

Abstract: in order to promote the harmonisation of the railway safety performance and railway regulation across Europe, the EU Legislators have approved in April 2004 the railway safety directive 2004/49/EC. That directive allocates amongst others the task of defining a Common Safety Method (CSM) on risk evaluation and assessment to the European Railway Agency. The objective of this paper is to summarise and highlight the main characteristics of the associated "Commission Regulation on a Common Safety Method on risk evaluation and assessment" (EC) N° 352/2009 published in the Official Journal of the European Union on 29th of April 2009.

Keywords: common safety method (CSM), risk evaluation and assessment, mutual recognition

Foreword

Until beginning of 2000, Member States of the European Community have developed their own railway safety rules and railway standards, often based on national technical and operational concepts. This has progressively led to differences in principles, approaches and safety cultures making it difficult to break through barriers and to establish international rail transport operations. Simultaneously, the economic integration and rapid growth in trade has progressively transformed the European Union's railway transport needs. The construction of a safe and integrated railway network, without national frontiers, became one of the EU's major priorities. This requires a strong European regulation in the fields of both technical and safety requirements, the two being inextricably linked.

The European Railway Agency was set up with the aim of helping to create this integrated railway area by establishing a European approach to railway safety⁽¹⁾ and interoperability⁽²⁾. Its main task is to develop economically viable common technical specifications (TSI's), including the unique ERTMS signalling solution, and harmonised approaches to safety, working closely with railway sector stakeholders, national authorities and other concerned parties, as well as with the European institutions. All of the Agency's work is aimed at facilitating the growth and development of freight and passenger traffic by harmonising safety processes, technical procedures and reducing delays caused by incompatible national systems.

Harmonised approach for risk assessment - CSM on risk assessment

Purpose: the purpose of the CSM on risk assessment is to contribute to the overall objective of the EU. It facilitates the access to the market for rail transport services and enables the mutual recognition of results from risk assessment, by harmonising:

- (a) the risk management processes used to assess the safety levels and the compliance with safety requirements;
- (b) the exchange of safety relevant information between different actors within the rail sector in order to manage the safety across the different interfaces which may exist within this sector;

(c) the evidence resulting from the application of a risk management process.

Requirement for a harmonised approach: Article 6(3)(a) in safety directive 2004/49/EC explicitly requires the development of a harmonised approach for risk assessment. The application of the CSM on risk assessment is also implicitly required through:

- (a) Article 9 and Annex III in safety directive 2004/49/EC which define the requirement for procedures and methods to be put in place by the railway undertakings (RU's) and

infrastructure managers (IM's) in their safety management system (SMS) for managing the safety of the railway system during its operation. One of the SMS processes [see Annex III(2)(d)] explicitly requires the RU/IM SMS to contain procedures and methods for managing changes. The application of the CSM on risk assessment will enable the RU and IM to control the risks that arise from changes to the railway system;

and

- (b) Article 15 in interoperability directive 2008/57/EC which identifies

(1) See provisions in "Railway Safety Directive 2004/49/EC".

(2) See provisions in "Railway Interoperability Directive 2008/57/EC".



amongst others the need for a safe integration of structural sub-systems before authorising their placing into service. The application of the CSM on risk assessment will also enable to control the risks that arise from the integration of a sub-system into the railway system.

Strategy for developing the CSM: the safety directive 2004/49/EC acknowledges that the safety levels in the Community rail system are generally high, in particular compared to road transport. In order to ensure that these safety levels are maintained, and improved, when and where necessary and reasonably practicable, it was important:

- (a) to base the development of the CSM on existing methods in the Member States that enable them to continue to achieve high safety levels;
- (b) to define and agree on a harmonised process for risk assessment based on those existing methods and on EN standards.

Who shall apply it? The CSM on risk assessment shall be applied by the person in charge of implementing the change under assessment. This person, referred to as the “proposer”, can be one of the following actors:

- (a) the railway undertakings and infrastructure managers, in the framework of the risk control measures they have to implement in accordance with Article 4 of the safety directive 2004/49/EC;
- (b) the contracting entities and the 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.

Where necessary, the proposer shall ensure, through contractual arrangements, that suppliers and service providers, including their subcontractors, participate in the risk management process described in the CSM.

When to apply it? The CSM on risk assessment shall apply to any change of the railway system in a Member State, as referred to in point (2) (d)⁽³⁾ of Annex III to safety directive 2004/49/EC, which is considered to be significant. If there are no notified national rules defining whether a change is significant or not in a Member State, the proposer shall decide, by expert judgement, on the significance of the change based on criteria that are provided in Article 4 of the CSM on risk assessment: “*failure consequence, novelty used in implementing the change, complexity, monitoring and reversibility of the change*”. If the change is not significant, the CSM does not need to be applied but the decision needs to be documented to allow the national safety authority to check it during inspections. For non significant changes, the expert judgement shall always evaluate whether the sum of all non significant changes since the last application of the CSM becomes a significant change when added up.



(3) Annex III(2)(d): the RU/IM SMS shall contain “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”. The change can thus be of technical, operational or organizational nature.

Harmonised CSM process: in order to enable the mutual recognition of the results and to ensure that the existing safety levels are maintained in the Community rail system, the CSM harmonises the process for risk assessment. It specifies only **what** requirements must be fulfilled **without specifying how** to fulfil them. As illustrated in Figure 1, this harmonised process is a typical iterative risk management process. It is structured around the following three main steps:

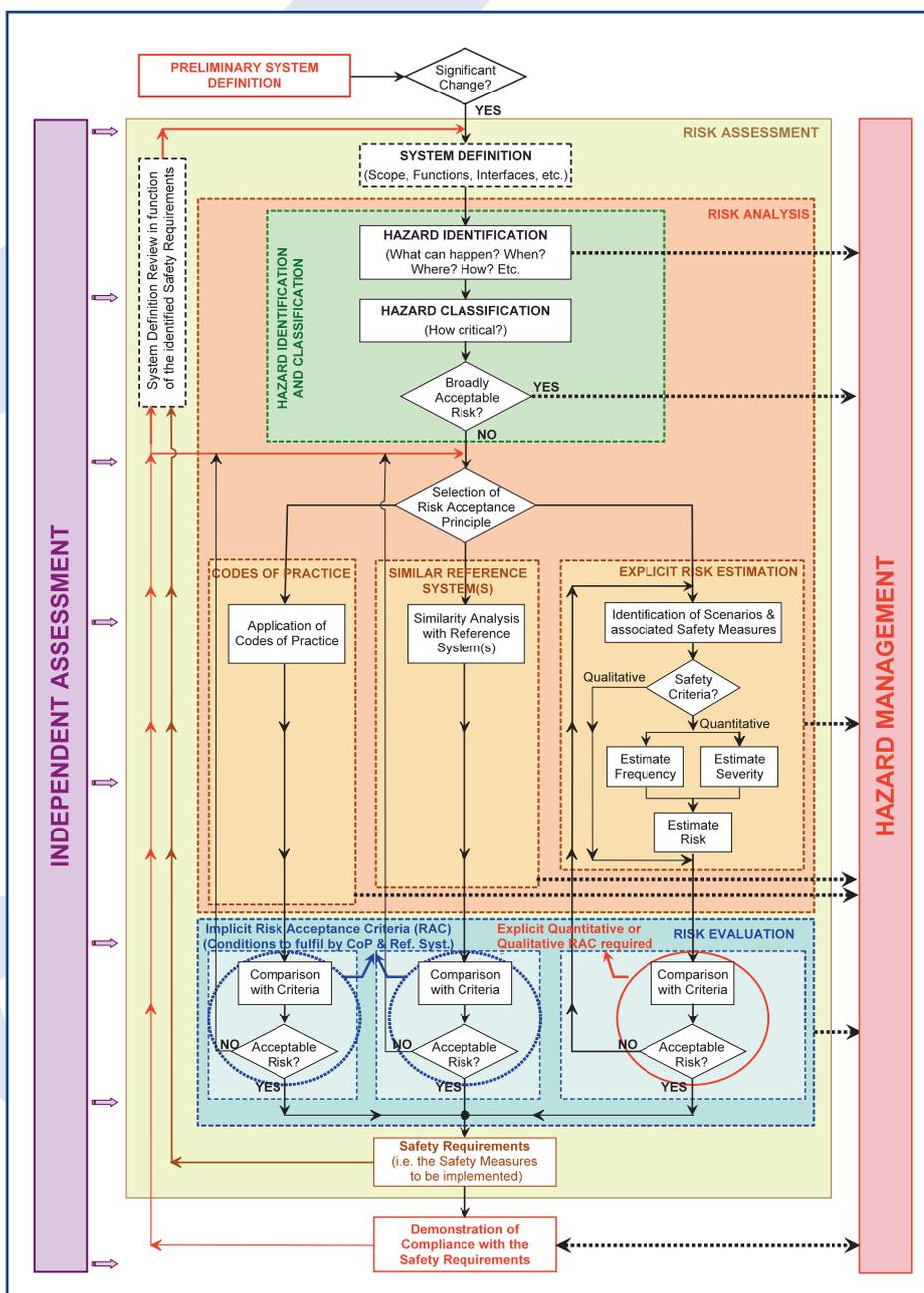
- the systematic identification of the hazards, based on the definition of the system under assessment, of the associated safety measures and of the resulting safety requirements;
- the risk analysis and the risk evaluation;
- the demonstration of the system compliance with the identified safety requirements.

In addition to these classical steps, the following ones were specified in the

CSM process, mainly to enable the mutual recognition of results from such risk assessments:

- the hazard management documentation using "hazard records" both for controlling the exchange of safety requirements between the different actors involved in the significant change (interfaces), as well as for managing the status of the hazards under the proposer's responsibility;
- an independent assessment by an assessment body of the correct application of the overall CSM process.

Figure 1: Risk management process and independent assessment.



Existing Risk Acceptance Principles:

again in order to ensure that the existing safety levels are maintained in the Community rail system, the CSM on risk assessment is based on existing methods for controlling the identified hazards and the associated risks. It allows one of the following three risk acceptance principles to be used interchangeably (i.e. without any order of priority being specified) during the risk analysis and risk evaluation step:

- codes of practice (TSI, Notified National Rules, European Standards);
- similar reference systems;
- explicit risk estimation and harmonised risk acceptance criteria.

The link between the hazard and the risk acceptance principle applied for controlling it shall be registered in the hazard record to help with the accountability of the decision making process. This is a key issue for the mutual recognition of the results of the application of CSM on risk assessment.

It should be noted that the level of detail of the hazard identification will depend on the risk acceptance principle and risk acceptance criteria used by the proposer for controlling the identified hazards.

Entry into force of the Commission CSM Regulation on risk assessment

The associated “Commission Regulation on a Common Safety Method on risk evaluation and assessment” (EC) N° 352/2009 was published in the Official Journal of the European Union on 29th of April 2009. Due to the relative novelty of some aspects of the formal CSM process for risk assessment, this CSM Regulation will have a gradual implementation. To help this, its application does not take effect until 19 July 2010. From then on, it should be applied:

- (a) to all significant technical changes affecting vehicles as defined in Article 2(c) of Directive 2008/57/EC;
- (b) to all significant changes concerning structural sub-systems, where required by Article 15(1) of Directive 2008/57/EC or by a TSI.

The CSM Regulation remains voluntary with respect to operational or organisational changes until 1 July 2012, in order to give sufficient time to the

actors concerned, where needed, to learn and apply the new common approach as well as to gain experience from it.



More information

The complete “Commission Regulation on CSM on risk assessment” can be found on the EUR-Lex site under the following link, where the English version of the text will be made available also in all EU languages:
<http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2009:108:SOM:EN:HTML>

Guide for the application of the CSM on risk assessment: to help the railway sector actors applying the CSM on risk assessment, the European Railway Agency has also issued the following two informative and not legally binding documents:

- (a) “Guide for the application of the Commission Regulation on CSM on risk assessment”;
- (b) “Collection of examples of risk assessments and some possible tools supporting the CSM”.

These two documents are translated in all EU languages where Member States operate railways. They will be made available soon on the European Railway Agency web site, under the Railway Safety link: <http://www.era.europa.eu>