

Amendment of the Commission implementing Regulation N° 402/2013 on the CSM for risk evaluation and assessment

**CER, EIM and UNIFE position on the Agency draft
recommendation**

19 December 2014

1. REFERENCE DOCUMENT

Agency draft recommendation on the amendment of the Commission implementing Regulation N° 402/2013 on the CSM for risk evaluation and assessment

Reference: ERA-CON-2014-04-SAF

Publication Date: 29/10/2014

2. CORE POSITION

CER, EIM and UNIFE support the proposed legal text. An agreement of these design targets is a valuable and significant step forward for the Sector in the application of the CSM RA regulation. Some minor clarifications are still proposed to further improve the text. The proposal are present at the end of the paper.

We would also insist that the application guide supporting the legal text should be available at the stage when the recommendation will be put to vote by the Member States. CER, EIM and UNIFE are already working on inputs for the guidance and will support ERA preparing the document. The content of the application guide should address the following subjects:

- Introduction
- Explanations and Principles (definitions)
 - o Links/relationships with standards
 - o Relevance of using/not using CSM-DT
- Description of the Steps for Applying CSM Design Targets - already covered
- Level of Application of CSM DTs
- Explanation regarding use of barriers, internal and external
 - o Provide guidance for internal and external barriers, and for when barriers can be used - not within the scope of mutual recognition however as barriers are not harmonized
- Examples for assigning severity categories
 - o List of examples is included
 - o Examples that are out of scope - address the application regarding track workers example
- Use of design targets for mechanical systems
 - o Clarify that it is primarily for use of electrical/electronic systems

CER, UNIFE and EIM are ready to provide support in the development of this guide and welcome the involvement of the Member States in the development and validation of the guide.

3. PROPOSED MODIFICATIONS

N°	Reference (e.g. Art, §)	Type/ Assess *	Reviewer's Comments, Questions, Proposals
1.	Systematic failure :	P	<p>Definition proposed by ERA is different from CENELEC standard.</p> <p>We believe that the definition from CENELEC standard is the most appropriate, thus the legal text should not include a definition of “systematic failure” in order not to define a specific case different than the general EN definition. Therefore the definition should be deleted from the legal text.</p>
2.	Barrier	P	<p>EIM concerned about intentionally and propose to delete. Implemented could be sufficient. An example could be track circuit which are not “intentionally” implemented even they could be used as a barrier.</p> <p>The guide shall remind how a barrier should be implemented. It is essential that the effectiveness and quality of the barrier can be controlled. Some examples and the link/difference between barrier and in general “safety measures” should be developed. Internal note (not for position): there is not specific link between barrier and systematic failure.</p>
3.	2.5.5	U / CN	10-9and 10-7 should be written properly (in superscript).
4.	2.5.6	U / CE	<p>We propose to add the <u>bold underlined</u> text</p> <p><i>The risks <u>arising from failures of functions of technical systems</u> in point 2.5.5 shall be considered as acceptable if the following requirements are fulfilled:</i></p> <p>(a) <i>The applicable harmonised design target is achieved;</i></p> <p>(b) <i>The associated systematic failures are controlled by adequate safety and quality processes commensurate with the applicable harmonised design target to the technical system;</i></p> <p>(c) <i>The safe integration of the technical system under assessment into the railway system is demonstrated.</i></p>
5.	2.5.8.a	U / CE	<p>We propose to add the <u>bold underlined</u> text and delete the text strikethrough:</p> <p><i>When estimating the typical severity of the consequences of the analysed functional failure in order to derive which of the harmonised design targets is applicable for the assessed risk, the proposer shall apply the following conditions:</i></p> <p>(a) <i><u>expert shall use, if available, applicable</u> if no trustworthy statistical data or expert estimates are available, then a more demanding but credible severity of consequence shall be chosen.</i></p> <p>(b) <i>The outcome to consider shall be an outcome greater than the average but not the worst case event.</i></p>
6.	2.5.9.	U / CE	<p>We propose to add the <u>bold underlined</u> text :</p> <p><i>The application of less demanding design targets <u>for the technical system</u> shall be permitted if the proposer demonstrates that the use of barriers external to the technical system reduces further the frequency or the severity of the consequence of the hazard that arises from the failures of the functions of the technical system.</i></p>

(*) **Type of Comment** : [U: Understanding], [P: Proposal]
Assessment : [CN: Correction necessary], [CE: Correction expected]

**CER, EIM AND UNIFE POSITION ON THE
AGENCY RECOMMENDATION TO AMEND
CSM ON RISK ASSESSMENT**



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