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

Karen Davies

Virtual workshop

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Outline

- 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

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What is new?

What is new?

ERA as new authority

June 2019

One-stop shop

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

OR

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NSA

Single safety certificate

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

ERA organisation

- **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**.

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

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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)

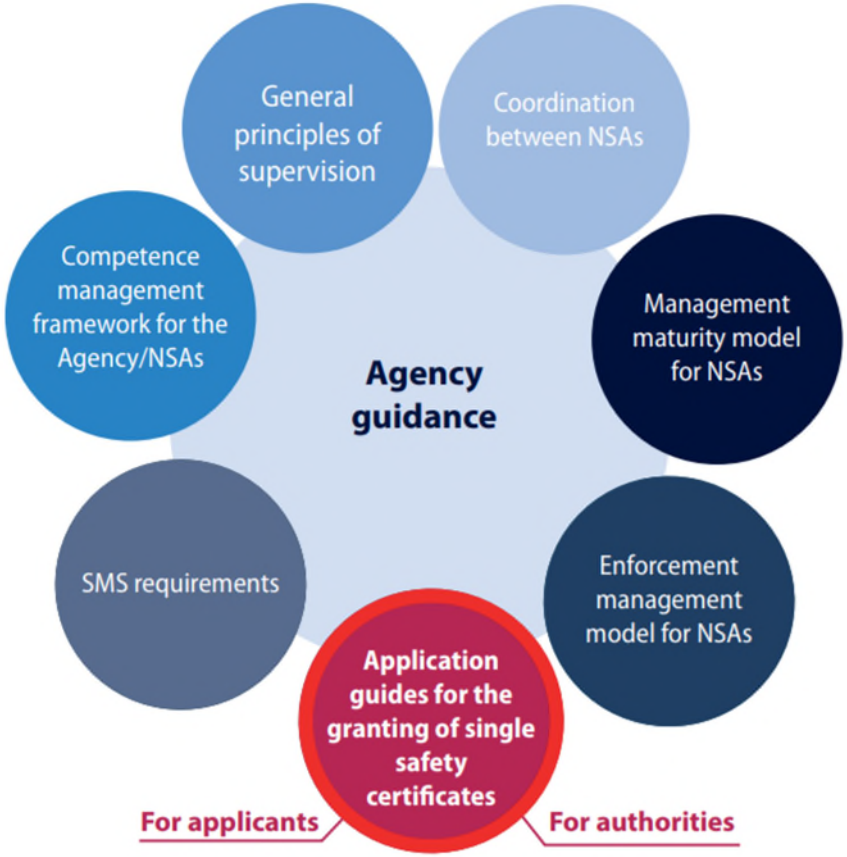
Regulation concerning the International Carriage of Dangerous Goods by Rail (RID)

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

Outline

- Board of Appeal
- Fees and charges

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Board of Appeal

Board of Appeal

Remedies

- 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

Appeal body

- 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.

Board of Appeal

- 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 **appea**l 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.

Board of Appeal

- Any request for arbitration or appeal before the Board of Appeal must be submited to the Registrar of the Board of Appeal (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

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Fees and charges

Fees and charges

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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

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Fees and charges

- 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 r**easonable extension of the time limit for payment and payment by instalments**

Fees and charges

- 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

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Questions so far

NO issues

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.

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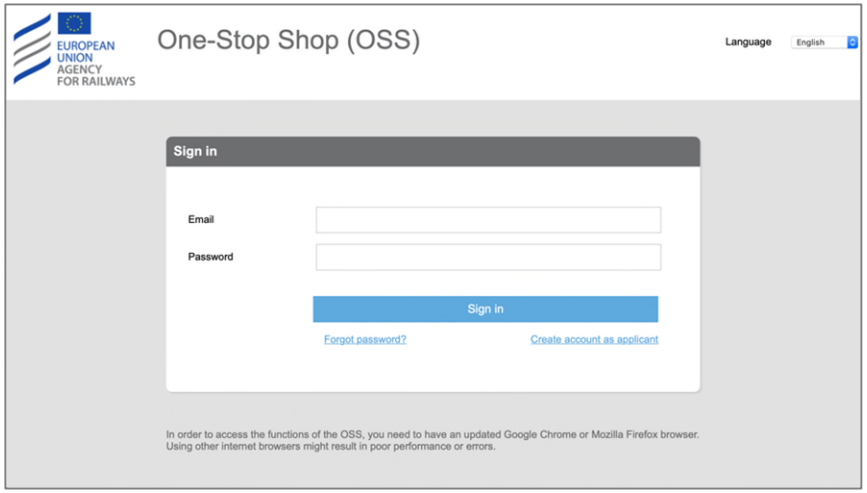
How to apply?

How to apply?

Submission of the application

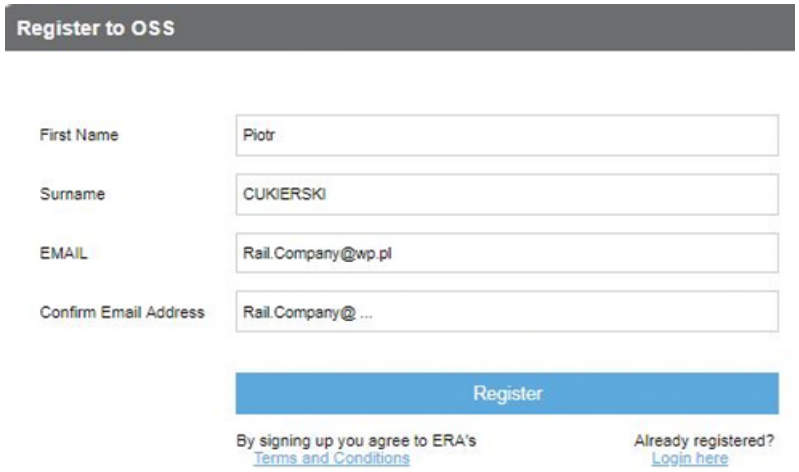
- Railway undertakings submit any application for a single safety certificate through the **one-stop shop** IT tool, available from the Agency website or by using the following URL: https://oss.era.europa.eu/logon.html



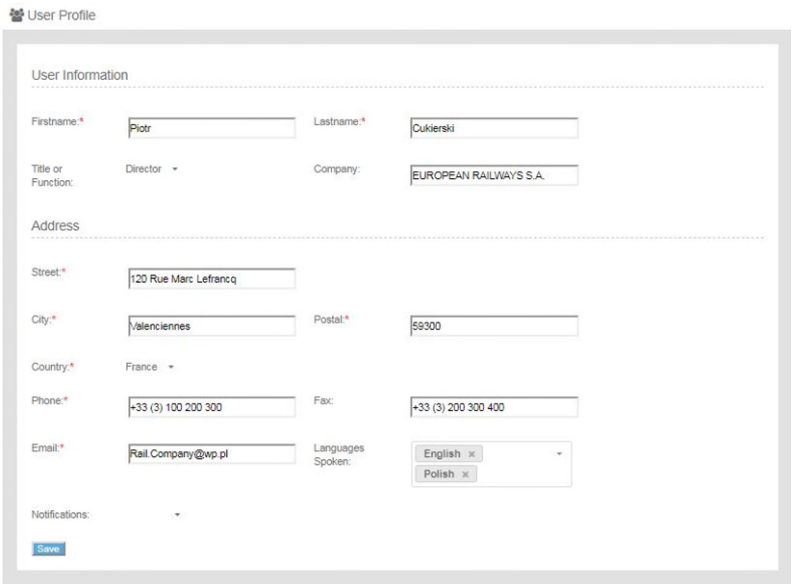
- It is recommended that an application for a single safety certificate is submitted in advance to any possible deadline (at least 6 months)

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

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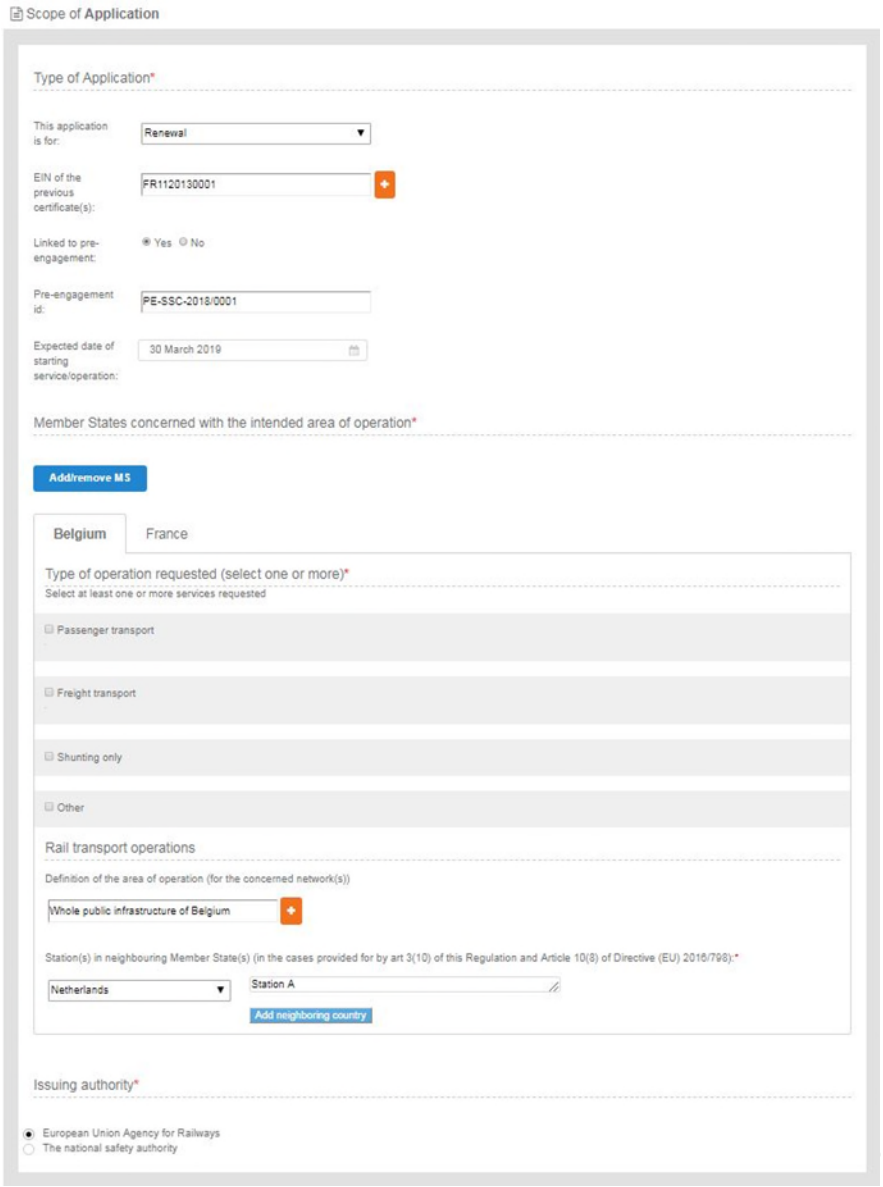
Application Process in the OSS: **step 1**

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

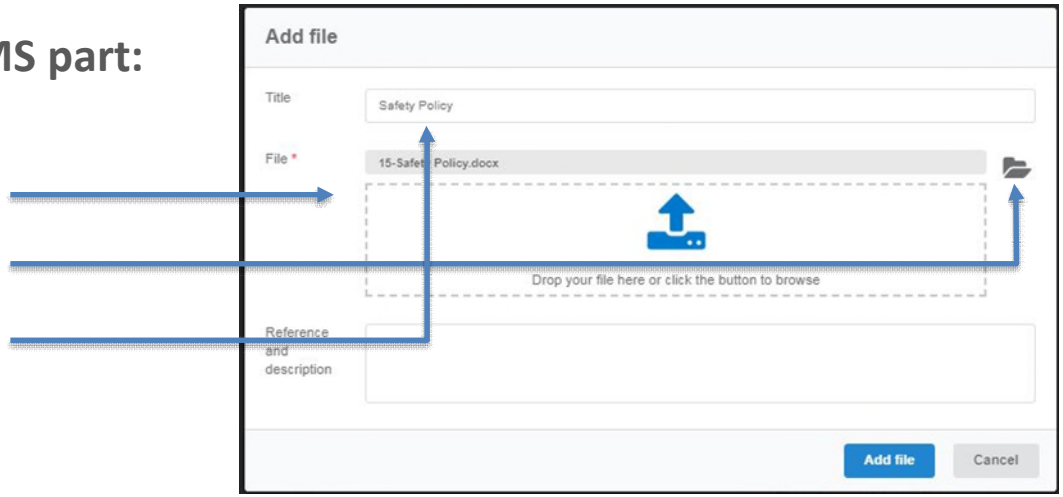
This is covered by the Annex I to Practical Arrangements



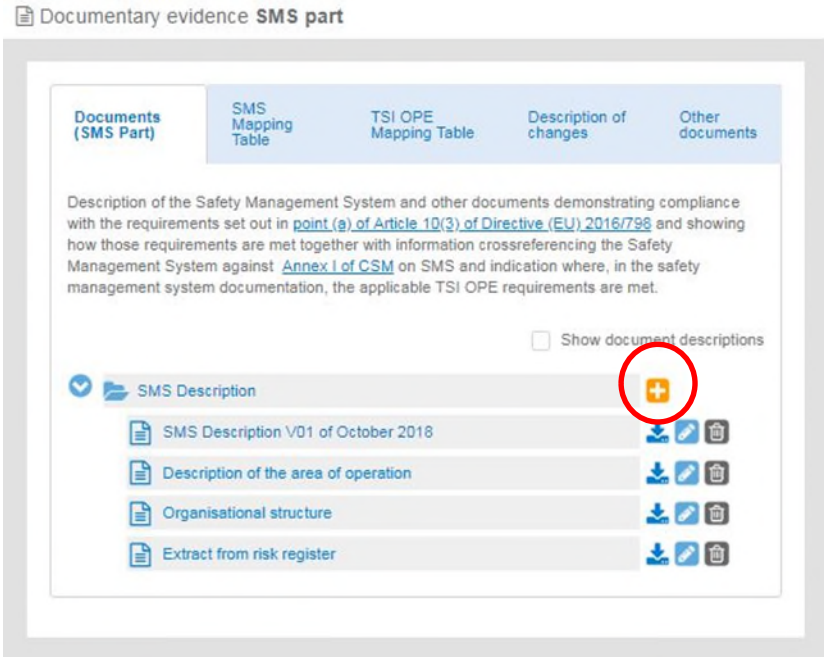
Application Process in the OSS: **step 2/1**

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

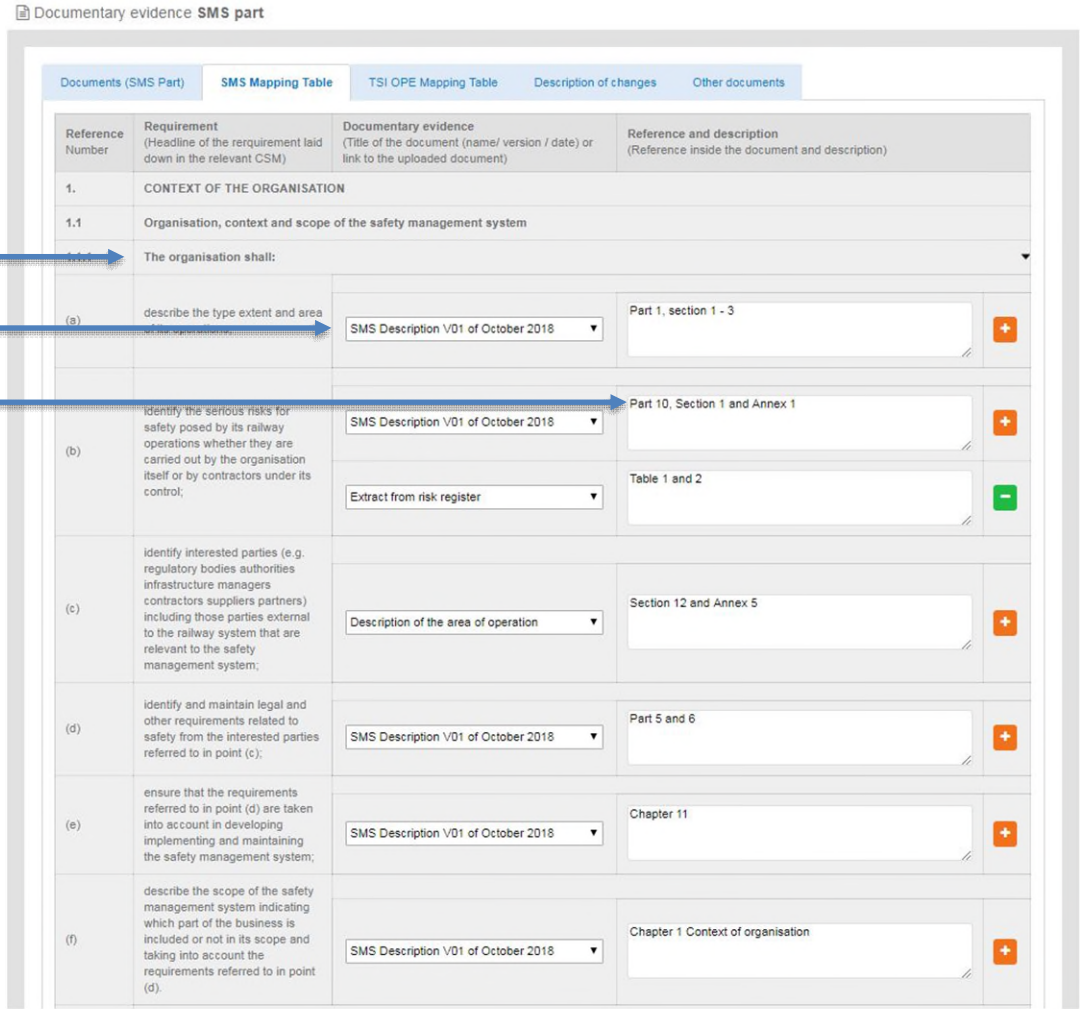


Application Process in the OSS: step 2/2

Cross reference you evidence with relevant requirements:

SMS Requirements

- SMS Requirement
- Your evidence
- Description

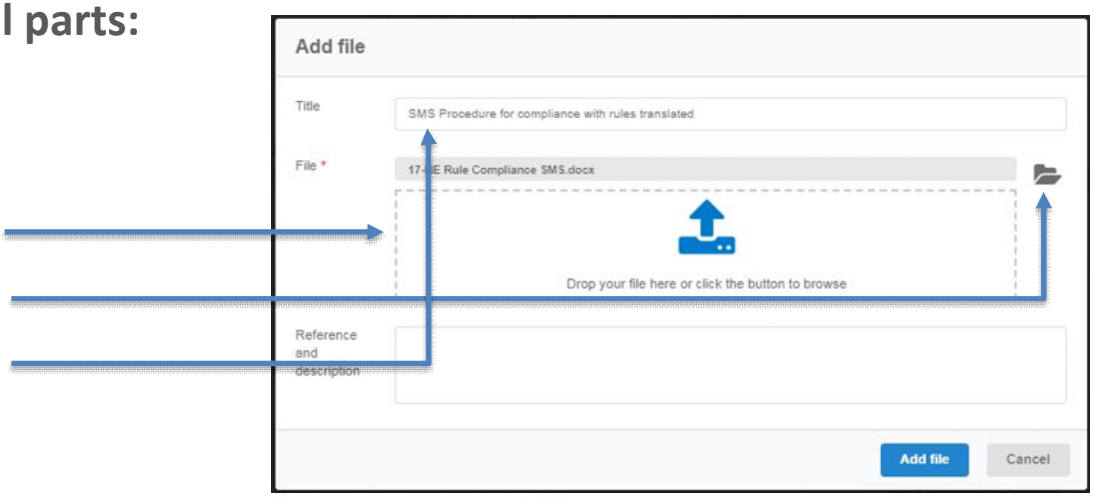


Application Process in the OSS: step 3

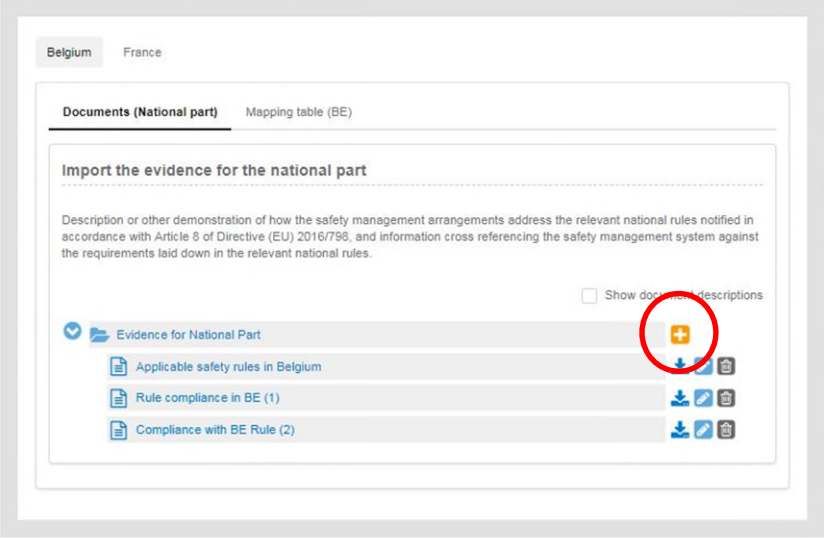
Upload evidence for the national parts:

National requirements

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



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 4

Upload additional documents:

- Legal Entity Form (LEF)
- Any other document

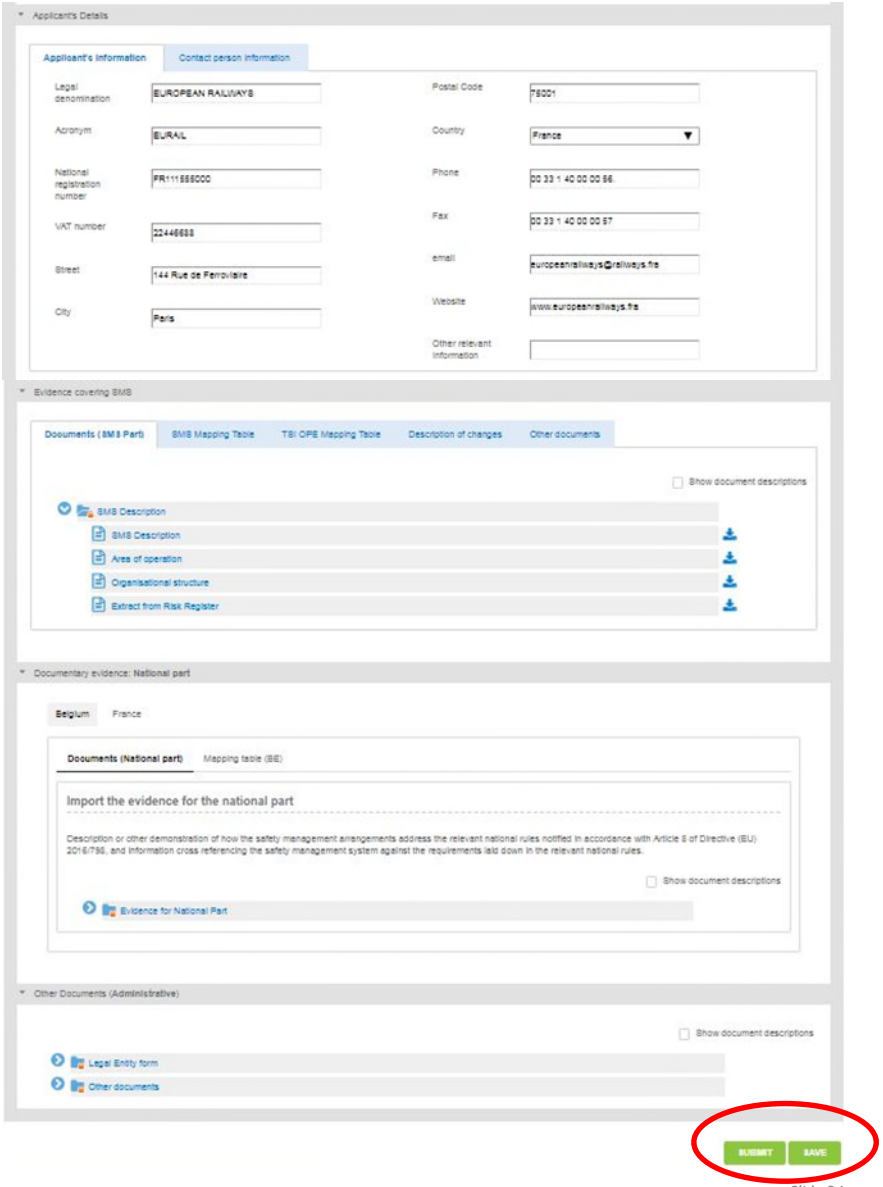
Do not upload here any evidence for SMS or national parts. It's only for administrative and financial documents

Application Process in the OSS: step 5

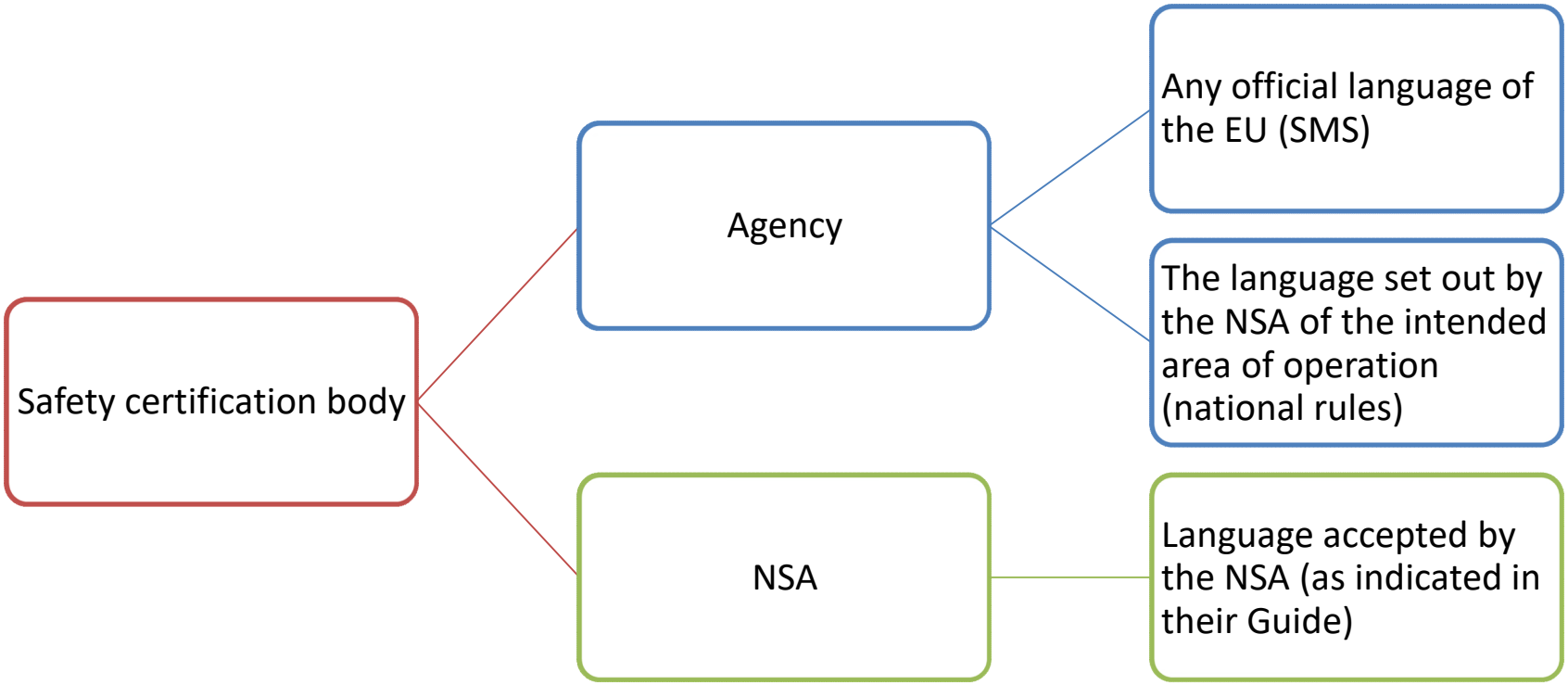
Review + sign + submit:

- 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



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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)

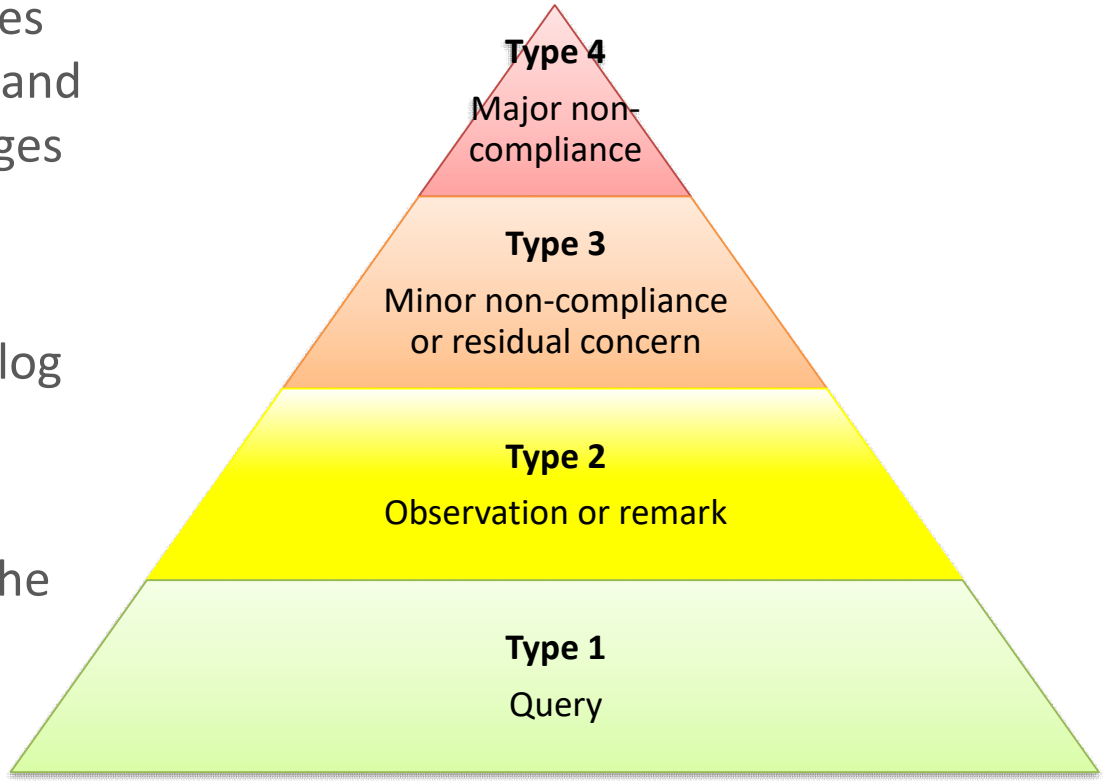
Communication arrangements

- 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

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Questions so far

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Update and renewal of a single safety certificate

Update and renewal of a single safety certificate

Update and renewal

- **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

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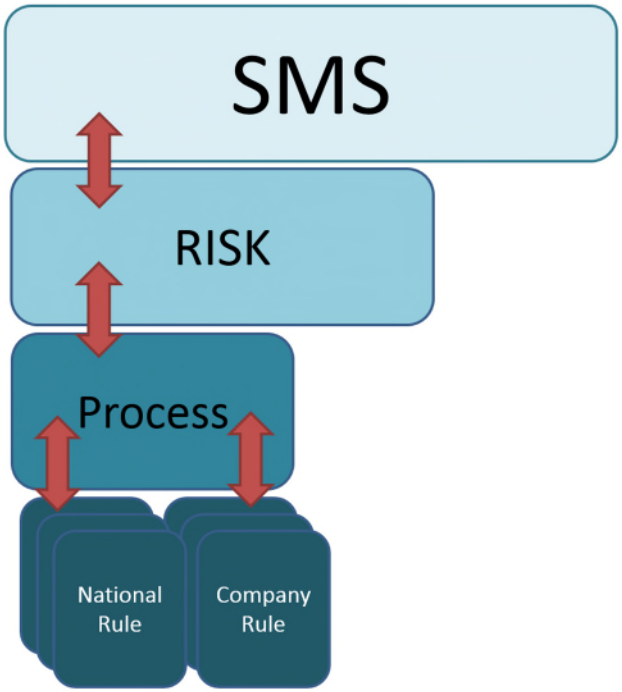
Safety management systems

Safety management systems

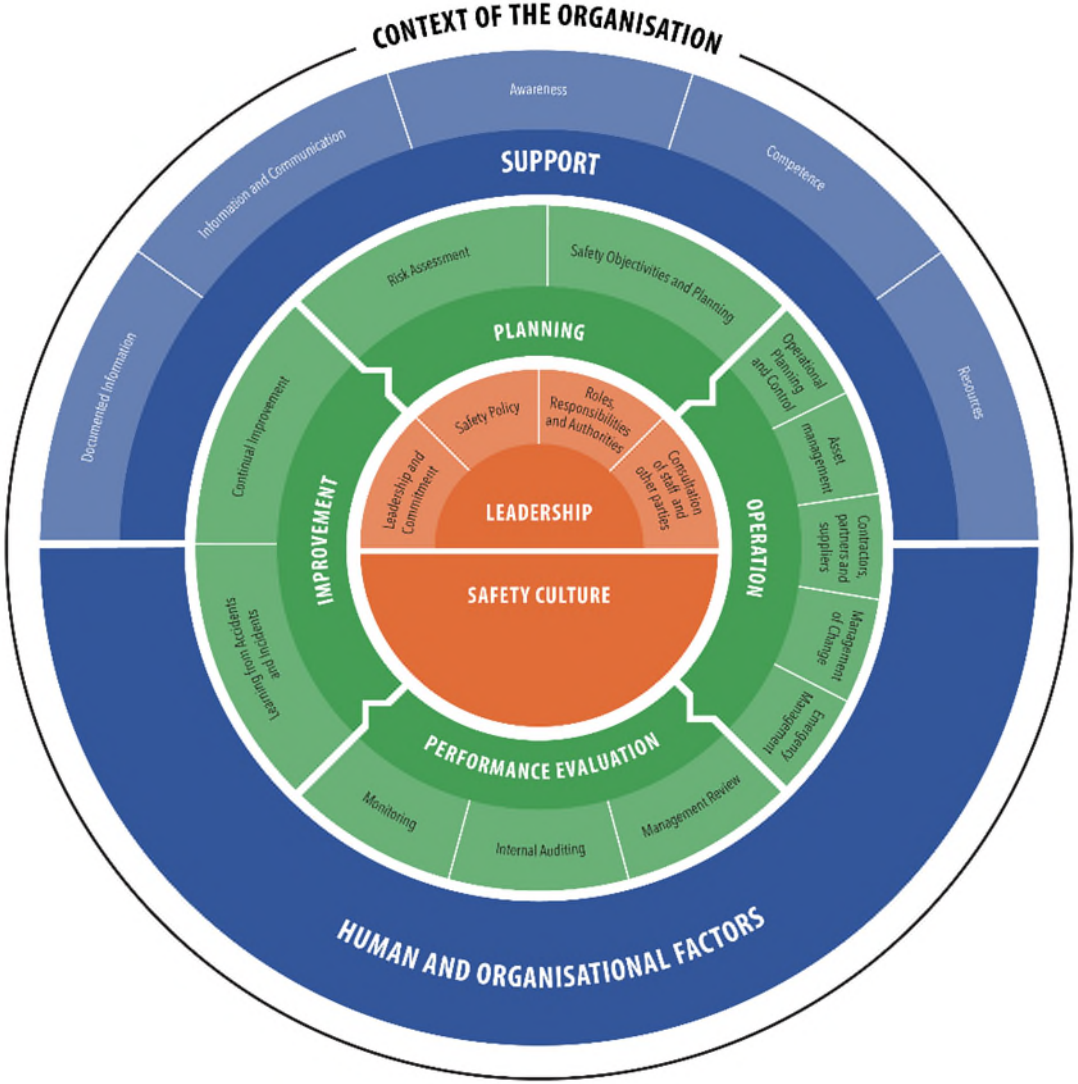
What is a safety management system (SMS)?

- 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

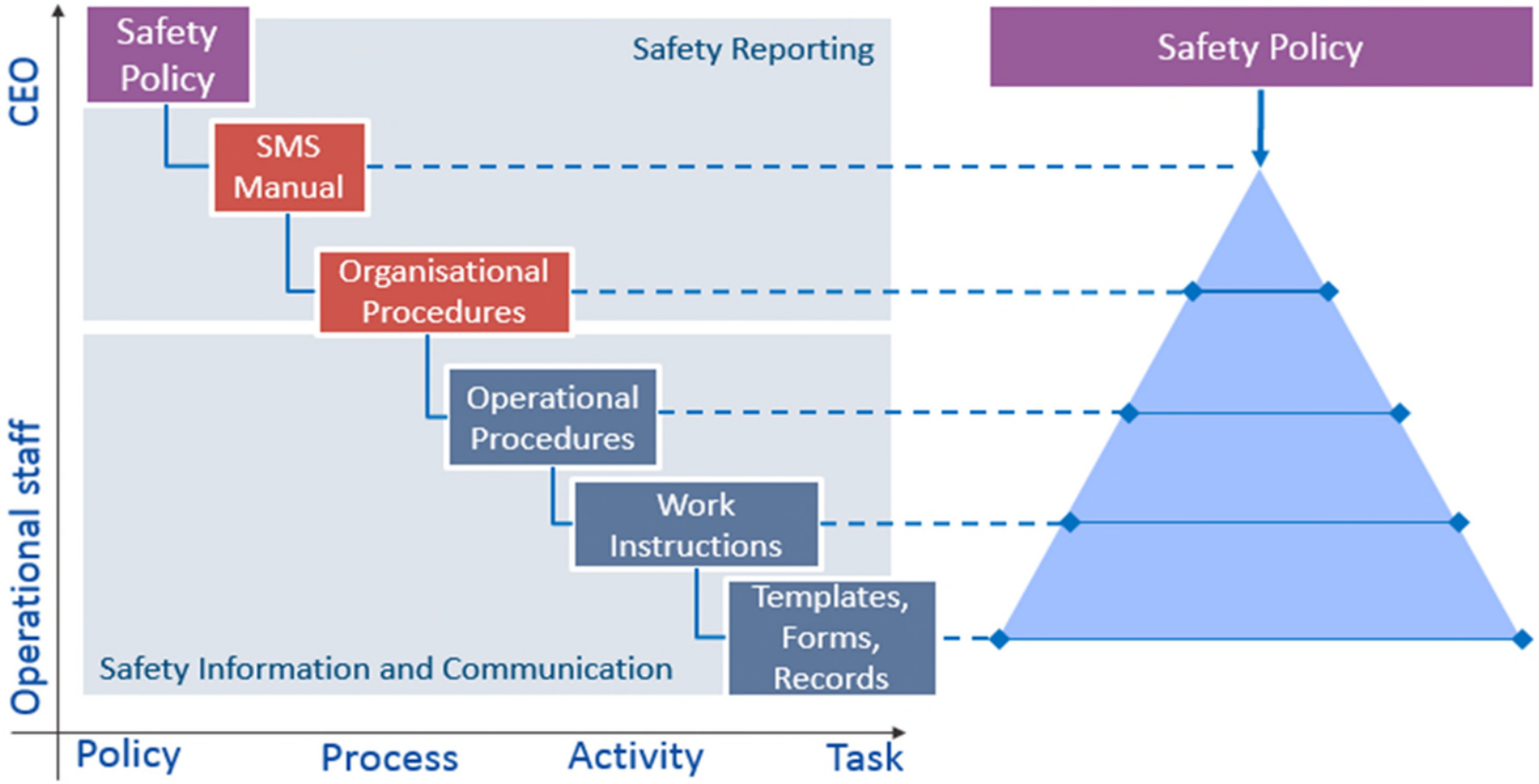


Download on the App Store

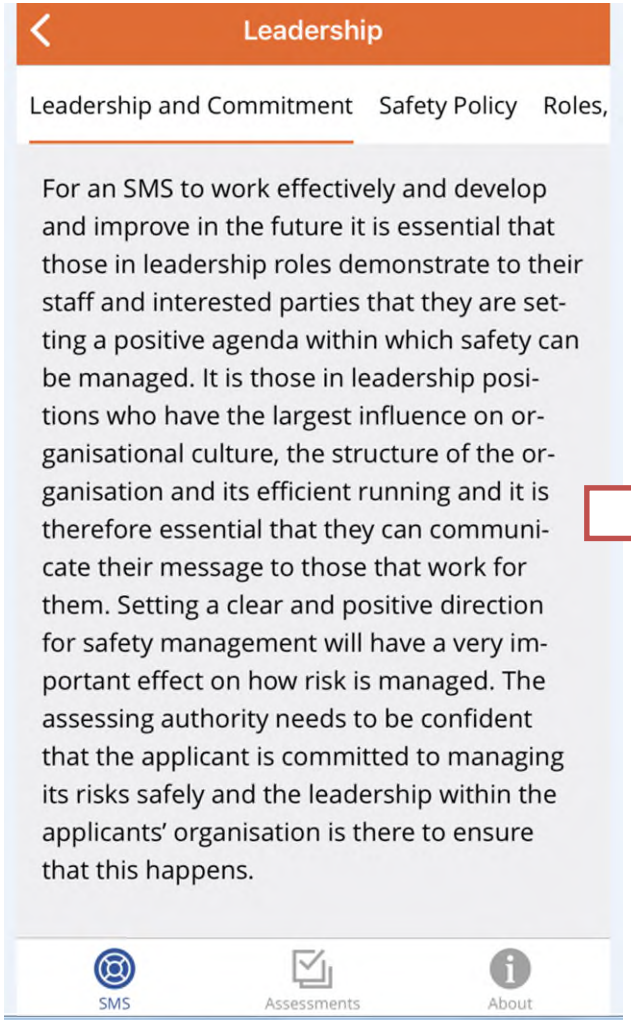
GET IT ON Google Play

SMS content architecture

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



SMS application - leadership



Demonstration of commitment

Communication

Safety culture

Risk management and responsibility

SMS application – safety culture

F1 CONTROL MAJOR RISKS

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.

F2 UNDERSTAND WORKPLACE REALITY

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.

F3 LEARN FROM EXPERIENCE

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.

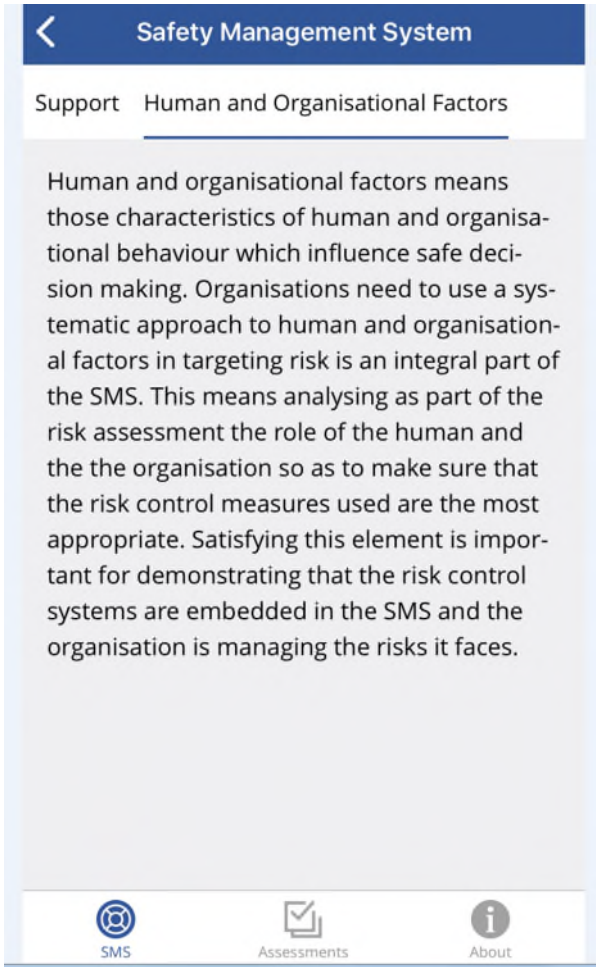
F4 INTEGRATE SAFETY CONSISTENTLY

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.

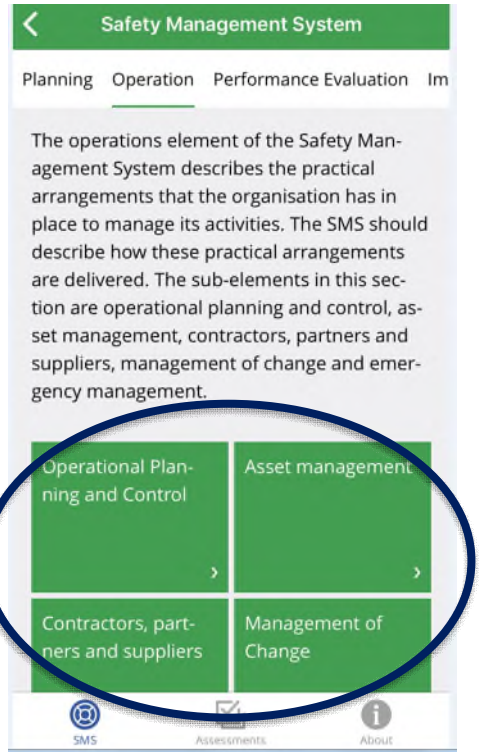
SMS application – Human and organisational factors (HOF)

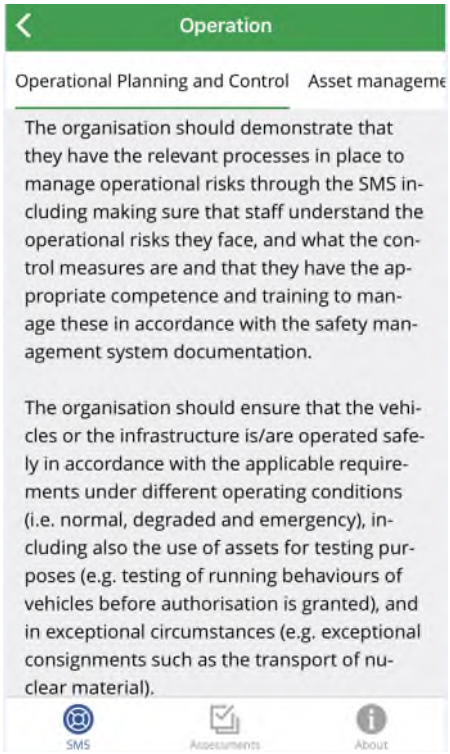


Those HOF factors which influence safe decision making

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 and operations

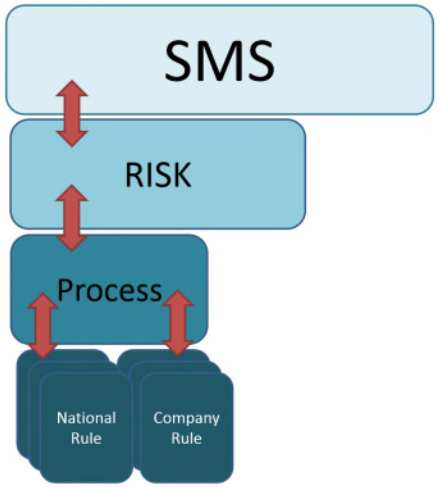
Framework for operations:

- 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

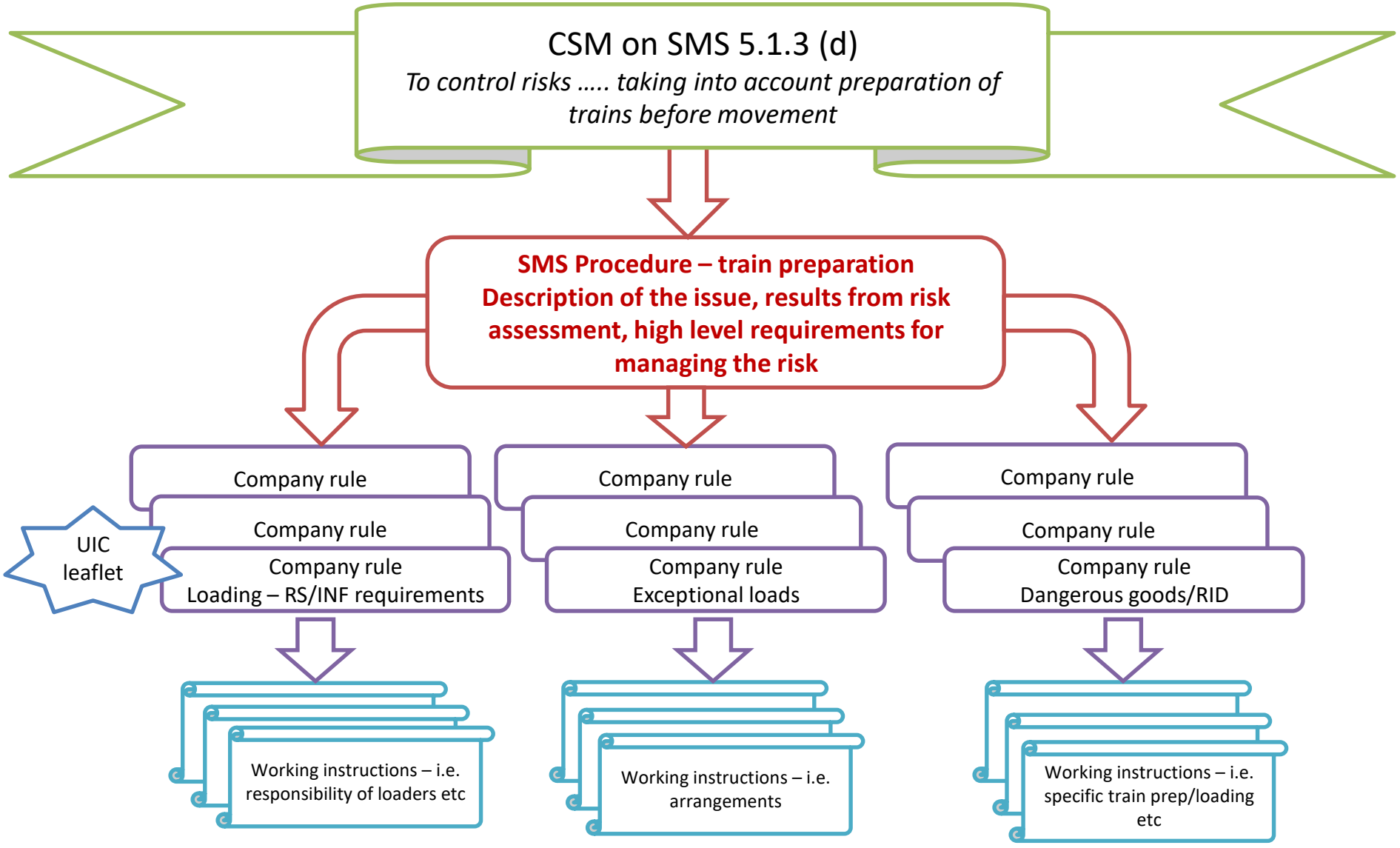
SMS and operational rules

- 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



FAQ & Questions

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

era.europa.eu

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Questions so far

Return of Experience since June 2019

Return of Experience

26

SSC APPLICATIONS (ERA 30, NSA 15)

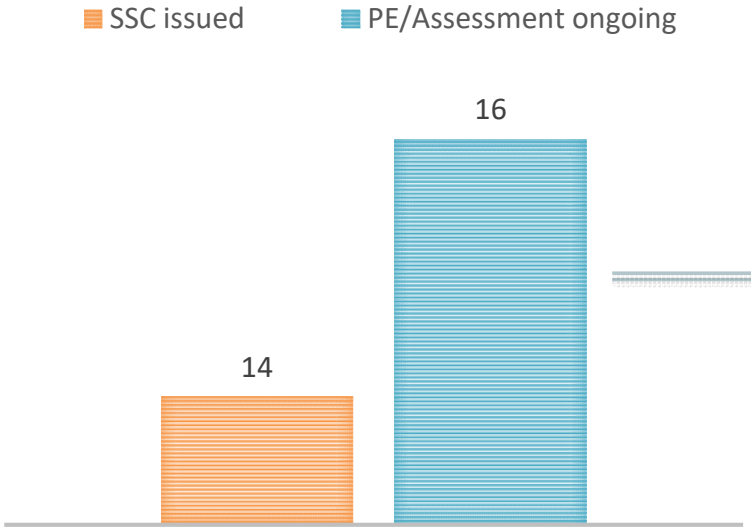
11 SSC issued (ERA 14, NSA 6)

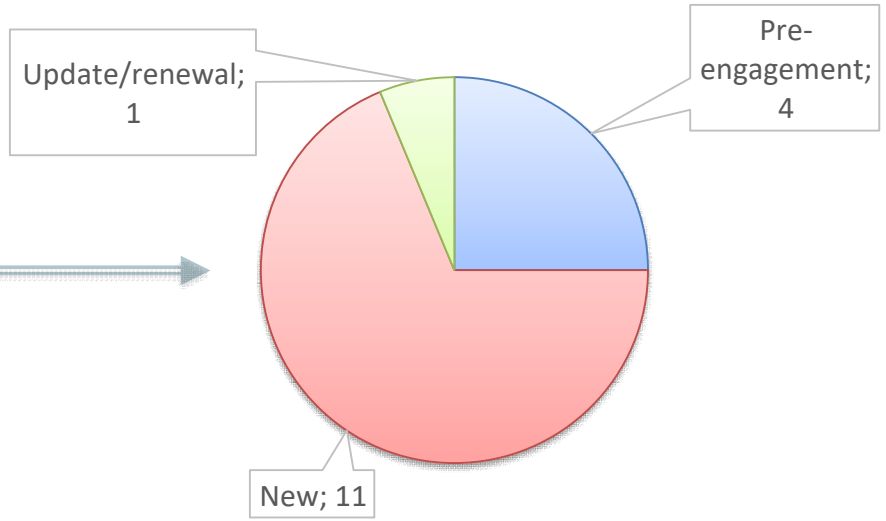
888

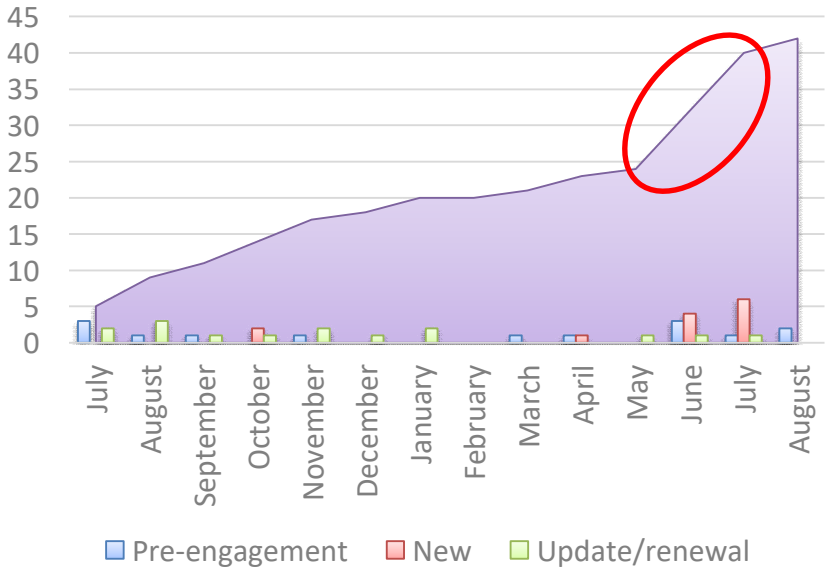
ONE-STOP SHOP USERS

681 applicants, 207 ERA+NSA

Figures







Significant increase of applications!

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Sowing the seeds for success

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First steps… and first challenges

Assessment

Trafik-, Bygge- og Boligstyrelsen
Danish Transport, Construction and Housing Authority

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epsf

Service public fédéral Mobilité et Transports

Eisenbahn-Bundesamt

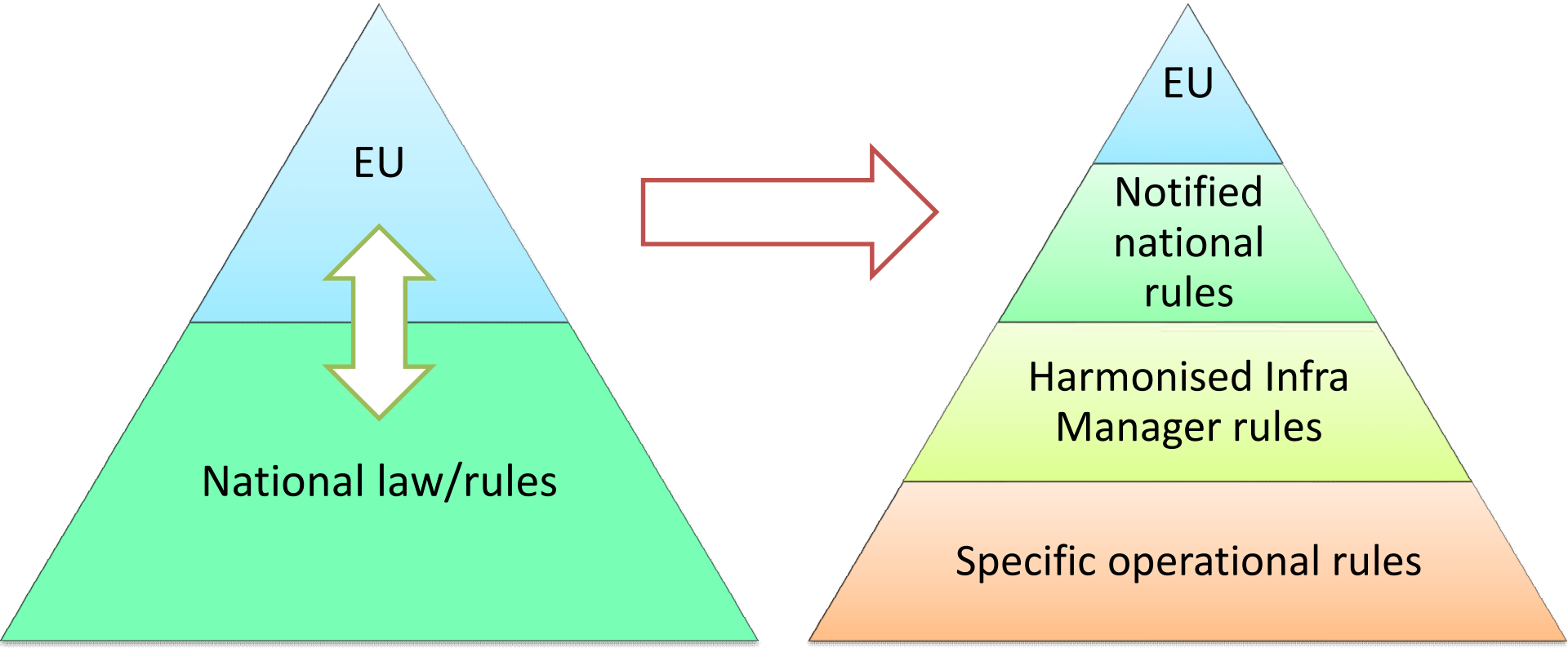
...

EU Regulations
National rules

National rules

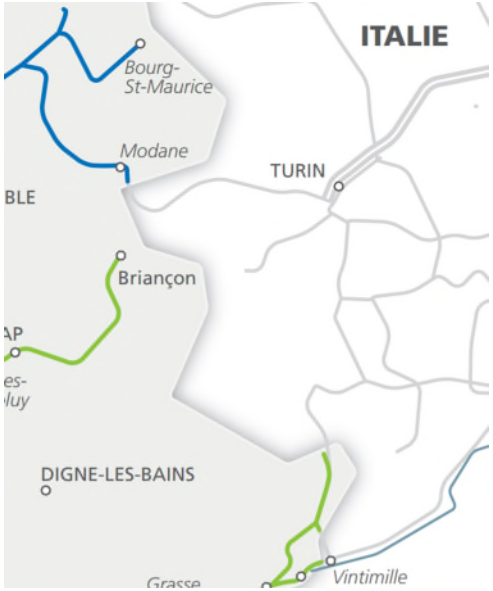
Kør forsigtigt
Caution- Expect stop or
proceed wih reduced speed

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


EU
National law/rules
EU
Notified national rules
Harmonised Infra Manager rules
Specific operational rules

Border stations

- 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



Supervision

- 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

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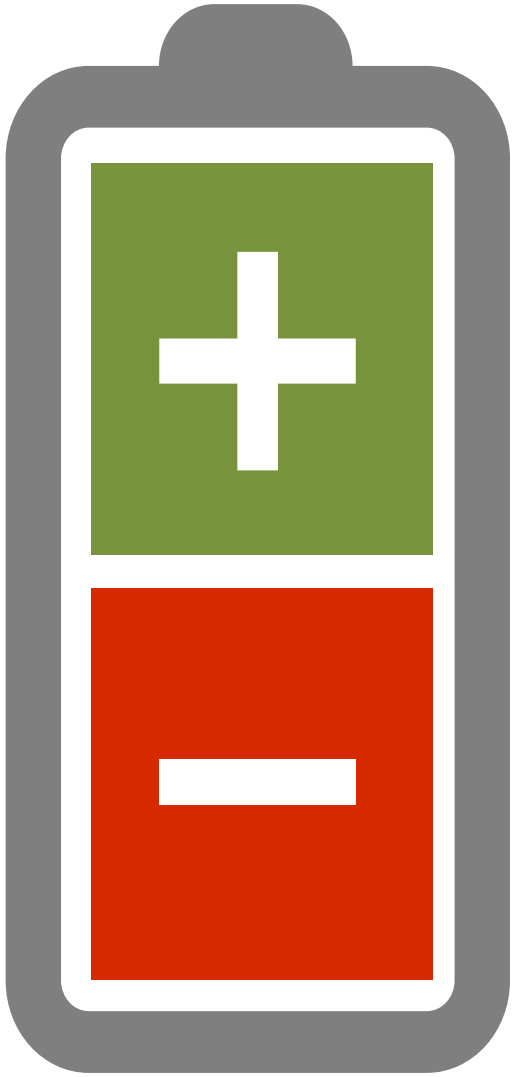
One-stop shop



- Submission of applications
- Team assignement 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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ISO 9001:2015
BUREAU VERITAS
Certification