

<b>ECONOMIC EVALUATION UNIT</b>	
<b>STUDY: RISK ACCEPTANCE CRITERIA ON TECHNICAL SYSTEMS IMPACT ASSESSMENT REPORT</b>	
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**AMENDMENT RECORD**

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## ERA ECONOMIC EVALUATION UNIT

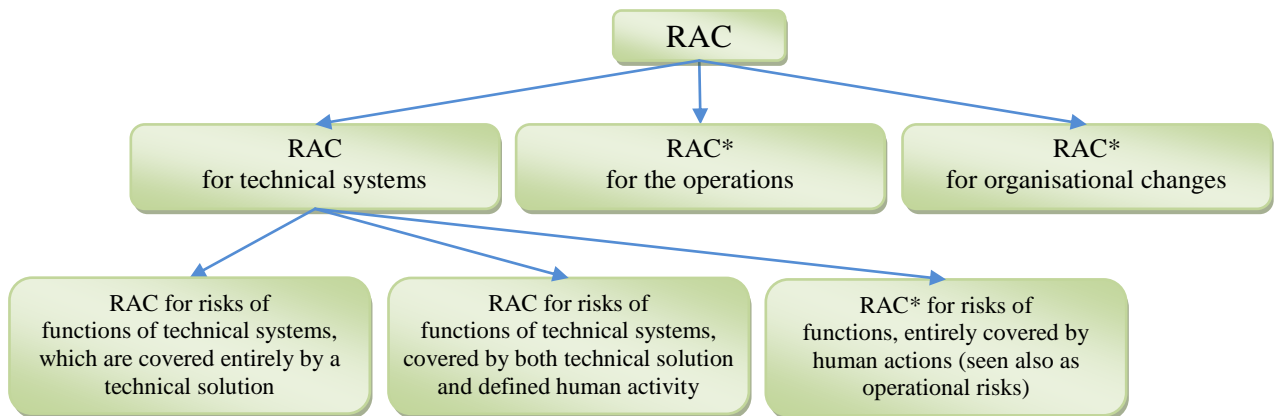
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## 1. INTRODUCTION

### 1.1 CONTEXT

- 1.1.1.1 The Risk Acceptance Criteria (RAC) are a part of the Regulation 352/2009/EC on the Common Safety Method for Risk Assessment (“the CSM Regulation”). They are a term of reference, by which the acceptability of specific risks is being assessed. They are used to determine that the level of a risk is sufficiently low that it is not necessary to take any immediate action to reduce it further system [Article 3, point 15 from (2)].
- 1.1.1.2 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 priority to any of them):
- The application of codes of practice;
  - The comparison with similar reference systems;
  - The use of explicit risk estimation.
- 1.1.1.3 The risks, which 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. Additionally, whenever the third risk acceptance principle - **the explicit risk estimation** – is used and in order to be able to determine whether the residual risk is acceptable, **Risk Acceptance Criteria** are used.
- 1.1.1.4 When a system or part of a system has already been accepted following the risk management process specified in the CSM Regulation (2), the resulting safety assessment report shall not be called into question by any other assessment body in charge of performing a new assessment for the same system. **The recognition shall be conditional on demonstration that the system will be used under the same functional, operational and environmental conditions as the already accepted system, and that equivalent risk acceptance criteria have been applied.** [Article 7, point 4 from (2)]
- 1.1.1.5 The picture below illustrates briefly the general framework for the RAC (see also explanatory note on the development of RAC [3]).



*\* It has to be noted that since the bigger part of the items on this picture is currently under development, there is yet no clear or agreed separation between some of the included boxes.*

**Picture 1: Illustration of the different types of RAC**

1.1.1.6 The present document contains the impact assessment from safety and economic (cost impact) points of view by the introduction of RAC for technical systems. The impact assessment has been developed by ERA's Economic Evaluation Unit (EE) in conjunction with the ERA CSM on RA team.

## **2. REFERENCE, TERMS AND ABBREVIATIONS**

### **2.1 REFERENCE**

The documents listed below are referred to by numbers in round brackets, e.g. (5). Footnotes use letters, such as: <sup>(a)</sup>.

<b>Number</b>	<b>References</b>
(1)	Economic Evaluation: Methodology Guidelines
(2)	“Proposal for Risk Acceptance Criteria to be included in the Revision of Regulation 352/2009/EC – Executive Summary”, Version 2.0, 28/06/2011
(3)	Explanatory note on the development of RAC, Version 1.3, 25/11/2010
(4)	Questionnaire on risk acceptance criteria, Version 1.1, 29/06/2011
(5)	Commission Regulation No 352/2009 on the adoption of a common safety method on risk evaluation and assessment

Quotations from the above are in *italics*.

### **2.2 UNITS**

International units and metric system have been used. Kilometres per hour are km/h, never kph. For thousands, millions and billions (= thousands of millions), the letters k, M and G are prefixed; for instance: 1 M€ = one million Euros.

For numbers, the decimal separator is a dot “.”; thousands are separated by spaces “ ” (neither “,” nor “.”).

### **2.3 DEFINITIONS AND ABBREVIATIONS**

<b>Term or abbreviation</b>	<b>Definition</b>
CBA	Cost-Benefit Analysis
ESG	Economic Survey Group. The group has been set up by ERA and is managed by its Economic Evaluation Unit. ESG is considering the impact assessment work undertaken for the different recommendations of ERA from the point of view of consistency and correctness of methodology.
IM	Infrastructure Manager (as defined in Directive 2001/14/EC)
RAC	Risk Acceptance Criteria
RU	Railway Undertaking (as defined in Directive 2001/14/EC)
RST	Rolling Stock

### 3. PROBLEM DESCRIPTION

3.1.1.1 The CSM-regulation does currently contain only RAC for catastrophic consequences described in 2.5.4 of the CSM-regulation:

2.5.4. 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:

For technical systems where a functional failure has credible direct potential for a catastrophic consequence, the associated risk does not have to be reduced further if the rate of that failure is less than or equal to  $10^{-9}$  per operating hour.

3.1.1.2 The lack of RAC for lower severity consequences (less than catastrophic) could lead to a lack of mutual recognition when using explicit risk estimation method.

3.1.1.3 The CSM-regulation does currently not contain any reference to the usage of barriers that exist outside the system under assessment. The different methodologies which barriers and how barriers can be taken into account, could also lead to a lack of mutual recognition when using explicit risk estimation.

## **4. DEFINITION OF OBJECTIVES**

- 4.1.1.1 The main objective of this impact assessment is to verify the acceptance of the proposal described in (2). Therefore, the scenarios described are limited to “do nothing” and “propose change”. The study will focus on three aspects.
- 4.1.1.2 Step 1: investigate how big the problems are in the current situation due to a lack of mutual recognition when using explicit risk estimations. This step identifies the potential benefits of the proposed change.
- 4.1.1.3 Step 2: perform an analysis of the proposal to verify if and consequently in what way the proposed change as described in scenario 1 will contribute for the solution of the problem (of lack of mutual recognition) .
- 4.1.1.4 Step 3: perform a safety and cost impact of introducing each defined RAC.



## **5. SCENARIOS**

### **5.1 INTRODUCTION**

In the framework of this study, two scenarios are described. This impact assessment study focused on the proposed values within the CSM-regulation and their added value in the process of mutual recognition, possible impact on technical design, cost & safety.

### **5.2 SCENARIO 0: CURRENT SITUATION (DO NOTHING)**

5.2.1.1 In its Revision the CSM Regulation remains as it currently is, without any changes with reference to the RAC. By consequence, there remains only one RAC, which refers to catastrophic consequences.

### **5.3 SCENARIO 1: PROPOSE CHANGE**

5.3.1.1 With reference to the RAC, the CSM Regulation is changed in its revision so as to include the proposed set of RAC, described in the picture below.

<b>Severity of the estimated consequences</b>	<b>Acceptable rate of occurrence (R) of the analysed unwanted direct consequence (e.g. of an accident with catastrophic consequences)</b>
multiple fatalities	$R \leq 10^{-9}/h$
single fatality and/or multiple serious injuries	$10^{-9}/h < R \leq 10^{-8}/h$
single serious injury and/or multiple light injuries	$10^{-8}/h < R \leq 3 \times 10^{-7}/h$
single light injury	$3 \times 10^{-7}/h < R \leq 10^{-5}/h$
non safety related consequence	not applicable

**Picture 2: RAC-proposal for the link between severity and acceptable rate of occurrence**

It is necessary to mention that this table presents provisional acceptable rates of occurrence and that the analysis of the answers to questionnaire leads to values presented in 7.3.7.2. The notion of per hour relates to operating hours of the assessed function.

5.3.1.2 Based on the received answers from this impact assessment questionnaire, it could be expected that (especially for the proposed acceptable rates of occurrence) a calibration of the proposal could be necessary.

5.3.1.3 In accordance with the RAC defined in the current version of the CSM Regulation, the proposed set of RAC refers to functional failures with direct

consequences. In terms of consequences, typical bad outcomes are considered. As a supplement to this, the current proposal adds also explicitly the option that if barriers exist outside the system under assessment, then the proposer could take them into account and derive a less demanding RAC for demonstration.

## **6. METHODOLOGY**

- 6.1.1.1 A task force was established to define harmonized RAC-values. Its proposal was formally reviewed, discussed and agreed by the members of the CSM on Risk Assessment Working Party. Consequently, in order to validate the RAC-values defined by the task force, a questionnaire has been distributed to the sector organisations. It has been designed so as to enable to receive inputs on the comparison between the proposed RAC and the levels of risk acceptability, which nowadays are set as acceptable requirements within the contracts of RUs, IMs and manufacturers, whenever designing or ordering new equipment, as well as in the process of authorisations for placing into service. The questionnaire is composed of several parts, in which following sections are used for this impact assessment.
- Section 1 aims to evaluate the advantages, benefits and possible drawbacks or costs to have a harmonized set of RAC of the proposed type as compared to the current arrangements;
  - Section 2 aims to evaluate some elements defined within the proposal for the RAC to check the effectiveness of the proposed solutions in terms of economic cost and safety;
- 6.1.1.2 The revision of the CSM regulation also led to a detailed half-year validation and application analysis of the proposed RAC-values within CER-UIC (see results of the analysed about 50 technical systems and 100 hazard scenarios in annex 10.1).

**7. ASSESSMENT: GENERAL RESULTS**

**7.1 STEP 1: IDENTIFY CURRENT PROBLEMS WITH EXPLICIT RISK ESTIMATIONS**

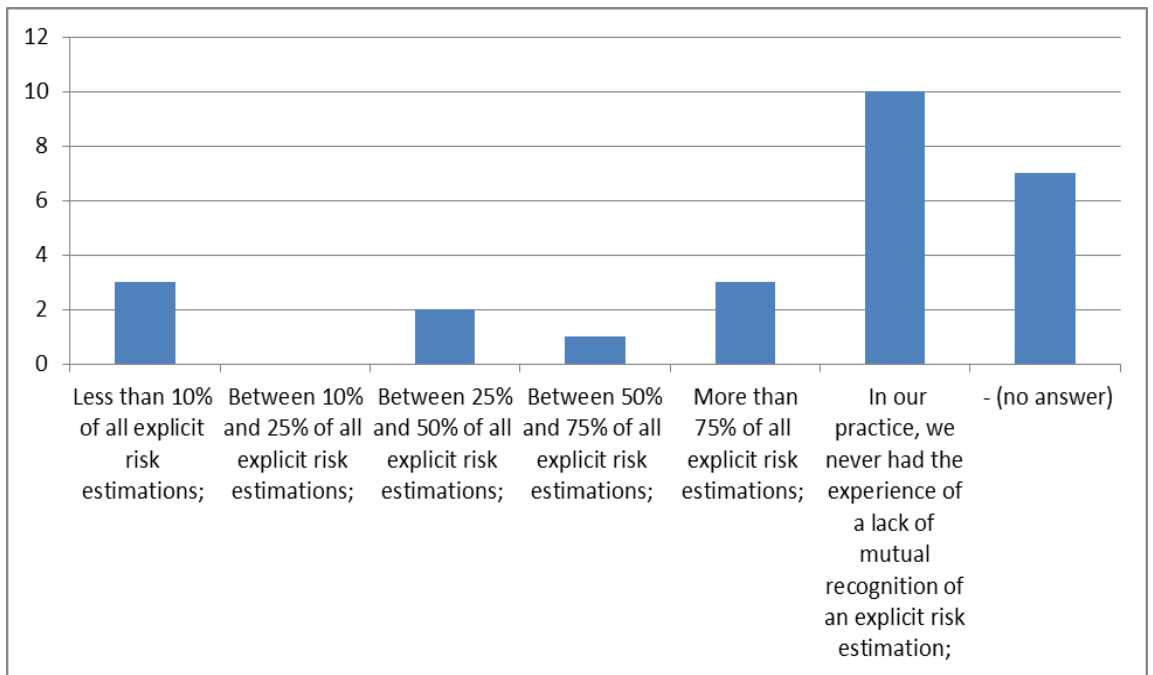
**7.1.1 LACK OF MUTUAL RECOGNITION WHEN USING EXPLICIT RISK ESTIMATION**

7.1.1.1 Answer on question 9: “According to your current experience, the number of explicit risk estimations, which need to be redone due to lack of mutual recognition comprises about:

Please tick the boxes below as appropriate:

- Less than 10% of all explicit risk estimations;
- Between 10% and 25% of all explicit risk estimations;
- Between 25% and 50% of all explicit risk estimations;
- Between 50% and 75% of all explicit risk estimations;
- More than 75% of all explicit risk estimations;
- In our practice, we never had the experience of a lack of mutual recognition of an explicit risk estimation;

7.1.1.1.1 Summary of answers (excluding answers from sector organisations CER, EIM, UNIFE)



Respondents indicated it is a huge work to retrieve this information from previous contracts. Unfortunately, it was not possible to determine the absolute number of cases, and therefore the order of magnitude of benefits (in million euro) remains undefined.

The above picture helps only to make a qualitative statement that in general, in this impact assessment, railways indicate a number of cases of lack of mutual recognition due to the requirement of different RAC.

The analysis of the above graphic show that the respondents, who have indicated that they didn't have cases of a lack of mutual recognition, are mostly NSAs.

7.1.1.1.2 Following table indicates which organisations have experience of lack of mutual recognition of an explicit risk estimation:

	<b>No experience of lack of mutual recognition of an explicit risk estimation</b>	<b>Experience of lack of mutual recognition of an explicit risk estimation</b>	<b>Question not answered (“?”)</b>	<b>Total</b>
<b>NSA</b>	<b>4</b>	<b>1</b>	<b>4</b>	<b>9</b>
<b>IM</b>	<b>2</b>	<b>3</b>	<b>1</b>	<b>6</b>
<b>RU</b>	<b>2</b>	<b>1</b>	<b>0</b>	<b>3</b>
<b>IM/RU/ECM</b>	<b>1</b>	<b>3</b>	<b>1</b>	<b>5</b>
<b>Manufacturer</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>1</b>
<b>Other</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>2</b>
<b>Total</b>	<b>10</b>	<b>9</b>	<b>7</b>	<b>26</b>

7.1.1.1.3 Answers from respondents, who have experienced lack of mutual recognition, mention following reasons:

*“When a probabilistic approach is used, data used and calculation methods are always discussed and challenged by NSA, much more than the quantitative target itself (but could happen or has happened?). To gain a true mutual confidence between NSA, it is more important to facilitate mutual recognition of the way studies and calculations are performed and of hypotheses are taken into account, than of the target value (RAC) itself.”*

7.1.1.1.4 Answer UNIFE: between 50% and 75% of all explicit risk estimations need to be redone. Supporting explanation:

*Systematic reworks are required due to*

- *different RAC/severity definitions in the contractual requirements (cause 1)*
- *different operational context and assumptions (cause 2)*
- *different interpretations by customers/NSAs/ISA of the correct application of a numerical requirement (cause 3)*
- *different interpretations by Independent Assessors (cause 4)*

7.1.1.1.5 Answer CER-UIC:

*“For most contributors to this questionnaire there is to date no such experience. However, one of the contributors expects that 75% of the explicit risk estimations need to be redone. He stresses the importance of the way how studies and calculations are performed and of the adoption of hypotheses for explicit risk estimation. It is therefore necessary to also reach a common understanding and practice in these respects not just with regard to setting target values, such as RAC.”*

**7.1.1.2 Preliminary conclusion: the answers from the impact assessment demonstrate the existence of lack of mutual recognition when using explicit risk estimation, but the answers did not enable to identify cost figures related to systematic reworks to be redone (and potential benefits) due to the different causes of lack of mutual recognition. The answers indicate a limited use of purely quantitative explicit risk estimations as a stand-alone risk acceptance principle. They show that such estimations are done often and that they are well combined with the usage of Codes of Practice or Reference Systems. The answers indicate a limited use of RAC-values for lower severity consequences classes.**

**7.1.2 TYPE OF SYSTEMS WHERE EXPLICIT RISK ESTIMATIONS ARE CURRENTLY USED;**

7.1.2.1 In the questionnaire, some questions are added to identify for which technical systems explicit risk estimation are currently used. These questions should clarify the need to limit the CSM-regulation to specific technical systems as requested by some participants within the CSM on Risk Assessment Working Party.

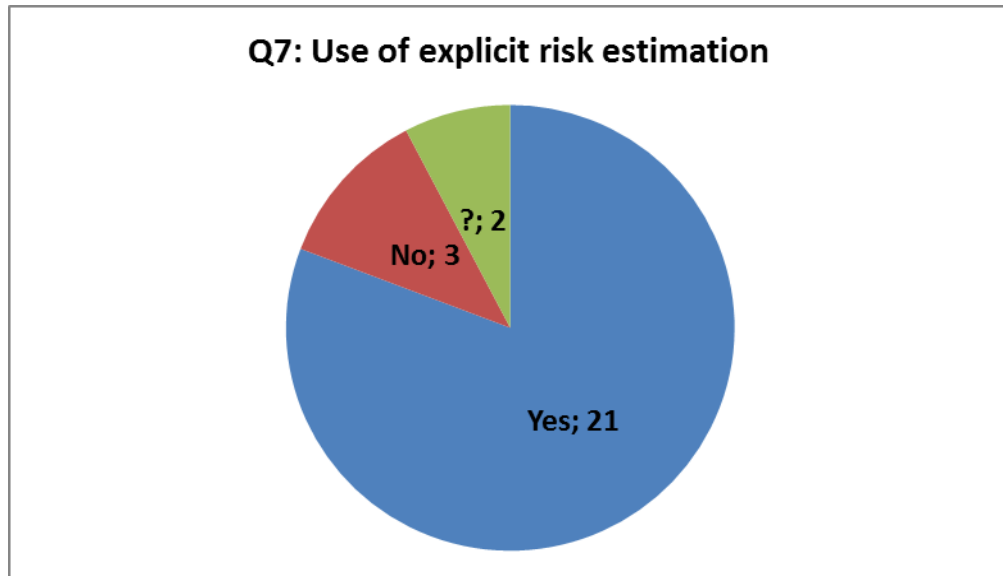
7.1.2.2 Answers on question 7: **Do you use in current practice explicit risk estimation as a risk acceptance principle?**

*Please tick the boxes below as appropriate:*

Yes;

No;

7.1.2.3 Summary of answers (excluding answers from sector organisations CER, EIM, UNIFE)



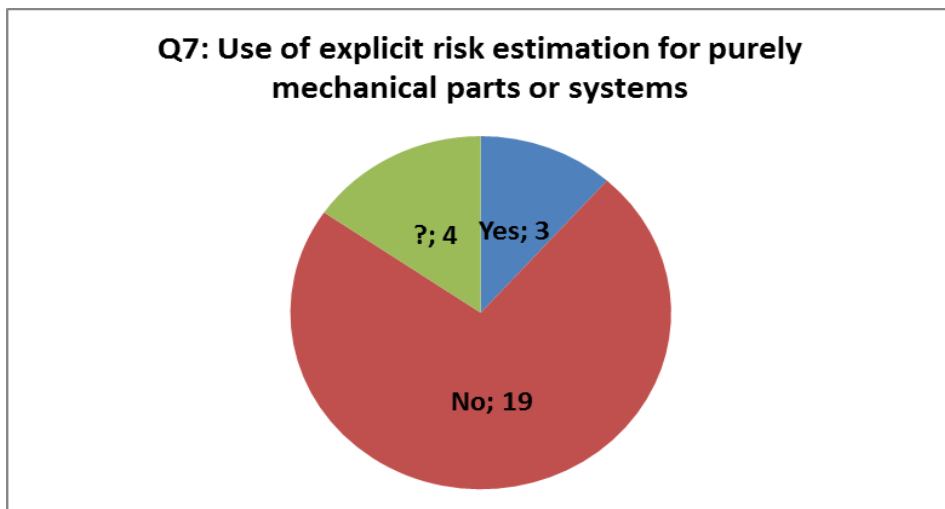
7.1.2.3.1 Answer from UNIFE : yes

7.1.2.3.2 Answer from CER-UIC : yes

7.1.2.4 Problem description: for which type of systems explicit risk estimation is currently used as risk acceptance principle?

7.1.2.5 Use of explicit risk estimation **for purely mechanical parts or systems**

7.1.2.6 Summary of answers (excluding answers from sector organisations CER, EIM, UNIFE)



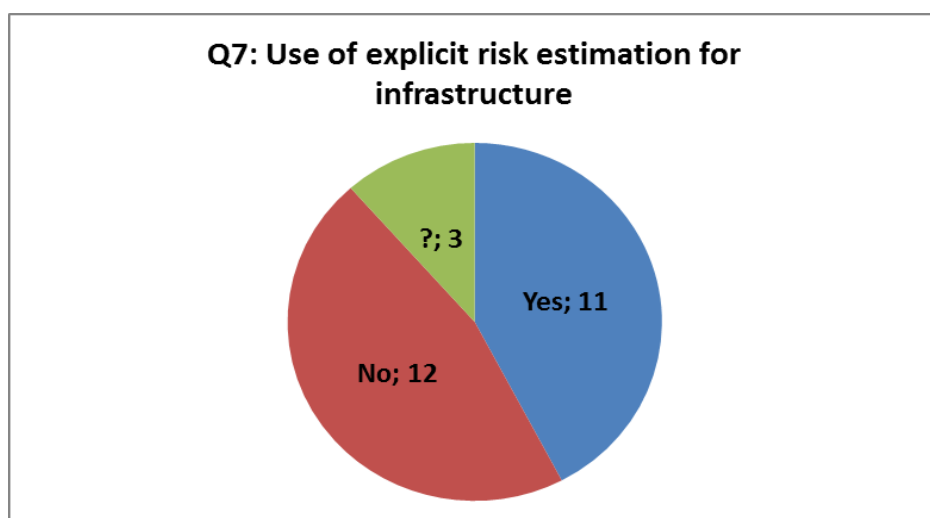
7.1.2.6.1 Answer from UNIFE : yes

7.1.2.6.2 Answer from CER-UIC : no (with the exception of one of their members)

7.1.2.6.3 Following types of mechanical parts or systems are mentioned: bogies, doors, main switches/pantographs or power distribution protection switches, relay technology or solutions with a switch (button);

7.1.2.7 Use of explicit risk estimation for **infrastructure** (as described in the Interoperability Directive)

7.1.2.8 Summary of answers (excluding answers from sector organisations CER, EIM, UNIFE)



7.1.2.8.1 Answer from UNIFE : no



7.1.2.8.2 Answer from CER-UIC : yes

**7.1.2.9 Conclusion: the answers from the impact assessment demonstrate the current use of explicit risk estimation for purely mechanical parts or systems and infrastructure. Therefore, these systems should not be excluded from the proposal.**

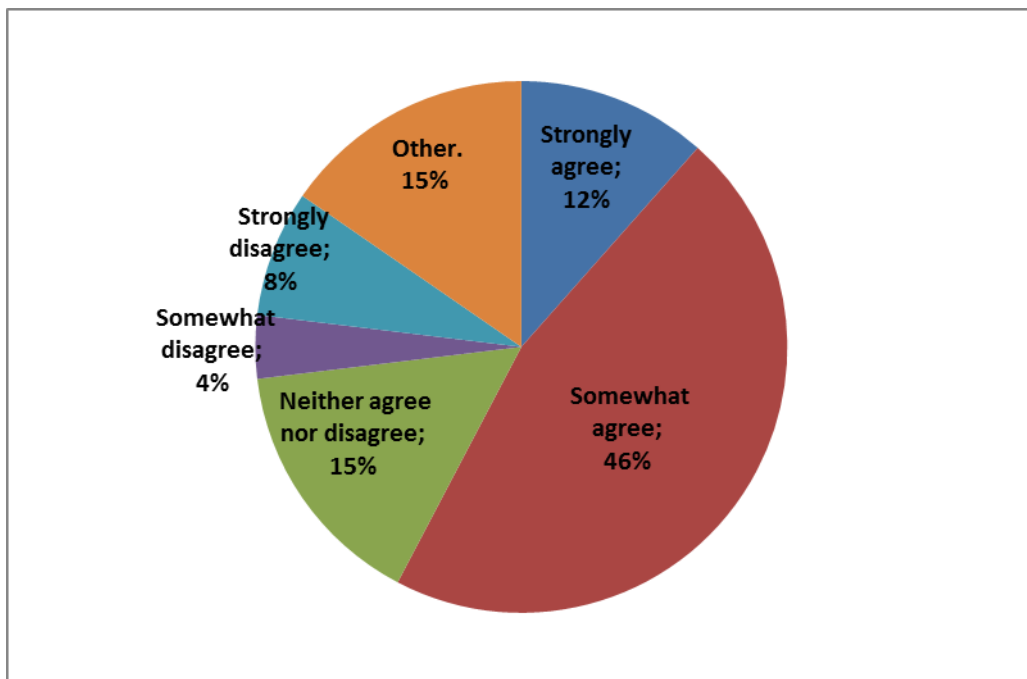
**7.2 STEP 2: EVALUATE PROPOSAL TO SOLVE IDENTIFIED PROBLEMS IN STEP 1**

7.2.1.1 Answers on question 6: *Do you agree that harmonized RAC of the proposed type would play a role for solving any current difficulties regarding the mutual recognition of risk assessments?*

*Please tick one of the boxes below as appropriate:*

- Strongly agree;
- Somewhat agree;
- Neither agree nor disagree;
- Somewhat disagree;
- Strongly disagree.
- Other.

7.2.1.1.1 Summary of answers (excluding answers from sector organisations CER, EIM, UNIFE)



7.2.1.1.2 Answer from UNIFE : somewhat agree

*“As said above, the RACs are valuable, if they are expressed in a way that they ensure harmonisation. This turns to the opposite the more they allow interpretations which could lead to requests for more paperwork (not really improving safety) as it’s the case*

today. The answer above is given under the assumption that the RACs really represent a harmonisation for the sector.”

7.2.1.1.3 Answer from CER-UIC : neither agree nor disagree

*“Cross-acceptance is ensured for all three types of risk acceptance principles, i.e. the use of codes of practice, reference systems and explicit risk estimation. The advantage of harmonised RAC compared to the two other principles is that they are explicit reference values that are stated in the Regulation which can be applied in a common way across all member states when mutual recognition is being sought.*

*Achievement of these positive expectations is subject to solving the drawbacks (see Question 4). In addition the application of RAC can only be beneficial if the system integration aspect is being given due consideration.*

*There is a possibility that the RAC would be adopted by NSAs and companies as “mandatory” requirements rather than maximum levels. This could lead to equipment being over-specified in instances where the RAC is not necessary, desirable or appropriate. There are strong apprehensions that diverging interpretations and lack of control of the notions used*

*in the RA process may lead to :*

- *long and expensive safety demonstration,*
- *different levels of acceptance in different member states*
- *economically damaging excessive technical requirements,*
- *rejection of practical safe measures,*
- *increase of the gap between NSAs*

*But the situation with today CSM is unclear what regards the application of  $10^{-9}$  requirement”.*

7.2.1.2 Answers on question 8: *Considering your experience so far, would you please provide some examples where harmonized RAC of the proposed type could have played a role for solving any difficulties regarding the mutual recognition of a risk assessment, of a safety demonstration or of their parts?*

7.2.1.2.1 Answer from UNIFE: *“Although it is not directly relevant here: Different countries/customers’ requirements specify RACs different to our “standard” RACs. This creates a lot of work. (On some not only worldwide contracts the definitions of severity/RAC are different). There are a lot of examples for quantified safety requirements, but not so much examples for solving difficulties regarding mutual recognition. Most of the quantified design targets are related to safety related loss of a specific function. In best case the targets take into*

consideration the known context of the future operator. In worst case the target does not refer to any operational context. In this case the chance for mutual recognition is very low because a different context for application of the target could be claimed by the second NSA. Having the same or similar operational context all over Europe would be the most important precondition for applying successfully RAC-TS and reaching mutual recognition.”

7.2.1.2.2 Answer from CER-UIC: *“At the current time the contributors to this questionnaire have no evidence that safety demonstrations of the past would be carried out with less effort using RAC.”*

**7.2.1.3 Conclusion: Harmonised RAC are a necessary condition to exploit the potential benefits, but are not a sufficient condition. According to several answers, having a harmonised operational framework all over Europe would be the most important precondition for achieving automatic mutual recognition when applying successfully RAC-TS. Remaining conditions are related to the methodology how to handle barriers and human factors in order to be able to harmonise/define acceptable rates of occurrences for failures of functions with indirect consequences (including availability requirements of technical systems). Guidance on these remaining conditions will be necessary to achieve a harmonised approach.**

## 7.3 STEP 3: EVALUATE RAC VALUES

### 7.3.1 INTRODUCTION

7.3.1.1 In the evaluation of the safety impact, limited answers are provided within the answers related to the validation of RAC-values indicated in scenario 2.

7.3.1.2 In some answers, the respondent indicates an impact on safety (increase/decrease) for reasons not directly linked to the definition of the RAC-values, but due to other effects. Following reasons are mentioned:

- Increase in safety due to harmonisation of RAC-values
- No change in safety due to explicit risk estimation method (and RAC-values) are not used
- Decrease in safety due to focus on lower severity consequences

7.3.1.3 Although we add an overview of the distribution of answers, this analysis will focus on the reasons that respondents gave when they estimate there will be a change in safety.

### 7.3.2 SAFETY IMPACT OF RAC FREQUENCY RELATED TO MULTIPLE FATALITIES

7.3.2.1 Answer from UNIFE: the proposal would lead to no change of safety

*“The  $10^{-9}/h$  in the actual CSM RA is recognized as an agreed value in the railway sector for catastrophic hazards and is present in several contracts. But it is common consensus that real catastrophes are in the focus and not severities of e.g. two fatalities*

*The most valuable benefit of this RAC is to limit the demonstrations to this frequency value in order to avoid any work on predictions of more demanding targets which do not have any additional benefit for safety.”*

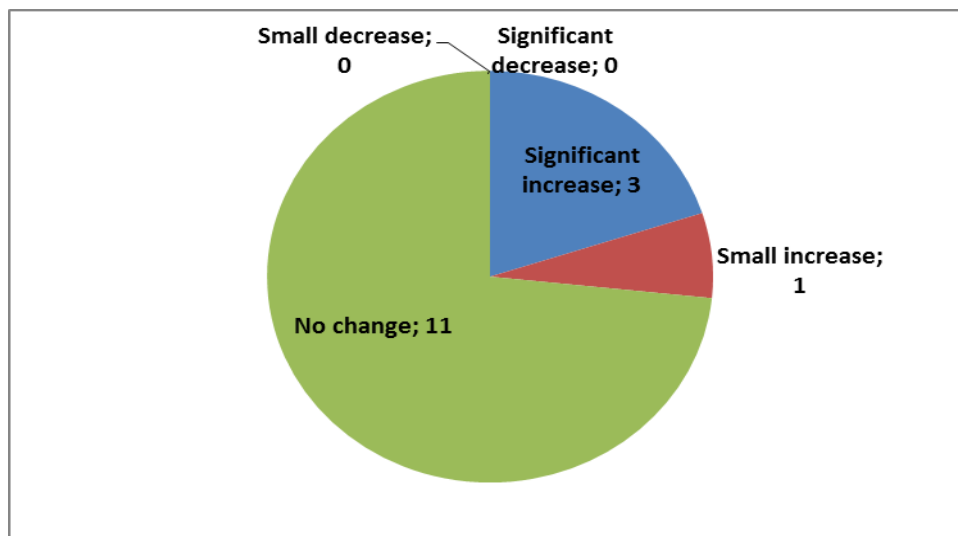
7.3.2.2 Answer from CER-UIC: Small increase in safety

*“For the majority of technical systems and failure scenarios that have the direct potential for collective fatalities, the RAC design criteria proposed by ERA appear to be set at a level such that if they were to be used without modification for the design of technical systems (without taking into account effects of any external barriers) there would be an increase in safety*

*within the member states (so long at the conditions of application and safety or integration are also assured). Usually, a number of external barriers is implemented in combination with a technical function. Therefore the influence of the design of technical solutions on safety will be indirect. For more detailed statements and CER's alternative proposal for harmonised RAC please refer to the Position Paper covering the SSMG/CER "Application Exercise" concerning the RAC "design criteria" values presented in ERA draft revision recommendation for regulation 352/2009"*

*Proposal CER to change text: For a failure that has a credible potential to lead directly to those types of events that have the expectation to affect a group of people and result in collective fatalities, the frequency of the failure of the function does not have to be reduced further if it is demonstrated to lie within the range  $1 \times 10^{-9}$  to  $1 \times 10^{-8}$  failures per operating hour appropriate to the assessed function.*

7.3.2.3 Distribution of answers on safety impact



7.3.2.4 Additionally, some answers from individual organisations that have indicated a change in safety level due to the defined RAC-values, are:

7.3.2.4.1 *"The comparison between current requirements and the proposed ERA RAC is difficult as severity and frequency are not expressed in the same way and thus let the door open for uncertainties based on the assumptions that have been implicitly chosen. However, the current formulation could lead to a **significant increase in safety**, as "more than one fatality" could be understood as "at least 2 fatalities".*

*In France, the 10-9/h is applied only to accident where “multiple fatalities” occur; in the sense of a “collective risk”, not an “individual risk”. A concrete example would be the door system, where an inopportune door opening would be considered catastrophic only in a suburban train, and critical in all other cases.”*

7.3.2.4.2 **“Significant decrease in safety:** *Currently the 10-9 risk acceptance criteria would apply to this scenario as any system that could cause a single fatality would also be expected to be able to cause a multi fatality. This implies SIL4 for single fatality outcomes as being acceptable EU-wide.”*

**7.3.2.5 Conclusion:** **The responses show that for the reference to a failure with potential to lead directly to more than one fatality, the defined value does not change what already exists in the current CSM-regulation and in the railway practice. The term ‘multiple fatalities’ from the RAC task force proposal note (2) is in most cases interpreted in the sense of accidents related to collective risk.**

**7.3.3 SAFETY IMPACT OF RAC FREQUENCY RELATED TO SINGLE FATALITY OR MULTIPLE SERIOUS INJURIES**

7.3.3.1 Answer from UNIFE: the proposal would lead to a small increase in safety  
*“IMPORTANT NOTE: This RAC would probably not increase safety in reality but increase safety requirements and the resulting paperwork/approval costs.*

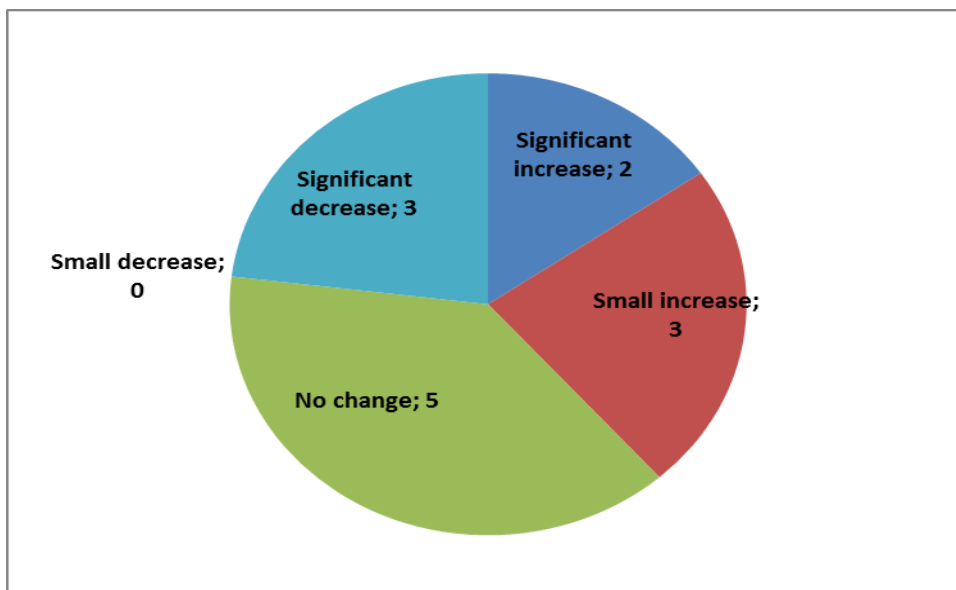
*The requirement would lead to the fact, that two fatalities would be linked to the catastrophic RAC. This is not acceptable and would create much more work.*

*If one up to a few number of some fatalities is meant, the value of the frequency is in line with contracts/NSA requirements experienced.”*

7.3.3.2 Answer from CER-UIC: small increase in safety for majority of cases; small decrease in safety for minority of cases

*“For the majority of technical systems and failure scenarios that have the direct potential for one fatality, the RAC design criteria proposed by ERA appear to be set at a level such that if they were to be used without modification for the design of technical systems (without taking into account effects of any external barriers) there would be an increase in safety within the member states (so long at the conditions of application and safety or integration are also assured). For some technical systems and failure scenarios it appears to CER that the opposite conclusion would be true, namely that the RAC design criteria proposed by ERA would lower safety within the member state. Usually, a number of external barriers are implemented in combination with a technical function. Therefore the influence of the design of technical solutions on safety will be indirect.”*

7.3.3.3 Distribution of answers on safety impact:





- 7.3.3.4 Additionally, some answers from individual organisations that have indicated a change in safety level due to the defined RAC-values, are:
- 7.3.3.4.1 *IM/RU-significant increase: Warning: no difference is made between severe injuries and fatalities, thus multiple severe injuries would be considered as “catastrophic”.*
- 7.3.3.4.2 *Supplier - small increase: the 2 cases of single fatalities and/or multiple serious injuries can be considered differently. But generally in line with contract experimented.*
- 7.3.3.4.3 *NSA-significant decrease; Yes, we can compare with what is being done by the NSA in the allocation of SIL on E/E/PES systems. However, since there is a risk of "death", the SIL 4 is chosen and the specific aim of 10-9/h.*
- 7.3.3.4.4 *IM-significant decrease: Currently the 10-9 risk acceptance criteria would apply to this scenario as any system that could cause a single fatality would also be expected to be able to cause a multi fatality. This implies SIL4 for single fatality outcomes as being acceptable EU-wide.*

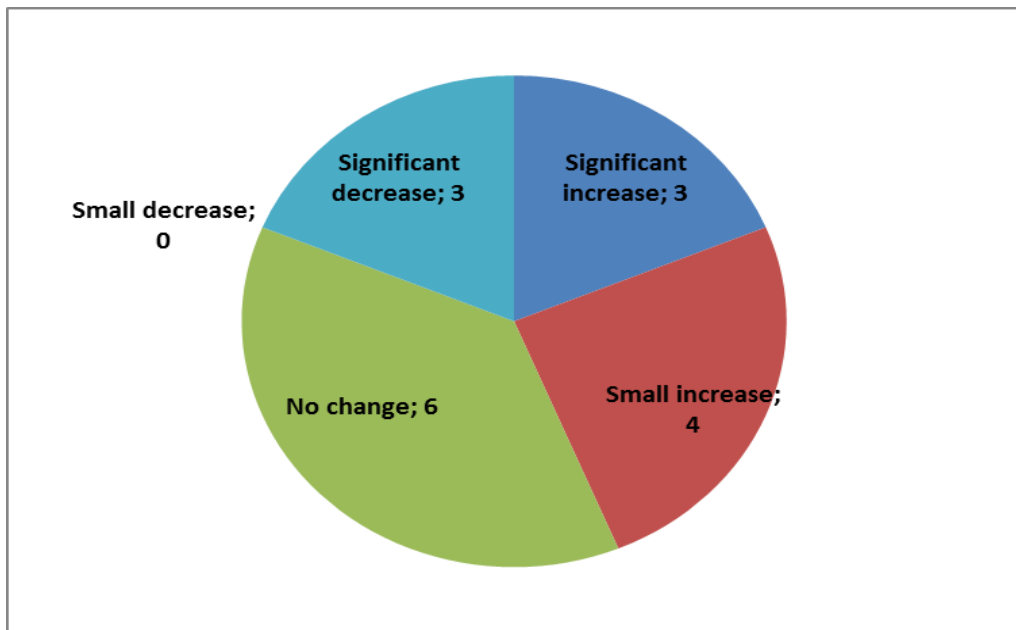
<p><b>7.3.3.5 Conclusion: most answers reflect on the interpretation of the severity class, and do not question the frequency rate.</b></p>
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**7.3.4 SAFETY IMPACT OF RAC FREQUENCY RELATED TO SINGLE SERIOUS INJURY AND/OR MULTIPLE LIGHT INJURIES**

- 7.3.4.1 Answer from UNIFE: the proposal would lead to a significant increase in safety / no change in safety (see text)  
*“This RAC would probably not increase safety in reality but increase safety requirements and the resulting paperwork / approval costs.  
The problem is on the possible variety of interpretation.”*
- 7.3.4.2 Answer from CER-UIC: small increase in safety for majority of cases; small decrease in safety for minority of cases. Same answer as in previous section:  
*“For the majority of technical systems and failure scenarios that have the direct potential for one fatality, the RAC design criteria proposed by ERA appear to be set at a level such that if they were to be used without modification for the design*

*of technical systems (without taking into account effects of any external barriers) there would be an increase in safety within the member states (so long at the conditions of application and safety or integration are also assured). For some technical systems and failure scenarios it appears to CER that the opposite conclusion would be true, namely that the RAC design criteria proposed by ERA would lower safety within the member state. Usually, a number of external barriers are implemented in combination with a technical function. Therefore the influence of the design of technical solutions on safety will be indirect.”*

7.3.4.3 Distribution of answers on safety impact



7.3.4.4 Additionally, some answers from individual organisations that have indicated a change in safety level due to the defined RAC-values, are:

7.3.4.4.1 IM/RU - Significant increase: *“Warning: the differentiation between “light” and “severe” injuries was not analysed in terms of “time in hospital”, light injuries would not always need hospitalization. Furthermore, the precision of used failure rates does not allow to be precise enough to ensure being inferior to  $3 \cdot 10^{-7} / h$ . Precision is only at the level of decades ( $10^{-7} / h$  means “we are somewhere between  $10^{-6}/h$  and  $10^{-8}/h$ , more precision is impossible given available data, and would only mean giving too much confidence to pure mathematical calculations, the more precise the number being, the less close to reality it is).“*

7.3.4.4.2 IM - significant decrease: *“The IM considers that this type of serious injury/multiple light injuries will be become extremely difficult to define with the*

*result that it cannot be applied in practise and as a consequence projects are delayed and cross-acceptance of risk assessments is not achieved. As with question 11 any scenario which can credibly result in a serious injury might be expected to result in multiple serious injuries. This implies SIL2 for a single serious injury outcome as being acceptable EU-wide.*

**7.3.4.5 Conclusion: Most answers confirm the statements made by CER and the reasons to indicate a significant increase or decrease are related to the interpretation of the severity class.**

**7.3.5 SAFETY IMPACT OF RAC FREQUENCY RELATED TO SINGLE LIGHT INJURY**

7.3.5.1 Answer from UNIFE: the proposal would lead to a significant increase in safety / no change in safety (see text)

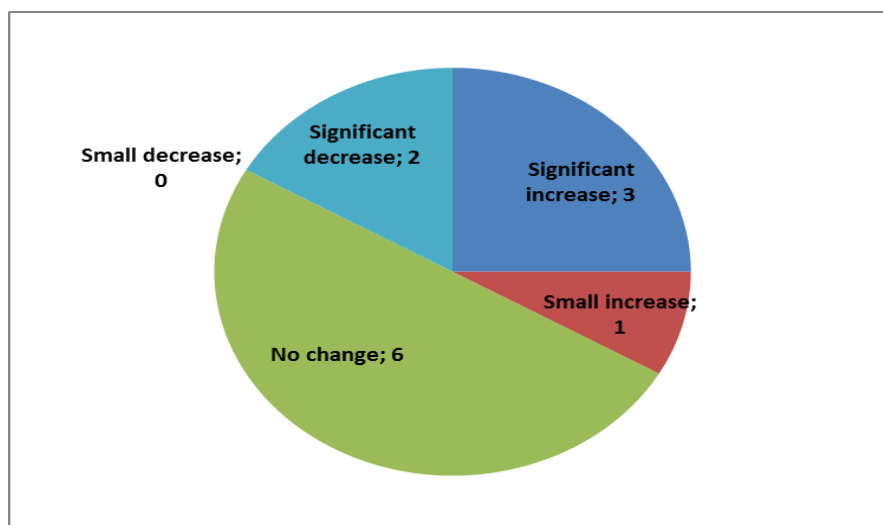
*“IMPORTANT NOTE: This RAC would probably not increase safety in reality but increase safety requirements and the resulting paperwork / approval costs.*

*The problem is on the possible variety of interpretation and the demonstration which was never requested before for light injuries.”*

7.3.5.2 Answer from CER-UIC: the proposed category has to be removed from the regulation

*“This severity class is found to be of limited value compared to the other severity classes (only one organization assessed one function) and should be removed from the regulation.”*

7.3.5.3 Distribution of answers on safety impact



7.3.5.4 Additionally, some answers from individual organisations that have indicated a change in safety level due to the defined RAC-values, are:

7.3.5.4.1 IM/RU - significant increase: *Warning: the differentiation between “light” and “severe” injuries was not analysed in terms of “time in hospital”, light injuries would not always need hospitalization. The proposed objective does not take into account the latest conclusions of the new EN 50128, where low consequences are considered with SILO qualitative requirements, which are applicable for “higher than 10-5/h”, e.g. 10-3/h. Demanding at least 10-5/h forbids the use of SILO and demands the use of SIL1 as a minimum.*

7.3.5.4.2 IM - Significant decrease: *“The IM considers that this type of light injuries will become extremely difficult to define with the result that it cannot be applied in practise and as a consequence projects are delayed and cross-acceptance of risk assessments is not achieved. If a light injury is defined at too low a level, then conceivably all hazards will have the potential to fall into this category with the result that the default frequency of occurrence becomes 10-5 per operating hour for all components of a system. This needs to be assessed against the current frequency of occurrence found on the EU rail network to determine its impact on safety and cost. It is quite possible that a blanket application of a target like this will cause safety related spending on projects to be diverted from high risk multi-fatality hazards to low level hazards that are currently considered acceptable. This implies SIL1 for a single minor injury outcome as being acceptable EU-wide. See comments on Q4 and Q6. This is unlikely to be used to any great extent.”*

<p><b>7.3.5.5 Conclusion: EIM, CER and UNIFE propose to delete this severity class and RAC-value due to the limited number of examples for its usage, which they could find during the impact assessment exercise.</b></p>
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### 7.3.6 CER-UIC APPLICATION EXERCISE

7.3.6.1 In annex 9, the position paper of CER-UIC is added in order to give detail on the performed exercise on the RAC values. Conclusions of this exercise are integrated in the answers on RAC values in the previous sections. The proposal made by CER on RAC-values is summarised in following table:

## ERA ECONOMIC EVALUATION UNIT

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*The values proposed by CER are consistent with the SIL approach, as in EN50129:*

(a)	(b)	(c)
Collective fatalities	Single fatality / collective serious injuries	Single serious injury

$10^{-9}$        $10^{-8}$        $10^{-7}$        $10^{-6}$

*Guidance to indicate that the operating hour appropriate to the assessed function will differ depending on whether the technical system is train-based or infrastructure-based.*

*Guidance in the form of a table to indicate the known technical systems, functional*

**Picture 3: Extract from CER-UIC Application Exercise**

7.3.6.2 Main significant impact (increase on safety and costs) on the proposal is mentioned by SNCF.

The SNCF approach noted that the SAM F 015 value scale is consistent with the fact that when SIL is used, primarily for software, SIL4 and SIL3 development requirements are identical. It is the same for SIL2 and SIL1 (see EN 50128). With ERA values, the  $10^{-8}$  value would be in the middle of the "SIL4 + SIL3" class, while the SNCF proposed  $10^{-7}$  value is at the border between "SIL4 + SIL3" and "SIL2 + SIL1" classes. The consequence is that if the ERA value was chosen, SNCF noted that nearly all SIL2 developments would become SIL4 developments.

The SNCF conclusion is the use of ERA value scale would result in a significant increase in requirements and therefore in costs because:

- when the 3rd risk acceptance principle is applied to a new system, requirements derived from RAC would be more demanding than those usually applied to existing systems whose failures have the same severity class.
- nearly all SIL2 developments for software systems would become SIL4 developments.

7.3.6.3 Link with CENELEC-standards: in the above analysis of CER, the increase in safety impact is mainly due to the link with the CENELEC-standards and the corresponding SIL-levels. In order to keep the same safety level, a link between the defined RAC-values within the CSM-regulation and CENELEC-norm should be guaranteed. This means that the frequency values (if any) within the CENELEC-norm should be aligned or refers to those used within the revised CSM-regulation.

This subject was handled with CENELEC-representatives at a coordination meeting between CER-UNIFE-ERA (11/01/2012) with following conclusion:

*“The revised standards will include the risk matrix but only with examples for its calibration. It will explain that if there are any legal requirements (such as the RACs from the CSM RA), then these have to be used for risk acceptance if the matrix is applied. WG14 will ensure that the severity definitions for calibration do not contradict to the Acceptance Principles from the CSM RA Regulation.”*

**7.3.7 CURRENT STATUS ON RAC VALUES**

7.3.7.1 As a consequence of the discussions based on CER’s impact assessment / validation and application exercise, the RAC-table was proposed to be modified in the following sense:

- Deletion of the “single light injury” severity category (reasons: no acceptance of the RAC-value itself and limited added value of such severity category for achieving mutual recognition)
- Adaptation of RAC-table in order to be in line with current RAMS-standards

7.3.7.2 During the meeting of the CSM on Risk Assessment Working Party, which took place on 21<sup>st</sup> February 2012, the sector organisations have indicated interest that they evaluate the impact of the solution of keeping  $10^{-9}$  /h for some ‘high’ catastrophic consequences (such as failures of functions of technical systems such as interlocking system, braking system which can lead to a complete loss of a train), and evaluate the possibility to make a distinction in the upper severity consequence class (“multiple fatalities”).

<b>Severity of the estimated consequences</b>	<b>Acceptable rate of occurrence of the analysed unwanted direct consequence (e.g. an accident with catastrophic consequences)</b>
<i>Multiple fatalities - category 1 (to be redefined)</i>	$R \leq 10^{-9} /h$
<i>Multiple fatalities – category 2 (to be redefined)</i>	$10^{-9} /h < R \leq 10^{-8} /h$
Single fatality and/or multiple serious injuries	$10^{-8} /h < R \leq 10^{-7} /h$
Single serious injury	$10^{-7} /h < R \leq 10^{-6} /h$

- 7.3.7.3 Due to the limited experience for the examined types of failures with explicit risk estimation as a stand-alone risk acceptance principle (not in conjunction with the usage of Codes of Practice and Reference Systems) and to limit interpretations on definitions, additional guidance is suggested to be added to show some examples on
- functional failures, typical severities of their consequences, as well as typical measurement units (in the form of a table)
  - the usage of barriers;
- 7.3.7.4 In order to at least maintain the safety level within Member States (Article 4 of Safety Directive), Member States will compare the impact of the proposed harmonised RAC-values (when they are actually used by a RU or IM), with the safety levels achieved by the use of usual Codes of Practice, Reference Systems or national RAC-values (if existing). Depending on the output of this exercise, this could lead to the notification of further national safety rules (by application of clauses 2.5.5 or 2.5.6, which are quoted underneath)..
- 2.5.5. Without prejudice to the procedure specified in Article 8 of Directive 2004/49/EC, a more demanding criterion may be requested, through a national rule, in order to maintain a national safety level. In the case of additional authorisations for placing in service of vehicles, the procedures of Articles 23 and 25 of Directive 2008/57/EC shall apply.
- 2.5.6. Whenever the proposer demonstrates compliance with a harmonised risk acceptance criterion defined in point 2.5.4, the principle of mutual recognition of Article 7(4) is applicable for the acceptance of the assessed risk.
- Nevertheless, if the proposer can demonstrate that the national safety level in the Member State of application can be maintained with a less demanding criterion for risk acceptance than a harmonised risk acceptance criterion, then this less demanding criterion can be used instead of the harmonised one. However, in this case, the mutual recognition, which is applied whenever harmonised risk acceptance criteria are demonstrated, is not automatic.
- 7.3.7.5 Case studies (see annex within CER-UIC position paper) provided by companies (*not by NSAs*) suggest that such cases may realistically appear.

## **8. OVERALL CONCLUSIONS**

- 8.1.1.1 The sector organizations are expected to agree on the final setting of the RAC-values.
- 8.1.1.2 If no agreement can be found, it is advised to determine what further steps need to be undertaken in this field (“proportionality principle”). This demonstration includes an elaboration of “applied methodology” to define which evidence will be sufficient to agree on RAC-values.



## **9. MONITORING AND EX-POST EVALUATION**

9.1.1.1 If the assessed proposal for harmonised RAC would be accepted, then the monitoring can be performed by the follow up of the notified safety rules introduced by Member States. An ex-post evaluation should identify

- a) the number of notified safety rules with a lower safety requirement than defined by using RAC-values according to clause 2.5.6
- b) the number of notified safety rules with a higher safety requirement than defined by using RAC-values according to clause 2.5.5
- c) the number of mutually recognised explicit risk estimations
- d) the number of not mutually recognised explicit risk estimations and the reason of which they are not recognised (including all associated costs)

**10. ANNEXES**

**10.1 CER-UIC POSITION PAPER**



CER-UIC position  
paper on RAC applica