

# Workshop on the Technical Pillar of the 4<sup>th</sup> RP

## SSC in the framework of the 4<sup>th</sup> RP

Karen Davies

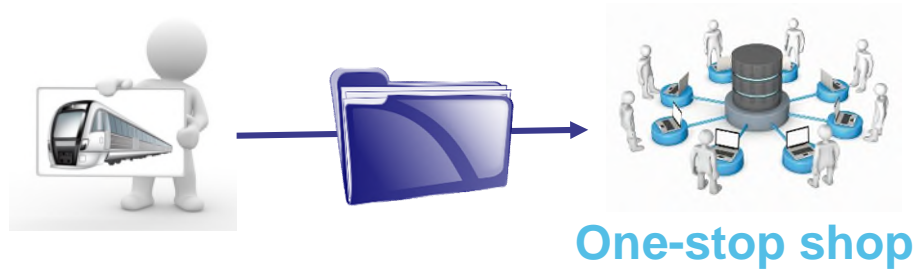
Virtual workshop

- 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 new?

June 2019

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



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

- **All applications** for single safety certificates or vehicles authorisations are **projects**.
- ERA appoints a project team for the part of the assessment it is responsible for (i.e. the assessment of the safety management system).
- The **project manager** is responsible for the coordination of the assessment. S/he is the **contact point** for the applicant and the NSA(s) concerned.
- The **decision** to issue (or not) the single safety certificate, including a link to the final assessment report, is **notified to the applicant via the one-stop shop**.

Before
Safety certificate part A issued by the relevant NSA
One or more safety certificates part B issued by the relevant NSAs
Applications managed in accordance with national arrangements
Assessment process defined by each NSA in accordance with its own rules
Assessment based on EU criteria (to be applied by NSAs) and national rules
No obligation from authorities to pre-engage with the applicant

After
Single safety certificate issued by a safety certification body: either the NSA or the Agency
All applications managed through the one-stop shop IT tool in accordance with arrangements set out in EU law
Harmonised assessment process set out in EU law
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
Authorities must pre-engage on request of 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)

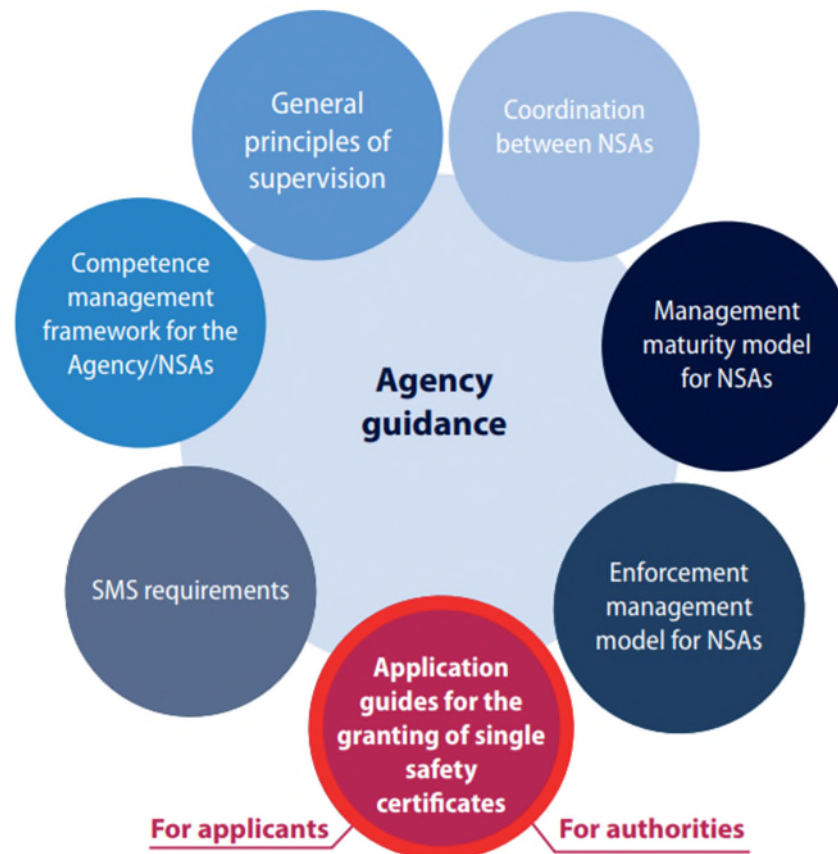
Regulation concerning the International Carriage of  
Dangerous Goods by Rail (RID)

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



# 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



- Board of Appeal
- Fees and charges

# Board of Appeal

- Different remedies against the decisions taken by an authority issuing single safety certificates or vehicle authorisations:
  - **Review** of the negative decision (only for the applicant)
  - **Appeal** before an appeal body (for the applicant or any natural or legal person for which the decision is addressed to that person, or of direct and individual concern to that person)
  - **Actions for the annulment or for failure to act** before the Court of Justice of the EU (ERA) or a national court (NSA)
- The applicant must first submit a request for the review of the decision taken by the authority before lodging an appeal

- The competent appeal body depends on the authority responsible for taking the decision:
  - The **Board(s) of Appeal** established by the Agency (ERA)
  - **An appeal body in accordance with national law**
- The members of the Board(s) of Appeal established by ERA are independent of any parties involved and cannot assume other roles within the Agency
- The Board of Appeal of the Agency plays a role during:
  - the **arbitration procedure** on request of the NSA(s) during the assessment
  - the **appeal lodged by the applicant** after the decision has been taken by ERA
- The NSA(s) concerned may request an **arbitration** before the Board of Appeal when ERA disagrees with a negative assessment carried out by the NSA(s) if a mutually acceptable assessment cannot be agreed within a month following the notification of its disagreement by ERA to the NSA(s)
- As regards **arbitration**, the Board of Appeal decides whether to confirm the Agency's draft decision.

- Where the Board of Appeal finds that the grounds for **appeal** are founded, it remits the case to the Agency. The Agency takes its final decision in compliance with the findings of the Board of Appeal and provides a statement of reasons for that decision. The Agency informs the parties to the appeal proceedings accordingly.
- An lodged **appeal** does not suspend the application. However, upon request by the parties involved, the Board of Appeal may decide that the appeal in question is to have suspensory effect, if it considers that circumstances, such as impact on safety, so permit. In such a case, the Board of Appeal provides a statement of reasons for its decision.

- Any request for arbitration or appeal before the Board of Appeal must be submitted to the Registrar of the Board of Appeal ([BoA@era.europa.eu](mailto:BoA@era.europa.eu))
- The findings of the Board of Appeal will be available in the one-stop shop by the Registrar
- [Commission Implementing Regulation \(EU\) 2018/867 of 13 June 2018 laying down the rules of procedure of the Board\(s\) of Appeal of the European Union Agency for Railways](#)

# Fees and charges

- The fees and charges levied by the Agency should cover the full costs of the services rendered by the Agency.
- The fees and charges payable to the Agency should be set in a transparent, fair and uniform manner, in particular with the objective of simplification. They should not result in the imposition of unnecessary financial burden on enterprises and should not jeopardise the competitiveness of the European railway sector.
- The fees and charges are calculated based on:
  - The time spent by the Agency staff (and external experts when applicable), multiplied by an hourly rate of 130€
  - The statement of costs provided by the NSA(s) concerned

- The Agency shall, at the request of the applicant, issue a **non-binding estimate** of the amount of the fees and charges related to the application (including pre-engagement as appropriate) and provide information on when the invoices will be issued
- Applicants shall ensure that the Agency receives **payment of the amounts due**, including any bank charges related to that payment, **within 60 calendar days** from the date of notification of the invoice
- The Agency may invoice interim amounts every 6 months (during pre-engagement stage)
- Where the applicant is a small or medium-sized enterprise, the Agency shall take into account requests for a **reasonable extension of the time limit for payment and payment by instalments**

- [Commission Implementing Regulation \(EU\) 2018/764 of 2 May 2018 on the fees and charges payable to the European Union Agency for Railways and their conditions of payment](#)

# Questions so far



**Q. Will OSS be a part of it or is it better to do a separate webinar about this? Or are you planning a digital OSS training course in the near future?**

**A. OSS trainings are organised on a regular basis. The training dates and registration details are available on the ERA website. We can provide the link**

**Q. How will the NSAs be involved in the process of evaluation of an application for SSC?**

**A. If this SSC is to be issued by ERA, either as part of the ERA team assessing the SMS part (through the Pool of Experts) and/or (2) assessing the national part against NRs. In any case, ERA ensures coordination between all the concerned authorities.**

**Q. What is the estimated cost and duration of an application for SSC?**

**A. Average duration for issuing SSC: 4,25 months – Light increase of duration which gets closer to 5 months, justified in most cases by the additional time taken by NSAs to provide ERA with their opinions**

**Average work effort (irrespective of the type of application and number of resources involved): 114 hours (~15k€) – it should be distinguished the average work for new applications from the one for renewal/update applications, the latter pulling down the average.**

**Those figures are purely indicative!!! We need more applications to be able to draw reliable stats. As mentioned above, on the longer term we should retrieve the average by type of application (new, update and renewal).**

**Q. Which language can be used if the application for SSC is concerning two countries including Norway.**

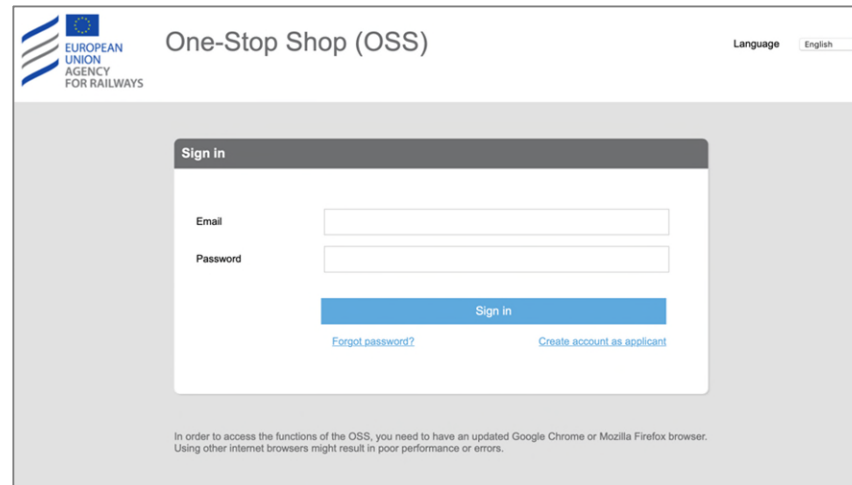
**A. This will mainly depend what the EEA agreement will say about it. The latter has not been signed yet.**

**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>



The screenshot shows the 'One-Stop Shop (OSS)' login interface. At the top left is the European Union Agency for Railways logo. 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' box with two input fields for 'Email' and 'Password'. Below these fields is a blue 'Sign in' button. Under the button are two links: 'Forgot password?' and 'Create account as applicant'. 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)

# 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**

## Register to OSS

First Name	<input type="text" value="Piotr"/>
Surname	<input type="text" value="CUKIERSKI"/>
EMAIL	<input type="text" value="Rail.Company@wp.pl"/>
Confirm Email Address	<input type="text" value="Rail.Company@ ..."/>

Register

By signing up you agree to ERA's  
[Terms and Conditions](#)

Already registered?  
[Login here](#)

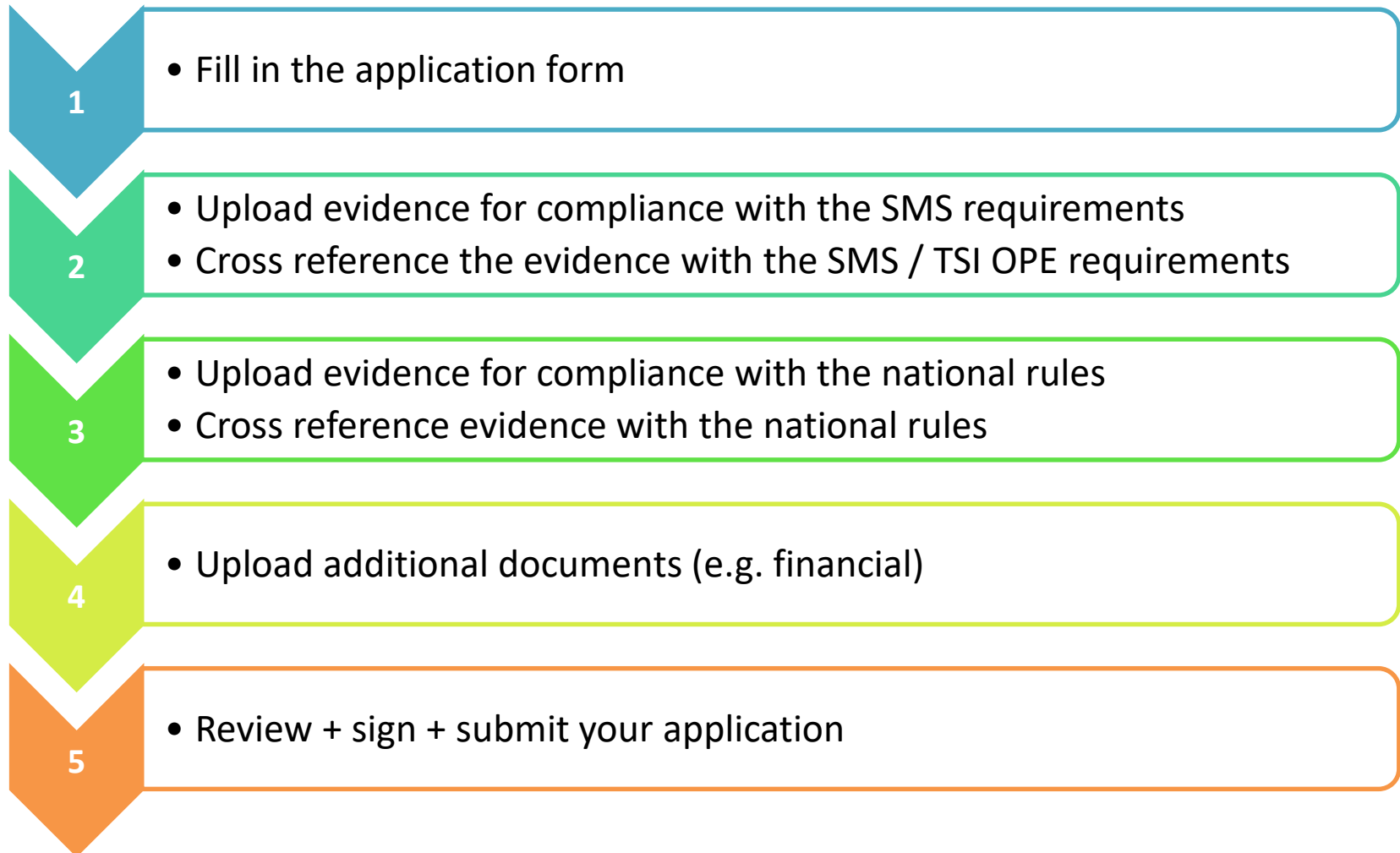
## User Profile

### User Information

Firstname:*	<input type="text" value="Piotr"/>	Lastname:*	<input type="text" value="Cukierski"/>
Title or Function:	Director ▾	Company:	<input type="text" value="EUROPEAN RAILWAYS S.A."/>
Address			
Street:*	<input type="text" value="120 Rue Marc Lefrancq"/>		
City:*	<input type="text" value="Valenciennes"/>	Postal:*	<input type="text" value="59300"/>
Country:*	France ▾		
Phone:*	<input type="text" value="+33 (3) 100 200 300"/>	Fax:	<input type="text" value="+33 (3) 200 300 400"/>
Email:*	<input type="text" value="Rail.Company@wp.pl"/>	Languages Spoken:	<div>English x Polish x</div>
Notifications:	▾		

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\*

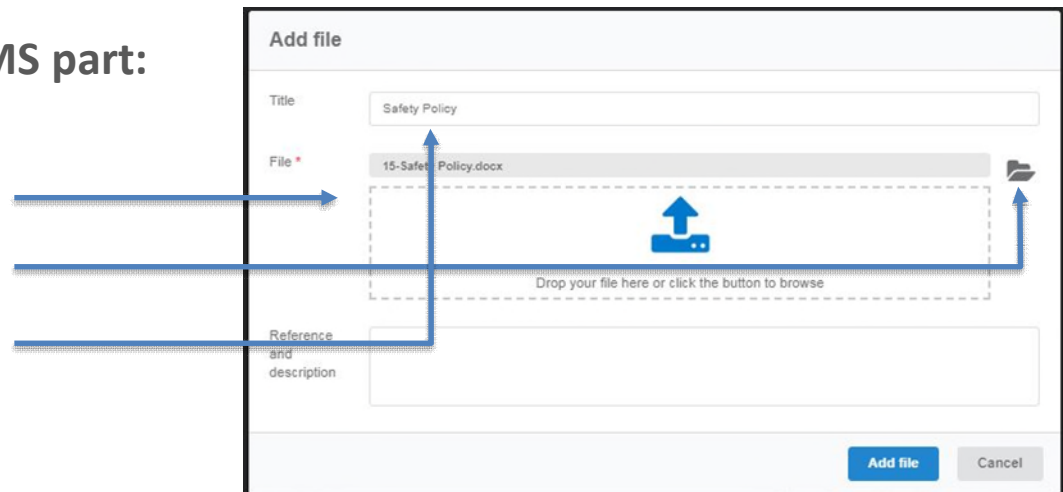
☒ European Union Agency for Railways  
☐ The national safety authority

### Upload your evidence for the SMS part:

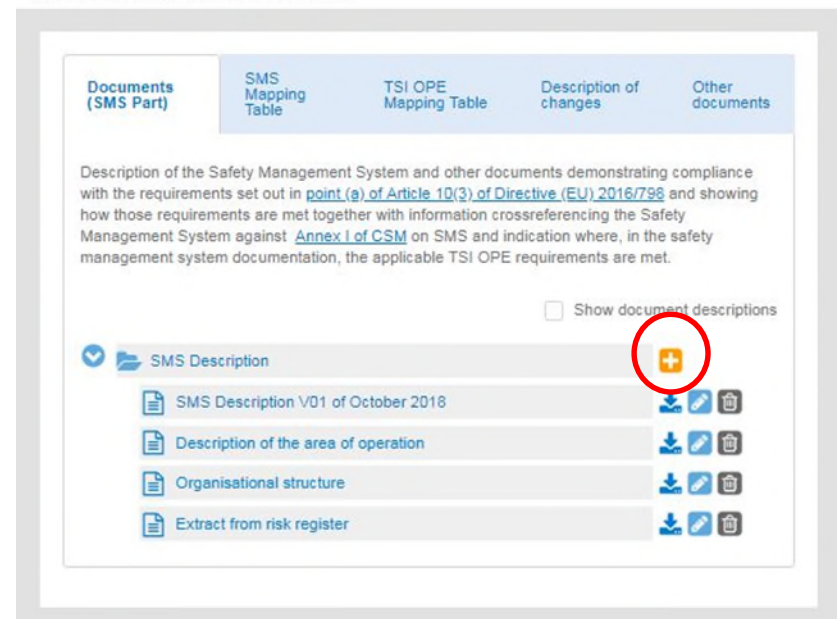
- use drag and drop function
- or upload from your folders
- provide clear titles



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



### Documentary evidence SMS part



Documents (SMS Part)	SMS Mapping Table	TSI OPE Mapping Table	Description of changes	Other documents
Description of the Safety Management System and other documents demonstrating compliance with the requirements set out in <a href="#">point (a) of Article 10(3) of Directive (EU) 2016/798</a> and showing how those requirements are met together with information crossreferencing the Safety Management System against <a href="#">Annex I of CSM</a> on SMS and indication where, in the safety management system documentation, the applicable TSI OPE requirements are met.				
<input type="checkbox"/> Show document descriptions				
+ SMS Description				
SMS Description V01 of October 2018				
Description of the area of operation				
Organisational structure				
Extract from risk register				

## Cross reference you evidence with relevant requirements:

### SMS Requirements

- SMS Requirement
- Your evidence
- Description

Documentary evidence SMS part

Documents (SMS Part)	SMS Mapping Table	TSI OPE Mapping Table	Description of changes	Other documents
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			
	The organisation shall:			
(a)	describe the type extent and area of the operation;	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	+

## Application Process in the OSS: step 3

### Upload evidence for the national parts:

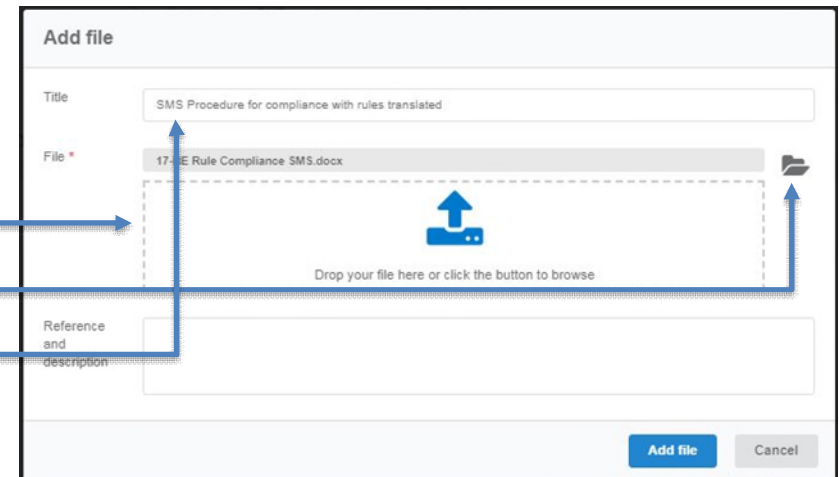
#### National requirements

- 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

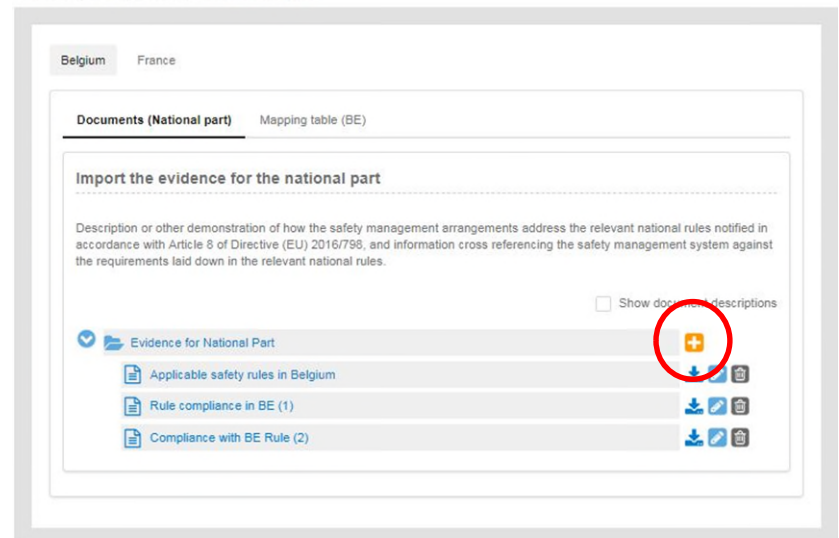


The 'Add file' form contains the following fields and elements:

- Title:** A text input field containing 'SMS Procedure for compliance with rules translated'.
- File:** A file selection area showing '17-EE Rule Compliance SMS.docx'. Below it is a dashed box with an upload icon and the text 'Drop your file here or click the button to browse'.
- Reference and description:** A text input field.
- Buttons:** 'Add file' (blue) and 'Cancel' (grey).

Three blue arrows point from the text 'use drag and drop function', 'or upload from your folders', and 'provide clear titles' to the 'File' field, the dashed drop area, and the 'Title' field respectively.

Documentary evidence: **National part**



The 'Documents (National part)' section shows a list of documents for Belgium:

- Documents (National part):** Mapping table (BE)
- Import the evidence for the national part:** Description or other demonstration of how the safety management arrangements address the relevant national rules notified in accordance with Article 8 of Directive (EU) 2016/798, and information cross referencing the safety management system against the requirements laid down in the relevant national rules.
- ☐ Show document descriptions
- Evidence for National Part:** A list of documents with icons for download, share, and delete.
  - Applicable safety rules in Belgium
  - Rule compliance in BE (1)
  - Compliance with BE Rule (2)

A red circle highlights the '+' icon next to the 'Evidence for National Part' header.

## Application Process in the OSS: step 4

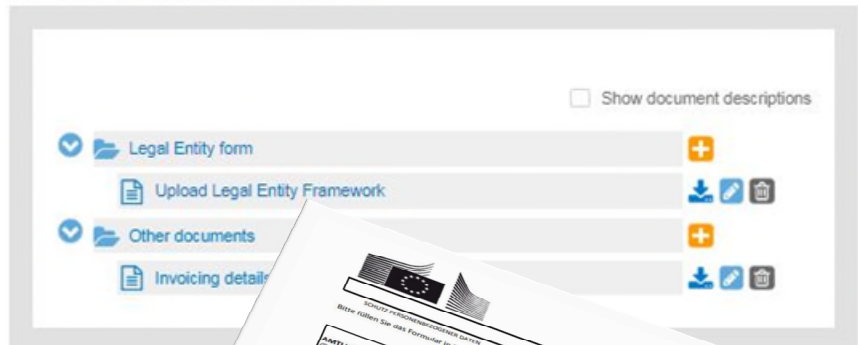
### Upload additional documents:

- 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

#### Other Documents (Administrative)



## Application Process in the OSS: step 5

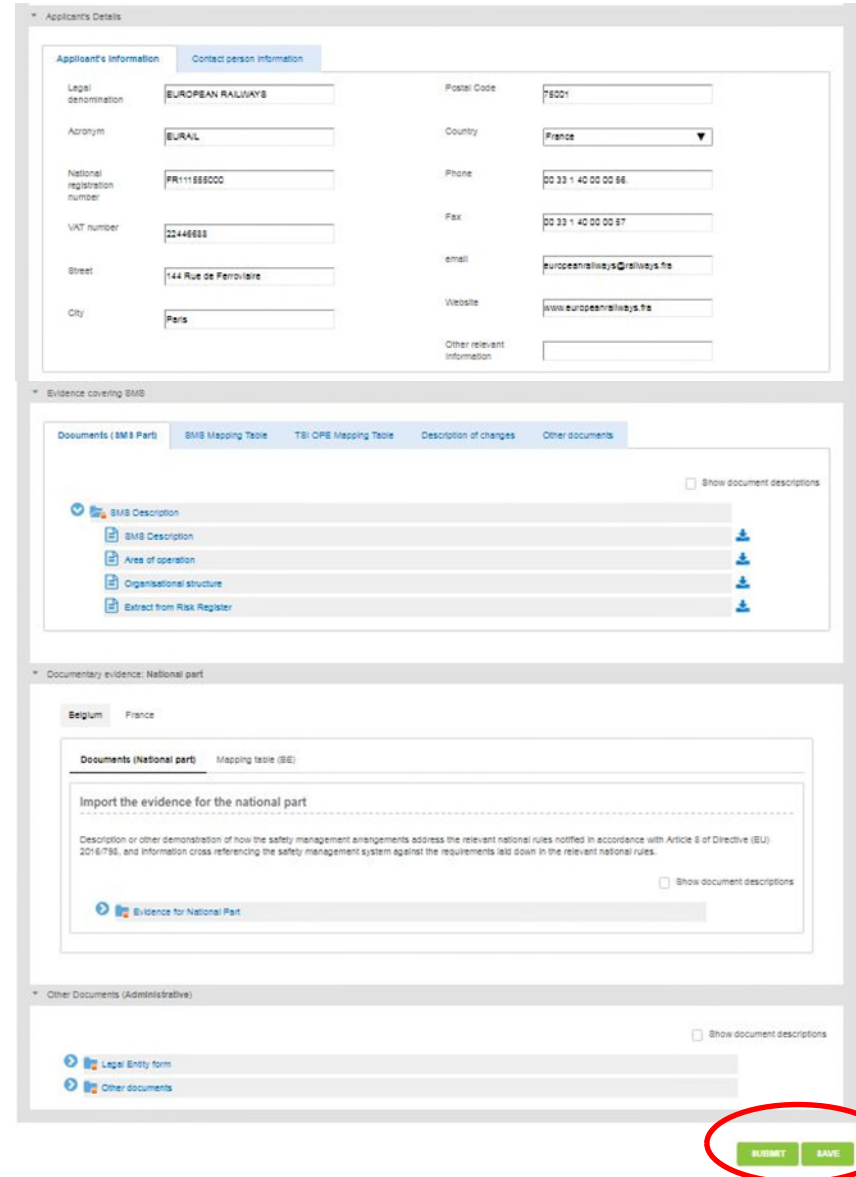
### Review + sign + submit:

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

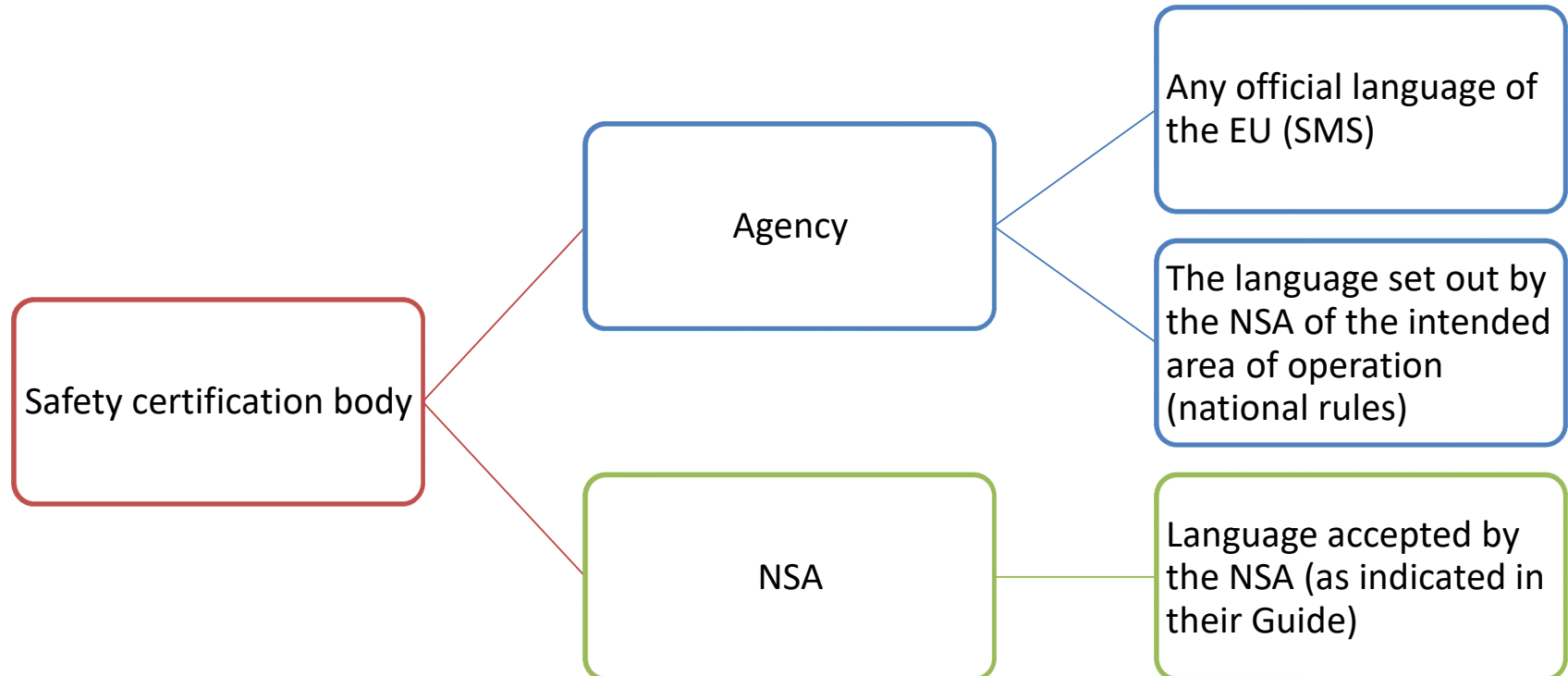


**You will be automatically notified about receipt of your application and about the starting date of the assessment**

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



The screenshot displays the 'Applicant's Details' form, which is divided into two tabs: 'Applicant's Information' and 'Contact person information'. The 'Applicant's Information' tab is active, showing fields for Legal denomination (EUROPEAN RAILWAYS), Postal Code (75001), Acronym (EURAIL), Country (France), National registration number (FR11588000), Phone (00 33 1 40 00 00 66), VAT number (22446688), Fax (00 33 1 40 00 00 67), Street (144 Rue de Férussaire), email (europeanrailways@railways.fr), City (Paris), Website (www.europeanrailways.fr), and Other relevant information. Below this is the 'Evidence covering SMS' section, which includes tabs for 'Documents (SMS Part)', 'SMS Mapping Table', 'TBI OPE Mapping Table', 'Description of changes', and 'Other documents'. The 'Documents (SMS Part)' tab is active, showing a list of documents: 'SMS Description', 'SMS Description', 'Area of operation', 'Organisational structure', and 'Extract from Risk Register'. Below this is the 'Documentary evidence: National part' section, which includes tabs for 'Belgium' and 'France'. The 'France' tab is active, showing a sub-section for 'Documents (National part)' and 'Mapping table (BE)'. The 'Documents (National part)' sub-section is active, showing a list of documents: 'Import the evidence for the national part', 'Description or other demonstration of how the safety management arrangements address the relevant national rules notified in accordance with Article 8 of Directive (EU) 2016/798, and information cross referencing the safety management system against the requirements laid down in the relevant national rules.', and 'Evidence for National Part'. At the bottom of the form, there is a section for 'Other Documents (Administrative)' with tabs for 'Legal Entity form' and 'Other documents'. The 'Legal Entity form' tab is active, showing a list of documents: 'Legal Entity form' and 'Other documents'. At the bottom right of the form, there are two buttons: 'SUBMIT' and 'SAVE', which are circled in red.



# 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

### **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)

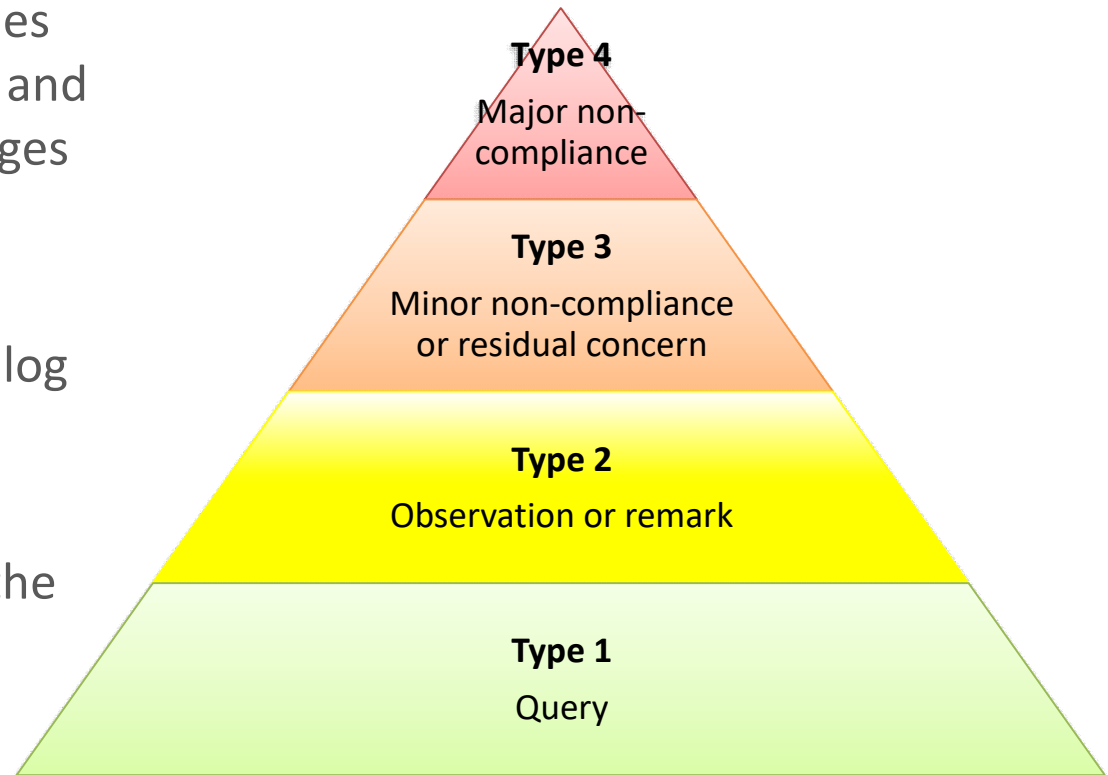
## Communication arrangements

- 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

- 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

# Questions so far



## **Update and renewal of a single safety certificate**

Update and renewal of a single safety certificate

- **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.

- **Renewal** at the expiry of the certificate

## 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

## 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

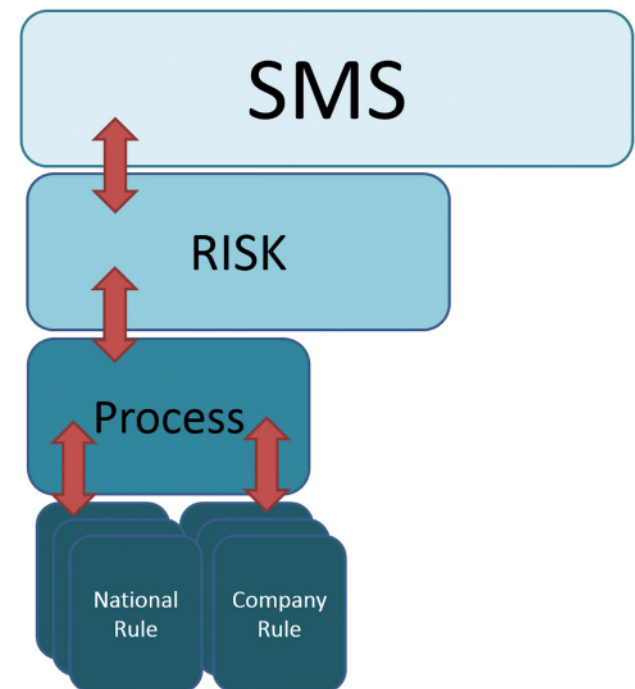


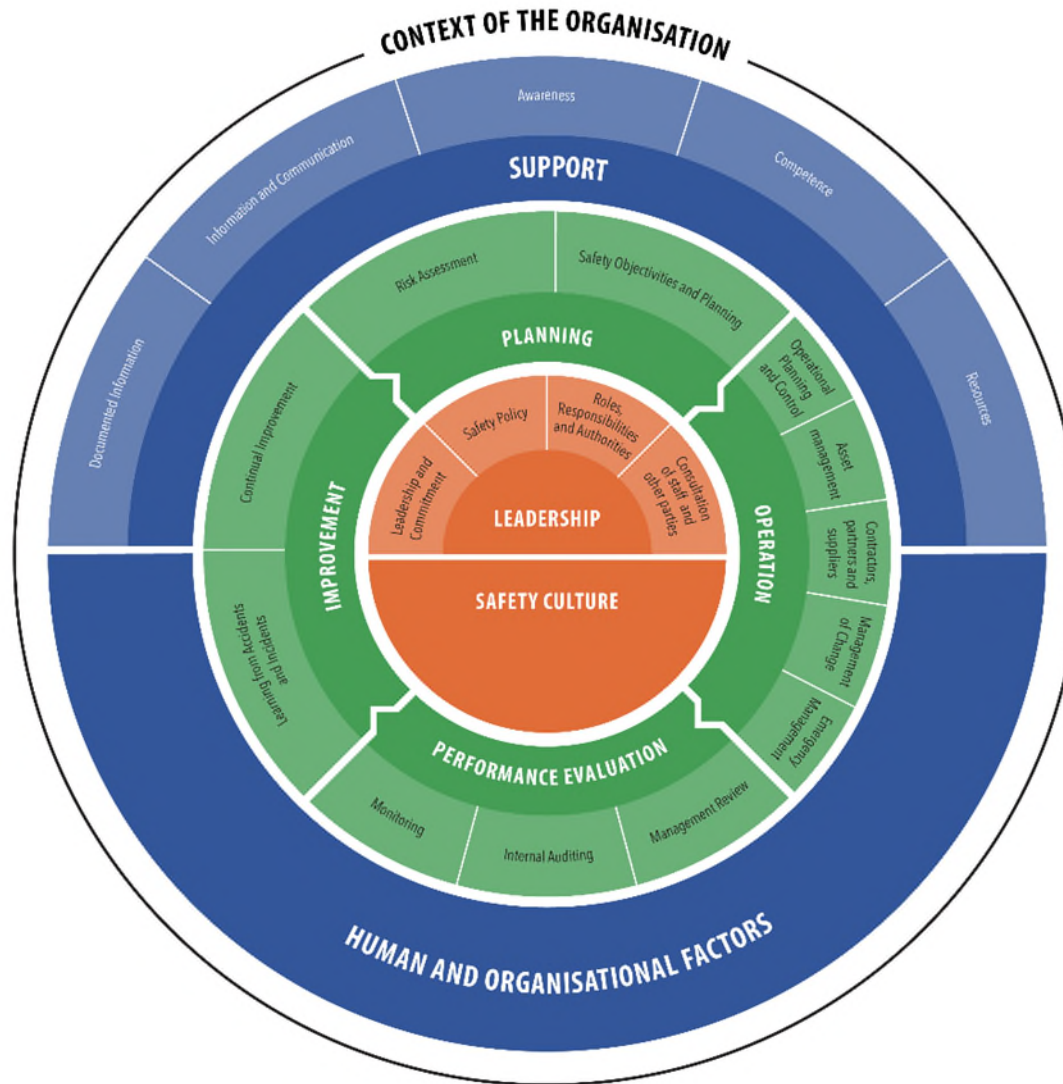
# **Safety management systems**

Safety management systems

## What is a safety management system (SMS)?

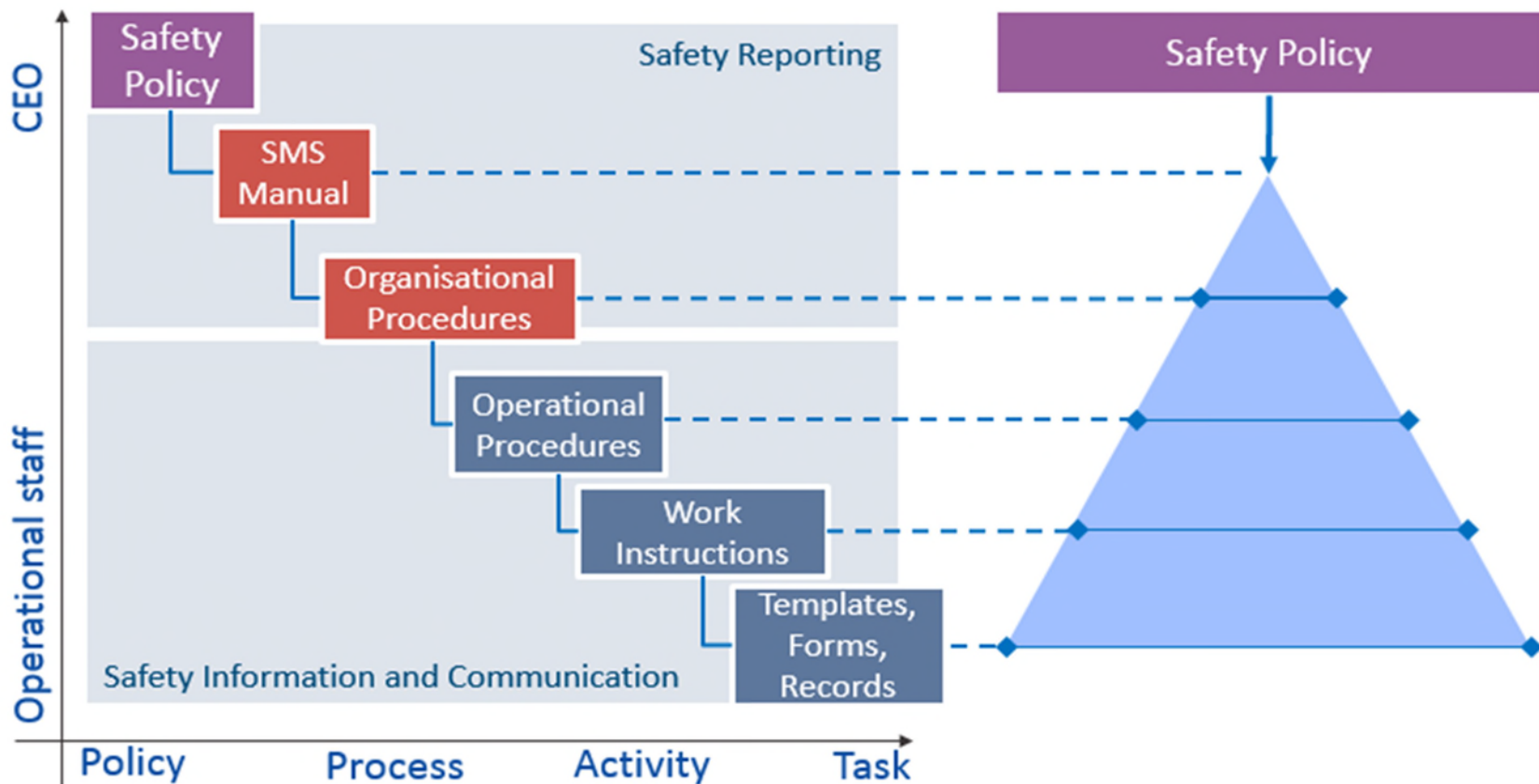
- The **safety management system (SMS)** is a living system of linked processes and procedures, which control **risk** to ensure the safe management of rail operations
- **Risk** means the frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity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



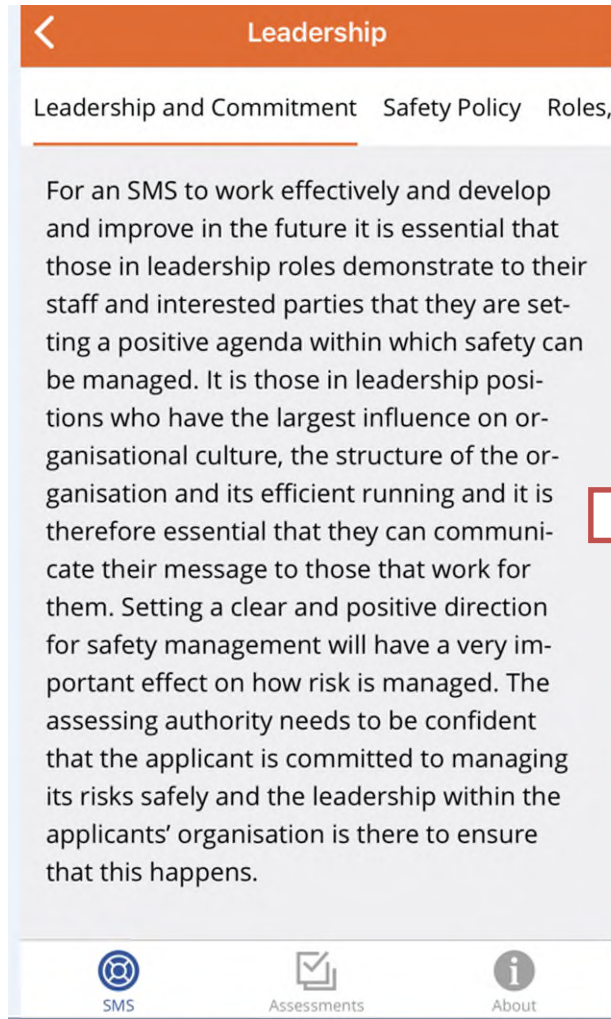


## SMS content architecture

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



## SMS application - leadership



**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   Assessments   About**

Demonstration  
of commitment

Communication

Safety culture

Risk  
management  
and  
responsibility

# SMS application – safety culture

## F1.3 Questioning attitude

Individuals at all levels avoid complacency, challenge assumptions, encourage and consider opposing views.

## F1.2 Resilience

The capability to operate safely under unexpected situations is developed.

## F1.1 Risk awareness

Individuals at all levels are aware of major risks and understand their personal contribution to safety.

**CONTROL  
MAJOR  
RISKS**

**F1**

## F2.3 Reporting

Routine and abnormal deviations are recognised and reported. Measures to identify and mitigate organisational silence are implemented.

## F2.2 System complexity

The organisation recognises that its technologies and systems are complex and can fail in unpredictable ways.

## F2.1 Working conditions

The organisation recognises that working conditions, such as time pressure, workload and fatigue influence safe behaviours.

**UNDERSTAND  
WORKPLACE  
REALITY**

**F2**

## F3.3 Learning from others

The organisation actively seeks learning opportunities.

## F3.2 Improvement

Safety related feedback is perceived as an opportunity to improve performance and is acted upon.

## F3.1 Analysis

Reporting is systematically analysed to identify those factors that allow organisational learning and improvement.

**LEARN  
FROM  
EXPERIENCE**

**F3**

## F4.3 Decision making

Individuals at all levels are convinced that safety and operations go hand in hand.

## F4.2 Resource allocation

Safety is a primary consideration in the allocation of resources.

## F4.1 Safety vision

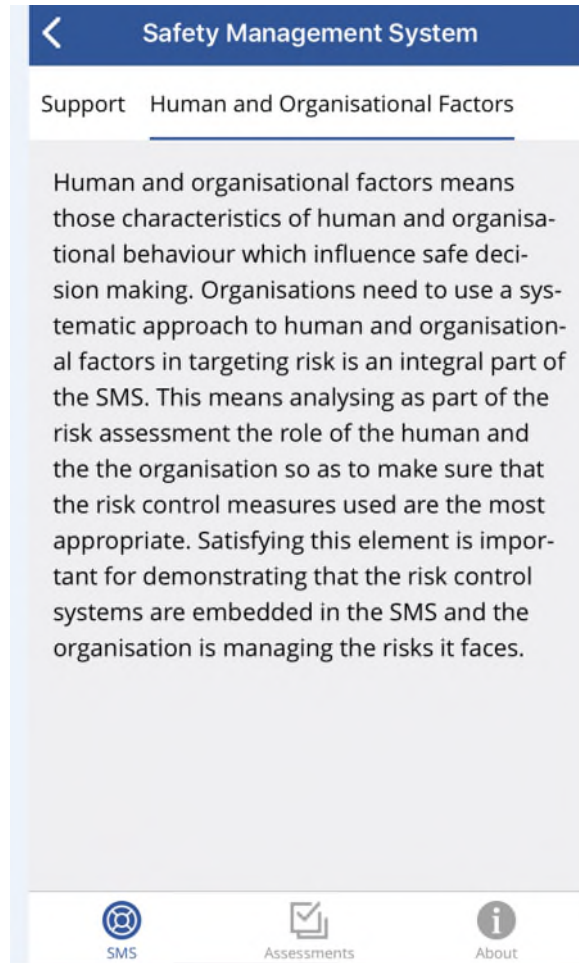
The organisation develops and implements a safety vision to support the achievement of business objectives.

**INTEGRATE  
SAFETY  
CONSISTENTLY**

**F4**



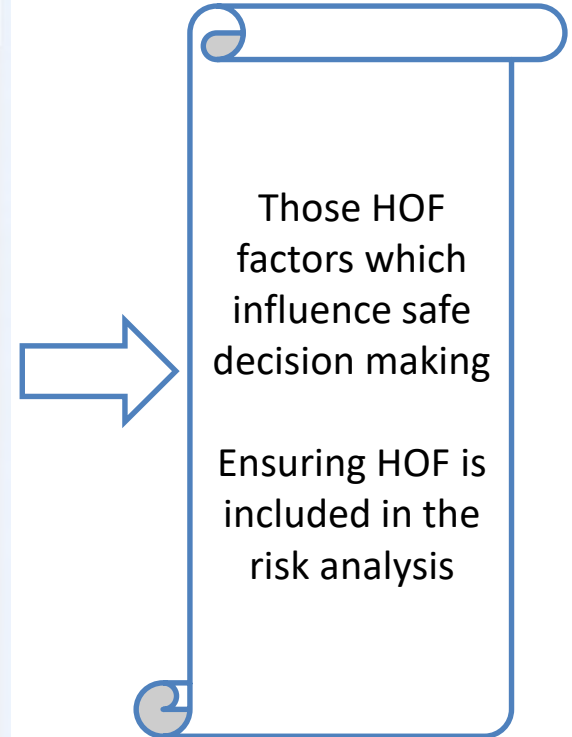
# SMS application – Human and organisational factors (HOF)



The screenshot shows the 'Safety Management System' application interface. The title bar reads 'Safety Management System'. Below it, the section 'Support Human and Organisational Factors' is highlighted. The main text area contains the following paragraph:

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.

The bottom navigation bar includes icons for 'SMS', 'Assessments', and 'About'.



Those HOF factors which influence safe decision making

Ensuring HOF is included in the risk analysis

## SMS application - operations



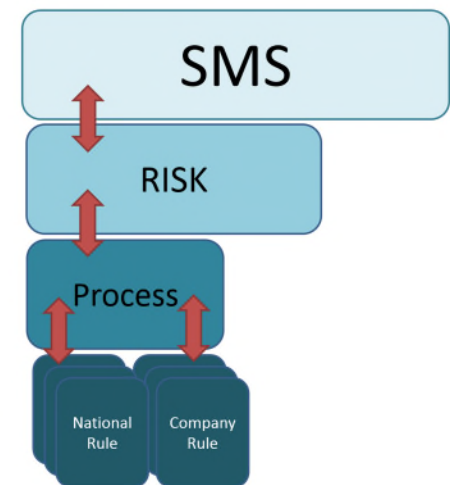
Arrangements to manage activities  
Processes to manage risks  
Staff understand and apply  
Vehicles are operated safely under different operating conditions

## Framework for operations:

- The operational requirements of the railway is the starting point for deciding the suitability of operational procedures
- It should include a description of standards, performance data, management system, risk assessment
- 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 operation the information from the risk assessment should be used to ascertain whether the operation is safe and the risks are controlled by either procedures or rules
- The issue of normal, degraded and emergency operations should also be based on outputs from the risk assessment including control measures (i.e. rules or working instructions) for what is needed to prevent unsafe operations
- The SMS process for 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 in the SMS procedures/company rules
- 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

### CSM on SMS 5.1.3 (d)

*To control risks ..... taking into account preparation of trains before movement*

**SMS Procedure – train preparation**  
**Description of the issue, results from risk assessment, high level requirements for managing the risk**

Company rule

Company rule

Company rule  
Loading – RS/INF requirements

Company rule

Company rule

Company rule  
Exceptional loads

Company rule

Company rule

Company rule  
Dangerous goods/RID

UIC  
leaflet

Working instructions – i.e.  
responsibility of loaders etc

Working instructions – i.e.  
arrangements

Working instructions – i.e.  
specific train prep/loading  
etc

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

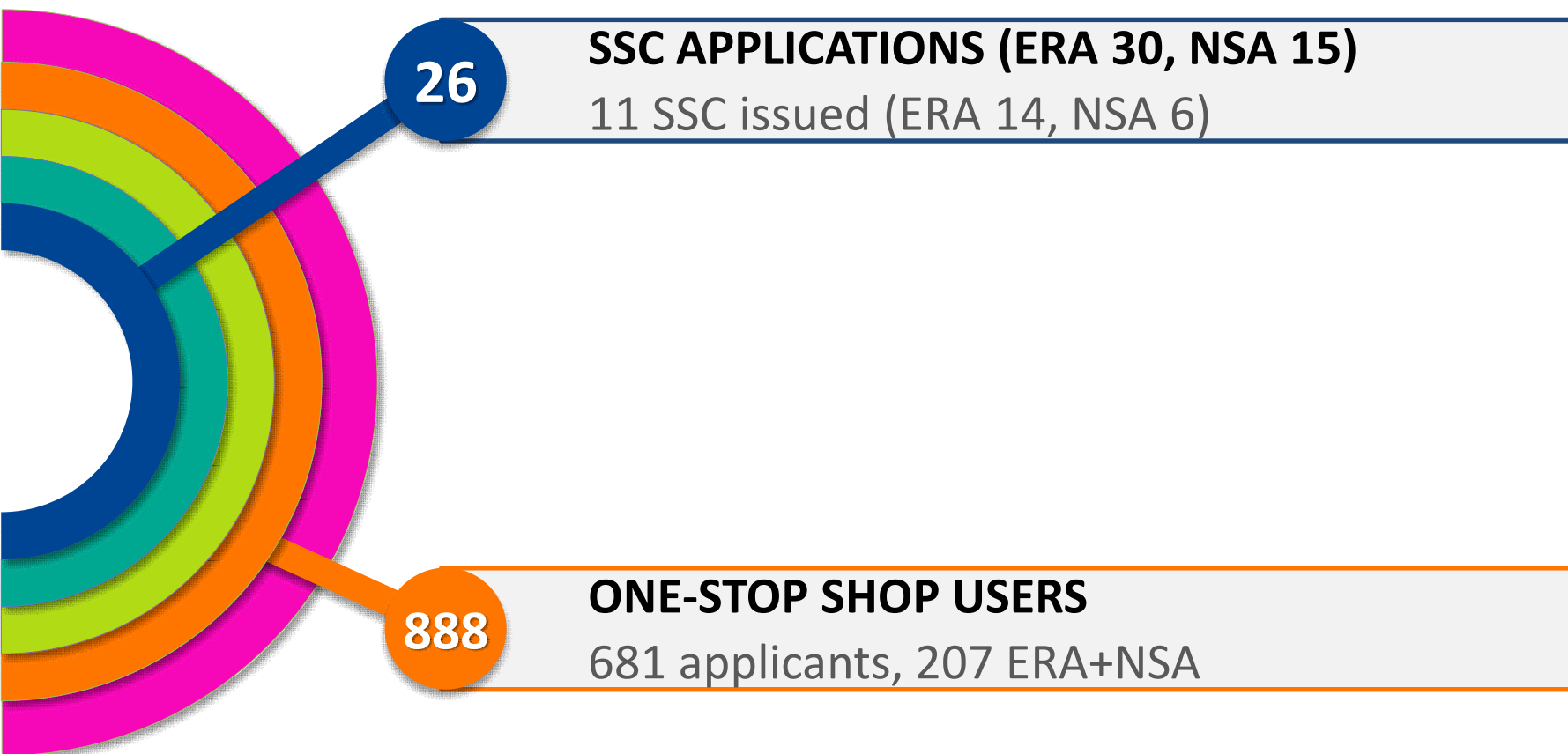


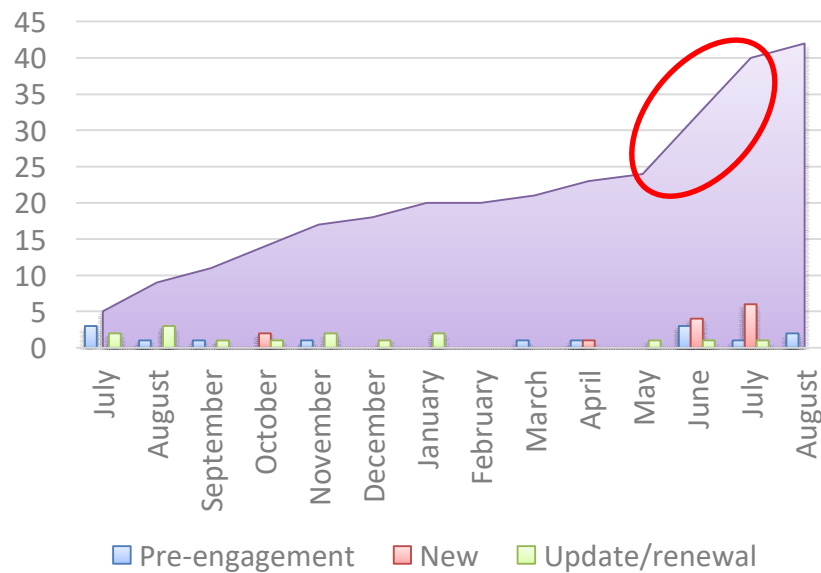
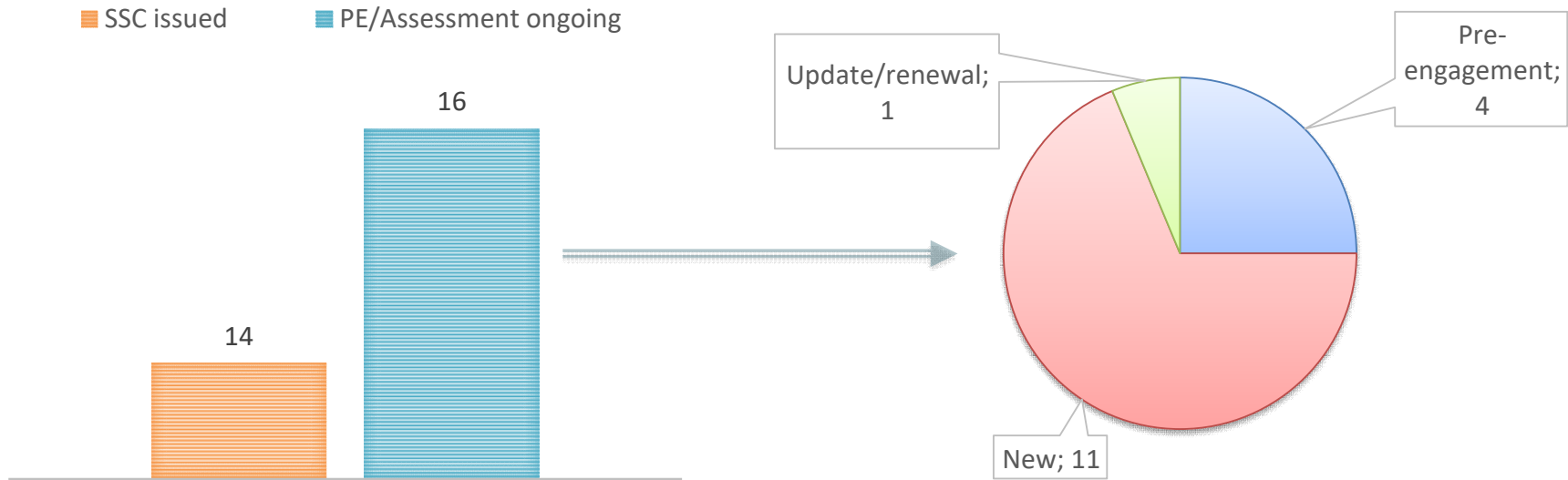
# Questions so far



**Return of Experience since June 2019**

# Return of Experience





**Significant increase of applications!**







ASSESSMENT

A hand holding a blue marker, positioned as if it has just finished writing the word 'ASSESSMENT' on a whiteboard.

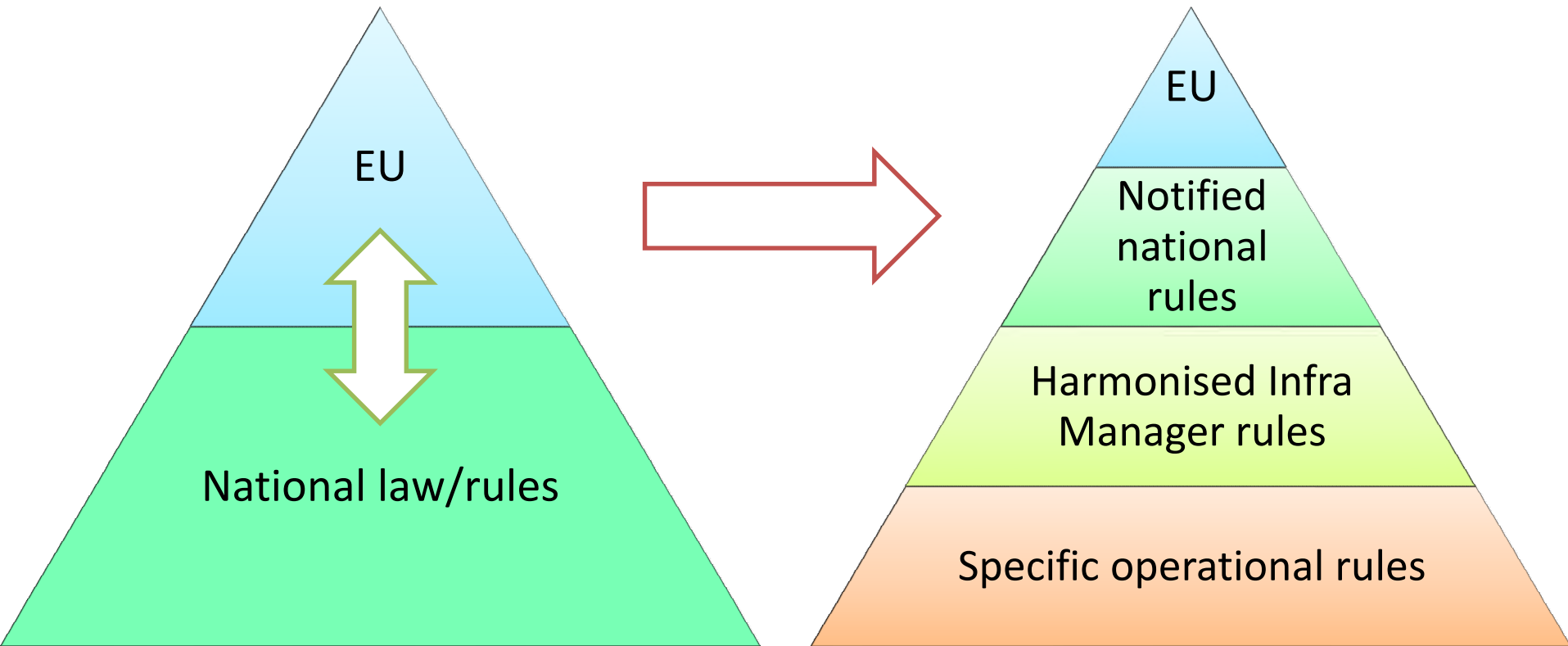
EU Regulations  
National rules



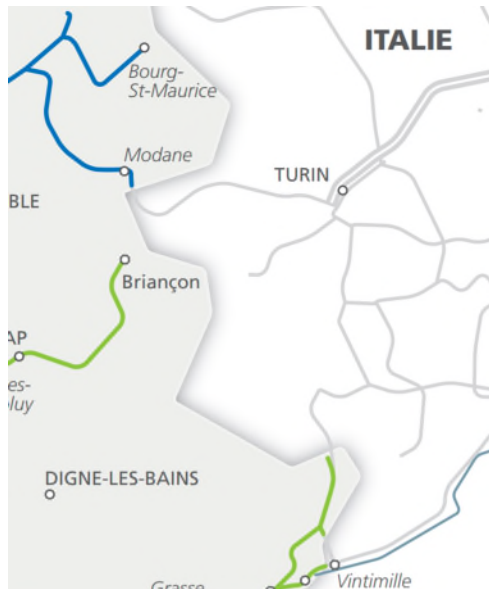
...



- National law vs. national rules
- National rules redundant by EU law (TSI, CST, CSM etc.)
- National rules notified in NOTIF-IT database



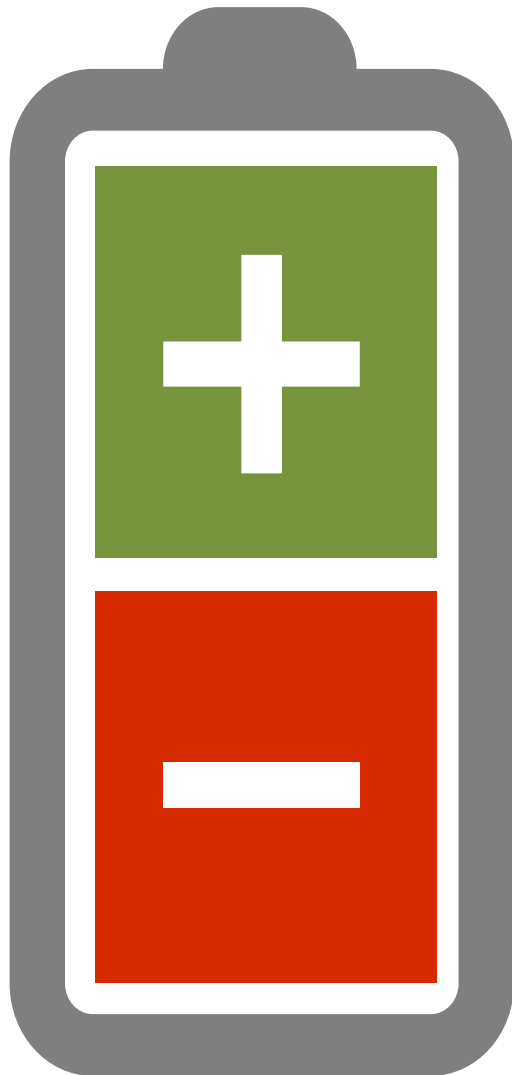
- Concept of border station - A border station is not the same thing as an agreement between member states as to where the real border is (border point)
- Consultation required between NSAs concerned
- NSA to set up specific arrangements, as appropriate, in the cases where the NSA or ERA is safety certification body



- Good information on how the safety management system of the applicant is performing is critical in performing an efficient and effective assessment
- Importance to share the supervision results with a level of details (scope, context, findings) sufficient for ERA to understand the impact on the SMS and to have a targeted approach







- Submission of applications
  - Team assignment and user rights management
  - Use of web forms
  - Publication of certificates
- Ergonomy (complexity)
  - Creation of an application from pre-engagement
  - Notifications
  - Update of the content of the certificate

# Final questions





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