

Making the railway system
work better for society.

Document Review – Comment Sheet

Document commented: Common Safety Methods on the assessment of Safety Level and Safety Performance of railway operators at national and Union level (CSM ASLP)

<i>Requestor:</i>	Consultation.ERA1219@era.europa.eu
<i>Deadline for submitting comments:</i>	17 March 2021

	<i>Reviewer 1</i>	<i>Reviewer 2</i>	<i>Reviewer 3</i>	<i>Reviewer 4</i>	<i>Reviewer 5</i>
<i>Date:</i>	17/03/2021				
<i>Name:</i>					
<i>Organisation:</i>	ANSFISA				
<i>Email:</i>					

Document History

<i>Version</i>	<i>Date</i>	<i>Comments</i>
0.1		
0.2		
0.3		

--	--	--

Conventions:

<i>Type of Comment</i>		<i>Reply by requestor</i>	
<i>G</i>	General	<i>R</i>	Rejected
<i>M</i>	Mistake	<i>A</i>	Accepted
<i>U</i>	Understanding	<i>D</i>	Discussion necessary
<i>P</i>	Proposal	<i>NWC</i>	Noted without need to change

Review Comments <if necessary add extra lines in the table>

<i>N°</i>	<i>Reference (e.g. Art, §)</i>	<i>Type</i>	<i>Reviewer</i>	<i>Reviewer's Comments, Questions, Proposals</i>	<i>Reply</i>	<i>Proposal for the correction or justification for the rejection</i>
1		G		<p>The CSM draft structure is very cumbersome. It is made up of annexes and technical document, but it is not clear the difference attributed to each of them containing obligations and not only explanatory methods. At the same time, it does not exhaustively define the legal effect of the results.</p> <p>The legal text does not clearly define the effects on supervision activities and on the issuing of safety certificates and authorizations, considering the links between supervision and assessment.</p> <p>The data and the information collected should provide an important overview for the safety authorities, especially in case of serious risk, which requires action by the authority itself.</p>	A	The CSM final version has been simplified and obligations are directly identifiable from the core articles.

N°	Reference (e.g. Art, §)	Type	Reviewer	Reviewer's Comments, Questions, Proposals	Reply	Proposal for the correction or justification for the rejection
				At the same time, it is important for the sector that the obligations for the operators are clear: the document settles who can report but not who must report		
2	Art. 4 (2) Annex II 4.1 Annex V 4.1	G		<p>Article 4(2) stated that <i>“each national safety authority, TDG competent authority and the Agency shall be entitled to request a review of reported data and information”</i>.</p> <p>The table reported in Annex II paragraph 4.1 about <i>“Validation date and time”</i> stated that <i>“At this stage the National supervisory authority is entitled to request a review of the self-estimation by the concerned railway operator, in accordance with the implementation of the CSM on Supervision and with Article 4.2 of this Regulation.”</i></p> <p>Annex V paragraph 4.1 stated <i>“Safety performance indicators of a single railway operator are corresponding to the self-estimations reported by the concerned railway operator, possibly after a request for review by a national supervisory authority, in accordance with Article 4(2)”</i>.</p> <p>The references above are to be coordinated in the formulation and detailed in the connected modalities and responsibilities.</p>	NWC	<p>National supervisory authority is the term that is consciously used considering that Member States have allocated supervision responsibilities to a wide range of types of organisations.</p> <p>Besides that we want to emphasize that the CSM ASLP does not change the roles and responsibilities of NSAs as established by other pieces of EU legislation, neither by introducing new nor by removing existing responsibilities.</p>

N°	Reference (e.g. Art, §)	Type	Reviewer	Reviewer's Comments, Questions, Proposals	Reply	Proposal for the correction or justification for the rejection
				<p>It must be clear that in this way an obligation of control by the NSA on the data and information is not emerging.</p> <p>It is necessary to define the “national supervisory authority”.</p>		
3	Art. 6	G		<p>The GoA (Group of Analyst) [art.6 / Annex VII] assumes a strategic role.</p> <p>The draft lacks the necessary application details, the definition of which is delegated to the GoA. In addition, to analyze the information and data collected through the ISS and the consequent management, the GoA is responsible for defining the "technical documents" as well as the ISS (Information Sharing System) manual. Article 5 of Regulation (EU) 2016/796 provides for the establishment of working groups only for fixed purposes as guidelines and recommendations based on a legal text in force. It is necessary to define more clearly in the legal text duties: functions, composition and responsibilities of GoA.</p> <p>The relationship between GoA and JNS needs to be clarified.</p>	A	<p>The CSM explains at the right level of detail the GoA roles and responsibilities. Some further clarifications have been introduced in the final draft concerning the implications of the GoA to the preparation of recommendations.</p> <p>This is in line with the Agency Regulation.</p> <p>In addition, detailed functioning of the GoA working party will be described in the Working Arrangements (terms of reference), and shall be approved by the Agency’s MB in accordance with the Agency Regulation.</p> <p>In the proposed Working Arrangements, the JNS is integrated as a sub-group of the GoA working party.</p>
4	Art.6 (3)	P		The participation of NSA representatives in the GOA should be made explicit.	NWC	It is a requirement for Working Parties already included in the Agency Regulation, and the GoA is established as a working party.
5	Art.3	G		To guarantee an effective and efficient coordination about data collection avoiding duplication or inconsistencies, it is advisable to	NWC	A CSM is establishing EU harmonised rules, as it is also required by the CSM ASLP mandate. The CSM proposal allows

N°	Reference (e.g. Art, §)	Type	Reviewer	Reviewer's Comments, Questions, Proposals	Reply	Proposal for the correction or justification for the rejection
				carry out more clarification on the consistency between the SL data collection and the national rules in force about timing and reporting of accidents and incidents.	D	the national systems to be used when they are existing. The further interactions with national rules may be discussed when developing the ISS business requirements and related guidelines.
6	Art.3 (e)	P		"Category A event" is defined as "any accident directly resulting in victims or damages". It is necessary to define the term "victim" or the definition to be taken as a reference.	A	It is proposed to use the following wording: 'fatality or injury or damage' In this case the word 'victim' does not need to be defined.
7	Annex III	P		A category A event can be caused by multiple causes and multiple indirect causes and therefore may have more than one related RCM. This requires keeping an explicit track of the connections detected for each event in the reporting. In the same way, it is important to define the main characteristics of the operational context in which the safety measures have been grafted. In fact, it is difficult to analyze the effectiveness of RCM without an adequate level of detail on the particularities that can distinguish the specific case. Even this information should also be reported in the reporting template of each event.	NWC	The current CSM proposal allows for a full description of RCM, including operational context, including the possibility to use free text description. The method for ROS allows for multiple cause reporting, and detail reporting also contains the possibility to use free text in order to supplement any information that is not codified by the harmonised reporting structure.
8	Annex (5.1.2.2)	I P		The use of AIS scale needs a review of the CSI related definitions of the Safety Directive to ensure consistency	NWC	AIS reporting is optional in the first phase, in complement of the fatalities and serious injuries as defined in the RSD. It has not impact on the CSIs reporting.

N°	Reference (e.g. Art, §)	Type	Reviewer	Reviewer's Comments, Questions, Proposals	Reply	Proposal for the correction or justification for the rejection
9	Annex General Part	I P		The transmission times of ROS and RCCM are not defined.	A	Clarified in the re-drafted Article 4
10	Annex III 3.3.1	P		The " <i>contributing factors</i> " referenced in the Annex III 3.3.1, must be defined in the draft. It is no present a definition in the regulation.	A	Clarification will be made with reference to the definition of 'contributing factors' provided by Article 2 of Regulation (EU) 2020/573.
11	Annex III Part B	P		In the context of the Common Safety Method a distinction is made between the ' <i>risk control measures</i> ' functions and performance and the " <i>management of the risk control measures</i> " established to set-up, operate and maintain the designed functions and the expected performance limits. The relevant definitions must be inserted in the text.	D	In the context of the CSM simplification, this explanatory part has been removed because these explanations are relevant for a guidance but do not specify the method, role or responsibilities. It is thus not needed anymore to introduce definitions for the management of RCM in the CSM ASLP. Further guidance can be provided outside of the CSM ASLP, taking also SMS requirements into account.
12	Art.3 (e) Art. 10 Art. 11	P		From articles 3, 10, 11 and Annex I Part A, the follow aspects arise: <ul style="list-style-type: none"> ▪ the definitions of "<i>serious consequences event</i>" and "<i>significant consequence event</i>" do not correspond to the definition of "<i>serious accident</i>" and "<i>significant accident</i>" in the Directive 2016/798 ▪ In the transitional phase, only category A events classified as "serious consequences events" are reported. It is necessary to use the definitions of the Directive 2016/798 in order to avoid mistakes during the collection of data for CSI due to the similarities with CSM ASLP data; it may be	NWC	This is correct. Serious and Significant accidents are smaller groups included in the bigger group of Cat A events. The Cat A event are actually using consistently the 'Accident' and the 'incident' definitions of the RSD. The collection of CSIs is not affected by the CSM ASLP. Further clarifications can be provided in a guide. Please see also answer to comment 6.

N°	Reference (e.g. Art, §)	Type	Reviewer	Reviewer's Comments, Questions, Proposals	Reply	Proposal for the correction or justification for the rejection
				appropriate to extend the application to the “significant accidents” as defined in the Safety Directive.	D	Future evolution of the RSD are possible to simplify the EU legislation concerning the monitoring and supervision of railway accident and incidents when the CSM ASLP will be implemented with a stable and effective regime.
13	Art.3 (e) Annex I- Part A	G		The collection data and information required for “category A events” as defined in the Annex I - Part A, includes accidents involving 'trespasser' as defined in Annex I of the Safety Directive. It could be more useful and effective for the analysis not to have the details of the single event but to request a report (related to a specific period) from the operators in which the phenomenon is analyzed.	NWC	Such reports should be developed collectively with the GoA to establish lessons. However the analysis of scenarios of accidents (ROS) will also allow operators to better understand the causes of accidents and try to improve their risk control measures
14		P		It is proposed to always use the term "event" and not to use "occurrence".	NWC	We consider that we use the terms ‘event’ and ‘occurrence’ in an understandable manner because it is in coherence with the definition which can be found in general dictionaries. The way we use these terms is also consistent with RSD definitions.
15	Art. 4 (1)- a)	P		It refers to “relevant volume of operations” but it isn’t defined. It would be more useful to simply refer to “operational volumes” as defined in Annex I	A	Redrafted as following: “Each railway operator shall report, at the latest 1 month after the end of each assessed period in accordance with Article 5, and in accordance with Appendix C – Part D, the ‘Volumes of Operation Performed’ during each period. And The dataset in Appendix C is specifically mentioning which volume of operation has to be reported.

N°	Reference (e.g. Art, §)	Type	Reviewer	Reviewer's Comments, Questions, Proposals	Reply	Proposal for the correction or justification for the rejection
16	Art.5 (2)	U		<p>Article 5 (2) stated that “Having received the above mentioned confirmation, the Agency shall provide each assessed railway operator with the following elements: (a) estimation of the achieved safety level applicable to each type of operation; (b) estimation of the achieved safety performance”.</p> <p>It is not clear because the estimation of the achieved safety performance is a self-estimation, and it is not assessed by the Agency by a definition.</p>	A	<p>Clarified as following:</p> <p>5.2. Having received the above mentioned confirmation, the Agency shall prepare the following elements for each assessed railway operator:</p> <p>(a) Estimation and assessment of the achieved safety level applicable to each type of operation, for each three months calendar period and each complete year; (b) Estimation and assessment of the achieved safety performance, on each complete year.</p>
17	Art. 5 “Assessment of Safety Level and Safety Performance”	G		<p>In the description of the assessment process, it would be appropriate to clarify the timing to guarantee an obligation for operators to reply.</p> <p>The process should also consider ways of linking the information deriving from IM and from RU and regarding the same event. This may require a validation process with contradictory between operators.</p> <p>If this activity were not included in the process, as it emerges from the experience, there could be significant discrepancies in the representation provided between IM and RU.</p>	<p>A</p> <p>NWC</p> <p>NWC</p>	<p>Article 5.1 clarified ‘the Agency shall ask in due time each concerned railway operator to confirm, within one month, the data and information to be considered valid for the reporting period’</p> <p>Sharing of information is enabled in accordance with Appendix D (former Annex VI). The NSA will have access to any occurrence information reported by the different parties.</p> <p>When contradicting, the NSA may ask for a review in accordance with Article 4.</p> <p>The CSM provides a process to control this issue.</p>

N°	Reference (e.g. Art, §)	Type	Reviewer	Reviewer's Comments, Questions, Proposals	Reply	Proposal for the correction or justification for the rejection
				This would imply that the data would not be usable in both cases or, anyway, in useful time.		
18	Art. 11	G		The actual entry into force of the CSM depends on the issuance of technical documents by the GoA and on the development and activation of the ISS. These aspects represent tools that complement the CSM in its operational level contents. Therefore, it is uncertain not only the plausible times of entry into force of the CSM but also to parts of its content.	A	The Article 11 has been redrafted to ensure that a phase is only applied when all the conditions are fulfilled to ensure its practicability. In particular the GoA has given a positive proposal and the ISS version enable the implementation.
19	Art. 11 (3)	P		It is not defined the “immediately available solution provided by the Agency” to be used during the period of implementation of the regulation.	NWC	In any case the operators and authorities will be informed in advance of the solution to be used. If necessary, the reporting could be done using Extranet. However, it is to be noted that in the first phase of implementation the required level of reporting is corresponding on average to less than one event per operator. The Agency is currently trying to find a good solution for the operators, the NSAs and the Agency.
20	Art. 11 (3)	M		In the article 11 (3) it is referred the article 11(10) that is not present in the draft.	A	Article 11 is redrafted and corrected.
21	Annex II (3.4) Appendix B (Article 5)	G		It isn't clearly defined the criteria used for SP. The comment related to the self-estimation in the table at the paragraph 3, stated that “ <i>In case no element of proof can be shared for a given situational aspect the minimum maturity score (1) will be allocated for the considered area</i> ”.	NWC	The criteria are those defined in the tables of appendix B to estimate the level of maturity. It is based on the provision of reference to elements of proof (or justified equivalent element) readily accessible on request by the Authorities. The CSM on SMS sets the minimum requirements to obtain a certificate/authorisation. Elements of proof are already

N°	Reference (e.g. Art, §)	Type	Reviewer	Reviewer's Comments, Questions, Proposals	Reply	Proposal for the correction or justification for the rejection
				<p>It is not possible to assume minimum maturity score with no effect on the operator as defined in the article 5 (1.1) Appendix B.</p> <p>According to "Management Maturity Model" ERA Guideline Maturity, level I means an "inadequate level" which brings the level of performance below the legal minimum that was required for the granting of a single safety certificate or a safety authorisation.</p>		<p>described in the guidance on SMS requirements and management maturity model.</p> <p>There exists a consistency with the MMM, the safety culture model as well as with already existing requirements from the regulatory framework.</p> <p>No elements of proof are established for level 1.</p> <p>It is the level allocated in case the railway operator is not able to provide the reference elements for demonstrating the achievement of level 2.</p>
22	Appendix B	G		<p>In most cases requirements elements of proof for maturity levels correspond to the minimum documentations required during the assessment process for single safety certification and safety authorisation (coping level). Very often, reference is made to the availability of management processes and not to the proofs of the effectiveness of the process itself to guarantee, beyond the coping level, a higher maturity level.</p> <p>It is also necessary that consistency between the Annex B and the MMM ERA Guidance is guaranteed.</p>	NWC	<p>Yes, there exists a consistency with the MMM, the safety culture model as well as with already existing requirements from the regulatory framework.</p>

<https://www.era.europa.eu/content/data-protection#meeting1>

I have read the Data Protection Notice and I accept the processing of my personal data accordingly.

I accept that the comments I have submitted can be published on the ERA website along with: my name my e-mail address