the applicants since 16th February 2019 for preparing their revised application

2. ERA and NSA to provide assistance if required

3. Submission of applications will be possible from 16th June 2019

4. Assessment of applications under the 4RP can only start on 16th June 2019

5. Where the date for authorisation falls shortly after the relevant date, the applicant should contact the Agency sufficiently in advance of the entry into force of the Regulation (EU) 2018/545

   – Engage with the Agency in the Learning Cases activity (informal pre-engagement)

# Authorisation of vehicles from third countries

Vehicles from third countries are covered by a different regime:

**Article 21(16) of Directive (EU) 2016/797** - Freight wagons and passenger coaches in shared use with third countries, the track gauge of which is different from that of the main rail network within the Union
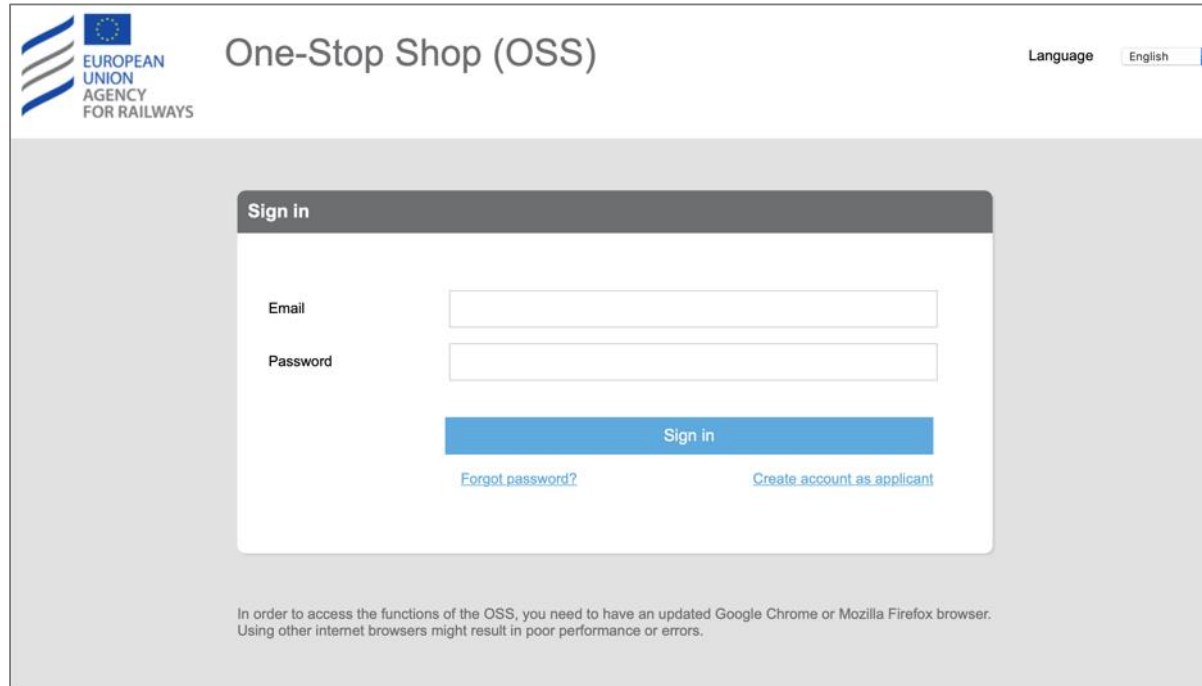
- Different vehicle authorisation procedure (rules of this procedure to be notified to the European Commission)
- Conformity of vehicles with the essential requirements ensured by the railway undertaking

**Article 21(17) of Directive (EU) 2016/797** - Locomotives and self-propelling trains arriving from third countries until a station that is situated close to the border

- Vehicle authorisation for placing on the market not mandatory
- Conformity of vehicles with the essential requirements ensured by the railway undertaking

# One-Stop Shop

The one-stop-shop (OSS) is the IT system designed, developed and managed by the Agency through which all applications for single safety certificates, vehicle authorisations and vehicle type authorisations shall be submitted either to the relevant National Safety Authority or to the Agency.

The one-stop shop shall be used by the applicants irrespective of the intended area of operation or area of use (one or more Member States).

The One-Stop Shop will enable efficient and effective communication between all the organisations involved in the process:
- all issues identified by the respective authority during the assessment,
- the replies of the applicant, and
- the final decision

will be communicated with the use of the one-stop-shop.

All users representing the Agency and the NSAs shall be registered in advance in the one-stop-shop by their own organizations.
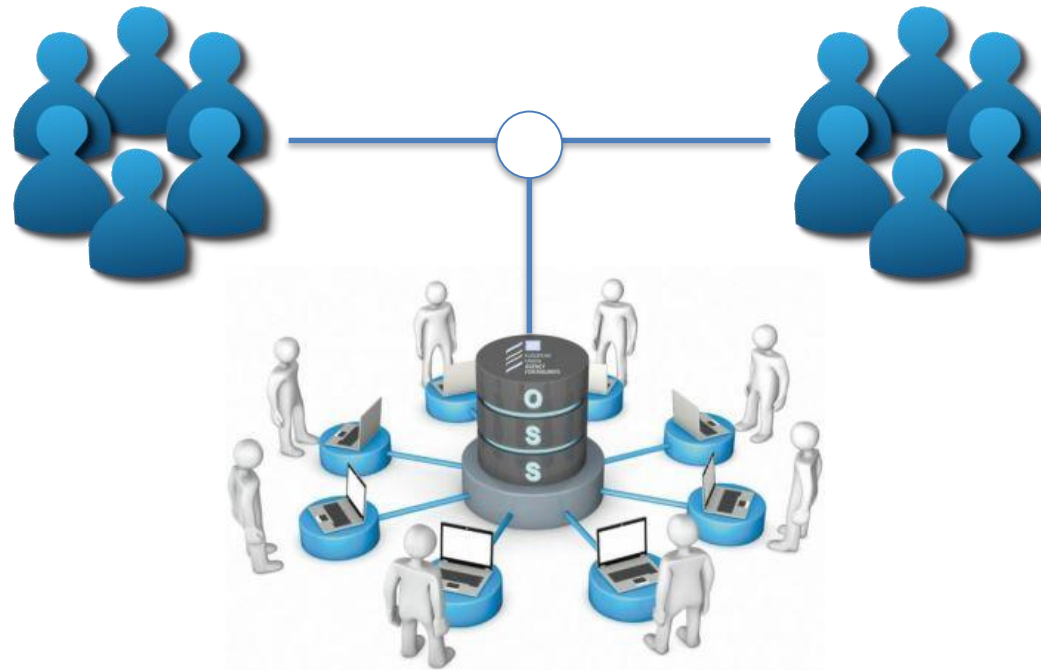


An applicant, before submitting its application, shall go through the registration process.

The One-Stop Shop will be delivered in a number of releases with different sets of functionalities available.

Different releases have been made available for testing purposes (Users Acceptance Tests with sector representatives and NSAs).
The release supporting VA applicants in the preparation of their revised application files has been deployed on the 16th of Feb 2019.

The release supporting the complete VA, SSC and ERTMS TA processes will be put in production on the 16th of June 2019.
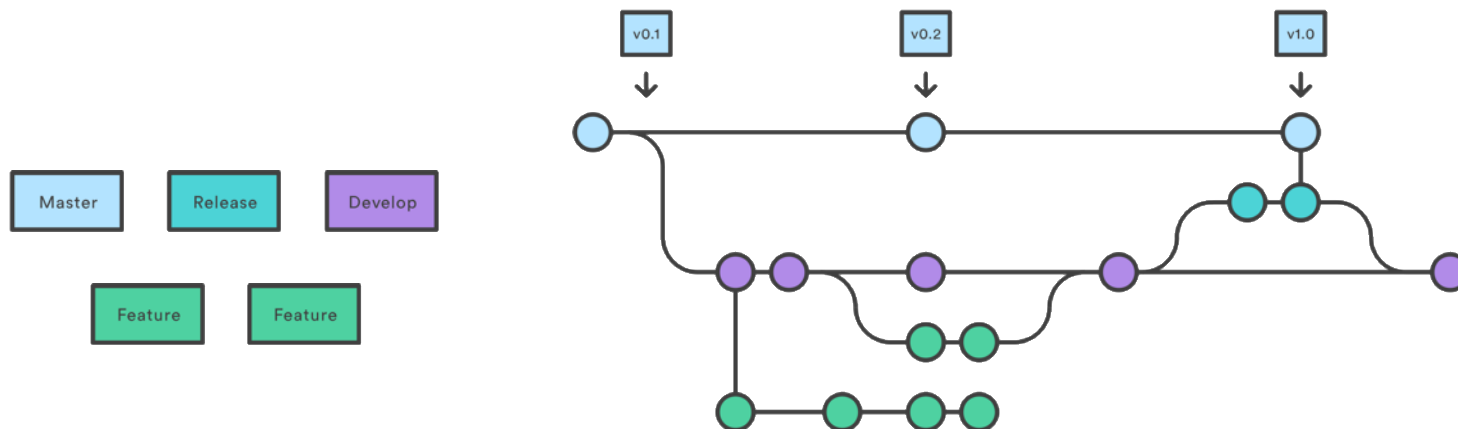
# Fees and charges

Fees and Charges payable to the Agency are ruled by the Regulation (EU) 2018/764:

- The fees and charges should be equal or lower than the current average;
- For applications submitted to the NSAs their national charging principles apply;
- For applications submitted to the Agency, principles set by the regulation on fees and charges payable to the EU Agency for Railways apply;
  – The fee should consist of the fee for the assessment made by the Agency and the fee for the assessment made by the relevant NSAs;
  – The part of the fee for the Agency assessment shall be based on hourly rate and the one for the NSA assessment shall be based on national principles;
- Upon request of the applicant the Agency together with relevant NSA shall issue a non-binding estimate of the amount of fees and charges to be paid;
- The Agency together with relevant NSAs shall monitor their costs and inform the applicant when the cost risks exceeding the estimate by more than 15%;
- Payment of fees and charges shall be denominated in Euro;
- The invoice shall be issued through the one-stop-shop.

# Board of appeal

The functioning of the Board of Appeal is regulated by Regulation (EU) 2018/867

Key elements:

- The Board of Appeal is the arena of last resort
- Appeals against decisions made by the Agency should be rare
- This is because they will only be used where the Agency declines to issue or restricts a Single Safety Certificate giving its reasons for doing so and the applicant wishes to appeal this decision

In practice use of the Board of Appeal would mean that all other attempts to resolve the matter through the assessment process have failed to reach a satisfactory resolution.

# Cooperation agreements

- The Management Board of the Agency has adopted, in June 2018, guidelines and the list of main elements
- The NSA sub-group has reached an agreement on draft cooperation agreements clauses
- The Agency is currently engaged in bilateral meetings with NSAs to conclude with each of them the relevant cooperation agreement
- Cooperation is needed over the results from Supervision and Assessment

# Making the railway system work better for society.

Follow us on 🐦 ERA_railways

Discover our job opportunities on **era.europa.eu**

# An overview on the latest developments in  the railway policy and legislation

Risto Saari, Ministry of Transport and Communications

Traficom, 3 May 2019

**LV** LIIKENNE- JA
VIESTINTÄMINISTERIÖ

# Implementation of the EU 4th RP

- Finland has finalised the transposition measures of the EU 4th RP (market pillar and technical pillar), even though the Railway Safety Directive still needs to be notified:

- Railway Transport Act (1302/2018)

- Three Government Decrees:
  - Government Decree on services provided for railway undertakings (1489/2015);
  - Government Decree on scheduling and capacity allocation (1308/2018);
  - Government Decree on the interoperability of the railway system (284/2019).

- Three Regulations of the Transport and Communications Agency on the railway safety.

- Act Amending Act on Transport Services (1303/2018): contingency measures.

- Act Amending Act on Safety Investigations (187/2019): investigation of accidents and dangerous situations.

# Dates

- Railway Transport Act and Act amending Act on Transport Services entered into force on **1 January 2019**, but provisions concerning railway safety and interoperability will enter into force on **16 June 2019.**

- Government Decree on services, scheduling and capacity allocation entered into force on **1 January 2019.**

- Government Decree on interoperability of railway system will enter into force on **16 June 2019**.

- Regulations of Traficom on railway safety will enter into force on **16 June 2019**.

- Act amending Act on Safety Investigation will enter into force **on 16 June 2019**.

# Parliamentary election 14.4.2019

- Preliminary discussions for establishing a new Government have started: the aim is that the new Government could be appointed by the beginning of June.
    - The European Parliament election will be held on 26 May.
    - The Finnish EU Presidency will start 1 July 2019.
- Transport policy priorities, including railway transport policy priorities depend on the Government programme.
- All major parties are committed e.g. in the climate change abatement -> requires investments in public transport and railway network.

# EU Presidency

- Finland´s Presidency of the Council of the European Union will start on 1 July 2019.

- The EP election in May and appointment of new Commission in fall 2019 will have an impact on the Presidency: new initiatives are not expected and the main emphasis is promoting progress of ongoing activities.

- As to railway traffic Finland aims at reaching General Approach of the Council on the proposal for a Regulation on rail passenger rights and obligations.

# Railway market opening

- During the Government period 2015-2019 an effort has been given with the aim at opening domestic passenger services to competition.

- Three new companies should be established:
    - Rolling stock;
    - Real estates;
    - Services and service facilities (daughter company of VR-Group Ltd.).

- The Government decided in 2017 that the passenger rail services should be opened to competition in stages, and the comprehensive availability of these services across Finland should  be secured under **concession contracts which should be tendered one by one**.

# Passenger transport in the rail network

- **Commuter rail services by Helsinki Region Transport (HSL)**: 63 million journeys (1.2 billion passenger-kilometres):
  - HSL is tendering services for period starting June 2021.

- **Other passenger rail transport**: 12 million journeys (3 billion passenger-kilometres):
  - MINTC is the competent authority.



Passenger journeys on rail network in Finland in 2016

Long-distance traffic 12,047 million
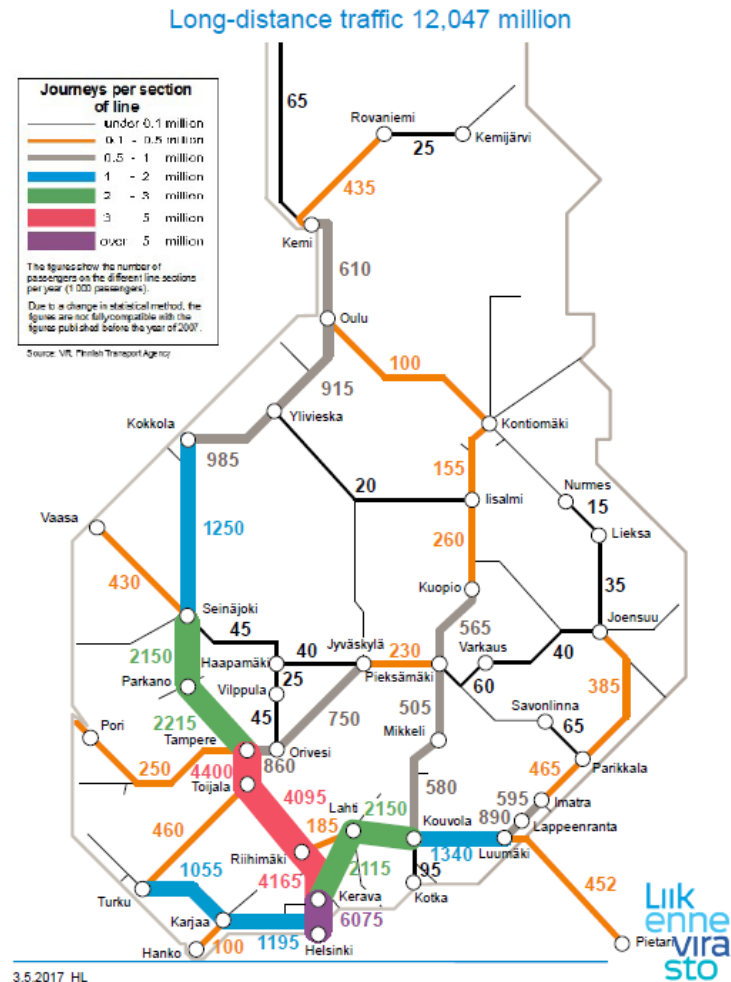
# Southern Finland regional rail services

- The Government decided in 2018 that the opening to competition should start with tendering of regional rail services in Southern Finland.
    - The objective has been that the tendering process completed and the services up and running in summer 2022.
    - Comprises commuter traffic, with the Helsinki region area and large urban centres (Riihimäki, Tampere, Lahti, Hämeenlinna, Kouvola, Kotka).
    - Concerns purchased or obligated rail services by the Ministry.

# Transport System Plan 2020-32

- Government proposal for the Parliament in the first half of year 2020:
  - Major challenges, such as climate change, regional development, urbanisation and digitalisation and how the transport system should react to these changes;
  - Development of transport system on the whole, including major infrastructure investments and services.

LIIKENNE- JA
VIESTINTÄMINISTERIÖ

# Thank you for your attention!

# Uusi sääntelykehys ja ohjeistus

Une Tyynilä

# Uusi sääntelykehys

> ERA-asetus (EU) 2016/796
>> Ohjaa ERA:n toimintaa, ei edellytä täytäntöönpanoa

> Yhteentoimivuusdirektiivi (EU) 2016/797
>> Ohjaa ja edistää EU:n rautatiejärjestelmän yhteentoimivuutta (erityisesti rataverkkoa ja kalustoa koskevat kysymykset).
>> Täytäntöönpano raideliikennelailla 1302/2018 ja yhteentoimivuusVNA:lla 284/2019.

> Rautatieturvallisuusdirektiivi (EU) 2016/798
>> Ohjaa erityisesti rautatieliikenteen harjoittajien ja rataverkon haltijoiden toimintaa ja turvallisuustyötä. Koskee myös esimerkiksi onnettomuuksien tutkintaa.
>> Täytäntöönpano raideliikennelailla 1302/2018, turvallisuustutkintalain (525/2011) muutoksella 187/2019 ja määräyksellä rautatiejärjestelmän turvallisuudesta (annetaan lähiviikkoina).

# Komission sääntely

> Kuten ERA:n aamuisesta esityksestä kävi ilmi komissio on antanut lukuisia direktiivejä tarkentavia säädöksiä

>> Ne on annettu asetuksilla, joten niiden osalta ei ole ollut tarvetta kansalliselle sääntelylle

>> Linkit näihin löytyy sekä ERA:n että Traficomin nettisivuilta.

>> ERA:n linkki vie eurlexissa kyseisen säädöksen viitetietosivulle, josta löytyy linkit kaikkiin kieliversioihin

>> Traficomin linkki vie suoraan suomenkieliseen versioon

> Kansallinen sääntely löytyy Traficomin nettisivuilta

>> Nettisivujen vasemman reunan valikkojen käyttö helpottaa hakemista

# Linkit komission sääntelyyn

> [Komission täytäntöönpanoasetus (EU) 2018/545](#) raideliikenteen kalustoyksikköjen markkinoillesaattamislupa- ja tyyppihyväksyntämenettelyä koskevista käytännön järjestelyistä Euroopan parlamentin ja neuvoston direktiivin (EU) 2016/797 nojalla

> [Komission täytäntöönpanoasetus (EU) 2019/250](#) Euroopan parlamentin ja neuvoston direktiivin (EU) 2016/797 mukaisista rautateiden yhteentoimivuuden osatekijöitä ja osajärjestelmiä koskevien EY-vakuutusten ja -todistusten malleista, raideliikenteen kalustoyksikköjen hyväksyttyä tyyppiä koskevan vaatimustenmukaisuusvakuutuksen mallista ja osajärjestelmiä koskevista EY-tarkastusmenettelyistä sekä komission asetuksen (EU) N:o 201/2011 kumoamisesta

> Lisäksi kaluston ja reitin yhteensopivuustarkastelua koskeva menettely kuvataan OPE YTE:ssä, joka annetaan toukokuun aikana.

# Soveltamisohjeet

> ERA:n hakuohjeet pitäisi olla viimeistään 16.6 saatavilla myös suomeksi.

> Traficomin oma ohjeistus tulee Traficomin nettisivuille.

Issuing a vehicle/vehicle type authorization

Markkinoillesaattamis-
luvan hakeminen

Mauno Pajunen

# EU legal framework for technical aspects

- Key new/amended features of the framework
- Requirements capture process
- Technical rules
- EC verification procedure
- Registers
- Route compatibility check

Overview of the EU legal framework not directly related to the Vehicle authorisation process but necessary to achieve the objectives of the 4RP

General knowledge and understanding of :
- Technical aspects related to vehicle authorisation
  - Requirements capture
  - TSIs, NRs
  - EC verification
- EU Registers :
  - Vehicle authorisation : RDD-SRD, ERATV, ERADIS
  - Others: RINF, NVR
- Vehicle authorisation vs route compatibility check
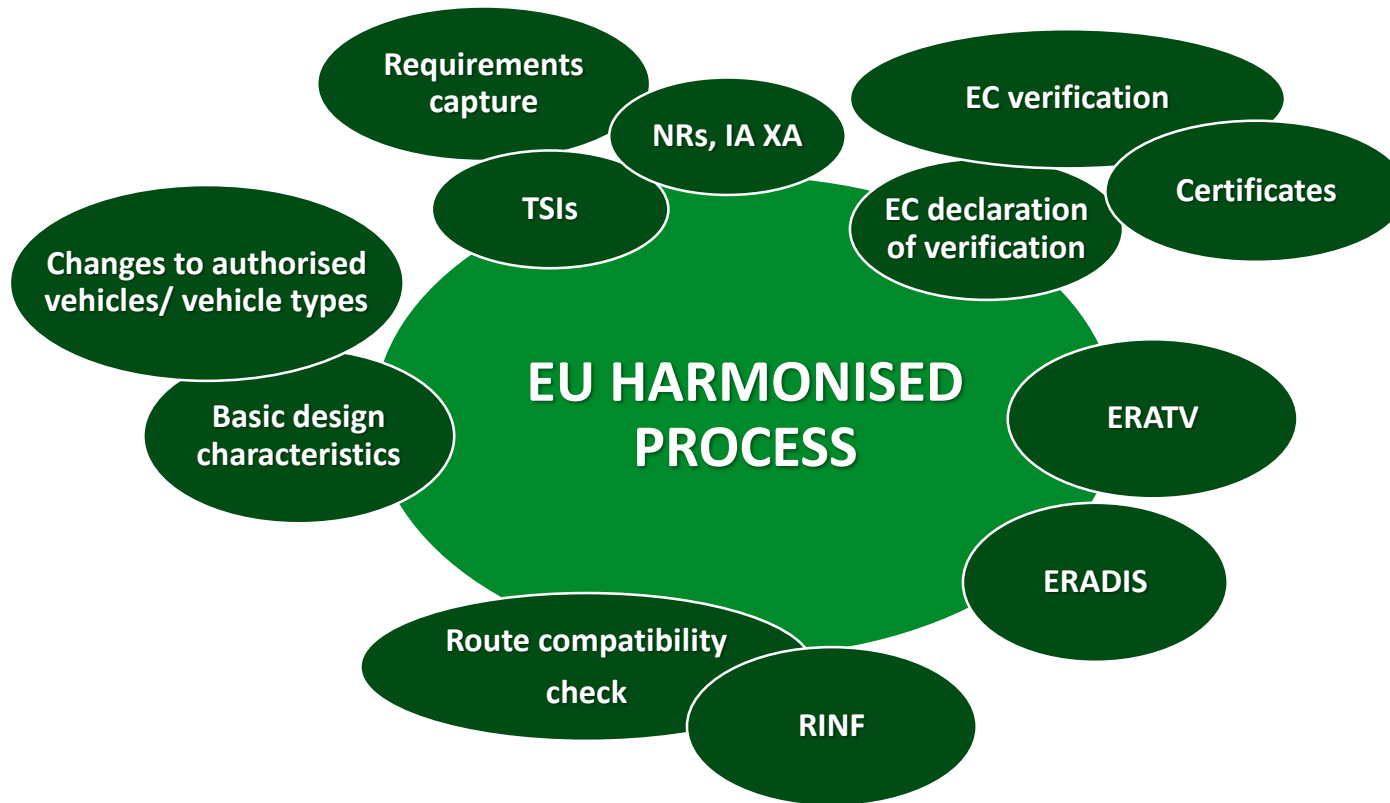
- Requirements capture is performed to ensure that relevant requirements are:
  - Identified
  - Assigned to functions/subsystems
  - Implemented; Validated  and
  - Addressed through conditions for use or other restrictions

  with the objective of managing and mitigating the identified risks to an acceptable level

▪ Requirements capture covers:

- Essential requirements for subsystems
- Technical compatibility of the subsystems within the vehicle
- Safe integration of the subsystems within the vehicle
- Technical compatibility of the vehicle with the network in the area of use
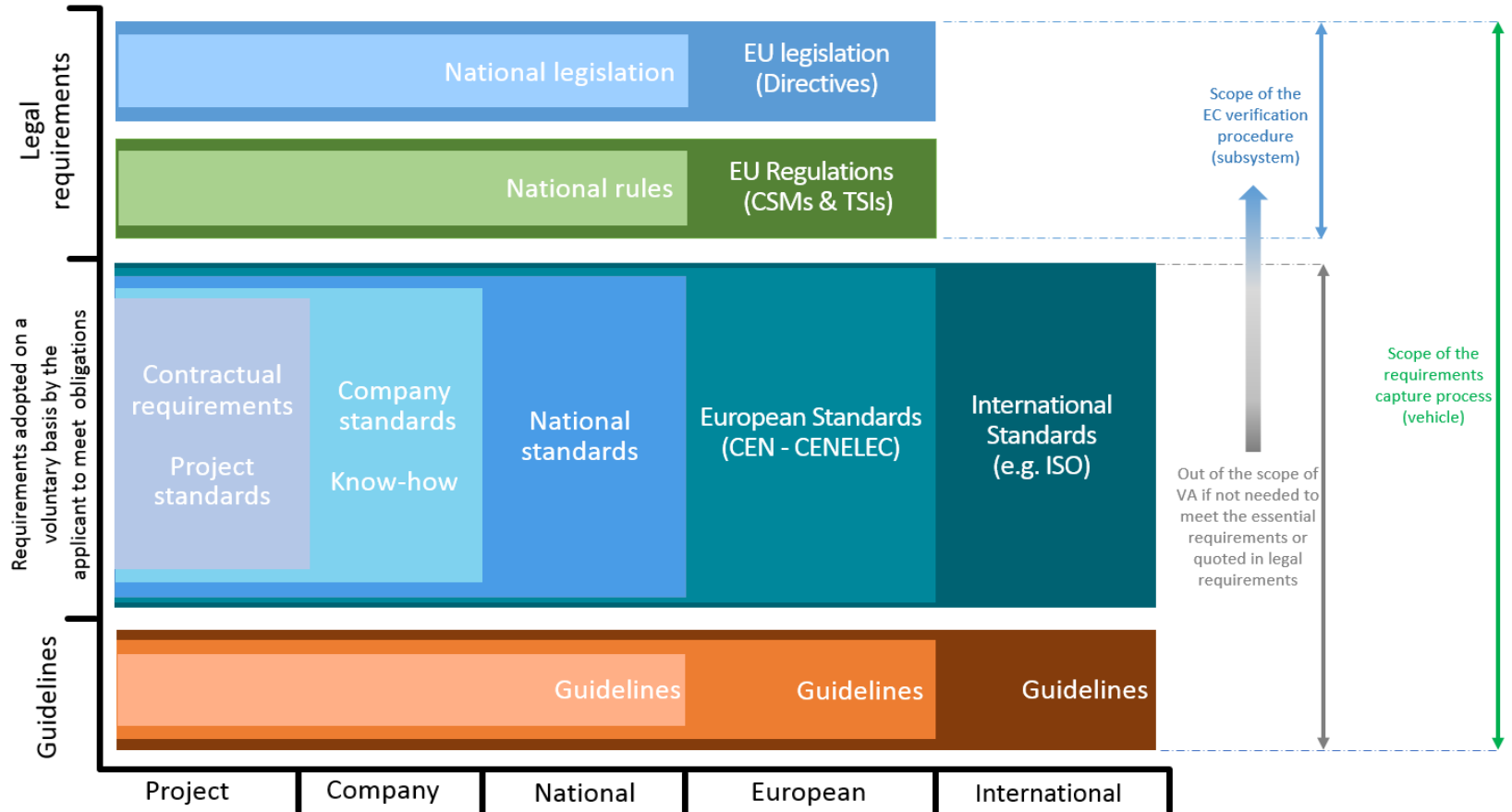
- Applicant :
  - Responsible for performing the requirements capture process

  - Use the Risk management process (Annex I of Regulation (EU) 402/2013) as the methodology <u>for safety related aspects</u>

  - Can use the risk management process as the methodology for requirements capture <u>for other essential requirements</u>

- Assessment body (CSM RA):

  - Gives assurance that the processes are systematic and are able to capture, understand, analyze and mitigate hazards
  - Provides a judgement of the correct application of the risk assessment process and suitability of the results
  - Focus on the process. Not an exhaustive check of all the evidence supporting the requirements capture
  - Some detailed assessments (sampling) may be needed (vertical slice assessment of key aspects)

- Authorising entity :
  - Checks completeness, relevance and consistency of evidences (Risk declaration, safety assessment report) when regulation (EU) 402/2013 is used
  - May challenge the assessment report if it demonstrates existence of serious safety risk (burden of proof allocated to authorities)
  - Performs further checks if another methodology is used (when allowed) :
    - Assess the details of the methodology
    - Assess the details of the evidences of the application of the methodology

RISC 84 (JAN2019): voted

| LOC&PAS TSI | • ERA 006REC1025<br>• ERA REC 111, 120, 120-1 |
|---|---|
| WAG TSI | • ERA 006REC1025<br>• ERA REC 117 |
| CCS TSI | • 011REC1028 |
| ERATV | • ERA 006REC1025 |
| RINF | • ERA 003REC1047 |

Should be vote in RISC April 2019

| OPE TSI | • ERA 006REC1025<br>• ERA REC 125 |
|---|---|

NEWS

- **Basic design characteristics**
  - TSIs LOC & PAS, WAG and CCS : Chap 7
- **Route compatibility check**
  - TSIs LOC & PAS, WAG and CCS : Chap 4.9
- **Close Open points** : TSIs LOC & PAS, WAG, CCS (TDS)
- **Standards and improve the clarity of the text** : TSIs LOC & PAS, WAG and CCS

Basic Design characteristics is a subset of the vehicle design describing the important/significant elements relevant for technical compatibility or operation of the vehicle (restrictions, conditions of use)

A change having an impact to a basic design characteristic can generate either :

- A new vehicle type version or
- A vehicle type variant or new vehicle type

**Principles** to be applied by the applicants and the authorising entities
**List** the basic design characteristics of a vehicle type

**Changes** triggering a new vehicle type version or variant

**Particular** rules for existing RST not covered by an EC declaration of verification

| TSI clause | basic design characteristic(s) | Changes generating vehicle type version | Changes generating vehicle type variant |
|---|---|---|---|
| 4.2.2.2.3 End coupling | Type of end coupling | Change of end coupler type | N/A |
| 4.2.3.1 Gauging | Reference profile | N/A | Change of reference profile the vehicle is conform to |

- EC verification covers the compliance of the subsystem(s) to all essential requirements:
  - TSIs, National rules, Safety assessment report
  - Other requirements needed
- Applicant :
  - Performs the EC verification procedure for the subsystem(s)
  - Responsible for ensuring the subsystem(s) compliance with other applicable legal acts of the Union and any verifications by the assessment bodies required by the other rules
  - Establish the EC Declaration of Verification
  - EC Declarations of Verification incl accompanying <u>technical files</u> are part of the application  (Annex I 18.5 of 2018/545)
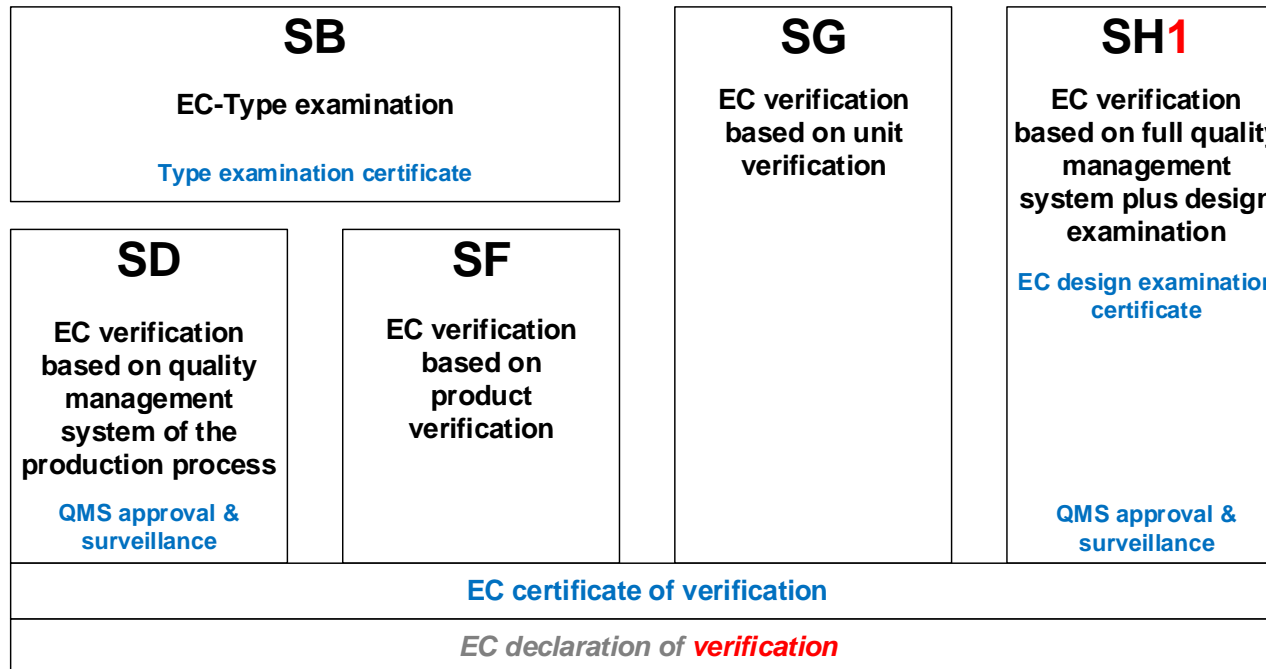  - No need for national declaration

- Applicant :
  - EC Declaration of conformity or suitability for use of ICs
  - EC Declaration of verification of subsystem
  - Declaration of conformity to an authorised vehicle type

- NoBo/DeBo:
  - Intermediate Statement of Verification
  - Certificate of conformity/suitability for use of ICs
  - Certificate of verification of subsystem

EC Verification procedure is based on application of assessment Modules.

Modules :

- Are described in decision <u>2010/713/EC</u>*
- Cover procedures for conformity assessment (ICs) and EC verification (subsystems)
- Define responsibilities of participants in the procedures : Manufacturer, applicant, notified body etc.
- Specify documents necessary  to attest conformity

*Decision 2010/713/EC   would be amended to apply to DeBo

**SB**

EC-Type examination

*Type examination certificate*

**SG**

EC verification based on unit verification

**SH1**

EC verification based on full quality management system plus design examination

*EC design examination certificate*

**SD**

EC verification based on quality management system of the production process

*QMS approval & surveillance*

**SF**

EC verification based on product verification

*QMS approval & surveillance*

*EC certificate of verification*

*EC declaration of **verification***

**Documents issued by notified bodies**
*Documents issued by **applicant***
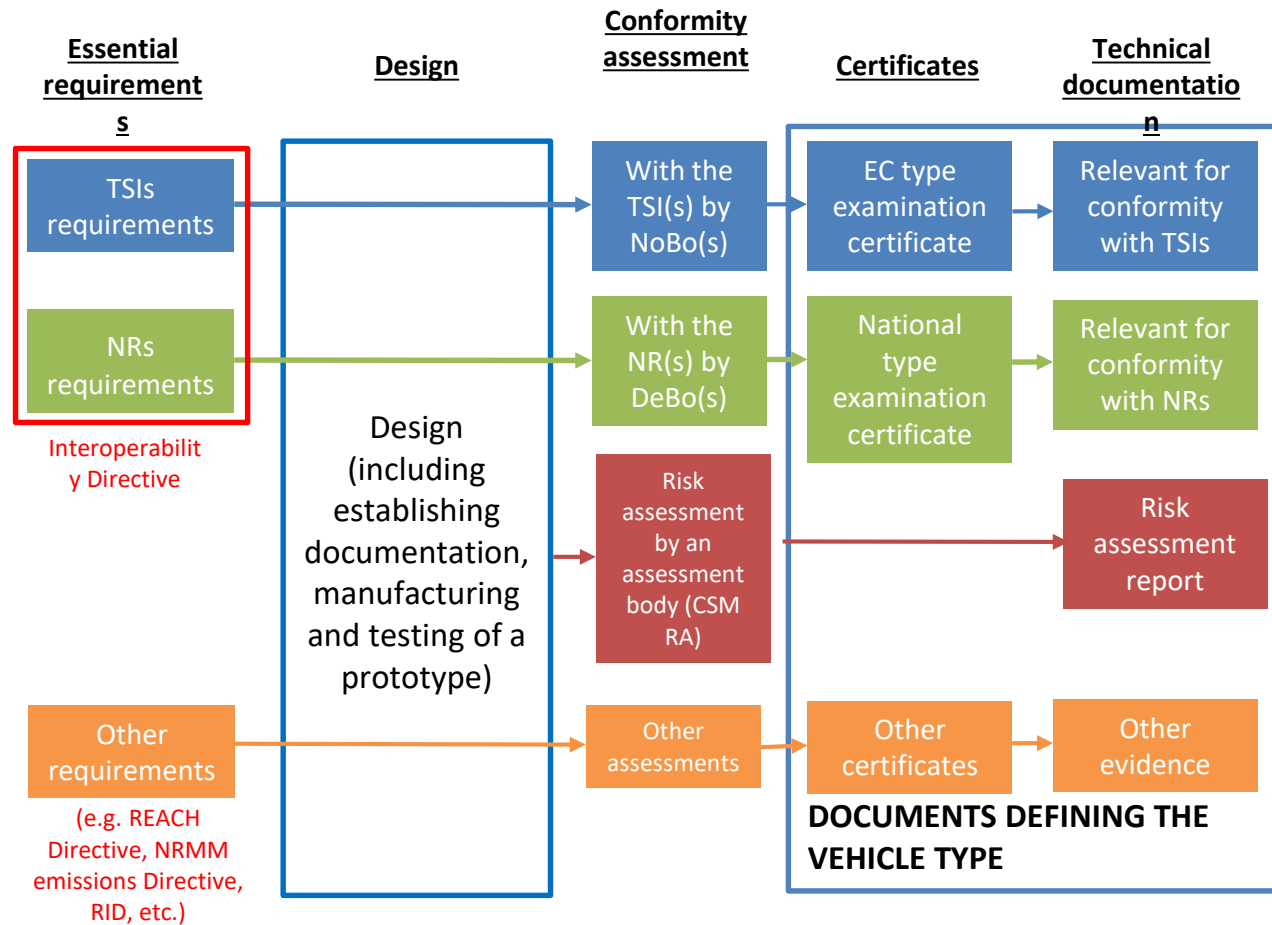*(contracting entity or **manufacturer**)*

▪TSIs specify the application of modules in chapter 6 .

▪Some modules can be used only in combination with others.

▪Modules may involve third party assessment (NoBo) or self-assessment  (modules CA, CC).
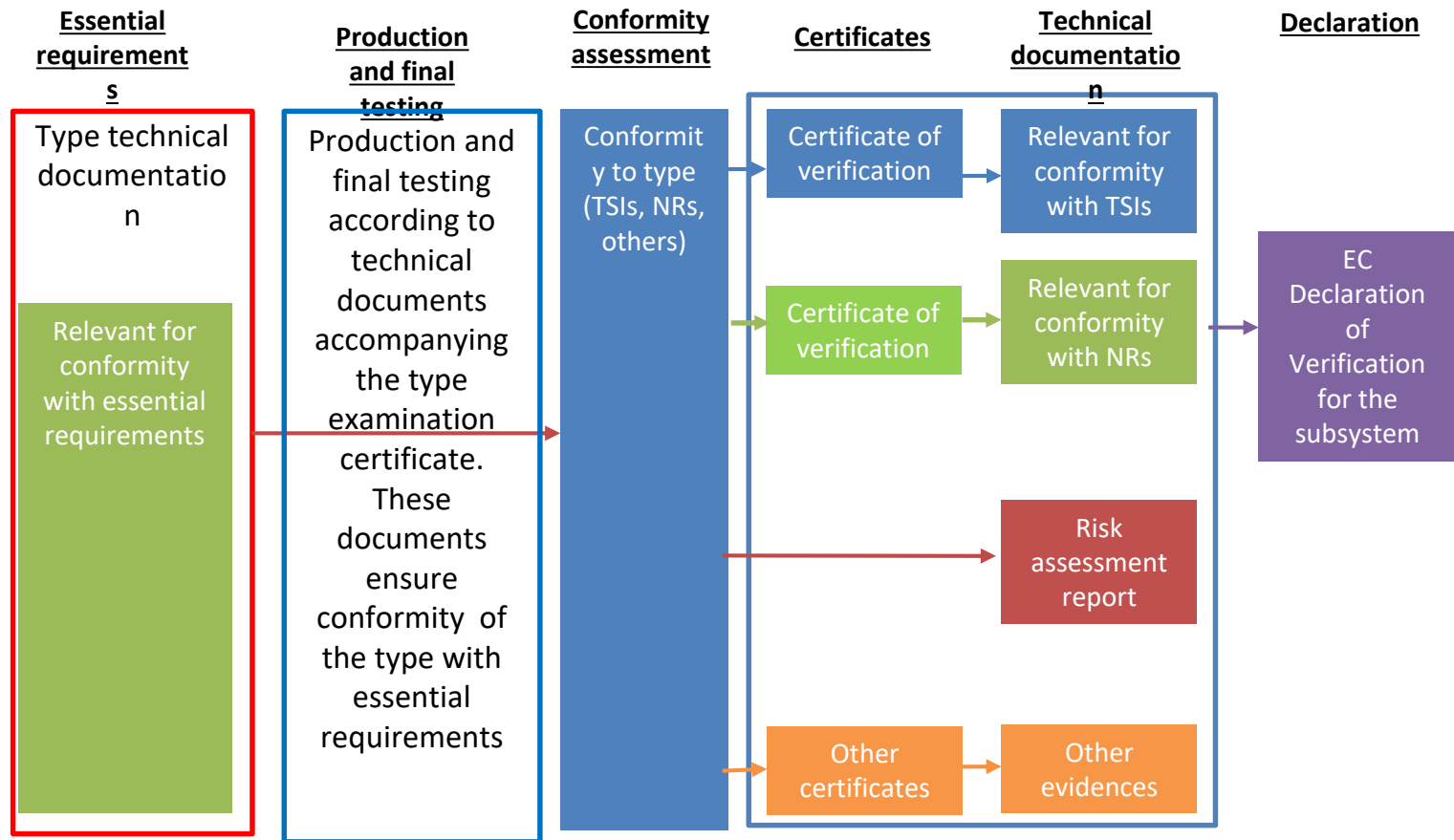
▪<u>TSI Loc&Pas 1302/2014 for ICs (Eg. For coupler) :</u>

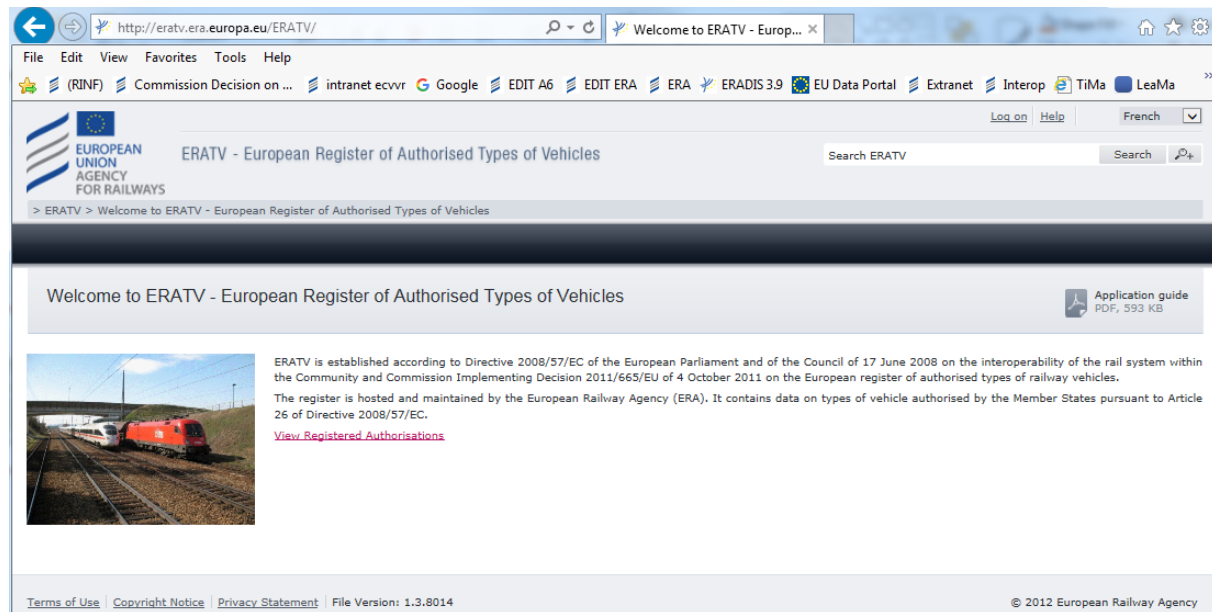| Point | Constituents to be assessed | Module CA | Module CA1 or CA2 | Module CB + CC | Module CB + CD | Module CB + CF | Module CH | Module CH1 |
|-------|------------------------------|-----------|--------------------|-----------------|-----------------|-----------------|-----------|-----------|
| 5.3.1 | Automatic centre buffer coupler | | X (*) | | X | X | X (*) | X |
| 5.3.2 | Manual end coupling | | X (*) | | X | X | X (*) | X |

▪<u>TSI Loc&Pas 1302/2014 for RST:</u>

▪ Applicant chooses one combinations of modules : (SB+SD) or (SB+SF) or (SH1). The assessment is done according to the combination of modules chosen.

| Essential requirements | Design | Conformity assessment | Certificates | Technical documentation |
|---|---|---|---|---|
| TSIs requirements | | With the TSI(s) by NoBo(s) | EC type examination certificate | Relevant for conformity with TSIs |
| NRs requirements | Design (including establishing documentation, manufacturing and testing of a prototype) | With the NR(s) by DeBo(s) | National type examination certificate | Relevant for conformity with NRs |
| | | Risk assessment by an assessment body (CSM RA) | | Risk assessment report |
| Other requirements | | Other assessments | Other certificates | Other evidence |

Interoperability Directive

(e.g. REACH Directive, NRMM emissions Directive, RID, etc.)

**DOCUMENTS DEFINING THE VEHICLE TYPE**

102

**Essential requirements**

Type technical documentation

Relevant for conformity with essential requirements

**Production and final testing**

Production and final testing according to technical documents accompanying the type examination certificate. These documents ensure conformity of the type with essential requirements

**Conformity assessment**

Conformity to type (TSIs, NRs, others)

**Certificates**

Certificate of verification

Certificate of verification

Other certificates

**Technical documentation**

Relevant for conformity with TSIs

Relevant for conformity with NRs

Risk assessment report

Other evidences

**Declaration**

EC Declaration of Verification for the subsystem

103

- Contains authorised vehicle type
- In operation since beginning of 2013
- 548 type authorisations in ERATV as of today.
- Publicly available:
  https://eratv.era.europa.eu/eratv

## Applicant:

- Responsible for the integrity of the data provided to the authorising entity.
- Can fill-in part of the required data (technical data) on behalf of the authorising entity.

## Authorising entity:

- <u>Always issues a vehicle type authorisation</u> even if the applicant has requested to have only a vehicle authorisation for placing on the market.
- Responsibility for the data recorded in ERATV

Aligned with 4RP (section 0 to 3) :

- Type version(s) and type variant(s)
- Aligned with the IA on 'EC' declaration of verification of subsystems and templates
- Area of use
- Reference to written declaration by the proposer referred to in Article 3(11) of Regulation (EU)402/2013
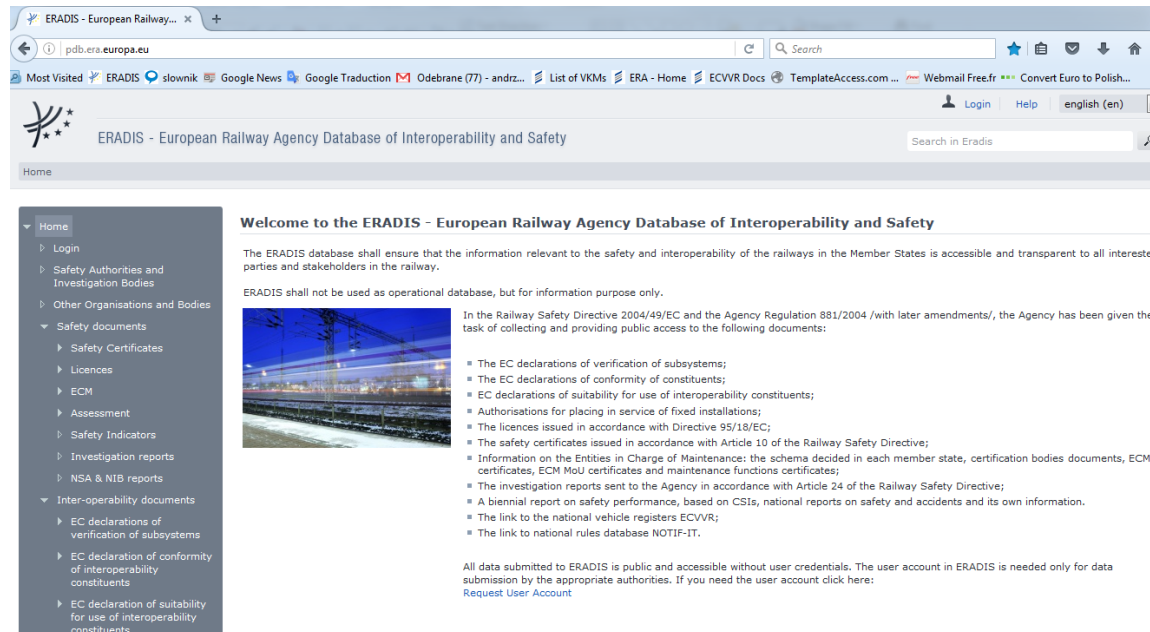- Identification of the authorisation holder

# Aligned with BDCs: Section 4 – Technical characteristics of the vehicle

| Parameters Status | Number | Comments |
|---|---|---|
| Total number of parameters (including headings) | 163 | |
| No change | 53 | |
| Updated | 19 | |
| New | 18 | |
| Deleted | 73 | Not considered as basic design characteristics by the working parties (LOC&PAS TSI, WAG TSI and CCS TSI).<br><br>Among the 73 deleted parameters :<br>- 5 relate to Noise,<br>- 12 relate to PRM,<br>- 20 relate to train detection systems |

Contains certificates, declarations
Publicly available: http://eradis.era.europa.eu

## Applicant of subsystem, Manufacturer of ICs:

- Submits EC declarations

## NoBo:

- Submits EC certificates

## DeBo:

- No obligation however, the principle of ''mutatis mutandis'' could be applied

## Authorising entity:

- Ensures that ERADIS is updated before issuing authorisation

RINF

Provides main features of the European Railway infrastructure.

Publicly available: http://rinf.era.europa.eu/RINF

In particular, provides the value of the parameters to be used to check the compatibility between vehicle and route

May be used for vehicle authorisation when RINF is referenced by TSIs (e.g TSI Loc&Pas 4.2.8.2.9.4.2 on contact strip) or NRs

Not part of vehicle authorisation

National Vehicle Register: NVR Decision amended by by Decision (EU) 2018/1614

Register of all vehicles in service:

- Kept by each MS

- Contains information on authorisation and associated Keeper, Owner, ECM

- NVRs and search engine 'Virtual Vehicle Register' in ERA constitute European Centralized Virtual Vehicle Register.

- All the information on every vehicle is available via the ECVVR.

- ECVVR in operation since 2009: https://vvr.era.europa.eu/VVR

Over 1 million vehicles available in ECVVR

## Vehicle Keeper :

- Requests vehicle registration
- Ensures that data submitted is up-to-date and accurate

Registration Entity (MSs):

- Grants EVN and Registers vehicles
- MSs ensures quality and integrity of data registered by the designated registration entity

When the area of use of the vehicle :

- Is limited to one MS: vehicle is registered in the NVR of that MS.
- Covers more than one MSs: the keeper decides in which MS to register the vehicle, the registration is done in one NVR.

When the area of use of the vehicle is extended :

- vehicle is registered only in the NVR of the MS where the vehicle was authorised. In any case the registration is done in just one NVR.

**TRAFICOM**
Finnish Transport and Communications Agency

**Applicant** defines and demonstrates:

❑ **Area of use** (e.g France, Belgium)

❑ **Vehicle Technical compatibility with the Network(s) of the area of use** (e.g 3kV, 25kV, KVB, TBL1+, D4 etc.)

❑ **Conditions for use and other restrictions** (e.g max speed 140km/h)

**Railway Undertaking** checks using its SMS process :

❑ Vehicle(s) is authorised and Registered

❑ Compatibility between Vehicle(s) and indented Route(s)

❑ Proper integration in the train composition

Vehicle authorisation for placing on the Market (art 21)

Checks before the use of authorised vehicles (art 23)

## "Vehicle/Train" compatibility over the route:

- Checked after VA during the "route compatibility" phase
- On the basis of vehicle/train data from OPE TSI (incl appendix D1) and RINF (and information from IM)
- Responsible: RUs (with information/support from IM as needed)
- Consist of several phases (OPE TSI): from checks before use of vehicles/route compatibility (checked once) to the preparation of the train before departure (train composition/train compatibility).
- (Cross-)check the compatibility between the vehicle and the specific route → **Route compatibility Check (RCC)**

Path request

Operation

Authorised & Registered

**Vehicle Route Compatibility Check**

Train composition & other aspects

Vehicle data

RINF

Under Safety Management System

# TRAFICOM
Finnish Transport and Communications Agency
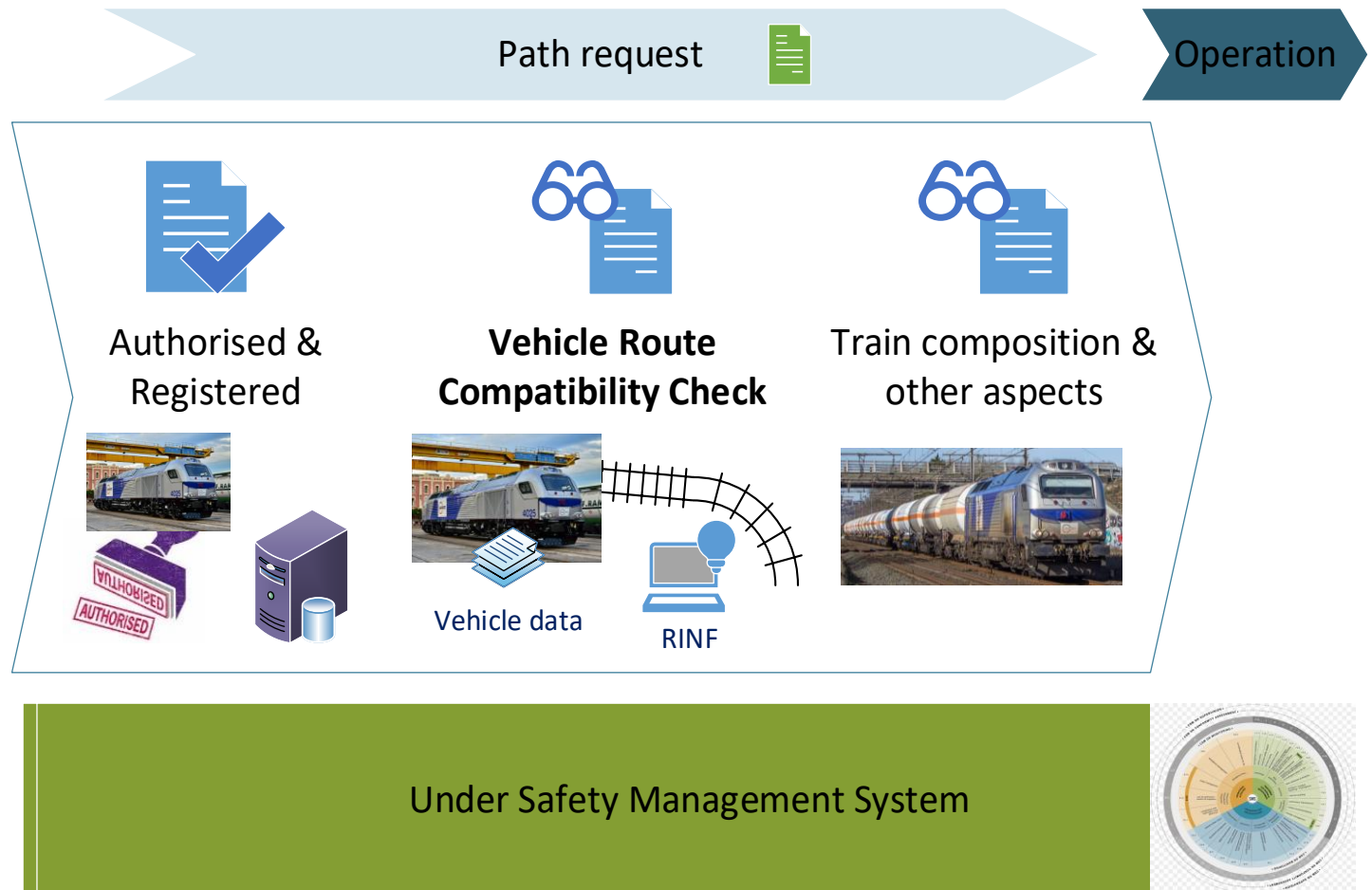
## Most of the Route compatibility items require a simple comparison

| Interface | Vehicle data in ERATV and technical file | | Route information available in RINF or provided by IM | | Results |
|---|---|---|---|---|---|
| | ERATV | Value | RINF ref | Value | |
| Gauge | 4.2.1 | G1 | 1.1.1.1.3.1.1 1.2.1.0.3.4 | G1 | |
| Train detection systems | 4.14.1 | track circuits axle counters loops | 1.1.1.3.7.1 | track circuits axle counters | |
| Wheel set gauge | 4.1.3 | 1435 mm | 1.1.1.1.4.1 1.2.1.0.4.1 | 1435 mm | |
| Minimum in-service wheel | 4.8.2 | 991 mm | 1.1.1.1.5.2 | 330 mm | |

Slide 116

## Some items to be checked need specific competencies
(e.g Traffic loads and load carrying capacity of infrastructure)

| Interface | Vehicle data in ERATV and technical file | | Route information available in RINF or provided by IM | | Results |
|---|---|---|---|---|---|
| | ERATV | Value | RINF ref | Value | |
| • Design mass (working order, normal and exceptional payload), 4.5.2 : 121000 kg<br>• Static axle load (working order, normal and exceptional payload), 4.5.3: 20160 kg<br>• Maximum design speed , 4.1.2.1 : 120km/h<br>• Vehicle length, 4.8.1 : 23.02m<br>• F | | | | | Compatible with lines classified C4<br><br>Slide 117 |



1538

3589        14600        1800  1800        3589
                      23020

**▪Summary**

- **Requirements capture** covers:
  - Steps of the design from specification to verification & validation
  - Not only TSIs and NRs but all relevant rules to demonstrate compliance to ERs
  - AssBo is mandatory for safety requirements, recommended but not mandatory for the other ERs

- **Technical requirements - TSIs**
  - Basic design characteristics: to be considered in case of change requiring creation of type version or a type variant or new type.
  - Route compatibility checks: one harmonised way to check the compatibility between a vehicle/train and an intended route using TSI OPE and RINF

▪**Summary**

- **Technical requirements - NRs**
  - National Rules in additions to TSIs cover: : Open points, Specific cases not described in TSIs, Technical compatibility with existing networks and Others (e.g. if TSI is deficient)
  - Classification of NRs:
    - Agency is responsible for classification of NRs
    - Procedure under development (task force)
  - Notification of NRs in RDD/SRD

- **EC verification procedure**
  - EC declaration of verification covers compliance of the subsystem(s) to all ERs
  - Common and harmonized templates for NoBo, DeBo and applicant
  - No national declaration needed

- **Registers**
  - ERATV and ERADIS are always completed before an authorisation can be issued
  - RINF is used when required by NRs or TSIs for VA and for the purpose of Route compatibility check
- **Vehicle autorisation vs Route compatibility check (RCC)**
  - RCC is not Vehicle authorisation.
  - RU is responsible for RCC - IM to support.
  - TSI OPE (section 4.2.2.5 and appendix D1)
  - Most of the RCC  items require a simple comparison, some of them need further analysis
  - SMS of RUs and IMs might have to be revised to include RCC.
  - Results of vehicle route compatibility check are also used for Train composition (which is a different process from the Vehicle RCC).

States of a VA application

Slide 121
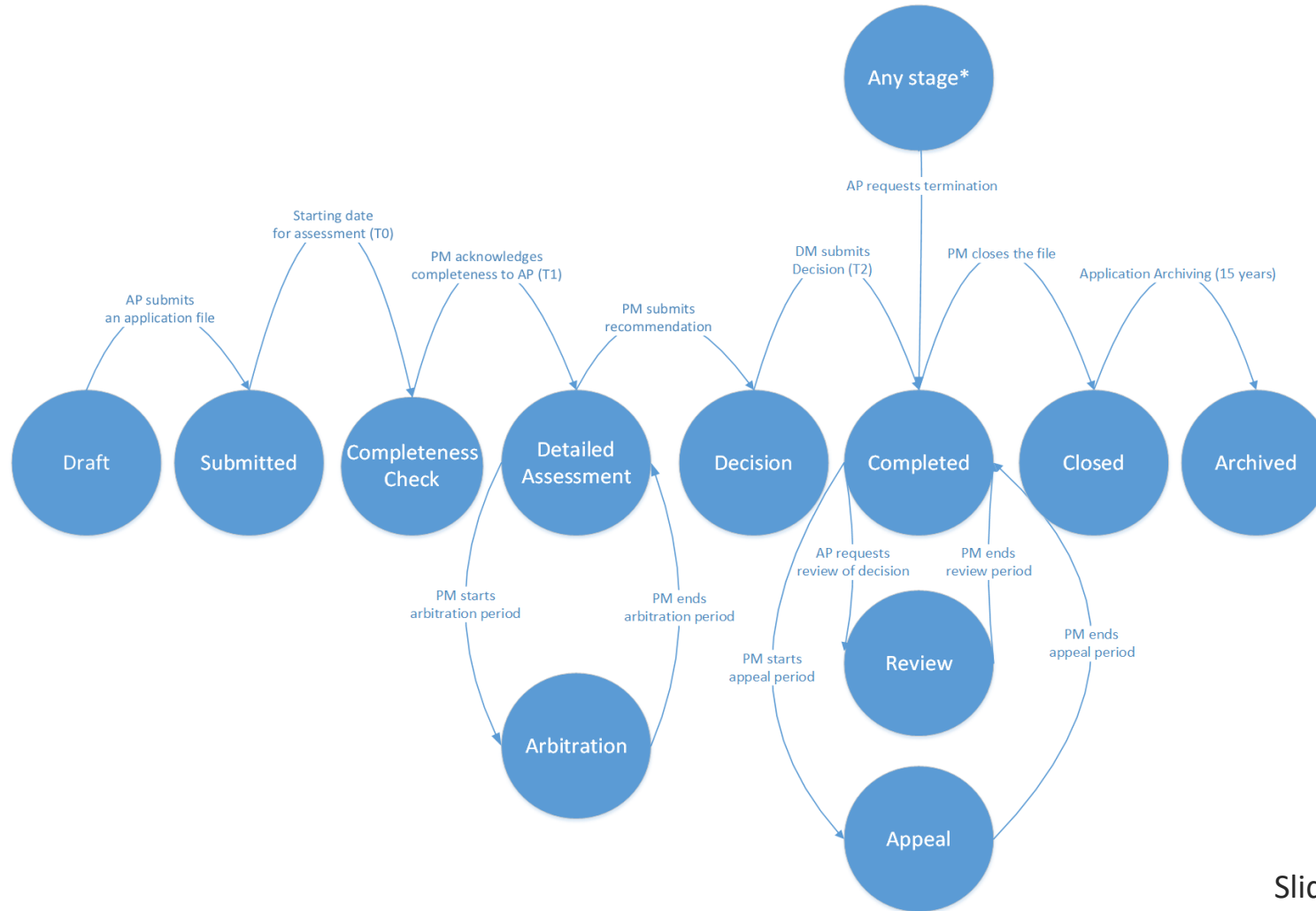
# Koulutamme ja opastamme

Mauno.pajunen@traficom.fi

www.traficom.fi

# Traficomilta haettavan markkinoillesaattamisluvan hinta ja muutoksenhakumahdollisuudet

Une Tyynilä

# Hinnat ja maksut

**ERA:lta haettava markkinoillesaattamislupa**

> [Komission täytäntöönpanoasetus](#) (EU) 2018/764 ERA:n maksuista ja palkkioista

>> Markkinoillesaattamisluvan käsittelyn tuntihinta 130 €/h.

>> ERA:n työn lisäksi hakijalta laskutetaan hakemuksen käsittelyyn osallistuvien NSA:iden maksut.

>> ERA hoitaa laskutuksen.

**Traficomilta haettava markkinoillesaattamislupa**

> Traficomin liikennettä koskeva maksuasetus [1148/2018](#).

>> Markkinoillesaattamisluvan käsittelyn tuntihinta 250 €/h.

>> (Huom. määrittää myös Traficomin työn arvon ERA:n käsittelemissä lupa-asioissa.)

# ERA:n päätös markkiniollesaattamislupasasiassa

> Muutoksenhaku uudesta ERA:n valituslautakunnasta (Board of Appeal)

> Valituslautakunnan toimikausi on 4 vuotta ja se aloittaa työnsä 16.6.2019 seuraavalla kokoonpanolla:

>> Varsinaiset jäsenet Marcel Verslype (pj.), Joanna Marcinkowska ja Andreas Thomasch

>> Varajäsenet Gilles Dalmas, Patrizio Grillo ja Kaisa Sainio

> Puheenjohtaja vastaa työn laadusta ja esittelijäksi valittava valituslautakunnan jäsen ratkaisuehdotuksen laatimisesta.

> Apuna työssä kirjaajana toimiva ERA:n virkamies.

> Valituslautakunnalta voi hakea muutosta sekä itse lupa-asiaan että siihen liittyvään laskutukseen.

# ERA:n päätös markkinoillesaattamislupaasiassa, jatkuu…

> Muutoksenhaku on käynnistettävä toimittamalla valituslautakunnalle hakemus sähköisessä muodossa 2 kk:n kuluessa päätöksen tiedoksiantamisesta.

>> Muutoksenhakupyyntö jälkeen ERA:lla vielä mahdollisuus oikaista asia.

> Valituslautaakunnan käsittely lähtökohtaisesti kirjallista. Todistajien kuuleminen kuitenkin mahdollista, samoin väliintulohakemukset.

> Jos valituslautakunta ratkaisee asian hakijan eduksi, ERA:n on annettava 1 kk:n kuluessa valituslautakunnan ratkaisun mukainen päätös.

> Hakijan eduksi tehtävät ratkaisut maksuttomia. Jos valitus peruutetaan tai sitä hyväksytä, hinta on joko 10 000 € tai valitukseen johtaneen päätöksen hinta, riippuen siitä kumpi on alempi.

# Traficomin päätös markkinoillesaattamislupa-asiassa

> Traficomin antamaan päätökseen voi hakea oikaisua Traficomilta 1 kk:n kuluessa päätöksen tiedoksisaannista.

> Traficomin oikaisuun antamasta päätöksestä voi hakea muutosta hallinto-oikeudelta (ja hallinto-oikeuden päätökseen korkeimmalta hallinto-oikeudelta, jos KHO antaa valitusluvan).

> Traficomin päätöksestä perittävään maksuun voi hakea oikaisua Traficomilta, jos hakija katsoo, että maksun määräämisessä on tapahtunut virhe.

> Ohjeet menettelyihin toimitetaan markkinoillesaattamislupaa koskevan päätöksen liitteenä.

# Mikä muuttuu ERTMS-ratalaitteiden hyväksynnöissä?

Jukka Leino

# Hyväksynnän dokumentit ja tausta (EU säädökset)

- **Euroopan parlamentin ja neuvoston direktiivi (EU) 2016/797, rautatiejärjestelmän yhteentoimivuudesta Euroopan unionissa;**
  - **artikla 18; Kiinteiden laitteiden käyttöönottolupa**
  - **artikla 19; ERTMS:n yhdenmukainen täytäntöönpano unionissa**
  - **artikla 55; Muut siirtymäsäännökset**

- **Euroopan parlamentin ja neuvoston asetus EY:n rautatievirastosta ERA (EU) 2016/796,**
  - **artikla 22; Ratalaitteiden ohjaus-, hallinta- ja merkinanto-osajärjestelmien käyttöönotto**
  - **artikla 30; ERTMS:n veturi- ja ratalaitteiden osajärjestelmien yhteensopivuus**

- **Komission täytäntöönpanoasetus (EU) 2018/867 Euroopan unionin rautatieviraston valituslautakunnan/valituslautakuntien työjärjestyksestä**

- **Komission täytäntöönpanoasetus (EU) 2018/764**, Euroopan unionin rautatievirastolle maksettavista maksuista ja palkkioista sekä niiden maksuehdoista

# Komission suositus / 2018/C 253/01

- **Yleiset säännökset**

  - **1. Hakija ottaa virastoon (jäljempänä ERA) yhteyttä heti, kun se suunnittelee järjestävänsä ERTMS-ratalaitteita koskevan tarjouskilpailun, johon tarvitaan viraston hyväksyntä.**

  - **2. Hakija toimittaa riittävän yksityiskohtaiset tekniset asiakirjat, joiden avulla ERA voi tarkistaa, että toteutettavaksi tarkoitetut tekniset ratkaisut ovat täysin yhteentoimivia.**

  - **3. ERA ja toimivaltainen kansallinen turvallisuusviranomainen (jäljempänä NSA) tekevät yhteistyötä ja jakavat tietoja ennakoidakseen mahdollisia teknisiä ongelmia ja puuttuakseen niihin ja näin ollen helpottavat NSA:n tehtävää myöntää osajärjestelmän käyttöönottolupa. NSA voi antaa lausuntoja teknisistä seikoista ja suunnittelusta keskitetyn palvelupisteen välityksellä menettelyn missä tahansa vaiheessa.**

  - **4. Hyväksyntämenettelyn aikana toimitetut tiedot annetaan NSA:n käyttöön.**

# Komission suositus / 2018/C 253/01

- **Yleiset säännökset**

  - **5. Hakija ja ERA noudattavat kolmivaiheista hyväksyntämenettelyä:**
    a) alustava vaihe;
    b) hakemuksen jättäminen ja täydellisyyden tarkistaminen;
    c) arviointi ja päätöksenteko.

  - **6. Hakija toimittaa keskitetyn palvelupisteen (jäljempänä OSS) kautta mahdollisimman varhaisessa vaiheessa hyväksynnän saamisen edellyttämän seuraavanlaisen hakemuksen, myös kuvauksen suunnitellusta teknisestä ratkaisusta ja asiakirjatodisteet siitä, että suunniteltu tekninen ratkaisu on asiaankuuluvan ohjaus-, hallinta- ja merkinanto-YTE:n mukainen, kuten direktiivin (EU) 2016/797 19 artiklassa luetellaan; ->**

# Komission suositus / 2018/C 253/01

a) Luonnos tarjouseritelmiksi tai suunnitellun teknisen ratkaisun kuvaus
   - Hankekuvaus, mukaan lukien yksityiskohtaiset tiedot hankkeen piiriin tai hankkeiden yhdistelmän piiriin kuuluvasta radasta, ratojen ryhmästä tai verkosta: maantieteellinen sijainti, yksi- ja kaksiraiteisten ratojen kilometrimäärä, ERTMS-taso, perusversio ja versio, yhteentoimivuuden osatekijät sekä asemat.

   - Todisteet siitä, että tarjouskilpailu tai sopimus tai molemmat sisältävät asiankuuluvan ohjaus-, hallinta- ja merkinanto-YTE:n perusversion ja version.

   - Hankesuunnitelma, josta käyvät ilmi suoritteet, välitavoitteet ja määräajat.

   - Luettelo täytäntöönpantavista ERTMS-toiminnoista.

   - Asetuksen (EU) 2016/919 5 artiklassa ja kyseisen asetuksen liitteessä olevassa 6.1.2.3 kohdassa tarkoitetut suunnittelusäännöt ja toiminalliset testiskenaariot.

   - Testausstrategia ja testaussuunnitelmat.

# Komission suositus / 2018/C 253/01

b) Asiakirjatodisteet edellytyksistä, jotka ovat tarpeen osajärjestelmän teknisen ja toiminnallisen yhteensopivuuden varmistamiseksi asiaankuuluvassa verkossa liikennöimään tarkoitettujen kalustoyksikköjen kanssa.

c) Asiakirjatodisteet siitä, että suunniteltu tekninen ratkaisu on asiaankuuluvan ohjaus-, hallinta- ja merkinanto-YTE:n sekä muiden asiaankuuluvien asiakirjojen, kuten NSA:n lausuntojen, tarkastusvakuutusten ja vaatimustenmukaisuustodistusten mukainen.

- Jos saatavilla, NSA:n antama edellinen ERTMS:n ratalaitteita koskeva lupa, joka on merkityksellinen hakijan esittämien suunniteltujen teknisten ratkaisujen kannalta.

- Jos saatavilla, yhteentoimivuuden osatekijöiden EY-vaatimustenmukaisuustodistukset ja yhteentoimivuuden osatekijöiden EY-vaatimustenmukaisuusvakuutus, myös ERA:n sertifiointimalli ja ERA:n antamassa suuntaviivassa määritellyt poikkeamat.

# Komission suositus / 2018/C 253/01

c)   Asiakirjatodisteet suunnitellusta teknisestä ratkaisusta jatkuu..

- Jos saatavilla, osajärjestelmän tarkastustodistukset ja tapauksen mukaan suunnittelua koskevat välivaiheen tarkastuslausumat ja osajärjestelmän EY-tarkastusvakuutus, myös sertifiointimalli ja ERA:n antamassa asiaankuuluvassa suuntaviivassa määritellyt poikkeamat.

- Sen osoittaminen, miten ongelmalokin sisältämän kunkin ongelman yhteentoimivuudelle aiheuttamiin riskiin on puututtu.

- Hankkeeseen sovellettavat ERTMS:iin liittyvät kansalliset säännöt.

-  Jos hakija on saanut poikkeuksen yhden tai useamman YTE:n tai YTE:ien osien soveltamisesta, poikkeuksen myöntävä direktiivin (EU) 2016/797 7 artiklan mukainen jäsenvaltion antama asiakirja.

# Hyväksynnän prosessikuvaus
## (vuokaavio sovellusoppaassa)

- **luonnos prosessista, julkaistu ensimmäisen kerran työpajoissa 11/2016 ja 2/2017**

- **Komission suositus 2018/C 253/01 Euroopan rautatieliikenteen hallintajärjestelmän yhdenmukaista täytäntöönpanoa unionissa koskevasta ohjeistuksesta**
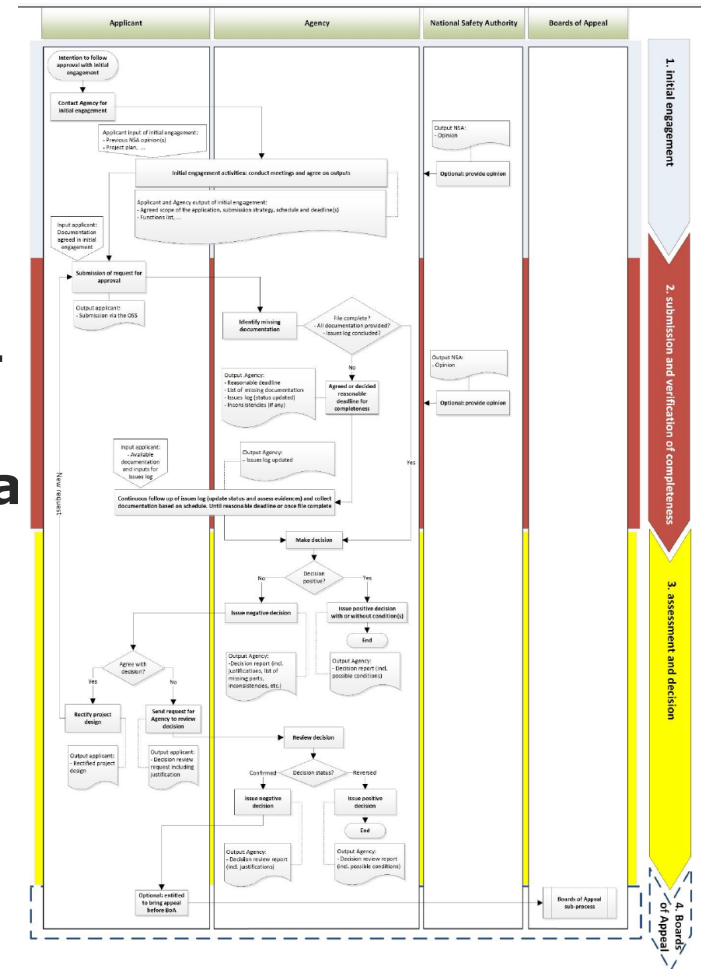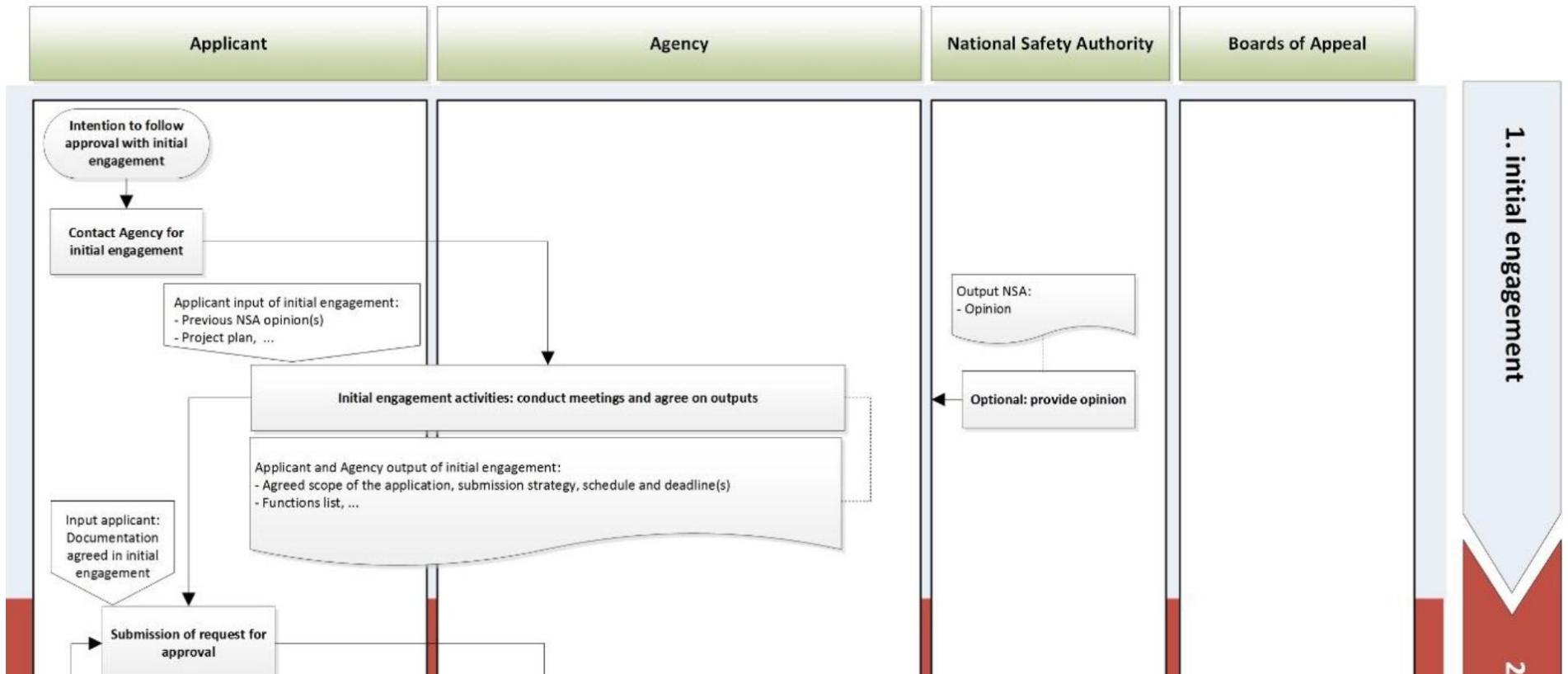
# Hyväksynnän prosessikuvaus (vuokaavio sovellusoppaassa)

Hyväksyntä koostuu seuraavista vaiheista: 1 alustava vaihe, 2 hakemuksen jättäminen ja täydellisyyden tarkistaminen, 3 arviointi ja päätöksenteko, 4 valituslautakunta (tarvittaessa);

# Hyväksynnän prosessikuvaus (vuokaavio sovellusoppaassa)

# Hyväksynnän prosessikuvaus (vuokaavio sovellusoppaassa) Komission suositus/2018/C 253/01

## Ensimmäinen vaihe – alustava vaihe

Hakija käynnistää ennen hakemuksen virallista jättämistä vuoropuhelun ERA:n kanssa hyväksyntämenettelyn helpottamiseksi.

Alustava vaihe alkaa ennen ERTMS-ratalaitteita koskevia tarjouskilpailuja ja kun hakija ilmoittaa ERA:lle aikomuksestaan esittää hyväksyntäpyyntö.
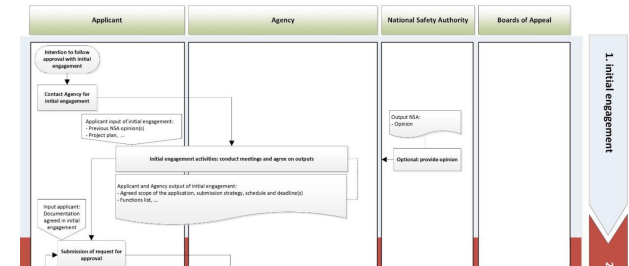
# Hyväksynnän prosessikuvaus (vuokaavio sovellusoppaassa)
# Komission suositus / 2018/C 253/01

**Ensimmäinen vaihe – alustava vaihe**
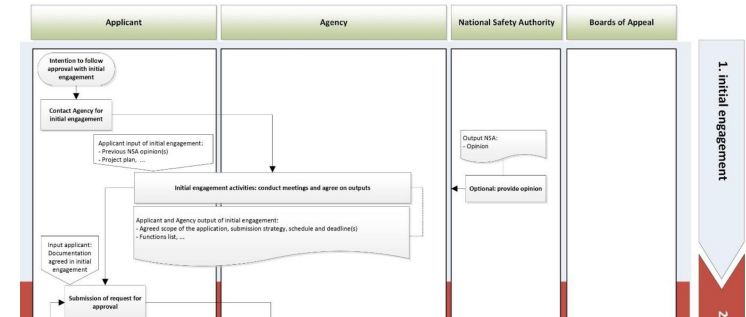


**Alustava vaihe käsittää rajallisen määrän keskusteluja, joissa hakija esittelee suunnitellun hankkeen sekä suunniteltujen teknisten ratkaisujen yksityiskohdat, mukaan lukien mahdollisuuksien mukaan 6 kohdassa luetellut asiakirjat.**

# Komission suositus/2018/C 253/01
## Ensimmäinen vaihe – alustava vaihe

Alustava vaihe saatetaan loppuun allekirjoittamalla ERA:n ja hakijan välillä järjestely, kattaen seuraavat seikat (kohta 17):

(a) Hakemuksen kohde;

(b) Aikataulu, mukaan lukien seuraavat päivämäärät:
- kunkin 6 kohdassa luetellun asiakirjan toimittaminen;
- ongelmalokin päivitykset;
- päätöksenteon määräaika;

(c) Ongelmaloki.

NSA osallistuu alustavaan vaiheeseen ja antaa lausunnon em. kohtiin.

Hakija rekisteröi asiakirjat käyttäen OSS:ia.

# Hyväksynnän prosessikuvaus (vuokaavio sovellusoppaassa)
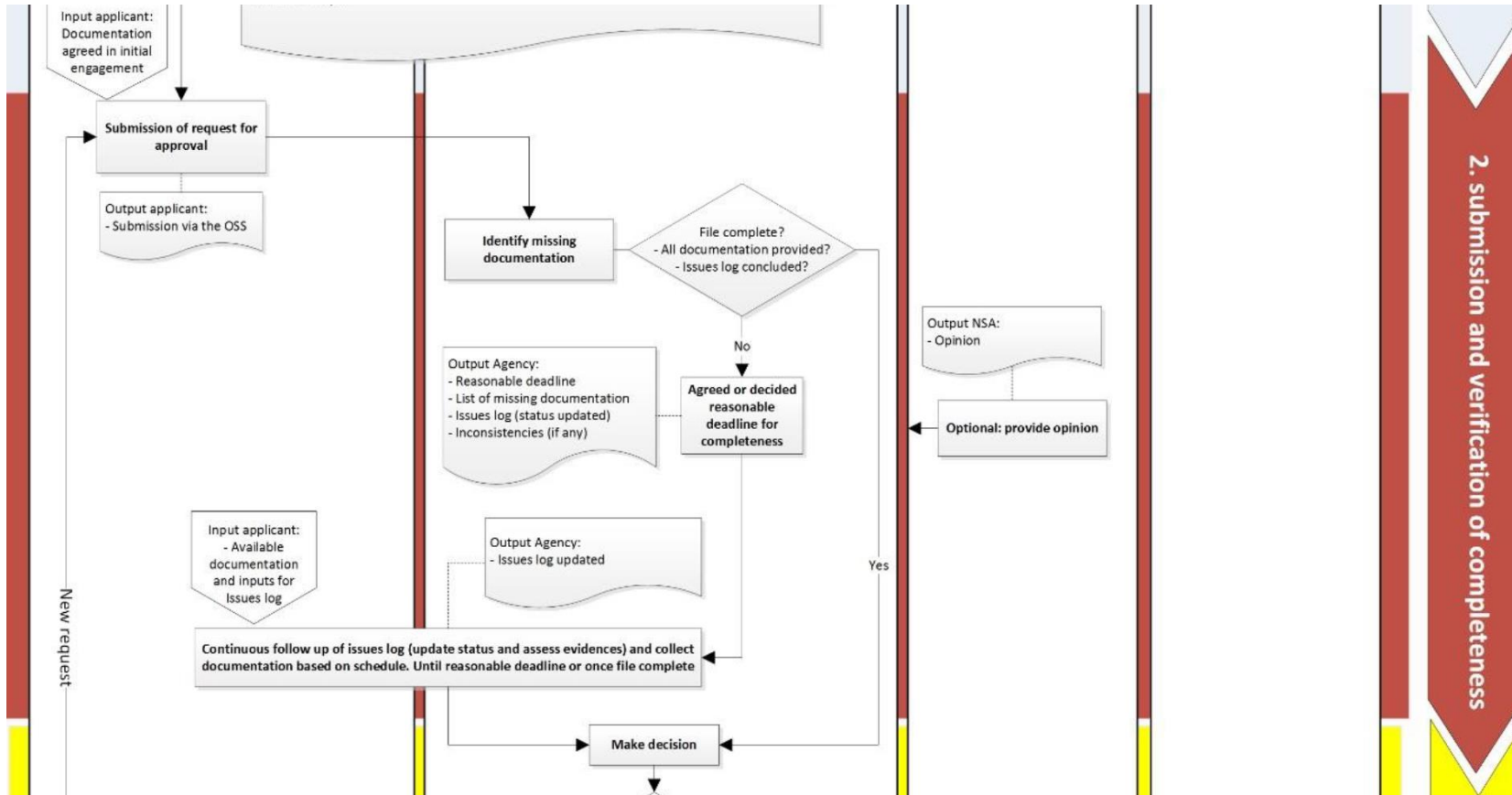
# Komission suositus/2018/C 253/01
## Toinen vaihe–Hakemuksen jättäminen ja tietojen täydellisyyden tarkistaminen

Hakemuksen jättämisen ja tietojen täydellisyyden tarkistamisen vaihe alkaa alustavan vaiheen jälkeen, kun hakija esittää OSS:n kautta pyynnön tehdä hyväksyntää koskeva päätös.

Hakija toimittaa kaikki 6 kohdassa luetellut asiakirjat. Jos joitakin näistä asiakirjoista oli mahdollisesti aiemmin toimitettu OSS:n kautta, hakija voi yksilöidä nämä asiakirjat ja vahvistaa, että kyseiset asiakirjat pätevät edelleen hankkeeseen ilman muutoksia tai lisäyksiä. Jos asiakirjoja on muutettu tai niihin on tehty lisäyksiä, hakijan on toimitettava päivitetyt asiakirjat.

ERA arvioi jätetyn hakemuksen täydellisyyden sekä tarkistaa, että jätetty hakemus on ladattu OSS:iin, että se sisältää kaikki 6 kohdassa luetellut asiakirjat ja ettei yhdelläkään ongelmalokiin kirjatuista ongelmista ole statusta "ongelma avoin".
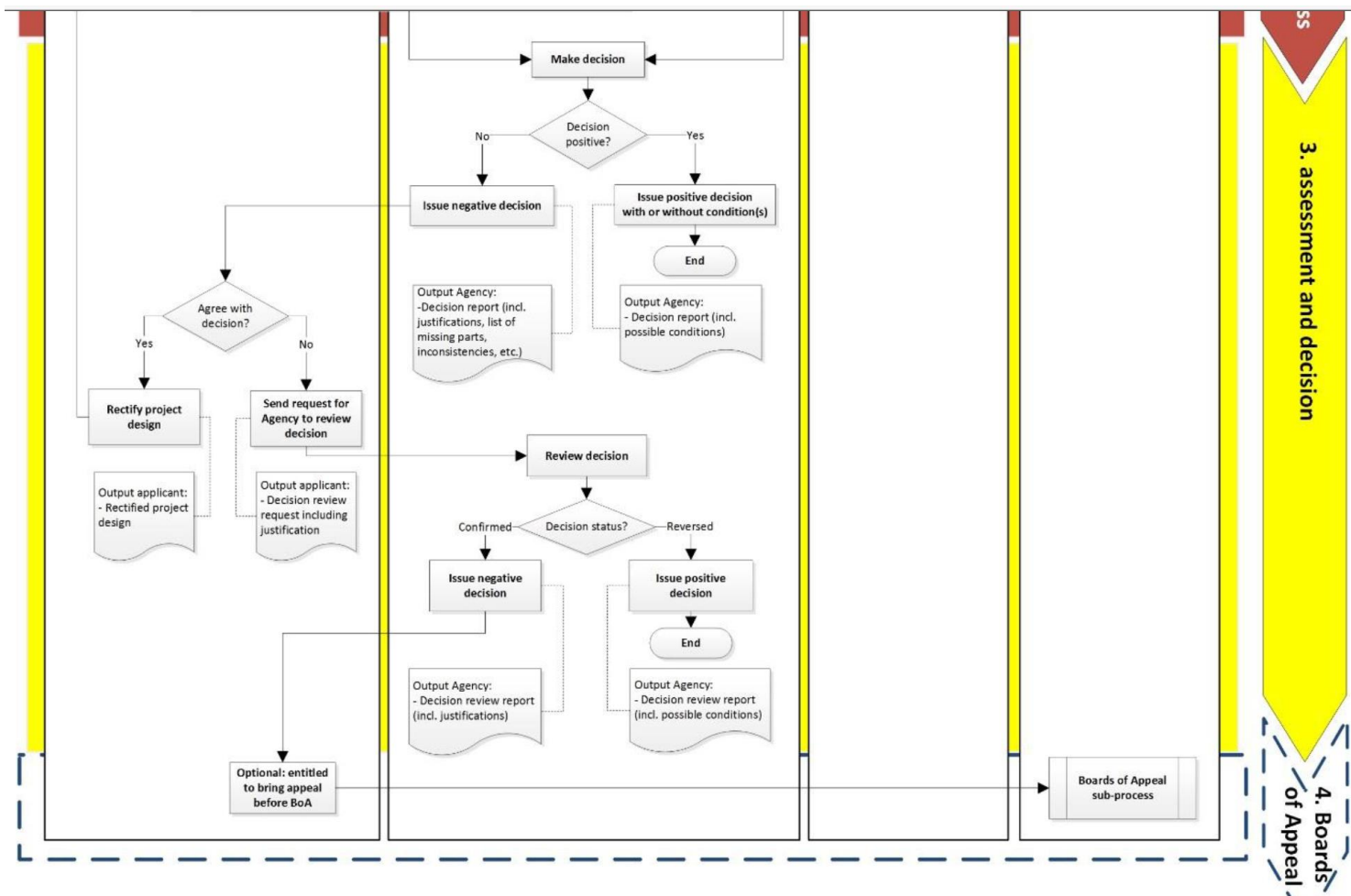
# Komission suositus/2018/C 253/01
## Toinen vaihe–Hakemuksen jättäminen ja tietojen täydellisyyden tarkistaminen

ERA arvioi, onko jätetty hakemus relevantti ja johdonmukainen suhteessa 6 kohdassa lueteltuihin asiakirjoihin ja 17 kohdassa tarkoitettuihin alustavassa vaiheessa sovittuihin järjestelyihin.

ERA tiedottaa hakijalle OSS:n kautta kuukauden kuluessa virallisen hakemuksen vastaanottamisesta, jos jätetyt tiedot eivät ole täydellisiä, esittää tästä asiaankuuluvat todisteet ja täsmentää, mitä muita asiakirjoja on toimitettava alustavan vaiheen aikana sovitussa määräajassa.

Kun ERA katsoo, että hakemus on täydellinen, relevantti ja johdonmukainen, se tiedottaa tästä hakijalle OSS:n kautta.

# Hyväksynnän prosessikuvaus (vuokaavio sovellusoppaassa)

# Komission suositus/2018/C 253/01
## Kolmas vaihe–Arviointi ja päätöksenteko

Kun hakemuksen jättämisen ja tietojen täydellisyyden tarkistamisen vaihe on saatu päätökseen, alkaa arvioinnin ja päätöksenteon vaihe.

ERA tekee joko myönteisen tai kielteisen päätöksen kahden kuukauden kuluessa arvioinnin ja päätöksenteon vaiheen alkamisesta sellaisesta teknisten ratkaisujen osiosta, josta ERA ei ole aiemmin tehnyt myönteistä päätöstä.

ERA ottaa huomioon NSA:n hyväksyntäpyynnöstä mahdollisesti esittämät lausunnot.

ERA tekee myönteisen päätöksen, jos toinen vaihe on saatu onnistuneesti päätökseen ja kaikilla ongelmalokiin kirjatuilla ongelmilla on status "ongelma käsitelty loppuun".

# Komission suositus/2018/C 253/01
## Kolmas vaihe–Arviointi ja päätöksenteko

ERA tekee kielteisen päätöksen jos yhdellä tai useammalla ongelmalokiin kirjatuista ongelmista on status "ongelma käsitelty loppuun, mutta ratkaisua ei voida hyväksyä" tai jos toisen vaiheen arviointi on saatu päätökseen mutta hakemusta ei pidetä täydellisenä, relevanttina ja/tai johdonmukaisena.

ERA tekee myönteisen päätöksen ehdollisena seuraavissa tapauksissa:
(a) yhden tai useamman ongelmalokiin kirjatun ongelman status on "ongelma käsitelty loppuun ehdollisesti"; ja
(b) yhdenkään ongelman status ei ole "ongelma käsitelty loppuun, mutta ratkaisua ei voida hyväksyä".

ERA esittää selityksen ehdoista, jotka hakijan on täytettävä myöhemmässä vaiheessa ja jotka NSA:n on tarkistettava, ja yhteenvedon vielä ongelmalokiin kirjattuina olevista ongelmista.

# Komission suositus/2018/C 253/01
## Kolmas vaihe–Arviointi ja päätöksenteko

**Jos hakija ei pysty täyttämään ERA:n tekemässä myönteisessä päätöksessä vahvistettua ehtoa, NSA suosittaa, että hakija**

**(a)toimittaa pyynnön uudelleen ERA:n hyväksyttäväksi. Tällöin hakija mainitsee ERA:lle toimitettuun edelliseen hyväksyntäpyyntöön sisältyneet asiakirjat, jotka ovat edelleen päteviä, eikä ERA arvioi kyseisiä asiakirjoja uudelleen;**

**(b)soveltaa asetuksen (EU) 2016/796 30 artiklan 2 kohtaa. Tällöin ERA tarjoutuu päivittämään ongelmalokin OSS:ssa.**

**Jos ERA tekee kielteisen päätöksen, hakijalla on oikeus korjata hankesuunnitelmaa, jättää uusi hakemus, mainita hankkeen osat, jotka säilyvät muuttumattomina, sekä asiakirjat ja todisteet, jotka ovat edelleen päteviä.**

# Komission suositus/2018/C 253/01
## Kolmas vaihe–Arviointi ja päätöksenteko

Jos hakija toimittaa ERA:lle direktiivin (EU) 2016/797 19 artiklan 5 kohdan nojalla perustellun pyynnön tarkastella ERA:n päätöstä uudelleen, pyyntö voidaan esittää OSS:n kautta ja siihen voidaan liittää yksityiskohtainen perustelu niiden ongelmien osalta, joita ERA ei hakijan mielestä ole arvioinut asianmukaisesti. ERA:n olisi vahvistettava päätöksensä tai tarkistettava sitä keskittyen perustelussa esille tuotuihin ongelmiin. Uudelleentarkastelun tuloksista olisi tiedotettava hakijalle OSS:n kautta kahden kuukauden kuluessa siitä, kun hakija esitti pyynnön.

ERA toimittaa hakijalle tarkoituksenmukaiset perustelut, jos se vahvistaa alkuperäisen kielteisen päätöksensä.

Jos ERA vahvistaa alkuperäisen kielteisen päätöksensä, hakijalla on oikeus valittaa siitä asetuksen (EU) 2016/796 55 artiklan mukaisesti perustetulle valituslautakunnalle.

# Lisätietoa ERA:n kotisivuilta;

# Lisätietoa ERA:n kotisivuilta;

## How do I make an application?

Applicants should read the Commission Recommendation on the harmonised implemented of ERTMS in the Union and the related application guide which provides information about the legislation, application process and what is required from the applicant.

All applications for an ERTMS trackside approval must be electronically submitted through the One-Stop Shop (OSS).

> ⚠️ It is highly recommended that an applicant contacts the Agency and informs it of its intention of submitting an ERTMS trackside project for approval before submitting its application.

The Agency and the applicant then can engage in a dialogue (called 'Initial Engagement') where the applicant is expected to present the intended project and further details of the technical solutions envisaged that defines the scope of the request for approval. As a result of this dialogue, the applicant and the Agency can confirm the scope of the application and arrange an effective application.

The National Safety Authority or Authorities (NSAs) involved in the authorisation can collaborate in the initial engagement stage and provide an opinion on the proposal of arrangements with the applicant and can also provide an opinion in later stages of the approval process.

Also, in case of changes to the draft tender specifications or to the descriptions of the envisaged technical solutions that occurred after the positive decision of the Agency, the applicant is requested to make use of the OSS to inform the Agency and the NSA(s) involved.

## Where can I find the decision about my application?

All decisions following an application for an ERTMS trackside approval can be found in the One-Stop Shop (OSS). The Applicant can only access information pertaining to its respective applications.

TRAFICOM

# Lisätietoa ERA:n kotisivuilta;

## When does the ERTMS Trackside approval apply?

The ERTMS trackside approval applies to any call for tenders relating to ERTMS trackside equipment which are launched after 16 June 2019, or were launched before but have not been closed on that day

Even though the ERTMS trackside approval is requested for the authorisation of trackside subsystems involving ERTMS, as mentioned in Directive (EU) 2016/797 ☑, transitional provisions are defined in Article 55 of this Directive. Due to these transitional provisions, and for the cases of any ERTMS trackside equipment which was not yet subject to an approval, the Agency must be informed before authorising the placing in service.

### Legal framework

🔗 Commission Recommendation of 18 July 2018 on guidance for the harmonised implementation of the European Rail Traffic Management System in the Union

### Related guidance

📄 Application guide for ERTMS trackside approval (851.52 KB)

### Related links

🔗 European Rail Traffic Management System

🔗 FAQ

# Keskitetyn palvelupisteen (One Stop Shop) käyttöopastus esimerkein

(esitetty OSS-järjestelmää suoraan näyttämällä)

Hannu Timperi