

Moving Europe towards a sustainable and safe railway system without frontiers.

OPINION - deliverable of SPD 2022 ERA/OPI/2022-12

OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for

the European Commission

regarding

detailed methods for the common safety methods for assessing the safety level and the safety performance of railway operators at national and Union level

Disclaimer:

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1. General Context

On 19 May 2021 the Agency addressed a Recommendation (ERA1219) to the Commission on the common safety methods for assessing the safety level and the safety performance of railway operators at national and Union level (CSM ASLP).

The Recommendation contained general principles on how the safety level (SL) and safety performance (SP) of operators should be estimated and assessed. No detailed methods were however included.

The Recommendation therefore contained a placeholder under Appendix C - Part C¹ for detailed methods for the assessments of operators, which were to be further developed.

By the end of 2021, the CSM ASLP Working Party launched a call for nominations for a subgroup that would develop the detailed assessment methods. This subgroup was named Group of Analysts / Subgroup C (hereinafter GoA Subgroup C) and brought together 14 topic experts. The proposal by GoA Subgroup C is provided as part of the report that accompanies this Opinion.

GoA Subgroup C developed the proposal with the detailed estimation and assessment methods over the course of several meetings:

- Meeting 1: 16 February 2022
- Meeting 2: 16 April 2022
- Meeting 3: 8 June 2022
- Meeting 4: 14 September 2022

In addition, there were six dedicated meetings on the safety level (SL) method, and three dedicated meetings on the safety performance (SP) method.

This document describes the legal background, the opinion of the Agency and provides the assessment methods in the annexes.

2. Legal Background

The Agency's 2022 Single Programming Document (SPD) prescribed that a technical Opinion on SL and SP assessments should be developed, complementing the Agency Recommendation ERA1219. The development process of the Opinion is described in section 1.

The intermediate proposal prepared by the GoA Subgroup C concerned an Annex to the draft CSM ASLP Regulation and was discussed with the GoA Plenary Working Party on 5 May 2022. The final proposal was endorsed by the GoA Plenary Working Party on 19 October 2022.

After a review of the endorsed proposal, the Agency decided to issue this Opinion in accordance with Article 10 (2) of Regulation (EU) 2016/796².

¹ The Appendix was subsequently renamed as Annex III in the draft CSM ASLP Delegated Regulation. This Opinion sticks to the numbering and semantics as used in the draft delegated regulation in order to facilitate the future integration. ² Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union

Agency for Railways and repealing Regulation (EC) No 881/2004, OJ L 138, 26.5.2016, p. 1.

3. Analysis

The Agency concludes that the proposal by GoA Subgroup C provides a solid foundation for the detailed methods of the SL and SP assessments and is in line with the assessment principles as set out in its Recommendation ERA1219 of 19 May 2021.

The Agency supports that introducing the SL and SP assessment methods (hereinafter assessment methods or methods), including the proposed detailed methods, will allow railway operators to gain detailed insights into how their safety levels evolve and how they perform compared with other railway operators. For many railway operators it will provide novel possibilities to take fact-based actions to improve safety, contributing to a safer European railway system. Likewise, National Safety Authorities (NSAs) will be empowered to monitor safety in a more efficient and thorough fashion.

In the next sections the Agency highlights the main benefits of the detailed methods for the SL and the SP assessments. Several observed limitations are discussed as well.

The Agency underlines that this Opinion shall act as input for an Agency Recommendation, upon which the European Commission can consider revising the annexes of a future CSM ASLP delegated Regulation currently under the adoption process. The time prior to the Recommendation shall be used to further investigate the identified limitations and optimise the methods where needed.

3.1. Opinion on the SL method

The SL method brings:

3.1.1. Clarity

A key benefit of the SL method is that it builds on Bayesian inference. This Bayesian approach allows to express changes in terms of probability rather than in terms of p-values, which can be better understood by a large audience that is not necessarily well-versed in statistics. An additional benefit is that the degree of the change can be determined. Understanding changes in safety levels in terms of magnitudes is invaluable input for safety analyses and speaks in favour of the chosen Bayesian approach.

The Agency thus concurs that the Bayesian approach is more straightforward and informative than the analysed alternatives.

3.1.2. Accuracy

Simulations confirmed that the SL methods have a high statistical power so that they are capable of correctly detecting changes in distributions. The two-stepped approach for the severity test was introduced to increase power even more.

3.1.3. Proven method

The method for the assessment of the frequency of events has been extensively tested and applied by NSA Switzerland (CH). That method received positive feedback and it is confirmed that a Bayesian approach increases the understanding and impact of SL assessments.

3.1.4. Limitations

While the method for the assessment of the frequency of events has been tested in practice by NSA CH, the method for the assessment of the severity of accidents has not. An evaluation should take place to reflect on the limitations and use of the severity assessments. The same applies to the Safety Level Scores. While the first simulations underline their added value, a future evaluation should critically reflect on its strengths and weaknesses.

It is acknowledged that the implementation of the methods is more complex than, for instance, the common safety method for assessment of achievement of safety targets (Commission Decision 2009/460/EC).

Therefore, the Agency proposes to develop and provide access to a 'ERA certified' digital script, the same as the one used by the Information Sharing System (ISS), written in a widely used programming language (e.g. R), to enable interested parties to perform the analyses. Sharing a script will increase the understanding of the method and allows interested parties to further develop methods and visualisations. Ultimately, this could lead to improvements to the CSM ASLP methods and ISS.

Another point of concern regarding the method's relative complexity concerns the computational requirements. It is estimated that up to 800 000 assessments need to be performed each 3-month period to complete the SL assessment in its current form. Some filters (e.g. no calculation if no events occur in both the assessed and reference period) can be applied to bring the number of assessments down. But even in that case a large number of assessments remain to be done. The ICT infrastructure should be able to cope with the corresponding computational needs. If not, the assessment scope may need to be adjusted, but without affecting the core approach of the proposed statistical method.

A final point concerns how the method deals with accidents that were not caused by the operator but by the unauthorised presence of a third-party. After multiple discussions, the Agency agreed that analyses excluding such events may have an analytical value. It was therefore decided that the ISS shall enable that the assessments can be repeated for each railway operator and event type excluding those events where the unauthorised presence of a third-party was the sole cause of the event.

3.2. Opinion on the SP method

The SP method brings:

3.2.1. Clarity

As anticipated by Recommendation ERA1219 of 19 May 2021, the possibility to perform advanced statistical analyses on the self-evaluation data for assessing Safety Performance is limited. However, the proposed twostep assessment respects the principles of the method while complying with well-founded methodological assumptions.

The Agency believes that the framework is straightforward to apply and informative. Moreover, as changes in maturity level need to occur in more than one area before an improvement or deterioration is noted, it is not overly sensitive to limited changes.

3.2.2. Analysis and evaluation

The Agency observes that the method enables various analyses. The results by area and general overview shall provide a clear picture of the safety performance of every single operator today and over the past years. It is also possible to identify deviant changes in performance. The three area results (lower, stable/average, higher) combined with the four areas, means that there are 81 (i.e. 3^4) possible patterns. By assessing pattern frequencies amongst all operators, outliers can be easily detected.

As such, the SP method provides additional tools for operators and NSAs to understand and monitor the performance of railway safety management and take evidence-based decisions for improvement.

3.2.3. Robustness

As illustrated by the examples in the accompanying report, the SP method can be applied regardless of the distribution of the maturity levels within a group, making it apt even for unlikely safety performance scores. The robustness of the method was a prerequisite for the Agency.

3.2.4. Limitations

The Agency shares the consideration of GoA Subgroup C that the direction of the change in maturity level is of greater relevance than the magnitude of change, as changes in maturity levels are unlikely to change with more than one level on a year-to-year basis. When more experience with the method is gained and sufficient

data becomes available, the GoA may want to evaluate whether the magnitude of the change should be considered in the SP assessment method. Subsequently, more statistically advanced methods may be considered.

3.3. Feedback

Beyond numerous interactions and feedback rounds within GoA Subgroup C, the proposals were presented to the CSM ASLP Plenary Working Party on 5 May 2022 and 19 October 2022. This Working Party reflected positively on the work delivered and endorsed the proposal.

The Opinion is moreover shared with the NSA Network, NIB and NRB for consultation.

3.4. Impact assessment

An impact note was drafted for this Opinion in addition to the initial full impact assessment done in 2021 accompanying the Recommendation ERA1219. No novel elements were introduced in the methods that would warrant an update of this assessment. The annexed impact note (Annex 4) clarifies these points.

4. The opinion

This opinion consists of the following annexes:

- Annex 1: Detailed methods for the assessments of operators.
- Annex 2: Minor consequential changes of the recommendation ERA REC1219 concerning the assessment of safety levels.
- Annex 3: Minor consequential changes of the recommendation ERA REC1219 concerning the assessment of safety performance.

The Agency is of the opinion that the annexes provide sound detailed methods for the common safety methods for assessing the safety level and the safety performance of railway operators at national and Union level.

The Agency considers that the publication of this Opinion provides clarity to the railway sector and national authorities on the likely content of the future detailed methods of the CSM ASLP. Moreover, the annexes can be used and tested by the interested parties as a reference for the future CSM ASLP implementation.

To facilitate the testing of the methods the Agency can provide a script that implements the assessment methods. Depending on the future ICT structure/specification of the Information Sharing System, this script will be made available through the ISS or independently from it.

The detailed methods may be adapted, if needed and justified, before their introduction by means of an Agency recommendation to be addressed to the European Commission, with the aim to introduce them as binding methods of the CSM ASLP Delegated Regulation.

Valenciennes, 16/01/2023

Josef DOPPELBAUER Executive Director

ANNEX 1 - Detailed methods for the assessments of operators

Annex III – PART C

DETAILED METHODS FOR THE ASSESSMENTS OF OPERATORS

PART C1 - DETAILED METHODS FOR THE SAFETY LEVEL ASSESSMENT OF OPERATORS

1. Methodology for the safety level (SL) assessment of operators

1.1 Scope

The safety level assessment consists of an assessment on the frequency of events and an assessment on the severity of accidents.

For each railway operator the assessment on the frequency of events, as detailed in section 1.2, shall be applied to each Category A and Category B event type.

For each railway operator the assessment on the severity of accidents, as detailed in section 1.3, shall be applied to each Category A event type.

A separate assessment shall be performed for each type of operation, as defined by Annex IV – Part C, on which the railway operator reported.

For each three-month calendar period and each completed year an assessment of the achieved safety level shall be performed. The assessed period is the latest available one-year period.

The reference period for the SL assessment in accordance with Annex III Part A 2.3.(a) is the three-year period prior to the assessed period.

The reference period for the SL assessment in accordance with Annex III Part A 2.3.(b) is the same as the assessed period. The operational volumes for the reference period are derived from all operators that perform the type of operation under assessment.

1.2 Assessment on the frequency of events

The assessment on the frequency of events is performed using Bayesian inference.

1.2.1 Safety level estimation

The total number of events is denoted as n_a for the assessed period and n_r for the reference period.

The shape parameter values are set as $\alpha = 1$, $\beta = -(\log_2(1 - \eta))^{-1}$, where the exposure η is determined by formula

$$\eta = \frac{\text{operational volumes in the assessed period}}{\text{operational volumes in the assessed and reference periods}}$$
(1)

The prior f(p) is set by a gamma distribution

$$f(p) = \frac{\Gamma(\alpha + \beta)}{\Gamma(\alpha)\Gamma(\beta)} p^{\alpha - 1} (1 - p)^{\beta - 1}$$
⁽²⁾

The posterior probability density function is

$$f(p|n_a, n_r) = \frac{P(n_a, n_r|p)f(p)}{Z}$$
(3)

With likelihood function

$$P(n_a, n_r | p) = \binom{n_a + n_r}{n_a} p^{n_a} (1 - p)^{n_r}$$
(4)

And normalizing constant

$$Z = \int_{0}^{1} P(n_a, n_r | p) f(p) \, dp$$
(5)

The posterior probability density function is used to calculate the following probability

$$P(p > \eta | n_a, n_r) = \int_{\eta}^{1} f(p | n_a, n_r) \, dp$$
(6)

Finally, the degree of the change, called the minimal change of frequency (MCF), can be determined by the formula

$$P(p > k\eta | n_a, n_r) = \int_{k\eta}^{1} f(p | n_a, n_r) \, dp$$
(7)

which is valid for any factor $k \in (0, 1/\eta)$.

1.2.2 Safety level assessment

The estimation shall be assessed using the following probabilities and associated assessments.

SL Class	Probabilities	SL assessment in accordance with Annex III Part A 2.3.(a)	SL assessment in accordance with Annex III Part A 2.3.(b)
1	90% - 100%	Strong evidence for deterioration	Strong evidence for a lower level
2	75% - 90%	Moderate evidence for deterioration	Moderate evidence for a lower level
3	25% - 75%	No evidence for improvement or deterioration	No evidence for a lower or higher level
4	10% - 25%	Moderate evidence for improvement	Moderate evidence for a higher level
5	0% - 10%	Strong evidence for improvement	Strong evidence for a higher level

The MCF shall be provided for each assessment where an improvement or deterioration is noted. In case there is strong evidence for an SL class, the MCF shall also be given for the moderate evidence SL classes.

1.3 Assessment on the severity of accidents

The estimation on the severity of accidents is performed in two steps.

First, for each railway operator a DTS test shall be performed to determine whether there is a significant difference between the severity of the accidents in the reference and assessed period.

Second, for those cases where a significant difference was detected, a Bayesian test shall be applied to classify the direction and degree of the change.

1.3.1 Safety level estimation

The severity distributions are denoted as F_a for the assessed period, F_r for the reference period, and F_c for the combined distribution of F_a and F_r . The symbol 'n' stands for the total number of events for F_c .

Step 1

For each event type a DTS test shall be performed on the count of fatalities and weighted serious injuries (FWSI).

$$DTS = \int_{x \in R} \left(\frac{|F_a(x) - F_r(x)|}{\sqrt{2F_c(x)(1 - F_c(x))/n}} \right)^p$$
(8)

The next step shall be taken if the p-value of the DTS test is lower than 0.05. If not, no further test shall be performed, and it is concluded that no evidence is found for a change in severity of accidents for the assessed event type (i.e. SL class 3).

Step 2

A Bayesian version of the two-sample Wilcoxon signed-rank test for paired data shall be conducted.

First, the combined dataset from the assessed and reference periods shall be sorted and assigned ranks R_1 , ..., R_n . Then, transform the ranks to quantiles (inverse-normal rank transformation) as

$$1 \to \Phi^{-1}\left(\frac{1}{2n}\right), 2 \to \Phi^{-1}\left(\frac{3}{2n}\right), \dots, n \to \Phi^{-1}\left(\frac{2n-1}{2n}\right)$$
 (9)

The prior is set by

$$\mu_{a}, \mu_{r} \sim Uniform(\mu_{min}, \mu_{max})$$

$$\sigma_{a}, \sigma_{r} \sim Uniform(0, \sigma_{max})$$

where the hyperparameters are defined as

$$\mu_{min} = \frac{1}{2} \left(\Phi^{-1} \left(\frac{1}{2n} \right) + \Phi^{-1} \left(\frac{3}{2n} \right) \right)$$
(10)

 $\mu_{max} = -\mu_{min}$

$$\sigma_{max}(n) = -\Phi^{-1}\left(\frac{1}{2n}\right) \tag{11}$$

The posterior probability density function is proportional to the likelihood and the prior

$$f(\mu_a, \mu_r, \sigma_a, \sigma_r \mid n_a, n_r) \propto P(n_a \mid \mu_a, \sigma_a) P(n_r \mid \mu_r, \sigma_r) f(\mu_a) f(\mu_r) f(\sigma_a) f(\sigma_r)$$
(12)

where n_a and n_r stand for the inverse-normal rank transformed data from assessed and reference periods, respectively.

Gibbs sampling is used to sample from the posterior distribution and make inference about parameters μ_a , μ_r , σ_a , σ_r as follows:

- 1. Set initial values $\mu_a = 0$, $\mu_r = 0$, $\sigma_a = 1$, $\sigma_r = 1$. Set k = 1.
- 2. Let $j = k \mod 4$. To obtain the next sample, update the *j*-th parameter while keeping the others unchanged. Randomly draw the parameter from either $Uniform(\mu_{min}, \mu_{max})$ in the case of μ_a, μ_r , or $Uniform(0, \sigma_{max})$ in the case of σ_a, σ_r .

3. Set
$$k = k + 1$$
.

4. Repeat steps 2 and 3 until sufficient samples were drawn.

Subsequently, the probability of interest is calculated by

$$P(\mu_a > \mu_r | n_a, n_r) = \int_{\mu_a > \mu_r} f(\mu_a, \mu_r, \sigma_a, \sigma_r | n_a, n_r) \,\mathrm{d}\theta \tag{13}$$

where θ is a shortcut for all the four parameters $\mu_a, \mu_r, \sigma_a, \sigma_r$.

Finally, the extent of a shift in the medians, called the minimal change of severity (MCS), can be evaluated through the probability

$$P(\mu_a > \mu_r^{shift} \mid n_a, n_r^{shift}) = \int_{\mu_a > \mu_r^{shift}} f(\mu_a, \mu_r^{shift}, \sigma_a, \sigma_r^{shift} \mid n_a, n_r^{shift}) d\theta$$
(14)

where the superscript *shift* means *after shifting the original data*. The above probability can be calculated for any value of the *shift* ranging from -max{FWSI in the reference period} to max{FWSI in the assessed period}.

1.3.2 Safety level assessment

The table under section 1.2.2 shall also be used to assess the estimation under section 1.3.1.

2. Safety level score

For each event type a safety level score shall be determined to support the identification of safety-related improvement needs and opportunities. The safety level score equally facilitates the comparison of safety levels between railway operators and countries.

A safety level score shall be determined for the SL assessment in accordance with Annex III Part A 2.3.(a), separately for Category A and Category B event types, and for the SL assessment in accordance with Annex III Part A 2.3.(b), only for Category A event types. In case a railway operator performs multiple types of operations, as defined by Annex IV Part C, safety level scores shall be determined per type of operation.

The safety level score for the assessment on the frequency of events is performed as

$$SLS \ F_{SL \ class} = MCF_{SL \ class} \times \frac{N_{RP}}{V_{RP}} \times S$$

The safety level score for the assessment on the severity of accidents is performed as

$$SLS \ S_{SL \ class} = MCS_{SL \ class} \times \frac{N_{RP}}{V_{RP}} \times S$$

With

$MCF_{SLclass}$	-	Minimal Change of Frequency for a given credibility level CL [%] derived from
		the assessment on the frequency of events
MCS _{SL class}	-	Minimal Change of Severity for a given credibility level CL [%] derived from the
		assessment on the severity of accidents
N _{RP}	-	Number of events in Reference Period
V _{RP}	-	Volume of transport of the railway operator in the Reference Period
S	_	Severity factor derived from mean severity (in FWSI) per event in the
		reference period, considering all reported events in ISS.

The safety level score shall be determined for the SL classes 1, 2, 4, and 5 as defined in section 1.2.2. This results in an overview of safety level scores for each event and sub event type.

Subsequently, the safety level score per event type is determined by selecting the score that is highest, either a) the safety level score of the event type or b) the sum of the safety level score of all related subevents.

The SL score for the railway operator is set as the highest value after the following calculations:

- the sum of the SL scores for all event types for fatalities (ESF) and severity (ESS) per SL class.
- The overall SL score for the operator for fatalities (ESF) and severity (ESS) per SL class (i.e. without calculating SL scores per event type). In this situation, S is set as the mean severity of all accidents in the reference period.

3. Assessment of safety level at national and Union levels

The methodology for the safety level assessment of railway operators as outlined in section 1 shall also be applied to each country. The differences are as follows:

The word railway operator shall be understood as 'country'.

- For each country, the assessments shall be performed separately for each type of operation as defined by Annex IV Part C.

The methodology for the safety level assessment of railway operators as outlined in section 1 shall also be applied to the European Union. The differences are as follows:

- The word railway operator shall be understood as 'European Union'.
- SL assessments in accordance with Annex III Part A 2.3.(b) shall not be performed.
- the SL assessments shall be performed separately for each type of operation as defined by Annex IV Part C.

Based on the assessments, the safety level scores at national and Union levels shall be determined.

4. Information on the implementation of the safety level assessments

A script that implements the assessments under section 1 shall be made publicly available by the Agency.

The ISS shall enable that the assessments under sections 1.2 and 1.3 can be repeated for each railway operator and event type excluding those events where the unauthorised presence of a third-party was the sole cause of the event.

PART C2 - DETAILED METHODS FOR THE SAFETY PERFORMANCE ASSESSMENT OF OPERATORS

1. Methodology for the safety performance assessment of operators

1.1. Assessments

The safety performance assessment of a railway operator consists of an assessment for each of the four areas established by Annex II – Part C, followed by the assessment of the combined results for all four areas. This two-stepped assessment applies to each of the three objectives specified by Annex III – Part B.

1.2. Methodology for assessing the levels by area

The method for assessing the areas under each objective is specified in the table below. The result is that the area safety performance is either lower, stable/average, or higher.

	Objective assessed			
Area result	a)	b)	c)	
	Maturity level in assessed	50% of operators in the	Maturity level in assessed	
	period	group have a higher	period	
Lower	<	maturity level in than the	<	
	maturity level in reference	operator in the assessed	maturity level mode in	
	period	period	reference period	
	Maturity level in assessed		Maturity level in assessed	
	period	The result of the	period	
Stable/Average	=	assessment is	=	
	maturity level in reference	neither lower nor higher	maturity level mode in	
	period		reference period	
	Maturity level in assessed	50% of operators in the	Maturity level in assessed	
	period	group have a lower	period	
Higher	>	maturity level than the	>	
	maturity level in reference	operator in the assessed	maturity level mode in	
	period	period	reference period	

The following additional rules apply:

- For objective b):

A railway operator belongs to each group as defined by Appendix D - Part B for which the railway operator indicates that operations were performed in the assessed period. The assessment shall be applied separately for each group to which the railway operator belongs.

For objective c):

If there is no single maturity level mode in the reference period, the mode will be determined by including the maturity level in the assessed period. If there is still no mode, the highest most frequently reported maturity level will be selected.

1.3. Methodology for assessing the overall results

The overall safety performance assessment shall be performed using the combined results for the four areas, as assessed per objective according to section 2.3.

The table below prescribes how the assessment category, as specified under Annex III - Part B 3.2, is determined by establishing the number of times a certain result has been obtained.

Area recult	Number of areas in which the result was obtained			
Area result	1 area	2 areas	3 areas	4 areas
Lower	Class 3	Class 2	Class 1	Class 1
Stable/Average	Class 3	Class 3	Class 3	Class 3
Higher	Class 3	Class 4	Class 5	Class 5

The following additional rules apply to come to a final safety performance assessment:

- If Class 1, 2, 4, or 5 is noted, the safety performance assessment will never be Class 3.
- If Class 2 and Class 4 are both noted, the safety performance assessment shall be both classes.

2. Aggregation of Operators' safety performance at national and Union levels

All railway operators that reported on operations in a country shall be included in the aggregation at national levels.

The aggregation shall be performed for three groups as shown in the table below based on the entity codes as defined by Appendix D - Part B. There shall be a weighted and unweighted assessment for each of the three groups. The respective weighting factors are shown in the table below.

Aggregation group	Entity codes included	Weighting factor (Volume)	
IM	IM-1	Number of train-kilometres	
RU	RU-1, RU-2, RU-3, RU-4	Number of train-kilometres	
Terminal operator	IM-2, RU-5	Number of railway vehicles processed in terminals	

The results of the aggregation are a weighted and unweighted overview per group showing the proportion of railway operators with a certain maturity level, split by area.

The following formula shall be applied to determine the unweighted proportion of railway operators with maturity level 'i' of the total number of operators 'n' per country:

$$Share_i = \frac{\sum Operators_i}{\sum Operators_n}$$

The following formula shall be applied to determine the weighted proportion of railway operators with maturity level 'i' of the group total 'n' per country. It does so by taking the sum of the volumes of all railway operators with maturity level 'i', divided by the sum of the weighting factor for all railway operators within the group:

$$Share_i = \frac{\sum Volume_i}{\sum Volume_n}$$

The same method shall be applied to determine the values on the Union level.

ANNEX 2 – Minor consequential changes of the recommendation ERA REC1219 concerning the assessment of safety levels

Annex III – PART A

ASSESSMENT OF SAFETY LEVELS

Text in ERA REC1219

- 3. Applicable reference values and periods of time
- 3.2. Safety level assessment results

For each assessed objective and assessment period referred to in section 3.1 the Agency shall use the detailed process and criteria described in Appendix C – Part C and shall determine which of the following possible situations is applicable to the operator:

- (a) Strong evidence for deterioration
- (b) Moderate evidence for deterioration
- (c) No evidence for improvement or deterioration
- (d) Moderate evidence for improvement
- (e) Strong evidence for improvement

Each assessment shall be accompanied by the consideration of statistical uncertainties in accordance with section 6.

Text proposed by this Opinion

- 3. Applicable reference values and periods of time
- 3.2. Safety level assessment results

For each assessed objective and assessment period referred to in section 3.1 the Agency shall use the detailed process and criteria described in Appendix C - Part C and shall determine which of the following possible situations is applicable to the operator:

SL	SL assessment in accordance with 2.2.a)	SL assessment in accordance with 2.3	
class	SE assessment in accordance with 2.5 a)	b)	
1	Strong evidence for deterioration	Strong evidence for a lower level	
2	Moderate evidence for deterioration	Moderate evidence for a lower level	
3	No evidence for improvement or	No evidence for a lower or higher level	
	deterioration		
4	Moderate evidence for improvement	Moderate evidence for a higher level	
5	Strong evidence for improvement	Strong evidence for a higher level	

Each assessment shall be accompanied by the consideration of statistical uncertainties in accordance with section 6.

Text in ERA REC1219

- 5. Generic formula applied for individual railway operator's safety level estimation
- 5.1. Allocation of occurrences to involved railway operators
- 5.1.2. The following methods apply to the allocation of the counting of an occurrence to the category of railway operators responsible for the prevention or mitigation of the deemed cause of the accident occurrence.
- 5.1.3. The following counting rules apply:
 - (a) In case only one deemed cause Cat. B event type is identified. In this case the counting of the occurrence for the safety level estimation is allocated to the railway operator involved in the occurrence that is responsible for the part of the system which is deemed to have caused the occurrence.
 - (b) In case several combined causes several Cat. B event types are identified. In this case the counting of the occurrence for the safety level estimation is allocated in the applicable proportion(s) to the railway operator(s) involved in the occurrence that are responsible for the part(s) of the system which are deemed to have caused the occurrence.
 - (c) In case the cause(s) Cat. B event type(s) are not identified or there is a disagreement between the involved operators. In this case the counting of the occurrence for the safety level estimation is equally shared between the involved railway operator(s).

Text proposed by this Opinion

- 5. Generic formula applied for individual railway operator's safety level estimation
- 5.1. Allocation of occurrences to involved railway operators
- 5.1.2. (sic) The following methods apply to the allocation of an occurrence to the category of railway operators responsible for the prevention or mitigation of the deemed cause of the accident occurrence:
 - (a) where only one deemed cause (one category B event) of an occurrence is identified, the occurrence is allocated for the purpose of the safety level estimation to the railway operator involved in the occurrence that is responsible for the part of the system which is deemed to have caused the occurrence.
 - (b) where several combined causes (several category B events) of an occurrence are identified, the occurrence is allocated for the purpose of the safety level estimation once to each railway operator involved in a cause.
 - (c) where the causes (category B events) are not identified or there is a disagreement between the involved operators, the occurrence is allocated for the purpose of the safety level estimation to all involved railway operators.

ANNEX 3 - Minor consequential changes of the recommendation ERA REC1219 concerning the *assessment of safety performance*

Annex III – PART B

ASSESSMENT OF SAFETY PERFORMANCE

Text in ERA REC1219

3. Applicable reference values and periods of time

- 3.2. For each assessed objective and assessment period referred to in section 3.1 the Agency shall determine the situation applicable to the assessed operator by implementing the detailed method of Appendix C Part C, allowing the following categorisation:
 - (a) Probable performance deterioration
 - (b) Potential performance deterioration
 - (c) Stable performance
 - (d) Potential performance improvement
 - (e) Probable performance improvement

Text proposed by this Opinion

3. Applicable reference values and periods of time

3.2. For each assessed objective and assessment period referred to in section 3.1 the Agency shall determine the situation applicable to the assessed operator by implementing the detailed method of Annex III - Part C, allowing the following categorisation:

SP class	SP assessment in accordance with 3.1 a) and c)	SP assessment in accordance with 3.1 b)
1	Strong evidence for deterioration	Strong evidence for lower performance
2	Moderate evidence for deterioration	Moderate evidence for lower performance
3	No evidence for improvement or deterioration	No evidence for lower or higher performance
4	Moderate evidence for improvement	Moderate evidence for higher performance
5	Strong evidence for improvement	Strong evidence for higher performance

ANNEX 4 – Draft Impact Note to the Group of Analysts proposal

1. Introduction

Further to the Agency recommendation on the Common Safety Methods for assessing the safety level and the safety performance of railway operators at national and Union level (CSM ASLP), the Agency and sector experts continue developing the annexes of the CSM ASLP.

One of these annexes, Annex III – Part C, concerns the detailed methods for the assessment of operators. The sub-group experts develop this appendix with the primary aims to:

For safety level assessments:

- Assess the extent to which a railway operator is reducing safety risks to fulfil the requirement of maintaining and continuously improving railway safety and
- to identify railway operators with significantly higher or lower risks with the aim to support the definition of possible action plans, where needed.

For safety performance assessments:

- Assess, based on the self-estimations provided by each railway operator, the extent in which a railway operator fulfils the requirement of maintaining and continuously improve railways safety in the domain of risk control measures.

Statistical inference and tests shall be used to provide harmonised assessments to each railway operator.

The task was to create methods that comply with these principles while ensuring that the results are understandable, insightful, and are obtained in a computationally efficient manner.

Here it is important to note that the full impact assessment of the CSM ASLP Recommendation already considered the detailed assessment methods. The main question for this Opinion's impact assessment is therefore whether the impacts on the delegated regulation that would follow from the Agency Opinion have been sufficiently considered by the full impact assessment for agency recommendation ERA1219 (hereafter 'CSM ASLP IA').

2. CSM ASLP IA

The CSM ASLP IA considered the following elements to determine the costs and benefits of the detailed methods:

- Contribution to GoA activities
- Contribution to monitoring, auditing, supervision
- Contribution to operator action plans
- Costs of monitoring and managing the tests within ISS

The annual costs of the SL assessment and SP assessment would be 50 000 EUR in total.

3. Opinion text

The Agency does not expect that the proposed methods lead to an increase in costs beyond what was anticipated by the CSM ASLP IA. Nor is it expected that there are other benefits vis-à-vis what was assumed in the IA. The rather limited costs do imply a high level of automation in the ISS.

4. Conclusion

The Opinion does not introduce any novel requirements nor causes impacts that were not already assessed in the CSM ASLP IA. As such, the CSM ASLP IA remains leading when discussing the anticipated impacts of the SL and SP assessment methods.