

Workshop on the Technical Pillar of the 4th RP SSC in the framework of the 4th RP

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Budapest, 5 June 2019



- Introduction
- What is new?
- EU legal framework
- Transition period
- How to apply for a single safety certificate?
- Outline of the safety assessment process
- Update and renewal of the certificate

What is **Introduction** new?

The Technical Pillar of the 4th Railway Package



Entry into Force:
15 June 2016

Key Elements of the Technical Pillar

After a **three year transition period***, the Agency will issue single **EU-wide vehicle authorisations** and **safety certificates** to train manufacturers and railway undertakings

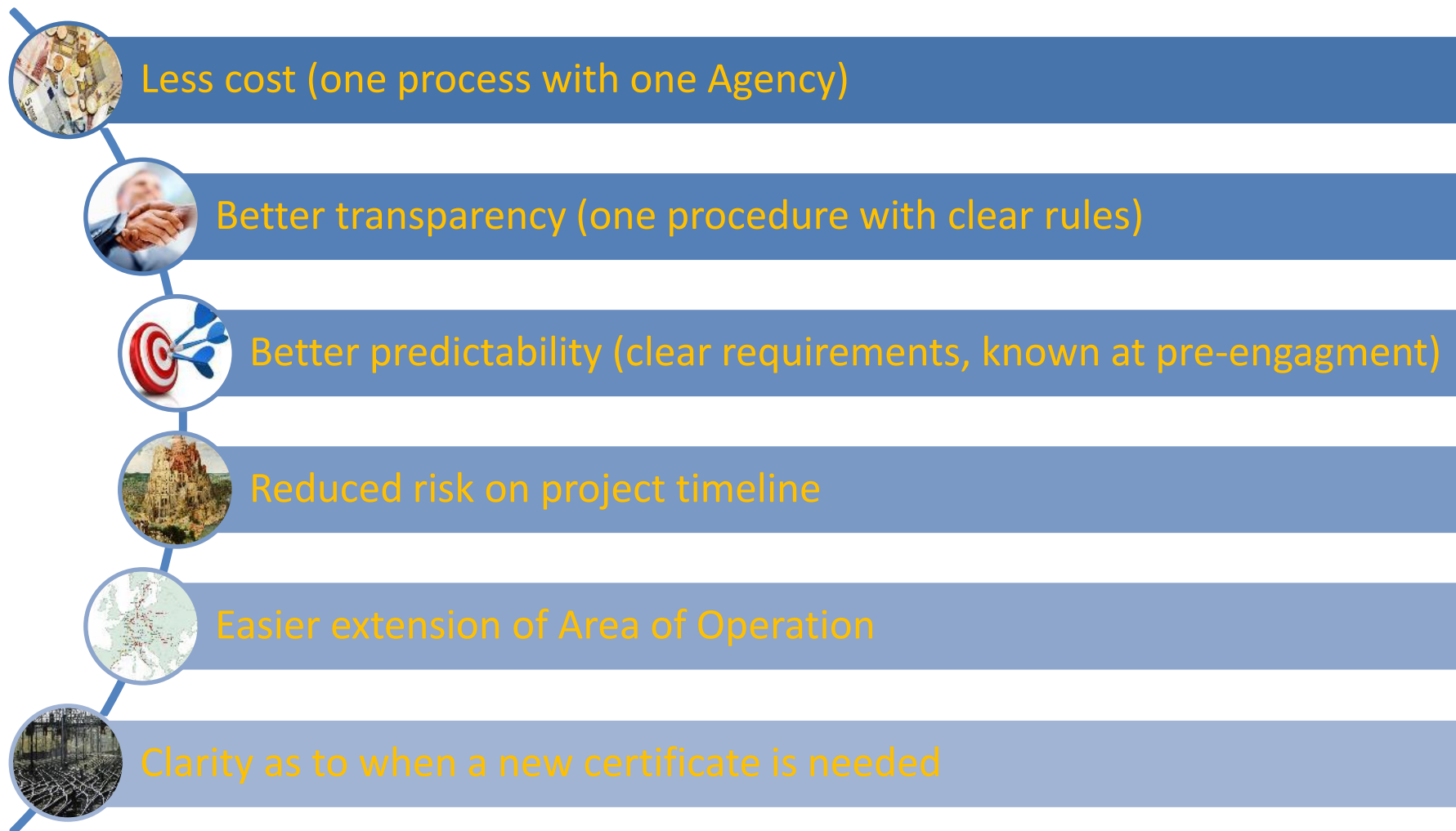
The Agency will be in a position to issue an **approval required for the NSA authorisation of ERTMS trackside projects** (a binding opinion on ERTMS trackside specifications)

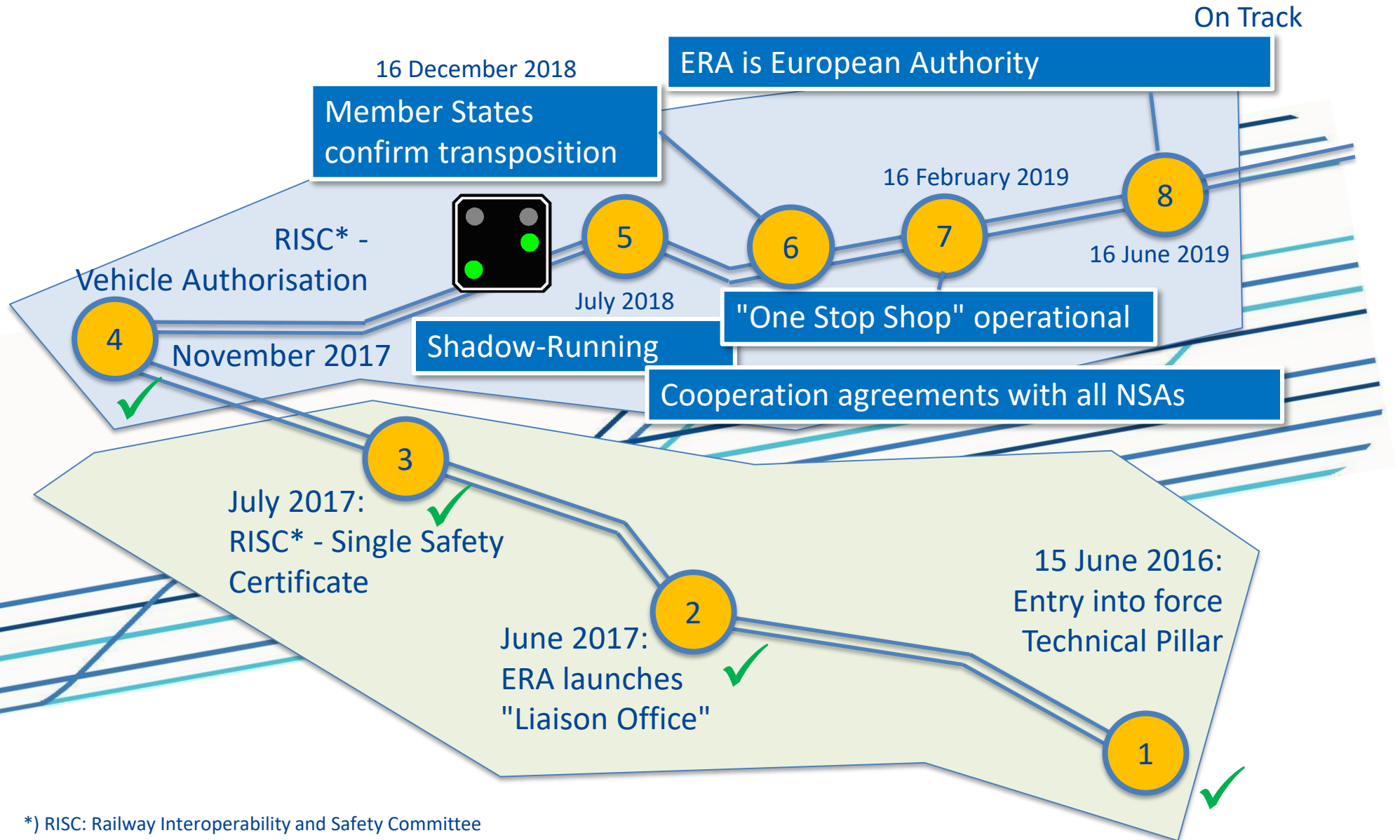
In order to support the above processes, the Agency will develop the so-called **One-Stop-Shop**

- Covering applications at the Agency, but all national applications for Safety Certification, Vehicle Authorisation, and trackside/infrastructure authorisation as well

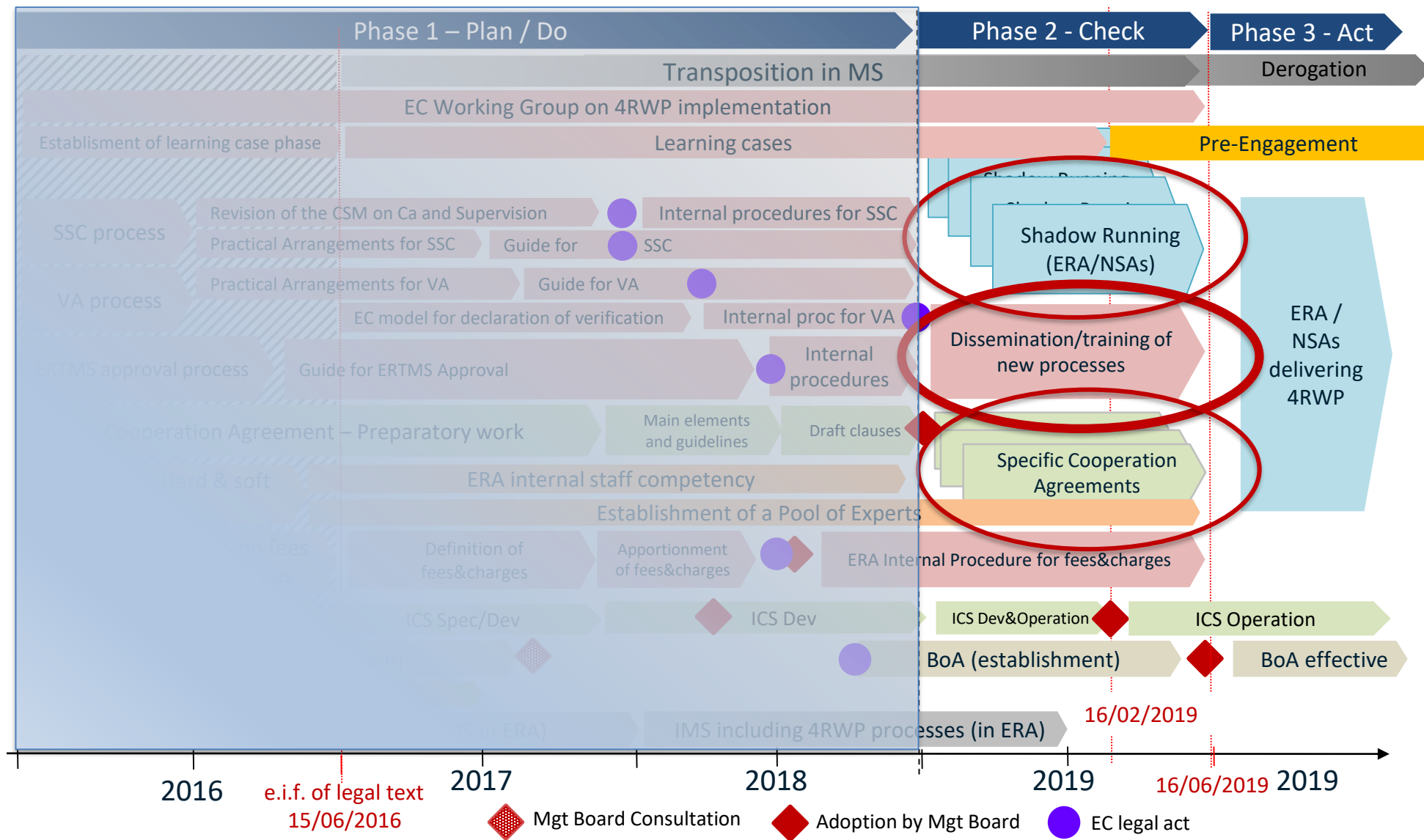
*) member states could opt for four years

Expected Benefits of the Single Safety Certificate process

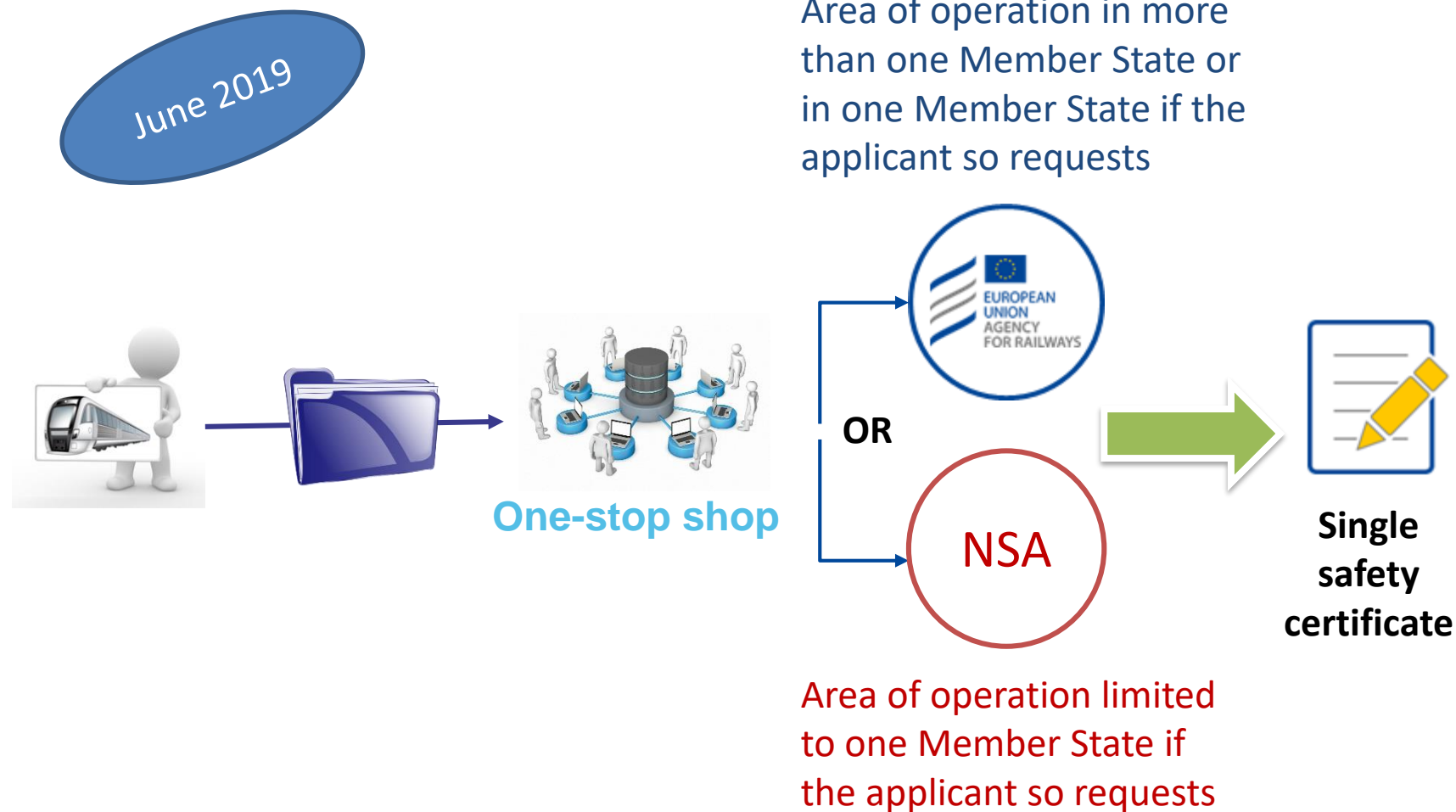




ERA Preparation Programme



What is new?
What is new?



Before	After
Safety certificate part A issued by the relevant NSA	Single safety certificate issued by a safety certification body: either the NSA or the Agency
One or more safety certificates part B issued by the relevant NSAs	All applications managed through the one-stop shop IT tool in accordance with arrangements set out in EU law
Applications managed in accordance with national arrangements	Harmonised assessment process set out in EU law
Assessment process defined by each NSA in accordance with its own rules	Homogeneous safety management system requirements (aligned with ISO management system standards, to be applied by both the authorities and the applicants) and cleaning up of national rules
Assessment based on EU criteria (to be applied by NSAs) and national rules	Authorities must pre-engage on request of the applicant
No obligation from authorities to pre-engage with the applicant	

EU legal framework

Directive

2016/798 – Railway Safety Directive

Regulations

2018/762 – Common safety methods on safety management system requirements

2018/763 – Practical arrangements for issuing single safety certificates to railway undertakings

2015/995 – Technical specification for interoperability relating to the ‘operation and traffic management’ subsystem

2019/773 – Technical specification for interoperability relating to the ‘operation and traffic management’ subsystem

402/2013 – Common safety method for risk evaluation and assessment

1078/2012 – Common safety method for monitoring

2018/761 – Common safety method for supervision



Directives

2016/797 – Interoperability Directive

2007/59 – Train Drivers Directive

Regulations

445/2011 – Certification of entities in charge of maintenance

2016/796 – Agency (ERA) Regulation

2018/764 – Fees and charges payable to the Agency (ERA)
and their conditions of payment

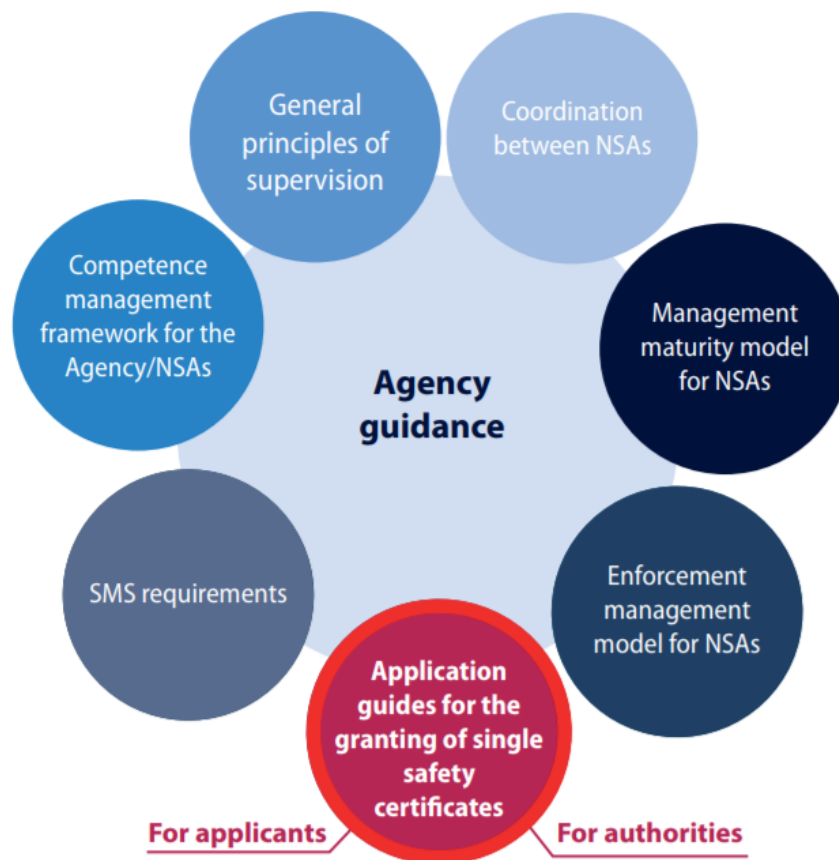
2018/867 – Rules of procedure of the Board(s) of Appeal of
the Agency (ERA)

Regulation concerning the International Carriage of
Dangerous Goods by Rail (RID)

Technical specifications for interoperability relating to the
structural subsystems (ETCS, wagons, etc.)



- New set of guidance to support the implementation of the new EU safety regulatory framework



Where can you get the information from?

- ERA website

ERA > Applicants > Applications for single safety certificates

ERA > Activities > Common Safety Methods

 **Common Safety Methods on safety management system requirements**

 **Common Safety Methods on supervision**

ERA > Can we help you? > FAQ

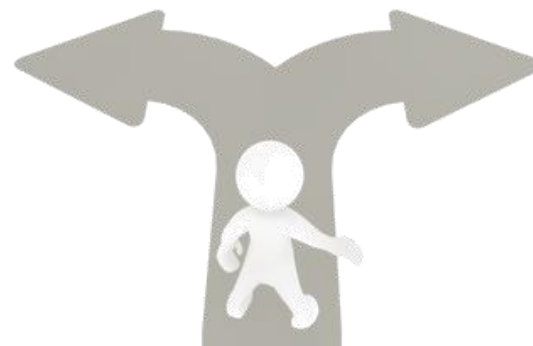


Transition period



Transition period?

- As of 16 of June 2019, ERA is responsible for issuing single safety certificates **when the area of operation entails at least one Member State** that has transposed Directive (EU) 2016/798 by that date
- The national safety authorities of the Member States that postponed the transposition of the new legal framework by one year continue to issue safety certificates in accordance with Directive 2004/49/EC until 16 June 2020

Transposition by 16/06/2019



Transposition by 16/06/2020

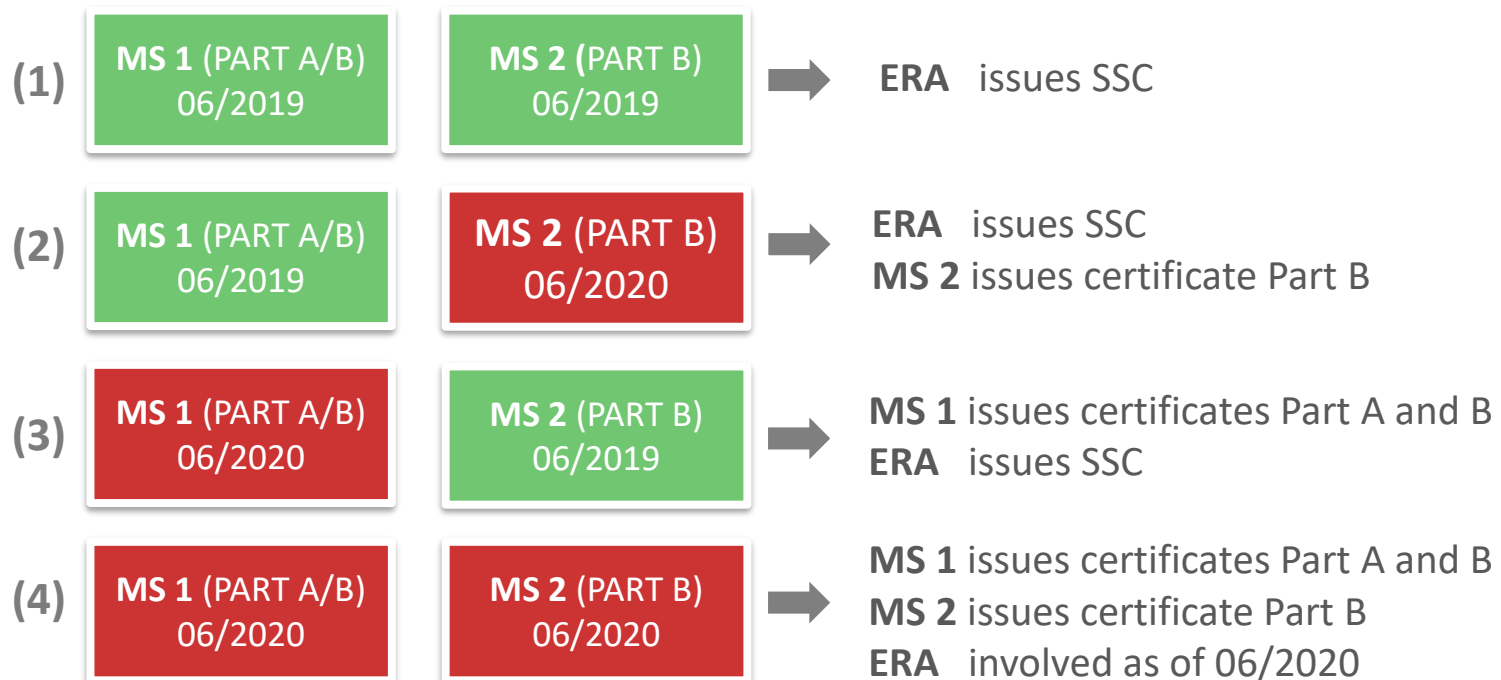
-  16/06/2019
-  16/06/2020



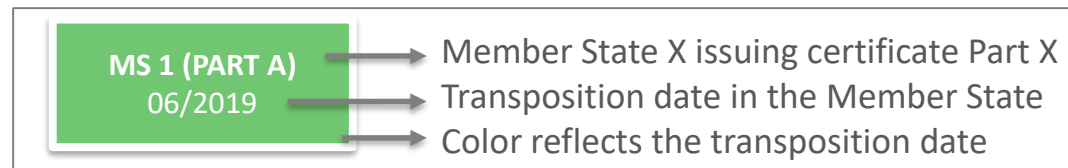
- Safety Directive allowed Member States to choose one of the two possible transposition dates
- Notification of chosen dates was to be done by 16/12/18
- Single safety certificate to be issued when any part of the certificate (A or B) expires in the Member State that transposed Directive (EU) 2016/798 in 2019



- During that period some of the railway undertakings need to follow two different regimes at the same time



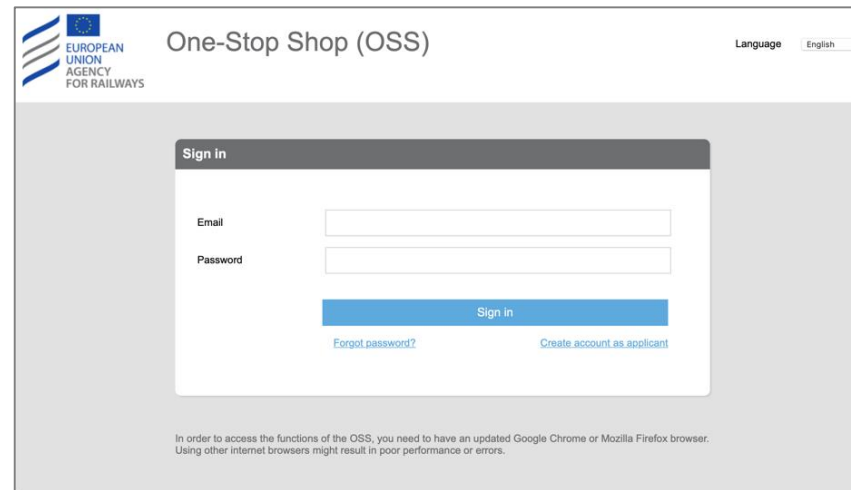
EXPLANATION:



How to apply?

How to apply?

- Railway undertakings submit any application for a single safety certificate through the **one-stop shop** IT tool, available from the Agency website or by using the following URL:
<https://oss.era.europa.eu/logon.html>



The screenshot shows the login interface for the One-Stop Shop (OSS). At the top left is the logo of the European Union Agency for Railways. The title "One-Stop Shop (OSS)" is centered at the top, and a language dropdown menu is set to "English" on the right. The main content area features a "Sign In" form with two input fields: "Email" and "Password". Below the fields is a blue "Sign In" button. Two links are positioned below the button: "Forgot password?" on the left and "Create account as applicant" on the right. At the bottom of the page, a small note states: "In order to access the functions of the OSS, you need to have an updated Google Chrome or Mozilla Firefox browser. Using other internet browsers might result in poor performance or errors."

- It is recommended that an application for a single safety certificate is submitted in advance to any possible deadline (at least 6 months)

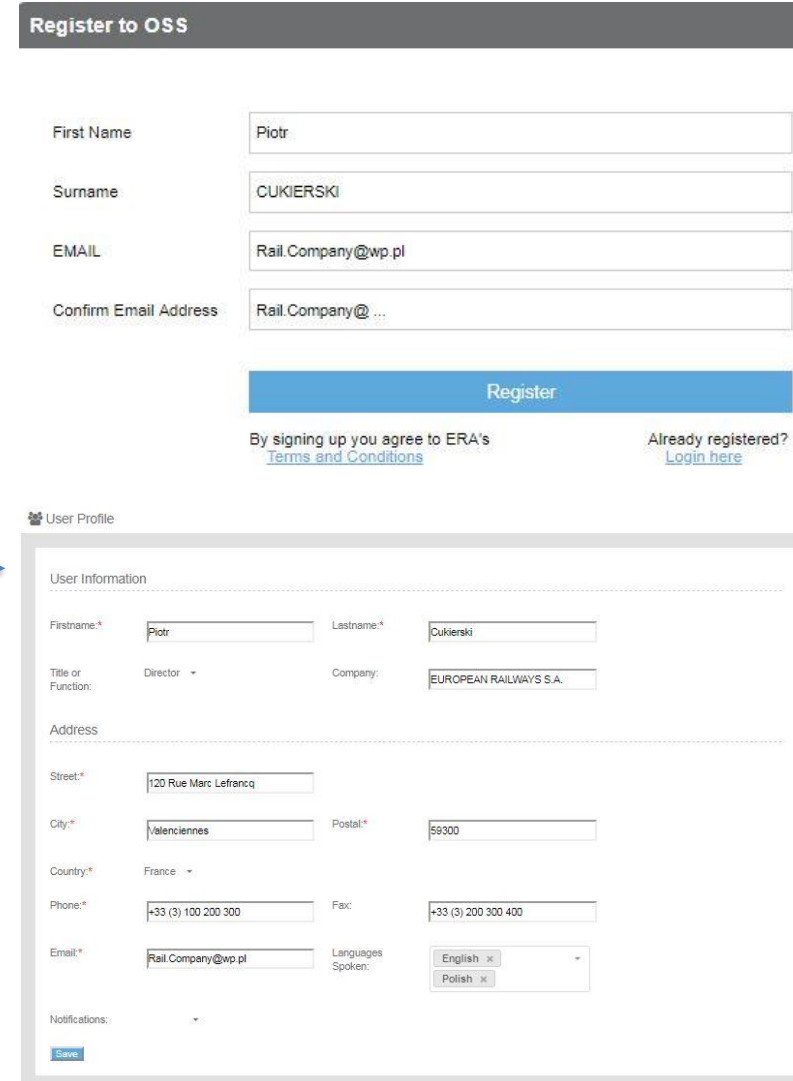
1. Register yourself
2. Log in to the OSS
3. Complete user profile

4. Registered user:

- Can draft application in the OSS
- Can submit application in the OSS
- Can share application with other user
- Is automatically a contact person



You have to decide internally how to manage the access rights in your organisation



Register to OSS

First Name: Piotr

Surname: CUKIERSKI

EMAIL: Rail.Company@wp.pl

Confirm Email Address: Rail.Company@...

Register

By signing up you agree to ERA's [Terms and Conditions](#) [Already registered? Login here](#)

User Profile

User Information

Firstname: Piotr Lastname: Cukierski

Title or Function: Director Company: EUROPEAN RAILWAYS S.A.

Address

Street: 120 Rue Marc Lefrancq

City: Valenciennes Postal: 59300

Country: France

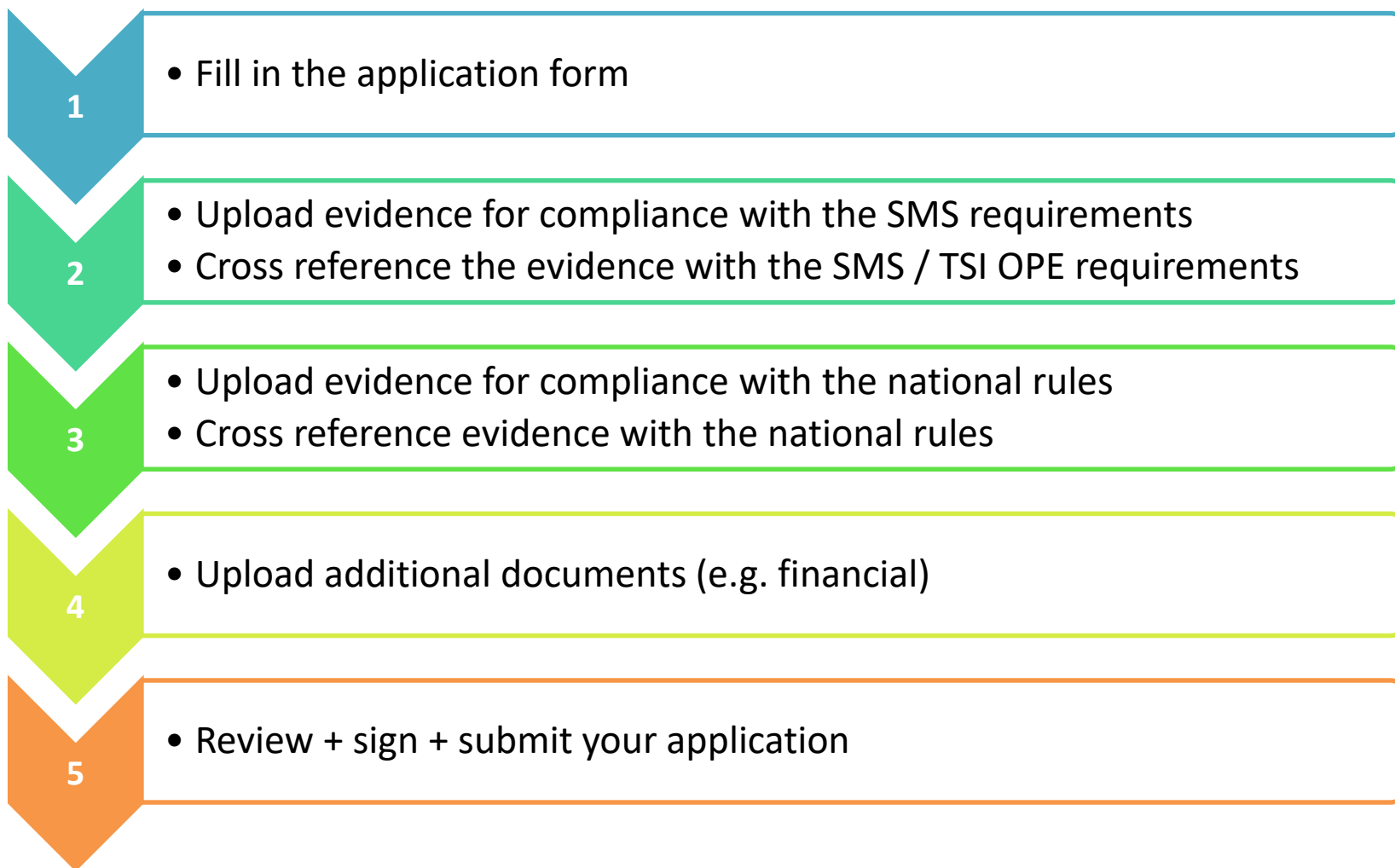
Phone: +33 (3) 100 200 300 Fax: +33 (3) 200 300 400

Email: Rail.Company@wp.pl Languages Spoken: English Polish

Notifications: [dropdown]

Save

Submit your application in seven steps:



Fill in the application form:

- type of request
- area of operation
- type of operation
- networks concerned
- border stations (if any)
- information on the applicant
- information on the contact person



This is covered by the
Annex I to Practical Arrangements

Scope of Application

Type of Application*

This application is for:

EIN of the previous certificate(s):

Linked to pre-engagement: Yes No

Pre-engagement id:

Expected date of starting service/operation:

Member States concerned with the intended area of operation*

[Add/remove MS](#)

Type of operation requested (select one or more)*
Select at least one or more services requested

Passenger transport

Freight transport

Shunting only

Other

Rail transport operations

Definition of the area of operation (for the concerned network(s))

Station(s) in neighbouring Member State(s) (in the cases provided for by art 3(10) of this Regulation and Article 10(8) of Directive (EU) 2016/798):*

[Add neighboring country](#)

Issuing authority*

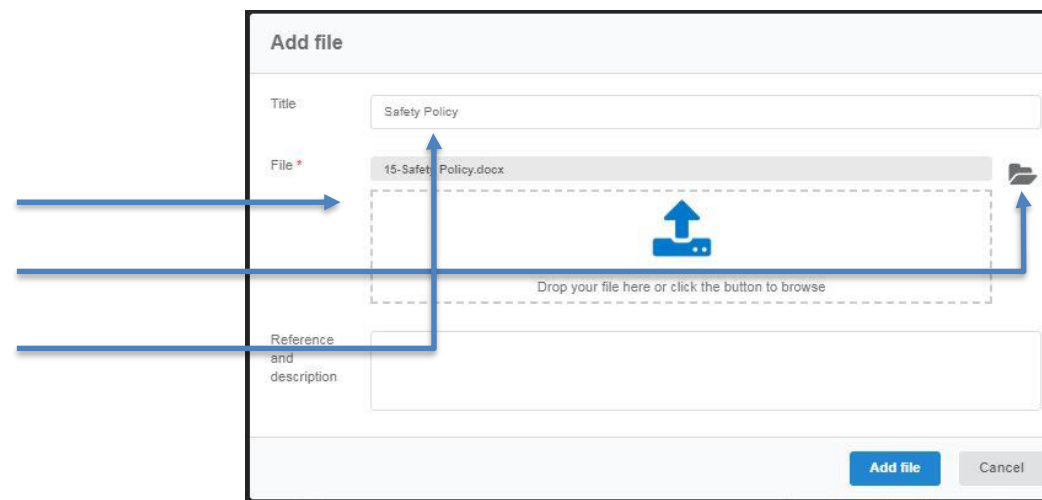
European Union Agency for Railways
 The national safety authority

Upload your evidence for the SMS part:

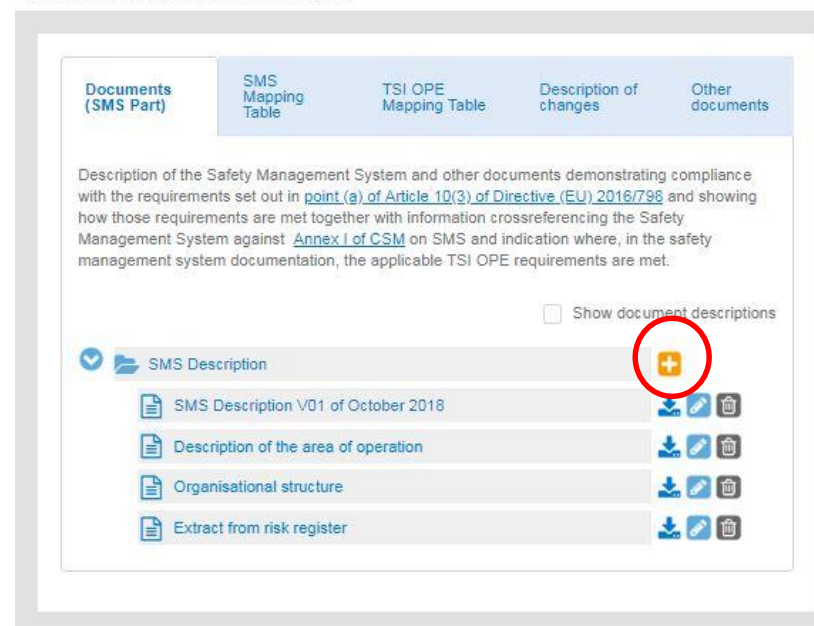
- use drag and drop function
- or upload from your folders
- provide clear titles



You decide how to structure your evidence but clear structure and not too extensive documents facilitate assessment



Documentary evidence **SMS part**



Cross reference you evidence with relevant requirements:

SMS Requirements

- SMS Requirement
- Your evidence
- Description

TSI OPE Requirements

- Under development



Documentary evidence SMS part

Reference Number	Requirement (Headline of the requirement laid down in the relevant CSM)	Documentary evidence (Title of the document (name/ version / date) or link to the uploaded document)	Reference and description (Reference inside the document and description)
1.	CONTEXT OF THE ORGANISATION		
1.1	Organisation, context and scope of the safety management system		
1.1.1	The organisation shall:		
(a)	describe the type extent and area of its operations	SMS Description V01 of October 2018	Part 1, section 1 - 3
(b)	Identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself or by contractors under its control;	SMS Description V01 of October 2018 Extract from risk register	Part 10, Section 1 and Annex 1 Table 1 and 2
(c)	Identify interested parties (e.g. regulatory bodies authorities infrastructure managers contractors suppliers partners) including those parties external to the railway system that are relevant to the safety management system;	Description of the area of operation	Section 12 and Annex 5
(d)	Identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);	SMS Description V01 of October 2018	Part 5 and 6
(e)	ensure that the requirements referred to in point (d) are taken into account in developing implementing and maintaining the safety management system;	SMS Description V01 of October 2018	Chapter 11
(f)	describe the scope of the safety management system indicating which part of the business is included or not in its scope and taking into account the requirements referred to in point (d).	SMS Description V01 of October 2018	Chapter 1 Context of organisation

Upload evidence for the national parts:

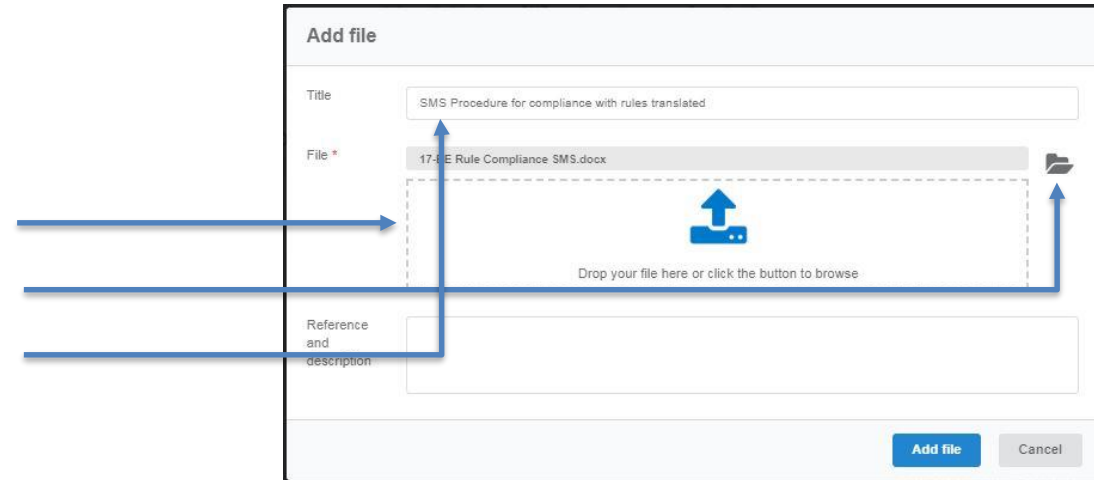
National requirements

- use drag and drop function
- or upload from your folders
- provide clear titles

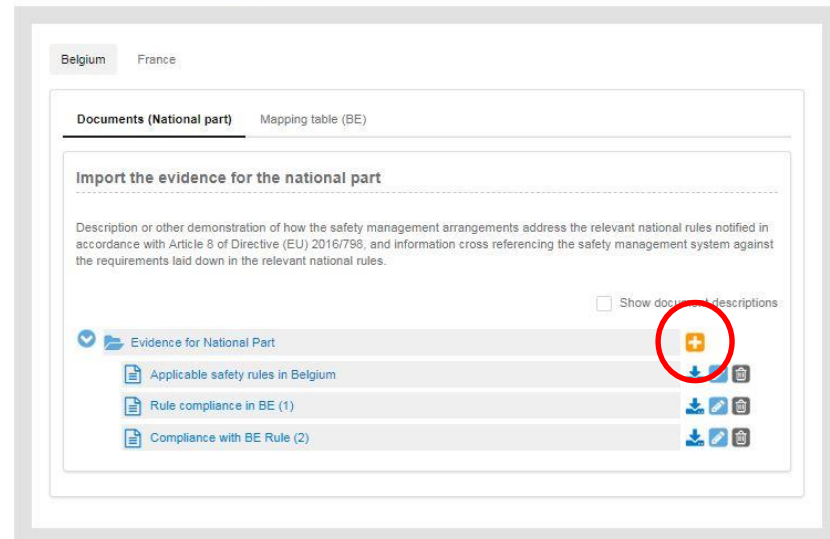


Check National Application Guides
to find out the list of applicable
rules

Upload information separately for
each of the areas of operation



Documentary evidence: National part



Cross reference your evidence with the national requirements

Option 1:

- Build your own mapping table
- Complete the table providing:
 - Requirements captured in guides
 - The evidence you have uploaded
 - Reference and description

Documentary evidence: National part

Belgium France

Documents (National part) **Mapping table (BE)**

	Reference (Reference to the applicable notified national safety rule)	Requirements (Headline of the requirement laid down in the applicable notified national safety rule)	Documentary evidence (Title of the document (name/version/date) or link to the uploaded document)	Reference and description (Reference inside the document and description)	
<input type="checkbox"/>	Rule 1	Requirement 1	Rule compliance in BE (1)	See content of Annex 1	<input type="checkbox"/>
<input type="checkbox"/>	Rule 2	Requirement 1	Compliance with BE Rule (2)	See Chapter 1	<input type="checkbox"/>
<input type="checkbox"/>	Rule 2	Requirement 2	Compliance with BE Rule (2)	See Chapter 2	<input type="checkbox"/>
<input type="checkbox"/>	Rule 2	Requirement 2	Compliance with BE Rule (2)	See Chapter 3	<input type="checkbox"/>
<input type="checkbox"/>	Rule 3	Requirement 1	SMS Procedure for compliance with rules translated	SMS Procedure translated into French	<input type="checkbox"/>

+ Add requirement

Option 2:

- Complete the table in paper
- Upload it as a file

Documentary evidence: National part

Belgium France

Documents (National part) **Mapping table (FR)**

Import Mapping Table file

Upload here the filled-in copy of your Mapping Table in document format.

Show document descriptions

Mapping Table

Mapping table for France

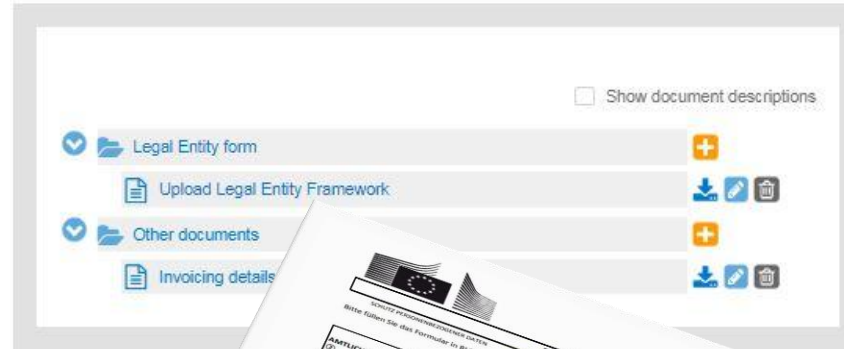
Upload additional documents:

- Legal Entity Form (LEF)
- Any other document



Do not upload here any evidence for SMS or national parts. It's only for administrative and financial documents

Other Documents (Administrative)



Other Documents (Administrative)

Show document descriptions

- Legal Entity form
- Upload Legal Entity Framework
- Other documents
- Invoicing details



RECHTSTRÄGER
ÖFFENTLICH-RECHTLICHE EINRICHTUNG

AMTLICHER NAME
AKRONYM
HAUPTREGISTERNUMMER
SEKUNDÄRE REGISTERNUMMER
DATUM DER ENTRAGUNG ODER
HAUPTNUMMER IM REGISTER
UMSATZSTEUERIDENTIFIKATIONSNUMMER
AMTLICHE ANSCHRIFT
POSTLEITZAHL
LAND
E-MAIL
DATUM
UNTERSCHRIFT DES BEVOLLMÄCHTIGTEN
STAMPSEL

DIESES FORMULAR IST AUSGEFÜLLT, UNTERZEICHNET UND ZUSAMMEN MIT EINER KOPIE DER AMTLICHEN DOKUMENTE
(ENTWICKLUNG, GESETZ, HANDELSREGISTER, AMTSLAUF, MEHRWERTSTEUERREGISTRIERUNG USW.) ALS BELEG FÜR IHRE ANGABEN
VORZULEGEN

① Öffentlich-rechtliche Einrichtung mit Rechtspersönlichkeit, d. h. eine öffentliche Einrichtung, die sich selbst
vertritt und auf eigenen Namen handeln kann, die also klagen oder verklagt werden kann, Eigentum erwerben und
zur Gründung der Einrichtung (ein Gesetz, ein Dekret usw.)
② Nationale Bezeichnung und ihre Übersetzung ins Englische oder Französische, falls vorhanden.
③ Nummer der Eintragung im nationalen Handelsregister.

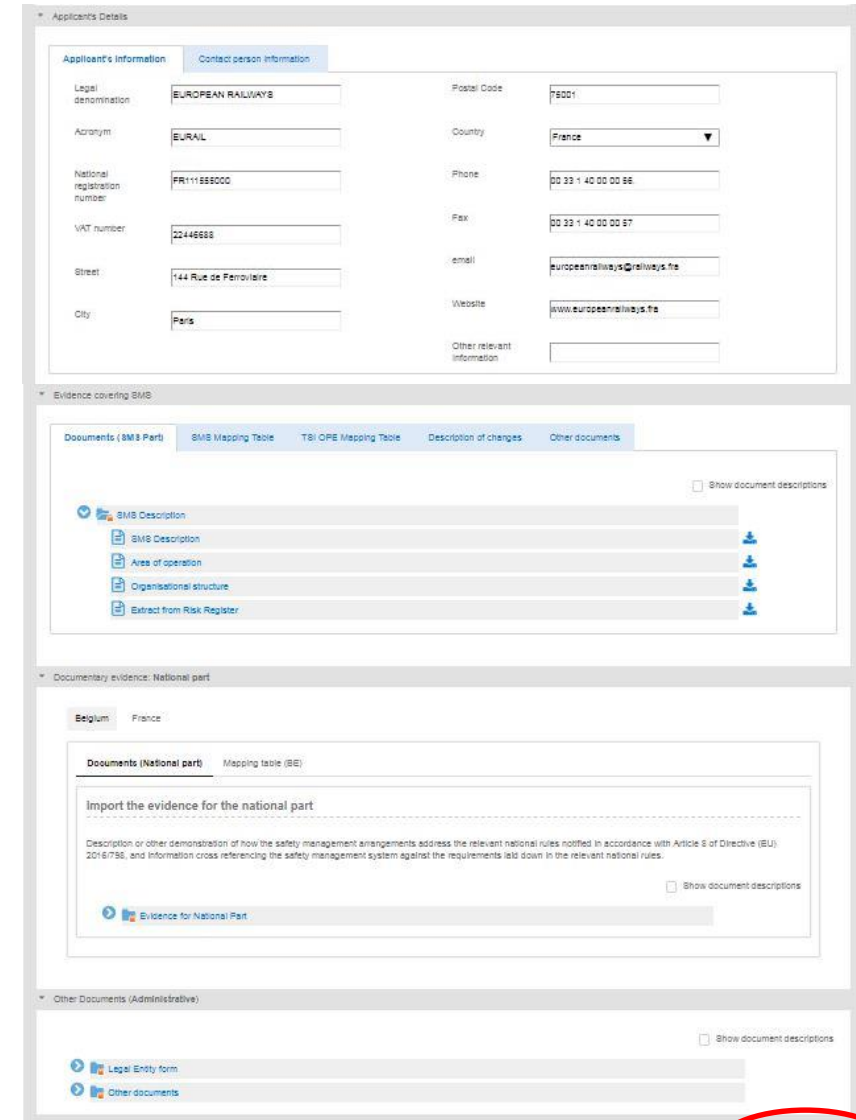
Review + sign + submit:

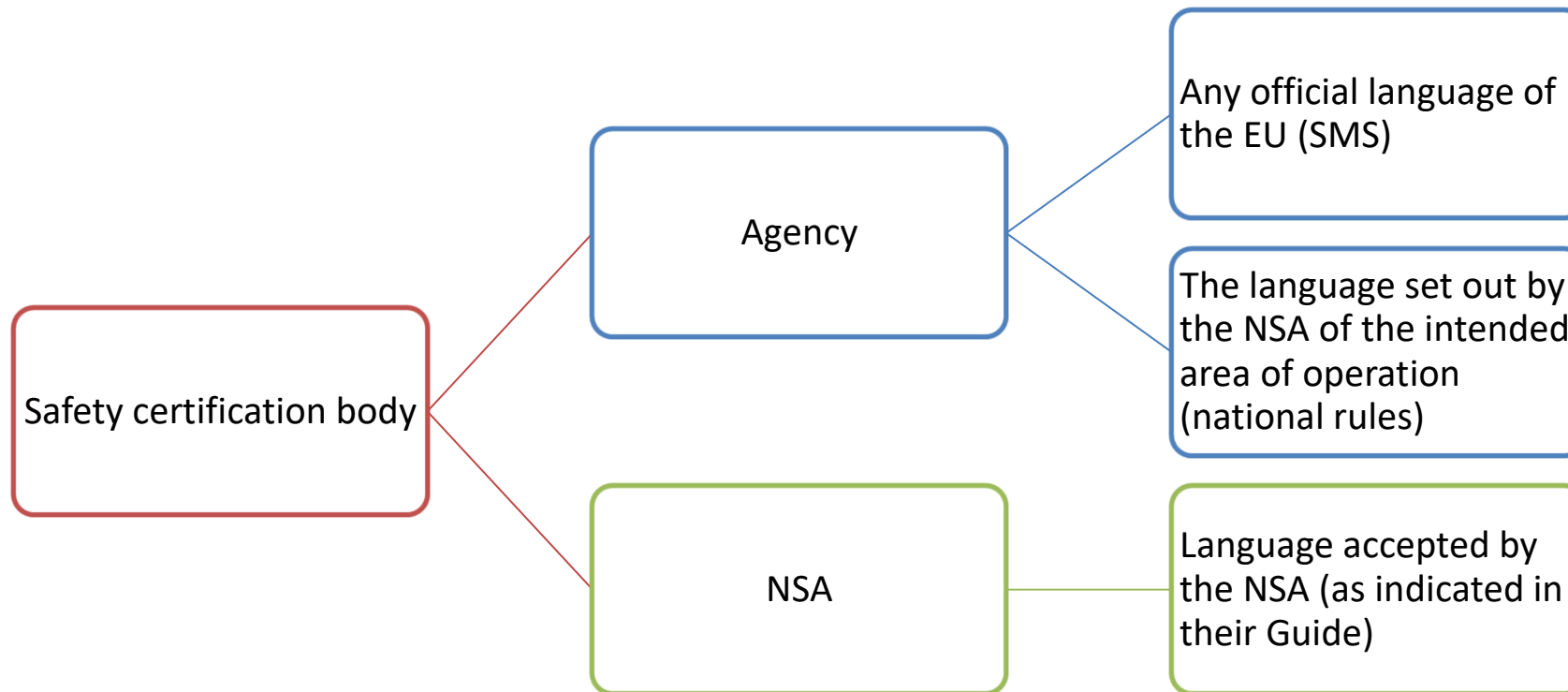
- Check quality of data
- Check completeness of file
- Check uploaded documents
- and
- Submit your application



You will be automatically notified about receipt of your application and about the starting date of the assessment

Submitted file will be frozen and you will be able to update it only in reply to issue logged in by the assessors





The safety assessment process

**The safety assessment
process**



Pre-engagement stage (optional)

Advantages
Facilitating early contact
Developing the relationship between assessors and applicant
Gaining familiarity with applicant's SMS level of maturity
Mitigating the embryonal risks of delays in issuing the SSC
One-stop shop used to submit the request, info can be re-used for later submission
Not mandatory, but highly recommended



Disadvantages
Long-time perspective
Extra and constant commitment by the applicant
Subject to charges



The applicant chooses a safety certification body when requesting pre-engagement but this can be changed at later stage

Aim:

- To check that the documents submitted by the applicant (i.e. the evidence) are sufficient, relevant and consistent
- If not, the safety certification body (and the NSA(s) concerned with the area of operation) may request for additional information
- The timeframe for the provision of missing information is agreed with the applicant
- The request is managed through the issue log of the one-stop shop

Aim:

- To check that the evidence complies with the legal requirements (both EU and national)
- If not, the authority or authorities concerned with the area of operation may request for additional information
- The timeframe for the provision of missing information is agreed with the applicant
- The request is managed through the issue log of the one-stop shop
- An assessment report is issued by the authority or authorities concerned; If the Agency is the safety certification body, it aggregates the different reports to produce a final assessment report available in the language of the applicant

Aim:

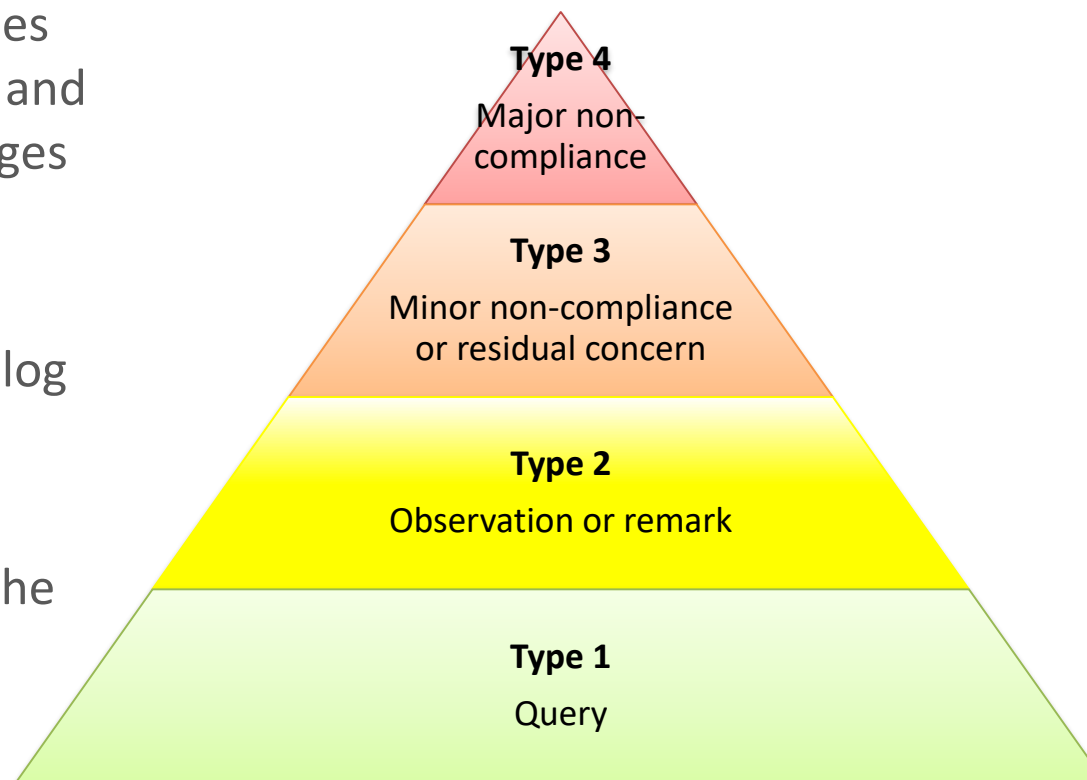
- To notify the applicant of the safety certification body's decision
- Negative decision means:
 - Rejection of the application
 - Inclusion of restrictions/conditions of use
- Negative decision can be subject to review, appeal and actions before the Court of Justice (EU/national)

- The exchange of information between the applicant, the Agency and the NSA(s) concerned with the area of operation is managed through the one-stop stop or via other communication channels (phone, videoconferencing, email etc.)



- A project manager is responsible for the coordination of the assessment. S/he is the point of contact for the applicant and the NSA(s) concerned

- Assessors may raise issues during the initial screen and detailed assessment stages
- Issues are recorded and categorised in the issue log of the one-stop shop
- The applicant provides the requested information through the issue log



- The authorities involved in the safety assessment may conduct audits, inspections or visits on the site of the applicant

Aim:

- To collect additional evidence and to ascertain the applicant's awareness on some areas of concern



- These activities do neither replace nor duplicate the supervision carried out by the NSA

Update and renewal of a single safety certificate

Update and renewal of a single safety certificate

1. **Update** in case of:

- substantial change to the type or extent of the operation, or
- extension of the area of operation, or
- substantial change to the legal framework if the Agency or the NSA so requires



The railway undertaking is responsible for engaging with the safety certification body when it plans a change to the conditions under which the single safety certificate was issued. Changes can be of technical, operational or organisational nature.

- Changing the type of operation means adding or removing:
 - Passenger transport (including high speed services)
 - Freight transport (including dangerous good services)
 - Shunting services

- Changing the extent of operation means increasing or decreasing:
 - The number of passengers and/or volume of goods
 - The estimated size (micro, small, medium sized, large) of the company in terms of employees

2. Renewal at the expiry of the certificate

Restricting or revoking a single safety certificate

- A SSC may be restricted or revoked by the safety certification body that has issued it
- Such a restriction or revocation happens when the safety certification body is notified by a NSA that, following its supervision activities, the holder of the certificate no longer satisfies the conditions under which it has been certified
- If the NSA identifies a serious safety risk it may decide to take proportionate enforcement action, including where necessary suspending the rail operations

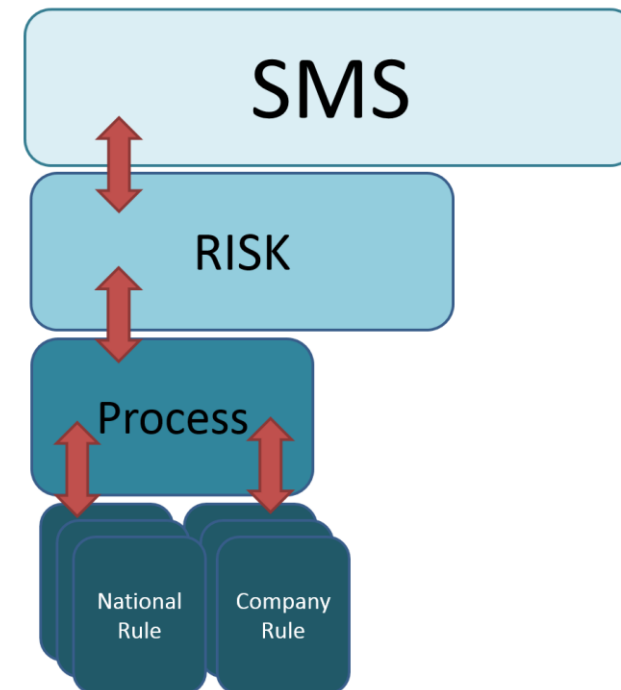


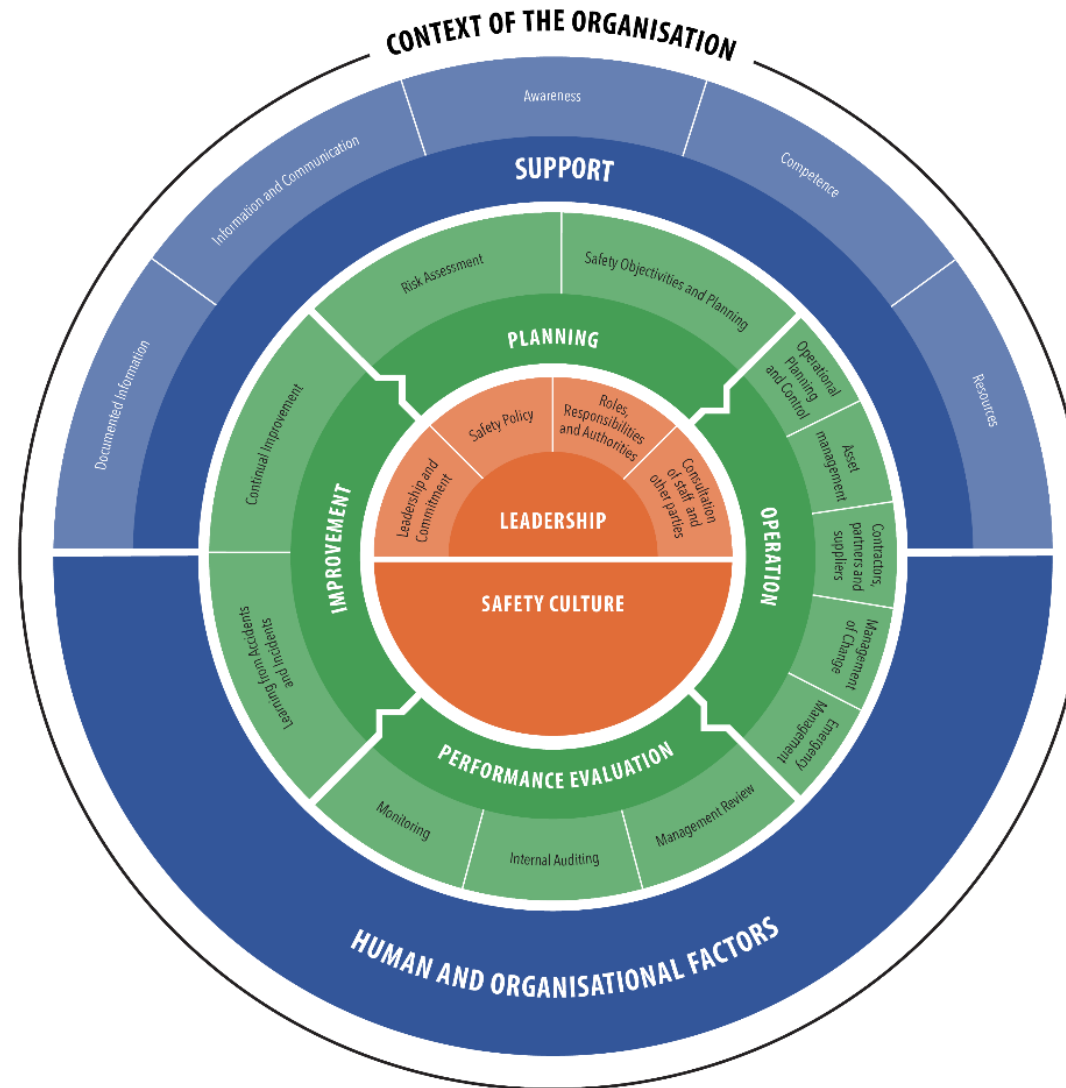
Safety management systems

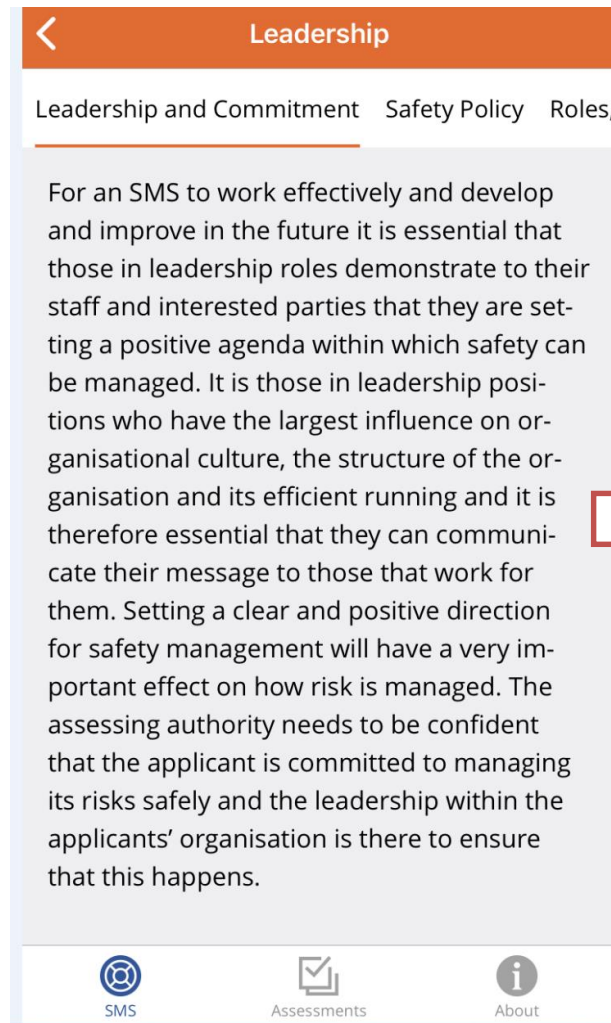
Safety management systems

What is a safety management system (SMS)?

- The **safety management system (SMS)** is a living system of linked processes and procedures, which control **risk** to ensure the safe management of rail operations
- **Risk** means the frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm (*Regulation (EU) 402/2013, Art. 3(1)*)



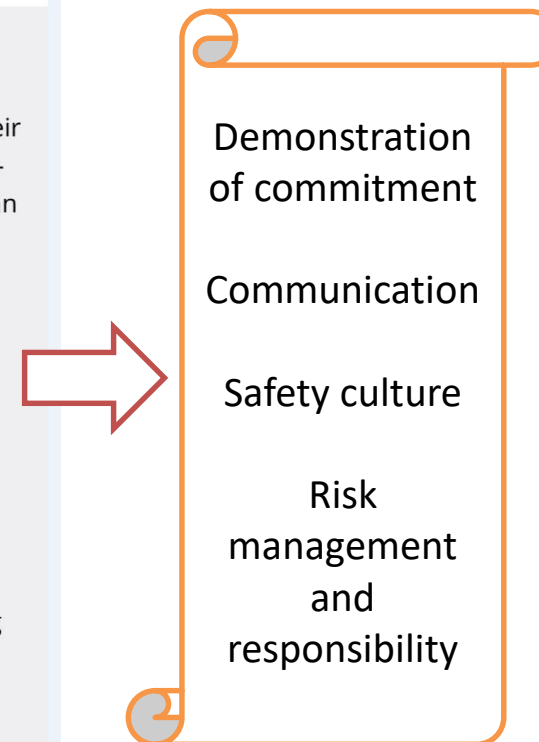


Leadership

Leadership and Commitment Safety Policy Roles,

For an SMS to work effectively and develop and improve in the future it is essential that those in leadership roles demonstrate to their staff and interested parties that they are setting a positive agenda within which safety can be managed. It is those in leadership positions who have the largest influence on organisational culture, the structure of the organisation and its efficient running and it is therefore essential that they can communicate their message to those that work for them. Setting a clear and positive direction for safety management will have a very important effect on how risk is managed. The assessing authority needs to be confident that the applicant is committed to managing its risks safely and the leadership within the applicants' organisation is there to ensure that this happens.





SMS application – Human and organisational factors (HOF)



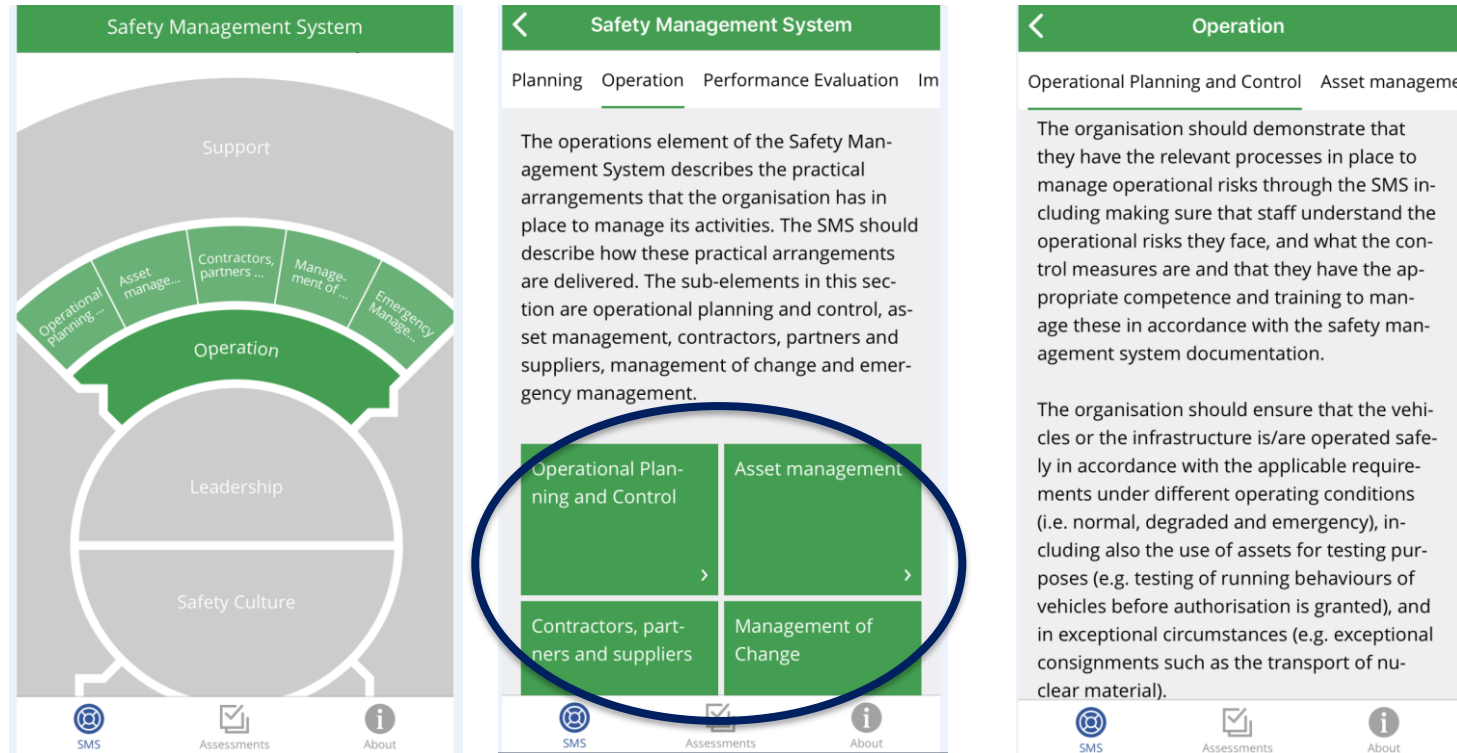
Safety Management System

Support Human and Organisational Factors

Human and organisational factors means those characteristics of human and organisational behaviour which influence safe decision making. Organisations need to use a systematic approach to human and organisational factors in targeting risk is an integral part of the SMS. This means analysing as part of the risk assessment the role of the human and the the organisation so as to make sure that the risk control measures used are the most appropriate. Satisfying this element is important for demonstrating that the risk control systems are embedded in the SMS and the organisation is managing the risks it faces.

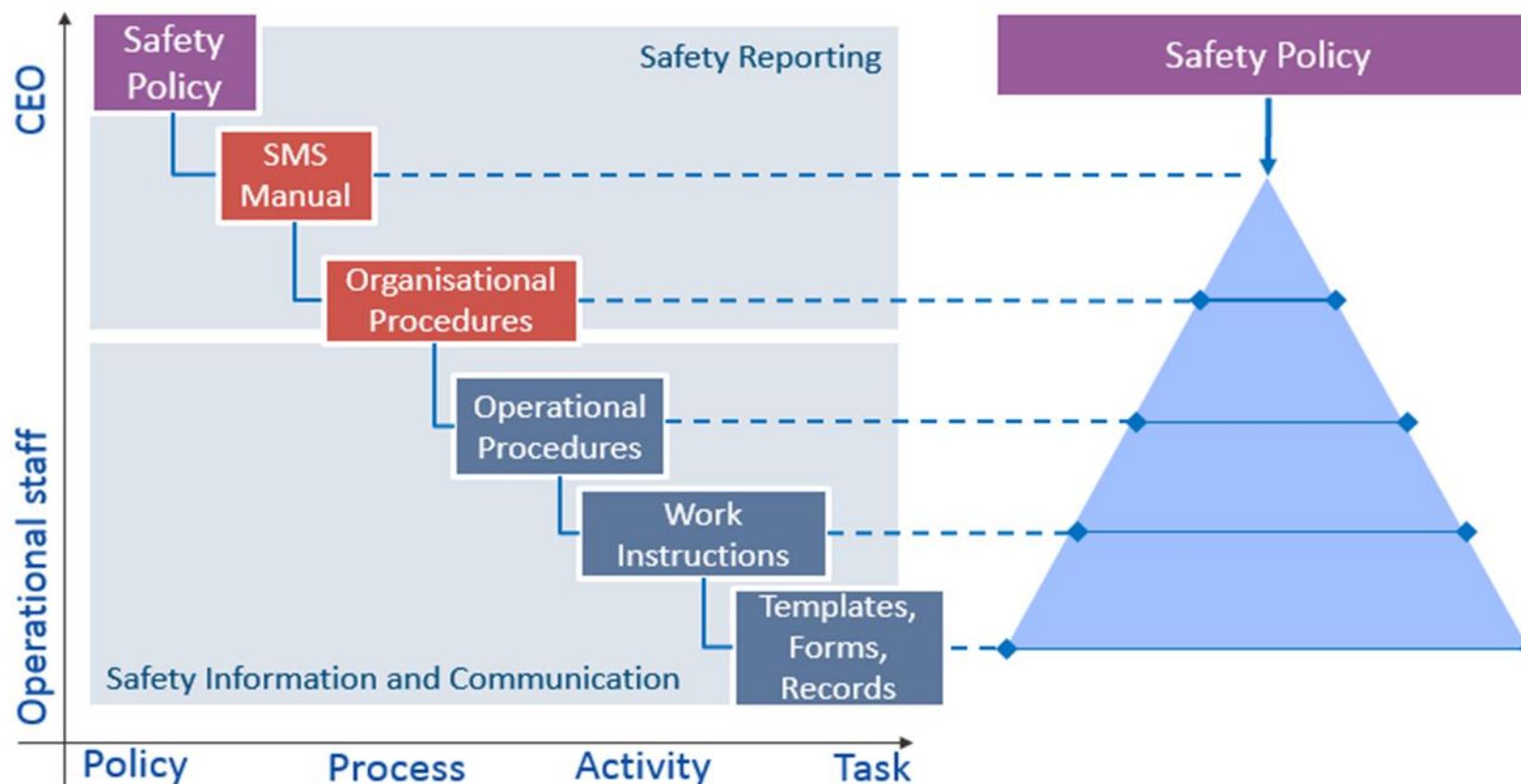
Those HOF factors which influence safe decision making

Ensuring HOF is included in the risk analysis



Arrangements to manage activities
Processes to manage risks
Staff understand and apply
Vehicles are operated safely under different operating conditions

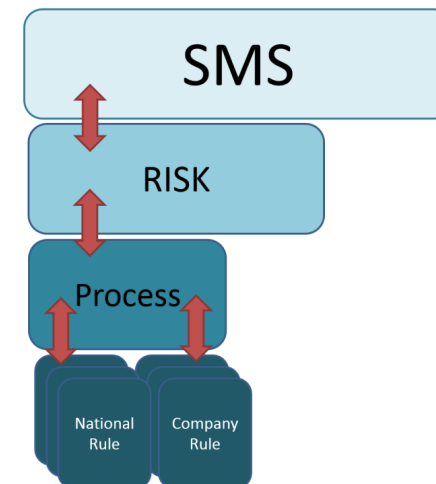
- SMS is a process document, which needs to link to more detailed operational procedures/company operational rules/work instructions

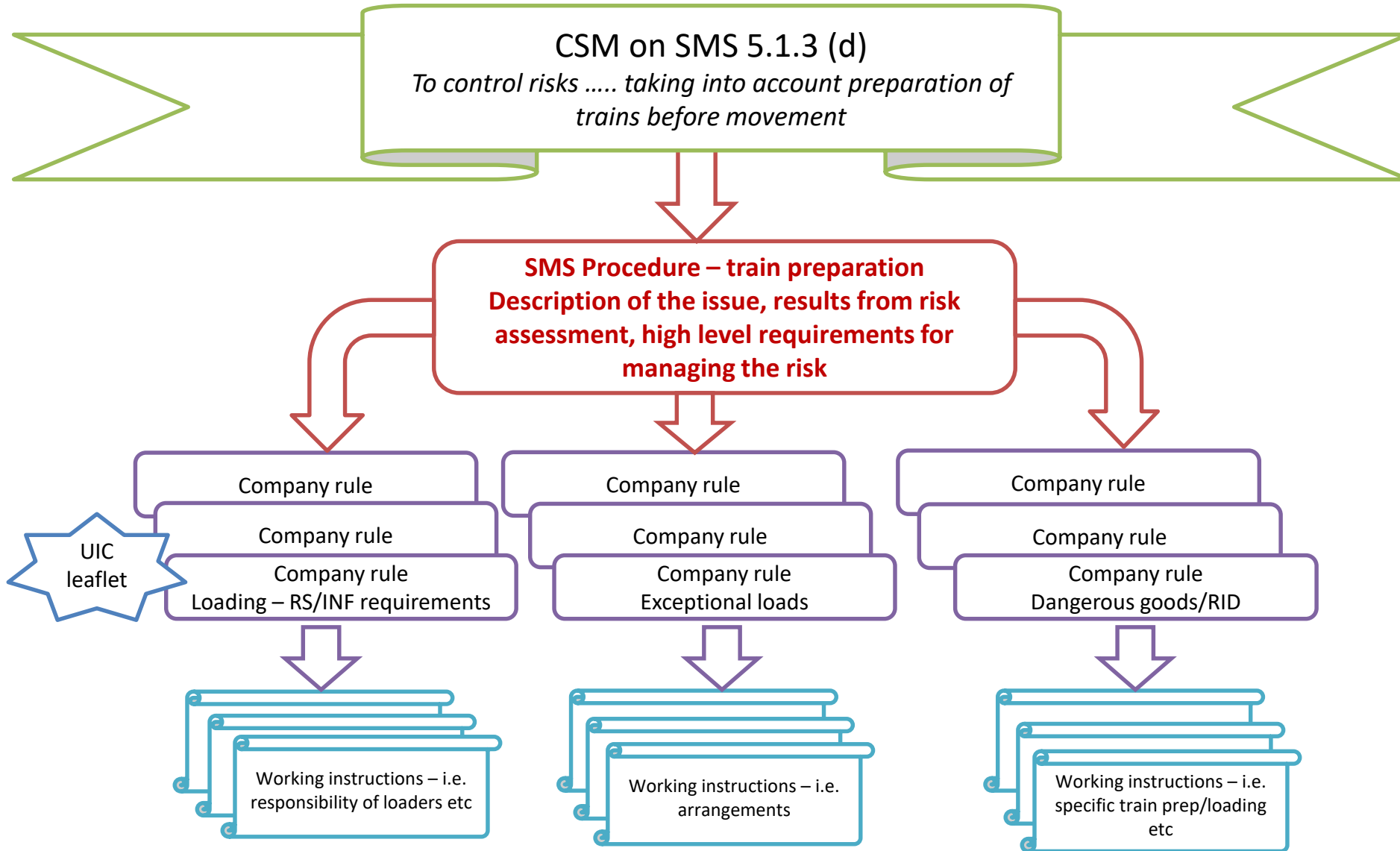


Framework for operations:

- The operational requirements of the railway are the starting point for deciding the suitability of operational procedures
- It should include a description of how standards, performance data, management system, risk assessment are integrated
- National Rules can be used providing they control the risks, are relevant, up to date and can be applied
- For planning reviewing or developing any new or updated operations the information from the risk assessment should be used to ascertain whether the existing or new operation is safe and the risks can be controlled by either procedures or rules
- Normal, degraded and emergency operations should be considered during risk assessment, leading to adequate control measures (i.e. rules or working instructions) for preventing unsafe operations
- The need for and effectiveness of the operational requirements should be regularly monitored and reviewed as part of the CSM Monitoring requirements

- The operational requirements are linked to a number of SMS processes and it is important that these are risk based and clearly identifiable
- For example:
 - Tasks to be performed by safety critical staff (e.g. train driving, accompanying train, preparing train, testing train, shunting, authorising train movements)
 - Train Preparation
 - Loading/RID
 - Train composition,
 - Tests and checks before departure,
 - Maintenance, diagnostic and repairs,
 - ...





The FAQ webpage in the Agency website provides further explanations about the issuing of single safety certificates





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