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## 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>	06/04/2021				
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### *Document History*

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

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*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	3 (b)	M	UNIFE	Safety level is not properly defined, only by a reference inside the document. It should be better defined a "frequency of occurrence..." or a standard definition should be used	NWC	The definition is resulting from the discussion and final agreement of the working party at its 8 <sup>th</sup> meeting, after long discussions.  A guidance may be developed by the Group of Analysts to avoid any confusion.
2	3(c)	MP	UNIFE	Safety Performance is a misnomer. It contradicts the normal usage in engineering. It should be "Risk Management Maturity" or similar.	NWC	See comment number 15.
3	§ 3 (f)-(g)	M	UNIFE	The definitions depend on the definition of cause, which is not given. See e. g. Pearl's "The Book of Why" for possible definitions, e. g. counterfactual definitions of causality. In any case state the definition of cause directly here.	NWC	The definition of 'cause' is already provided by the Directive (EU) 2016/798 with which the CSM proposal is consistent. It is not necessary to duplicate it in the CSM.  A guidance may be developed by the Group of Analysts to avoid any confusion.

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4	Annex I, §3	U	UNIFE	To be clarified the reason of the need of such information as "Reporter contact name, e-mail". This comment also applies to all other sections where these information are asked	NWC	It was explained at the Working party meetings that those information are necessary for ensuring the functioning of the data and information sharing process. It is to be considered for facilitating processing of datasets, including updates and potential corrections requiring a contact with the initial reporter.  To be noted that those information are covered by personal data protection rules defined in Annex VI, meaning this is used on the need to know basis.
5	Annex I, §3, 5	U	UNIFE	To be clarified for which occurrence is needed to apply a SR and for which a DR. Some details provided in Annex A part A, B and C, but not fully clear.	A	The reporting requests are all included in the re-drafted article 4, and not anymore in the annexes which have been restructured. This is in accordance with the comments reported by many other parties.
6	Annex I, §5.1.2.1, 5.1.2.2	P	UNIFE	It could be added the cause of the occurrence	NWC	The DR is supposed to be purely factual reporting of victims and damages as well as factual description of context.  The analysis of cause is covered by Simple reporting where the cause is immediately considered, and then updated at any time with more certain information, can be validate when investigation has taken place.
7	Annex I - Part A, B and C	U	UNIFE	To be clarified what is meant with "event type": for Annex 1 – Part A the event is an accident; for Annex 1 – Part B, C the event is a cause	NWC	The meaning of 'event type' is provided by definition 3(h) and supplemented in Appendix A.

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8	Annex I, 9	P	UNIFE	Risk control measure should be provided but a Risk assessment is not asked. It could be useful to introduce it	NWC	Risk assessment requirement is required at the planning stage, it is considering RCM already at this stage and reported in accordance with Safety Performance and CSM on SMS.  When an accident happen CSM on SMS requires already to investigate the cause and to review the risk assessment as far as needed.
9	Annex II, §3	U	UNIFE	To be clarified how to complete the Self-estimated level for the different areas. An example of possible evidence could be provided to support.	NWC	Guidance will be provided on the practical implementation of SP self-estimation.
10	A III 3.3	MP	UNIFE	For a particular event OR gates express only uncertainty or even wrong information. If the cause is uncertain it should not be reported at this time, but later. So OR gates should not be used, see also IEC 62740.  As an alternative only events connected by AND gates need to be reported and this would simplify reporting as only a list of A, B and C type events would need to be reported.	NWC	This topic has been discussed in detail during several working party meetings. We agree that it should as much as possible be avoided by operators to use the OR gate when reporting an occurrence scenario.  The proposal in Annex III is compatible with the standard as also confirmed by other WP members <i>“The use of AND, OR and UNDEVELOPED gates is known from standards and applications for occurrence scenario modelling”</i> .  In some cases (for instance when the reported occurrence scenario would serve as an input for a JNS procedure) it would be very useful if the operator could narrow down the potential causes and contributing events, by reporting making use of the OR gate. After conclusion of a thorough investigation (within or outside of the GoA) the reported scenario can then be updated in the ISS. This update would then be expected to remove the residual OR gates.

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11	A IV 5.2.2	M	UNIFE	<p>The given formula much too general and is not justified as the severity parameters are undefined, but it seems that such parameters should be used. It is not meaningful to take severity into account as it has the highest variance of all involved parameters. Uncertainty measures need to be added.</p> <p>In the discussions at WG level two proposals for statistical procedures have been proposed, that deliver almost the same results and can be shown to be optimal. For legal certainties these procedures shall be included in the text and the choice of the particular method shall be by the operator.</p>	NWC	The formula was chosen as it allows the two proposals to be further discussed and assessed within the framework of Subgroup C, while at the same time providing a level of certainty on the direction of the safety level assessment.
12	A V 2.4	M	UNIFE	<p>Statistical inference is almost meaningless for categorised data that are built on qualitative judgement. The number have no meaning! What is the statistical model for such inference? There has never been any evidence given in the WG or by ERA how such a model could be defined.</p> <p>This section must be deleted.</p>	NWC	<p>We want to contend this position and further elaborate on the possibilities and limitations of statistical inference on SP data in the framework of Subgroup C.</p> <p>For now we want to emphasize two points. Firstly, there are statistical methods to make inferences based on categorical data (e.g. ordinal logistic regression). Secondly, the qualitative data (SP estimation) is not merely a judgement, but can be validated through several checks and balances (e.g. provision of evidence, guidelines, and requests for review by a national supervisory authority).</p>

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13	A V 5.1	M	UNIFE	Also aggregation may be meaningless number jumbling as the numbers are only used as labels not as numerical values.  Delete the aggregation formulas etc.	NWC	We agree that the method for assessing an aggregate for categorical data shall be different than for interval/ratio data. Subgroup C shall take that fully into account.
14	General	G	UNIFE	The document is extremely difficult to follow in terms of the information that must be recorded. It would hugely benefit from a “road map” of what those providing the data should be doing – referencing the respective parts of the document.	A	The CSM is re-structured and some articles have been re-drafted (2, 4, 11) to ensure a straight forward understanding of the requirements applicable to operators and other entities.  This will be complemented by Guidance, as needed.
15	Annex II – General Part	P	UNIFE	Some aspects notably Annex III – General Part “COLLECTION OF DATA AND INFORMATION ON OCCURRENCE SCENARIOS AND RISK CONTROL MEASURES” are almost impossible to follow without further explanation and definitions of the terms used.	NWC	Guidance will be provided.  The method is based on long term and well known developments. Is it notably based on the following elements: ISO/IEC 15504 about process capability (especially module 15504-2); EN 50126 norm (V-cycle); CSM on Safety Management System – Directive (EU) 2016/798 CSM on Risk Evaluation and Assessment – Regulation (EU) 402/2013 CSM on Monitoring – Regulation (EU) 1078/2012

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16	General	P	UNIFE	There is very little reference to manufacturers. We believe that it would be useful to place requirements on those reporting data which relates to equipment/components supplied by third parties (eg manufacturers) to consult with them to ensure the accuracy of the data they include in the ISS.	NWC	<p>This is correct and it is because for the moment the mandate indicate that ECM are not in the scope, and in turn it would be illogical that manufacturers are given visible roles while ECM not.</p> <p>Both parties can anyway report on voluntary basis, on any occurrence, with any type of reporting, when they deem necessary to bring safety related information.</p>
17	General	G	UNIFE	The role of National Safety Authorities in them having access to data and the use they may make with it in terms of their Supervisory role should be clarified such that those responsible for including data in the ISS are not discouraged from doing so.	A	<p>The Article 4 has been improved and clearly indicate that authorities shall act in line with their role and competence.</p> <p>“Each national safety authority, TDG competent authority and the Agency shall be entitled, <b>in duly justified cases</b>, to request the reporting operators to perform a review of reported data and information, <b>provided that the requested operator and the concerned data and information falls within the competence of the requesting entity</b>”</p> <p>This topic is also already cover by Article7</p> <p>“<b>Within the limits of the sharing rules established</b> by the Appendix D, any registered entity shall be entitled to use the data and information from the Information Sharing System for which they have access rights <b>in order to fulfil the roles and responsibilities placed on them by the European Union legislation</b>”</p> <p><b>The competence of NSAs is unchanged by the CSM ASLP.</b></p>

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18	Whereas number (23)	U	UNIFE	Does this mean that the NSA cannot take enforcement action on the basis of information shared as a result of this regulation.	NWC	<p>It can take, what it is regulated here is that the information is used in way that allows persons to report in line with this Regulation.</p> <p>Staff should not be subject to any prejudice due to the mere fact that they have provided information on their own initiative in line with this Regulation. If there has been manifest, severe and serious disregard, causing foreseeable damage to a person or to property, or seriously compromising the level of safety, in this case action can be taken against them. Action is not supposed to be taken against them on the basis of the mere fact that they have reported information in line with this Regulation.</p>
19	ANNEX VI – GENERAL PART: Clause 3.1	U	UNIFE	How is this clause to be interpreted in the context of a national safety authority taking action in respect of its Supervision duties?	NWC	It does not interfere, what is the aim here is to allow persons who are aware of information that has not been reported to do so, without fearing persecution as long as this information has been shared within the framework set in this Regulation.

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20	ANNEX VI – PART A – Table in Clause 3.1, Row entitled “the authority(ies) from the EU MS where the targeted railway operator operates (NSA, NIB, TDG CA)”	U	UNIFE	This implies that the NSA can get all data generated by this regulation for each and every railway operator in their Member State. Is this correct? Will this not potentially deter those inputting data to the ISS if they think it may lead to regulatory action.	NWC	Yes this is correct.  NSAs have already this possibility with the CSM on Supervision.  However, the CSM introduce a certain level of harmonised treatment of information, which is not existing today, putting on them unbalanced level of requirements.
21	Article 4 Safety performance maturity levels	U	UNIFE	The definition of the maturity levels places requirements which go far beyond the recording of occurrences and data in relation to safety performance. Are these intended to impose additional requirements other than those required to obtain a safety Certificate for their operations?	NWC	The CSM ASLP does contains the requirements for issuing certificates, it is The CSM on SMS which sets the minimum requirements to obtain a certificate/authorisation. Elements of proof are already described in the guidance on SMS requirements. There exists a consistency with the Management Maturity Model, the safety culture model as well as with already existing requirements from the regulatory framework

*Note: This table could be changed according to the requestor's needs*

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