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

Rudolph SPANHOFF, Stijn MICHIELS

Budapest, 5 June 2019

EUROPEAN UNION AGENCY FOR RAILWAYS

Outline

- 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

EUROPEAN UNION AGENCY FOR RAILWAYS

Introduction

What is new?

The Technical Pillar of the 4th Railway Package

Official Journal of the European Union

L 138

Volume 59

26 May 2016

English edition

Legislation

Contents

I Legislative acts

REGULATIONS

1 ★ Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (1) 1

DIRECTIVES

2 ★ Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (1) 44

3 ★ Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (1) 102

Entry into Force:
15 June 2016

EUROPEAN UNION AGENCY FOR RAILWAYS

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

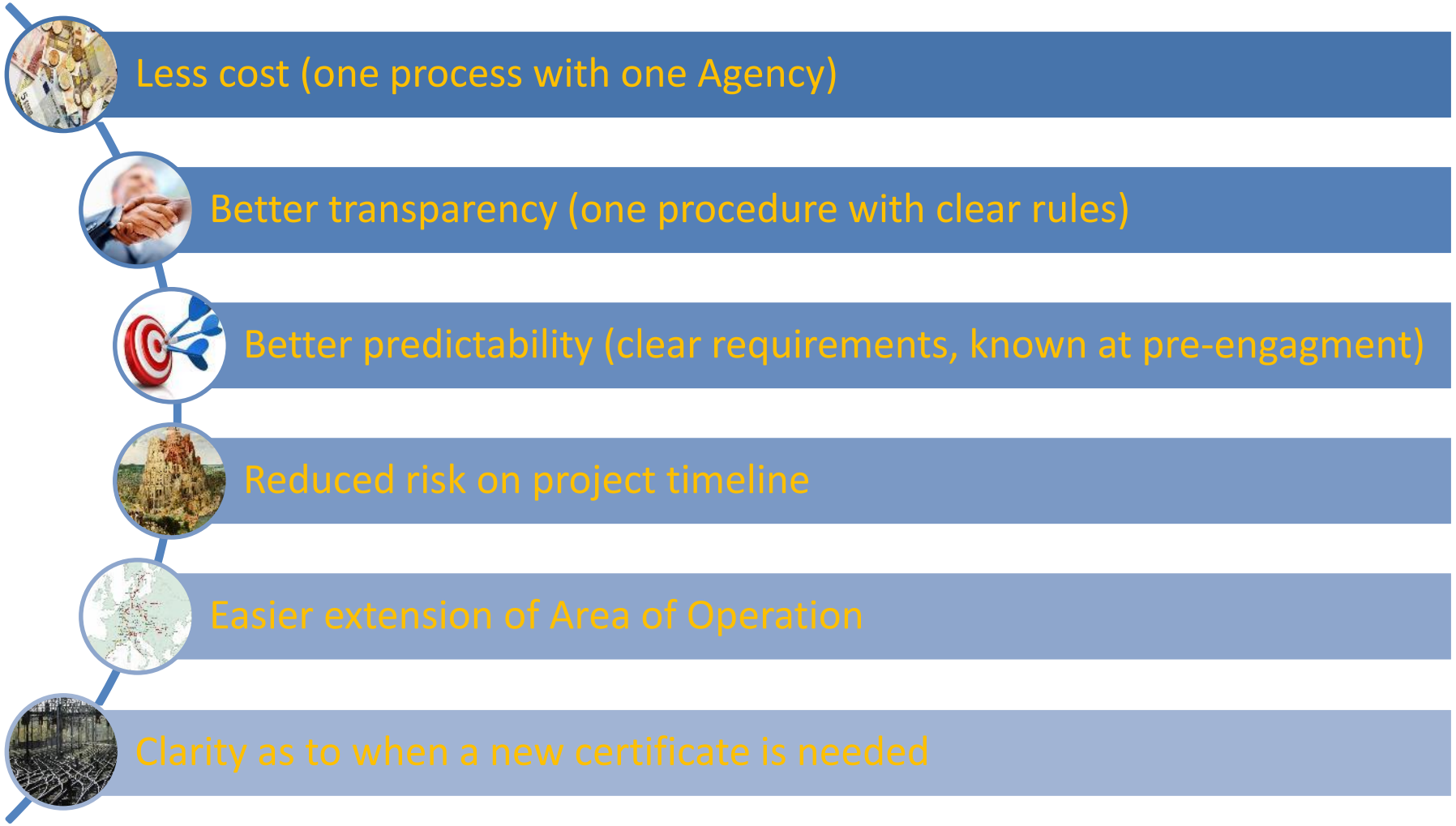
The Agency will be in a position to issue an **approval required for the NSA authorisation of ERTMS trackside projects** (a binding opinion on ERTMS trackside specifications)

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

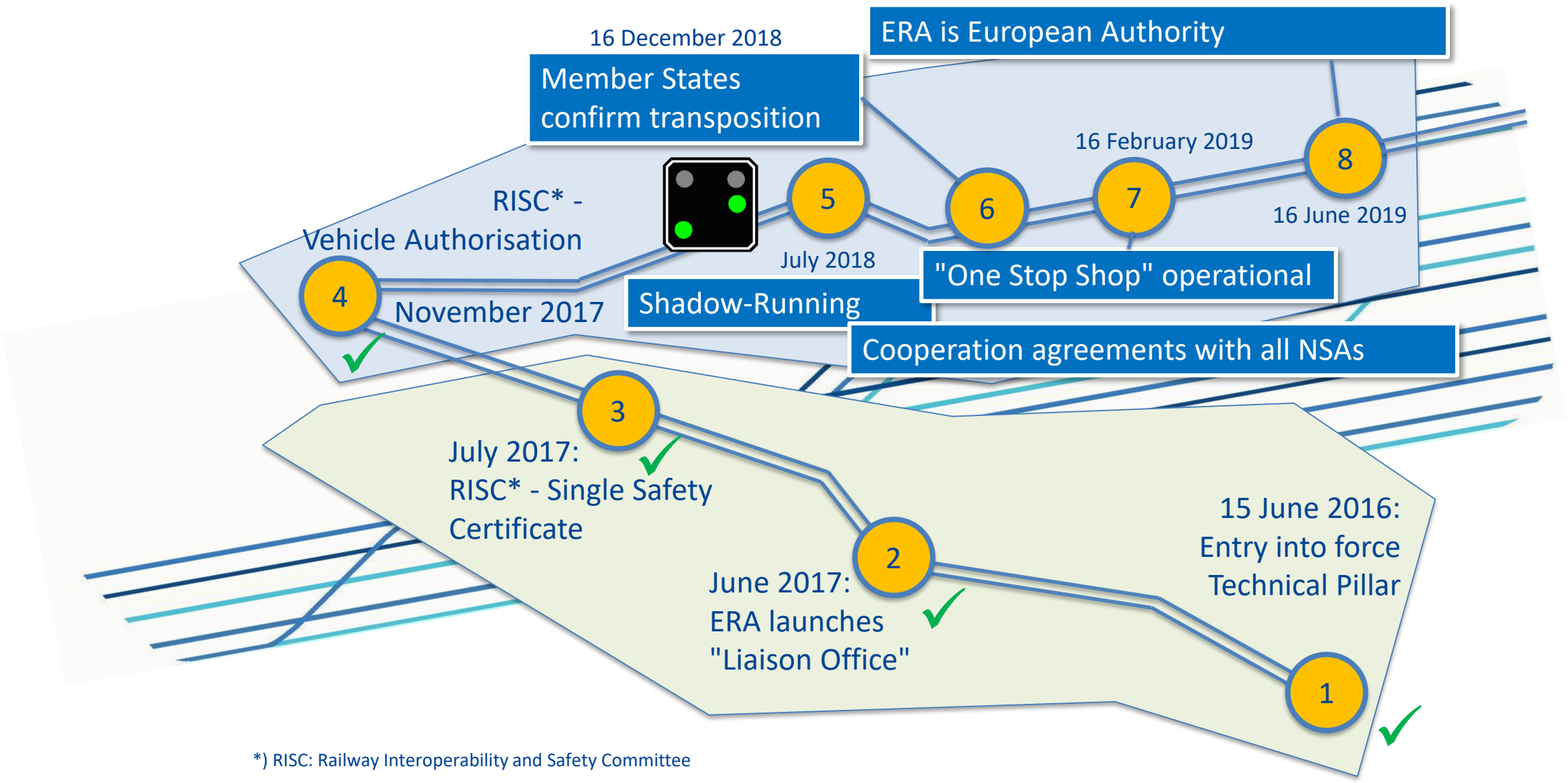
*) member states could opt for four years

Expected Benefits of the Single Safety Certificate process



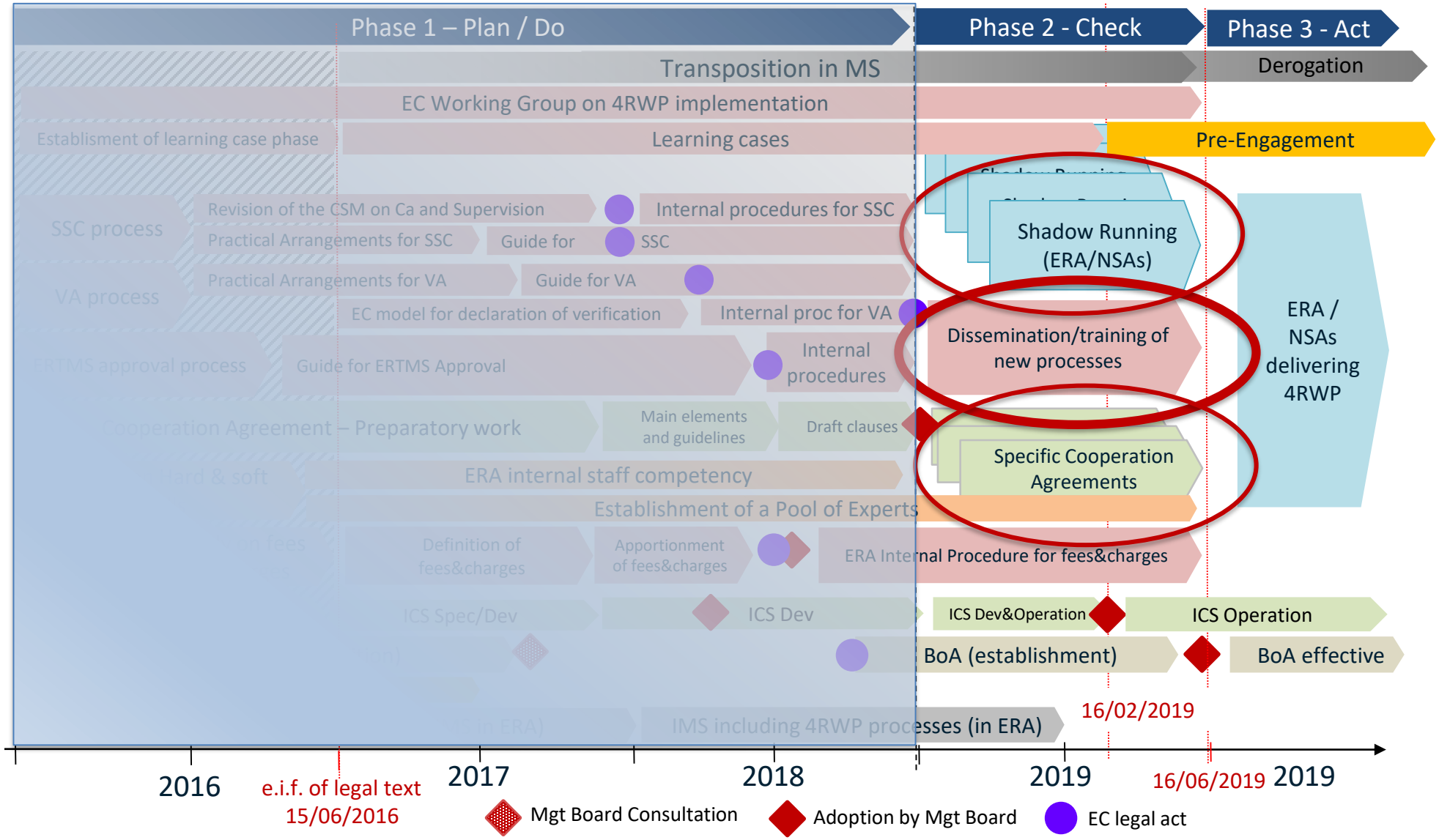
EUROPEAN UNION AGENCY FOR RAILWAYS

On Track



*) RISC: Railway Interoperability and Safety Committee

ERA Preparation Programme



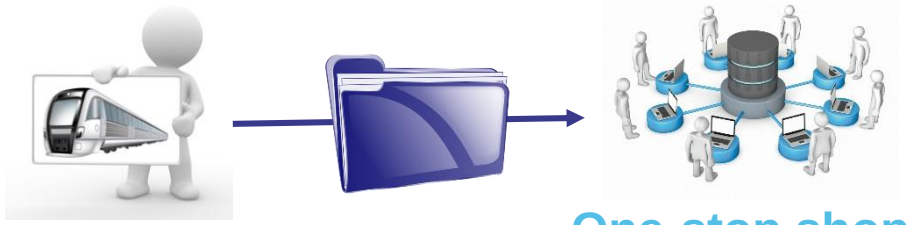
EUROPEAN UNION AGENCY FOR RAILWAYS

What is new?

What is new?

ERA as new authority

June 2019



Area of operation in more than one Member State or in one Member State if the applicant so requests

OR

NSA

Single safety certificate

Area of operation limited to one Member State if the applicant so requests

Main changes

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	
Applications managed in accordance with national arrangements	All applications managed through the one-stop shop IT tool in accordance with arrangements set out in EU law
Assessment process defined by each NSA in accordance with its own rules	Harmonised assessment process set out in EU law
Assessment based on EU criteria (to be applied by NSAs) and national 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
No obligation from authorities to pre-engage with the applicant	Authorities must pre-engage on request of the applicant

EUROPEAN UNION AGENCY FOR RAILWAYS

EU legal framework

EU legal framework

Applicable legislation

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

eur-lex.europa.eu

Auxiliary legislation

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)

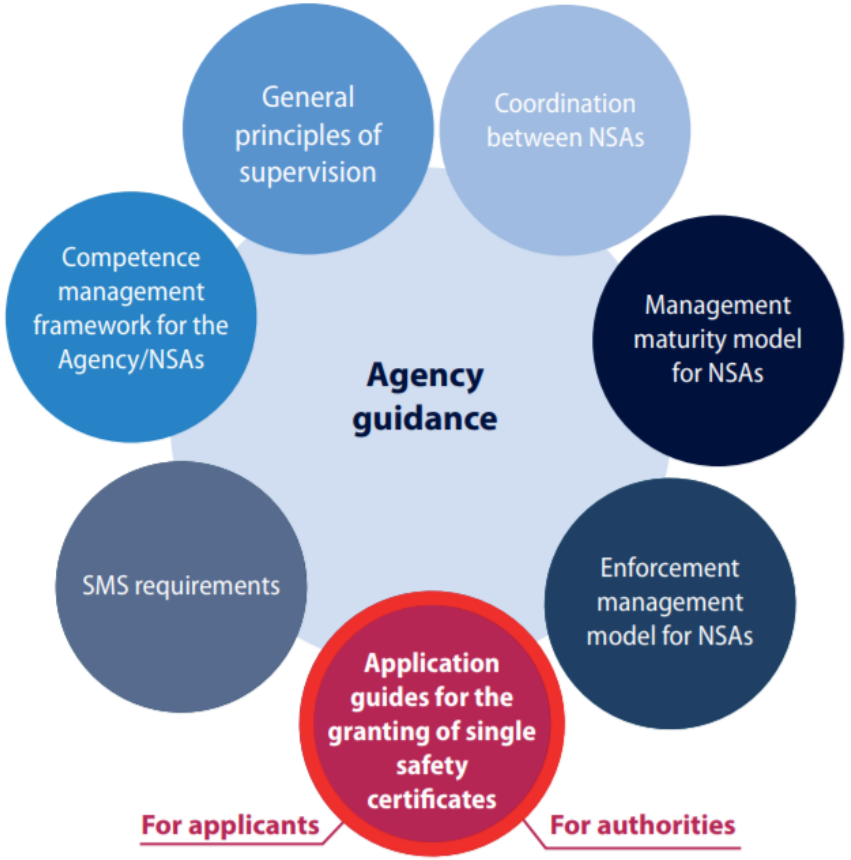
Regulation concerning the International Carriage of Dangerous Goods by Rail (RID)

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

eur-lex.europa.eu

Compendium of Agency guidance

- 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

era.europa.eu

EUROPEAN UNION AGENCY FOR RAILWAYS

Transition period

Transition period?

Transitional 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

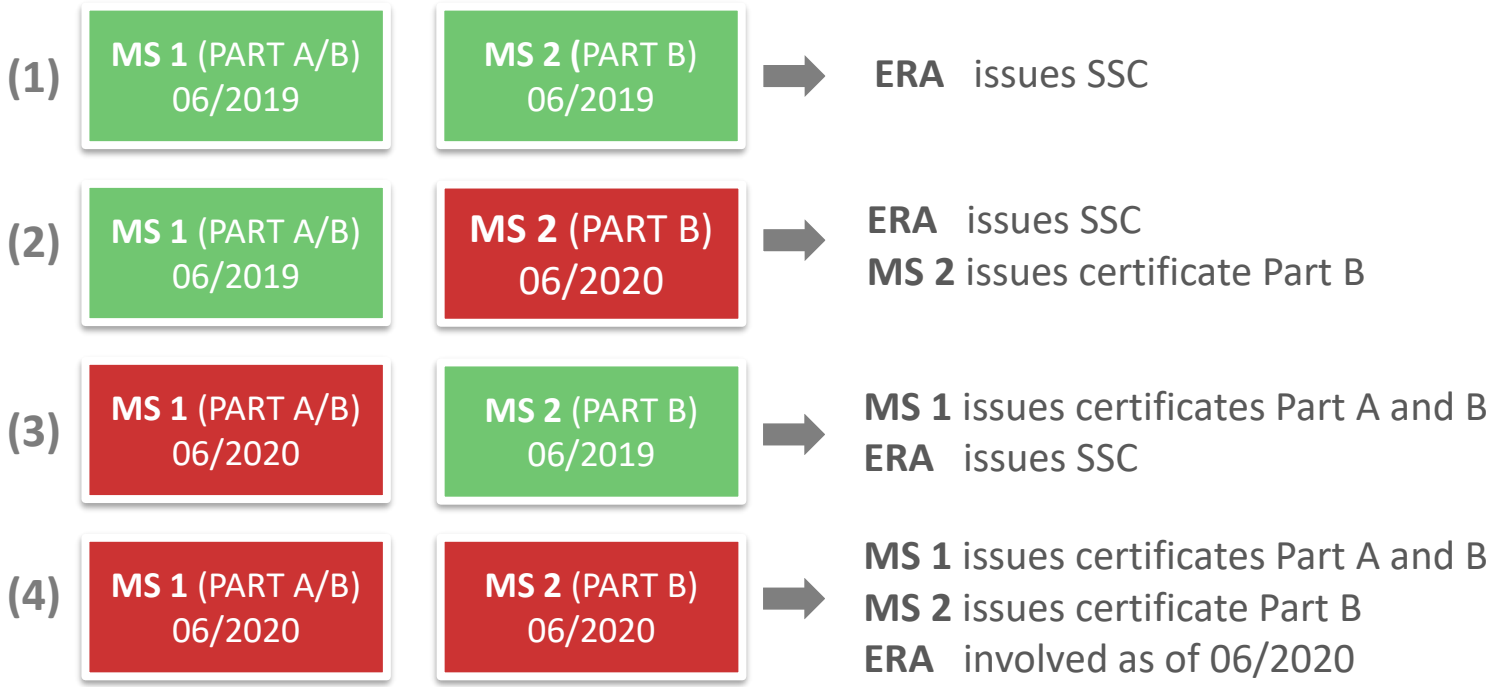
Transitional period

16/06/2019

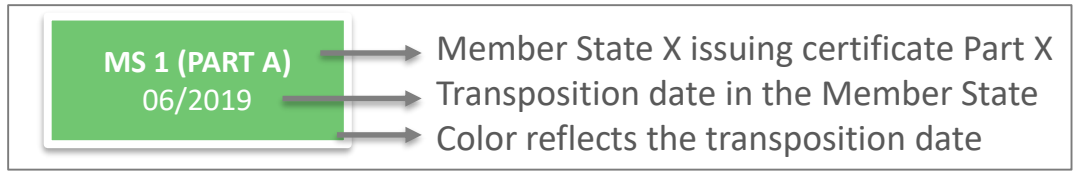
16/06/2020

- Safety Directive allowed Member States to chose 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

Transitional period



EXPLANATION:



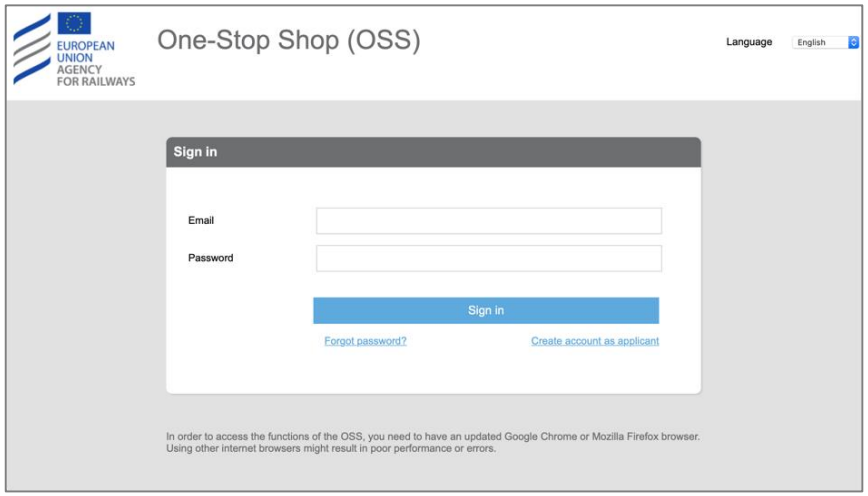
EUROPEAN UNION AGENCY FOR RAILWAYS

How to apply?

How to apply?

Submission of the application

- 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



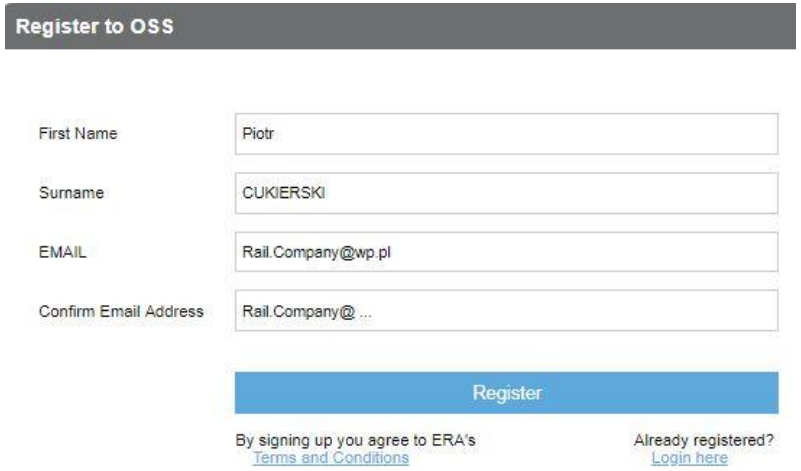
- It is recommended that an application for a single safety certificate is submitted in advance to any possible deadline (at least 6 months)

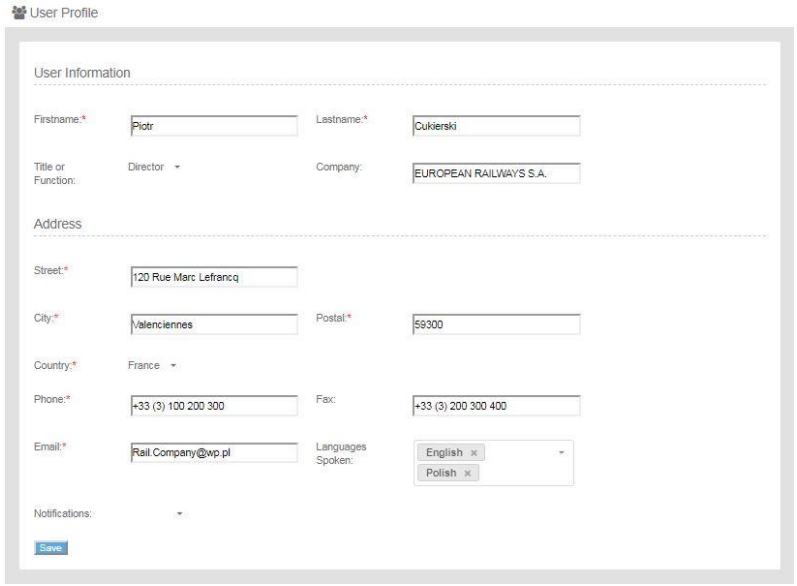
Application Process in the OSS

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





Application Process in the OSS

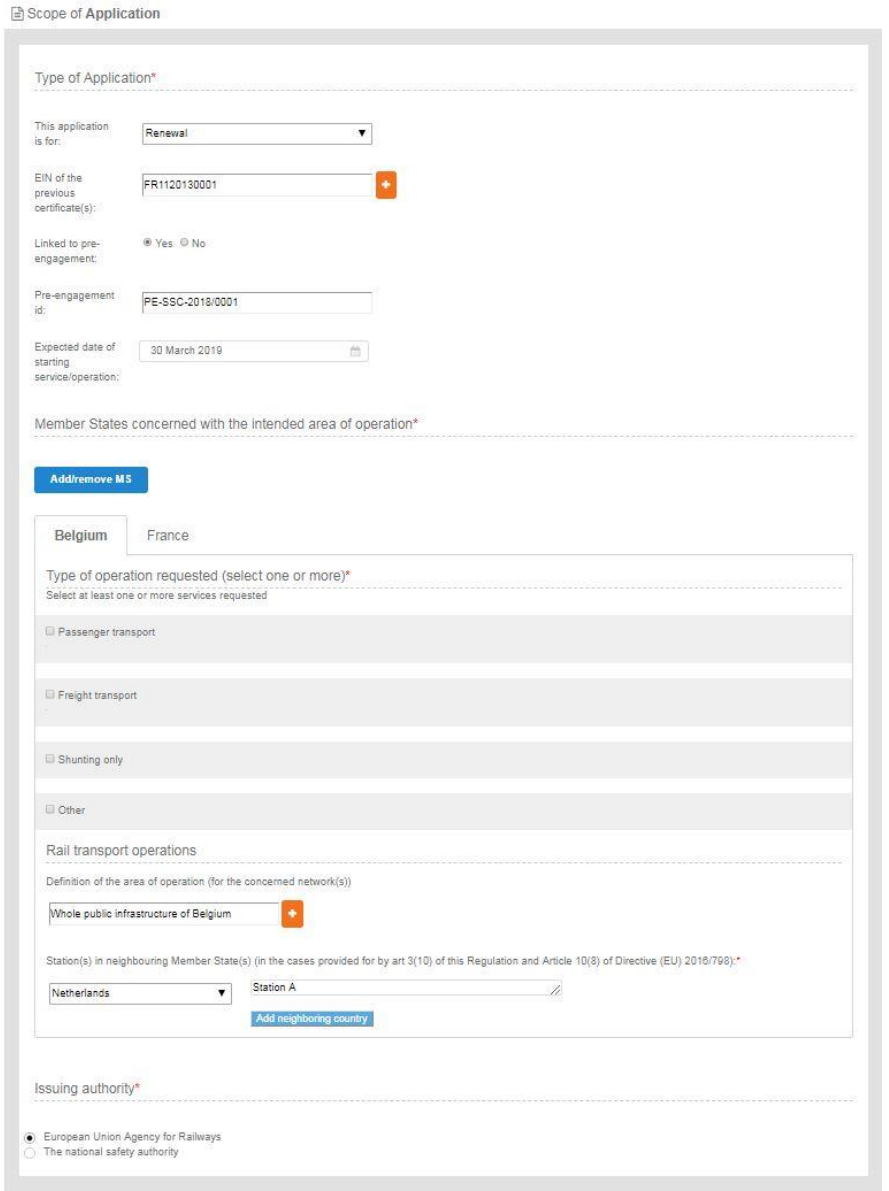
Submit your application in seven steps:

1. Fill in the application form
2. Upload evidence for compliance with the SMS requirements
   - Cross reference the evidence with the SMS / TSI OPE requirements
3. Upload evidence for compliance with the national rules
   - Cross reference evidence with the national rules
4. Upload additional documents (e.g. financial)
5. Review + sign + submit your application

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

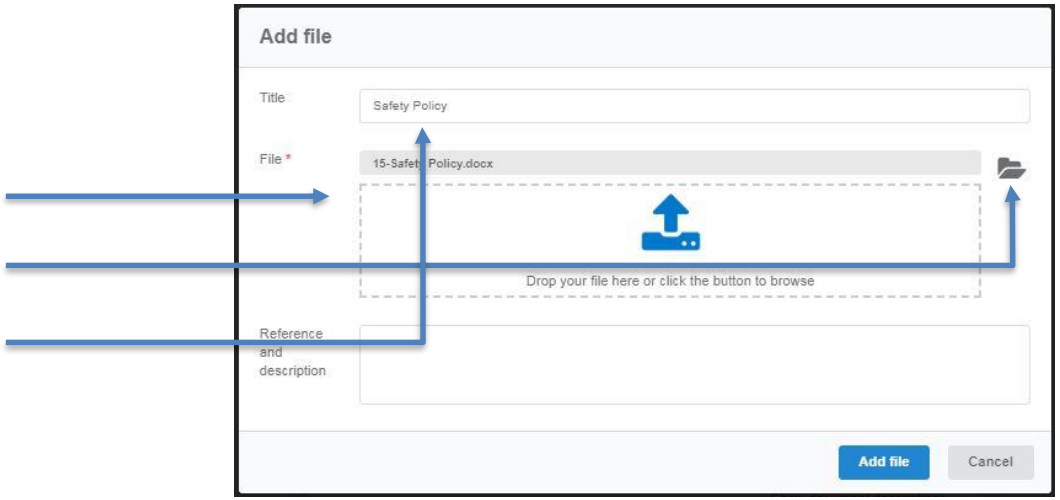
This is covered by the Annex I to Practical Arrangements

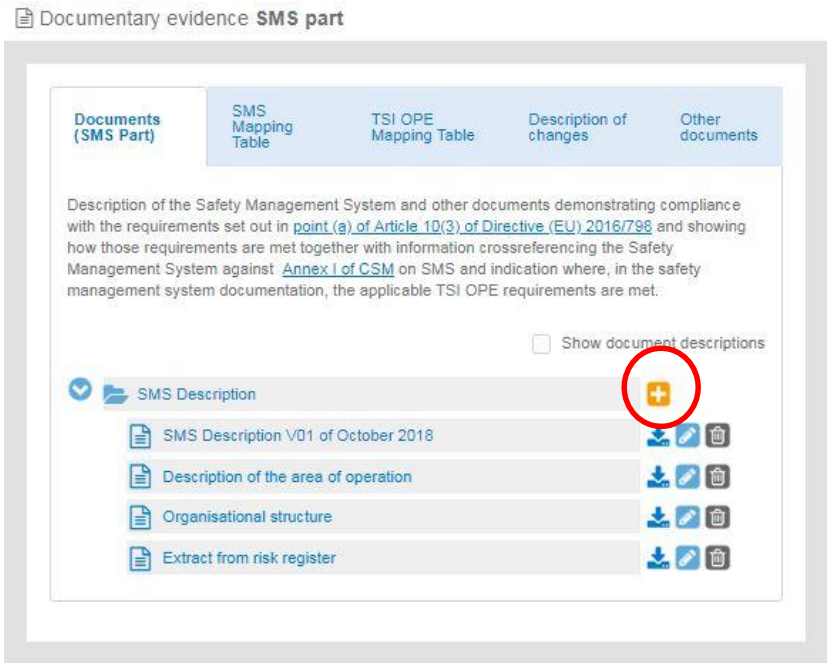


Upload your evidence for the SMS part:

- 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





Application Process in the OSS: step 2/2

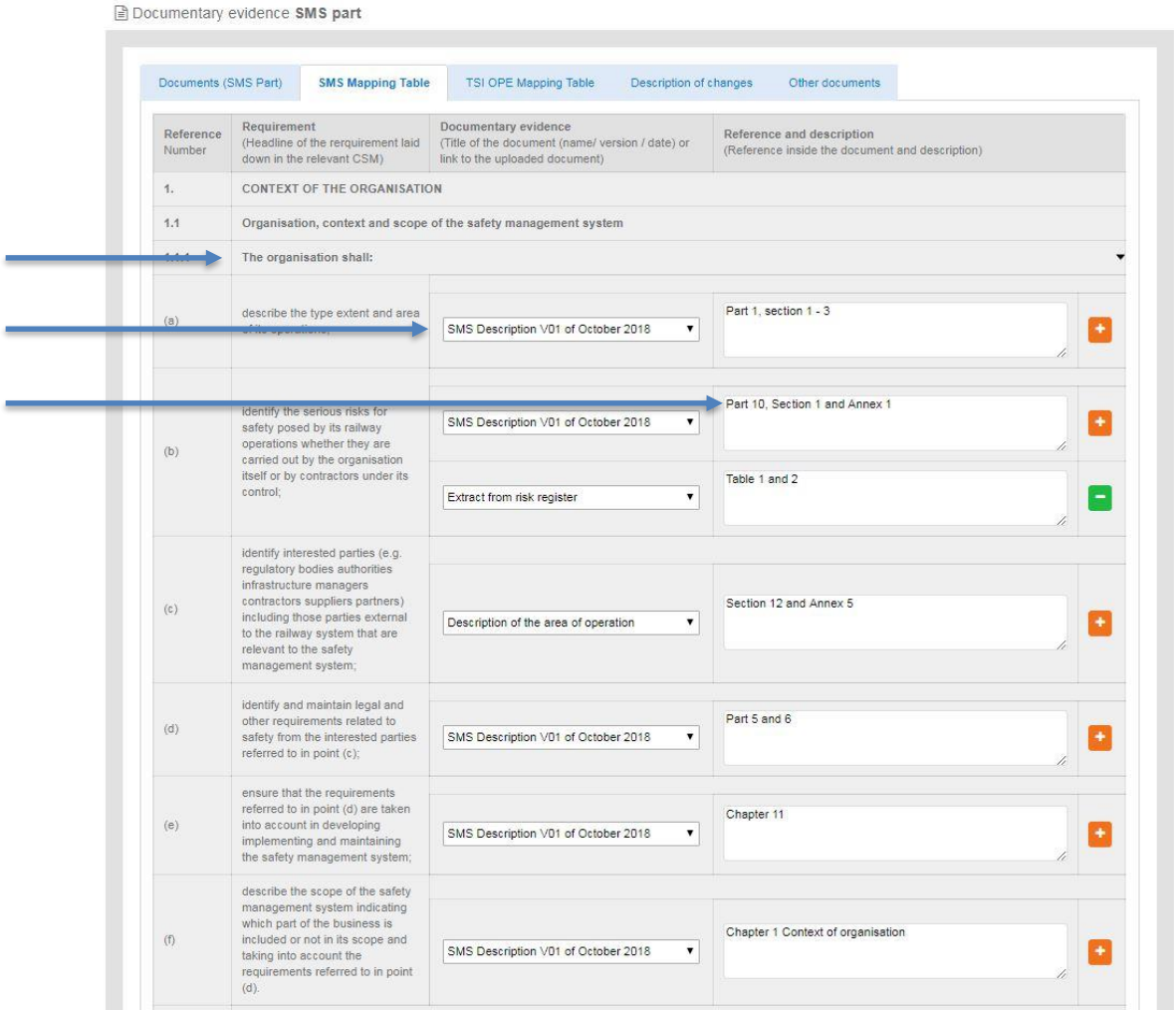
Cross reference you evidence with relevant requirements:

SMS Requirements

- SMS Requirement
- Your evidence
- Description

TSI OPE Requirements

- Under development

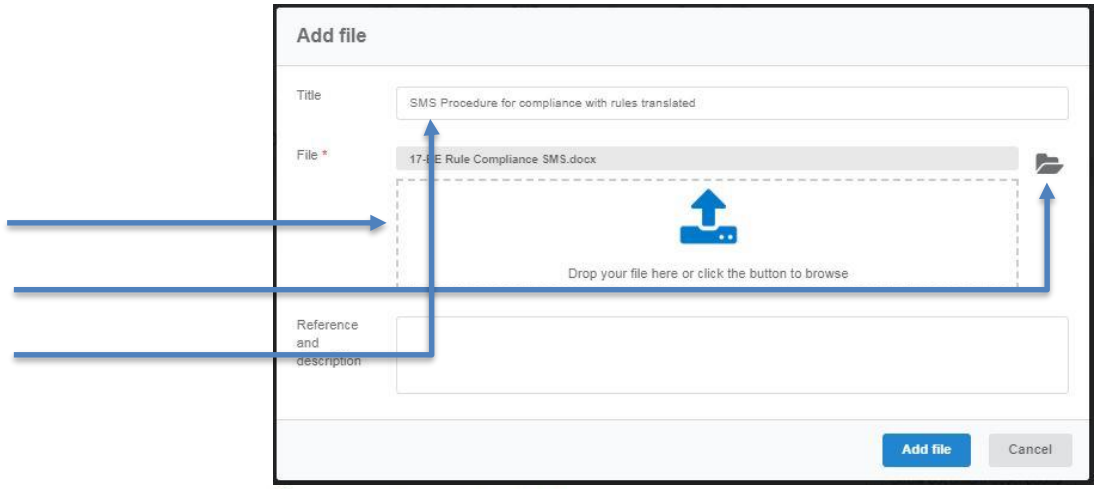


Application Process in the OSS: step 3/1

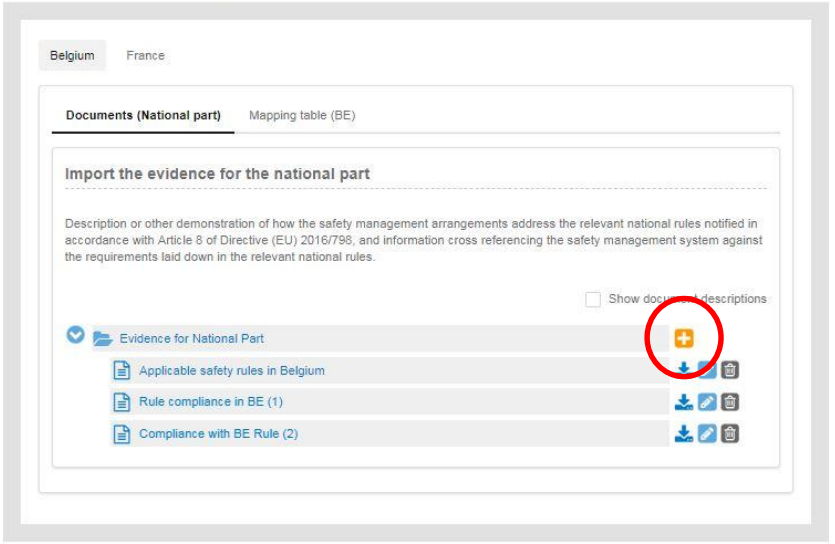
Upload evidence for the national parts:

National requirements

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



Documentary evidence: **National part**



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

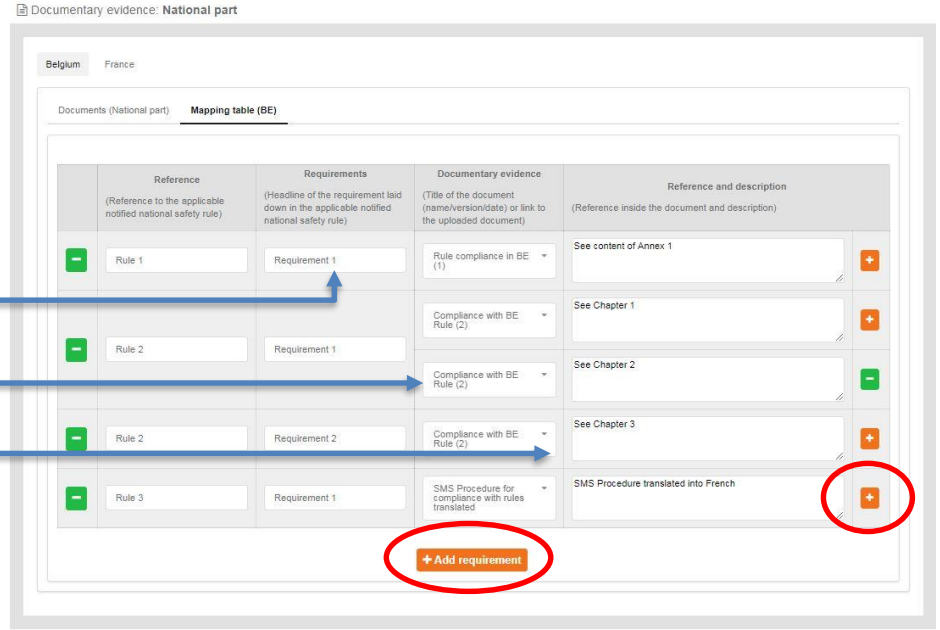
Upload information separately for each of the areas of operation

Application Process in the OSS: step 3/2

Cross reference your evidence with the national requirements

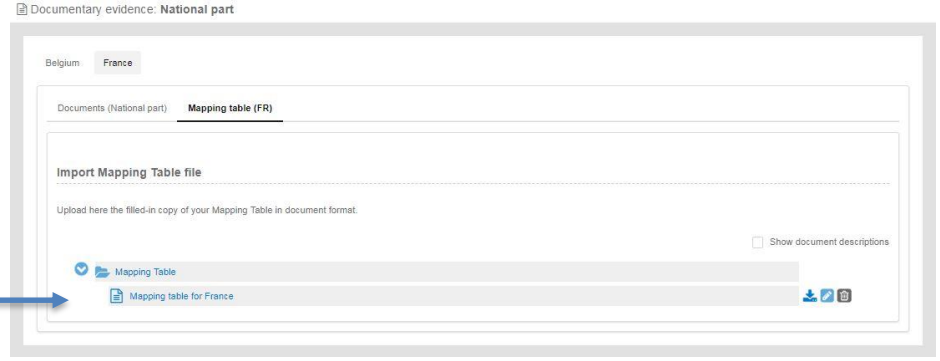
Option 1:

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



Option 2:

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



Application Process in the OSS: step 4

Upload additional documents:

- Legal Entity Form (LEF)
- Any other document

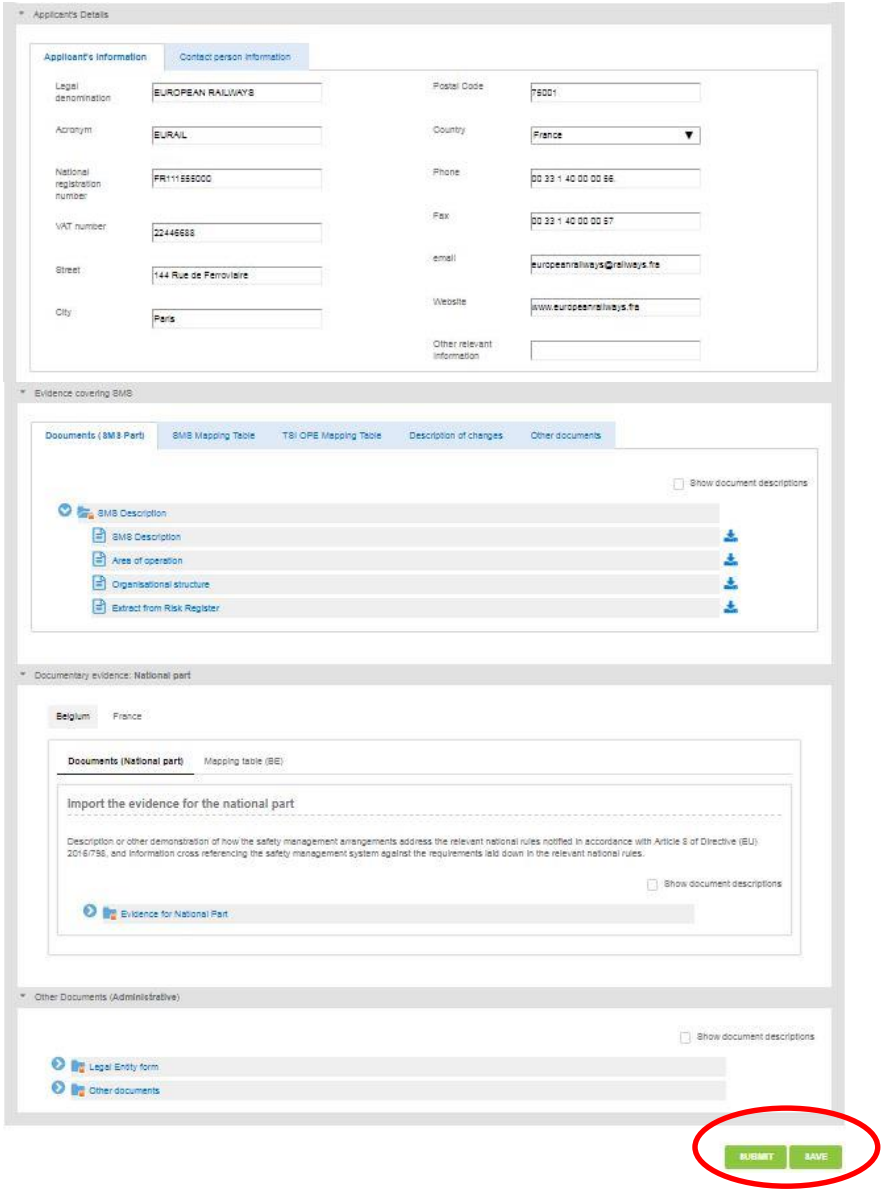
Do not upload here any evidence for SMS or national parts. It's only for administrative and financial documents

Application Process in the OSS: step 5

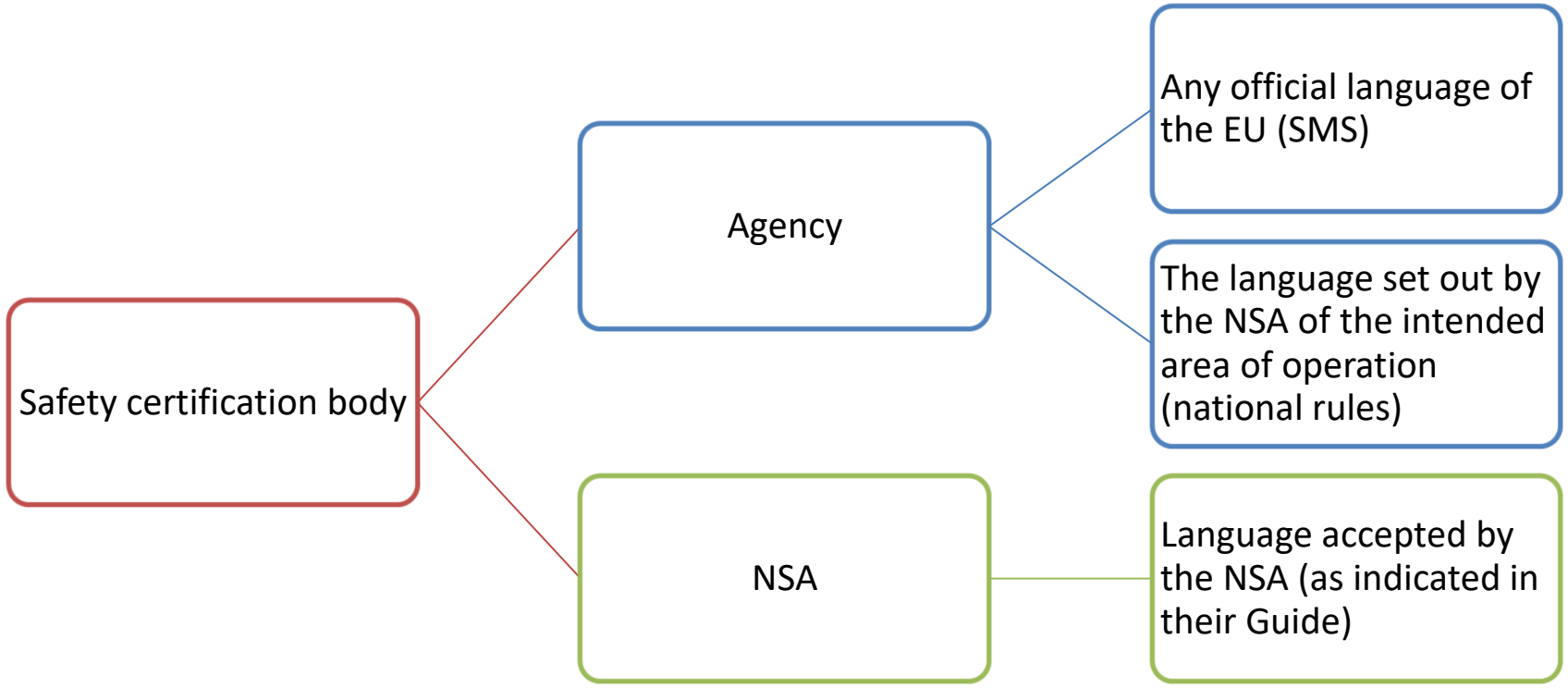
Review + sign + submit:

- 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



Language policy



EUROPEAN UNION AGENCY FOR RAILWAYS

The safety assessment process

The safety assessment process

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

Initial screen 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

Detailed assessment stage

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

Decision stage

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)

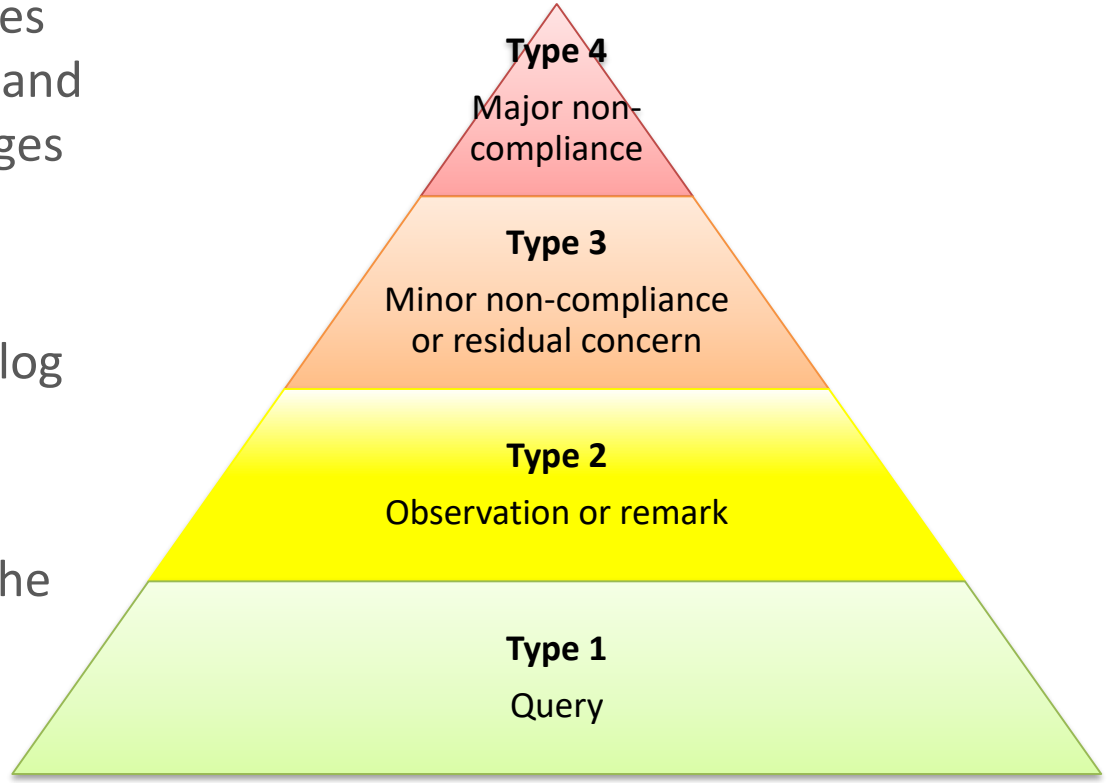
Communication arrangements

- 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

Management of issues

- 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



Audits, inspections or visits

- 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

EUROPEAN UNION AGENCY FOR RAILWAYS

Update and renewal of a single safety certificate

Update and renewal of a single safety certificate

Update and renewal

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.

Type & extent of operation

- 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

EUROPEAN UNION AGENCY FOR RAILWAYS

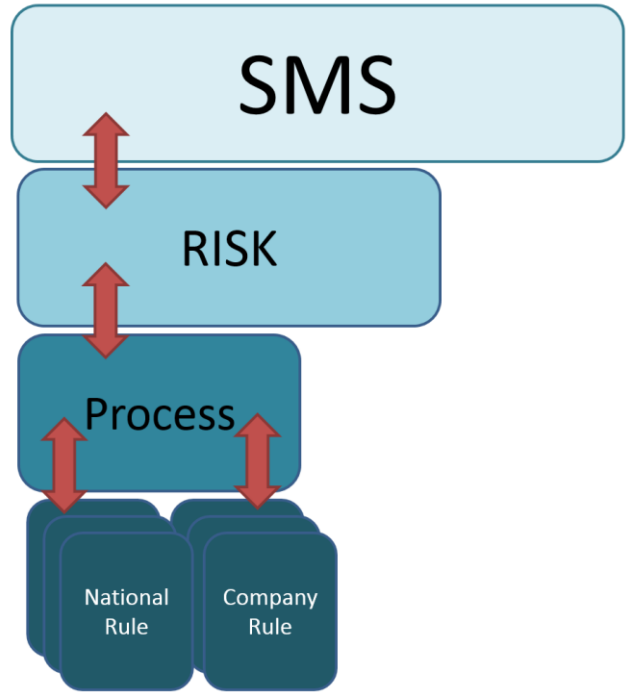
Safety management systems

Safety management systems

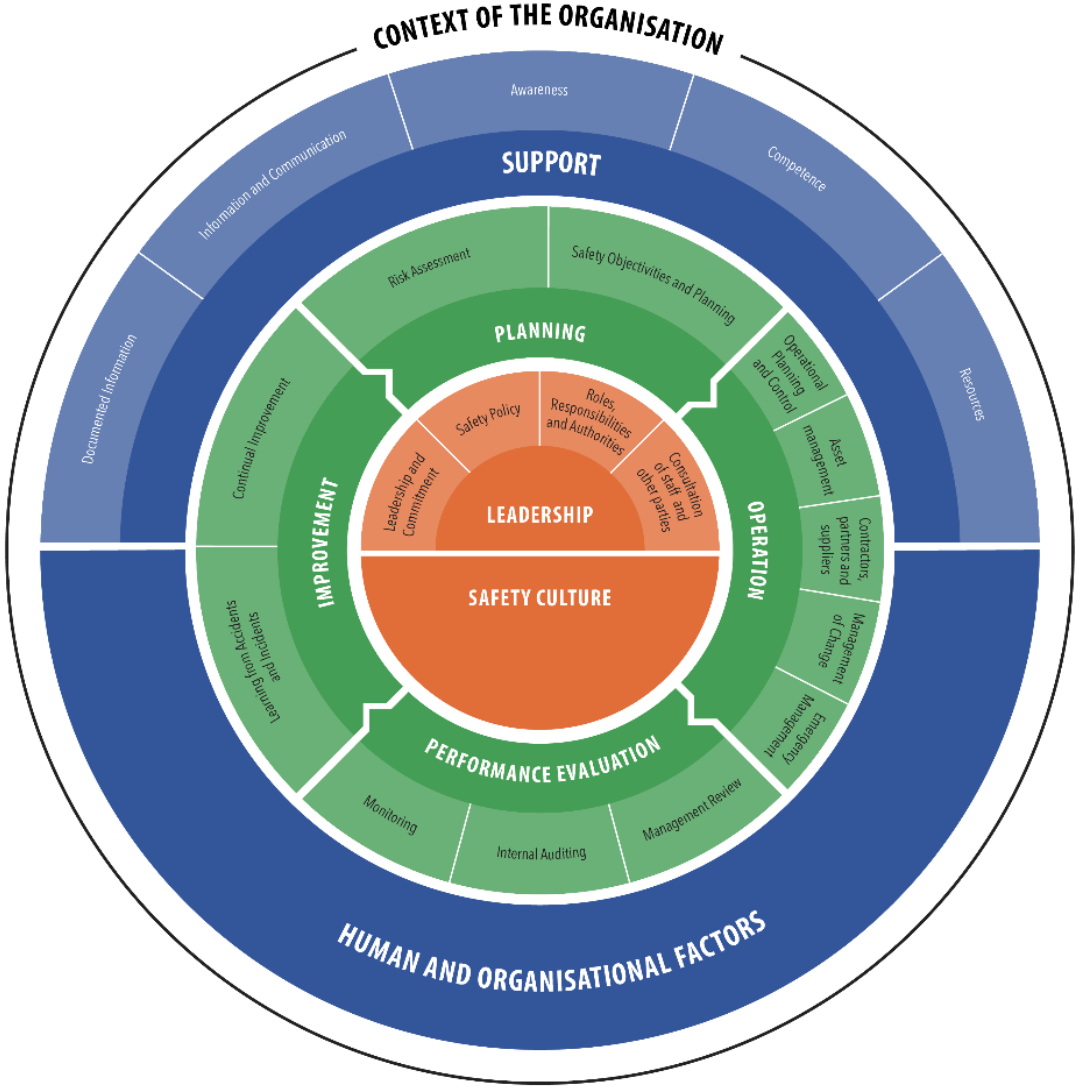
What is a safety management system (SMS)?

- 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)*)



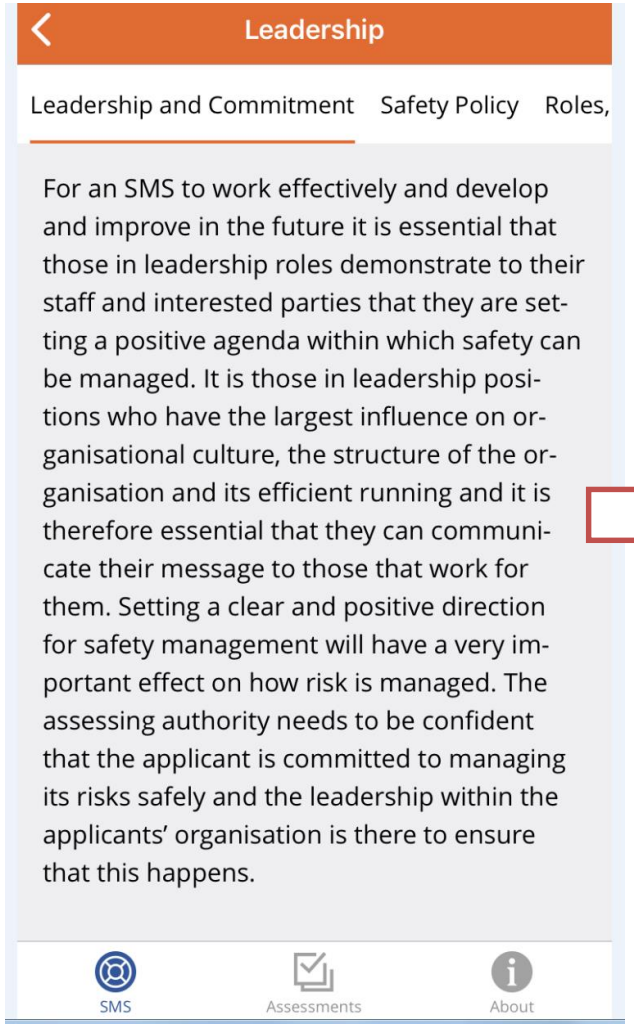
ERA SMS wheel/Mobile App



Download on the App Store

GET IT ON Google Play

SMS application - leadership



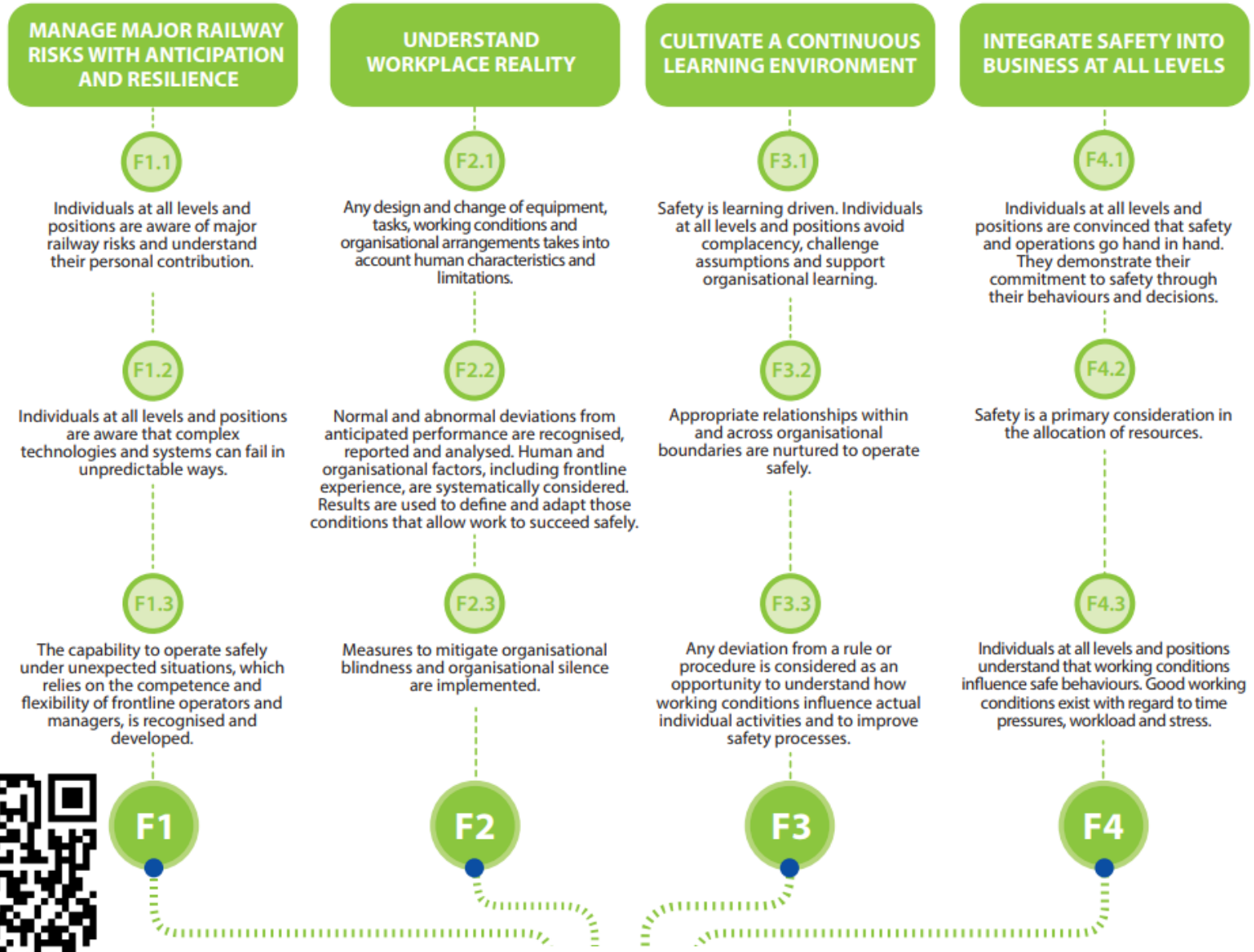
Demonstration of commitment

Communication

Safety culture

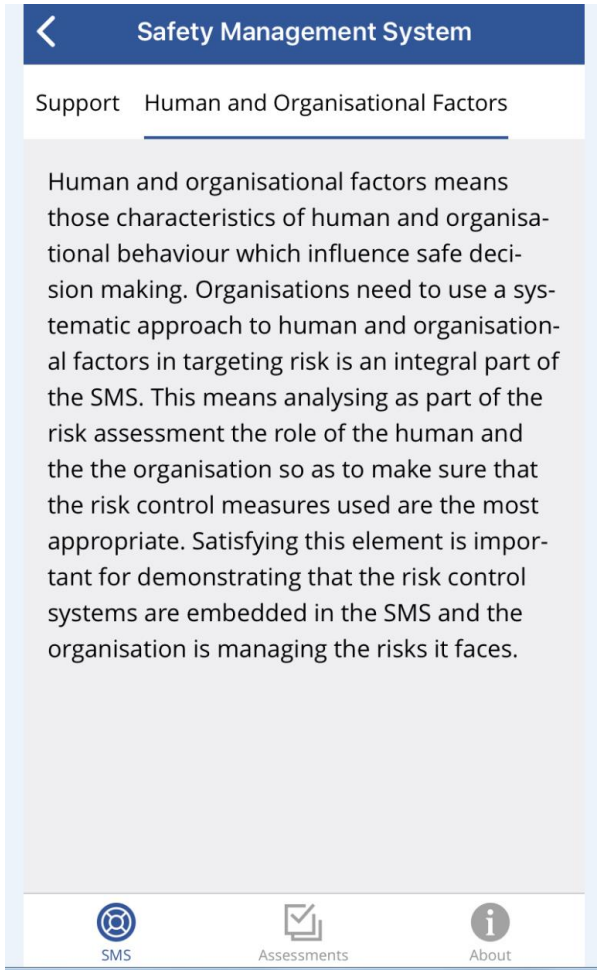
Risk management and responsibility

SMS application – safety culture



era.europa.eu

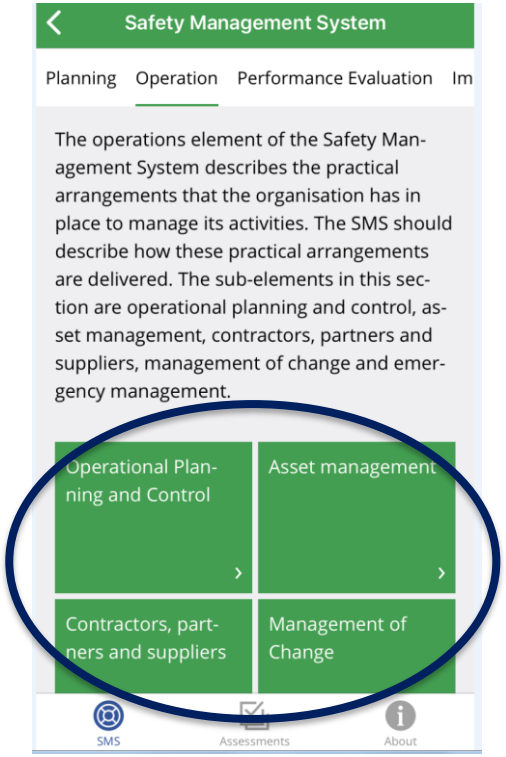
SMS application – Human and organisational factors (HOF)

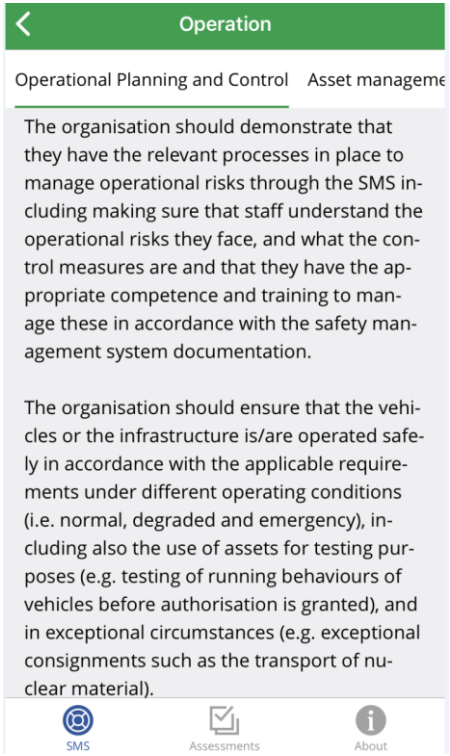


Those HOF factors which influence safe decision making

Ensuring HOF is included in the risk analysis

SMS application - operations

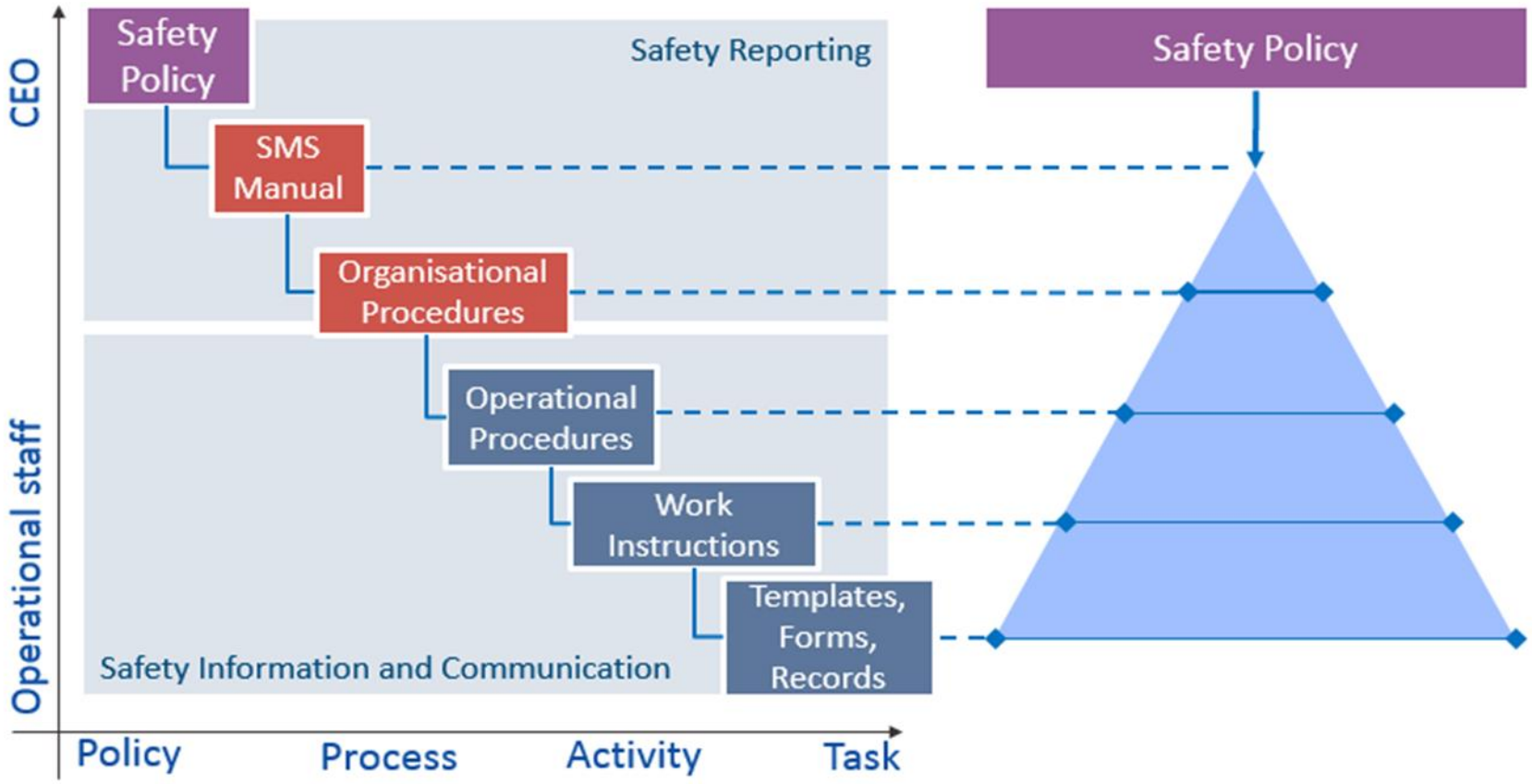




Arrangements to manage activities
Processes to manage risks
Staff understand and apply
Vehicles are operated safely under different operating conditions

SMS document architecture

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



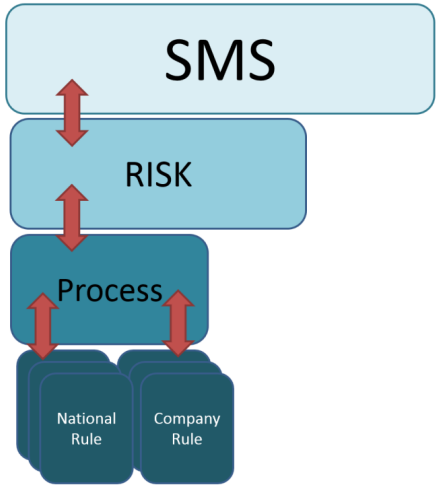
Framework for operations:

- 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

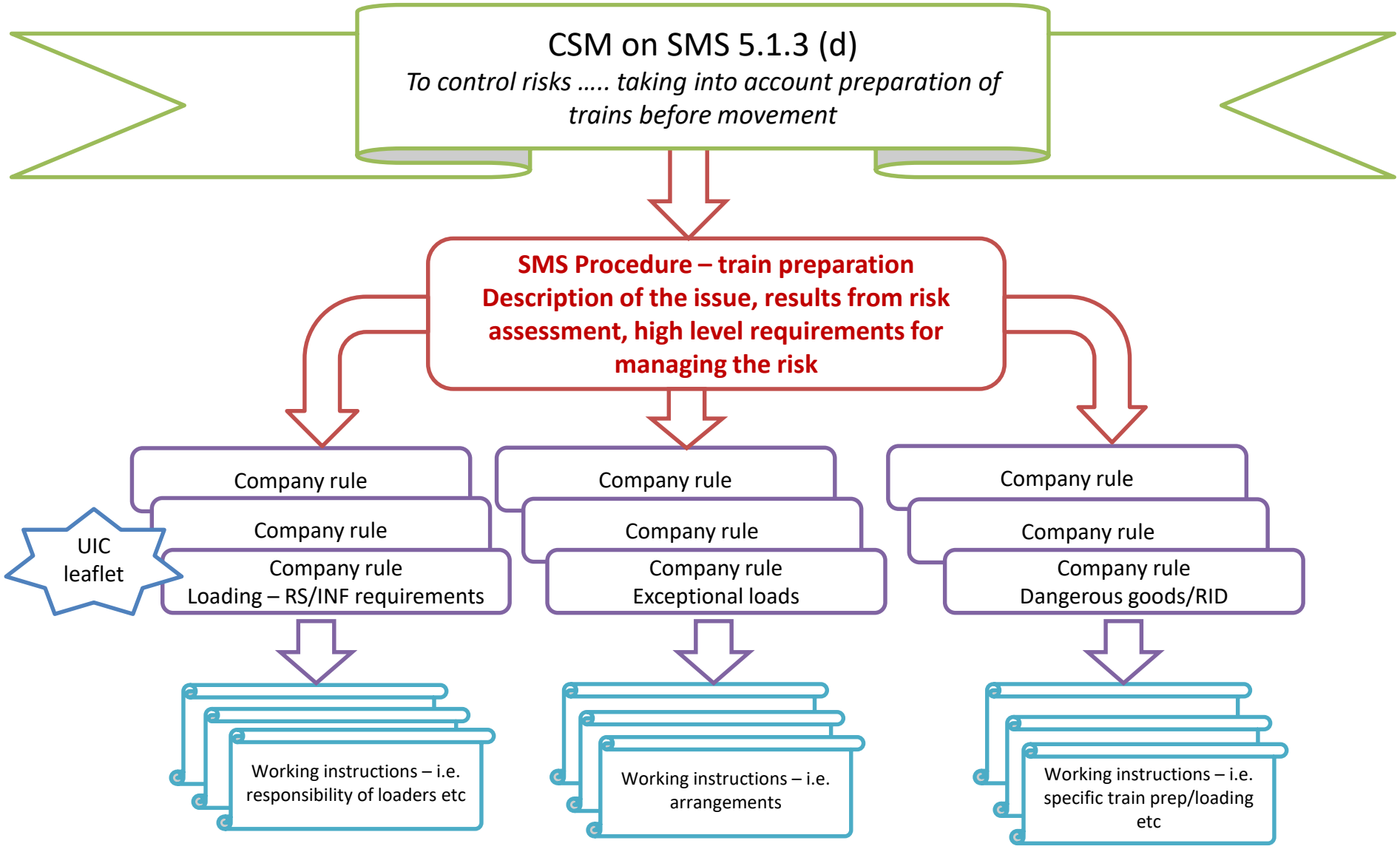
SMS and operational rules

- 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,
  - …



SMS and operations – an example



FAQ & Questions

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

era.europa.eu

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**

ISO 9001:2015
BUREAU VERITAS
Certification