Dissemination Workshop of the CSM for Risk Assessment

(Regulation No 352/2009)

Vilnius (Lithuania), 29th & 30th January 2013
European Railway Agency
Time schedule for workshop

1st day of workshop

1st day, January 29th 2013 from 9:00 to 17:30

- 09:30: Welcome coffee
- 10:00: Opening of the workshop
- 10:20: Introduction on the European Railway Agency
- 10:50: Place of the CSM for risk assessment in the EU railway legislation
- 11:30: Basics on Risk Management
- 12:10: Lunch Break
- 13:30: Risk Assessment in Regulation 352/2009
- 14:30: Presentation(s) from NSA, RU, IM and/or ECM
- 15:15: Coffee Break
- 15:45: Example of application of Regulation 352/2009 to an organisational change
- 16:45: Plenary session and open discussion with all attendees
Time schedule for workshop
2nd day of workshop

2nd day, January 30th 2013, 9:00 to 15:30

- 09:00: Opening of the workshop
- 09:15: Summary on the main elements of Risk Assessment
- 10:00: Example of application of Regulation 352/2009 to an operational change
- 10:45: Coffee Break
- 11:15: Example of application of Regulation 352/2009 to a technical change
- 12:00: Lunch Break
- 13:30: Presentation of the requirements for a Safety Management System
- 14:30: Plenary session and open discussion with all attendees
- 15:30: End of the workshop
Introduction on the European Railway Agency

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Role of the European Railway Agency

Content

1. Role and work program
2. Work method
3. Impact on national legislation
4. Examples of benefits for the railway sector and society
Role of the European Railway Agency
EU white paper: targets for the regulatory environment

- Creation of the Single European Railway Area
- Removal of administrative and regulatory barriers
  - Full market opening
  - Effective, non-discriminatory, dissuasive enforcement of EU-legislation across all Member States
- Stronger role for the European Railway Agency and strengthening of the National Safety Authorities and Regulatory Bodies
- Effective structural separation: infrastructure management/rail service provision
- Rail Freight Corridors: improved cross-border traffic and infrastructure management
• European Railway Agency (ERA), Valenciennes (F)
• established 2004/2005, approx. 155 staff
• core domains: Interoperability, Safety, ERTMS

Offices in Valenciennes

Conference centre in Lille

Founded by Regulation (EC) 881/2004
Role of the European Railway Agency
The work programme of the Agency aims:
« to make the railway system work better for society »

ERA work programme 2013 (activities)

1. Developing/promoting a common understanding of Safety Management Systems
2. Developing/promoting harmonised principles for accident investigation bodies
3. Developing/promoting a harmonised safety regulatory framework
4. Monitoring of railway safety performance: processes and outcome
5. Facilitation of Vehicle Authorisation
6. ERTMS System Authority
7. Technical Specifications
8. Railway Staff
9. Shared Databases and registers
10. Monitoring Interoperability
11. Economic Evaluation of Agency products

ERA main products

- SMS guideline
- Common Safety Methods
- Risk Acceptance criteria
- Accident investigation guide
- ECM certification scheme
- Technical Specs for Interop. (TSIs)
- Parameters for vehicle authorisation in MS + cross acceptance
- National legal frameworks on authorisation processes
- Databases/registers
- ETCS Baseline 3 + GSM-R
- TSIs: TAF + TAP, PRM, OPE

ERA strategic objectives

- Single Safety Certificate
- Simplified Vehicle Authorisation
- Single EU train control system
- Meeting EU customer’s needs
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Role of the European Railway Agency
Regulatory framework

Interoperability Directive (2008/57/EC) and TSIs

NEW approach (Decision 2008/768/EC)

2007/59/EC

Other European legislation (like 89/391/EC, 2008/68/EC)

2001/14/EC

Safety Directive (2004/49/EC) and CSMs

2008/57/EC
Article 3 of Agency Regulation (EC) N° 881/2004 obliges Agency to set up working groups according to tasks given in regulation and by Agency Work Programme.

* List established by Article 21 Committee on 22 February 2005
No decision power for the Agency. The Agency gives recommendations to the Commission and technical opinions upon specific request!

European Railway Agency

- Working Party (CER, EIM, UNIFE, NSA, ...)
- NSA Network ...
- Internal reconcilement ...

Role of the European Railway Agency

Decision Process (Commitology)

Adoption

- Parliament Scrutiny
- Commission / RISC
- Agency Recommendation

Social Partners
Passengers/Customers
Composition:

- 1 representative per Member State
- 4 Commission representatives
- 6 representatives of sector organisations (RUs, IMs, industry, trade unions, passengers, freight customers) – *no voting rights*
- Norway as EEA state – *no voting rights*
- Croatia: observer since March 2012 – future member as of 1 July 2013

Powers:

- Appoints the Executive Director
- Adopts the Annual report and gives an opinion on the annual accounts for the previous year
- Adopts the Work programme and the budget for the following year
- Adopts the internal control standards for the Agency

Sub-Committee on budgetary, financial and staff issues (since 2009)
Role of the European Railway Agency

Legal framework: Ultimate goal in EU Directives

Safety Management System of Infrastructure Manager

Complete set of common rules (TSIs, CSTs, CSMs, etc.), no exceptions

Coordinated interfaces and company (operating) rules

Information

Safety Management System of Railway Undertaking

Route book

Rule book
Role of the European Railway Agency
Legal framework: Ideal situation in transition period

Safety Management System of Infrastructure Manager

Common rules (TSIs, CSTs, CSMs, etc.) with some exceptions and:

NSR and NTR for these exceptions

Coordinated interfaces and company (operating) rules

Information

Safety Management System of Railway Undertaking

Route book
Rule book
Role of the European Railway Agency

Legal framework: Need to clarify uncertainties & remove obstacles

Safety Management System of Infrastructure Manager

Common rules (TSIs, CSTs, CSMs, etc.) with some exceptions and

In transitional period:
NSR and NTR for these exceptions

Current situation:

Coordinated interfaces and company (operating) rules

Information

Safety Management System of Railway Undertaking

Route book

Rule book
National Rules may only cover exceptions in EU law =
National Rules may remain … until covered by EU law

Scope for National Safety Rules today:
- Some operating NSR
  - As allowed by OPE TSIs, Directive 2008/68/EC and RID (transport of dang. goods)
- Risk acceptance criteria
- Criteria for significant change

Scope for National Technical Rules today:
- open points in TSIs
- derogations from TSIs
- « generic » specific cases in TSIs
- OFF-TEN network, when still no TSI
- NTR for rolling stock (EC Decision 2011/155/EU)

Specific railway safety requirements
Only mandatory rules, made binding by law
Implementing essential requirements for interoperability

Priority: Common rules → report deficiencies to the Commission
Temporary measure: National Rules → notify in draft before adoption
Now - 25 fire extinguishers in each cab
- A different one for each country

With Cross-Acceptance
- Only one in each cab
- because any one of the 25 extinguishers is capable of meeting the essential requirement of putting out a fire
A visible success:

October 2010

250,000 down to 70,000 train border stops

from 2011 onwards

Freight trains stopped at border points

Free movement of freight trains

Legend
- Lamp
- Reflective plate
- Arrow
Role of the European Railway Agency
Application of EU tools will reduce vehicle authorisation costs

Mn EUR/year for loco authorisation (EU total)

Each scenario ceteris paribus

- **Status Quo incl. TSI**
- **Common application (DV 29 effective)**
- **Cross Acceptance fully applied**
- **no more open points in TSIs**
- **scope extension to the full network**
- **Full technical harmonisation**

**Stage 1**
- Open systems

**Stage 2**
- One system

**Evolution**

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Slide n° 19
The EU framework makes a difference at European level

- The Agency has developed a number of measures that are under implementation (CSI, CSM, CST, certification schemes, etc.)
- **BUT**: the regulatory framework must be put in place in Member States and applied consistently

The Agency represents a centre of competence for

- Exchange of experience and demonstration of good examples
- Conducting discussions based on facts
- Understanding of differences in safety culture
- Collecting and publishing information
Many thanks for your attention!

Q & A

You have Questions
We have Answers

Place of the CSM for risk assessment in the EU railway legislation

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1°) Open the railway market to competition for the rail transport services and the railway supply industry!

2°) Remove historical barriers to free circulation of trains and make railways business oriented and competitive!

3°) Prevent the sector from using safety as a barrier to market access or an excuse to resist change!
1. At least maintain the existing level of safety in the EU railways, and increase it when reasonably practicable

2. Create a basis for mutual trust
Cornerstones in EU legislation for market opening

- Technical harmonisation (interoperability)  
  TSIs – NOBOs – DEBOs

- Separation of former vertically integrated railway companies  
  RUs – IMs

- Change from self-regulated railways to regulation by public authorities  
  Regulatory Body + NSA (safety regulator)

- Introduction of a framework for entry into market for railway undertakings  
  Licensing & Safety Certification

- Maintain at least, and increase when reasonably practicable, existing safety level and create a basis for mutual trust  
  Development of common approaches to safety [SMS & CSMs]

- Transparency of safety data  
  CSI, CST & CSMs
Main stakeholders resulting from railway market opening

Incumbent Railway Company

NSA

+ 

RU & IM

+ 

ECM

Keepers

Manufacturers Suppliers

NoBos

DeBos

Customers (Passengers & Freight)

CSM Assessment Body

ECM Certification Body

National Investigation Body
When opening the railway market, in order to:

1) Maintain at least the existing level of safety in the EU railways, and increase it when reasonably practicable

2) Create a basis for mutual trust with many new railway actors and interfaces

- It is necessary to set up a common approach for:
  - safety regulation
  - safety management
  - safety supervision

in line with the "new Commission approach" for the creation of a single European railway market
Common approach to safety within an open railway market

EU railway legislation

Safety Regulation

Safety Management

Safety Supervision

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- Existing national railway systems usually based on use of rules and retrospective review of «bad experiences»

- Directive 2004/49 introduces concepts of risk and requiring to LOOK both forward and retrospective

- Instead of thinking in «reacting and fixing» «predict» what can happen and then «prevent» it to happen

- → only new element from existing national railway systems: develop a «predict and prevent» way of thinking

- Key question: «What are the likely risks and the risk control measures I should put in place to manage safely my activities?»
Common Safety Regulation
Concerning RUs and IMs, in Directive 2004/49:

- Article 4(3): "... RUs and IMs responsible for safe operation of railway system and control of risks associated with their activities. Where appropriate they shall cooperate with each other..."

- Article 9(2) & Annex III: "...requirements and basic elements for SMS..."

- Article 10 & 11: SMS certified by a National Safety Authority

Concerning ECMs, in Directive 2004/49 2008/110:

- Article 14a(1): "Each vehicle, before placed in service or used on network, shall have an assigned & registered ECM..."

- Article 14a(3): "...to ensure that vehicles are in a safe state of running, ECM must have a system of maintenance..."

- Article 14a(4): "in case of freight wagons, ECM shall be certified by a body accredited or recognised ..., or by a NSA..."
Common approach for Safety Regulation in all Member States
Safety Certification of RU SMS & Safety Authorisation of IM SMS

- **RU's**
- **IM's**

**Certification Bodies**

- NSA [home country]
  - Part A + B
- NSA [foreign country]
  - Part B

**Implementation of an SMS and network-specific provisions**

- **RU's**
- **IM's**

**High-level initial assessment and granting of certificate**

- **RU's**
- **IM's**

**Support**

- **SMS Guidelines** (published by Agency)
- **Network specific guidelines** (published by network or MS)

**CSM for Conformity Assessment**

i.e. vs. Regulations 1158/2010 & 1169/2010 containing legally binding Criteria and Procedures for Conformity Assessment by NSA + General Principles for post-award supervision

- According to Articles 10 & 11 of Directive 2004/49
- Art. 9 & Ax III of Directive 2004/49

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Slide n° 32
Common approach for **Safety Regulation and Safety Surveillance** of ECM System of Maintenance

- System of Maintenance Procedures
- Accredited or Recognised ECM Certification Body or NSA
  - High level assessment
  - Safety Certification
  - ECM
- Implementation of SMS Procedures
- Implementation of System of Maintenance Procedures

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Common Safety Supervision
Common approach for **Safety Supervision** of RU/IM SMS by the National Safety Authority

**SMS Procedures**

- **Certification**
  - Implementation of SMS Procedures
  - Safety Authorization
  - Safety Certificate

- **Post-award supervision**
  - Monitoring of Safety Performance
  - Using CSM for Supervision (1077/2012)

**Safety Performance**

- Post award supervision of delivery

**Using CSM for conformity assessment**

(1158/2010 & 1169/2010)

**IM**

**RU**

**NSA**
Common approach for Safety Regulation and Safety Surveillance of ECM System of Maintenance

System of Maintenance Procedures

Accredited or Recognised ECM Certification Body or NSA

Implementation of SMS Procedures

High level assessment

Accredited or Recognised ECM Certification Body or NSA

Annex III of ECM Regulation 445/2011

Implementation of System of Maintenance Procedures

Safety Performance

Post-award surveillance

ECM

Monitoring of Safety Performance

Annex III of ECM Regulation 445/2011

Post award surveillance of delivery

Monitoring of Safety Performance

ECM
Common Safety Management
Conclusions about SMS

- **A documented and structured framework** for safe management of all company activities

- Ensures appropriate **processes, procedures, and rules** exist for controlling all company risks

- Enables identification of hazards and **continuous management** of risks related to the company activities, with the **aim of preventing accidents**

- Uses scientific "**risk management**" tools to support company managers in taking consciously decisions for their business
Common Safety Methods
Article 6(3) of Directive 2004/49/EC

How many CSMs are there?

- Harmonised method for assessing safety performance of Community railways
  - CSM for assessment of achievement of safety targets *(for ERA)*
    [Art. 6(3)(a) & Art. 3(f)] → Decision 2009/460

- Harmonised approach for certification of RUs/IMs ability to manage safely their activity, including checking of their effectiveness:
  1. CSMs related to implementation of an **SMS by RUs and IMs** in accordance with Article 9 and Annex III of Directive 2004/49/EC
    - CSM for risk assessment [Art. 6(3)(a)] → 352/2009
    - CSM for monitoring [Art. 6(3)(c)] → 1078/2012
  2. CSMs related to certification and supervision **by NSAs** of RU/IM SMS
    - CSM for conformity assessment [Art. 6(3)(b)] → 1158/2010 & 1169/2010
    - CSM for supervision [Art. 6(3)(c)] → 1077/2012

- Harmonised approach for certification **system of maintenance** *(ECM)* of entities in charge of maintenance [Art. 14a(4)] → 445/2011
Basically CSM is an iterative process made of 3 steps:

(a) Identification of hazards, associated safety measures and resulting safety requirements

(b) Risk analysis and risk evaluation based on exiting risk acceptance principles

(c) Demonstration of the system compliance with the identified safety requirements

Necessary requirements for mutual recognition:

(a) Hazard Management

(b) Independent Assessment (Assessment Body)
Main steps in the process:

(a) **definition** of a strategy, priorities and plan(s) for monitoring;

(b) **collection and analysis** of information;

(c) **definition of an action plan**, for the identified non-compliances that are not acceptable;

(d) **implementation** of the action plan, if such plan is defined;

(e) **evaluation** of the effectiveness of the action plan measures, if such plan is defined.

Action plan includes review of its impact on monitoring strategy, priorities and plan(s) or on RU/IM SMS [ECM system of maintenance].
Main steps:

(a) develop a supervision strategy and plan;
(b) collect and analyse information from a wide variety of sources;
(c) use outcomes of supervision to deliver requirements under Article 16.2(f);
(d) review strategy and plan in light of experience;
Use of Regulation 352/2009

(CSM for risk assessment)
WHO? CSM shall be applied by the proposer who can be [Art. 3(11)]:

(a) a railway undertaking or an infrastructure manager which implements risk control measures in accordance with Article 4 of Directive 2004/49/EC;

(b) an entity in charge of maintenance which implements measures in accordance with Article 14a(3) of Directive 2004/49/EC;

(c) a contracting entity or a manufacturer which invites a notified body to apply the “EC” verification procedure in accordance with Article 18(1) of Directive 2008/57/EC or a designated body according to Article 17(3) of that Directive;

(d) an applicant for an authorisation for the placing in service of structural sub-systems [Manufacturer, RU or Keeper];


Directive 2008/57 - Authorisation for placing in service (APIS)
The obligation for RUs/IMs to have a risk assessment process in place is a basic element of the SMS in Annex III of directive 2004/49/EC.

Article 9 requires that "IM and RU shall establish their SMS..."


Annex III(2)(d): "Procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations"

One of the SMS processes in Annex III

RU and IM SMS will thus achieve the compliance with the procedures and methods required by the associated "conformity assessment criteria" [developed by ERA Safe Certification Sector] by referring to the CSM on Risk Assessment.
Article 15 requires among others that before authorising "the placing into service of those structural subsystems constituting the rail system which are located or operated in its territory", "in particular" the Member State "shall check":

- "the technical compatibility of these subsystems with the system into which they are being integrated",
- "the safe integration of these subsystems in accordance with Article 4(3) and Article 6(3) of Directive 2004/49/EC".

**Article 4(3) of Directive 2004/49/EC:**
"Member States shall ensure that the responsibility for the safe operation of the railway system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings,..."
"Without prejudice to civil liability in accordance with the legal requirements of the Member States, each infrastructure manager and railway undertaking shall be made responsible for its part of the system and its safe operation,"

**Article 6(3)(a) of SD referred to also in Articles 23(5) and 25(4) of ID**

**Article 6(3)(a) of Directive 2004/49/EC:** "The CSMs shall describe how the safety level, and the achievement of safety targets and compliance with other safety requirements, are assessed by elaborating and defining risk evaluation and assessment methods"
Roles and responsibilities for placing in service

Safe Integration

Authorisation Process for Vehicles

Manufacturer: design, production and testing

RU: checks technical compatibility and safe integration with the network

RU: placing in service, operation and maintenance

Technical File
Operational and Maintenance rules

Technical compatibility and safe integration within the vehicle

TSI, NNR conformity check: NoBo, DeBo

CSM Risk Assessment: Assessment Body

Technical compatibility and safe integration with infrastructure

Done by RU with RINF/NNR/RA

RU SMS
ECM MMS

Supervision by NSA

NSA Authorisation for placing in service

RU decision of placing in service

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Slide n° 50
When making a **change** ask yourself whether change is significant [Article 4]

1) **Not significant:**
   a) because *not safety related*: document for transparency reasons;
   b) *safety related* but not significant because *activities well known and under control*

   → SMS obligation to demonstrate that all risks related to change are managed. Proposer applies his procedures/process for risk management

2) **Significant** → apply Regulation 352/2009
Applicant = either Manufacturer or Railway Undertaking

- Case 1: Applicant = Manufacturer
  - **Role of Manufacturer:** manage authorisation of placing in service
    - Design, construction and installation vs. TSI & NNR
    - Risk assessment and risk management of technical solution
    - Check of technical compatibility and safe integration of technical solutions within vehicle using CSM for risk assessment
    - Production of a Technical File with all necessary Operational and Maintenance Rules (or constraints)

- **Role of Railway Undertaking**
  - Check of technical compatibility and safe integration of vehicle within infrastructure [Network] **supported by infrastructure manager**
  - Update SMS vs. Operational Rules/Constraints from Technical File
  - Chose ECM and make available Technical File (including maintenance rules)
What does update of SMS mean?

- Functions impacted by new Rolling Stock:
  - Training
  - Maintenance
  - Operations
  - Document management,
  - Etc.

- Examples of improvement of training process:
  - Development of technical instructions for drivers
  - Development of Emergency procedures to apply in case of accidents

- Examples for maintenance:
  - Choice of ECM (Is old procedure – e.g. for diesel - still valid for electrical?)
  - Maintenance plan (mileage & time scheduling) and technical instructions
  - Technical File (list of spare parts, drawings, etc.)
  - Impact assessments for maintenance workshops

- Examples for operations:
  - Process or procedure to manage the new fleet
  - Procedure for shift management of drivers
  - Etc.
Case 2: Applicant = Railway Undertaking who will thus manage "authorisation of placing in service"

Usually, RU will subcontract and manage the following activities:

- Design, construction and installation vs. TSI & NNR
- Risk assessment and risk management of technical solution
- Check of technical compatibility and safe integration of technical solutions within vehicle using CSM for risk assessment
- Production of a Technical File with all necessary Operational and Maintenance Rules (or constraints)

RU will then ensure the following:

- Check of technical compatibility and safe integration of vehicle within infrastructure [Network] supported by infrastructure manager
- Update SMS vs. Operational Rules/Constraints from Technical File
- Chose ECM and make available Technical File (including maintenance rules)
Roles and responsibilities of different bodies involved in a change

Tasks of different involved BODIES (avoid duplication of work)

- Assessment Body in CSM: check correct application of CSM risk management process and suitability of results
- NSA delivers Safety Certificates & Safety Authorisations for RUs/IMs SMS
- NSA delivers Authorisations for placing in service structural subsystems based on
  - NOBO's "EC verification of conformity with TSI requirements" applicable to structural sub-systems
  - Applicant "EC declaration of conformity with TSI requirements" applicable to structural sub-systems
  - Designated Body's check of conformity with national rules applicable to structural sub-systems,
  - check by Assessment Body of correct application of the CSM regulation on risk assessment.
Risks identified with CSM on risk assessment

1. National Rules (DeBo)
2. Other measures (AB)
3. TSI's (NoBo)

Safety demonstration + NSA authorisation based on evidences of:
- Safe integration (AB)
- Check of technical compatibility
- Compliance with TSI's [NoBo] & National Rules (law) [DeBo]
Nothing revolutionary when using CSM

- Basically CSM is an iterative process made of 3 steps:
  
  (a) Identification of hazards, associated safety measures and resulting safety requirements
  
  (b) Risk analysis and risk evaluation based on exiting risk acceptance principles
  
  (c) Demonstration of the system compliance with the identified safety requirements

- Necessary requirements for mutual recognition:
  
  (a) Hazard Management
  
  (b) Independent Assessment (Assessment Body)
- When **notified national rules** do not define what is significant change, proposer evaluates the significance of change **based on expert's judgement and criteria in CSM**

- 1\textsuperscript{st} check whether change safety related?
  1) **NOT** safety-related \(\rightarrow\) not significant \(\rightarrow\) no CSM, but record decision ;
  2) **YES** safety-related \(\rightarrow\) use other criteria to evaluate whether change significant

- Proposer should analyse all criteria and decide on their importance, but could take decision based on only one or some of them

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**Article 4 of CSM Regulation**

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## Examples of Technical, Operational & Organisational Changes

<table>
<thead>
<tr>
<th>OPERATIONAL</th>
<th>ORGANISATIONAL</th>
<th>TECHNICAL</th>
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</thead>
<tbody>
<tr>
<td>• New operational procedures (e.g.: driver only operated train; implementation of centralised traffic control system)</td>
<td>• Incorporation/ separation of companies</td>
<td>• New infrastructure</td>
</tr>
<tr>
<td>• Procedures adapted in relation to:</td>
<td>• Changes in services provided (e.g.: freight&gt;passengers)</td>
<td>• Upgrade of infrastructure</td>
</tr>
<tr>
<td>❑ deployment of a new signalling system / CCS / ...</td>
<td>• New services</td>
<td>• New control-command</td>
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<tr>
<td>❑ new /changed services</td>
<td>• Outsourcing activities</td>
<td>• Upgrade of control-command</td>
</tr>
<tr>
<td>❑ new interfaces</td>
<td>• Change/New contractors</td>
<td>• New signalling system</td>
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<tr>
<td>❑ Contract services</td>
<td></td>
<td>• Upgrade of signalling system</td>
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<tr>
<td>❑ Etc.</td>
<td></td>
<td>• New rolling stock</td>
</tr>
<tr>
<td>• Change to standards / new standards</td>
<td></td>
<td>• Upgrade of rolling stock (e.g. for on board signalling system)</td>
</tr>
<tr>
<td>• Change / new maintenance rules and/or practice</td>
<td></td>
<td>• New products (constituents)</td>
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<tr>
<td>• Change / new routes</td>
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See guidance on Reg. 352/2009/EC + collection of examples

Discussions/Questions

Many thanks for your attention!

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Basics on Risk Management

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Basics on Risk Management

Introduction
Main target

Opening of the market to competition for the rail transport services and the railway supply industry

How?

• Removing technical and organizational barriers to the free circulation of trains through the Member States
• Prevent the sector from using safety as a barrier to market access or an excuse to resist change!
The European approach on Safety

Safety objective at EU level

- Maintain at least, and increase when reasonably practicable, the existing level of safety in the EU railways;
- Mutual trust among the MSs → Opening of borders

How Safety can be preserved and harmonized?

- Through a common approach for safety regulation, safety management and safety supervision;

Movement from existing national railway systems to the SMS based approach required from Directive 2004/49/EC
Previous situation:

Existing national railway systems usually based on use of rules and retrospective review of «bad experiences».

The new approach:

Directive 2004/49/EC introduces the obligation to control Risks through a SMS. The concept of **RISK MANAGEMENT** requires to LOOK both FORWARD and RETROSPECTIVE.

Key question:

«What are the **likely risks** and the **risk control measures** I should put in place to **manage safely my operations**?». 
The role of the SMS in controlling risks

**Role of rules in SMS:**

- EU regulatory framework is not a conflict of risk against rules approaches but a combination of both.
- Identify and understand how rules fit into the whole management system?
- Not only NNTRs and NSRs but all rules needed to deliver the safe operation of the RU/IM to consider in SMS.

**Why should I have a measure/procedure?**

**How can I avoid or decrease the risk?**

**What do I already have in place for that?**
SMS provides a structured framework to ensure that:

1) **PLAN**: the organisation is designed to deliver operations in a safe way.

2) **DO**: operational and support processes are deployed.

3) **CHECK**: effectiveness of processes is monitored.

4) **ACT**: preventive or corrective measures are taken.

**Objective of SMS**: keep "set rules" up to date.

SMS is **not an alternative** to the existing set of safety-related technical and operational rules. It is a structured way to apply them **taking into account** the risks related to the specific activities of the RU or IM.

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Slide n° 67
Conclusions about SMS

- A **documented and structured** framework for safe management of all company activities
- Ensures appropriate **processes, procedures** and **rules** exist for controlling all company risks
- Enables identification of hazards and **continuous management** of risks related to the company activities, with the **aim of preventing accidents**
- Uses scientific "**risk management**" tools to support company managers in taking consciously decisions for their business
Elements of the SMS derived by Article 9 and Annex III of the Directive 2004/49/EC have been classified according to their characteristics and purpose

Link on ERA web page:

http://www.era.europa.eu/tools/sms/Pages/default.aspx
Basics on Risk Management

Main concepts
History

Mathematical instruments for the decision making process have been used in the XVIII by shipping insurances companies to assess risks. Since then the decision making process is based on a probabilistic approach which allows to “forecast” unwanted events, providing financial benefits.

Domains of application

Due to the continuous refinement and improvement, the Risk Management became a reliable instrument to perform business and to grant safety in the following domains:

- Financial, banking, capital investment;
- Medicine;
- Nuclear power;
- Telecommunication;
- Energy;
- Aviation;
- Railways;
In many domains a gradual improvement of safety resulted from costly experiences and lessons learned from accidents.

Prevention of similar events was regulated reactively (after the occurrence of such events) with the establishment of new laws, codes of practice, rules or standards.

EVENT

REACTION

Change in the legislation, rules, standard or code of practice to avoid a new accident of the same type. This changes don’t protect the system from different hazards.

Accidents are used to prevent accidents
A proactive safety management **based on risks** ensures, before the event occurs, that:

- Hazards are identified, the causes and consequences (risks) analysed;
- Acceptable Risk Control Measures are defined and implemented to prevent the hazard and/or to protect from consequences.

**ANALYSIS**  **SAFETY MEASURES**  **EVENT**

Competence and analysis are used to prevent accident
Reactive approach

**Accidents are used to prevent accidents**

- Costly with high impact on the system and the society;
- Unable to control unknown risks.

Proactive approach

**Competence and knowledge are used to control risks, then to prevent accidents**

- No impact on the system and the society;
- Can effectively prevent the occurrence of events.
Risk Management is a logical and systematic method of identifying the hazards and analysing, treating and monitoring the associated risks involved in any activity or process of a company.

Risks can be managed:
• building your knowledge looking at the past;  
  REACTIVE
• using competence and analysis, trying to foresee the consequence of changes, actions, etc.  
  PROACTIVE

Risk Management is based on the analysis of past events and probable events (PAST + FUTURE)

A decision making process based on Risk Management allows the company to improve its efficiency, facilitating the allocation of resources, protecting the business from unexpected financial outcomes, due to sudden and unwanted event.
Difference between Hazard and Risk

What is a HAZARD?

It is a source or situation or act with a potential for harm in terms of human injury or damage to environment or both (e.g. Toxic or flammable substances, electric energy, height etc.)

→ Hazard is something that has a potential to cause harm or injury

What is a RISK?

Combination of the likelihood of an occurrence of a hazardous event and the severity of injury, damage to environment or damage to property that may be caused by the event

→ Risk is the likelihood of harm resulting from a hazard
The system has a relevant importance on the identification of the hazards. Something that could be hazardous in one context, could be totally innocuous in a different one.
Risk: definitions and parameters

Generic definition of Risk

Risk is typically defined in two dimensions

Risk = Frequency x Severity

How often will an event occur?

E.g. once per year, once every 10 years, every day...

If the event does occur what could be the consequences?

E.g. one person injured, €10000 damage, multiple fatalities
To understand ‘risk’, it’s important to know some "key concepts"

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Explanations (not definitions from EU legislation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accident</td>
<td>Event (or sequence of events) that causes harm</td>
</tr>
<tr>
<td>Incident</td>
<td>Event that could cause harm (but may not)</td>
</tr>
<tr>
<td>Hazard</td>
<td>A condition that could lead to an accident or an incident</td>
</tr>
<tr>
<td>Frequency</td>
<td>Number of times the hazard occurs in a specified period of time</td>
</tr>
<tr>
<td>Probability</td>
<td>Likelihood of an event occurring (usually per demand)</td>
</tr>
<tr>
<td>Severity</td>
<td>The magnitude of harm from a hazard</td>
</tr>
<tr>
<td>Risk (level of...)</td>
<td>The combination of frequency and severity of a specified hazard causing defined harm</td>
</tr>
</tbody>
</table>
Frequency assessment

Frequency can be expressed in a number of ways…….

A train has derailed one time in 20 years

- The frequency of derailment is 1 in every 20 years
- The average number of years between each derailment is 20 years
- The frequency of derailment is 0.05 per year
- The frequency of derailment is 0.05/year
- The frequency of derailment is $5 \times 10^{-2}$/year
- The frequency of derailment is $5E-02$/year
Severity assessment

Severity can be expressed in a number of ways......

1 serious injury, damage estimated at EUR 6.5 million

- The cost of damages;
- Fatalities;
- Injuries;
- Hours, minutes of service disruption;
- Environmental impact;
- Etc.
Avoiding common mistakes...

The frequency of an event is defined as ‘the number of times an event occurs in a given time period’

• If a telephone fails 10 out of 1000 times in one year then the failure frequency is 10 per year = 10/year

Do not confuse frequency with probability!

The probability is defined as ‘the likelihood of an event occurring over a specified period of time or on demand’

• If a telephone fails 10 out of 1000 times in one year, the failure probability is 10/1000 = 0.01 per demand
• However the probability of having a failure in that year is 1
Firstly, sensible scales need to be developed for both frequency and severity.

### Building scales for risk ranking through a Risk Matrix – One example

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Once in 10 years</td>
</tr>
<tr>
<td>2</td>
<td>Annually</td>
</tr>
<tr>
<td>3</td>
<td>Monthly</td>
</tr>
<tr>
<td>4</td>
<td>Weekly</td>
</tr>
<tr>
<td>5</td>
<td>Daily</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>No or slight injury</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Minor injury</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Single major injury</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Single fatality or multiple minor injury</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Multiple fatalities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

It is important that the scales are divided into clearly defined categories that are distinct.

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Vilnius, January 29th and 30th 2013
The ranking is then carried out for each hazard, by considering the frequency of the hazard leading to an accident, and determining the consequences of that accident.

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Frequency</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Wildfowl on the track</td>
<td>&quot;Once per week&quot; = 4</td>
<td>&quot;No injury&quot; = 1</td>
</tr>
<tr>
<td>2) Train door opens during movement</td>
<td>&quot;Once a year&quot; = 2</td>
<td>&quot;One major injury&quot; = 3</td>
</tr>
<tr>
<td>3) Gap between train and platform</td>
<td>&quot;Once a month&quot; = 3</td>
<td>&quot;One fatality&quot; = 4</td>
</tr>
<tr>
<td>4) etc.</td>
<td>Etc.</td>
<td>Etc.</td>
</tr>
</tbody>
</table>
Risk: definitions and parameters

Risk Ranking

When the hazards are plotted in the matrix based on their scores, it becomes clear which hazards are high, medium and low priority and therefore which ones should be dealt with first.

Risk ranking using a risk matrix

“Gap between train and platform” should be dealt with first since it is the ‘medium risk’ closest to ‘high risk’.
Risk Management is a generic **7 step based process**

- Defining context (System Definition)
- Risk Assessment
  - Hazard/Risk Identification
  - Risk Analysis
  - Risk Evaluation
- Risk Control
- Risk Monitoring and Review
- Communication with and consult staff on company and their activity risks

‘Risk’ is dynamic and subject to constant change
Indepenently on whether complex or simple, Risk Assessment follows a common 4 step process

1. Identify Hazards
2. Estimate Frequency
3. Estimate Severity
4. Reduce Risks where required

... for each hazard you estimate risk by estimating frequency and severity
... you then evaluate acceptability of risk and prioritise ...
... If necessary you then take action to mitigate/control risk
Risk Management includes also **monitoring** of risks and their **communication**
Why giving importance to Risk Management and Risk Assessment? (2/2)

WARNING

- Risk assessment is a means to an end, not an end in itself. The aim is to keep people safe, not have good paperwork.

- The risk analysis process depends on the experience, knowledge, imagination, creativity and integrity of the individuals doing the analysis. The only application of these techniques without appropriately talented/competent staff does not ensure a proper and thorough risk analysis result.

- The most important step in any risk assessment is that hazards can only be controlled if they are identified.

- You must not say ‘never.’ Risk assessment predicts probabilities. Although a particular event may be infinitesimally improbable, the probability is always greater than zero.
### Risk Assessment

<table>
<thead>
<tr>
<th>What can happen?</th>
<th>How likely is it to happen?</th>
<th>What are the consequences if it happens?</th>
</tr>
</thead>
</table>

### Risk Management

| What can be done? | What are the benefits, costs and risks of each option? | What are the impacts of each option on future options? |

---

**Risk assessment is a means to an end, not an end in itself - the aim is to keep people safe, not have good paperwork.**
Basics on Risk Management

Generic examples of Risk Management
Examples of Risk Management

1) Mechanical Press accidents

2) Driving a vehicle for good transport instead of a car
Example of Mechanical Press

- Description:
  - Operator shall put a metal sheet into machine
  - Operator shall press a button to get final product (e.g. car wing)

Regularly observed accidents

- Operator's hand caught by machine moving parts
- Hand cut by mechanical press

Improvement of safety

- Ensure both Operator's hands needed to start machine

→ Fit machine with "two operating push buttons" instead of only one push button
Reactive Risk Management
Example of improvement of mechanical presses safety (2/2)

Observations
- Number of accidents decreased
- Some Operator's hand still continues to be caught and cut by machine moving parts → problem not prevented

Investigations
- Injured staffs are smokers who systematically block one of push buttons into "activated" state to have other hand free

Additional improvement of safety
- Still both Operator's hands needed to start machine
- But machine starts only when "two operating push buttons" are released

Conclusions
- A Reactive approach does not guarantee anticipation of all problems
- Non systematic method based on review of occurred bad experiences
- Safety improved only when an unwanted event already happened
Proactive Risk Management
Example of a predictive risk assessment (1/5)

Change

- Driver uses its small individual vehicle
- Driver wants to rent a van for good transport (e.g. transport a new fridge)

Description

- **System 1:**
  - Small and short vehicle
  - Fitted with windows on all sides
  - Light vehicle
  - Driver experienced with a manual gear box vehicle

- **System 2:**
  - Long and heavy vehicle
  - Rear and lateral sides closed
  - Heavy vehicle
  - Automatic gear box

**Question:** is it preferable to rent the van or should I pay more to get my goods delivered at home? ➔ Risk Assessment to take decision
**Risk Assessment**

- What can go wrong?
  - What are consequences?
  - What is level of risk?

  - Longer vehicle $\rightarrow$ manoeuvres harder [guage] hence a risk to damage environment or vehicle  
    [Risk Medium]

  - Less lateral windows lead to decreased visibility $\rightarrow$ risk to damage environment or vehicle  
    [Risk High]

  - Heavier vehicle requiring longer breaking distances $\rightarrow$ risk not to stop safely in emergency cases  
    [Risk Medium]

  - Driver unfamiliar with automatic gear box  
    Risk to provoke road accidents – [Risk High]
Risk Management: implement risk control measures

- Longer vehicle makes manoeuvres harder
  → get assistance/help
  [Risk Medium to Low]

- Less lateral windows lead to decreased visibility
  → drive more carefully
  [Risk High to Medium]

- Heavier vehicle requiring longer breaking distances
  → drive slowly and with higher attention to be able to stop safely in emergency cases
  [Risk Medium to Low]

- Driver unfamiliar with automatic gear box
  → never use left leg and drive with higher attention to avoid accidents
  [Risk High to Medium]

Risk Acceptance:

- Decision to rent or get goods delivered depends on expert judgement whether risk is sufficiently reduced by risk control measures
### Proactive Risk Management

#### Example of a predictive risk assessment (4/5)

<table>
<thead>
<tr>
<th>Function</th>
<th>Hazard</th>
<th>Cause</th>
<th>Additional information</th>
<th>Consequence</th>
<th>Initial risk level</th>
<th>Risk Control Measure</th>
<th>Risk with RCM</th>
<th>Responsible</th>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drive a long vehicle for goods transport [gauge]</td>
<td>Driver underestimates vehicle behavior during manoeuvres</td>
<td>Driver has no experience of driving such type of vehicles</td>
<td>Driver has appropriate driving licence</td>
<td>Damage to environment (other vehicles or road infrastructure) and/or to vehicle itself during maneuvers</td>
<td>M</td>
<td>Ask for assistance/help to carry out necessary manoeuvres</td>
<td>L</td>
<td>Driver</td>
<td></td>
</tr>
<tr>
<td>Drive a long vehicle for goods transport [gauge]</td>
<td>Driver underestimates vehicle gauge on the road</td>
<td>Driver has no experience of driving such type of vehicles</td>
<td>Driver has appropriate driving licence</td>
<td>Damage to environment (other vehicles or road infrastructure) and/or to vehicle itself while driving</td>
<td>M</td>
<td>Drive with increased attention</td>
<td>L</td>
<td>Driver</td>
<td>Do not forget to monitor your attitude when driving</td>
</tr>
<tr>
<td>Drive without rear windscreen</td>
<td>Driver does not see vehicles running behind him</td>
<td>Lack of rear windscreen</td>
<td>Driver has appropriate driving licence</td>
<td>Driver can change traffic line whereas another road user already started an overpassing</td>
<td>H</td>
<td>Do not change traffic lines</td>
<td>M</td>
<td>Driver</td>
<td></td>
</tr>
<tr>
<td>Drive without rear windscreen</td>
<td>Driver does not see vehicles running behind him</td>
<td>Lack of rear windscreen</td>
<td>Driver has appropriate driving licence</td>
<td>Driver can change traffic line whereas another road user already started an overpassing</td>
<td>H</td>
<td>Do not change traffic lines</td>
<td>M</td>
<td>Driver</td>
<td></td>
</tr>
</tbody>
</table>
## Proactive Risk Management

### Example of a predictive risk assessment (5/5)

<table>
<thead>
<tr>
<th>Function</th>
<th>Hazard</th>
<th>Cause</th>
<th>Additional information</th>
<th>Consequence</th>
<th>Initial risk level</th>
<th>Risk Control Measure</th>
<th>Risk with RCM</th>
<th>Responsible</th>
<th>Other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drive a heavy vehicle</td>
<td>Increased braking distances</td>
<td>Greater vehicle weight than one usually driven</td>
<td>Driver unfamiliar with behaviour of vehicles for good transport</td>
<td>Driver cannot stop safely in case of emergency situation</td>
<td>M</td>
<td>Drive slowly to avoid braking in emergency</td>
<td>L</td>
<td>Driver</td>
<td>Do not forget to monitor your attitude when driving</td>
</tr>
<tr>
<td>Drive a vehicle with automatic gear box</td>
<td>Braking when thinking to change the gear</td>
<td>Driver unfamiliar with automatic gear box vehicles</td>
<td>When driver get his driving licence, there was no difference between manual or automatic gear box licences</td>
<td>Accident due to an unnecessary emergency braking</td>
<td>H</td>
<td>Never use left leg and drive with higher attention to avoid accidents</td>
<td>M</td>
<td>Renting company should warn the customer that vehicle is with automatic gear box Driver</td>
<td></td>
</tr>
</tbody>
</table>
Do you need help?

European Railway Agency is available for answering questions you may have when applying the CSM regulation on risk assessment:

Contact person: Dragan JOVICIC
Dragan.JOVICIC@era.europa.eu
Many thanks for your attention!

Q & A

You have Questions
We have Answers
Risk Assessment requirements in Regulation No 352/2009

Dragan.JOVICIC@era.europa.eu
Risk Management is a key process of the SMS

«The safety management system shall ... (omissis)... ensure the control of all risks associated with the activity of the infrastructure manager or railway undertaking, including the supply of maintenance and material and the use of contractors...»

SMS shall ensure the control of all risks. How?

«Procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations“.

Risk Management
Main elements taken into account for CSM development

Harmonisation, Safety and Trust

- **CSM provide Common Principles but do not fix the Tools**
  The Railway Sector has already a strong safety culture: freedom is left to each organisation to use its already approved Tools or Techniques for assessing the risks, according to their SMS procedures.

- **CSM privileges use of standards and reference systems**
  Advice of Risk Assessment “tools” done in a guideline developed alongside the CSM.

- **CSM allows to manage interface defining actor’s responsibilities**
  The systematic analysis of the activities, functions and interfaces will support the actor in the definition of tasks and responsibilities.
WHO?

CSM shall be applied by the proposer who can be:

a) RU or IM (new in revised CSM: ECM)

b) contracting entities or manufacturers when they invite a notified body to apply the "EC" verification procedure in accordance with Article 18(1) of the Interoperability Directive 2008/57/EC

c) the applicant of an authorisation for placing in service of vehicles;

d) or other actors where necessary (through contractual arrangements, e.g. suppliers and service providers, including their subcontractors)

WHEN?

when performing a significant technical, operational or organizational change to the railway system and that can impose new risks on the infrastructure or on operations
Basically CSM is an **iterative process** made of 3 steps:

1. **Identification of hazards**, associated safety measures and resulting safety requirements

2. **Risk analysis and risk evaluation** based on exiting risk acceptance principles

3. **Demonstration** of the system compliance with the identified safety requirements

Necessary requirements for **mutual recognition**:

- Hazard Management;
- Independent Assessment *(Assessment Body)*

The CSM shall be implemented internally using the SMS processes and procedures
Some details on the CSM for Risk Assessment
Evaluation of the significance of the change

1. Safety relevant?
   Can the change generate an event that can impact on the safety level of the company?

   - failure consequence: credible worst-case scenario in case of failure, considering the existence of safety barriers outside the system;
   - novelty used in implementing the change: it concerns either the railway sector either the RU/IM/ECM
   - complexity of the change;
   - monitoring: the inability to monitor the implemented change throughout the system life-cycle and take appropriate interventions;
   - reversibility: the inability to revert to the previous system;
   - additionality: all recent safety-related modifications must be taken into account.

Is the change safety related?

Is the change significant?

CSM for RA

Article 4 of CSM Regulation
The process of deciding the significance of the change shall be included in the SMS

- The **minimum criteria** to be used to make the decision are reported in the EC Regulation 352/2009 – Art. 4 – Significant Changes;

- Even when changes are “not significant”, the **decision must be traceable**, for example the following parameters can be recorded:
  - How the decision has been made and from whom (brainstorming, participants, etc..)
  - The criteria used (list of criteria, weight, etc..).

- **Traceability is always an added value**, of course it can facilitate the supervision activity of the NSA, but it is also very important for the proposer to understand if non-significant changes can become significant after further changes.

  CSM for Risk Assessment **does not require** the Assessment Body to check the evaluation of significance
Agency and taskforce of experts from railway sector analysed typical examples of borderline cases, the analysis has shown that:

- it is not possible to identify harmonised thresholds or rules;
- it is not possible to provide an exhaustive list of significant changes;
- decisions are unlikely to be same for all proposers.

**Summarising on the evaluation of significance:**

- The evaluation shall be carried out in compliance with the CSM for RA and according to the SMS procedures.
- The significance of a change in a Member State can be defined by Notified National Rules.
- The significance of a change is strictly linked with the scenario.
CSM for Risk Assessment
System Definition

from STEP 1

System Definition

to STEP 3

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System

The system definition should contain at least:

a) system **objective**, e.g. intended purpose;

b) system **functions** and elements, where relevant;

c) system **boundary** including other interacting systems;

d) physical and functional **interfaces**;

e) system **environment**;

f) existing **safety measures** and, after iterations, definition of the **safety requirements** identified by the risk assessment process;

g) assumptions which shall determine the limits for the risk assessment.
The ensure a **systematic approach** to the system definition, a **procedure** should foreseen within the **SMS**.
CSM for Risk Assessment
Hazard Identification and Classification

from STEP 2

Hazard Identification

Hazard Classification

Broadly Acceptable

Yes

No

to STEP 4

STEP 3

Hazard Record
Hazard Identification and Classification
Hazard ID - What is it?

Hazard Identification is first step in risk analysis process, it provides the basis to develop the Risk Assessment.

It is possible to describe the Hazard Identification with a few simple questions:

- What can happen?
- How can it happen?
- In which conditions?
- Etc.

The idea is to try to foresee what can go wrong when the system has been changed.

The Hazard Identification needs to be reiterated and completed until all reasonably foreseeable hazards have been identified correctly. It is important because, if hazards are not identified, they will not be assessed and covered by the risk management process.
Which is the required level of detail in the Hazard ID?

- Level of hazard identification should correspond to scope of significant change under study and requirements for proving risk is acceptable.

- If a Code of Practice or a Reference System is used, then level of detail for which hazards are defined, needs only to correspond to level defined by Code of Practice or Reference System.

- It may involve several iterations in order to obtain necessary level of detail to ensure that correct decision is made on necessary control measures.
What are Hazard Classification and Risk Ranking?

- Risk Ranking is used to compare hazards according to their risks allowing the actors to prioritise the use of resources to cancel or mitigate not acceptable risks;

- Risk Ranking can be quantitative or qualitative.

- The risk ranking can be done according to standards (e.g. 50126) or according to proprietary solutions. In any case an SMS process/procedure shall be foreseen to create a systematic approach.
What is “broadly acceptable”?

- A part of the “Hazard Identification” process is decision if hazards are **broadly acceptable** or **not broadly acceptable**. This means:
  - considering and reviewing all reasonably foreseeable hazards;
  - classifying them according to estimated risk arising from them;
- This process ensures that correct priority is assigned to each of hazards enabling right selection of risk control measures (Risk Ranking);
- The decision is based on expert judgement.

**Broadly acceptable risks**
- Nothing further required
- Registered in the Hazard record

**Not broadly acceptable**
- Follow the risk management process
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CSM for Risk Assessment
Risk Analysis and Risk Evaluation

RISK EVALUATION (vs. Risk Acceptance Criteria)

Codes of Practice
Similar Reference Systems
Explicit Risk Estimation

Safety Requirements
(i.e. Safety Measures to be implemented)

to STEP 5
4 – Risk Analysis and Evaluation ➔ Principles?
Hazard Control based on 3 Risk Acceptance Principles (RAP):

- Risk acceptability of non broadly acceptable hazards evaluated by one or more 3 Risk Acceptance Principles (RAP):
  1. application of codes of practice
  2. comparison with similar Reference Syst

- Proposer is responsible to:
  1. demonstrate selected RAP adequately applied
  2. check selected RAP used consistently

- Output: set of safety requirements and measures to implement + demonstration of their achievement

CSM does not impose any order of priority between the 3 RAP

Iterative Risk Management Process
The Codes of Practice (CoP) shall at least satisfy the following requirements:

(a) be widely acknowledged in railway domain. If not the case, CoP have to be justified and be acceptable for the assessment body;

(b) be suitable for the control of the considered hazards;

(c) upon request, be available to assessment bodies who shall either assess or, where relevant, mutually recognise, the suitability of the application of the risk management process and the appropriateness of the results.

Examples of CoP:

- TSIs and other mandatory European standards;
- Notified National Safety and Technical Rules (technical standards or statutory documents) and if relevant non mandatory European standards;
- If the conditions for the usage of CoP are fulfilled, then internal rules or standards issued by an actor of the railway sector might be used as CoP too.
- **CoP from other industries** (e.g. nuclear power, military and aviation) can also be applied for railway systems, if CoP is effective for railway hazards.
If the conditions for the usage of CoP are fulfilled, then for the hazards, which are controlled in this way:

- The risks need not be analysed further and are considered as acceptable;
- The risk management process may be limited to:
  - hazard identification;
  - registration in the Hazard Record of the use of CoP as a safety requirement for these hazards;
- Therefore, in this case, the application of the complete CSM Process includes:
  - the correct application of the requirements from CoP;
  - the documentation of the evidences;
  - the independent assessment of the application of CoP.
What to do when there are deviations from the CoP and the identified hazards cannot be controlled (completely) by a CoP?

- If one or more conditions from the CoP are not fulfilled by the system under assessment, then the related CoP can still be used for controlling the hazards, provided that the proposer demonstrates that at least the same level of safety is achieved.

- If for a hazard, the risk cannot be made acceptable by the application of CoP, or if a CoP does not sufficiently cover identified hazards (e.g. CoP not applicable to full range of hazards), additional safety measures shall be identified for controlling those hazard(s) by using either other CoP or one of other 2 RAP (Ref Syst or Explicit Risk Estimation).

The applicability of the CoP shall be carried out according to the SMS procedures.
The Reference Systems (Ref Syst) shall at least satisfy the following requirements:

- it has already been proven in-use to have an acceptable safety level and *would still quality for approval* (i.e. would be accepted) in the Member State where change is to be introduced
  
  “*would still be accepted in the Member State*”? E.g. it can happen that the safety performance of the considered Ref Syst is not appropriate for the system under assessment, because it is based on a too old technology.

- it has similar functions and interfaces as system under assessment
- it is used under similar operational conditions as system under assessment;
- it is used under similar environmental conditions as system under assessment.

If the conditions for the usage of the Ref Syst are fulfilled, then for the hazards controlled in this way:

- the risks are considered as acceptable (*no further risk analysis required*);
- the safety requirements for the hazards covered by the RefSyst may be derived from the safety analysis, or from an evaluation of the safety records of the RefSyst
- these safety requirements shall be registered in the Hazard Record as safety requirements for the assessed hazard.
What to do when there are deviations from the RefSyst and the identified hazards cannot be controlled completely by a RefSyst?

The risk evaluation shall demonstrate that the system under assessment achieves at least the same safety level as the Ref Syst.

Therefore, on deviations:

- Possible necessity for explicit risk estimation in order to show this correspondence (that the level of risk is at least as good as that of RefSyst);

If the same safety level as the one of the reference system cannot be demonstrated (or if the conditions are not fulfilled), then additional safety measures shall be identified for the deviations, applying one of the 2 other RAP (CoP or Explicit Risk Estimation)

The applicability of the RefSyst shall be carried out according to the SMS procedures
When hazards cannot be covered by CoP or RefSyst then the demonstration of risk acceptability is to be performed by explicit risk estimation and evaluation

• Risks shall be estimated either quantitatively or qualitatively, taking into account the existing safety measures within the system

• As soon as the risk(s), which are controlled by an explicit risk estimation are considered acceptable, then the identified safety measures are registered in the Hazard Record
For example, the need for the use of an explicit risk estimation could typically arise:

- when the system under assessment is entirely new, or
- where there are deviations from a CoP or a RefSyst, or
- when the chosen design strategy does not allow the usage of CoP or similar Ref Syst because e.g. of a wish to produce a more cost effective design that has not been tried before.
In order to evaluate whether risks are acceptable or not, Risk Acceptance Criteria (RAC) are necessary. They can be either “implicit” or “explicit”:

- risks controlled by the application of a CoP or by a comparison with a RefSyst are considered acceptable without a need to apply an additional “explicit” risk estimation;

- whereas the acceptability of risk(s) controlled by the application of an “explicit risk estimation” requires “explicit RAC” to be defined.
CSM for Risk Assessment
Safety Requirements

from STEP 4

Hazard Record

Safety Requirements
(i.e. Safety Measures to be implemented)

to STEP 6

Dissemination Workshop of the CSM for Risk Assessment
Vilnius, January 29th and 30th 2013
In order to make risks acceptable, normally it is necessary to define Safety Measures:

- In case of **CoP**, the Safety Measures are included in the code of practice to be implemented. In case of deviations it is possible that some safety measures are defined in order to demonstrate the same safety level granted by the full application of the CoP;

- In case of **RefSyst**, the Safety Measures are also included in the System taken as reference (Hazard Log or System Analysis), in case of deviations from it, further Safety Measures shall be probably be defined.

- In case of an “**explicit risk estimation**”, to **cancel or mitigate risk(s)** classified as “Not Acceptable” it is necessary to define Safety Measures.

In general a Safety Measure can be define as a technical / operational / organisative measure to be designed and implemented to control risk(s)
CSM for Risk Assessment
Demonstration of system compliance with the safety requirements

from STEP 5

Demonstration of system compliance with the safety requirements

Hazard Record

STEP 6
Prior to safety acceptance of change, fulfilment of safety requirements must be demonstrated *(see next slide)*;

- The demonstration is under the supervision of the proposer;
- But each actor is responsible for the demonstration of safety requirements for its part of the system;
- Approach chosen for the demonstration of compliance and the demonstration itself must be independently assessed by Assessment Body;
- Inadequacies of safety measures or new hazards discovered during the demonstration must be reassessed vs. CSM.
Demonstration of system compliance with safety requirements

Proposer’s Responsibility – Other Actor’s Responsibility

- Proposer has overall responsibility for coordinating and managing demonstration of compliance
- But each actor, including proposer where relevant, must demonstrate compliance of sub-system it is responsible for with:
  - Safety requirements allocated to sub-system by proposer
  - Safe. Req. transferred to relevant actor by other actors via interfaces
  - additional and internal SR from safety assessments and safety analyses done at sub-system level

SYSTEM LEVEL
All identified safety requirements (SR)

- Sub-System 1
- Sub-System 2
- Sub-System N

To other sub-systems

From Proposer

From other actors INTERFACE

From Internal Risk Analyses

To other sub-systems

Registered in sub-system Hazard Records
Example of Figure A.4 of EN 50 129: Definition of hazards with respect to the system boundary

Causes of hazards at level of system under assessment may be considered as hazards at the sub-system level (with respect to sub-system boundary).
• Approach for demonstrating the compliance with the safety requirements + the demonstration itself independently assessed by AB;

• If there are no contractual obligations or MS legal requirements, each actor is free to appoint AB for the part of the system the actor is in charge;

• more than one AB can be involved in same the project;

• Proposer, with support of its AB, responsible for integrating different sub-systems and for coordinating different AB involved in the project.
If inadequacies of safety measures or new hazards are discovered during the demonstration they need to be reassessed vs. CSM;

E.g. choice of technical solution for design of system or sub-systems, not foreseen by safety requirements, could create a new hazard;

- New hazards ➔ registered in Hazard Record;
- Deviations and/or new hazards ➔ considered as new inputs for a new loop in iterative risk assessment process.
Hazard Records need to be created and updated by the proposer - Annex 1.4 of CSM Regulation;

They are an important part of the hazard management process;

They track the progress of the process – identification of the hazard, the potential risk and how the risk needs to be controlled through the selected risk acceptance principles:

- Codes of practice;
- Reference systems;
- Risk estimation.
• If there are a number of actors involved in the project each may have responsibility for their part of the system under assessment. They will keep a record of the hazards for their part of the project.

• There should be one overall actor (proposer) who has responsibility for the main record which covers all the necessary elements of the system under assessment.

• It does not have to contain all the information from the actors involved, only the links and key safety related

• Exchange of information will be important if the hazard cannot be controlled by one actor alone.
Hazard Record

What information should they contain?

- All the **hazards** that the actor is **responsible for**, the associated safety measures, and the resulting safety requirements issued from the risk assessment process;

- All the **assumptions** taken into account within the definition of the system under assessment. These assumptions determine the limits and the validity of the risk assessment;

- All the **hazards** and the associated safety measures received from **other actors** in compliance with the project. These include all the assumptions and restrictions of use and generic product safety cases that are produced by the manufacturers;

- The **status** of the hazards (i.e. controlled or open) and of the associated safety measures (i.e. validated or open);

- Note the level of detail required is related to the level of risk.
Whenever:

- a new hazard is discovered or a new safety measure is identified
- a new hazard is identified during the operation and maintenance of the system after its commissioning, so that the hazard can be assessed in compliance with the CSM as to whether it represents a significant change (this will be part of the SMS – Annex III (g))
- it could be necessary to take into account accident and incident data
- there are changes to the safety requirements or the assumptions about the system
What are the benefits to the project?

- Help map out and record the decision making process – provide transparency and consistency
- Allow corrective actions to be taken promptly and quickly (link to SMS)
- Exchange of information – allow for a number of players to contribute
- Evidence of continuing compliance - accountability
- Do not have to be complicated – targeted on the key issues
Example received in other workshops

Hazard Record – example (1)
## Hazard Record – example (2)

**Example received in other workshops**

<table>
<thead>
<tr>
<th>HAZARD LOG</th>
<th>N°</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HAZARD DESCRIPTION (Short description in the first line):</th>
<th>HAZARD CAUSE:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TRIGGERING EVENT:</th>
<th>EXPECTED POSSIBLE CONSEQUENCES:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SEVERITY:</th>
<th>SAFETY ANALYSES REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>FREQUENCY:</td>
<td></td>
</tr>
<tr>
<td>RISK RANKING:</td>
<td></td>
</tr>
</tbody>
</table>

**CREATED BY:** AS RAMS Dept

**DATE:**  | **List Rev.** | **Rev.** | **DATE:**  |
|------------|---------------|----------|-----------|

**RECOMMENDED ACTIONS:**

1. 

2. 

**NOTES:**

**ACTIONS UNDERTAKEN:**

1. 

<table>
<thead>
<tr>
<th>REVISION</th>
<th>1</th>
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<th>3</th>
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<td></td>
<td></td>
</tr>
<tr>
<td>RISK RANKING:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CLOSED ON:**  | **BY:** | **RAMS ENO APPROVAL:** | **DATE:** |
|----------------|---------|------------------------|----------|

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Dissemination Workshop of the CSM for Risk Assessment
Vilnius, January 29th and 30th 2013

Slide n° 156
Discussions/Questions
CSM for Risk Assessment

Independent Assessment
An independent assessment of the complete risk management process undertaken by the proposer shall be performed by an independent body to verify the significant change and the demonstration of compliance with the identified requirements.
General background / legal framework concerning Assessment Bodies:

- For **significant changes** it is required to have an **independent assessment** of the **correct application of the CSM** regulation by an Assessment Body;

- Assessment Body is **appointed/selected by the Proposer** (if there is no contrary national legal obligation);

- Assessment Body shall issue a **safety assessment report** to support the Proposer in the decision to accept the significant change;

- There shall be a **mutual recognition** of the independent assessments performed by the Assessment Body in the scope of the CMS on risk assessment.
To enable to mutual recognition of the independent assessments there is a need to establish **sufficient trust** of work performed by AB

- Different questions to be answered
  - **WHY** is Assessment Body needed?
  - **WHO** shall be Assessment Body?
  - **WHEN** shall independent assessment be done?
  - **WHAT** shall be assessed?
  - What is the interaction with other assessments (i.e. Safety certification & authorisation process for placing in service structural sub-systems)?
  - What are the **additional requirements** for the assessment body?
  - **HOW** assessments shall be performed?
  - **WHICH** scheme could ensure **similar quality** of the assessments?
• Different from NOBO work who checks formal conformity of a sub-system with predefined requirements whereas **Assessment Body makes judgements**;

• To make this judgement, a complete and thorough review and follow up of all activities of Proposer and of its subcontractors for design and implementation of change may not be cost effective and also is not necessary;

• Rather a **3 steps approach** shall be undertaken based on:
  • thorough understanding of the change and of its specification;
  • assessment of safety and quality processes put in place for the change;
  • assessment of the application of these processes for the design and implementation of the change based on e.g. auditing and sampling techniques till the delivery of the assessment report.
The criteria are listed in Annex II of the CSM regulation 352/2009/EC:

- Independence from the design, manufacture, construction, marketing, operation or maintenance of the system
- Professional integrity
- Competence (skills, training, knowledge and experience) to perform the tasks required for them
- Civil liability insurance
- Commercial confidentiality

Following entities can be Assessment Bodies: NSA, NOBOs, Designated Bodies, in house ISA, external ISA (if they fulfil criteria in Annex II of CSM regulation)

Choice made by the Proposer if not imposed by national legislation

Different practices exist in the Member States
WHICH scheme could ensure similar quality of the assessments?

RECOGNITION AND ACCREDITATION OF CSM ASSESSMENT BODY
Requirement of mutual recognition necessitates sufficient trust in the work performed by assessment bodies.

ACCREDITATION IS A WAY TO ACHIEVE THIS TRUST BUT:

- **Regulation 765/2008 article 5(2)** → when a MS decides not to use accreditation it shall demonstrate, to the Commission and the other MS, the equivalence of the national recognition scheme with the CSM AB accreditation scheme.

- The **CSM accreditation scheme** (ISO 17020:1998 + Regulation 352/2009 - annex II) are the reference document for the demonstration.
Accreditation by a National accreditation body

Accreditation scheme covering the safety assessment activity

Recognition scheme covering the safety assessment activity

Recognition, by the Member State or NSA
Assessment Bodies
Accreditation scheme

**European cooperation accreditation**

- **European co-operation for Accreditation**
  - Supervises, monitors (cross auditing) (ISO 17011)
  - One per Member State
  - European wide

**National Accreditation Body**

- Checks the criteria (e.g. competences) and gives the accreditation
- Several per Member State
- European wide

**Assessment Body**

Assess the risk assessment

**Safety Assessment Report**

- one per significant change - Result accepted everywhere in Europe

---

Dissemination Workshop of the CSM for Risk Assessment
Vilnius, January 29th and 30th 2013

Slide n° 167
Assessment Bodies
Recognition scheme

**DELIVERS**

- **Equivalence EA**
  - Supervises, monitors (cross auditing) (ISO 17011)
  - Peer review using the same principles as the ones described in Article 10 of regulation 765/2008/EC

- **Recognition Body**
  - NSA or designated by MS
  - Checks the criteria (e.g. competences) and gives the recognition

- **Assessment body**
  - Several per Member State National recognition
  - National recognition

**Safety Assessment Report**

One per significant change - Result accepted in whole Europe

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The safety assessment report shall at least contain the following information:

(a) Identification of the assessment body

(b) The independent assessment plan

(c) The definition of the scope of the independent assessment as well as its limitations

(d) The results of the independent assessment including:
   1) Detailed information on the independent assessment activities providing the compliance with the provisions of this Regulation
   2) The identified non compliances and the assessment body recommendations

(e) The conclusions of the assessment
Do you need help?

European Railway Agency is available for answering questions you may have when applying the CSM regulation on risk assessment:

Contact person: Dragan JOVICIC

Dragan.JOVICIC@era.europa.eu
Many thanks for your attention!
Organizational Change
Internal reorganization of a Railway Undertaking

Application of the CSM for Risk Assessment
Introduction to the system definition

A railway undertaking has been re-organised into two divisions. This change has been subject to a risk evaluation and assessment under the terms of CSM 352/2009.

This change is classified as an Organisational Change to the Operations and Traffic Control asset category.

The railway undertaking operated traditionally as one entity covering all passenger train operations in that country.

It has however been decided that a regional structure would serve the business purposes in a better manner in future.

Therefore an activity to separate the organisation into two units was undertaken.
The new units were to be a “Regional division” and an “Eastern division”. The new organisational structure is to be supported by common functions, such as Finance, Human Resources and Projects and Developments.

Organizational change:

Creation of two business lines: Regional and Eastern
Evaluation of the significance of the change

Safety relevant? YES
Worst case scenario: mismanagement in application of safety procedures → train accident

Significant? YES → CSM for Risk Assessment

Examples: (only two elements)

Failure consequences? → SEVERE
Worst case scenario: train accident

Low complexity? → NO
Attribution of new tasks and responsibility requires a good training and transitional period.

The RU has an SMS procedure to evaluate the significance
Organizational change applied to a Railway Undertaking

Hazard Identification

Hazard Identification: the methods

• **Technique:**
  - Brainstorming

• **Participants:**
  - Leaders in Equipment, Traffic, Planning and Train Operational departments;
  - Employees (including union representatives) affected by the change;
  - Personnel with knowledge of the future organization.

The RU has an **SMS procedure** to identify Hazards in a correct and systematic way
Hazard Identification: meeting organization

Meeting Etiquette:
- No “meetings within meetings”.
- No mobile phones.
- The meeting had the objective of identifying the hazard and its importance, not necessarily to solve the problem.
- Listen to the speaker.
- A 10 minute break every 50 minutes.

Meeting inputs:
To facilitate discussion, a “checklist” was developed. Checklists can be used as prompts to ensure full coverage of the change and its potential hazards.
Hazard Identification: meeting guide-list

**HUMAN FACTORS**
- **Resources:** Number, availability, knowledge, contractors
- **Cooperation:** Venues, network, communication, change, leadership
- **Competence:** Education, experience
- Etc...

**“HARD” FACTORS**
- **Time delays:** Too late/early, conflicts, risks, prioritizing
- **Projects:** Requirements, existing, planned, conflicts, delays, risk management
- **Documentation:** Ownership procedures, change management, authority, requirements
- **Reporting:** Systems, skills, ownership, follow-up, venues
- Etc...

**EXTERNAL FACTORS**
- **Authorities:** Audits, change, regulations, certificate, permits
- **External:** Other actors, local authorities, emergency, coordination
- **Third parties:** Follow-up, certificate, conflicts of interest, quality
- Etc...

**TRAFFIC SAFETY**
- **Train accident:** Fire, derailment, collision
- **Planning:** New, old, maintenance, monitoring, accountability, coordination
- **Working Environment:** Noise, design, temp, space, vapours, gases, psychosocial
- Etc...
Hazard Identification: meeting methodology

To identify hazards, the meeting facilitator asked:

- "What negative consequences can arise from the organisational change that may affect the traffic safety, compared to current levels?"

The facilitator, to aid discussion, introduced a relevant guideword, such as:

- “Availability of resources”

The meeting participants discussed the issue being considered, until such time as causes (if any) leading to a deterioration in safety were identified. The meeting should also assign the appropriate risk level to this hazard / cause.

Note: In some cases the meeting may identify a solution during the workshop.
The result of the HAZARD ID has been summarised in a table, a shortened version is reported below.

The RU has an **SMS procedure** to classify Hazards in a correct and systematic way.

### Hazard classification:

<table>
<thead>
<tr>
<th>#</th>
<th>Guideword</th>
<th>Hazard description</th>
<th>Cause</th>
<th>Effect</th>
<th>Actor in charge</th>
<th>Sev.</th>
<th>Occ.</th>
<th>Safety Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Resources</td>
<td>Increased bureaucracy in the document management system</td>
<td>Roles and responsibilities are not clearly defined</td>
<td>Updates of the route book are not delivered</td>
<td>RU</td>
<td>M</td>
<td>M</td>
<td>SMS Update on responsibilities and interface management</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Safety procedures are not delivered</td>
<td></td>
<td>RU</td>
<td>H</td>
<td>M</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lack of training and background</td>
<td>Mismanagement in delivering safety procedures (emergency, rolling stock, etc.)</td>
<td>RU</td>
<td>H</td>
<td>M</td>
<td>SMS Update on competence management system</td>
</tr>
</tbody>
</table>
Which Risk Acceptance Principle?:

Explicit risk estimation: ALARP (other solutions are possible)

The RU has SMS procedures to perform an explicit risk estimation. It contains also methods that can be used.
Risk Control Measures (Safety Measures)

1. Clarify the roles and responsibilities of the various entities involved in the change.
2. Define interaction meetings / interfaces. Mandate participation at such meetings.
3. New safety training is required to be developed and implemented by HR department in the new structure.
4. ...

SMS Improvement: examples of processes
- Leadership, structure and responsibility;
- Competence Management System

How? → SMS documentation → Procedure
The safety measures issued from the risk assessment and the application of risk acceptance principles were registered and managed in a hazard record.

<table>
<thead>
<tr>
<th>#</th>
<th>Guide word</th>
<th>Hazard description</th>
<th>Cause</th>
<th>Effect</th>
<th>Actor in charge</th>
<th>Safety Measure</th>
<th>Used R.A.Principle</th>
<th>Export</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Resources</td>
<td>Increased bureaucracy in the document management system</td>
<td>Responsibilities are not assigned</td>
<td>Updates of the Route Book are not delivered</td>
<td>RU</td>
<td>SMS procedure RU_REGIO_1234</td>
<td>Explicit Risk Estimation - ALARP</td>
<td>NO</td>
<td>Closed</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Safety Procedures are not delivered to ope staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lack of training and background</td>
<td>Mismanagement in delivering safety procedures (emergency, rolling stock, etc.)</td>
<td>RU</td>
<td>SMS procedure RU_REGIO_5678</td>
<td>Explicit Risk Estimation - ALARP</td>
<td>NO</td>
<td>Closed</td>
<td></td>
</tr>
</tbody>
</table>

The table offers a short extract of the original hazard log

The template of the Hazard Log is part of the SMS documentation
Demonstration of the system compliance with safety requirement:

- Follow up of the **definition of processes and procedures**;

- When an action is complete, the hazard Record is filled with the information.
Do you need help?

European Railway Agency is available for answering questions you may have when applying the CSM regulation on risk assessment:

Contact person: Dragan JOVICIC

E-mail: Dragan.JOVICIC@era.europa.eu
Many thanks for your attention!

Q & A

You have Questions
We have Answers
Summary on the main elements from day 1

January 29th 2013
Q & A

You have Questions
We have Answers
Operational Change

“Driver Only” Operated Train

Application of the CSM for Risk Assessment
IMPORTANT DISCLAIMER

The content of this presentation it’s not intended to be exhaustive and it doesn’t represent a legal reference or a mandatory way to design or implement the SMS for RUs and IMs.

With this presentation the European Railway Agency means to support Railway actors in the implementation of a SMS through the understanding of the basic principles of the European legislation.
Basic information about the example

**Type of actor:** Railway Undertaking  

**Main topic:** re-organization of staff engaged in operation on low passengers volume routes  

**Generalities:** need of the change arising from the sustainability of the railway service on low passengers volume routes  

**Safety target:** to maintain at least the current safety level
The result of the system definition should:

• Describe the existing system: “explain clearly which tasks were performed by driver and which other ones were carried out by onboard staff (or guard) to assist the driver”

• Describe of change of driver's responsibilities due to removal of onboard assisting staff, “e.g. door closing before train departure”

• Define additional technical requirements for system to cover needed changes in Driver Only Operation

• Describe existing interfaces between onboard assisting staff, train driver and trackside staff of infrastructure manager

The System Definition has been carried out according to the SMS procedures
“OLD” System: Transport Service

SMS procedures includes also tasks to be performed

“Driver only” operated train
System Definition
Evaluation of the significance of the change

Safety relevant?  YES
Worst case scenario: SPADs, Passengers accidents

Significant?  YES

On what basis?  CSM for Risk Assessment

Failure consequences, Additionality, Complexity, Monotorability, etc

Examples: (only two elements)

Failure consequences?  SEVERE
A failure of the system can result in major safety consequences (collisions, etc.)

Low complexity?  NO
Redesign of working procedures for drivers

Is the change safety related?

Is the change significant?

CSM for RA
Hazard Identification: (e.g. HAZOP)

- **Aim:** find **all hazards**, with a relevant influence on risk brought by the change applied to the system;

- **Technique:** HAZOP (i.e. brainstorming)
  - Safety experts
  - Technical experts
  - Representative of RU’s operational Staff
  - IM’s staff involved in track-side operations

- **Criteria** for selection of participants:
  - Competence, experience, task normally performed, etc..
  - Interface (e.g. IM’s staff)
Hazard classification:

- A level of severity of risk and consequences was assigned (high, medium, low)
- A level of occurrence was assigned (high, medium, low)

Finally the impact of the proposed change against the safety performance was evaluated to check if it is Increased, Unchanged or Decreased.

<table>
<thead>
<tr>
<th>№ HZD</th>
<th>Origin</th>
<th>Hazard description</th>
<th>Cause</th>
<th>Additional information</th>
<th>Actor in charge</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Safety Performances</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HAZOP report R_X</td>
<td>Opening of doors – risk of passenger fatality</td>
<td>Driver</td>
<td>Driver error through lack of competence or seating position</td>
<td>RU</td>
<td>High</td>
<td>High</td>
<td>Decreased</td>
</tr>
</tbody>
</table>

None of the risks are broadly acceptable
Particularly, **hazard identification** looked at what key operational hazards could **arise from the lack of on-board staff**.

A key element is the analysis of procedures in which the on-board staff has a role, e.g.:

- Interactions with doors;
- Interface with IM’s staff.

**Example of identified hazards** during HAZOP (one way of proceeding):

<table>
<thead>
<tr>
<th>ID</th>
<th>Hazard</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Train departure with open doors</td>
<td>Passenger could fall on the track</td>
</tr>
<tr>
<td>2</td>
<td>Door opening on wrong side</td>
<td>Passenger could fall on the track</td>
</tr>
<tr>
<td>3</td>
<td>Door closing while passengers are getting in the train</td>
<td>Passenger could be caught between doors</td>
</tr>
<tr>
<td></td>
<td>Others...</td>
<td>...</td>
</tr>
</tbody>
</table>
Which Risk Acceptance Principle?:

- **Code of Practice** (i.e. a set of standards for Driver Only Operation)
- **Reference Systems**

Both are used to define *safety requirements* for identified hazards, such as:

- **Revised operational procedures** for the drivers
- **Extra technical equipment** necessary onboard or on track to ensure safe and reliable means of train dispatch;
- **A checklist** for ensuring that the driver's cab is suitable.

Operational rules shall be revised in **compliance** with the requirements from the applicable **codes of practice** and the relevant **reference systems**.
System Definition

"Driver only" operated train

NEW System: "Driver Only" Transport Service

SMS procedures includes also tasks to be performed

Dissemination Workshop of the CSM for Risk Assessment
Vilnius, January 29th and 30th 2013

Slide n° 201
According to the SMS of the RU, the identified hazards were registered in a **hazard record** with the safety requirements controlling the associated risk, *(i.e. reference to additional onboard and trackside equipment as well as to the revised operational procedures).*

<table>
<thead>
<tr>
<th>N°</th>
<th>Origin</th>
<th>Hazard description</th>
<th>Cause</th>
<th>Additional information</th>
<th>Actor in charge</th>
<th>Safety Measure</th>
<th>Used Risk Acceptance Principle</th>
<th>Exported</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HAZOP report (R_x)</td>
<td>Opening of doors – risk of passenger fatality</td>
<td>Driver</td>
<td>Driver error through lack of competence or seating position</td>
<td>RU</td>
<td>Training Cab design</td>
<td>Code of Practice</td>
<td>Partly</td>
<td>Partly closed</td>
</tr>
<tr>
<td>2</td>
<td>HAZOP report (R_x)</td>
<td>Failure of the CCTV – driver cannot see the platform</td>
<td>CCTV</td>
<td>Vandalism Incorrect/insufficient maintenance</td>
<td>IM</td>
<td>Protection of the equipment Regular checks</td>
<td>Code of Practice</td>
<td>No</td>
<td>Closed, measures in place</td>
</tr>
</tbody>
</table>

The application and the effectiveness of the **Safety Requirements** were monitored, and reviewed when needed, to ensure that the identified hazards continue to be correctly controlled during the operations.
Demonstration of the system compliance with Safety requirements:

- System implemented vs. Safety Requirements;
- Integration of the new operational procedures in the SMS of the RU;
- Revision of the monitoring process to include the monitoring of the new safety requirements. The aim is to check if they are applied and effective and if they need to be improved to preserve the same level of safety provided by the old system.
Do you need help?

European Railway Agency is available for answering questions you may have when applying the CSM regulation on risk assessment:

Contact person: Dragan JOVICIC - E-mail: Dragan.JOVICIC@era.europa.eu
Many thanks for your attention!
Technical Change

Speed upgrade of Rolling Stock

Application of the CSM for Risk Assessment
Technical Change as consequence of Operational change.

The Engineering Department of a Railway Undertaking (RU) would like to increase the maximum speed limit of one class of passenger trains from 160 kph to 200 kph.

This will eventually allow the merging of two rolling stock fleets into one.

This is an **Operational Change applied to Trains** (Rolling Stock). The application of the risk assessment process to this change resulted in the definition of **Safety Requirements**, which are of **Technical and Operational natures**.

The technical safety measures were regarded as technical changes covered by the CSM and were consequently assessed for potential hazards.

**There was no risk assessment for the safety measures that did not involve any technical change.**
Technical change applied to Rolling Stock System Definition

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Train on track

ROUTE (Max Speed 220Kph)

Coaches

Boogie Y32

Sub#1 → Sub#N

Brake (NO anti-lock)

Axle → Wheels

Sleepers

Tracks

Signalling

Breaking distance

Sub#3 → Sub#N

Sub#4

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Slide nº 208
The coaches

3 types: 1st class, 1st class bar and 2nd class.

The coaches are fitted with **bogies** (named Y32 bogies), they are to run at a maximum speed of **160 kph**. The bogies Y32 are already on Corail trains already operated, by the RU, at a maximum speed limit of **200 kph**.

From a comparison of the Corail with the coaches there are some relevant **differences**: coaches have **wider bodies**, and are **slightly heavier**.

With small technical improvements (changes), these bogies will be used in the new operations (max speed of 200 kph).

**Operational Change:**

Increasing maximum speed from 160kph to 200kph
The locomotives

The locomotives are designed to run with a max. speed of 220 kph and have already been safely tested at 200 kph with other coaches fitted with the same Y32 bogies (Corail).

The infrastructure

The infrastructure already supports trains running at a maximum speed of 220 kph. It is characterised by a small distance between signals.

Comment:

Please note that the Corail train could represent a Reference System.
Evaluation of the significance of the change

Safety relevant? YES
Worst case scenario: Derailment at 200kph

Significant? YES
On what basis? → CSM for Risk Assessment

Failure consequences, Additionality, Complexity, Monitorability, etc.

Examples: (only two elements)

Failure consequences? → SEVERE
A failure of the system can result in major safety consequences (derailment)

Low complexity? → YES
Technical changes are simple

Is the change safety related?

Is the change significant?

CSM for RA
Hazard Identification: (e.g. HAZOP)

- **Aim**: find *all hazards*, with a relevant influence on risk brought by the change applied to the system;

- **Technique**: Brainstorming
  - Safety experts
  - Technical experts
  - ECM Staff
  - Manufacturers (Bogies, RS, Bearings, Brake)

- **Criteria** for selection of participants:
  - Competence, experience, task normally performed, etc..
  - Interface (e.g. ECM)
### Hazard classification:

- Severity of risk and consequences was assigned (high, medium, low)
- A level of occurrence was assigned (high, medium, low)

<table>
<thead>
<tr>
<th>#</th>
<th>Origin</th>
<th>Hazard description</th>
<th>Cause</th>
<th>Additional information</th>
<th>Actor in charge</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Safety Performances</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HAZOP report R_X</td>
<td>Abnormal wear Bearings – axle lock with derailment</td>
<td>Weight of coaches</td>
<td>Due to the dimensions and weight of the coaches compared</td>
<td>RU</td>
<td>High</td>
<td>High</td>
<td>Decreased</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>HAZ_Re</td>
<td>Wave-like movement - Derailment</td>
<td>Weight - Speed</td>
<td>See n.1</td>
<td>RU</td>
<td>High</td>
<td>High</td>
<td>Decreased</td>
</tr>
</tbody>
</table>
Example of identified hazards:

“Dynamic behavior of the coach”, i.e. “Wave like movement of the bogie that can lead to a derailment”

Safety Level: DECREASED

How to preserve the Safety Level? SAFETY REQUIREMENTS

The technical changes proposed

- Improvement of the brake system: Anti Blocking System
- Improvement of boogies: dampers and conical roller bearings
Technical change applied to Rolling Stock
New system including safety requirements

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Summary of the changes

- Operational: maximum speed increased from 160kph to 200kph;
- Technical: Conical bearings;
- Technical: Dumpers;
- Technical: Improvement of the brake system with anti-lock system.

An operational change can include technical changes

Improvement of the brake system: Anti Blocking System

Improvement of boogies: dampers and conical roller bearings
Technical change applied to rolling stock

Risk Analysis and Evaluation

Which Risk Acceptance Principle?:

- **Code of Practice** for the *technical change*:
  - i.e. Fiche UIC for the dynamic behaviour of the coach

- **Reference Systems** for the *operational change*:
  - Corail train fitted with the same bogie

Both are used to define *safety requirements* for identified hazards, such as:

- Conical bearings;
- Dumpers;
- Improvement of the brake system with anti-lock system;
- Maintenance plan adapted
The **identified hazards**, the **safety measures** and the **resulting safety requirements** issued from the risk assessment and the application of the three risk acceptance principles were registered and managed in a hazard record using a similar form than the table below:

<table>
<thead>
<tr>
<th>N°</th>
<th>Origin</th>
<th>Hazard description</th>
<th>Cause</th>
<th>Additional information</th>
<th>Actor in charge</th>
<th>Safety Measure</th>
<th>Used Risk Acceptance Principle</th>
<th>Exported</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HAZOP report R_x</td>
<td>Axle locked when the train is running</td>
<td>Wear of bearing</td>
<td>Dedicated standards available</td>
<td>RU</td>
<td>Conical Bearing</td>
<td>CoP Manufacturer catalog</td>
<td>NO</td>
<td>Closed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Brake system without anti-lock</td>
<td>Dedicated standards available</td>
<td>RU</td>
<td>Anti lock brake system</td>
<td>CoP UIC Leaflet</td>
<td>NO</td>
<td>Closed</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>HAZOP report R_x</td>
<td>Wave-like motion</td>
<td>Weight of the rolling stock + speed</td>
<td>Dedicated standards available</td>
<td>RU</td>
<td>Dampers</td>
<td>CoP UIC leaflet</td>
<td>NO</td>
<td>Closed</td>
</tr>
</tbody>
</table>
Demonstration of the system compliance with safety requirement:

- Follow up of the installation of dumpers in the bogie;
- Follow up of the installation of conical bearing in the bogie;
- Follow up of the improvement of the brake system with Anti Lock System.

The traceability provided by the Hazard Record is crucial to support the demonstration of the system compliance to the safety requirements.
Do you need help?

European Railway Agency is available for answering questions you may have when applying the CSM regulation on risk assessment:

Contact person: Dragan JOVICIC
Dragan.JOVICIC@era.europa.eu
Many thanks for your attention!
Safety Management System
Basics design and implementation

Antonio.DAGOSTINO@era.europa.eu
Content of the presentation

1. References from Railway Safety Directive
2. What are the benefits of having a SMS?
3. Basics on the SMS design and implementation
4. SMS: Rules based or risk based?

Terminology

NSR = National Safety Rules;
RSD = Railway Safety Directive;
NSA = National Safety Authority
RU = Railway Undertaking
IM = Infrastructure Manager
TSI = Technical Specification for Interoperability
Basic elements from the Directive 2004/49/EC

From the Directive 2004/49/EC:

Art. 3.(i) – Definition of ‘Safety Management System’ - SMS

Art. 4.3 – Responsibilities, risks and SMS

Art. 9 – SMS general requirements

Art. 10.1 / Art. 10.2 – Safety certification*

Art. 11.1 – Safety authorisation*

Annex III – Requirements and elements of the SMS

* NSAs assess the SMS in order to grant safety certificates and safety authorisations

Safety Certification and Safety Authorization are not in the scope of this presentation
The **SMS must:**

- be documented in all relevant parts;
- describe the **distribution of responsibilities** within the organisation of the IM or the RU;
- show how control by the **management** on different levels is secured;
- show how **staff** and their representatives on all levels are involved;
- show how **continuous improvement** of the safety management system is ensured.

All these requirements shall be included in the SMS
The requirement of the **SMS** shall be fulfilled **through**:

- safety policy and corporate safety targets;
- compliance with standards or other prescriptive conditions;
- change management and risk management;
- operational and front-line staff competence management;
- communication and info exchange, document management;
- emergency management;
- reporting of unexpected outcomes;
- internal auditing of the SMS.

All these elements shall be defined in the organization of the company and shall be **DOCUMENTED**.
Do we need a Safety Management System?

**YES**

Why do we need the Safety Management System?

Compliance $\rightarrow$ Safety Certification

To control risks $\rightarrow$ Safe Business

Safety is a value, but it’s also a key process to improve and protect the business
Typical ‘Old’ Scenario

Regulator
(Self Regulation)

State Railway Company:
Railway Undertaking
Infrastructure Manager
Locomotive Manufacturer
Keeper
ECM
Infrastructure Maintenance
Cleanings
.....

Passengers
Freight Customers

Typical ‘New’ Scenario

European extension

Risk Based approach
(proactive)

Actors are responsible to control the risks related to their activities

Interaction among all the actors: INTERFACES

Why we need a Safety Management System
Definition of Safety Management System:

«The organisation and arrangements established by an IM or RU to ensure the safe management of its operations»

How to ensure the safe management of operations:

«The safety management system shall ... (omissis)... ensure the control of all risks associated with the activity of the infrastructure manager or railway undertaking, including the supply of maintenance and material and the use of contractors...»

Directive 2004/49/EC – art.3 (i)

Directive 2004/49/EC – art.9.2

Art. 9 - RSD
Annex III – RSD
NSRs, TSIs, ...

Basic Elements + Specific Elements
SMS
Risk Control
Safe Operations

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The definition of safety measures to control specific risks:

- Definition of the **activities** to be undertaken by the actor;
- Risk Identification;
- Risk Analysis;
- Definition of **Safety Requirements** and **Risk Monitoring**:
  - Technical Systems (i.e. ATP, IT support, etc.);
  - Internal provisions → **SMS procedures covering organizational and operational risks**
Basic SMS Requirements (art.9 + Annex III RSD)

Safety Requirements

- Processes for design and improvement
  - Management Commitment
  - Safety Policy
  - Corporate Safety Targets
  - Decision Taking
  - Management Control
  - Control of Risks
  - Change Management

- Processes for implementation
  - Distribution of responsibilities
  - Management accountability
  - Organizational structure
  - Workload Planning
  - Competence Management
  - SMS Documentation

- Operational Activities
  - Compliance with Rules
  - Use of contractors
  - Asset Management
  - Emergency Management
  - Coordination tasks for IM

Safety Management System

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Safety Management System

Introduction to the design of the SMS

Basic SMS Requirements (art.9 + Annex III RSD)
The Safety Management System Design – example of document structure

Structure of documentation composing the SMS

- CEO
- Safety Policy
- SMS Manual
- System Procedures
- Operating procedures
- Prescriptions
- Templates Forms
- Ope Staff
- Safety Reporting
- Safety Communication

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Example of Document Mapping in the SMS:

- Visual
- Process related
The **SMS** is a set of organizational tools, processes and procedures that shall be designed, implemented, monitored and improved.

The **aim of the SMS** is to ensure the deployment of safe operations.

Risk are also controlled using a logical and systematic approach to design, develop, monitor and improve operations.
The Safety Management System Implementation - PDCA

Management Commitment
- Culture and resources for safety
  - Expertise
  - Staff
  - Safety Culture
  - Leadership

Description of activities
- Business Plan
  - Interfaces
  - Activities

Identification of associated hazards and risk control
- National and European Legislation
  - Internal Rules and procedures
  - Technical Systems

Allocation of responsibilities
- Roles and responsibilities within the company
  - Roles and responsibilities of contractors

SMS Documentation
- Approval
  - Distribution
  - Management

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### The Safety Management System Implementation - PDCA

<table>
<thead>
<tr>
<th>Operations (Task execution)</th>
<th>Information Exchange (interface management)</th>
<th>Implementation of other SMS processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff</td>
<td>Asset</td>
<td>Contracts</td>
</tr>
</tbody>
</table>

#### Data Collection and Report

- Auditing
- IT support
- Responsibilities
### Analysis of Safety Performances

<table>
<thead>
<tr>
<th>Trends</th>
<th>Indicators</th>
<th>Matching with targets</th>
<th>Reporting to Management</th>
</tr>
</thead>
</table>

### Evaluation of the implementation of processes and procedures

### Evaluation of the effectiveness of processes and procedures

### Reporting to the Management

### Final Analysis

<table>
<thead>
<tr>
<th>Safety Meetings</th>
<th>Sharing safety performances</th>
<th>Management</th>
</tr>
</thead>
</table>
The Safety Management System
Implementation - PDCA

Definition of corrective and preventive actions

- Staff involvement
- Management involvement
- Risk Assessment
- Compliance with legislation

Approval of corrective and preventive actions

- Human, Technical and Organizational Resources
- Leadership

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**Question:**

The processes have been designed and described in the SMS documentation which has been revised and approved, do I have a fully working SMS?

**Answer:**

**NO.** The SMS is the result of the implementation of processes and procedures and to implement the SMS there is one essential requirement:

The commitment of the management
Dir. 2004/49/EC – Annex III – Art.2 (c) : ‘Basic Elements of the SMS’
«procedures to meet existing, new and altered technical and operational standards and other prescriptive conditions...»

Dir. 2004/49/EC – Annex III – Art.2 (d) : ‘Basic Elements of the SMS’
«procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations»

Rules are an important tool to improve the safety level of the railway system, RUs and IMs should manage their risks defining internal rules with a risk based approach

SMS is not an alternative to the existing set of rules
SMS is **not an alternative** to the existing set of safety related **technical and operational rules**. It’s a structured way to apply them **taking into account the risks** related to the specific activities of RUs and IMs.

Are all the risks covered by the applicable rules?

**No,** each of the operators has specific risks that need to be avoided or reduced, **BEFORE** an unwanted event occurs.

**From ‘React and Fix’ to ‘Predict and Prevent’**
Do you need help?

European Railway Agency is available for answering questions you may have about the Safety Management System:

Contact person: Antonio D’Agostino

E-mail: antonio.dagostino@era.europa.eu
Many thanks for your attention!

Q & A

You have Questions
We have Answers
Conclusions of the workshop
Conclusions

• **CSM regulation No 352/2009** defines the overall framework for a harmonised and transparent risk management and risk assessment process in all the Member States (i.e. **WHAT** must be done); the CSM **does not impose HOW** to fulfil those overall requirements (e.g. Hazard ID or Risk Estimation technique)

• The overall purpose is to:
  - **maintain** (and improve where necessary) the level of safety in European railways
  - enable the **mutual recognition** of results from risk assessments and **limit the additional assessments and demonstrations** only to the differences when going to operate in other Member States;

• **CSM regulation No 352/2009** There is nothing new in the CSM Regulation; It is based on existing EU practices for managing risks → freedom left to the Proposer to decide what detailed methods and tools he will use for achieving the CSM regulation requirements
Conclusions

• The regulation must be applied for significant changes;

• When a change is **not significant**, the proposer must control the risks according to the processes and procedures defined within the SMS.

• CSM regulation uses the **ISO standard terminology** related to risk management and risk assessment → EU railway actors need to:
  - compare their existing practices for managing railways safety with requirements in CSM regulation
  - identify the **few new steps/tasks** requested by CSM regulation
  - perform new risk assessments using this new harmonised process

The experience of other member states that apply such a process since long (e.g. Scandinavian countries) shows that for first applications the proposer produces too much documentation but with the increasing experience in risk assessment the amount of produced paper decreases
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CSM for RA requires that the proposer must:

- know why the safety requirements from Codes of Practice – Similar Reference Systems – Explicit Risk Estimation are used;
- identify the hazards related to the change and ensure that the associated risks are controlled + link the identified hazards to the RAP used for controlling the associated risk;
- document the risk management and risk assessment → use of a Hazard Record for recording the essential information;
- have a transparent and auditable process by an independent assessment body.

CSM for RA does not rule the risk management related to non significant changes, these type of changes must be managed according to the SMS of the operator.

Conclusions
Please remember:

<table>
<thead>
<tr>
<th>Risk Assessment</th>
<th>Risk Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>What can happen?</td>
<td>What can be done?</td>
</tr>
<tr>
<td>How likely is it to happen?</td>
<td>What are the benefits, costs and risks of each option?</td>
</tr>
<tr>
<td>What are the consequences if it happens?</td>
<td>What are the impacts of each option on future options?</td>
</tr>
</tbody>
</table>

Risk assessment is a means to an end, not an end in itself - the aim is to **keep people safe**, **not have good paperwork**
Plenary Session
&
Open Discussions
Contact information

• European Railway Agency is available for answering questions you may have when applying EU railway legislation

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  ✉ Other members not listed
Many thanks for your attention!