

Innovations in the legal framework on risk assessment for Railway Systems of the European Community

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PSAM 9 conference Hongkong, 20th May 2008



European Railway Agency

Challenges to develop Common Safety Methods



The single European market became more and more reality, but the reality of the railway community was still made of:

- Member States being owner and client at the same time
- no independent management
- only isolated cross-border organisations, as a lack of clarity regarding the split of responsibilities between states and railways constrained international cooperation
- no guarantee of end-to-end support service
- a capital structure that did not always reflect the real value of the assets
- technical systems that were developed on national level
- deep and detailed involvement of railways in the work of the supplier industry

The restructuring of the railway sector is on its way; the first and second railway packages have been adopted and will be or have been transposed into national law:

- separation of infrastructure and operation (Directives 91/440/EEC, 2001/12/EC and 2004/51/EC)
- Licensing of railway undertakings (Directives 95/18/EC and 2001/13/EC)
- Harmonisation of allocation of infrastructure capacity, levying of charges and safety certification (Directives 95/19/EC and 2001/14/EC)
- Forcing interoperability through harmonisation (Directives 96/48/EC, 2001/16/EC, 2004/50/EC and TSIs)
- Ensuring the maintenance of the high safety level of European railways (Directive 2004/49/EC)
- Establishing a European Railway Agency (Regulation (EC) N° 881/2004)

The single European railway market with the vision of an integrated railway area **will be reality and will be made of:**

- An economically sound sector through intra- and intermodal competition
- Technical harmonisation through widely implemented TSI conformity
- Common Safety Methods to ensure equal processes and treatment through comparable national approaches
- Common Safety Targets to ensure that the safety performance will be maintained or, where reasonably practicable, improved on Member State level
- Safety Certification of railway undertakings and Safety Authorisation of infrastructure managers to maintain or, where reasonably practicable, improve the safety performance on operational level

The European Railway Agency aims to contribute to the **creation of an integrated European railway area** where trains can run and be organized as transport services freely, safely, effectively and without interruption. The objective is to allow the rail transport sector to realize its inherent competitive advantages in relation to other transport modes.

Based on legal acts such as Directives, Mandates and Regulations the **mission of the European Railway Agency is, to give technical support to the European Commission** and to contribute, on technical matters, to the implementation of the EC legislation.

The activities carried out by the Agency aim at:

- **developing a common approach to safety**, safety regulation and accident investigation, by harmonization of safety assessment methods, safety targets and safety certification conditions;
- **improving the interoperability of the European rail system** by developing the conditions for the free and uninterrupted movement of trains through technical and operational harmonization, including conditions for mutual acceptance of railway vehicles;
- **facilitating the exchange of information within the railway sector** by networking with national bodies, providing registers and databases, issuing reports and giving guidance on the implementation of the regulatory framework.

Premises:

- ◆ Offices in Valenciennes
European Railway Agency
160, Boulevard Harpignies
BP 20932
F – 59307 Valenciennes CEDEX

- ◆ International meeting facilities in Lille
European Railway Agency
Espace International Lille
299, Boulevard de Leeds
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What are Common Safety Methods ?

- Following Railway Safety Directive 2004/49/EC :
*“**Common Safety Methods** are the methods .. to describe*
 - *how safety levels and achievement of safety targets and*
 - *compliance with other safety requirements*
are assessed”

Two types of methods need to be developed :

- **Statistical Methods** for the *assessment of safety performances describing the achievement of CSTs through the use of CSIs;*
- **Predictive Risk Assessment Methods** for the *assessment of safety levels and compliance with safety requirements* → *CSMs for Risk Assessment;*



How to do Risk Assessment ?



The **purpose of the CSM is to facilitate progress** towards a common approach to safety

Harmonisation of risk management processes used to assess the safety levels or the compliance with safety requirements

Focus on safety issues that may exist across the interfaces between the different actors of the rail sectors

To harmonise the type of documents / evidences to be provided to authorise the putting into service

Caution: There is already a strong safety culture in the Railway sector

Certain degree of freedom should be left to each actor to adapt the risk evaluation and assessment methods they are solely responsible for in accordance to their needs and already in use methods – it is not necessary to reinvent the wheel!

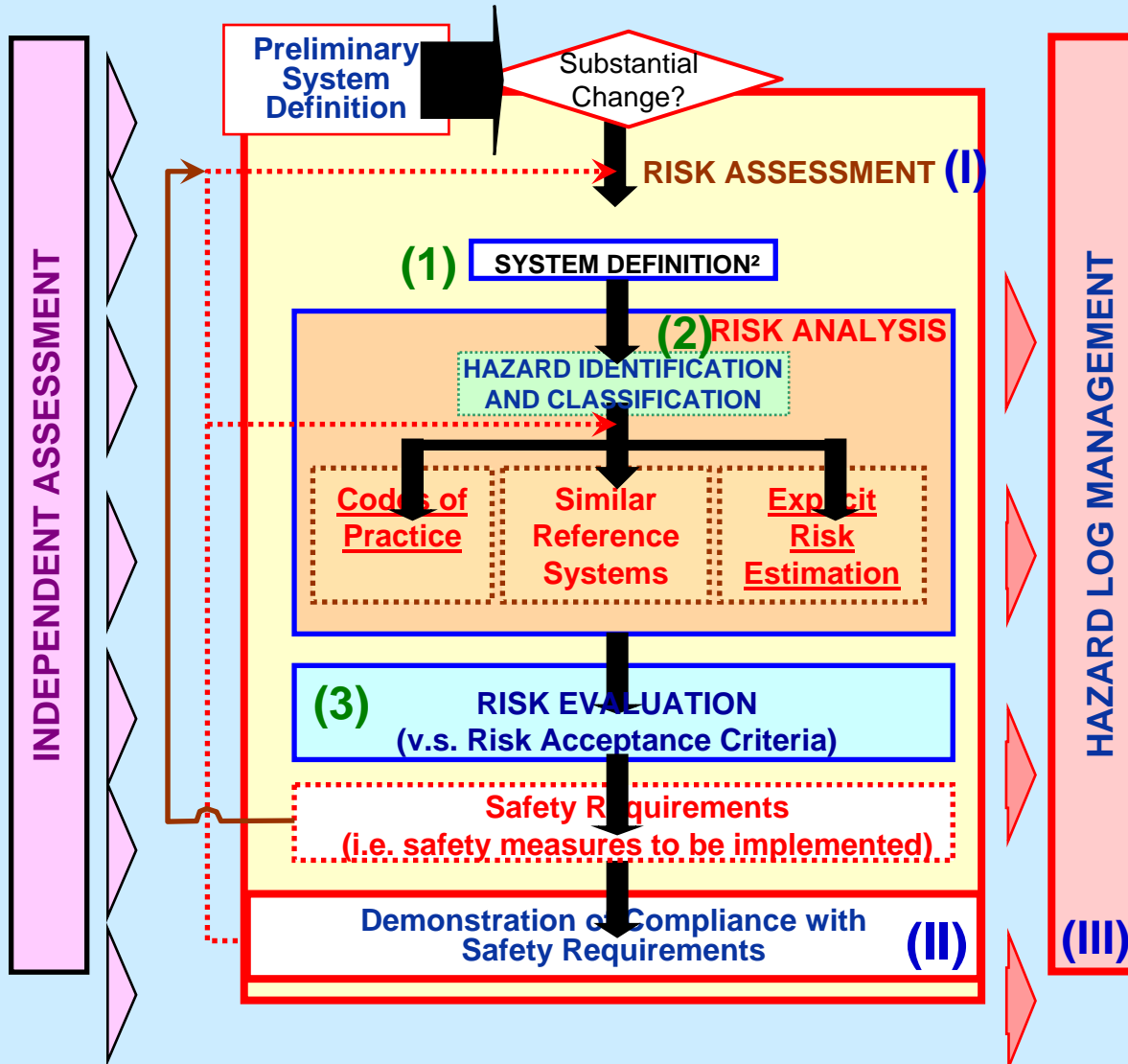
→ CSMs provide **Common Principles** but do not fix the Tools (e.g. FTA, FMECA)

More specifically, Risk Assessment methods shall apply to assess predicatively the safety of **substantial changes** of the Rail System in the Member States.

Changes could be either :

- Construction of new lines or significant changes of existing lines;
- Introduction of new and significantly modified technical systems or products;
- Operational changes (such as new or significantly modified operational rules and maintenance procedures);
- Significant changes within RU/IM Organisations;

The CSMs developed for the 1st Set apply to all changes that require a risk assessment in accordance to ANNEX III point 2d of Directive 2004/49/EC by IM's or RU's.



Risk Management is an iterative process that comprises:

(I) Risk Assessment Process to identify:

- ↻ the hazards;
- ↻ the associated safety measures;
- ↻ the resulting safety requirements;

(II) Demonstration of compliance with safety requirements;

(III) Management of identified hazards and associated safety measures;

Codes of Practices and risk evaluation

If an identified hazard is covered by codes of practice or existing adequate standards, the risk can generally be accepted.

Reference System and risk Evaluation

If there are similar approved systems used under same conditions as the one under assessment, the risk can be evaluated through similarity analysis.

Explicit Risk Estimation

In case none of the two options above can cover the evaluation of the hazard, the risk acceptability shall be demonstrated through explicit risk estimation

- Risk Estimation could be either quantitative or qualitative, and shall take into account the existing safety measures for the system;
- the methods used for explicit Risk Estimation shall reflect correctly the system under assessment and its parameters (including all operational modes);
- the results shall be sufficiently accurate to serve as robust decision support, i.e. minor changes in input assumptions or prerequisites shall not result in significantly different requirements.



Summary

- The purpose of the CSM is to facilitate progress towards a common approach to safety
- CSM will be used to describe how safety levels and achievement of safety targets (among others the CST) and compliance with other safety requirements are assessed
- The scope of CSM is thus the system as a whole (including its management and operation) and could be used whenever there is an explicit need to describe how compliance with safety requirements is assessed
- CSM for risk assessment and evaluation should be applied to processes described by the interoperability directives as well as those described in the safety directive
- CSM for risk assessment have to consider as risk acceptance principles
 - Codes of Practice
 - Similarity Analysis
 - Explicit Risk Estimation



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Thank you for
your attention!