

# POSITION PAPER

## Social consultation on the revised common safety method on risk evaluation and assessment

Draft of 19<sup>th</sup> March provided with ERA letter DJ/TB/C087-12/MV/020

4<sup>th</sup> May 2012

COMMUNITY OF EUROPEAN RAILWAY AND INFRASTRUCTURE COMPANIES - COMMUNAUTÉ EUROPÉENNE DU RAIL ET DES COMPAGNIES D'INFRASTRUCTURE - GEMEINSCHAFT DER EUROPÄISCHEN BAHNEN UND INFRASTRUKTURGESELLSCHAFTEN



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## EXECUTIVE SUMMARY

CER has critically and constructively supported the revision of the CSM regulation 352/2009/EC on risk evaluation and risk assessment and its objective to facilitate the access to the market for rail transport services through harmonisation of:

- a) the risk management processes used to assess the impact of changes on 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 safety across the different interfaces which may exist within this sector;
- c) the evidence resulting from the application of a risk management process.

CER believes that the specification of RAC at the correct level has the potential to improve mutual understanding of risk assessment, facilitate EU-wide acceptance of safety demonstration and safety-related equipment, and therefore to reduce cost.

CER, together with UNIFE, in order to fully benefit from mutual acceptance across borders, is proposing more detailed risk acceptance criteria for Annex I § 2.5.4. Our proposal is based on internal review and validation amongst our members. CER is asking the European Commission and the European Railway Agency to motivate the concerned but yet silent stakeholders to validate our proposal. The inclusion of a robust set of more detailed explicit risk acceptance criteria with different severity classes as soon as possible is crucial for the CER members reduce cost while keeping the existing level of safety.

## 1. GENERAL COMMENTS

### General comments on the text of the draft regulation

#### Article 2 “Scope”, §1

- The scope has changed with the Regulation now applying to ALL changes of the railway system. It appears that there is now a requirement to apply the regulation to every change and record the decision to apply all the regulation or not. It is unclear if the requirement to document the non-application of the Regulation to those organisational changes which could not affect operations or maintenance, or how far to apply “could affect”.
- Is an organisational change in the manufacturing processes of a supplier also concerned by sentence?
- As it is not clearly understood to what “changes” the regulation shall be applied, a definition of the term “change” is required to make sure that only the intended changes are going to be applied according to this regulation. At least additional guidance is necessary.

#### Article 2 “Scope” §4

- It is not clear how the transition between the current CSM-RA regulation and the revised one shall be managed.
- Further explanation how the changes covered today or after 1/07/2012 by R 352/2009 is requested - Could a change managed under the CSM in force be concerned by the new revised regulation?
- The transition period created by Article 11 between entry into force and application shall be managed!

With reference to articles 3, 8 and 9, we need a more precise definition of “actor” and “proposer” to cover all the entities who are concerned by the application of this regulation.

What regards criteria which must be fulfilled by assessment bodies as laid out in annex II of the regulation proposal, there is no sufficient explanation how and that the ISO 17020 has to be applied by the CSM assessment body. The CECM regulation has a clear structure in its Annex II about the criteria for accreditation. This should be amended for CSM AB to make all the criteria transparent in this regulation as well.

### Comments on the text of the draft regulation from an economic point of view

The following comments reflect upon the ERA Impact Assessment Report related to the “Study: Risk Acceptance Criteria on Technical Systems”, version 1.2 of 19<sup>th</sup> March 2012.

It would be good if the impact assessment report could make some statement about how the conclusions of the report would change (if at all) if the focus of the impact assessment has been the current proposed RAC values by CER and UNIFE. We expect a significant impact of our proposal, which must be taken into account for the final impact assessment

Further detailed comments will be provided individually by our members to the ERA economic evaluation unit.

## **2. PROPOSAL FOR MORE DETAILED RISK ACCEPTANCE CRITERIA TO BE ADDED TO ANNEX I § 2.5.4.**

The proposal<sup>1</sup> for the new text is the following:

“Where hazards arise from failures of technical systems not covered by codes of practice or the use of a reference system, the following risk acceptance criterion shall apply for the design of the technical system:

- (a1) For a failure that has a typical credible potential to lead directly to an accident with catastrophic consequences, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than or equal to 1E-9 failures per operating hour appropriate to the assessed function.
- (a2) For a failure that has a typical credible potential to lead directly to an accident with multiple fatalities but not likely to lead to catastrophic consequences, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than or equal to 1E-8 failures per operating hour appropriate to the assessed function.
- (b) For a failure that has a typical credible potential to lead directly to an accident affecting an individual person and resulting in fatality, or affecting a group of people and resulting in serious injuries, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than or equal to 1E-7 failures per operating hour appropriate to the assessed function.
- (c) For a failure that has a typical credible potential to lead directly to an accident affecting an individual person and resulting in a serious injury, but not fatality, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to be less than or equal to 1E-6 failures per operating hour appropriate to the assessed function.”

In addition, the definition of “catastrophic” in article 3 (23) shall be modified as follows:

- “Catastrophic consequences: large number of fatalities, for example, major loss of survival space/structural integrity in one or more passenger carriages, a large release of dangerous goods or an uncontrolled train fire in a tunnel.”

## **3. DETAILED COMMENTS ON THE TEXT OF THE DRAFT REGULATION**

Detailed CER comments can be found in the attached review & comment sheet.

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<sup>1</sup> For the time being, this proposal is not supported by SNCF

## Disclaimer

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