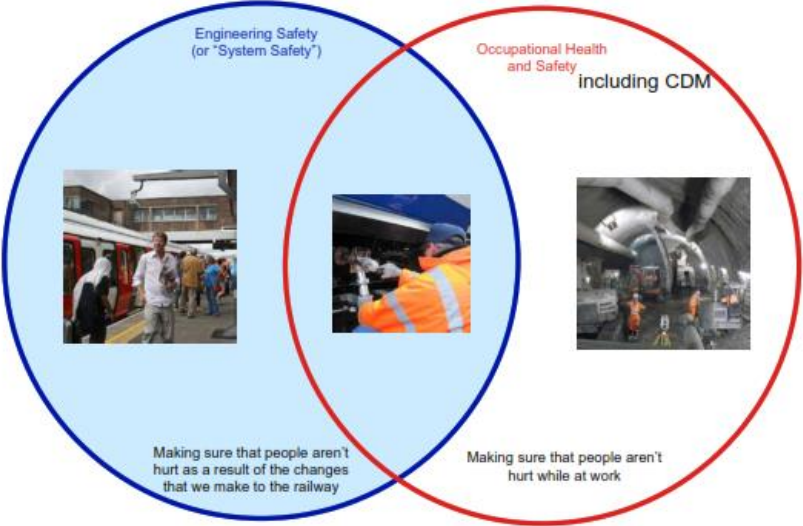


SaRS Webinar on 10 years of experience with CSM for risk assessment of 28th April and 18th May 2021

– Answers to the questions raised at the Webinar

Responses by: Dragan Jovicic, Pete Gracey, Carolyn Salmon and Ivan Lucic

N°	Question	Answer
1.	<p>I have a question about CSM v CDM, in particular on large construction projects with a small railway element, where the main players are not railway people. The large railway projects with small construction element are easy.</p>	<p>CDM stands for Construction Design and Management in construction works (as the name implies). It is subject to compliance with national Regulations.</p> <p>The analysis and management of railway system safety risks, and construction work risks, require not only risk analysts with different technical knowledge and competence but also a different level of granularity in the hazard identification, implying differences in management efforts of the two categories of risks. Combining both under an integrated safety management process requires a high maturity in risk management and the use of powerful tools and data bases for the Hazard Log management in order to differentiate clearly the two categories of risks.</p> <p>The set of skills to identify and manage the two categories of risks is different. It is also very rare to find a person that is fitted with both technical fields. This is true not only for the proposer which must apply the CSM RA but also for the independent AsBo.</p> <p>Consequently, although possible, it is preferable to allocate the two work streams to dedicated teams, each one with knowledge and experience of the right legislation and standards. Otherwise, there is a risk to mix concepts or worse, because of difference of granularity, to prioritise the management of one category to the disadvantage of the other one, leaving therefore some risks non identified, or uncontrolled.</p> <p>CDM risks are usually managed with a lower granularity, as they are identified without too much detail and structure. CDM risks are either prevented or controlled through a procedure (method statement). On the contrary, railway system safety risks need to be structured, and are usually managed through a higher level of detail of hazard identification, richer variety of mitigation options, need for evidence of sufficient safety justification, tests, etc.</p> <p>It is to note that in the scope of CSM risks, there can be a general high level hazard referring to the external documentation where the specific CDM risks are dealt with and managed.</p> <p>In addition to above, and as a point of clarification, the two, system safety and CDM and Occupational Health and Safety, overlap slightly as per diagram below.</p>

N°	Question	Answer
		 <p>The overlap is about making sure that once the works are completed and handed into use, the system is safe to maintain and operate. This area definitely fits under systems safety.</p>
2.	Which steps are to be done before the step significant change / not significant changes	<p>The most important is to have a sufficient “preliminary system definition”, i.e. enough information and knowledge concerning the intended change, the content of the change, as well as the impacts of the change on the neighbouring components or sub-systems through the interfaces. Knowledge of the interfaces of the system under assessment with the physical, functional, environmental, operational, and maintenance context is essential to be able to assess whether the change could have unintended, adverse and unacceptable effects on the safety of the rest of the system which is not changed.</p> <p>A good support for this is a functional block diagram which should include the overall information exchanged with the other parts and the unchanged parts of the system.</p> <p>Based on this information the proposer shall carry out a preliminary risk assessment to assess the impacts of the change on the safety of the railways. The preliminary risk assessment (PRA) will permit to identify which control measures can be put in place for controlling the preliminary risks and therefore whether more in-depth hazard identification and risk assessment is needed.</p>

N°	Question	Answer
		<p>Regardless whether a safety related change is “significant” or “non-significant” the risks arising from the change must be “systematically” identified and controlled to an acceptable level. For the significant ones, in addition to that the proposer must appoint an independent assessment body. Regulation 402/2013 on the CSM for risk assessment allows the use of in-house type B- or C AsBos.</p> <p>The proposer needs sufficient information of the proposed change to make the significance decision. The preliminary system definition and preliminary risk assessment should suffice. However, bear in mind that as the design and understanding of the change develops, the significance decision might need to be revised.</p> <p>For example, Network Rail developed templates and guidance supporting this approach as part of SI4D framework. All the material is available on the Network Rail SI4D hub.</p>
3.	<p>What is your definition of a “significant change”? There are a number of criteria in the CSM, but for a routine, well understood change, you can get a “non-significant” change, but still be safety related. Is this appropriate?</p>	<p>The author of the question well understands the objective, i.e. that risks arising from any safety relevant change must be identified and controlled. “Non-significant” but safety related change does not mean a permission to do nothing.</p> <p>Regardless whether a safety related change is “significant” or “non-significant” the risks arising from the change must be “systematically” identified and controlled to an acceptable level. For the significant ones, in addition to that, the proposer must appoint an independent assessment body.</p> <p>The proposer is responsible for making the decision on the significance of the change. The criteria in Article 4 of the regulation provide guidance on what should influence that decision. The NSA expects that the proposer will be able to show the decision making process and justify their decision. For non-significant decisions the proposer should continue to identify risks and manage them to an acceptable level.</p>
4.	<p>How is “Significant Change” defined?</p>	<p>The concept of significant change is not foreseen to avoid a systematic assessment and control of all reasonable risks that can arise from a safety related change. It is intended to help the proposer deciding :</p> <ul style="list-style-type: none"> • when a change is big, complex, etc. where strict risk assessment formalism is crucial, and where the witnessing by an independent pair of eyes of an AsBo is an additional assurance, and; • when a change is less complex and can be managed by well-known risk assessment and risk control processes, without the need for independent assessment by an AsBo. <p>Article 4 of the CSM RA lists 6 criteria through which the proposer shall go before deciding that a change is non-significant. The CSM RA is a tool to help the risk analyst going systematically through a reflection before deciding. It cannot replace the expert judgement of the risk analyst, who is the only one who can know whether the company processes for the risk assessment sufficiently control the considered risks, or whether the formalism of the process in Annex I of the CSM RA, with the assistance of an AsBo, is needed.</p>

N°	Question	Answer
		<p>However, the CSM RA does not oblige the proposer to demonstrate that a change is significant. The proposer can decide (if he wishes), based on a single criterion, that the considered change is significant; this implies the application of the process in Annex I of the CSM and the appointment of an AsBo.</p> <p>The proposer is responsible for making the decision on the significance of the change . The Article 4 of the regulation provide guidance on what should influence that decision. The NSA expects that the proposer will be able to show the decision making process and justify their decision. For non-significant decisions the proposer should continue to identify risks and manage them to an acceptable level.</p> <p>For example, Network Rail developed templates and guidance supporting the CSM significance test and a simplified approach as part of SI4D framework. All the material is available on the Network Rail SI4D hub.</p>
5.	<p>Is it possible to use CoP and reference systems to prove that a certain change is not significant? If so, do we need an AsBo in this case? (I am asking it because if you act like this you 'll 'leave' the flowchart at the first level.)</p>	<p>When a safety related change is non-significant, the CSM RA does not oblige to get it confirmed by an AsBo.</p> <p>Otherwise, yes (refer to the reply to question N°2) during the preliminary risk assessment, for the assessment of the significance of the change, the proposer can use codes of practice or measures from a similar reference system (provided they are relevant for the identified hazards and risks) to control the risks associated to the identified hazards. However, the proposer must comply fully with the requirements of the selected code of practice, or from the reference system.</p> <p>There is no requirement for an AsBo to verify the selection of CoP or reference system for non-significant changes. However, the NSA would expect a proposer to be able to justify the selection of a valid CoP or reference system.</p> <p>For example, Network Rail developed templates and guidance supporting the CSM significance test and a simplified approach as part of SI4D framework. All the material is available on the Network Rail SI4D hub.</p>
6.	<p>Ivan: you said that there is no guidance on "how". There is quite a lot of guidance on CSM-RA, from ERA, ORR and within Network Rail. Can you comment on that guidance?</p>	<p>Correct. The Agency wrote three guidelines on Regulation 402/2013, one on the roles and responsibilities of the AsBo, and one on the concept of significant change. All five documents are publically available on the Agency web page :</p> <ul style="list-style-type: none"> • Guide for the application of the CSM for risk assessment; • Collection of examples of risk assessments and some possible tools supporting the CSM; • Guideline for the application of harmonised quantitative design targets for technical systems (CSM-DT) defined in Regulation 2015/1136; • Explanatory note on the CSM assessment body; • Clarification Note On Safe Integration (reference ERA1209-63);

N°	Question	Answer
		<p>Although there is sufficient guidance from ERA, ORR and RSSB, additional succinct plain English guidance could be of help to project engineers on how to:</p> <ul style="list-style-type: none"> • develop a system definition; • undertake HAZID; • etc. <p>Ivan strongly believes something like a yellow book with clear and fairly detailed guidance on who does what; when and how is needed.</p>
7.	<p>What can we do to help people interpret the significance test well, as ultimately it is quite subjective, but if something is incorrectly judged not significant then the opportunity for the rigour of CSM RA is missed?</p>	<p>Yes, the decision on the significance of a change is subjective. However, regardless whether a safety related change is “significant” or “non-significant” the risks arising from the change must be “<u>systematically</u>” identified and controlled to an acceptable level. For the significant ones, in addition to that, the proposer must appoint an independent assessment body.</p> <p>That being said, the survey on the CSM RA done by ERA (see ERA website: Return of Experience (REX) with the use of the CSM for risk assessment) shows that a large majority of proposers likely does not have formal risk assessment to demonstrate that risks arising from non-significant changes are controlled to an acceptable level as well. Thereby, as the author of the question underlines, in practice the opportunity for applying the rigour of the CSM RA process is missed.</p> <p>The only action that can be taken is, what was repeated at the Webinar, educate, educate, educate and educate the stakeholders. This shall be part of any ERA or national training on Safety Culture and on increasing the Top Managers awareness on the importance to document all risk assessments.</p> <p>It is also necessary to continue to educate the wider railway community. Yes, to a certain extent the test on the significance is subjective, but the decision is down to the proposer and they should be able to demonstrate and justify how any such decision was reached. As explained at the webinar and in the other questions of this questionnaire, for a borderline case, the actual decision doesn’t matter as long as the risks arising continue to be managed and controlled to an acceptable level.</p> <p>For example, Network Rail developed templates and guidance supporting the CSM significance test and a simplified approach as part of SI4D framework. All the material is available on the Network Rail SI4D hub.</p>
8.	<p>What means "site safety"? Is it "health & safety"?</p>	<p>Outside the context of the slides and presentations, it is not possible to give an accurate answer.</p> <p>Site safety can well designate securing the trackside area or a work shop for carrying out the maintenance activities. It can include both railway risks arising from the operations related to the considered maintenance actions and to Health and Safety of workers at work, concerning for example any necessary tools or use of machines.</p>

N°	Question	Answer
		<p>In the context of CSM RA, the risk analysis is really about the steady states. The railway now, and the railway after the change is implemented (plus any interim states that impact railway operation).</p> <p>Site safety is about safety of operatives during construction or other work activities. This is not really covered by CSM RA but is covered by duties under other legislation.</p> <p>Please see also answer to question 1, site safety is about making sure people are not hurt while carrying the work, system safety is about making sure that people are not hurt after railway has been changed and is in use.</p>
9.	https://www.hse.gov.uk/construction/cdm/2015/index.htm	Nothing to add
10.	Is the use of CSM RA still mandatory in UK after Brexit?	<p>Theoretically, yes but via the OTIF UTP GEN G of 01.01.2016 which transposed the European Regulation 402/2013 on the CSM for risk assessment into an OTIF legal text. As UK is a non-EU contracting state of OTIF, it shall comply with that UTP GEN G.</p> <p>Use of CSM RA is required by ROGS 2006 (as amended). Commission Implementing Regulation (EU) 402/2013 is retained legislation post Brexit but is amended by "The Rail Safety (Amendment etc.) (EU Exit) Regulations 2019.</p> <p>The following website: https://www.rspb.co.uk/en/standards/defining-the-future-of-standards/brexit-faqs explains the impact of BREXIT on interoperability and safety in UK.</p>
11.	Ivan mentioned Yellow book no longer being maintained. The concept was picked up in iESM, which is.	<p>Former Yellow Book or CENELEC 50126, 50128, 50129 and 50657 are good complementary material helping to comply with the requirements of the risk management process in Annex I of Regulation 402/2013.</p> <p>In particular, CENELEC 50129 is a good guideline for the structuring and drafting of the Safety Case.</p> <p>iESM needs some more work and formality to achieve the same impact as the Yellow Book.</p>
12.	https://www.rspb.co.uk/safety-and-health/guidance-and-good-practice/management-of-change	Nothing to add
13.	How to define "non-safety related" changes? Technical modifications in existing rolling stock can be very small. A very simple example: add a sticker in the vehicle adds (a tiny bit) more fire hazard. So this then seems	<p>It is difficult to classify the change as non safety related. However, presumably affixing an informative sticker in rolling stock to warn about fire risks is likely to be the result from another process of the safety management system (SMS) of the railway undertaking.</p> <p>Then the risk control measures consists in following the requirement from the SMS.</p> <p>So, in the example, there is no need for risk assessment if that is the only change to rolling stock.</p>

N°	Question	Answer
14.	<p>safety related, but most likely not safety significant. Would you agree with this conclusion, or should this example not even be classified as safety relevant in the first place?</p> <p>There is nothing wrong with the Yellow Book, or many other methodologies for that matter; there's not much wrong with CSM RA either, I think. The problem lies in the widely varying attitudes of those who shall apply risk management.</p>	<p>Excellent summary of the approach and willingness to implement Regulation 402/2013 on the CSM for risk assessment. This is why greater education and understanding is needed!</p>
15.	<p>Ivan, you wish to use the Yellow Book, yet have started implementing ESM Gauge into Network Rail, which is based on Yellow Book and was intended to replace Yellow Book. Surely contradicting yourself?</p>	<p>ESM Gauge was not intended to replace the Yellow Book, it is simply a methodology for a “quick and dirty” yet objective assessment of a compliance of a project against good practice principles aimed at early identification of issues and correction so that we de-risk projects delivering safe solution. It was not based on Yellow Book, it used Yellow Book as one main input but also ‘checked’ against CSM, 50126, 7 and 8 etc.</p>
16.	<p>Yes. Regardless of EU membership status, 402/2013 is called upon in ROGS and this has not been repealed</p>	<p>Brexit does not change the UK obligation to comply with the methodology of the EU Regulation 402/2013 on the CSM for risk assessment. The OTIF UTP GEN G of 01.01.2016 transposes 100% the European Regulation 402/2013 on the CSM for risk assessment into an OTIF legal text. As UK is a non-EU contracting state of OTIF, UK is bound to compliance with that UTP GEN G.</p> <p>Yes, it was not repealed but modified by The Rail Safety (Amendment etc.) (EU Exit) Regulations 2019 to reflect the post-Brexit application in UK.</p> <p>The following website: https://www.rsb.co.uk/en/standards/defining-the-future-of-standards/brexit-faqs explains the impact of BREXIT on interoperability and safety in UK.</p>

N°	Question	Answer
17.	How do you manage Organisational Changes?	<p>Organisational changes fall within the scope of application of the CSM RA. Likely, the risk assessment will use explicit risk assessment and qualitative risk control measures for assessing and accepting the identified risks.</p> <p>It must be emphasised that operational and organisational changes require a closer risk monitoring during the operation and maintenance of the system under assessment in order to verify on the ground the effectiveness (i.e. real level of control) of the risk control measures.</p>
18.	<p>Note: I do agree on the poor writing style of CSM RA; to make matters worse, the translation into Dutch does not help either</p>	<p>There are certainly parts of the CSM RA that would deserve to be improved. However, in terms of the risk assessment process in Annex I of Reg. 402/2013, the CSM RA does not request anything new that the railways should not have already been doing earlier.</p> <p>Instead of looking for hidden, or twisted, interpretations of the requirements, use rather common sense and reasoning. You will see that the CSM RA does not request anything different from the CENELEC 50126:2017. The big difference is that the CSM RA defines the minimum framework for risk assessment, whereas CENELEC 50126:2017 is more detailed and contains guidance on how to comply with the high level requirements of the CSM RA.</p> <p>For example, Network Rail developed templates and guidance supporting the CSM significance test and a simplified approach as part of SI4D framework. All the material is available on the Network Rail SI4D hub. Network Rail is happy for anyone to use it; please just give Network Rail your feedback so Network Rail can improve further where needed.</p>
19.	<p>Changes non-significant but that will be authorised, is it necessary an AsBo? For non-significant changes is understood that safe integration is also verified, and according to Directive 2016/797, Annex IV, 2.4.(e) the file must include the AsBo assessment report.</p>	<p>Difference shall be made between mobile systems and fixed installations.</p> <ul style="list-style-type: none"> • Whenever a vehicle which integrates mobile sub-systems and components requires a <u>new authorisation for placing on the market</u>, then : <ul style="list-style-type: none"> ↳ according to Article 21 of the Interoperability Directive and to Article 13(3) of the Vehicle Authorisation Practical Arrangements 2018/545, the risk management process in Annex I of Regulation 402/2013 shall be applied. There shall also be an AsBo report, at least for the essential requirements related to safety; ↳ the applicant cannot escape from that obligation using the concept of significant change of Regulation 402/2013; • For fixed installations, the authorisation for placing into service is given by the national safety authority. There is no European legal text, equivalent to Reg. 2018/545 for vehicle authorisations, which prevents the infrastructure manager from sneaking out from the mandatory application of Annex I in the CSM RA, considering that the change is non-significant. It is likely that the infrastructure manager will use the processes of its safety management system (SMS) for the implementation and management of changes to infrastructures.

N°	Question	Answer
		<p>The only one who can challenge the infrastructure manager decision on the significance is the national safety authority (NSA) which is giving at the end of the project the authorisation of placing into service the line. The NSA might feel more confident if the risk assessment, its results and risk control measures were independently assessed by an AsBo.</p> <p>Regardless whether the change is significant or non-significant, the proposer must demonstrate the safe integration of the considered change within the railway system. Safe integration is not dependent on the outcome of application of Article 4 of Regulation 402/2013.</p> <p>For infrastructure changes, there is thus no absolute requirement for an AsBo if the applicant for authorisation determines the change is not to be significant. However, in practice in UK, most projects in this position choose to engage an AsBo to support the demonstration of safe integration. This could be achieved in other ways but to date the NSA did never see an infrastructure authorisation where the Technical File did not include a Safety Assessment Report from an AsBo.</p> <p>Nevertheless, some infrastructure manager experts do not believe for non significant changes they have to appoint an ASBO for doing independent verification. It can well be anyone internal to the business who is competent do undertake the task, and who is independent from the 'deliverer of the change to the railway'. Every nosiness as part of its Quality Management system shall have the independent internal assurance arrangements in place.</p> <p>ERA notices that this understanding is not incompatible with the concepts of types B and C of independence of AsBos, i.e. in-house AsBos, who can fulfil that role.</p>
20.	<p>Where the term "Authorised" is used, is this with respect to Interoperability? Whilst they're both system safety processes, they are separate and should be kept so. This is what is confusing a lot of our project teams and making application and conformity a lot more difficult than it needs to be</p>	<p>The term "authorised" or "authorisation" is used in different contexts of European railway legislation. It is indeed difficult to avoid using standard words from a dictionary.</p> <p>Safety Directive 2016/798 uses "Safety Authorisation" as the result of certification of the safety management system (SMS) of an infrastructure manager.</p> <p>The Interoperability Directive 2016/797 and the Vehicle Authorisation Practical Arrangement 2018/545 use "authorisation" for allowing the placing on the market of a vehicle which requires such a legal act.</p> <p>The applicant/proposer can also use the term "authorisation or authorise"(by himself) when it has complied with all relevant European legislation and can start operating the vehicle or infrastructure.</p> <p>Regardless the context where the term "authorisation" is considered, as well as whether a change is significant or non-significant, it is important that the proposer who carries out whatever change (technical, operational or organisational) systematically identifies which risks can arise from the design, operation or maintenance, of the system subject to change, and that it defines and implements risk control measures that keep the risk to an acceptable level.</p>

N°	Question	Answer
		<p>Therefore, do not confuse authorisation for placing into service interoperable sub-systems with application of CSM RA. They are related but follow different processes.</p> <p>Assessment for interoperability is essentially a technical compliance process, albeit with an element of essential safety requirements.</p> <p>CSM RA is about the assessment of system safety. The risk analysis and risk treatment of a system design in its applied context.</p>
21.	<p>In regards to the introduction of the 4th railway package: Article 21.12(b) in 2016/797 says a new vehicle authorization is needed if the overall safety level of the vehicle concerned may be adversely affected. This criterion is very broad, does the sector use the CSM RA for this and if yes, in what way?</p>	<p>Concerning Vehicle Authorisations, the requirements of the Interoperability Directive are complemented by the dedicated Vehicle Authorisation Practical Arrangement Regulation 2018/545.</p> <p>Whenever a new vehicle authorisation is needed, that Regulation requires the applicant to:</p> <ul style="list-style-type: none"> • apply the process in Annex I of Regulation 402/2013 at least for the requirement capture of the essential requirements related to safety, and: • appoint an AsBo for the independent assessment of the correct application of the application of that process, and of the appropriateness of the results from the risk assessment process. <p>As Regulation 2018/545 directly requests the application of Annex I of the CSM RA, it does not enable the applicant to sneak out from the mandatory application of the risk assessment process in Annex I in the CSM RA by pretending that the change in the vehicle is non-significant.</p> <p>It is to note that the 4th Railway Package has not been enacted in Great Britain. It is only applicable in the UK in relation to the Channel Tunnel and the Northern Ireland Agreement.</p>
22.	<p>Is there any evidence CSM-RA has made the railways safer?</p>	<p>The Safety Directive 2016/798 and the CSM RA do not question the existing level of safety in railways. Recital (5) of the Directive acknowledges that the <i>“safety levels in the Union rail system are generally high especially when compared to road transport”</i>.</p> <p>The objective of the CSM RA is to have a harmonised tool for assessing and accepting changes to the railway system, and to permit mutual recognition of the results from the risk assessment. The novelty of the CSM RA is the mandatory introduction of a proactive and systematic approach to risk identification, risk assessment and risk control before unsafe situations occur. This systematic approach includes the consideration of the variability of human and organisational interactions between the technical parts and the operational and organisational parts of the railway system.</p> <p>The implementation of the CSM RA is expected to support further technical development and innovations, maintaining the safety levels while at the same time improving the railway performances (increase of operational speeds and traffic density).</p>

N°	Question	Answer
		<p>The CSM RA was thus not about making the railways safer, it was about a consistent approach across the EU member states.</p> <p>The intent of CSM-RA was to harmonise methodologies for demonstration of safety across EU hence enabling ‘cross acceptance’ of products and subsystems. In UK, the CSM RA should not have caused a fundamental change in the way the safety is demonstrated, SFARAP (ALARP) allowed for three possible ways of doing stipulated in the CSM-RA. The only bit is a mandate of AsBo even where in past the ISA would not have been deployed.</p>
23.	<p>Alas, not the case! Existing Safety Measures need to be identified and many AsBo’s would raise Non Compliances if Broadly Acceptable Hazards are not listed!</p>	<p>Broadly acceptable hazards need also to be managed and registered in the Hazard Record/Log. The proposer shall thus be able to demonstrate to itself, as well as to the AsBo, that it correctly managed and implemented all requirements, including the existing risk control measures contained in the system definition.</p> <p>The process of the CSM RA does require the identification of existing safety measures. How else would one identify and analyse the change to the railway and the risks arising, without first understanding the railway before the change? Most existing broadly acceptable hazards are managed by an existing code of practice. Identify them and move on your risk assessment to those higher risks that really need to be analysed and treated.</p>
24.	<p>What is the legal context in terms of where the responsibilities sits with between different parties under the SRAC/hazard transfer process under CSM? i.e. Who has the final say when there is a dispute between the transfer and receiving parties.</p>	<p>When possible, for the interfaces shared among several actors, all involved parties shall cooperate in order to jointly identify the risks across those interfaces and agree on who will implement which risk control measures. This enables to avoid disagreement afterwards when the receiving party cannot understand the reasons for importing risks arising from another sub-system, or another actor.</p> <p>In practice because of insufficient cooperation between the relevant involved parties, or because of the placing of a new sub-system on the market without knowledge of the future users (i.e. clients), the applicant is obliged to export the hazard, as well as any relevant safety related application conditions (SRACs) that result from limits of the risk assessment and assumptions in terms of operation and maintenance of the technical equipment. Those SRACs are linked to risks across the interfaces with other sub-systems, and often with the human operators during the operation or maintenance of the technical equipment.</p> <p>The transfer of SRACs is an unavoidable concept. For example, for road vehicles, it is normal that the car manufacturer exports the SRACs related to preventive maintenance (e.g. replacement of suspension parts or brake pads) or regular servicing obligations in order to keep in good status of functioning the engine.</p> <p>Nevertheless, it is important that the one who exports the SRACs does not go beyond the scope of responsibility and domain of control of the actor who receives the measures. In practice, the manufacturer is expected to solve the risks arising from bad architectural design choices of a technical system instead of exporting heavy operational or maintenance constraints (e.g. need to calibrate once a week the accuracy of tachymetry radars).</p>

N°	Question	Answer
		It is incumbent on the party identifying the hazard or risk to manage it. Where that lies outside their responsibility they should bring the hazard to the party best able to manage it. Where the no single party can manage a hazard or risk then all relevant parties must cooperate to manage the risk to an acceptable level. However, the bottom line will always be that the relevant operational duty holder must be able to manage the risk within their own safety management system.
25.	Safer than what? SV with an ICP? unstructured discharge of duties under HASAW? Victorian engrg?	Not sure to understand the comment.
26.	Hello, in Austria, for example the NSA says, that a changed rule (operational change) from Infrastructure (ÖBB Infra) is a change that every railway undertaking has to do a risk assessment according to 402/2013, even if the railways are not the “proposer”. Is this in common sense of the “whereas” or the agency? Thanks	<p>Yes, operational changes at the level of the infrastructure might have an impact on all trains operating on the line. Therefore, the CSM RA requires that the infrastructure manager involves for the hazard identification all railway undertakings that operate on the line. That will enable to identify jointly the risks across those interfaces between the trackside and the trains and to agree on who will implement which risk control measures.</p> <p>Whenever a part of a system is changed, it could have adverse impacts also on the unchanged parts of the overall system. Therefore, the safe integration of the change within the rest of the railway system is necessary; this needs to be done in collaboration with all impacted actors.</p> <p>This is discussed further in the Agency Clarification Note On Safe Integration (reference ERA1209-63) available on the Agency web page.</p>
27.	Where can we find education/training for this subject (CSM-RA)	<p>For the moment, ERA has not yet developed detailed training/education material on the risk assessment and risk management concepts.</p> <p>The stakeholders can look for guidance in the CENELEC 50126;50128, 50129 and 50657 standards, or other IEC standards (e.g. ICE 61508).</p> <p>The Agency plans to work on it in future.</p> <p>In UK, there is guidance provided by ORR and RSSB, in addition to that provided by ERA. In UK most Assessment Bodies generally provide training and awareness courses on the CSM RA.</p> <p>Network Rail SI4D hub has CSM RA and interoperability e-learning available to all.</p>
28.	Much of the success of CSM Application depends on the competence of the individuals	The comment emphasises the right point. Proactive risk assessment and risk management cannot be successful if it is not done by staff with sufficient technical knowledge of the railway system and knowledge of risk assessment and risk management tools and techniques.

N°	Question	Answer
	involved. Do the speakers believe that the arrangements for both applicators and assessors of CSM are suitable and sufficient? What improvements (if any) would they like to see!	<p>For the moment, the European legislation does not set up harmonised requirements and criteria for the competence of staff in charge of risk assessment and risk management.</p> <p>Concerning the AsBos, the Agency is organising a Group of Cooperation of EU AsBos for developing recommendations for use (RFU) for the AsBos. The Agency is in charge of drafting those RFUs. The following two RFUs have been agreed and published till now:</p> <ul style="list-style-type: none"> • Recommendation for use 01 on the working method of the assessment body • Recommendation for use 03 on the AsBo technical knowledge and competence requirements for the different areas <p>Those two RFUs are intended to further harmonise the AsBo competence requirements and working method to avoid “box ticking AsBos”. All RFUs developed in the scope of the AsBo cooperation are intended to support the accreditation and recognition bodies for the accreditation and recognition of the AsBos.</p> <p>Those engaged in managing, developing and delivering changes to the railway and railway systems must be competent in the areas they are responsible for, or supervised by competent persons. Competence in application of railway systems safety (i.e. CSM RA) is just as important as competence in say railway signalling or track design.</p> <p>This is why Network Rail is running the CSM RA and RIR training courses and have specified competence requirements for those who need to deliver CSM RA and RIR artefacts. This is the reason why Yellow Book+ should be developed (maybe based on iEMS) by the industry for the industry</p>
29.	I'm not sure the sector is reluctant to use the CSM- I think it's more a question of understanding & clarity of CSM itself ...	<p>For one large majority of stakeholders, the statement in the comment is certainly true.</p> <p>Nevertheless, for the other ones, the survey the Agency did in 2018 indicates that the most likely reason for the sector reluctance to using Regulation 402/2013 is the main objective to avoid the mandatory formalism of Annex I of the CSM RA, and in particular the obligation to appoint an independent AsBo (although the CSM RA permits in-house accredited/recognised AsBos). They are not happy that independent entities intrude their organisational issues and request action plans for solving the identified non-compliances.</p> <p>This is why we need to continue to educate and improve competence.</p> <p>Please see also the answer to question 28</p>
30.	What happens post-BREXIT?	<p>Brexit does not change the UK obligation to comply with the methodology of the EU Regulation 402/2013 on the CSM for risk assessment. The OTIF UTP GEN G of 01.01.2016 transposes 100% the European Regulation 402/2013 on the CSM for risk assessment into an OTIF legal text. As UK is a non-EU contracting state of OTIF, UK is bound to compliance with that UTP GEN G.</p> <p>Pete</p>

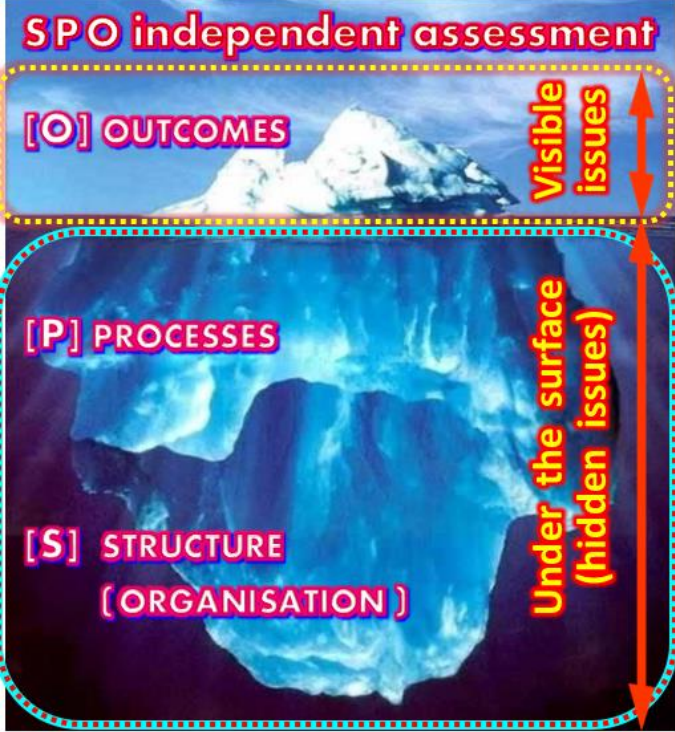
N°	Question	Answer
		<p>In respect of CSM RA, there is thus no change. It is still required by ROGS 2006 (as amended). Commission Implementing Regulation (EU) 402/2013 is retained legislation post Brexit but is amended by “The Rail Safety” (Amendment etc.) (EU Exit) Regulations 2019</p> <p>The following website: https://www.rsb.co.uk/en/standards/defining-the-future-of-standards/brexit-faqs explains the impact of BREXIT on interoperability and safety in UK.</p>
31.	<p>But what level of discipline competency? An AsBo may be deemed a “competent signalling engineer” but if their experience is say primarily in relay based signalling systems are they competent to AsBo a novel moving block signalling system?</p>	<p>The CSM RA requires that the AsBo has a minimum of technical knowledge and competence within the area of the system it assesses.</p> <p>The Agency administrates a Group of Cooperation of EU AsBos for developing recommendations for use (RFU) for the AsBos. The Agency is in charge of drafting those RFUs. The following two RFUs have been agreed and published till now:</p> <ul style="list-style-type: none"> • Recommendation for use 01 on the working method of the assessment body • Recommendation for use 03 on the AsBo technical knowledge and competence requirements for the different areas <p>Those two RFUs are intended to further harmonise the AsBo competence requirements and working method to avoid “box ticking AsBos”. All RFUs developed in the scope of the AsBo cooperation are intended to support also the accreditation and recognition bodies for the accreditation and recognition of the AsBos.</p> <p>The AsBo needs thus to be able to demonstrate competence in the systems it will be assessing. When employing AsBos, it is always necessary for them to demonstrate their team had suitable competence in the systems under assessment. When acting as AsBo, the AsBo should routinely provide competence evidence to its clients.</p> <p>Each activity should thus be assessed for competence requirements as well.</p>
32.	<p>Dragan, do you think that improvements in technology and fewer major accidents mean that people are more complacent about safety in rail?</p>	<p>Yes, too much self confidence is possible. However, complacency with a low number of major railway accidents is dangerous in absence of updated indicators on the continual effectiveness of the risk control mechanisms in place.</p> <p>Indeed, technical innovations and improvements, and better and systematic consideration and control of risks associated to human and organisational interactions with technical equipment certainly contribute keeping accident rates statistics at low levels. However, as risk is continually changing proper risk management requires:</p> <ul style="list-style-type: none"> • constant and close monitoring of the correct application of safety processes and the actual implementation of risk control measures identified by risk assessments, and; • constant and close monitoring of the effectiveness of those safety processes and risk control measures in actually controlling the company risks.

N°	Question	Answer
		<p>In the absence of effective risk monitoring, undetected technical, operational or organisational dormant failures can well exist in the railway system. If they are not detected, within the time another failure arises, when they are combined to the first ones, they could result in major accidents.</p> <p>A proactive safety culture cannot thus be measured only through low number of major railway accidents.</p> <p>This is all the more reason for ensuring a consistent application of railway system safety through the increased implementation of CSM RA.</p>
33.	<p>In my AsBo role, how much emphasis shall I place on CSM RA, Annex I, point 2.3.2 (b) "They must be relevant for the control of the considered hazards in the system under assessment."? Must the Proposer demonstrate plausibility?? Note: the same applies to point 2.4.2 (a), (b), (c), and (d).</p>	<p>Yes, the proposer must verify that the selected code of practice, or similar reference system, is relevant for sufficiently controlling the identified risks. The proposer must have documented evidence that the conditions in clauses 2.3.2 and 2.4.2 are fulfilled so that the proposer can reliably use the risk acceptance principle.</p> <p>So, as the AsBo is not expected to challenge the proposer, it is entitled to verify the evidence of the applicability of the selected risk acceptance principle!</p> <p>The risk mitigation measures should be mitigating the hazard.....</p>
34.	<p>Problem for railway undertakings is also, that different NSA's for example Germany vs. Austria have different opinions on the same stuff or decide different on same changes.</p>	<p>It is difficult to comment NSA expectations, especially in the absence of proposer's justifications to the NSA why a selected risk acceptance principle is relevant or appropriate for the specific risk of the system under assessment.</p> <p>Unless notified national rules exist, the CSM RA does not allow the NSA to setup risk acceptance criteria. By virtue of recital (11) of the CSM RA, and clause 2.1.4 in Annex I of the CSM RA, there is no mandatory order of priority for the application of the three risk acceptance principles/pillars of the CSM RA.</p> <p>Finally, unless notified national rules exist, according to the CSM RA, the proposer is also the sole responsible for the acceptance of the considered risk, based on the compliance with the requirements of either clause 2.3, 2.4 or 2.5 in Annex I of the CSM RA. That is not the responsibility of the NSA.</p>
35.	<p>How do system safety levels in railways compare with other forms of transport and more widely with other societal risks</p>	<p>The Agency does not have comparative indicators for societal risks of railways compared neither to other modes of transport nor to risks at home, in education, healthcare, etc.</p>

N°	Question	Answer																																								
	such as at home, in education, healthcare, retail, hospitality? Are the means to achieve the levels of safety in railways justified?	<p>Because of public perception in case of accidents (i.e. big number of victims in one single event), the Agency does not think appropriate comparing railway to societal risks in those other domains. The only relevant comparison is with respect to other modes of transport : road and aviation.</p> <p>Based on the European statistics (reference : "Transports 2050" : stratégie européenne pour accroître la mobilité et réduire les émissions), aviation is the safest mode of transport, immediately followed by railways. It is therefore legitimate to require equivalent obligations in terms of safety management and risk monitoring for railways as for the aviation.</p> <p style="text-align: center;">Fatalities per 1000 million pkm</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th>Fatalities 1997</th> <th>billion pkm 1997</th> <th>Fatalities per billion pkm</th> </tr> </thead> <tbody> <tr> <td>Pedestrians</td> <td>6 442</td> <td>163</td> <td>40</td> </tr> <tr> <td>Bicycles</td> <td>2 412</td> <td>70</td> <td>34</td> </tr> <tr> <td>Powered two-wheelers</td> <td>6 769</td> <td>121</td> <td>56</td> </tr> <tr> <td>Passenger cars</td> <td>23 275</td> <td>3 787</td> <td>6</td> </tr> <tr> <td>Buses and coaches</td> <td>173</td> <td>393</td> <td>0.4</td> </tr> <tr> <td>Goods vehicles</td> <td>2 017</td> <td>468</td> <td>4</td> </tr> <tr> <td>Other road vehicles</td> <td>451</td> <td>n.a.</td> <td></td> </tr> <tr> <td>Rail passengers *</td> <td>98</td> <td>270</td> <td>0.36</td> </tr> <tr> <td>Air passengers *</td> <td>73</td> <td>274</td> <td>0.27</td> </tr> </tbody> </table>		Fatalities 1997	billion pkm 1997	Fatalities per billion pkm	Pedestrians	6 442	163	40	Bicycles	2 412	70	34	Powered two-wheelers	6 769	121	56	Passenger cars	23 275	3 787	6	Buses and coaches	173	393	0.4	Goods vehicles	2 017	468	4	Other road vehicles	451	n.a.		Rail passengers *	98	270	0.36	Air passengers *	73	274	0.27
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36.	Which are the competences of experts in charge of risk management?	<p>Indeed, proactive risk assessment and risk management cannot be successful if it is not done by staff without sufficient technical knowledge of the railway system and in-depth knowledge of risk assessment and risk management tools and techniques.</p> <p>For the moment, the European legislation does not set up harmonised requirements and criteria for the competence of staff in charge of risk assessment and risk management.</p> <p>Concerning the AsBos, the Agency is organising a Group of Cooperation of EU AsBos for developing recommendations for use (RFU) for the AsBos. The Agency is in charge of drafting those RFUs. The following two RFUs have been agreed and published till now:</p> <ul style="list-style-type: none"> • Recommendation for use 01 on the working method of the assessment body • Recommendation for use 03 on the AsBo technical knowledge and competence requirements for the different areas <p>One part of the competence requirements defined for the AsBo in chapter II of RFU 03 is valid also applicable for the personnel in charge of risk assessment and risk management. That is related to relevant railway technical knowledge of,</p>																																								

N°	Question	Answer
		<p>and competence in, risk assessment and risk management standards. With the exception of personnel in charge of the internal monitoring of the SMS, the other staff does not need to have knowledge and competence in auditing quality and safety management systems. The Agency decided to write an Agency note on the competencies the proposer's staff must develop in order to pretend being able to carry out risk assessments. The Agency will involve the railway representative organisations before publishing that note.</p> <p>If you take a look at the Network Rail SI4D hub, you will find a competence management framework there, with competence definitions for system safety as well as other general SI activities.</p>
37.	<p>Dragan, your list of experiences about people seeing CSM as being a burden is very depressing. These are same issues we were seeing 20 years ago when CENELEC standards were first being required for projects, etc.</p>	<p>Admitting a lack of resilience to the new safety regulatory framework based on risk concepts is already an indicator of awakening awareness and formation of a safety culture embryo.</p> <p>The survey confirmed a large sector reluctance to voluntary use of the CSM RA; yes, that is somehow demotivating. However, as Lucius Annaeus SENECA said 2000 years ago, <i>"It is not because things are difficult that we do not dare, it is because we do not dare that they are difficult"</i>.</p> <p>Considering that every birth is accompanied with pain, the sector should start applying the CSM RA for more significant changes and learn by doing, exactly as the comment points out. The railway sector faced the similar reluctance and difficulties 20-25 years ago when contracts, or in some countries the legislation, made compulsory the compliance with the CENELEC standards.</p> <p>It is only by doing, experiencing difficulties, and learning on the field that the stakeholders will realise that the CSM RA does not request more than what the existing CENELEC 50126, 50128, 50129 and 50657 standards already require.</p> <p>In practice, application of the CSM RA is not difficult. In the UK anyone who had rigorously followed the Yellow Book should have been delighted by the aligned but simpler approach introduced by CSM RA. However, likely the problem was that few ever applied the Yellow Book principles fully. Thus they see CSM RA, and its independent assessment, as a burden. If you follow the CSM RA process ,then the risk assessment should be a formality and not an issue.</p> <p>In addition to that, a lot of resistance is coming from the way CSM RA (and in the past CENELCE standards) is implemented in the railway companies, with very blinkered view of the risk and some poor examples of application on the project as well as AsBos. The only way to fight it is to do it properly (pragmatically) and to demonstrate the value of doing it. Since Network Rail started doing it, including the Eastern Region (over 40 projects in last year and a half), the feedback Network Rail got from all but one project was only very very positive.</p>

N°	Question	Answer
38.	"Reference systems" are useful to derive new acceptance criteria in the explicit risk evaluation.	<p>Yes, that is the principle of comparing the system under assessment to a similar reference system. If the clause 2.4.2. of Annex I of the CSM RA is verified, the risk is acceptable if the same requirements as the one of the similar reference system are implemented.</p> <p>It would really be useful to see greater use of the reference systems approach in railway projects. Its use to date has been extremely limited in the UK.</p>
39.	Clearly not Pete! You can tell I had bad experiences! The way CSM-REA has been written leaves a lot to the interpretation of an AsBo and in my experience not a value for money process for Signalling Projects!	<p>Yes, the CSM leaves freedom on how to comply with the requirements of the method. As there is not a single way to comply with the CSM, it is therefore normal that the AsBo expert judgement is needed for the independent assessment of the correct application of the process requirements in Annex I of the CSM RA, as well as of the suitability of the results from the risk assessment to enable the system to fulfil safely the intended objectives.</p> <p>The purpose of the CSM RA is not to teach inspection bodies how to carry out their work. The following two recommendations for use available on the Agency website give additional information concerning the AsBos :</p> <ul style="list-style-type: none"> • Recommendation for use 01 on the working method of the assessment body • Recommendation for use 03 on the AsBo technical knowledge and competence requirements for the different areas <p>The Agency does not agree that the AsBos, which comply with those two RFUs, just do “box ticking” without added value for the proposer. On the contrary, that represents a critical SPO review of the proposer’s management of the change as represented in the figure below.</p> <p>In particular, for the CCS TSI, the AsBo is required to carry out all the independent safety assessment activities required by the CENELEC standards to the independent safety assessor (ISA). This includes for example an in-depth verification of the proposer’s compliance with the requirements of the CENELEC 50126, 50128, 50129 and 50129 standards. That is not possible to be done by “box ticking”.</p>

N°	Question	Answer
		 <p>The diagram shows an iceberg floating in water. The tip of the iceberg is above the water surface and is labeled "[O] OUTCOMES" in red text. To the right of this tip, a vertical double-headed arrow is labeled "Visible issues" in red text. The much larger part of the iceberg is submerged below the water surface and is labeled "[P] PROCESSES" and "[S] STRUCTURE [ORGANISATION]" in red text. To the right of this submerged part, a longer vertical double-headed arrow is labeled "Under the surface (hidden issues)" in red text. The entire diagram is titled "SPO independent assessment" at the top in red text.</p> <p>Negative or positive working experiences with an AsBo vary in function of every specific case, and with the proposer’s and AsBo’s maturity with the risk based concepts. The speakers sympathise with those who face difficulties. It is true that very different approaches can be observed with different AsBos. It is therefore important that the client ensures the AsBo remit/mandate is clear and there needs to be “open and clear two way communication” between parties.</p> <p>This is why in recent year for example Network Rail started having regular sessions with AsBos in order to capture and action lessons learned (both ways), and then to take unnecessary bureaucracy out.</p>
40.	I agree. Similar systems changes such as (for example) a new platform may identify repetitive hazards. Availability of reference	This is the principle of comparing to similar reference systems, with proven safe in use requirements, for designing safely new systems. For civil construction engineering, dedicated codes of practice also exist for different types of works. Compliance with those codes of practice gives presumption of control of the risks arising from such works without the need for proceeding to more in-depth hazard identification and risk assessment.

N°	Question	Answer
	<p>systems and their safety requirements could be made more readily available to proposers and the requirements for use made clearer</p>	<p>The collection of applicable reference systems, codes of practice, and various types of hazard lists and databases is a good idea. But that is not yet the role of the European Union Agency for Railways.</p> <p>As the European Union Agency for Railways does not act as proposer/applicant, it does neither hold its own rolling stock reference system databases and hazard lists, nor for recurrent infrastructure types of work. On the contrary :</p> <ul style="list-style-type: none"> • every manufacturer or railway undertaking, acting regularly as applicant for vehicle authorisations, should have a configuration of reference systems and processes for vehicle type upgrades in order to avoid reinventing the same concepts and requirements for every new project. • similarly, every infrastructure manager should have a configuration of reference systems and processes for different types of infrastructure projects and works in order to keep the costs under control and to avoid reinventing the same concepts for every new project. <p>The potential for efficiency in re-use of safety arguments and analysis has got to be a great benefit of the reference systems approach. Whilst no single repository of potential reference systems exists, it should not be beyond a large infrastructure manager to create such a system within its own remit.</p> <p>For example, Network Rail is developing a reference systems library by developing standard system definition, hazard record, safety management plan for specific categories of projects (stations works first, conventional signalling next, etc.)</p>
41.	<p>Will Application Guides of ERA regarding CSMRA incorporate new evolving topics as Cybersecurity (TS 50701)?</p>	<p>The process and main steps of the CSM RA are a standard risk assessment process. They are applicable to the identification and management of IT threats.</p> <p>However, for the moment, the IT Security threats, risk assessments and protection measures are not in the scope of the Safety Directive 2016/798, and thereby are not in the scope of the CSM RA, which is the result of Article 6(1)(a) of that Directive.</p> <p>At present, there is thus not a harmonised and mandatory framework at the level of the European Union for the management of IT Security or Cyber security threats and risks. An overall requirement requires that every EU Member State regulates the management and control of those types of risks at national level.</p> <p>As a general remark, independent from the comment, the Agency does not yet plan to revise the existing guidelines on Regulation 402/2013.</p>

N°	Question	Answer
42.	If it is used EN 50129/28 to design the safety function, then is it possible to say for the hazard, it is closed by only applying CoP?	<p>Yes, the reasoning is correct. However, the reader must keep in mind that applying correctly the CENELEC 50126, 50128, 50129, 50159, 50657, etc. does not imply nothing to do, or that the work is much lighter. Compliance with those standards is as demanding as the compliance with the CSM RA. The difference is that the CENELEC standards include more guidance on how to fulfil requirements contained in the standard. Similarly to the CSM RA, the CENELC standards also requires the proposer to :</p> <ul style="list-style-type: none"> • formally document the demonstration of compliance with the standards, including the risk assessment and risk management; • use a Hazard Log/Record for registering and managing the identified hazards and risks; • get independently assessed the correct application of the standards, the documentary evidence of demonstration of compliance, and the correctness of the results from the application of the standards. <p>It is to note that when the CENELEC, or any other relevant, standards are used as applicable codes of practice for controlling the identified hazards and risks, by virtue of the CSM RA, the independent safety assessment activities requested by those codes of practice must be carried out by an accredited or recognised AsBo, and not by the CENELEC independent safety assessors (ISA).</p>
43.	For example, "doors opened during the trip" and for this hazard as safety measure to implement SIL 2 the doors controls unit acc. to EN 50129/28...Then what is the right RAC for this hazard? CoP or ERE?	<p>For the example of the safety protection of an unwanted door opening, all three risk acceptance principles (CoP, Ref. Syst., explicit risk estimation) can be used for properly controlling the associated risks. The Annex I of the CSM RA lists the conditions for the use of every principle. Quantitative risk assessment is not always necessary.</p>

N°	Question	Answer
44.	Question to our presenters: Have you seen cases where CSM RA, Annex I, point 1.1.4 was applied by the Proposer? "1.1.4. The actors who already have in place methods or tools for risk assessment may continue to apply them if such methods or tools are compatible with the provisions of this Regulation and subject to the following conditions: (a) the risk assessment methods or tools are described in a safety management system accepted by a national safety authority in accordance with Article 10(2)(a) or Article 11(1)(a) of Directive 2004/49/EC; or ..."	<p>Annex I of Regulation 402/2013 defines the overall harmonised framework for the risk management process. It identifies the high level requirements and different process steps, every risk assessment project shall contain and go through. It specifies thus only WHAT the proposer shall do. But, the CSM RA does not prescribe any constraints or manner on HOW to fulfil those high level requirements.</p> <p>The quoted text deals with that flexibility CSM RA leaves to the proposer. Every railway undertaking, infrastructure manager, entity in charge of maintenance is expected to have included in its safety management system more details on how to implement the requirements of the CSM RA. The appropriateness of those in-house tools, instruments, methods, instructions, etc. is assessed during the assessment, certification and supervision of the RU, IM, ECM safety management system.</p> <p>In conclusion, it is not possible to comply with the requirements of the CSM RA if the proposer does not use additional processes and procedures on "how to do things". Naturally, that is an inherent and integral part of every company integrated quality and safety management system.</p>
45.	Can an international company Processes and Procedures qualify as CoP?	<p>Yes, that is permitted by the CSM RA. However, those internal processes and procedures shall be auditable and presented, on demand either to an AsBo or to an Authorising Entity (e.g. a national safety authority or the European Union Agency for Railways), when the proposer wants to benefit from the mutual recognition of the results of the risk assessment.</p> <p>The purpose of demanding access to internal codes of practice is to enable those other conformity assessment bodies to verify the relevance of the internal codes of practice for the considered risks.</p>
46.	Fulfilment of CENELEC can be a mean to show adherence to CSM (2019/776) but the ISA shall be AsBo in that case. Assessment reports of non-AsBo ISA should be rejected by AsBo/NoBo. What happens in the real life about that?	<p>The interpretation of the CCS TSI is correct. The independent safety assessment requested by CENELEC standards shall be performed by an AsBo accredited, or recognised, for the CCS area, instead of a CENELEC independent safety assessor (ISA).</p> <p>Considering that a harmonised European legislation exists for railways and aims at supporting the opening of the railway market by the mutual recognition of the results from its application, the European railway sector should be cooperative in applying it extensively to benefit from those advantages. This includes the need for increasing the rate of changes that should be judged significant, and which should undergo the formal process of Annex I of the CSM RA.</p>

N°	Question	Answer
		<p>Independently from the obligation to comply with the applicable legislation, the European Union Agency for Railways cannot promote the use of alternative methods and processes which unnecessarily duplicate roles and responsibilities of actors already clearly defined by European legislation. This is typically the case of independent safety assessment. Some stakeholders keep voluntarily using the CENELEC independent safety assessors (ISAs) instead of involving the assessment body (AsBo), defined in Article 6 of Regulation 402/2013 on the CSM for RA. This wilful disobedience to European regulation :</p> <ul style="list-style-type: none"> • makes very difficult the mutual recognition of demonstrations of compliance with the applicable legislation, and; • worse, keeps the other stakeholders confused on what is actually correct. <p>Based on that, the Agency encourages all stakeholders to cooperate and comply with the applicable European railway legislation for all new projects. In case of doubts, the Agency encourages the applicants and proposers to contact the Agency to share the views, before the applicant/proposer takes a final bad decision.</p> <p>That being said, a pragmatic solution needs to be found instead of categorically rejecting the reports of ISAs and unnecessarily entitling a NoBo, or an AsBo, to repeat the ISA independent safety assessments. A major difference must also be made between the following two cases :</p> <ul style="list-style-type: none"> • existing products, components, and sub-systems already placed on the market with the report of a CENELEC ISA; The applicant/proposer and the NoBo, or the applicant/proposer and the AsBo, need to find a way to be able to accept the report from the ISA, without unnecessarily repeating the checks and assessments already done by the ISA in the past, on products for which the design cannot be improved. <p>A pragmatic way for the acceptance of the ISA report is, if possible (i.e. if the ISA still exists), a bilateral discussion between the NoBo/AsBo and the ISA in order to get the assurance on the ISA working method, activities and results of the independent assessments, and verify whether the safety related application conditions (SRCAs) accompanying the product are clear and complete.</p> <ul style="list-style-type: none"> • on going, or new projects, which still need to be placed on the market. <p>The stakeholders shall comply with the EU legislation, instead of keep working conscientiously with ISAs, they shall appoint AsBos when this is required by the legislation.</p> <p>If an on-going project is assessed by an ISA, encourage the ISA to go through the accreditation process vs. Regulation 402/2013 in order to be formally entitled to work under EU railway legislation. Presumably good ISAs, which have a documented management system, already comply with all relevant requirements and criteria of Regulation 402/2013, ISO/IEC 17020:2012 standard referenced in Annex II of the Regulation and the RFUs 01 and 03. They just</p>

N°	Question	Answer
		<p>need to get their competence and capability formally acknowledged by an accreditation or recognition body, depending on the choice of the Member State where the ISA is located.</p>
47.	<p>What is the background of the mentioned 2-3% of changes that is considered significant? Is that the expected actual percentage of significant changes or is that the current number of significant changes that indicates avoidance of the use of CSM?</p>	<p>It is the current average rate of significant changes (between 2 to 3%, and not more than 5%) reported on the sector experience with the CSM RA. Yes, it indicates the sector avoidance in using the CSM RA. The Agency measured this rate through the eyes of national safety authorities, entities in charge of maintenance and AsBos in 2018. The expected rate of significant changes is likely to be higher than that.</p> <p>As the figure represents an average across the EU, some railway companies more familiar and mature with proactive risk assessments perform much better; nevertheless such actors are a very small minority.</p> <p>Knowing that big railway companies usually make between 500 and 1000 changes per year, the average number of significant changes does not exceed 50 changes over 1000.</p> <p>Although the Agency did not measure the percentage of changes that are actually safety related , the Agency expects a much higher rate of significant changes.</p> <p>For example, at the Webinar SaRS organised on 28 April 2021 on 10 years of experience with the CSM RA, Network Rail reported that 15 to 20% of all changes are actually significant from Network Rail point of view. This ration sounds to be more reasonable than 2 to 3% for the average of other railway companies. Network Rail also explained that many of other safety related changes, that are non-significant, also undergo a simpler in-house risk assessment in order to ensure that the associated risks are also systematically identified and controlled to an acceptable level.</p>
48.	<p>How do you ensure that the project is doing the right thing and following the right procedure for non-significant projects as there is no AsBo.</p>	<p>Regardless whether a safety related change is “significant” or “non-significant” the risks arising from the change must be “systematically” identified and controlled to an acceptable level. The CSM RA requires the proposer :</p> <ul style="list-style-type: none"> • for significant changes: appoint an accredited/recognised independent assessment body (which could be in-house as well) for checking the correct application of the risk management process in Annex I of Regulation 402/2013 and the results from that process; • for non-significant changes: justify the decision. <p>The CSM RA does neither prescribe how to justify that a safety related change is not significant nor oblige the proposer to appoint an AsBo. In practice, the only way to justify that a safety related change is non-significant is through a risk assessment. As the CSM RA does not prescribe any process for that, the proposer is free to use the process in Annex I of the CSM RA, or the risk management process in either the CENELEC 50126:2017 standard, the IEC 61508 standard or the ISO 31000 standard. All those four processes contain the same high level step requirements.</p>

N°	Question	Answer
		<p>Based on those explanations, during the supervision of the safety management system of the RU/IM (respectively the ECM), the national safety authorities (respectively ECM certification bodies) will be able to verify how the railway undertakings and the infrastructure manages (respectively entities in charge of maintenance) manage safely the changes. These are the controlling mechanisms foreseen in the European railway legislation permitting to verify that :</p> <ul style="list-style-type: none"> • the stakeholders do not cheat with the classification of significant and non-significant changes; • whenever a change is classified non-significant, the stakeholders have : <ul style="list-style-type: none"> ↳ a systematic risk assessment process which captures the hazards and necessary measures for controlling the risks arising from the non-significant change; ↳ sufficient documentary evidence to demonstrate that the associated risks are properly controlled. <p>Concerning manufacturers, they do not have so much the possibility to sneak out from the CSM RA with a non-significant change :</p> <ul style="list-style-type: none"> • the Vehicle Authorisation Practical Arrangement Regulation 2018/545 explicitly requires the applicant to apply the risk management process in Annex I of the CSM RA, and to appoint an AsBo, at least for the capture and management of the essential requirements related to safety; • section § 3.2.1 of the CCS TSI 2019/776 explicitly requires the applicant to : <ul style="list-style-type: none"> ↳ apply the risk management process in Annex I of the CSM RA, and appoint an AsBo for the assessment of compliance with the risk management process; ↳ or instead, use the CENELEC 50126, 50128, 50129 and 50159 as an acceptable means of compliance with the requirements of the CSM RA provided the CENELEC ISA is replaced by an AsBo accredited/recognised for the CCS area. <p>For example, in Network Rail, the Safety Review Panel (SRP) is empowered to request any project to attend for endorsement; including non significant; that is done so on a sample of projects.</p>
49.	<p>What is the agency/regulator's view on risk matrix / risk scoring under CSM process – Is addition or multiplication the preferred calculation method? Also the hazards that fall within the</p>	<p>The Agency does not have preference on risk prioritisation numbers (RPNs); although multiplication seems the most often used. The most important is that the proposer keeps consistent with the choice it adopts in order not to false the prioritisation of the risk management efforts.</p> <p>Concerning the tolerable or orange area of the risk matrix, the CSM RA is not prescriptive. It leaves the proposer the freedom to apply the ALARP principle. The ALARP is good common sense. If with a small additional cost the risk can be lowered down further, it is reasonable to apply the additional measures.</p>

N°	Question	Answer
	tolerable range/ALARP region are often open for interpretation, will ERA/ORR/RSSB look to publish further guidance to help with better quantification of the L&S to ensure a consistent approach across the industry?	<p>No, for the moment, The Agency does not plan to update the existing guidance material for further harmonisation. However, if future surveys on the return of the sector experience with the CSM RA report the sector interest and needs for it, it is not excluded to proceed to such harmonisation.</p> <p>A risk matrix is a simple tool to assist in prioritisation. As the current guidance says, the applicant should have a suitable process within their safety management system and it should be applied consistently</p> <p>In practice, risk matrixes can only be used to prioritise the work not to justify the decision making. As such risk matrixes have no scientific justification to fulfil that purpose.</p>
50.	Many thanks for the presentations and update on the subject. On the subject of Yellow Book mentioned by Ivan, is it useful to utilise GEGN8646 as a basis to revive and further develop the guidance to integrate practice and assessments on CSM-RA?	<p>Based on the speakers experience with the Yellow Book early 2000, this was a very useful guidance on how to implement the high level requirements of the CSM RA.</p> <p>It is also good sense to use any existing guidance to develop something like a new Yellow Book.</p>
51.	Why the GSN (Goal Structuring Notation) is not often used, for graphical argumentation, in the railway compared to other sectors?	<p>The use of any structured methods for representing and specifying the functional and technical requirements of a system is dependent on the system engineering processes of every company.</p> <p>The CSM RA and European legislation do not regulate this area yet.</p> <p>Although many GSN applications can be seen on UK railway projects, it is certainly not widespread. However, it is for the proposer to decide what tools they wish to employ.</p> <p>Although GSN can be of great support, it can not be a mandated format of making a safety argument.</p>
52.	Is it correct to consider that the assessment used by proposer to assess a change or a set of changes (of which some are safety related) does not require to be	<p>If I correctly understand the question, the comment is correct. The CSM RA does not request the proposer to appoint an AsBo just for confirming its decision on the significance of the change. Please refer also to the question N°48.</p> <p>If a change is classified significant, there is not any added value to request an AsBo to confirm his agreement with the proposer's opinion. However, the AsBo overview of how the proposer assessed the significance can support the AsBo in understanding the change and the proposer's organisation for managing safely the change.</p>

N°	Question	Answer
	<p>reviewed by an Independent Body? There has been discussion within our organisation on this topic. In my experience with a rolling stock manufacturer, the change assessment is given for review of an AsBo just for visibility. So far the AsBo has not objected or challenged the assessment.</p>	<p>Concerning vehicle authorisations, whenever a new vehicle authorisation is required, the applicant does not have the freedom not to follow the process in Annex I of the CSM RA and not to appoint an AsBo. Although the AsBo can look at the applicant's assessment of the significance of the change, that is not requested by the EU legislation.</p> <p>The Vehicle Authorisation Practical Arrangement Regulation 2018/545 explicitly requires the AsBo to independently assess the applicant's process for the capture and management of the essential requirements, at least those related to safety. That is the main role of an AsBo in the scope of the development life-cycle of a vehicle.</p> <p>In conclusion, although sharing the change assessment with the AsBo could help both sides, there is nothing in CSM RA that requires the AsBo to review it.</p>
53.	<p>What is your view on using the CSM process on changes to national functional requirement sets? Has it been implemented?</p>	<p>I am not sure I understand the question. It can have several interpretations.</p> <p>It can be understood as whether the CSM RA is to be used by the national safety authority, or the Member State, for defining new national rules or requirements, or even for removing existing rules, with the objective to prevent another German Wings case. In this case, there is no obligation to apply Regulation 402/2013 by the NSA or the Member State.</p> <p>It can be understood as the relation between the CSM RA and the applicable national rules or requirements. In practice, applying the CSM RA the proposer will identify hazards and associated risks. If they are controlled to an acceptable level by the single compliance to the national rules or requirements, the proposer can register the relevant national rule or requirement in the Hazard Log/Record, and the, manage and demonstrate the compliance with it. The proposer is not required to define additional risk control measures.</p> <p>Other interpretation than those two ones.</p>
54.	<p>Within CSM-RA, GSN is usually applied to ERE assessments if required. Prior to CSM-RA, under Yellow Book, it has been used for risk assessments as well.</p>	<p>GSN is not a risk assessment tool, but a graphical presentation of a reasoning model, so it is not obvious when and how it could be used for risk assessment. Another methodology for risk assessment, Weighted Factors Analysis, that combined BBN and graphics resembles to GSN graphics.</p>
55.	<p>Under YB, GSN is used to develop safety arguments</p>	<p>It is suggested as one of methods to develop safety reasoning.</p>
56.	<p>In Switzerland we have a normal gauge and special gauge network. The normal gauge network is mostly interoperable by means of IOD. The special gauge network is</p>	<p>The speakers do not know how the requirements of the European railway legislation are applied in Switzerland, in particular those contained in Article 1 of the Interoperability Directive 2016/797. It is therefore difficult to comment whether special gauge network is expected to comply with the CSM RA.</p>

N°	Question	Answer
	not interoperable. Is it correct that special gauge IM never have to mandate neither an accredited nor a recognized AsBo when they carry out a significant change on their network (cf. chap. 16 in the explanatory note of the CSM-RA)?	
57.	A question about SFAIRP (ALARP) application. It could be interpreted that some risk is tolerated (in comparison to other risk acceptance principles approaches) because cost is not affordable. How do you deal with this paradox?	<p>There is no paradox here:</p> <ul style="list-style-type: none"> • using reference method leads to the same conclusion in terms of risk acceptability simply because an underlying assumption is that in a previous case (used as a reference) the system has been accepted as ALARP solution. So by extrapolation if we are doing a same or very similar change to the railway somewhere else, the same solution will be acceptable as an ALARP solution. Indeed, prior to CSM RA, this was a valid argument to make to demonstrate ALARP (under Yellow Book as well); • using existing standards and good practice is based on an assumption that these deliver a solution that is already accepted as ALARP. Again prior to CSM this was a valid argument to make to demonstrate ALARP (under Yellow Book as well); • explicit risk estimation is about making a case that risk (explicitly defined) is managed to a level that is acceptable. In UK it would require a case to be made that no more can be done to manage the risk lower for a reasonable cost, effort, time, etc.
58.	Do Risk Acceptance Principles only apply to Hazards or equally to safety requirements which control multiple causes of a hazard.	Safety requirements are derived to manage hazards. So by default the Risk Acceptance Principles form and shape the safety requirements.