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THE COMMON SAFETY METHOD ON RISK ASSESSMENT AND ONE POSSIBLE EXAMPLE OF ITS APPLICATION

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Abstract: *In order to support the market opening across Europe, the European Member States have agreed to introduce a common and harmonised approach for managing the railway safety. To take this forward, in April 2004 the Railway Safety Directive 2004/49/EC has been approved. Amongst others this directive allocates to the European Railway Agency (ERA) the task of defining a Common Safety Method (CSM) on risk evaluation and assessment. The Regulation 352/2009/EC covering this CSM on risk assessment was published in April 2009 in the official journal of the EC. In order to support the railway actors in its implementation, as well as in order to gain inputs for upcoming revisions, the European Railway Agency takes all viable opportunities to disseminate its contents. The objective of this paper is to present one possible example of the application of the Common Safety Method on risk assessment.*

Key words: *EC, Common Safety Method, risk assessment, example, European Railway Agency.*

INTRODUCTION

The Railway Safety Directive 2004/49/EC [1] in its Article 6(3)(a) requires the development of a harmonised approach for risk assessment. This development led to a Commission Regulation on a Common Safety Method on risk evaluation and assessment (EC) N° 352/2009 [2], which was published in the Official Journal of the European Union on 29th of April 2009. Hereinafter, the current paper refers to this regulation as "the CSM Regulation".

The CSM on risk assessment applies to any change of the railway system in a Member State, as referred to in point (2) (d) of Annex III of the Railway Safety Directive [1], which is considered to be significant. It is 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:

♦ 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 Railway Safety Directive [1];

♦ 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 [3];

♦ the applicant of an authorisation for placing in service of vehicles.

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

The risk assessment and risk management processes, which the CSM Regulation describes, contain basically the following three steps:

(a) identification of hazards;

(b) risk analysis and risk evaluation based on existing risk acceptance principles, identification of safety measures and resulting safety requirements;

(c) demonstration of the system compliance with the identified safety requirements.

Additional requirements for mutual recognition belong to the CSM process. These are the hazard management and the independent assessment of the correct application and results of the CSM process, which is performed by an Assessment Body.

Due to the possible novelty of some of its aspects, the CSM Regulation has a gradual implementation. Already since 19 July 2010, it shall be applied for:

♦ all significant technical changes affecting vehicles as defined in Article 2(c) of Directive 2008/57/EC [3];

♦ all significant changes concerning structural sub-systems, where required by Article 15(1) of Directive 2008/57/EC or by a TSI.

Additionally, in order to give sufficient time to the concerned actors, where needed, to learn and apply the new common approach as well as to gain experience from it, the CSM Regulation is voluntary with respect to the operational or organisational changes until 1 July 2012. After this deadline, it will have to be applied also to these types of changes.

THE CSM DISSEMINATION AND THE SUPPORT OF EXAMPLES HOW IT CAN BE APPLIED

For the purpose of providing further support and detailed presentation of the CSM Regulation to all the actors from the European railway community, in the period of mid-2009 until mid-2010, the European Railway Agency (ERA) has organised a series of CSM dissemination workshops. This dissemination exercise was a part of the activity related to the fulfilment of the requirement in Article 9(3) of the CSM Regulation. It requests ERA to monitor and collect feedback on the application of the CSM on risk assessment in order to make recommendations to the Commission with a view to improving it. The dissemination workshops were supported by a questionnaire, which was filled in by the workshop participants in advance. The purpose was also to allow the Agency to see, at an early stage, how the railway actors understand the concepts defined in the CSM Regulation, to adapt its presentations to their needs and to collect feedback, ideas and suggestions how to improve the CSM in the scope of its upcoming revision.

The dissemination exercise has shown amongst others that the Agency needs to continue supporting the railway actors by disseminating the contents of the CSM Regulation. Furthermore, the railways have often expressed their wish to have the possibility for discussions on the Regulation based on further examples how it could be applied. It is therefore a purpose of this paper to present one relevant example how the CSM regulation can be applied.

RISK ASSESSMENT EXAMPLE OF AN OPERATIONAL SIGNIFICANT CHANGE – CHANGE OF TRAIN ROUTES AND DRIVING HOURS

The herewith described example has been used by the Agency and by the railway representatives within its working parties during the drafting of the Guidelines supporting and explaining the CSM Regulation [4], [5]. Consequently, to enable achieving the academic purpose of this paper it has been adapted and completed so as to better illustrate the CSM usage.

It is important to underline that this example is given **for information only**. Its purpose is to help the reader to understand the CSM risk assessment and management process. Nevertheless, the example itself shall not be transposed to or used as a reference system for another significant change. The risk assessment shall be carried out for each significant change in compliance with the CSM Regulation.

The example is about an operational change where a railway undertaking wanted to assign new routes and potentially new working hours to the drivers of its trains. The new working hours would have included also shift patterns and rotations of the train drivers, which were varying from the practice before the change was introduced.

In the following sections a description of the application of the steps of the CSM risk management and assessment process is presented.

THE SIGNIFICANCE OF THE CHANGE

Article 4 of the CSM Regulation describes that the proposer shall keep adequate documentation to justify his decision on the significance of the assessed changes to the railway system. When the proposed change has an impact on safety, and if there are no notified national rules defining whether a change is significant or not in a Member State, then the proposer shall take a decision, which is based on expert judgement. If the change is not significant, then the application of the full risk management process contained in the Regulation is possible but not legally mandatory.

The decision of the proposer on the question whether the proposed change is significant is based on the following criteria, which are provided in Article 4 of the CSM Regulation:

(a) failure consequence: credible worst-case scenario in the event of failure of the system under assessment, taking into account the existence of safety barriers outside the system;

(b) novelty used in implementing the change: this concerns both what is innovative in the railway sector, and what is new just for the organisation implementing the change;

(c) complexity of the change;

(d) monitoring: the inability to monitor the implemented change throughout the system life-cycle and take appropriate interventions;

(e) reversibility: the inability to revert to the system before the change;

(f) additionality: assessment of the significance of the change taking into account all recent safety-related modifications to the system under assessment and which were not judged as significant.

In the case of the example for CSM application, which is presented in this paper, the railway undertaking performed a preliminary analysis, which concluded that the operational change, which it wanted to introduce to the railway system was significant. As the drivers had to run on new routes, and possibly outside their usual working hours, the potential of passing signals at danger, of over speeding, or of ignoring temporary speed restrictions could not have been neglected.

When comparing this preliminary risk assessment with the criteria in Article 4 (2) of the CSM Regulation, it was possible to categorise the change as significant based on the following criteria:

1. safety relevance: the change is safety related as the impact of modifying the drivers' way of working could be lead to accidents with multiple fatalities;

2. failure consequence: the drivers' errors mentioned here above have the potential to lead to a to accidents resulting in multiple fatalities;

3. novelty: the railway undertaking would have introduced new ways of working for the drivers;

4. complexity of the change: modifying the driving hours could be complex as this could require a complete assessment and modification to the existing working conditions.

THE SYSTEM DEFINITION

The system definition has been described according to the requirements included in section 2.1.2 of the CSM Regulation. Initially it described amongst others:

1. the existing working conditions: working hours, shift patterns, etc.;

2. the changes of the working hours;

3. the interface issues (e.g. with the infrastructure manager)

Subsequently, during the different iterations of the risk assessment process, the system definition was updated with the safety requirements resulting from the risk assessment process. Key staff representatives were involved in this iterative process for the hazard identification and system definition update.

THE HAZARD IDENTIFICATION

In the presented example, the railway undertaking proposing the assessed change performed a hazard identification, satisfying the requirements of section 2.2 of the CSM Regulation.

The hazards and possible safety measures were identified by a brainstorming of a group of experts, including drivers' representatives, for the new routes and shift patterns.

An analysis of the drivers' tasks for the new conditions was performed. Its aim was to assess whether and how they were affecting the drivers, their workload, the geographical scope of their work and the time of the work shift system. The railway undertaking also consulted the worker unions to see if they could provide additional information. It reviewed the risk of fatigue and sickness levels that could be induced by a possible increase of overtime due to extended journeys on unknown routes.

Each of the identified hazards was assigned a level of severity of risk and consequences (high, medium, low) and the impact of the proposed change was reviewed against them. This allowed to have a thorough overview on the way how the change would influence the risk. A general scale of (increased, unchanged, decreased) risk was used.

THE RISK CONTROL TO AN ACCEPTABLE LEVEL

The CSM Regulation enables the evaluation of the risk acceptability of a significant change by using one or a combination of the following risk acceptance principles, without giving a priority to any of them:

(a) the application of codes of practice (for more details see section 2.3 of the Regulation);

(b) a comparison with similar systems (for more details see section 2.4 of the Regulation);

(c) an explicit risk estimation (for more details see section 2.5 of the Regulation).

The risks that are controlled by the application of codes of practice or by the safety requirements derived by a comparison with a similar reference system, are considered as acceptable provided that the conditions of application of these two risk acceptance principles are fulfilled and sufficiently documented. In the third case, often when the system under assessment (an operational or a technical one) is innovative, or when the available codes of practice or reference systems are not sufficient for the control of the identified hazards, then explicit risk estimation is used. Consequently, safety measures need to be defined until the residual risk (i.e. with those safety measures implemented) becomes acceptable.

The railway undertaking proposing the operational change described in this paper used codes of practice to revise the existing working conditions and to determine the new safety requirements. These codes of practice were related to risks of human fatigue and inappropriate working hours.

Consequently, the necessary operational rules were written according to the codes of practice for the new work shift system.

All necessary parties were involved in the revised operational procedures and in the agreement to proceed with the change.

THE DEMONSTRATION OF SYSTEM COMPLANCE WITH THE SAFETY REQUIREMENTS

In the presented example, the railway undertaking proposing the assessed change to the railway system performed a demonstration of system compliance with the safety requirements, satisfying the requirements of section 3 of Annex I of the CSM Regulation.

The revised operational procedures were introduced in the safety management system of the railway undertaking.

These revised operational procedures were monitored and a review process with clear responsibilities and time intervals for the reviews was put in place, in order to ensure that the initially identified hazards continue to be correctly controlled during the operation of the railway system.

THE HAZARD MANAGEMENT

In the presented example, the railway undertaking proposing the assessed change to the railway system dealt with the hazard management, in accordance with the requirements of section 4.1 of the CSM Regulation.

The hazard record was created and regularly updated by the proposer during the design and the implementation of the assessed change. The hazard record allowed for tracking the progress in monitoring risks associated with the identified hazards. Once the system has been accepted and is operated, the hazard record was further maintained by the railway undertaking as an integrated part of its safety management system. The revised procedures were monitored, and reviewed when needed, to ensure that the identified hazards continue to be correctly controlled during the operation of the railway system.

The hazard record included all identified hazards, all safety measures related to them (i.e. reference to the revised operational procedures) and all system assumptions made during the risk assessment process. For each identified hazard it also included a clear reference to the origin and to the selected risk acceptance principles. It identified clearly the actors in charge of controlling each hazard.

THE INDEPENDENT ASSESSMENT OF THE CSM APPLICATION

The risk assessment and risk management process were assessed by a competent person within the railway undertaking. This person was independent from the risk assessment process for the change and was fulfilling the requirements described in Annex II of the CSM Regulation. It assessed both the correct application of the CSM risk management process and its results (i.e. the identified safety requirements).

Consequently, the railway undertaking has based its decision to put the new system into effect on the independent assessment report produced by the competent person.

CONCLUSION AND OUTLOOK

In order to enable the mutual recognition of the risk management results and to ensure that the existing safety levels are maintained in the Community rail system, the CSM Regulation harmonises the process for risk assessment. It specifies only **what** requirements must be fulfilled **without** specifying **how** to fulfil them.

This is an important property of the Regulation, since the current practices for risk management vary between the different Member States. Usually, different tools are established and different practices for the assessment and evaluation of risks exist. Moreover, the specific physical and historical properties of the railways around Europe request different activities in their given context.

Therefore, it is necessary for the proposers to be able to comply with the CSM requirements, paying attention to their local particularities and adjusting their activities to the particular context of their work. In their activities, this freedom and flexibility are considered to be very important.

A typical source where the railway actors may find further **non-legally binding** information on **how** they could perform the different steps of the CSM risk assessment process so as to comply with the legal requirements, are the Guidelines supporting the CSM Regulation ([4] and [5]), which are translated in all EU languages where Member States operate railway and have been made available on the web site of the Agency. Further non-legally binding support may also be obtained using various existing standards (e.g. EN50126 [6], EN50128 [7], EN50129 [8], IEC 60812 [9], IEC 61025 [10], etc.).

Shortly after the publication of the CSM Regulation in April 2009, the European Railway Agency has started a series of activities for its dissemination. These have shown that examples of the application of the CSM risk management and assessment process are a valuable support for many of the European railway actors who must apply the Regulation partially since 19 July 2010, and fully - after 1 July 2012. Therefore, the present article presents an example of an operational change where a railway undertaking wanted to assign new routes and potentially new working hours (including shift patterns and rotations) to the drivers of its trains. The article describes how the railway undertaking considered the requirements described in the CSM Regulation, which enabled it consequently to ensure and demonstrate that it is controlling the potential risks arising from the introduction of the assessed significant change to the railway system to a level, which is acceptable.

REFERENCES

[1] Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive).

[2] Commission Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council.

[3] Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community.

[4] Guide for the application of the Commission Regulation on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of the Railway Safety Directive, Version 1.1. from 06/01/2009.

[5] Collection of examples of risk assessments and of some possible tools supporting the CSM Regulation, Version 1.1 from 06/01/2009.

[6] EN 50126:1999 - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS).
[7] EN 50128:2001 - Communications, Signalling and Processing Systems - Software for Railway Control and Protection Systems.
[8] EN 50129:2003 Railway Applications - Communication, signalling and processing systems - Safety Related Electronic Systems for Signalling.
[9] IEC 60812 (2006-01) - Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA).
[10] IEC 61025 (2006-12) - Fault tree analysis (FTA).

ОБЩИЯТ МЕТОД ЗА БЕЗОПАСНОСТ ПРИ ОЦЕНКА НА РИСКА И ЕДИН ВЪЗМОЖЕН ПРИМЕР ЗА ПРИЛАГАНЕТО МУ

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Ключови думи: *ЕК, метод за обща безопасност, оценка на риска, пример, Европейска железопътна агенция..*
Резюме: *За да подкрепят отварянето на пазара в цяла Европа, европейските държави-членки се съгласиха да въведат общ и хармонизиран подход за управление на безопасността в железопътния транспорт. За да се прилага това занапред, през април 2004 г. бе одобрена Директива 2004/49/ЕО за безопасност на железопътния транспорт. Наред с другото тази директива поставя на Европейската железопътна агенция (ERA) задачата за определяне на общ метод за оценка на безопасността (CSM) при оценката на риска. Регламентът 352/2009/ЕС, обхващащ този метод за оценка на риска, беше публикуван през април 2009 г. в официалния вестник на ЕК. За да се подкрепят железопътните компании в прилагането му, както и с цел да се получат материали за предстоящите ревизии, Европейската железопътна агенция прилага всички жизнеспособни възможности за разпространение на съдържанието му. Целта на този доклад е да представи един възможен пример за прилагането на общия метод за безопасност при оценка на риска*