EUROPEAN UNION AGENCY FOR RAILWAYS

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

Preparatory steps towards a CSM Review

Vision document

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Document History

Version	*Date*	*Comments*
0.1 – 0.5 draft	01/03/2024	Preparation of document structure and overarching principles
0.6 draft	15/03/2024	Contributions provided by Agency domain experts to chapter “Expanded quick scan”
0.7 draft	10/04/2024	Integration of improvements to contribute to general coherence of the document
0.8 draft	19/04/2024	Version shared with delegation of NRB/NSA representatives that participated in the workshop organised by the Agency
0.9 draft	15/12/2024	Restructured version of the document, taking into account the comments received from the NSA’s and RB’s participating in the workshops organised by the Agency
0.94 draft	27/01/2025	Restructured version of the document, taking into account the ‘red flag comments’ received from the NSA’s and RB’s participating in the workshop on Jan 20th 2025, organised by the Agency
1.0	06/02/2025	Final version to be presented to the RISC committee

Contents

1 Introduction

The development of this vision document arises from the need to review and enhance the Common Safety Methods (CSMs) in light of evolving challenges, stakeholder feedback, and emerging opportunities within the railway sector. Over the years, the application of the legislative framework, particularly through the tasks introduced under the 4th Railway Package—such as Single Safety Certificate (SSC) assessments and National Safety Authority (NSA) monitoring—has highlighted areas where the current CSMs could benefit from clarification, simplification, or further development. These practical experiences have provided valuable insights into how the CSMs function within real-world Safety Management Systems and supervision activities, identifying opportunities for refinement and improvement.

The Agency considers it necessary to obtain a new mandate to review the following Common Safety Methods:

- Common Safety Method for risk evaluation and assessment.
- Common Safety Method for monitoring.
- Common Safety Methods on safety management system requirements.
- Common Safety Methods on supervision.
- Common Safety Method on common safety targets.

The forthcoming CSM on Assessing Safety Level and Performance (ASLP) will introduce new mechanisms and instruments for assessing safety performance, including the use of an IT tool (ISS – Information Sharing System) to support operators in reporting occurrences. This tool will enable operators to feed relevant information into their Safety Management Systems and facilitate learning from occurrences. The CSM ASLP will also provide a taxonomy for event types and a harmonized approach to documenting occurrence scenarios, which can be leveraged by operators when applying other CSMs. Furthermore, the CSM ASLP will establish interfaces with other CSMs by addressing how alerts and data generated by the system should be managed and integrated into broader safety practices. These developments highlight the need to ensure the existing CSMs are adapted to reflect these interactions and maintain a consistent, coherent framework.

The legal basis for this review is rooted in the Railway Safety Directive. Article 6.5 mandates that the CSMs be revised at regular intervals, incorporating the experience gained from their application and global developments in railway safety. The aim is to achieve continual safety improvement, where reasonably practicable. Additionally, Article 6.1 highlights the need for harmonised methods across SMS processes at Union level, further reinforcing the importance of this exercise.

The development of this vision document followed a structured and collaborative working method, ensuring a comprehensive and well-aligned approach to the review of the Common Safety Methods. The process began with a quick scan, during which the Agency systematically identified existing reports and accumulated issues related to the implementation of the CSMs. This step involved the creation of a detailed table highlighting the main issues for each CSM, providing a solid foundation for the document's structure and content.

Building on this groundwork, the Agency engaged domain experts from within its organisation to identify specific areas prone to improvement for each CSM included in the review's scope. Recognising the broader context of safety management, additional expertise was incorporated for topics such as competence management—highlighting the added value of a dedicated CSM in this area—TSI-OPE (owing to its critical interface with CSMs), human and organisational factors, and safety culture. This expanded scope exercise facilitated a more holistic analysis and the drafting of detailed text for the vision document, outlining areas for improvement for each topic.

The first draft of the vision document was then subjected to extensive stakeholder consultation to align its proposals with the expectations and needs of the sector. This involved multiple workshops with National Safety Authorities and the Network of Representative Bodies, applying a risk-based approach to discuss key topics and ensure the document's relevance and applicability. These discussions incorporated valuable feedback, further refining the document.

When diverging views were identified during these consultations, the document includes clarification boxes to highlight differing stakeholder perspectives, ensuring transparency and providing a balanced account of the discussions.

The Agency organised four dedicated workshops to discuss and refine the vision document:

- April 16th, 2024: Initial presentation of key topics and framework.
- June 12th, 2024: Review and alignment of preliminary proposals.
- October 17th, 2024: In-depth exploration of risk-based approaches and detailed discussions on sector feedback.
- January 20th, 2025: Final workshop to consolidate the vision document and address any residual questions.

These workshops generated extensive stakeholder feedback, resulting in over 300 individual comments being reviewed and processed by the Agency. This rigorous process highlights the significant workload undertaken to ensure all perspectives were adequately captured and addressed. To support this effort, the Agency maintained a detailed Excel log of all comments, which will serve as a key reference for subsequent stages of the project. This systematic approach ensures transparency and traceability, further reinforcing the collaborative nature of the document's development.

The objective is to finalise the vision document by the end of January 2025, ensuring readiness for presentation at the February 2025 RISC (Railway Interoperability and Safety Committee) meeting. The document will serve as a key input for the European Commission as it prepares the mandate that will enable the Agency to develop an official recommendation for the review of the CSMs included in scope. This methodical process not only ensures a robust foundation for the review but also demonstrates the Agency's commitment to a transparent and collaborative approach, addressing the evolving needs of the railway sector.

2 Overarching Vision

2.1 Introduction

To ensure the successful review and enhancement of the Common Safety Methods, the Agency has proposed an overarching vision outlining the guiding principles for this project. This vision is rooted in extensive input from stakeholders across the railway sector, reflecting a collective understanding of the challenges, opportunities, and objectives ahead.

The overarching vision serves as a unifying framework, establishing clarity and alignment for all participants in the review process. It provides a strategic foundation that informs subsequent discussions, ensuring that the identified problem areas and proposed (future) solutions remain consistent with the sector's shared goals and commitments. Articulating this vision at the outset facilitates a cohesive and focused approach to the CSM review.

This vision establishes a unified understanding of the objectives and desired outcomes for the entire future project. Articulating the overarching vision at the outset ensures that all stakeholders, including railway operators, infrastructure managers, national safety authorities, and other entities, are guided by a shared framework throughout their engagement with the review process.

Defining this vision before identifying problem areas (See Annex §6 for description of areas prone to improvement) is crucial for several reasons. It provides clarity on what the project aims to achieve, setting a strategic direction aligned with the sector's commitment to safety, risk-based approaches, and continual improvement. Furthermore, it ensures that subsequent chapters, particularly those focusing on identifying problem areas, are informed by a structured understanding of the end goals, thereby avoiding fragmented or inconsistent conclusions.

This step-by-step approach ensures that the review process remains focused and cohesive, allowing proposed improvements to align with the foundational principles and overarching goals of the Common Safety Methods. This approach creates a robust framework for advancing safety management across the railway sector, driving innovation while maintaining alignment not only with the principles established in the CSMs but also with the broader legal framework set out in the Railway Safety Directive, including the allocation of responsibilities between different actors.

This methodology emphasises that improvements to the legal framework are not an end in themselves but a means to effectively and sustainably support the sector's safety objectives. Starting with a vision establishes a meaningful foundation for a review process that fosters alignment, consistency, and progress.

2.2 Vision

To further clarify and reinforce the overarching vision, the following figure provides a visual representation of the key guiding principles underpinning the review process. This figure serves as a roadmap, capturing the fundamental concepts shaping the project's direction and ensuring alignment with the sector's long-term safety objectives.

By summarising these principles visually, the figure offers stakeholders a clear and concise overview of the core elements driving the review. It illustrates how these principles interconnect to support a cohesive and strategic approach, bridging the gap between the current framework and the envisioned improvements.

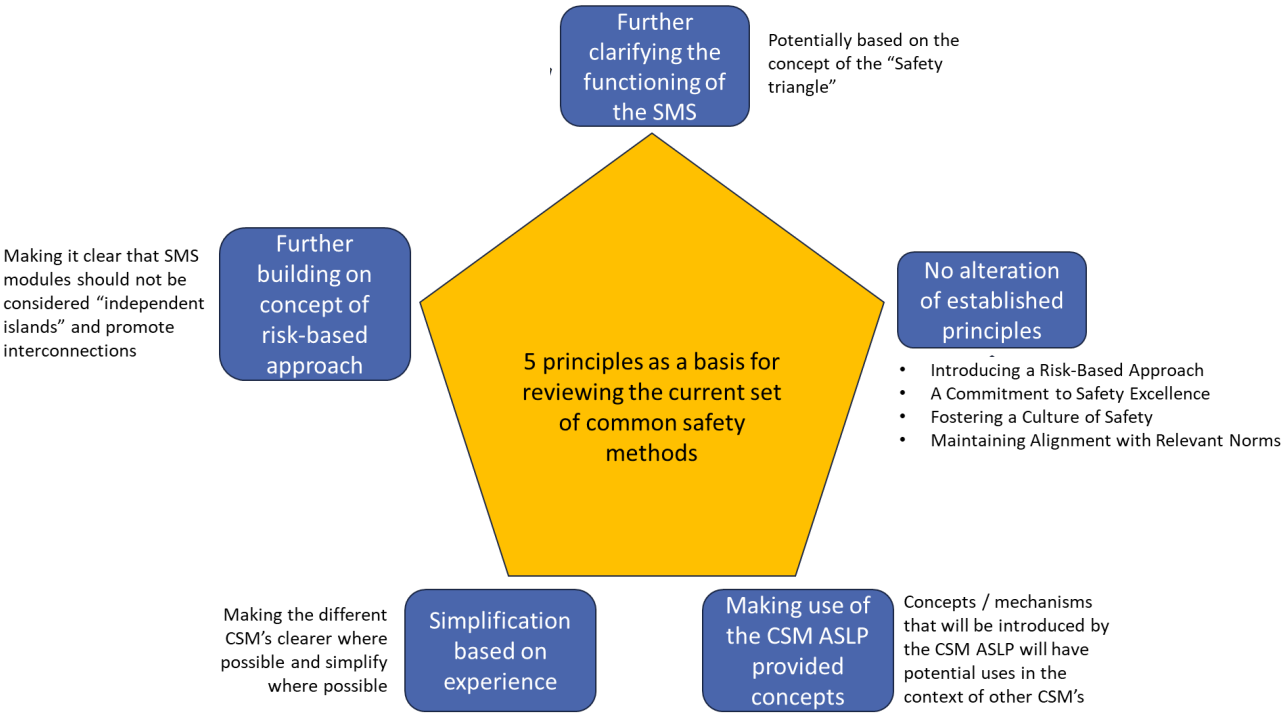

Figure 1: Visual representation of overarching principles for the CSM review exercise

2.3 Vision statement 1: Future CSMs should complement each other in support of an SMS aiming at continual improvement of safety (management)

This vision emphasises the pivotal role of a well-defined Safety Management System in driving continual safety improvements within railway operations. It highlights the SMS as an integrated framework composed of three key elements: the Safety Vision, formal safety processes, and cultural reinforcement.

The Safety Vision defines the organisation's core commitment to safety, guiding strategic and operational decisions. Formal processes translate this vision into actionable protocols for hazard identification, risk management, and performance monitoring. Cultural reinforcement ensures these principles permeate every level of the organisation, fostering shared values and behaviours aligned with safety excellence. By advancing this comprehensive and interconnected model, this vision supports a proactive, structured approach to achieving sustained safety improvements and embedding safety as a cornerstone of organisational success.

It is often misunderstood how these three aspects interact and how they collectively support the same objective of achieving a properly functioning SMS. The Safety Vision establishes the overarching goals, formal processes operationalise these goals into systematic actions, and cultural reinforcement ensures their integration into the organisation's daily activities. This interplay is crucial for creating a dynamic and effective SMS that aligns strategic priorities with operational realities.

The inclusion of the principle "Clarifying the Functioning of an SMS in Support of Achieving Continual Improvement of Safety (Management)" among the overarching principles of the CSM review reflects the need to address this misunderstanding. By clarifying these interactions, the principle aims to enhance the understanding and implementation of SMS frameworks, ensuring their full potential is realised in delivering continual safety improvements across the sector.

2.4 Vision statement 2: Future CSMs should continue building on established principles

This vision focuses on leveraging the foundational principles that have consistently guided the railway sector's approach to safety management. By reaffirming the sector's commitment to a risk-based methodology, continual improvement, and fostering a robust safety culture, the aim is to build upon what has already proven effective.

Rather than seeking radical shifts, this vision emphasises refinement and enhancement of existing practices to align with modern challenges and opportunities. It seeks to maintain harmony with established norms while promoting the seamless integration of safety into all operational levels, ensuring stability, consistency, and incremental progress towards safety excellence.

2.5 Vision statement 3: Future CSMs should make use of (future) CSM ASLP provided concepts / mechanisms

This vision underscores the potential of the CSM ASLP framework to strengthen safety management across the railway sector by introducing advanced concepts and mechanisms. It focuses on leveraging tools such as harmonised taxonomies, structured reporting of incidents, and self-assessment of safety performance to foster a culture of collective learning and continual improvement.

By encouraging operators to use shared methodologies like building blocks for risk assessment and reporting, this vision aims to create a more standardised and transparent approach to safety management. The ultimate goal is to provide a robust, data-driven foundation that enhances both individual operator performance and collective sector-wide safety outcomes.

2.6 Vision statement 4: Future CSMs should strive for simplification where possible, based on experience from SSC assessments, supervision activities, sector feedback, etc

This vision centres on streamlining the Common Safety Methods by incorporating lessons learned from practical implementation (Single Safety Certificate assessments), stakeholder feedback, and supervisory activities. By identifying areas of complexity or inefficiency within existing processes, the aim is to simplify the legal framework and enhance its usability for operators and national safety authorities.

This approach prioritises clarity, consistency, and practicality, ensuring that improvements are informed by real-world experiences and tailored to address challenges faced by the sector. The vision emphasises

reducing administrative burdens while maintaining a strong focus on achieving safety objectives effectively and efficiently.

2.7 Vision statement 5: Future CSMs should further incorporate a risk-based approach

This vision emphasises embedding a risk-based approach as the cornerstone of safety management in the railway sector. It advocates for a proactive methodology where risks are systematically identified, assessed, and mitigated based on their severity and likelihood.

By integrating risk management into all aspects of the Safety Management System, the vision seeks to enhance decision-making, prioritise resource allocation, and foster a culture of continual improvement. This approach ensures that safety is not only maintained but also evolves alongside operational and technological advancements, aligning with the dynamic nature of modern railway operations while supporting sustainable safety excellence.

2.8 Conclusion

The overarching vision statements presented in this chapter aim to provide a clear and unified direction for the review of the Common Safety Methods. They focus on ensuring that the CSMs complement each other effectively, supporting the seamless operation of a well-functioning Safety Management System without altering the foundational principles already established within it. Where necessary, improvements will be made to address new insights and incorporate innovative mechanisms, such as those introduced by the CSM ASLP, to enhance their relevance and applicability in a modern railway context.

The overarching vision also seeks to simplify elements of the CSMs where the sector has encountered challenges in applying their concepts, reducing complexity without compromising the integrity of safety management. Additionally, it aims to advance the understanding and implementation of the risk-based approach, providing clear guidance on how targeted, prioritised actions can be integrated into an SMS to address risks dynamically and effectively.

It should be noted that the aim of this vision document is not yet to develop specific solutions for the areas identified as being prone to improvement. Instead, the overarching vision statements outlined here are intended to provide users of this document with a clear indication of the strategic direction in which future solutions are likely to be developed. By articulating these overarching principles, this document ensures that stakeholders have a shared understanding of the intended path forward, facilitating alignment and anticipation of the changes to come.

Recognising that some key stakeholders have emphasised the importance of Vision Statement 4 in promoting simplification, enhanced clarity, and practical applicability, this vision statement will be treated as a priority within the review process. Its implementation will receive focused attention to ensure it effectively addresses the sector's needs while supporting the overarching goals of the CSM review.

For readers seeking a deeper understanding of the overarching vision statements outlined in this chapter, a more detailed description of each vision statement is provided in the annex (See Annex §5) of this document. These extended explanations offer additional context and insights into the principles guiding the review of the Common Safety Methods, further clarifying their application and significance within the railway sector.

3 Outcome/Results expanded scan

3.1 Introduction

This chapter outlines the results of the expanded scan, conducted as part of the Common Safety Methods review process. The review focuses on the following CSMs, identified as critical to advancing safety management across the EU railway sector:

- The Common Safety Method for Risk Evaluation and Assessment (CSM REA).
- The Common Safety Method for Monitoring (CSM MON).
- The Common Safety Method on Safety Management System Requirements (CSM SMS).
- The Common Safety Method on Supervision (CSM SUP).
- The Common Safety Method on Common Safety Targets (CSM CST).

Each section presents an analysis of the strengths, challenges, and areas for improvement identified through stakeholder feedback, regulatory experience, and lessons learned from implementation. The chapter also proposes a scaling of the level of review required for each CSM, serving as input for the mandate to be put in place by the European Commission. This scaling reflects the extent of updates deemed necessary to ensure the continued relevance and effectiveness of each CSM.

It is important to note that this chapter contains only a summary of the findings for each CSM and their proposed scaling. Readers interested in a more detailed description of the findings, including specific observations and improvement proposals for each CSM, can refer to the annex (see Annex §6) of this document. The annex provides a comprehensive analysis and further context to complement the summaries presented here.

Additionally, the chapter explores connections with related domains, such as competence management, human and organisational factors (HOF), safety culture, and the Technical Specification for Interoperability on Operation and Traffic Management (TSI OPE), where relevant.

The findings reflect the diverse feedback collected during the review process and provide a foundation for targeted updates and refinements to the CSMs. By focusing on areas where clarification, simplification, and harmonisation are needed, this chapter lays the groundwork for a cohesive approach to safety management across the EU railway sector, supporting the overarching vision of continual safety improvement.

The Agency and stakeholders involved emphasise that introducing more complex legal frameworks may not necessarily lead to better implementation by the sector. To mitigate this risk, the overarching vision explicitly commits to simplifying the current framework wherever feasible, enhancing clarity and ease of application. Furthermore, some stakeholders, particularly within the NRB network, have stressed the importance of improved guidance and support as essential elements in achieving more effective implementation of the legal framework.

3.2 CSM REA

The risk assessment process set out in Annex I to the CSM REA aligns with European and international standards such as ISO 31000, CENELEC EN 50126 and 50128, which have been in use for almost 30 years since their early versions. Despite 20 years of EU railway legislation aimed at transitioning from a rule-based approach to a risk-based approach, the railway sector still struggles to apply these standards in practice to meet the high-level requirements set out in the CSMs.

Although it is not proposed to amend the process outlined in Annex I, considering both the REX on CSM REA and the experience gained since the entry into force of the 4th Railway Package, a revision of the CSM would be appropriate to eliminate areas of interpretation and facilitate the understanding and harmonised application of the risk assessment process by all relevant actors, in line with new or amended legislation.

Some of the recommendations contained in the REX on CSM REA may still hold merit today. In particular, the application of a risk-based approach in railways could be enhanced by delivering proper and targeted training and education, including concrete examples presented in the native languages of railway experts across the European Union.

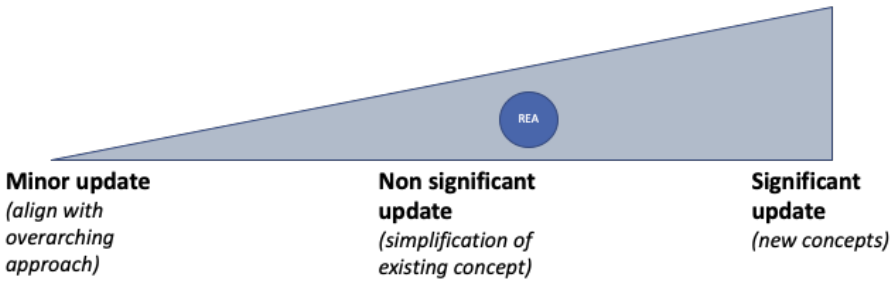

Figure 2: Proposal on significate of CSM REA update required

The CSM REA has been placed on the scale between “non-significant update” and “significant update” to reflect the dual nature of the potential changes under consideration. On one hand, existing experience and feedback have highlighted several areas where simplifications could improve the clarity and usability of the CSM REA. These potential adjustments would streamline the risk assessment process without necessitating fundamental changes to its structure.

On the other hand, there is an emerging perspective that the CSM REA should evolve towards a more uniform risk assessment/management process, extending beyond its current focus on changes to also encompass operational activities. Expanding the scope in this way could better align the CSM REA with broader safety management objectives but may require more substantial modifications to the framework. As such, while some of the proposed updates may appear non-significant, the inclusion of this broader application could necessitate a more significant update. This balance is the reason the CSM REA has been positioned as such on the scale.

3.3 CSM MON

The ERA report on the Common Safety Method for Monitoring and observations from Single Safety Certification activities highlight challenges and opportunities for enhancing safety management systems in the railway sector. A significant gap exists between the theoretical risk-based framework prescribed by the CSMs and its practical application by Infrastructure Managers and Railway Undertakings. This misalignment arises from differing interpretations and implementation of risk management principles. Some stakeholders regard the Safety Management System as a set of rule-based protocols rather than an integrated, dynamic framework, impeding its effectiveness and organisational integration. This is also evident in their approach to monitoring.

Enhanced education and training are essential to address this gap, fostering a cultural shift towards using the SMS as a proactive tool aligned with business objectives. Improved risk registers, effectively prioritised and linked to SMS components, are also critical. Clearer guidelines and tools are needed to ensure the SMS functions dynamically to assess, mitigate, and monitor safety risks.

The forthcoming CSM for the Assessment of Safety Levels and Performance (CSM ASLP) provides a structured, harmonised approach to tackling these challenges. By introducing a detailed taxonomy for event types and a structured approach to reporting occurrences, it aims to enhance risk identification and proactive monitoring capabilities. The taxonomy will facilitate a more systematic classification of safety events, enabling operators to better detect emerging risks, analyse trends, and implement preventive measures. Additionally, the use of these structured data sets in service of proactive monitoring will support a shift towards dynamic risk management, improving the sector's overall safety management practices. A review will be conducted to evaluate how the concepts and instruments introduced by the CSM ASLP can further contribute to improving the practical implementation of the CSM on monitoring, ensuring a coherent and integrated approach across the CSM framework.

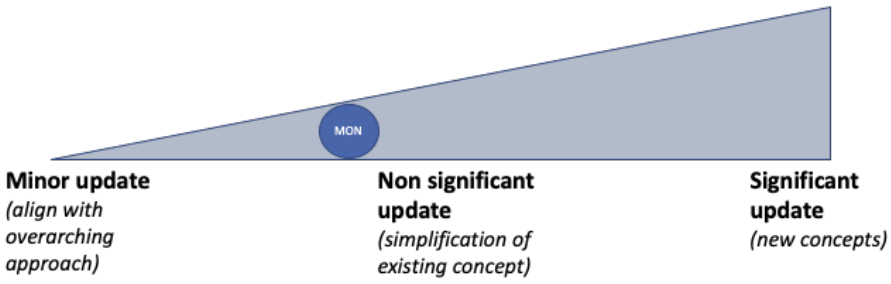

Figure 3: Proposal on significate of CSM MON update required

The positioning of the CSM on Monitoring (CSM MON) slightly to the left of requiring a non-significant update reflects its robust foundational framework while acknowledging the need for targeted refinements. These refinements aim to address the challenges faced by the sector in adopting a risk-based approach to monitoring. The need for updates arises less from deficiencies in the CSM MON itself and more from the necessity to clarify its interfaces with other Common Safety Methods and to improve its integration within a risk-based Safety Management System.

Key observations indicate that the practical application of the CSM MON would benefit from better alignment with other CSMs. In particular, there is a need to clarify how outputs from other CSMs—such as those relating to risk evaluation and assessment—should be utilised as inputs for monitoring activities. Similarly, the outputs of the CSM MON should be clearly defined in terms of how they can support other processes within the SMS. This bidirectional clarity would enhance the usability of the CSM MON and ensure its practical value within the overall safety framework.

Stakeholder feedback has highlighted varying perspectives, with some pointing to ambiguities not in the provisions of the CSM MON itself, but in how these provisions are understood and applied by those responsible for implementation. The review process will therefore consider whether these challenges stem from gaps in the legal text or inconsistencies in implementation across the sector. Furthermore, ensuring

alignment with the forthcoming CSM for the Assessment of Safety Levels and Performance and other related CSMs will be critical to promoting a more coherent and complementary approach.

The positioning of the CSM MON as requiring updates slightly to the left of requiring a non-significant update underscores the recognition that enhancements should focus on improving its integration, accessibility, and practical application without fundamentally altering its core principles. This measured approach will help maintain the relevance and effectiveness of the CSM MON within the overall CSM framework.

3.4 CSM SMS

Although the CSM SMS is relatively new, the Agency has gathered substantial feedback on its implementation through safety certification activities. This feedback has identified several opportunities for improvement. First and foremost, the risk-based approach, which is the core driver of the SMS, could be simplified by encouraging the same process to be applied whenever risk assessment is undertaken. As such a process already exists in the CSM REA, a more efficient synergy could be achieved between the two CSMs.

Secondly, the CSM SMS should take into account the evolution of the EU safety regulatory framework (e.g., the ECM Regulation, the TSI OPE, and the new CSM ASLP) and relevant standards (such as the ISO harmonised structure and associated management system standards, along with ENISA's good practices in cyber risk management) to ensure greater consistency, address new challenges in railway cybersecurity, and simplify the legal provisions wherever practicable. Interfaces with the domains of occupational health and safety, as well as the environment, could also be considered.

The strategy to improve safety culture and facilitate the integration of human and organisational factors often raises residual concerns during the safety assessment process for granting single safety certificates. Consideration should be given to the most appropriate ways to enhance railway companies' understanding (e.g., through guidance or training) while simultaneously avoiding additional complexity through amendments to the legal text.

Providing greater clarity on requirements that cause interpretative difficulties, explicitly indicating the required processes (rather than solely their outputs) in some requirements, and accounting for the specific needs of new entrants could also form key objectives of this revision. These objectives align with the overarching vision outlined in Chapter 2, particularly Vision Statement 4, which prioritises simplification based on experience from SSC assessments, supervision activities, and sector feedback. Furthermore, this revision reflects Vision Statement 1, which emphasises the importance of ensuring that CSMs complement each other in support of an SMS aiming at continual safety improvement. By ensuring greater clarity and consistency in the application of the CSM SMS, the review process remains in line with the structured, risk-based approach advocated in Vision Statement 5, reinforcing the sector's commitment to a harmonised and practical framework for safety management.

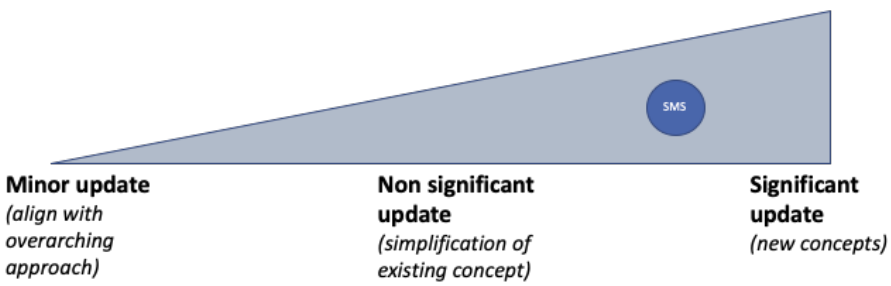

Figure 4: Proposal on significate of CSM SMS update required

The CSM on SMS requirements has been placed further to the right on the scale compared to the CSM REA, closer to the side of significant change. This positioning reflects the potential for more substantial updates, particularly due to broader discussions around expanding the scope of risk assessment processes and the implications this may have for the CSM on SMS requirements. Whilst the exact impact of integrating a more comprehensive risk-based approach for operational activities remains under consideration, it is evident that such an inclusion could necessitate significant changes to the SMS framework.

Additionally, the placement takes into account the potential outcomes related to competence management. If the Commission does not mandate a separate CSM on competence, the CSM on SMS requirements may need to incorporate significant updates to further develop its competence management section. This would involve deeper integration of competence-related processes, potentially requiring a redefinition of the existing framework to ensure it adequately addresses the sector's needs.

The position also acknowledges the complexity and importance of aligning the CSM on SMS requirements with evolving EU regulations and frameworks. These changes, whilst essential, suggest a higher degree of transformation compared to other CSMs. As such, the placement reflects both the anticipated scope of these updates and their potential to reshape the SMS requirements more significantly than updates to the CSM REA.

The placement of the CSM on SMS requirements on the scale reflects the possibility of more profound changes, driven by the integration of broader risk assessment processes and the need to address competence management comprehensively within its framework. These factors highlight the potential for significant development whilst maintaining a focus on harmonisation and consistency across the sector.

3.5 CSM SUP

It should be further assessed whether the Common Safety Method on Supervision (EU) 2018/761 can be clarified to facilitate more consistent implementation among NSAs. The appropriate level of detail in the requirements should be carefully discussed and evaluated. Indeed, overly detailed requirements could leave little room for manoeuvre for NSAs to adapt implementation to their own specificities and the characteristics of the sector in the relevant Member State.

To balance the risk of inadequate implementation due to a lack of clarity against the risk of overly prescriptive and inflexible requirements, a moderate revision of the CSM is recommended. This could address areas such as risk-based supervision, the supervision strategy and plan, Annex 1 on the supervision process, and Article 8 on coordination between NSAs and other bodies and authorities. Coordination with the proposed CSM on Competence will also be essential to ensure the two CSMs are correctly aligned on this subject.

To develop the most practical CSM for the sector, close consultation with stakeholders, particularly NSAs, should be established to efficiently revise the text of the CSM and the accompanying guidance.

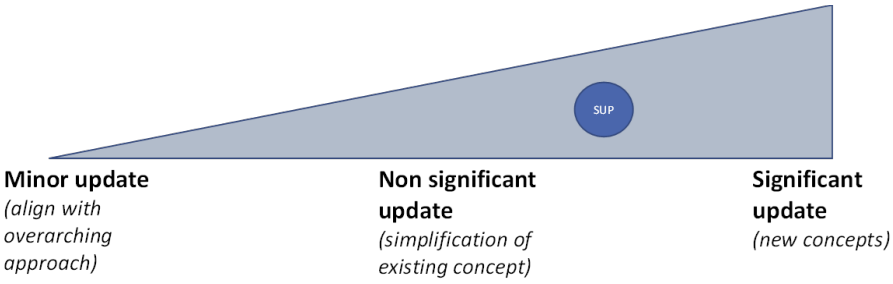

Figure 5: Proposal on significate of CSM SUP update required

The CSM on Supervision (CSM SUP) has been placed in the same position on the scale as the CSM REA, reflecting a similar balance between the need for increased clarity and the avoidance of overly prescriptive changes. This placement acknowledges that, whilst the CSM SUP has established a solid foundational framework, improvements are required to address ambiguities and ensure more consistent implementation by National Safety Authorities (NSAs).

The proposed changes primarily focus on clarifying the supervision process and strategy to enhance the effectiveness of risk-based supervision across Member States. A light revision of the CSM SUP would strike the appropriate balance between providing sufficient detail for NSAs and maintaining the flexibility needed to accommodate the specificities of different national contexts and sectors. This level of refinement indicates necessary but non-transformative adjustments, aligning with the scale of change anticipated for the CSM REA.

Ensuring alignment with the proposed CSM on Competence is another key consideration. Coordinating these frameworks will necessitate targeted updates, particularly to improve clarity and coherence in areas such as Annex 1 on the supervision process and Article 8 on NSA coordination. The importance of stakeholder consultation further underscores the need for refinement rather than an extensive overhaul of the CSM SUP.

The placement reflects that, whilst important updates are required to enhance clarity, coordination, and usability, these changes are not expected to fundamentally alter the framework. This moderate approach positions the CSM SUP alongside the CSM REA on the scale, recognising the need for improvement without indicating the requirement for significant structural changes.

3.6 CSM CST

The evaluation concluded that the CSM CST plays an important role in the EU legal framework for railway safety by providing structured safety performance data to Member States and the European Commission. However, this data remains predominantly reactive, limiting its usefulness for proactive safety management.

The Method's relevance has been undermined by the lack of revisions to the National Reference Values (NRVs) and Common Safety Targets (CSTs), which negatively impacts the accuracy of its results. Furthermore, as the CSTs are currently set equal to the highest NRV in Europe, the CSM CST has not promoted a reduction in the variance of safety levels across Member States. These issues, alongside other identified shortcomings, weaken its overall relevance.

The Method's effectiveness is limited due to low compliance with enforcement actions and insufficient engagement with Member States to drive safety improvements.

Despite these challenges, the efficiency of the Method is high, as it imposes minimal requirements on stakeholders while delivering benefits that far outweigh the associated costs.

The coherence between the CSM CST and other EU safety requirements is also high, with the Method often complementing national safety interventions.

Finally, while the CSM CST is frequently the only source of quantitative safety targets in Member States, its reactive nature limits its ability to drive forward-looking safety improvements. To enhance its effectiveness, efforts should be made to ensure it provides a more proactive and complementary role alongside the CSM ASLP.

Based on the evaluation, the following recommendations were made to improve the CSM CST:

- Update NRVs and CSTs in the short term.
- Promote faster publication of the assessment report.
- Make exclusive use of CSI data to avoid reliance on outdated Eurostat data when determining new NRVs.
- Implement automatic updates to NRVs to prevent the use of an outdated baseline.
- Ensure the enforcement of Article 5 actions, as its current implications are limited.
- Revise the CST concept.
- Adjust the statistical method to enhance its applicability and reliability.

It is noted that the forthcoming CSM ASLP could address many of the limitations of the CSM CST if the legislation introduces mechanisms to assess safety levels and performance at a country level.

Therefore, it is recommended to:

1. Revise the NRVs under the CSM CST to increase the Method's relevance while it remains in use.
2. Introduce requirements in the CSM ASLP to enable country-level safety assessments, including an enforcement clause similar to Article 5 of the CSM CST.

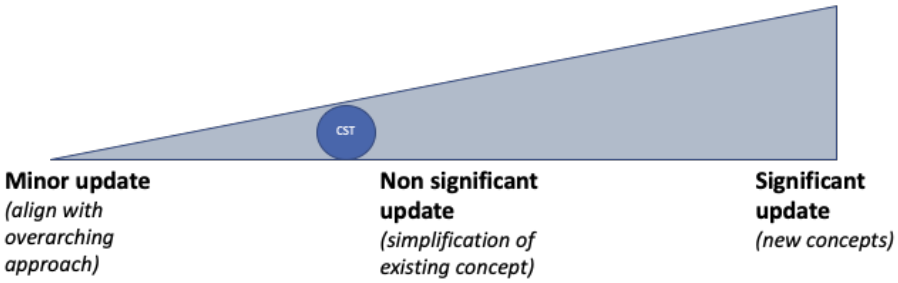

Figure 6: Proposal on significate of CSM CST update required

The CSM on Common Safety Targets (CSM CST) has been placed slightly to the left of non-significant change on the scale, indicating that whilst some updates are required, they are anticipated to remain moderate and focused rather than transformative.

One of the primary reasons for this placement is the need to revise the National Reference Values (NRVs) and the CSTs themselves. These updates are critical to improving the precision and utility of the CSM CST. Enhancing the timeliness of assessment report publications and ensuring the exclusive use of Common Safety Indicators (CSI) data to prevent inconsistencies with Eurostat data are also key areas for improvement. These adjustments aim to modernise the framework and address current limitations without requiring a fundamental redefinition of its structure.

Additionally, a significant consideration influencing this placement is the potential need for alignment between the CSM CST and the forthcoming CSM on the Assessment of Safety Levels and Performance . Ongoing discussions between the European Commission, the sector, and the Agency are evaluating which provisions will ultimately be incorporated into the CSM ASLP and which may remain or be introduced in the CSM CST. The outcome of these discussions could affect the extent of updates required for the CSM CST, making the current evaluation subject to further developments.

The placement of the CSM CST reflects the expectation that updates will focus on improving functionality, consistency, and alignment, particularly in revising NRVs and CSTs. Whilst currently assessed as closer to a minor update, the extent of required changes could evolve based on the resolution of discussions around the division of provisions between the CSM CST and the CSM ASLP. This positioning ensures flexibility for potential refinements whilst maintaining the core principles of the framework.

3.7 Competence management

The assessment of competence management systems indicates areas where further development is needed. Challenges include an over-reliance on national rules and difficulties in understanding the role that CSM provisions play in ensuring safe operations. While the EU regulatory framework provides the necessary parameters, railway operators sometimes face challenges in navigating these requirements, leading to confusion, bureaucracy, and duplication. Agency assessors have noted that distinguishing between national rules and CSM procedures often requires significant effort, with instances of overlapping or duplicated requirements observed in some NSA practices. This situation may result in increased assessment costs while yielding limited additional safety benefits.

Competence management is a fundamental responsibility of each railway operator within the Single European Railway Area. It needs to be well-integrated into their SMS to support safe operations and the effective management of identified risks. NSAs are encouraged to utilise all available tools, including EU Regulation 2018/761 on supervision, to ensure through their supervision activities that railway operators' SMS, including their provisions related competence management, are functioning effectively and addressing all relevant risks, including those related to human and organisational factors (HOF), such as staff competence management and training.
To maintain a high safety performance level, particularly in cross-border operations, railway operators must have the flexibility to adapt their SMS to different operational requirements and risks. However, the current arrangements for prescriptive national rules on competence can sometimes limit this adaptability.

With the suppression of open points in the 2023 version of TSI OPE, many national rules on competence will no longer be valid. This shift highlights the importance of further developing a risk-based approach to competence management systems.
The Agency recognises that current requirements, such as those in EU Regulations 2018/762 and 2019/779, may require further clarification to provide a stronger foundation for transitioning towards a fully risk-based competence management system. Additional guidance and support will be essential to assist railway operators and other stakeholders in this transition.

Collaboration with the sector, Member States, and NSAs is essential to address and consider the following points:

- The definition and role of a competence management system as part of SMS processes.
- The link between staff competence and task analysis for all roles that impact operational safety. Task analysis should identify what is required for safety-critical or safety-related roles in normal, degraded, and emergency situations. These analyses should inform staff selection, training, and competence maintenance. The analysis should also link to risk assessment results and related control measures, identifying activities where staff competence is critical for effective risk control.
- A systematic process covering the full competence lifecycle, from recruitment and selection to training, reassessment, and updating of competencies. This should include process review and auditing as part of overall SMS monitoring.
- Human and organisational factors affecting staff performing safety-critical tasks. This includes highlighting the role of non-technical skills in ensuring safe operations and controlling risks, integrating these skills into staff selection and competence management processes.
- Defining and managing safety-critical and safety-related functions, including identifying such functions as part of risk assessments and addressing situations where they form only a small part of an individual's responsibilities.
- Fitness for work and physical and psychological health, including managing fatigue and the abuse of alcohol and drugs.
- Roles and responsibilities of railway stakeholders in relation to competence, including contractual obligations and their integration into SMS.
- The supervisory role of NSAs in competence management systems.
- Reducing reliance on national rules for staff competence by ensuring that the EU legal framework addresses key aspects that facilitate the reduction and eventual elimination of such rules.

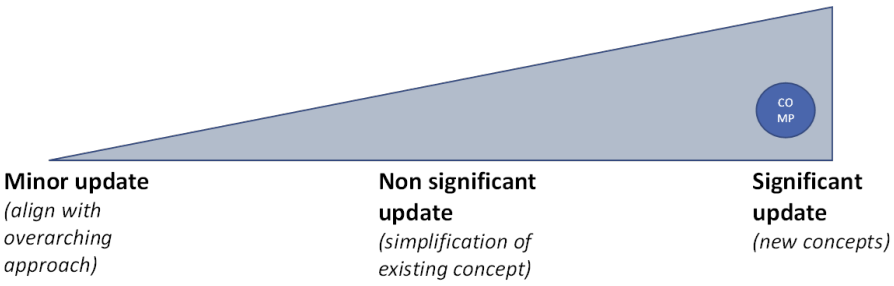

Figure 7: Proposal on significate of CSM COMP update required

The placement of the potentially new CSM on Competence Management at the far-right end of the scale reflects the significant need to establish this framework from scratch, marking a major development in the EU railway safety framework. Currently, no dedicated CSM exists for competence management, and the absence of a harmonised and risk-based approach in this domain has resulted in heavy reliance on national rules and inconsistent practices across Member States.

This positioning acknowledges that introducing a new CSM would constitute a substantial change, requiring the creation of a comprehensive framework aligned with existing safety management systems and EU regulations. A CSM on Competence Management would need to address critical aspects, including the definition and integration of competence management systems within SMS processes, the linkage between

task analysis and competence requirements, and the incorporation of human and organisational factors (HOF). These advancements are essential for transitioning from prescriptive national rules to a unified, risk-based approach.

Moreover, the suppression of open points in the 2023 version of TSI OPE, and the resulting invalidation of many national rules, further underscores the urgency of establishing this new CSM. Without such a framework, there is a risk of gaps in effectively managing competences, particularly in cross-border operations, which could undermine the safety and interoperability objectives of the Single European Railway Area.

The placement also reflects the complexity involved in aligning this new CSM with other related frameworks, such as the CSM on SMS requirements and the CSM on Supervision. Achieving this alignment will necessitate extensive consultation, collaboration, and development efforts to ensure the new CSM meets its objectives and integrates seamlessly into the broader safety framework.

The placement of the new CSM on Competence Management at the far-right end of the scale highlights the transformative nature of this initiative. It represents a critical step toward a harmonised, risk-based approach to competence management, addressing a major gap in the current EU railway safety framework and supporting sustainable and safe performance across borders.

Stakeholders are hesitant to introduce a specific new CSM on competence management, emphasising the importance of improving the practical application of existing rules through harmonisation, detailed guidance, and capacity-building initiatives to effectively address challenges such as inconsistent implementation and reliance on outdated national rules.

3.8 TSI OPE / National Rules

Although the TSI OPE does not fall within the scope of the CSM revision exercise and there are no proposals in this document to revise it, it has been included in the discussion due to its significant connections with the domains addressed in this report. While no modifications to the TSI OPE are proposed here, the Agency continues to explore potential improvements to enhance its effectiveness and alignment with other regulatory frameworks. The TSI OPE plays a critical role in defining functional and operational requirements for railway systems across Europe, and its interaction with other regulatory frameworks impacts key areas such as competence management, safety principles, and interoperability.

The ongoing clean-up of national rules has highlighted several challenges directly related to the TSI OPE. These include discrepancies in competence management systems, where detailed national rules often exceed the risk-based approaches expected of railway operators, and inconsistencies in safety principles that undermine interoperability between Member States. Additional issues include divergent national rules for train composition and braking, as well as operational requirements for technological and mechanical devices, all of which hinder seamless cross-border operations.

While the TSI OPE already addresses many of these topics, its effectiveness could be enhanced through better alignment with other regulatory frameworks. For example, removing overly technical aspects and placing them in structural TSIs while retaining the TSI OPE at a functional level could reduce inconsistencies and improve its usability. Additionally, ensuring coherence with related domains, such as competence management and safety principles, is essential to achieving harmonised and efficient railway operations.

The TSI OPE has been included in this discussion to emphasise its importance as a foundational document influencing multiple regulatory domains. Although it is not subject to revision within the scope of this exercise, its interaction with other frameworks highlights the need for continuous alignment and integration to support interoperability and safety across the European railway network.

3.9 HOF/Safety Culture

The vision document recognizes the critical role of Human and Organizational Factors (HOF) in enhancing the effectiveness of safety management systems across the railway sector. To ensure a thorough and integrated approach, observations and proposals for improvement specific to HOF have been identified for each individual Common Safety Method (CSM) and are detailed in the annex of this document.

Readers with an interest in exploring HOF-related aspects in greater depth are encouraged to refer to the, Annex §6.9 where specific observations and targeted improvement proposals for each CSM are outlined. These include insights into fostering a positive safety culture, addressing systemic factors, and better integrating human and organizational considerations into the practical application of safety management principles.

The inclusion of HOF considerations in the annex underscores their importance in the ongoing review of each CSM. These proposals will be carefully taken into account during the review process to ensure that HOF principles are seamlessly integrated into the updated CSMs, thereby contributing to a more holistic and effective safety framework for the railway sector.

Additionally, the annex includes a dedicated section on safety culture (see Annex §6.8), which provides a brief state of play regarding this topic at the time of writing this document, offering further context and insights into this key area.

3.10 Conclusions

The expanded scan conducted for the CSM review process outlines a detailed evaluation of the updates needed for each Common Safety Method (CSM). These evaluations are reflected in the figure accompanying this chapter, which positions each CSM on a scale ranging from minor to significant updates.

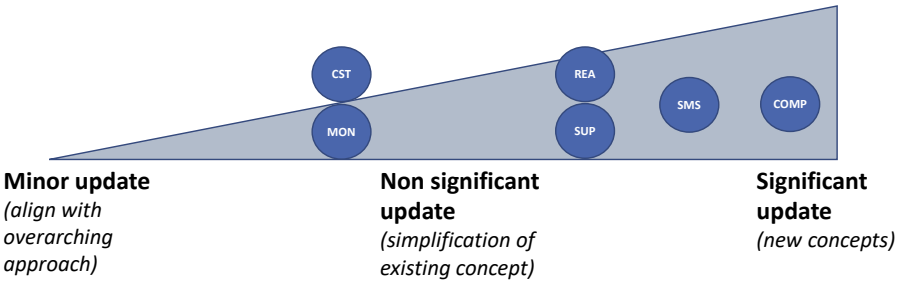

Figure 8: Proposal on significate of overall update required

Two CSMs—CSM on Common Safety Targets (CST) and CSM on Monitoring (MON)—are positioned between minor updates and non-significant updates, slightly to the left of non-significant. This placement reflects their

strong foundational frameworks but acknowledges targeted refinements to improve clarity, integration, and usability.

Slightly to the right of non-significant updates, CSM on Risk Evaluation and Assessment (REA) and CSM on Supervision (SUP) are placed, indicating the need for more structured adjustments to address evolving needs while maintaining their core principles.

The CSM on Safety Management System Requirements is positioned between non-significant and significant updates, reflecting the broader scope of enhancements required to expand its alignment with comprehensive risk-based approaches and address potential overlaps with other safety frameworks.

Finally, at the far-right end of the scale, the CSM on Competence Management is positioned, signifying the significant effort required to establish a comprehensive framework from scratch. This new CSM represents a transformative step towards a harmonised, risk-based approach to competence management, filling a critical gap in the EU railway safety framework.

The chapter's findings provide a concise summary of the proposed updates, while the annex contains a more detailed description of the findings for each CSM. Readers seeking a deeper understanding of the individual evaluations, including observations and proposals for improvement, are encouraged to consult the annex for additional context and supporting analysis.

The chapter's conclusions, coupled with the figure, highlight the diverse nature of updates required—ranging from minor refinements to significant reforms.

4 Next steps

Following the presentation of the final vision document to the RISC Committee, the process will transition back to the European Commission. The Commission will then determine how and when to establish a formal mandate for the review of the Common Safety Methods (CSMs). It will also decide to what extent the conclusions and proposals outlined in this vision document will be incorporated into the scope of the mandate.

Should the Commission decide to proceed with a mandate, this will initiate the process of preparing an agency recommendation. This recommendation will be developed in line with the Agency Regulation and in collaboration with the necessary formal working parties, which will be established as part of the process. The agency will lead the drafting of the recommendation, ensuring it aligns with the objectives set out in the mandate and addresses the areas for improvement identified in this vision document.

At the conclusion of the project, the Agency, together with the working party, will deliver a formal agency recommendation to the Commission. This recommendation will include proposed draft text for amending the legal framework, serving as a concrete input to guide the Commission on how the framework should be updated. This comprehensive approach will ensure that the review of the CSMs is robust, aligned with sector needs, and effectively enhances the legal framework governing railway safety in the European Union.

5 Annex – Detailed description of overarching principles for vision document

5.1 Introduction

For the proposed review of the Common Safety Methods, it is essential to outline a set of guiding principles that clarify the objectives and direction of the project for all stakeholders involved. These principles serve as a foundation for the exercise, aiming to ensure that all participants have a clear understanding of what the project seeks to achieve. Establishing these guiding principles is a strategic move designed to unify the approach to safety management across the sector. It creates a framework within which railway actors and regulatory bodies can operate, promoting a shared methodology and enhancing safety standards sector-wide. The principles provide essential direction for the review process, highlighting the importance of a proactive approach to safety and the goal of continual improvement and innovation within the framework of the existing CSMs.

By articulating these guiding principles, the project sets the stage for a comprehensive and cohesive review of the CSMs. This approach not only aligns with the foundational values and methods that have historically underscored the railway sector's commitment to safety but also ensures that the review process remains focused on building upon these principles. The clear delineation of these principles is also crucial for steering the review in a manner that supports and enhances the original spirit and objectives of the CSMs, fostering an environment of collective commitment to advancing safety standards within the railway sector.

5.2 Vision statement 1: Future CSMs should complement each other in support of an SMS aiming at continual improvement of safety (management) (Management)

5.2.1 Critical components of Safety Management

The Extended Safety Fractal is a conceptual model that entails the essence of safety management in a railway organisation. It is a symbolic representation that conveys the interconnectedness of three critical components:

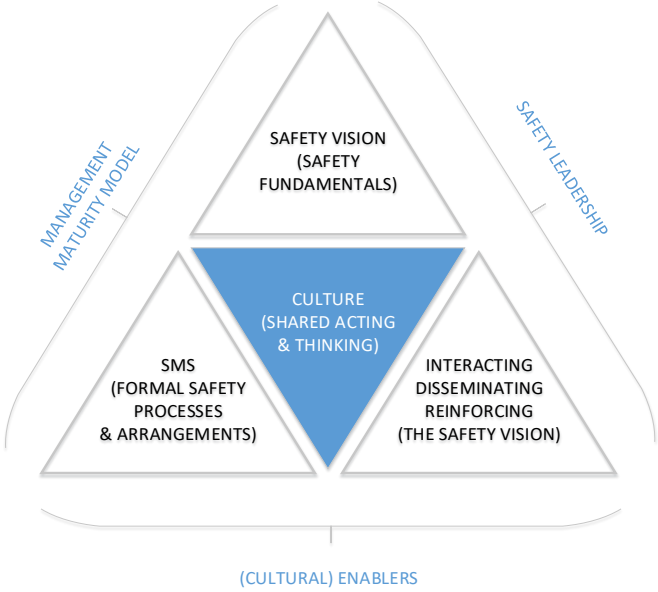

Figure 9: Extended safety fractal representation

- Safety Vision (Safety Fundamentals): This is the conceptual cornerstone, the development of an organisation's commitment to safety. It goes beyond mere compliance with regulatory mandates to champion a deeper, more intrinsic value system. It articulates a set of principles and aspirations that collectively define what safety means to the organisation and how the organisation want to manage safety. The Safety Vision is both a guiding principle that guides every safety decision and a measuring stick against which all safety activities are measured. How a risk-based approach is integrated into the functioning of an organisation is also an important consideration when developing a safety vision. See also section "The concept of risk-based approach" for more information.

- SMS Formal Safety Processes & Arrangements: The SMS represents the structural skeleton of an organisation's safety management, encompassing the formalised procedures and policies that dictate how safety is systematically managed. It is the framework that operationalises the Safety Vision into tangible processes—such as hazard identification, risk assessment, safety assurance, and the establishment of safety objectives. The SMS is the machinery that operationalizes the ethos of the Safety Vision into day-to-day actions and long-term strategic safety planning.

- Interacting, Disseminating, Reinforcing the Safety Vision: This aspect of the Extended Safety Fractal entails the active embodiment of the Safety Vision. It's the set of actions through which the vision is communicated, advocated, and ingrained within the organisation. From safety briefings to training sessions, from leadership speeches to visual safety reminders, this element is about keeping the Safety Vision at the forefront of every employee's mind and ensuring that it is more than just a document—it is a living, breathing part of the organisational culture.

- Central to this triangle is Culture (Shared Acting & Thinking), representing the collective cognitive and behavioural fabric of the organisation. Culture is the aggregate of shared values, beliefs, and practices that characterise how safety is perceived and enacted by everyone in the organisation. It influences and is influenced by the three key aspects of the triangle, underscoring the fact that a sustainable safety culture is both the seed and the fruit of rigorous safety management.

5.2.2 Looking at safety management from different angles

From the descriptions provided in the previous section, it is evident that each corner of the Extended Safety Fractal is not an isolated entity. Rather, they are points of convergence for a comprehensive and sustainable safety management. When observed from different perspectives, these points illuminate different facets of safety management. Each perspective provides a different lens through which to view the Extended Safety Fractal, allowing for a multi-dimensional analysis of safety management:

- Safety Leadership: This perspective examines the dynamic interplay between setting a clear and compelling Safety Vision and actively engaging with the workforce to ensure that vision is communicated and reinforced. Safety leadership is about embodying the principles of the Safety Vision and serving as a role model for safety behaviours.

  From the Safety Leadership angle, one can see how leadership is not just about setting the direction but also about actively engaging with employees, encouraging open communication, and creating an environment where safety is valued and actively discussed. It's leadership that fosters a culture where safety initiatives are enthusiastically embraced and where feedback loops contribute to the evolution of safety practices.

- Management Maturity: From this viewpoint, the focus is on how well the SMS integrates and executes the Safety Vision. It assesses the maturity of safety processes and how well they are embedded within the organisational fabric. A mature SMS is characterized by its ability to adapt and evolve, reflecting the continual journey towards achieving higher levels of safety performance.

  The Management Maturity perspective highlights the progression from nascent systems to a fully matured, integrated SMS that operates seamlessly across the organisation. A mature system is one where safety is not a siloed function but is interwoven into all business operations, where safety processes are clear and understood by all, and where continual improvement is part of the organisational ethos.

- (Cultural) Enablers: This angle is concerned with how well the Safety Vision is embedded into the DNA of the organisation and how effectively the SMS supports and is supported by the safety culture. It looks at the reciprocal relationship between the formal structures of safety management and the less tangible, but equally crucial, aspects of safety culture.

  The (Cultural) Enablers perspective accentuates how the organisation's culture enables and amplifies the principles set forth by the Safety Vision and operationalised through the SMS. This perspective is integral because it emphasizes that the cultural fabric of an organisation can either bolster or undermine safety efforts. A positive safety culture, where shared values and beliefs about the importance of safety are deeply ingrained, enables the Safety Vision and SMS to be more than just theoretical concepts or procedural mandates. It catalyses them into actionable, lived experiences that define the organisation's approach to safety.

  Examining the system through the (Cultural) Enablers perspective sheds light on the underpinnings that make safety protocols effective. It acknowledges that for any safety process or policy to be effective, it must be undergirded by efforts that actively supports and practices those safety principles. It's about aligning every facet of the organisation, from the boardroom to the frontline, with the values and behaviours that prioritise safety.

5.2.3 End-objectives for Infrastructure managers and railway undertakings by having an SMS

In the detailed framework of railway operations, the Safety Management System serves as a critical component that aligns legal compliance, operational safety, and business efficiency. Designed to encompass more than mere adherence to legal requirements, the SMS integrates the pursuit of safety with the broader goal of effective business management.

An SMS reflects a railway organisation's commitment to not only comply with legal standards but also to prioritize operational safety as a core business value. It serves as a proactive mechanism for identifying risks, implementing preventive measures, and fostering a culture of continual improvement based on insights gained from operational experiences.

The value of an SMS extends beyond being a mere collection of procedures; it is an adaptable and evolving framework that integrates with an organisation’s operational ethos. By aligning safety with strategic business objectives, it ensures that operational decisions are not only safe but also aligned with the company's long-term goals, making safety an integral part of operational excellence.

The design of an SMS emphasises clarity, ease of integration, and empowerment, avoiding unnecessary complexity. It aims to make safety management an intuitive aspect of daily operations, promoting a straightforward approach to achieving safety objectives.

The overarching aim of implementing an SMS is to support the organisation's broader mission and vision. It underscores the ambition to maintain safety standards while focusing on customer satisfaction, market reputation, and innovation. As such, the SMS acts as a facilitator, reinforcing the idea that safety management can coexist with and even enhance business growth and development strategies. It positions safety as a key strategic asset, contributing to the organisation’s sustainability and leadership in the industry. Therefore, an SMS is not merely a regulatory requirement but a strategic tool that enables railway organisations to maintain safe operations, build trust among customers and stakeholders, and secure a competitive position in the market. It embodies an organisation’s commitment to a foundation of safety, upon which it constructs its goals for efficiency and profitability, integrating legal compliance, safety, and business strategy into a unified approach that represents an organisation at its best: safe, efficient, and prosperous.

5.2.4 Continual vs. Continuous in Safety Management

In the domain of Safety Management Systems for railway operators, grasping the distinction between continuous and continual improvement is pivotal. Continuous improvement implies a relentless progression, comparable to a non-stop journey toward higher safety standards. However, in the context of an organisation's development, this concept may not always align with the practical, stepwise maturation of safety practices.

Continual improvement (stepwise), more aptly, embodies the journey of an organisation enhancing its safety maturity through phased, methodical advancements. It recognises the necessity for an organisation to consolidate and integrate each new level of proficiency before advancing. Much like the careful and deliberate process of building a structure, the foundation must be solid, and each subsequent layer meticulously developed to ensure overall integrity and function.

This philosophy is essential in safety management for railway operations, where each stage of growth is built upon the last. The aim is not to sprint ahead without due diligence but to move with deliberation, securing

each milestone before pursuing the next. The approach is comparable to a carefully prepared expedition, where the readiness of the team at each camp is ensured before ascending to higher altitudes.

In this model, railway operators are seen as entities growing in capability, where initial stages involve mastering regulatory compliance and essential safety protocols. This forms the base from which all further improvements are launched. As proficiency in these areas solidifies, the organisation may then scale up to integrate more sophisticated safety initiatives, such as proactive risk management and the nurturing of a widespread safety culture.

Improvement in safety management should be viewed as a deliberate, structured progression, ensuring at every stage that the organisation is equipped and ready for the next leap forward. This allows for a more realistic, achievable pathway to elevating safety standards, where the journey of improvement is measured, understood, and strategically executed for sustainable advancement.

In the pursuit of elevating safety management standards among railway operators, the concept of continuous improvement, while valuable, is not without its limitations. Continuous improvement—defined as the perpetual stream of enhancements without intervals—may not always be the most effective approach in the context of improving safety within the rail industry.

Continuous improvement assumes an organisation has the capacity to absorb and implement changes rapidly and effectively. However, in the complex and highly regulated railway sector, such an unceasing pace can lead to a series of unintended consequences:

- Resource Constraints: Railway operators often operate within fixed budgets and human resource limits. Continuous improvement initiatives can strain these resources, leading to staff burnout and financial overstretch.
- Safety Overload: The implementation of too many changes in quick succession can overwhelm employees, potentially leading to confusion and errors. It can dilute the focus on essential safety practices that require steady and deep integration into daily operations.
- Dilution of Efforts: Continuous efforts to improve can result in a scenario, where the depth and quality of improvements are compromised in favour of quantity and speed.
- Incomplete Integration: For changes to be meaningful, they must be fully assimilated into the organisation's operational fabric. Continuous change may not allow sufficient time for each improvement to be properly embedded and for its impact to be fully realized and measured.
- Resistance to Change: Humans are naturally averse to constant change. A relentless pace of improvement may breed resistance among staff, leading to cynicism and reduced engagement with safety initiatives.
- Compliance and Verification Challenges: Regulatory compliance requires thorough documentation and verification processes. Continuous improvement can disrupt these processes, complicating compliance and possibly undermining the credibility of the safety management system.
- Innovation Fatigue: Constant demands for improvement can lead to innovation fatigue, where the organisation's drive to innovate is dulled by the relentless pressure to change.

For these reasons, railway operators might find a more periodic, well-planned, and strategically paced approach to improvement—synonymous with continual improvement—to be more desirable. Such an approach allows for the careful planning of changes, sufficient time for implementation and assimilation, and a balanced workload for staff, which together foster a more sustainable improvement in safety management. It permits an organisation to maintain stability while still advancing its safety objectives, thus ensuring that the journey towards safety excellence is both effective and resilient.

5.3 Vision statement 2: Future CSMs should continue building on established principles

5.3.1 General

In the process of reviewing the Common Safety Methods, a critical aim is to build upon a series of well-established principles already embedded within the current set of CSMs. These foundational principles have guided the development and application of safety management practices across the railway sector, forming the backbone of the railway sector's collective approach to ensuring operational safety. As the review exercise will embark, it will be very important to emphasize the enduring commitment to these principles, ensuring that any enhancements or modifications to the CSMs continue to reflect the sector's long-standing values and established methodologies for managing safety.

The continuation of these principles signifies a dedication to a risk-based approach, the pursuit of safety excellence, the nurturing of a robust safety culture, and the alignment with relevant safety norms. It is these principles that have underpinned the railway sector's advancements in safety and will continue to do so as the project will seek to adapt and improve the CSMs in response to emerging challenges and technological advancements.

This approach is also accepted and deeply embedded in high-risk sectors, such as aviation, nuclear energy production, etc.

Reaffirming the commitment to established principles provides clarity for all participants in the review process. The aim is to refine and enhance the current safety framework, maintaining alignment with the original ethos and goals of the Common Safety Methods and upholding a safety-centric approach.

As the review of the CSMs unfolds, it will do so with an intention to build upon the foundations laid by the original framework. Adherence to shared principles is crucial as it propels railway safety improvements. The review is shaped by insights into what has effectively contributed to a robust safety management system, with any proposed changes designed to bolster its strength. These principles emphasize the critical role of embedding safety within the organisational culture. Safety is envisaged as a central pillar at every operational level, integral to the very identity and day-to-day functions of an organisation.

Defining these guiding principles is instrumental in assuring that the review of CSMs will continue in the direction set by the original CSMs, rather than restarting the work or veering towards a radically new direction. This approach ensures that the project remains aligned with the spirit of the Railway Safety Directive and the initial CSMs, fostering an environment where safety is a primary concern and a collective commitment.

5.3.2 Established principle 1: Risk-based approach

Railway Safety Directive:

Art 4 (1) With the aim of developing and improving railway safety, Member States, within the limits of their competences, shall: (a) ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Union law and international rules and of technical and scientific progress, and giving priority to the prevention of accidents;

...

Art 4 (2) The Agency shall ensure, within the limits of its competences, that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Union law and of technical and scientific progress and giving priority to the prevention of serious accidents.

Extracts from current legal framework: CSM on SMS requirements: §2.1. Leadership and commitment - §2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:
(f) ensuring that the safety management system is effective in controlling the safety risks posed by the organisation;
(i) ensuring that safety is considered when identifying and managing the organisation's business risks and explaining how conflict between safety and other business goals will be recognised and resolved;
Safety objectives and planning
3.2.1. The organisation shall establish safety objectives for relevant functions at relevant levels to maintain and, where reasonably practicable, improve its safety performance.
3.2.2. The safety objectives shall:
(b) be linked to the priority risks that influence the safety performance of the organisation;
CSM on monitoring - Annex of COMMISSION REGULATION (EU) No 1078/2012:

2.2. The decision on what to prioritise shall take into account information from areas that give rise to the greatest risks and, if not monitored effectively, could lead to adverse consequences for safety. An order of priority for monitoring activities shall be set, and the time, effort and resources required shall be indicated. Prioritisation shall also take into account results from previous applications of the monitoring process.

The implementation of a risk-based approach in the current set of Common Safety Methods has introduced a first step towards shaping effective safety management in the railway sector. This approach has laid the groundwork for a systematic and proactive way of addressing safety, emphasizing the importance of anticipating and managing potential risks before they materialize into safety incidents.

The preservation of a risk-based approach is crucial as it underpins a system that will allow for a strategic and thoughtful reduction of risks in railway operations. As the CSMs undergo a review, it will be vital to honour this approach, ensuring that any refinements to the methods build upon this chosen strategy. The goal of the review is to continue on this established principle and to carry forward the insights and advancements it has facilitated.

The forthcoming review is committed to sustaining the momentum gained through this approach. It will seek to reinforce and deepen its integration into safety management practices, ensuring that it remains a central driver of the CSMs. This continuity is key to providing the sector with the stability it needs to maintain and enhance the safety achievements it has made thus far.

See section “Incorporating Risk-Based Approach” for more information (see §5.6.2).

5.3.3 Established principle 2: Commitment to continually improving safety

RSD Article 6, point 5:
The CSMs shall be revised at regular intervals, taking into account the experience gained from their application and the global development of railway safety and with the objective of generally maintaining and, where reasonably practicable, continuously improving safety

A commitment to continually improving safety, where reasonably practicable, embodies the railway sector's dedication to achieving the highest standards of safety, transcending mere compliance with regulatory requirements to promote a culture where safety is the central concern.

At the heart of a commitment to safety excellence is the recognition that safety is not a fixed target but a continual journey. This journey is marked by an ongoing pursuit for improvement, where every process, system, and protocol is subject to scrutiny and potential enhancement. It's about adopting a proactive stance towards safety, one that anticipates risks and seeks innovative solutions to mitigate risks before they can manifest as safety incidents or accidents.

This principle requires an organisation-wide commitment that is embedded in every level of operation. From the executive level to the front lines, every member of the organisation is empowered and expected to contribute to the safety dialogue, helping to put in place an environment where safety concerns are voiced and addressed openly and constructively. It is this collective commitment that propels an organisation towards safety excellence. This integration demonstrates that safety excellence and operational efficiency are not mutually exclusive but mutually reinforcing.

Additionally, achieving safety excellence requires the establishment of robust monitoring and reporting mechanisms. These mechanisms facilitate a data-driven approach to safety management. By systematically tracking safety indicators, based on anticipated risks and learning from incidents, organisations can identify trends, uncover root causes, and implement targeted interventions to prevent recurrence. This continual learning cycle is critical to advancing safety knowledge and practices within the organisation.

A commitment to safety excellence is manifested through continual investment in training and development. By equipping employees with the knowledge, skills, and competencies required to perform their roles safely, organisations not only enhance individual performance but also fortify the organisation's overall safety culture. This investment in human capital underscores the belief that the most valuable asset in any organisation is its people, and their safety is of the highest importance.

5.3.4 Established principle 3: Fostering a Culture of Safety, with attention for human- and organisational factors in all aspects of the SMS

RSD Art. 9, point 2:
There shall be a clear commitment to consistently apply human factors knowledge and methods.
Through the safety management system, infrastructure managers and railway undertakings shall promote a culture of mutual trust, confidence and learning in which staff are encouraged to contribute to the development of safety while ensuring confidentiality.

Cultivating a Culture of Safety, with attention to human and organisational factors in all aspects of the SMS entails a holistic approach to safety management, recognizing that many essential aspects of safety are deeply woven in the behaviours, attitudes, and values of individuals and the organisation as a whole.

At its core, nurturing a culture of safety means creating an environment where safety is universally regarded as a core value, not just a compliance requirement. It's an environment where every employee, from top management to frontline staff, feels personally responsible for safety and is empowered to act to preserve it. This collective commitment to safety becomes the driving force behind every operational decision and action, making safety an integral part of the organisational identity.

Central to this cultural transformation is the recognition of human and organisational factors as critical components of the safety equation. Human factors encompass a wide range of psychological and physiological aspects, including perception, decision-making, workloads, ergonomics, and team dynamics, among others. Organisational factors, on the other hand, include policies, procedures, leadership, communication, and organisational structure. Together, these factors influence how safety practices are implemented and sustained on the ground.

Addressing human and organisational factors means going beyond the technicalities of safety systems to understand how people interact with these systems in real-world scenarios. It involves examining how organisational culture, leadership styles, communication flows, and team dynamics can either enhance or undermine safety. This understanding enables organisations to design SMS components that are not only technically sound but are also acknowledging the human element, ensuring that safety processes/instructions are practical, intuitive, and conducive to positive safety behaviours.

Continuing building a safety culture also requires a commitment to open communication and continuous learning. An environment where employees feel safe to report safety concerns without fear of retribution is crucial. Such transparency not only fosters trust and collaboration but also enables the organisation to learn from near misses and incidents, turning every safety challenge into an opportunity for improvement. This learning culture ensures that the organisation remains agile and responsive to emerging safety risks.

Moreover, attention to human and organisational factors helps to tailor safety initiatives to the specific needs and contexts of different groups within the organisation. Recognizing that one size does not fit all, safety management becomes a dynamic, participatory process that engages employees at all levels, harnessing their insights and expertise to develop more effective safety solutions.

5.3.5 Established principle 4: Maintaining Alignment with Relevant norms/practices

CSM on SMS requirements – Whereas (4):
The purpose of the safety management system is to ensure that the railway undertakings and infrastructure managers achieve their business objectives in a safe manner. The safety management system is often integrated with other management systems to increase the overall performance of the organisation and reduce costs while mutualising the efforts at all levels of the organisation. To this end, the common framework of the ISO High Level Structure (6) is used to functionally cluster the requirements of the safety management system, as referred to in Article 9 of Directive (EU) 2016/798. This framework also facilitates the understanding and application of a process approach by the railway undertakings and infrastructure managers when developing, implementing, maintaining and continually improving their safety management system.

Maintaining Alignment with Relevant Norms/Practices emphasizes the importance of ensuring that Safety Management Systems within the railway sector are developed and operated in accordance with established international and sector-specific norms. This principle serves as a guide for integrating universally recognized frameworks into SMS practices, thereby enhancing the effectiveness and robustness of safety management efforts. It underscores the necessity of harmonising SMS components with norms such as the ISO harmonised structure (HLS) and CENELEC EN 50126, ensuring a cohesive and comprehensive approach to safety.

At the foundation of maintaining alignment with relevant norms/practices is the recognition that safety management benefits from a structured and consistent approach, one that is informed by best practices and validated methodologies. International norms, such as those developed by the International Organisation for Standardization (ISO) and the European Committee for Electrotechnical Standardization (CENELEC), provide a solid basis for designing, implementing, monitoring, and continually improving SMS:

- The ISO harmonised structure (HLS) offers a unified framework that is common across various ISO management system standards. Its universal structure, core definitions, and common terms and clauses enable organisations to integrate multiple management systems seamlessly, including those for quality, environmental, and occupational health and safety management. For railway undertakings and infrastructure managers, aligning their SMS with the ISO HLS facilitates the integration of safety management with other critical organisational functions, enhancing overall efficiency and effectiveness. By adopting the HLS, organisations can ensure that their SMS is not only comprehensive but also adaptable to changes in both internal and external contexts.

- CENELEC EN 50126, tailored to the global railway system, provides a detailed lifecycle approach applicable to railway application fields, including Command, Control, and Signalling, Rolling Stock, and Fixed Installations. It addresses aspects such as reliability, availability, maintainability, and safety (RAMS), offering a systematic process for managing risks throughout the entire lifecycle of railway systems. By aligning SMS practices with CENELEC EN 50126, railway operators ensure that their safety management efforts are grounded in sector-specific insights and methodologies, offering a comprehensive approach to addressing the unique challenges and risks inherent in railway operations.

- As regards developing harmonised solutions, the work of EU-Rail with ERA, in collecting all relevant potential or known harmonisation topics from the System Pillar and Innovation Pillar activities, must be taken into consideration. Needs and inputs must be considered both on the research and standardisation/regulation level for an optimal use and deployment of the research and standardisation outcomes[1]. The transfer of R&I results of EU-RAIL to the EU standardisation and regulation process is a crucial goal to enable the introduction of innovations into European rail, supporting interoperability as well as competitiveness[2]. The standardisation process for European Standards (EN) is launched by the European Commission if these standards shall become harmonised standards referenced in the TSI. The Commission brings forward a standardisation request to one of the recognised European Standardisation Organisations (CEN, CENELEC or ETSI). For EN standards which are not references in the official journal (non-harmonised standards), the request can be brought in by National Committees or Technical Committees representing a group of technical competent experts on the national or European level. CEN-CENELEC Management Centre (CCMC)

[1] The “Standardisation and TSI Input Plan” is the tool by which ERA and Standardisation Bodies (CEN, CENELEC, ETSI, SFR) allow modifications being introduced. EU-RAIL and System Pillar strategic plan is endorsed by the European Commission, ERA, the European Standardisation bodies, and the sector as a whole – through the approval of the System Pillar Steering Group.

[2] For example, operational processes that need to be harmonised to the identified level, need to be provided as an input by the System Pillar. This input shall include a clear identification of technological standardisation and a viable plan for transition.

identifies the relevant Technical Committee (TC) for creating a standard;[3] if needed national Committees can be included in the process for defining the new work item (NWI).

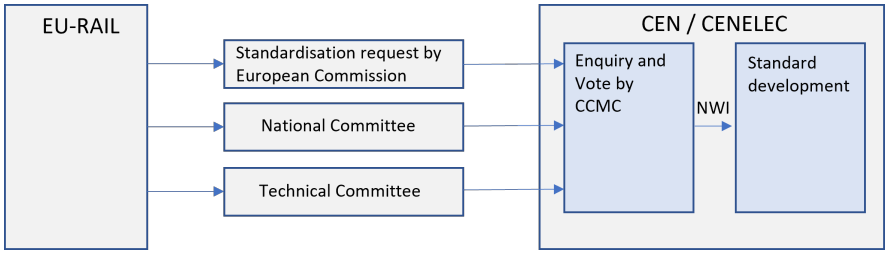

Figure 10: Process for defining Norm Work Items (NWI).

[3] The Technical Committee (TC) officers evaluate the proposal with support by the Chairman's Advisory Group (CAG).

5.4 Vision statement 3: Future CSMs should make use of (future) CSM ASLP provided concepts / mechanisms

The Common Safety Methods for assessing the Safety Level and the Safety Performance of railway operators at national and Union level will introduce several mechanisms to further strengthen the management of safety. The proposed assessment methods of the future CSM ASLP create an approach that is integrated with the existing relevant legislation and support the continual improvement of safety level and safety performance. The achievement of this aim is conditioned by the reporting of relevant – pre-defined and structured – information by operators. This information collected can form a basis for collective learning at national and Union level.

The concepts of safety level and safety performance are twofold:

- Safety level is a measurement that reflects the state of safety within railway operations, determined through the analysis of accidents, incidents, and their precursors. It provides valuable insights that help railway operators enhance their safety management practices and align their business objectives with safety priorities. Additionally, safety level assessments support Member States in making informed decisions regarding safety improvements and developments.

- Safety performance is a measurement that reflects the capability and maturity of an operator's processes to manage, prevent, or mitigate safety risks through effective risk control management activities. It provides a structured basis for operators to self-assess and enhance their safety management practices.

  Note : the Safety Performance scoring is derived from the safety maturity assessment model and does not duplicate / is not equivalent to the assessment made at the time of granting safety certificates or safety authorisations.

The reporting of information by operators is fundamental in making these concepts work and to achieve the benefits of collective learning. Today, the draft CSM ASLP includes a first step towards a sharing mechanism, by introducing the concept of the Group of Analysts (GoA). The GoA will have access to the information reported by operators as defined in the rules for sharing possible sensitive data and respecting confidentiality arrangements. This information can form the basis for sector-wide safety analyses.

Certain items are central to both these concepts, such as the use of a harmonized taxonomy for reporting event types, contributing factors and systemic factors. The CSM ASLP defines event types, enabling a category or classification of an occurrence, based on certain criteria or characteristics. Event types are categorised as A, B, or C, based on the potential consequences or effects of the event. Category A events are accidents that directly result in victims or damages. Category B events are incidents with the potential to directly cause a category A event. And category C events are incidents (variations) with the potential to directly or indirectly cause a category B event. Examples of event types in the context of the CSM ASLP include accidents, incidents, near-misses, or other safety-related events.

Furthermore, the CSM ALSP also introduces the concepts of 'systemic factors' and 'contributing factors' :

- Contributing factors are factors that play a role in an occurrence, but the elimination of which would not have prevented the occurrence from happening. Examples of contributing factors include fatigue, stress, time pressure, and communication breakdowns. These factors can affect the likelihood, timing, or severity of an occurrence, but they are not necessarily the root cause of the occurrence itself;
- Systemic factors are factors that are not directly related to the specific incident or accident, but may have contributed to its occurrence. The presence of systemic factors can lead to a deterioration of a

system's overall safety performance but in itself does not lead to an occurrence scenario. Systemic factors refer to the broader organisational and societal factors that may have contributed to the event, such as the lack of operational planning of maintenance, inadequate training of the maintenance crews, resource management, etc..

Also the CSM ASLP proposes a structure format for reporting information on risk control measures. This will provide the sector with a uniform vocabulary that facilitates and encourages dialogues between operators on finding the optimal risk reduction strategies. Furthermore, in the context of safety performance self-estimation, operators are expected to report information on their most important risk control measures, depending on their maturity level related to safety performance and resulting in a safety performance score. Operators will also provide proof to support their self-assessments, thereby providing information that can be useful for collective learning. This can be an important source of information for the GoA to carry out sector-wide analyses.

The above-mentioned elements are all captured in a harmonized way using taxonomy.

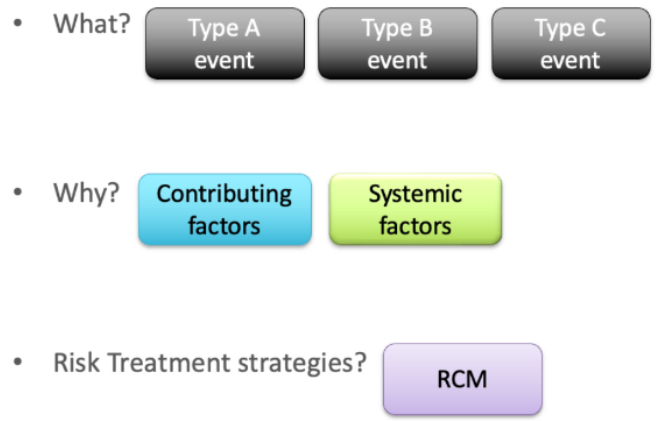

Figure 11 : harmonized taxonomy elements.

Having taxonomies for these information items is important for several reasons. Among others, it provides a standardised and organised way to categorise and classify different information on events and occurrences. This allows for clear and consistent reporting, which is essential for the accurate analysis of data and the identification of trends and patterns.

When reporting on events, the operators' analysis of the failure of the risk control measures in place is a vital element. The CSM ASLP foresees a methodology with which operators identify "building blocks" for reporting on their occurrences.

Building blocks allow to document the contextual relations between triggering and resulting events and allow to document how contributing and systemic factors played a role in the coming in existence of these relations. Building blocks also allow to document how Risk Control Measures play a role/influence these relations, allowing users to develop strategies to prevent similar events in the future.

See below an example of a combination of a possible relation between building blocks that link several underlying events that can lead to the event 'Overspeed'.

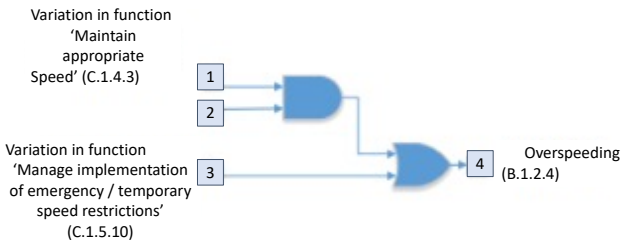

Figure 12: Example of a visual representation of a possible relation between building blocks describing safety events.

The CSM ASLP provides a detailed description of the information that needs to be collected and reported for each step of the building block reporting process. This information is used to conduct a comprehensive analysis of the occurrence scenario and its contributing factors, and to identify patterns, trends, and root causes of safety issues.

Various building blocks can be combined to create a complete risk scenario, linking all events and risk control measures involved. The integration of building block concepts into the fabric of common safety methods like the CSM REA provides a standardised risk management tool that can be consistently applied. This standardization ensures that the processes of risk assessment are uniform, thereby enhancing clarity in communication among all stakeholders involved. It enables organisations to streamline their risk management strategies, minimizing inconsistencies and potential oversights.

Further, the structured format of building blocks aids organisations in conducting structured and thorough risk analyses. It helps categorise complex information into manageable segments, such as contributing factors and systemic factors, granting a comprehensive view of the entire risk landscape. This granular approach to understanding risk scenarios facilitates informed decision-making and the formulation of precise risk mitigation tactics.

Also, it can be useful to apply the concept of safety performance on member state level. This could be integrated in the CSM on Common Safety Targets, giving member states the tools to self-assess and reflect upon the maturity of their implementation of railway safety legislation. For more information, see section (See 6.5 CSM CST).

Additionally, for railway operators, the safety performance approach complements both the CSM on SMS and the CSM on Monitoring. Operators' self-assessment of their safety performance not only supports their continual improvement endeavours, as required by the CSM on SMS, but also serves as a benchmark to track progress over time. The practice of regular self-assessment during the validity of a safety certificate or authorisation becomes a testament to their dedication to continuous enhancement of safety practices.

Furthermore, under CSM on Supervision, the harmonised performance assessment can serve as valuable input for supervisory activities, without replacing the intrinsic roles and responsibilities tied to supervision. It provides National Safety Authorities with a clear picture of an operator's development through the supporting elements of proof provided, aiding in a comprehensive understanding of their safety maturity levels.

Thus, the CSM ASLP's approach, with its emphasis on building blocks, event reporting, and operators' self-assessment of safety performance, fosters an ongoing mechanism that benefits not only the SSC and Safety Authorisation but also enhances and simplifies the processes of supervision and monitoring. It unlocks a wealth of opportunities to strengthen and support this review of Common Safety Methods.

5.5 Vision statement 4: Future CSMs should strive for simplification where possible, based on experience from SSC assessments, supervision activities, sector feedback, etc

The Agency has benefitted from interactions with the sector due to various interfaces on different activities and through different channels and identified opportunities for simplification and improvement of the existing CSMs.

These interactions stem from the Agency's tasks as defined in the 4th railway package, the support that the Agency provides in the Joint Network Secretariat (JNS) procedures, the interactions with the sector when drafting new legislation in working parties, through efforts aimed at clarifying questions and various other ad-hoc activities

5.5.1 Tasks allocated to the Agency following the introduction of the 4th railway package:

With the introduction of the 4th railway package, several new tasks were assigned to the Agency that are directly linked with the application of the Common Safety Methods:

ERA acts as certification body for Single Safety Certificates for railway undertakings whose business is to transport goods and/or passengers, whether or not their activities are limited to providing traction only. These operators must hold a valid single safety certificate for the given area of operation, i.e. a network or networks within one or more Member States where the railway undertaking intends to operate. The Agency is responsible for assessing the compliance of the operators' safety management system with the requirements set out in the CSM on SMS. This assessment considers also the application of the CSM on REA and the CSM on Monitoring by the operator.

Since the start of the certification activities in 2019, ERA has issued more than 200 Single Safety Certificates, in close cooperation with the National Safety Authorities involved. For the observations stemming from the 4th railway package, see the chapter "Outcome/Results expanded scan".

ERA monitors the performance and decision-making of national safety authorities through audit and inspections, on behalf of the EC, as mandated by Regulation (EU) 2016/796. The Agency is entitled to audit the capacity of national safety authorities to execute tasks relating to railway safety and interoperability as well as the effectiveness of the supervision by national safety authorities of safety management systems of actors as referred to by Directive (EU) 2016/798.

Since the starting up of the NSA Monitoring activities, ERA has completed a first audit cycle between 2019 and 2021. All NSAs were audited for two topics: management of competences and supervision. Since 2022, the Agency is performing full scope audits for all NSAs, covering all NSA tasks in relation to safety and interoperability.

These monitoring activities provided opportunities to capture possibilities for simplification and improvement for the CSM on Supervision. Possible areas are: clarification of the concept of risk-based supervision, decision-making criteria, harmonization of terminology, etc..

5.5.2 Feedback collected through the Joint Network Secretariat

The Joint Network Secretariat is a collaboration between the Representative Bodies and National Safety Authorities that aims at finding European harmonized solutions for issues linked to safety, interoperability or competitiveness. Actors can notify requests to launch an Urgent or Normal procedure after incidents or accidents with an impact on European level. When it is agreed to start a procedure, a dedicated Task Force

composed of experts is created. These Task Forces aim to create an atmosphere of trust in which the experts analyse the problem and propose solutions. This provides an opportunity to better understand the implementation of the legal framework by the actors involved, and capture areas for improvement or simplification. The Agency has acted as secretariat for a number of Urgent and Normal Procedures since the launch of the JNS in 2017:

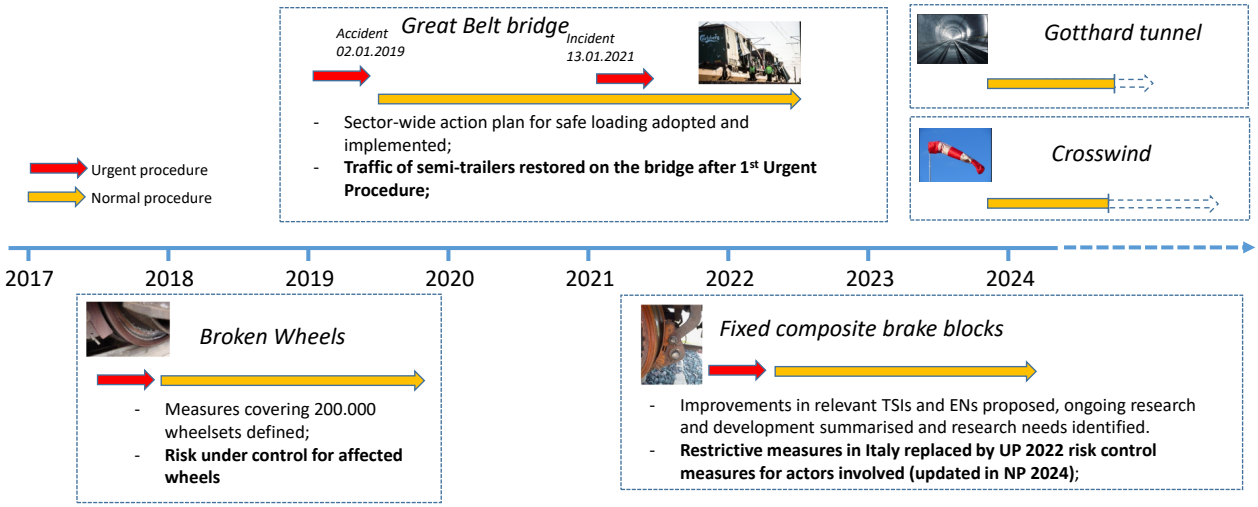

Figure 13 : overview of JNS activities since 2017.

Main procedures were:

- The JNS Urgent and Normal Procedure “Broken Wheels”;
- The JNS Urgent Procedure “Accident on the Great Belt bridge on 02.01.2019”, “Incident on the Great Belt bridge on 13.01.2021” and the Normal Procedure encompassing both Urgent Procedures;
- The JNS Urgent and Normal Procedure “Fixed composite brake blocks”

During these procedures, important feedback on the implementation of the European legal framework including the CSMs has been collected.

A recurrent issue is for example the risks linked to the interfaces between the railway undertaking and the infrastructure managers (with a link to the CSM REA).

Another important issue is the monitoring of risks linked to activities of contractors (with a link to the CSM on Monitoring).

5.5.3 Feedback collected during further developing the legal framework

During the meetings of various working parties, RISC and EC Expert Groups, sector representatives also shared observations on other CSMs that could be impacted by the expected new CSM ASLP.
Possible areas for improvement and simplification identified are :

- The need for harmonised approaches for risk management : use the principles and methods developed for the reporting of accidents and incidents, such as the building blocks, also in the pro-active identification of risks. This can be applied to the Common Safety Methods for Risk Evaluation and Assessment, for example;

- The importance of describing the risk control measures and their effectiveness and the need to document the continuous improvement through collecting of evidence. This can support the Common Safety Methods for Monitoring, for example.

5.5.4 Feedback collected from Information Requests

Furthermore, the Agency offers the sector the possibility to ask questions on the Common Safety Methods through the dedicated email address for information requests as mentioned on its website. Based on the questions received, the Agency has collected Frequently Asked Questions and published replies on its website. These questions already provide a good indication of where potential areas of improvement could be located.

5.5.5 Feedback collected from the various reporting activities

The Agency collects data and reports through various channels. The Report on Railway Safety and Interoperability in the EU for example, is a key element in the Agency's continuous effort to better understand the situation of European railways and its evolution over time in terms of safety and interoperability. The data contained in this report can be used to identify areas for improvement towards reaching a more efficient and effective railway system for all citizens of Europe: the Single European Railway Area. The report is also an important source of information for decision-making at EU and Member State levels. For the safety part this report is based on the Common Safety Indicators/Targets.

The ex-post analysis carried out to evaluate the effectiveness and impact of railway policies, regulations, and projects after they have been implemented, and in particular the ex-post analyses on the CSM Risk Evaluation and Assessment and the CSM Monitoring, are important for assessing the actual outcomes and identifying areas for improvement within the European rail sector.

The exercise of data collection provides proposals for improvement and simplification for the CSM on Common Safety Targets. These include for example concerning the National Reference Values:
See the chapter §6.5 for more information.

5.5.6 Other mechanisms for collecting opportunities for improvement

Finally, the Agency collected opportunities through various tasks of assistance to stakeholders, such as the European Commission, Member States, etc..

For example, Article 35.5 of the Agency Regulation stipulates the possibility for the Agency to undertake assessments for priority countries and provide assistance to the European Commission in case of serious accidents.

So far this has been done for about 5 Member States and for two serious accidents. Due to the sensitivity of the events, the findings have not always been made public. However, the Agency staff involved in these activities have been interviewed as part of the Quick Scan and the resulting improvement proposals have been captured.

5.6 Vision statement 5: Future CSMs should further incorporate a risk-based approach

5.6.1 General

The aim of this principle is to continue building on the pathway set forward by the current set of CSMs, as described in title “4.2.2. Risk-based approach”.

The current understanding of Safety Management Systems by some operators resembles a group of islands, where each module stands alone. This perspective, while meeting the letter of the law, often misses the spirit of a truly integrated and effective SMS—the essence of a risk-based approach. In rectifying this, the focus will be to bridge these islands, to move away from the siloed interpretation and towards a cohesive network where all elements of the SMS interact seamlessly. The vision is for each module—be it risk assessment, training, or safety assurance—to no longer be seen as an isolated entity but as part of an interconnected system to facilitate a risk-based approach.

The aim is not to reconstruct the SMS from its foundations but to strengthen the existing structures, ensuring they are interlinked in such a way that supports a robust, risk-based approach. This enhancement is critical to elevate the SMS from a regulatory obligation to a dynamic framework capable of navigating the complexities of modern railway operations with agility and foresight. Through this interconnectedness, the risk-based approach will become the current that runs through the SMS, energizing and uniting each aspect to achieve a higher standard of safety.

5.6.2 The concept of risk-based approach

A Risk-Based Approach forms the cornerstone of a comprehensive Safety Management System within the railway sector. This principle mandates that decisions related to safety are made not on a reactive or ad-hoc basis but through a systematic, evidence-based assessment of risks that could impact the operation's safety integrity.

At its core, a risk-based approach necessitates a proactive stance towards identifying potential hazards that could lead to safety incidents within railway operations. This involves a thorough analysis of all aspects of railway operations, from the design and maintenance of infrastructure and rolling stock to the management of human aspects and operational procedures. By prioritizing risks based on their severity and likelihood, railway operators can allocate resources more efficiently, focusing on mitigating risks with the highest potential impact on safety.

Incorporating a risk-based approach extends beyond proactive hazard identification and mitigation; it also shapes critical functions like performance review. Operators should use the organisation’s overall risk picture/risk scenarios as a steering mechanism to direct their monitoring efforts towards the areas where the highest value can be added in terms of risk reduction.

Also risk-based auditing represents a strategic pivot from traditional compliance checks to a more dynamic, intelligence-driven examination. This auditing method aligns the intensity and frequency of audits with the levels of risk identified, thus ensuring that audit resources are focused where they have the most impact on enhancing safety.

The implementation of a risk-based approach follows a structured process, encapsulated in the cycle of risk identification, risk assessment, risk mitigation, and monitoring. This cycle begins with a comprehensive

identification of all conceivable risks, followed by a detailed assessment to understand their nature, causes, and potential consequences. Risk mitigation strategies are then developed and implemented, tailored to reduce the risk to an acceptable level or eliminate it altogether. Finally, ongoing monitoring and review processes ensure that the risk management measures are effective and allow for adjustments in response to new information or changes in operational conditions.

Adopting a risk-based approach also means that safety management becomes a dynamic process, capable of adapting to new challenges and evolving safety landscapes. It acknowledges that as railway operations grow and change, so too do the risks they face. Therefore, a risk-based SMS is inherently flexible, designed to evolve and incorporate new data, technologies, and methodologies to continually enhance safety.

Moreover, this approach fosters a culture of continual improvement within the organisation. By regularly reviewing and updating the risk assessment and mitigation measures, railway operators not only comply with current safety standards but also anticipate future challenges. This forward-looking perspective ensures that safety management is not just about maintaining the status quo but about striving for higher safety standards and better performance over time.

In essence, a risk-based approach to safety management empowers railway operators to make informed decisions about where to focus their safety efforts. It promotes a culture where safety is not seen as a static requirement but as an integral part of operational excellence. Through systematic risk management, railway operations can not only prevent accidents and incidents but also optimize their operations, ensuring that safety and efficiency go hand in hand. This principle underscores the belief that effective safety management is both a strategic asset and a moral imperative, laying the foundation for a safer, more reliable railway sector.

The overarching vision for the review of the Common Safety Methods encapsulates a forward-looking framework designed to enhance safety management across the railway sector. At its heart is the ambition to unify safety practices under a cohesive and effective structure that builds on existing principles while addressing emerging challenges. This vision emphasizes a systematic, risk-based approach that integrates safety into the core of organizational operations, ensuring that safety is not merely a regulatory requirement but a fundamental value driving decision-making and performance.

A cornerstone of the vision is the conceptualization of the Safety Management System as a dynamic, interconnected framework that operationalizes safety through three critical components: the Safety Vision, formal safety processes, and cultural reinforcement. The Safety Vision sets the strategic direction, articulating a deep commitment to safety that transcends compliance. It provides the foundation upon which processes and actions are built, aligning daily operations with long-term safety aspirations. The SMS formalizes this vision into structured processes, ensuring that risk assessment, hazard mitigation, and continuous monitoring are systematically embedded into organizational practices. To reinforce this, the vision highlights the importance of cultivating a safety culture where shared values, behaviours, and practices create an environment of mutual trust and proactive engagement with safety.

This overarching vision also recognizes the necessity of continual improvement. Rather than pursuing relentless, uninterrupted progress, it advocates for measured, deliberate advancements that allow organizations to consolidate gains before moving forward. This approach ensures that safety improvements are sustainable, effectively integrated, and aligned with evolving operational needs.

By fostering a holistic understanding of safety management, the vision encourages collaboration and learning across the sector. It underscores the importance of aligning with international norms and practices, leveraging collective insights, and promoting innovation. Ultimately, this vision sets the stage for a transformative review process that prioritizes safety as both a moral imperative and a strategic enabler,

ensuring the railway sector remains resilient, efficient, and future-ready.

6 Annex – Detailed description of outcome/results of expanded scan

6.1 CSM REA

6.1.1 Main Observations

The ERA report on the EU railways sector experience with the CSM for risk assessment (hereinafter the "REX on CSM REA") includes the Agency analysis of the NSA, ECM Certification Body and AsBo inputs and the recommendations for improving the understanding and for helping with the implementation of the CSM. However, this report is based on a survey dated 2017 with a limited number of respondents and does not take into account the ERA experience accumulated in the following years after the 4th Railway Package, by which the Agency was entrusted with new responsibilities, particularly that of issuing single safety certificates (>200 since 2019). Nonetheless, its conclusions are still mostly applicable nowadays.

In general, the main problem seems to be a lack of broad understanding of a harmonised risk concept in the railway sector.

The REX on CSM REA shows that although the level of understanding and implementation of that CSM differs a lot across the EU, only a small minority of companies (especially those more mature with the risk management concepts), including IMs, RUs, ECMs and big manufacturers, well understands and correctly apply the method while a large majority of companies (usually more familiar with the application of rules rather than with risk management), RUs, ECMs and a few IMs, still face difficulties in understanding and correctly applying the method.

Experience also shows that although the process set out in the Annex I to the CSM REA is clear and consistent with European and other international standards, it appears from the current structure of the CSM that this process is in practice, for many operators, limited to the change management and, in particular to the "significant" character of a change. This leads to a twofold approach: On the one hand the CSM REA process is applied for significant change only and, often because of the cost and time, the change is seldomly declared as significant. On the other hand, risk assessment applied to RUs and IMs' activities is managed by means of another process.

In practice, demonstrating that a safety relevant change is non-significant already requires a proper and formal risk assessment of the intended change. No matter whether a safety-related change is significant or not, all risks arising from the change must be identified and assessed accordingly. Moreover, setting up a different risk assessment process for change management and for RUs and IMs' operational activities may impact the understanding of CSM REA as well.

Therefore, applying the process set out in the Annex I of the CSM REA (outside the question of the AsBo), as part of the general risk assessment process required by the CSM SMS, if possible without being limitative to significant changes, would clarify the scope of the CSM REA and facilitate the application of a common risk assessment process.

As already introduced before, instead of carrying out a proper risk assessment on changes to the railway system, the experience shows that the proposer of the change mainly focuses on trying to demonstrate that the intended change is non-significant. From the REX on CSM REA, it was already established that a very small minority of changes (less than 5%) are significant and those changes are mostly of technical nature. The

proposer of the change may not consider the independent safety assessment carried by an AsBo useful. The reason of this can also be related to the costs and time needed for assessment of each (also minor) change. Finding another way to involve the AsBo (e.g. once a year or once for the validity of SSC certificate) could improve the applicability of significant changes and meet the expected outcome of the CSM REA.

Another reason for the above-mentioned problem is that the assessment of the significance of a change is usually carried out through a qualitative approach using the criteria provided in Article 4 of the CSM REA. Quantitative support (such as a matrix) or a more efficient way of describing the various criteria could be helpful in assuring a more standardized way of assessing changes among the proposers.

As already reported in the REX on CSM REA, the latter is less understood and less applied to "operational and organisational" changes in comparison with technical changes. It is observed that companies do not know how to use the criteria set out in Article 4 of the CSM REA for deciding on the significance of those changes. So, the decisions on their significance are even more difficult than for the technical changes. To better understand this difficulty, the view of the RUs and IMs need to be considered as well. Clarifying the differences and the applicability may raise awareness of the railway sector.

Other items may also be considered such as:

1) Analyse the possibility to the requirements set on the NoBo's as a source of inspiration for AsBo's that are subject to equivalent obligations but also rights, including a legal base for the coordination and cooperation of AsBo's, for the development and application of RFUs, and for their monitoring;

   A proposal from CER, explicitly supported by NSA Germany, has been noted, which aims to analyse the possibility of strengthening the position of Assessment Bodies in the EU railway market. This proposal includes considering the establishment of a legal basis for the coordination and cooperation of AsBos, the development and application of Railway Functional Units (RFUs), and mechanisms for their monitoring. While the Agency supports recognising the significant role of AsBos, it acknowledges that any measures must respect the current remit and distinct responsibilities of AsBos, ensuring that they are not perceived or misinterpreted as certification bodies. This proposal is included in the vision document as a point for further analysis and discussion during the subsequent stages of this initiative.

   Additionally, CER has raised concerns about current AsBo reporting practices, noting that reports often emphasise the correct or incorrect application of the CSM REA method without sufficiently addressing the results of its application. This approach may stem from a desire to avoid perceived responsibility for the outcomes but limits the value of the reports. In instances where results are included, the analysis is often qualitative and has limited influence on the proposer's chosen safety measures.

   To address these issues, CER suggests strengthening the responsibilities of AsBos to ensure their reports include clear evaluations of both the application of the CSM REA method and the results it generates. Specifically, reports should contain assessments of the identified risks and the appropriateness of the proposer's chosen risk control measures.

2) If the proposal above does not meet a large consensus during the revision of the CSM REA, consider revising Article 4 to provide clearer guidance on distinguishing between significant and non-significant changes. The aim would be to ensure a balanced and practical application of the criteria while remaining aligned with the principles of a risk-based approach. Specific thresholds or numerical targets should not be included to avoid misinterpretation or inappropriate application. Instead, focus should be placed on qualitative criteria and sector-wide consensus to guide decision-

making;

3) Clarify the usability of the CSM REA for operational and organisational changes (see above), especially regarding the roles of an AsBo vs. the role of the Certification Body (NSA or ERA);

4) Clarify Article 6(4) and the roles of NSAs and ERA in the different listed options;

5) Based on the ERA return of experience with the monitoring of NoBo's and the weaknesses of accreditation bodies in finding competent railway experts to assess the specific scopes of accreditation of the AsBo's, consider on setting in place two scenarios for the acknowledgement of AsBo's (based on feedback received the issue is also applicable for NABs):
   a. preferred scenario: in the countries where the NSA has the capacity and resources, recognise the AsBo's based on a mutual acceptance of the preliminary accreditation of AsBo's vs. the ISO/IEC 17020 standard. The accreditation bodies would check the compliance with the ISO/IEC 17020, whereas the NSA would check the AsBo compliance with the railway specific criteria and requirements in Annex II of the CSM REA;
   b. alternative scenario: in the countries where the NSA does not have capacity and resources, keep the accreditation of the AsBo's by the national accreditation body for the compliance with both the ISO/IEC 17020 and the railway specific criteria and requirements in Annex II of the CSM REA;

6) Currently, it is not always clear at which level safe integration needs to be demonstrated—whether at the level of components, subsystems, or the entire system within the EU railway architecture. Providing added clarifications on this issue could help ensure a more consistent understanding and application of the safe integration concept, making it clearer how each element should interact and fit within the broader system.

7) Examine the existence of legal bases for including if possible the Cyber Security threats and risks, the identification and management of Occupational Health and Safety risks, as well as the environmental risks in the scope of the CSM REA;

8) Include explicitly the avoidance of Single Point Failures in the system under assessment (the system must be robust enough to avoid that one single fault can lead to a major accident);

The vision document acknowledges the importance of avoiding Single Point Failures (SPFs) to enhance system robustness. As suggested by stakeholders, when avoiding SPFs is not feasible, these should be explicitly documented, and the associated risks should be managed through appropriate control measures. Additionally, the consideration of historical data on SPFs, where available, could support a more informed decision-making process regarding proposed changes.

This approach aims to strike a balance between enabling continuous improvement and managing the risks posed by SPFs, ensuring that the implementation of necessary changes is not discouraged while maintaining a strong focus on safety.

9) Mention explicitly the HOF risks regarding the hazard identification of all foreseeable hazards.

10) Provide additional guidance to proposers of significant changes on how to involve the AsBo from the start of the change process. This ensures that the AsBo is involved early—starting from the

point when the significance of the change has been determined—to prevent delays and improve the planning and coordination of the project.

Stakeholders have expressed the view that the current scope of the CSM REA, as defined in Article 2, is primarily focused on change management. This focus may unintentionally limit the broader application of the CSM REA to the overall scope of risk management within a Safety Management System. In particular, the absence of explicit guidance on applying risk analysis for foundational activities, such as the development of a hazard log for a new Railway Undertaking, has been identified as a gap.

6.1.2 Conclusion

The risk assessment process set out in Annex I to the CSM REA is consistent with European and international standards such as ISO 31000, CENELEC EN 50126 and 50128, in use for almost 30 years from their early versions. Despite 20 years of EU railway legislation with the aim of moving from a rule-based approach to a risk-based approach, the railway sector still struggles how to put in practice these standards to fulfil the high-level requirements contained in the CSMs.

Although it is not proposed to touch upon the process set out in Annex I, considering both the REX on CSM REA and the experience gained since the entry into force of the 4th Railway Package, a revision of the CSM would be appropriate to avoid areas of interpretation and to facilitate the understanding and harmonised application of the risk assessment process by all relevant actors consistent with new or amended legislation.

Some of the recommendations contained in the REX on CSM REA may still have some merits today. In particular, the application of a risk-based approach in railways could still be enhanced by delivering proper and targeted training and education through concrete examples in the native languages of the railway experts across the European Union.

6.2 CSM on Monitoring

6.2.1 Main Observations

The ERA report on Return on Experience on the CSM for Monitoring (2017) has shed light on significant challenges that underscore a sector-wide issue: the misunderstanding and misapplication of risk-based safety management systems by Infrastructure Managers and Railway Undertakings. These challenges, crucially, are not defects of the CSM methodology itself but rather reflect a broader disconnect within the sector regarding the understanding and implementation of risk-based safety concepts. (This statement, after review, appears to be challenged by some of the stakeholders involved, more investigations therefor need to take place as part of the later project stage. This is also a reason request a mandate for a more significant update of the CSM on Monitoring).

It's evident that, although the methodology is effective for companies mature in risk management, there is an overarching need for a deeper knowledge and expertise in risk management methods consistent with European and international standards.

The feedback and observations within the ERA report on CSM for Monitoring provide valuable insights into the practical application and challenges of the current monitoring system.

The observations from this report have been supplemented or reinforced with the feedback the Agency obtained through the activities in the field of Single Safety Certification.

The primary concern identified is the significant gap between the theoretical risk-based approach outlined in the CSMs and its practical application across the sector. This gap manifests in several problematic behaviours among stakeholders, particularly a tendency among many IMs and RUs to treat the SMS as a static set of rule-based protocols rather than a dynamic outcome of systematic risk assessment processes. This approach often leads to the application of safety measures without a robust understanding of their scope or the specific risks they are designed to mitigate. A prevalent rule-based focus within the SMS can lead to misapplication of rules or their use in controlling risks outside their intended scope. Consequently, this could lead to organisations applying rules without fully grasping their purpose or applicability.

Furthermore, the observations highlight that merely having a risk register is insufficient unless it is comprehensive and properly prioritized according to the organization's specific safety objectives. Current practices often see risk registers that overlook or underestimate crucial threats, revealing a crucial oversight in risk prioritization. This deficiency points to a pressing need for establishing clearer connections between identified risks and the various SMS elements—rules, processes, and procedures—to ensure that monitoring activities are not just routine checks but proactive tools for safety verification. This highlights the need for a strategy that prioritizes risks aligning with the company's safety objectives.

The ERA report on Return on Experience on the CSM for Monitoring (2017) highlighted significant challenges faced by the sector in applying the principles of the CSM for Monitoring. These challenges were attributed to a widespread misunderstanding and misapplication of risk-based safety management systems by Infrastructure Managers (IMs) and Railway Undertakings (RUs). At the time, the report concluded that these difficulties were not caused by defects in the CSM methodology itself but rather reflected a broader disconnect in the sector regarding the understanding and implementation of risk-based safety concepts.

However, during the drafting and consultation process for this vision document, some stakeholders have raised concerns challenging this conclusion. They argue that the legal text of the CSM for Monitoring, or

its interfaces with other CSMs, may indeed contribute to the difficulties experienced by the sector. These stakeholders emphasize that ambiguities in the interfaces between different CSMs may obscure the specific inputs required from one CSM to another, complicating the practical application of the CSM for Monitoring.

Given this feedback, it is clear that further investigation is required to fully understand the root causes of these challenges. A more thorough review of the CSM for Monitoring, alongside its interfaces with other CSMs, may help clarify the required inputs and streamline its application.

In light of the sector's concerns and the need for deeper analysis, it may be necessary to request a broader mandate from the European Commission to enable a comprehensive review and potential update of the CSM for Monitoring. This would ensure that the methodology aligns more closely with the practical needs of IMs and RUs, while addressing any legal ambiguities or interface issues that could hinder effective implementation. Such a mandate would aim to strengthen the clarity and usability of the CSM, ultimately supporting the sector in achieving its safety objectives.

Another critical issue is the prevalent practice of monitoring based on post-occurrence measurements rather than pre-emptive actions. This reactive monitoring fails to capitalize on the potential of the SMS to actively prevent incidents by identifying and addressing deficiencies or latent errors before they lead to near-misses or accidents.

Next to this, feedback from ECM certification bodies has further illuminated challenges related to supervising subcontractors and ensuring their adherence to monitoring requirements. When conducting a review of the CSM on monitoring, a reflection should take place on how monitoring should be effectively organised when activities under the responsibility of an entity are externalised to subcontractors

The potential introduction of the Common Safety Method for the Assessment of Safety Levels and Performance is anticipated to address some of these challenges by providing a more structured and harmonized approach to risk control measures and incident reporting. The CSM ASLP aims to enhance the linkage between risk assessments and monitoring activities, thus promoting a more proactive safety management environment across the European railway sector.

6.2.2 Conclusion

The comprehensive analysis within the ERA report on the Common Safety Method for Monitoring (CSM MO) and the observations made during the Single Safety Certification activities provide significant insights into the existing challenges and opportunities for enhancement in the implementation of safety management systems across the railway sector. This conclusion synthesizes the main observations and outlines strategic directions for future developments that can impact the CSM on Monitoring.

Firstly, it is evident that a profound gap exists between the theoretical framework of the risk-based approach prescribed by the CSMs and its practical application by Infrastructure Managers (IMs) and Railway Undertakings (RUs). This misalignment is largely due to a lack of deep understanding and effective implementation of risk management principles. Many stakeholders continue to perceive and employ the Safety Management System not as a dynamic and integrated framework driven by systematic risk assessment but as a disparate collection of rule-based protocols. This fragmented approach not only undermines the efficacy of safety measures but also hampers the holistic integration of the SMS into organizational practices.

To bridge this gap, there is a pressing need for enhanced education and training initiatives aimed at deepening the sector's comprehension of risk-based safety management. This involves not only broadening

the knowledge base but also fostering a cultural shift towards viewing the SMS as an essential, proactive tool in the operational strategy rather than a compliance obligation. Such a shift will ensure that safety management becomes an integral part of the organizational ethos, aligning with business objectives and enhancing operational integrity.

Additionally, the observations highlight the critical need for more robust and comprehensive risk registers that are effectively prioritized according to actual safety threats. Enhancing the linkage between identified risks and the components of the SMS is crucial. This would involve the development of clearer guidelines and tools that aid in the accurate assessment, mitigation, and monitoring of risks, ensuring that the SMS functions as a dynamic and effective framework for managing safety.

The forthcoming CSM for the Assessment of Safety Levels and Performance presents a promising opportunity to address these challenges. By integrating new concepts, mechanisms, and building blocks, the CSM ASLP is poised to provide a more structured and harmonized approach to safety management. This approach will not only streamline the process of risk identification and mitigation but also enhance the proactive capabilities of monitoring systems. The adoption of the CSM ASLP could catalyse a significant advancement in the sector's ability to manage safety risks more effectively.

In conclusion, while the current observations underscore significant challenges, they also delineate a pathway towards substantial improvements in safety management across the European railway sector. The adoption of the CSM ASLP, coupled with an increased emphasis on risk-based safety education and a cultural shift towards integrated safety management, will be pivotal in advancing the sector towards higher standards of safety and operational excellence. As such, the ongoing review and enhancement of the CSM framework is not just a regulatory necessity but a strategic imperative to ensure the continued safety and reliability of railway operations in Europe.

6.3 CSM SMS

6.3.1 Main Observations

Regulation (EU) 2018/762 applies since June 2019 to both railway undertaking and infrastructure managers applying for a single safety certificate or for a safety authorisation in accordance with the provisions set out in the recast Safety Directive. From the different CSMs subject to revision in the present document, this is therefore the most recent one with a return of experience mainly limited to the new role of ERA as safety certification body both assessing compliance of the railway undertakings' safety management system against Annex I to CSM SMS and also fostering exchange views with the national safety authorities in view of harmonising the safety certification process and the decision-making across the EU.

The CSM SMS is a cornerstone of the safety of rail operations and the SMS is expected to be risk-based. The risk management should then be the core engine of the SMS driving its different processes. In that respect, the role of the risk assessment and its interface with the different SMS processes could be further emphasized (e.g. the results of monitoring activities nurturing the risk assessment process, the application of the risk assessment process to identify competency requirements for carrying out safety-related tasks). However, it should still be weighed if such a change would create added value and if the CSM SMS is the best place to do it (instead of other CSMs being referred to in the CSM SMS or possibly new CSMs under development or to be newly developed). As the CSM SMS also provides an overarching system approach making consistent links between its processes and other relevant CSMs (e.g. risk assessment and CSM REA, monitoring and CSM on Monitoring), the impact of any changes made in these CSMs should then be analysed and where relevant, reflected in the CSM SMS. On the other hand, the CSM SMS could also benefit from the simplification of other CSMs that create barriers for its effective implementation. As it is acknowledged above that the SMS is driven by a risk-based approach, the application of Annex I of CSM REA to identify, analyse and evaluate the risks of the company's activities would streamline the approach to risk assessment while encouraging the same process to be applied irrespective of a change. As it currently stands, it is often the case that companies applying the CSM SMS end up with a risk assessment process and a change management process when in fact the risk assessment process could perfectly handle both situations (i.e. analysing the company's activities as well as analysing proposed changes).

Moreover, since the adoption of the CSM SMS, other Regulations such as the ECM Regulation and the TSI OPE have been amended. In the case of ECM Regulation, the requirements for asset management were set out at the time that the scope of ECM Regulation was limited to freight wagons. Now, the scope of ECM Regulation has been extended to all vehicles which allows for a simplification of the CSM SMS requirements on asset management. In the same way, the adoption of the future CSM ASLP will also have an impact on the CSM SMS' requirements on monitoring knowing that the CSM ASLP will encourage the operators to perform a self-reflection exercise on the maturity of the risk management activities of their SMS as part of a yearly safety performance self-assessment. Therefore, the CSM SMS requirements should be re-evaluated considering the evolutions of the EU safety regulatory framework and international standards (such as ISO management system standards, whereby the structure of the current CSM SMS derives from, and cybersecurity in railways).

The CSM SMS introduced the concepts of safety culture and human and organisational factors. In most of applications processed by ERA, the "strategy" worked out to improve them is often understood in different ways and results in actions that are motivated by the safety certification but not really by an ambition to improve with clear motivations and expectations. Moreover, it is quite difficult for railway undertakings to link those concepts with the reality of day-to-day operations. The guidance supporting the CSM SMS has been

updated to highlight human and organisational factors and safety culture. Even though changes to the legal text to improve understanding of these concepts may not be easily identifiable, we cannot exclude that this point could merit reflection as part of the CSM review exercise.

The revision of the CSM SMS (and/or the supporting guidance) could also contribute to refining the wording or the content of some of the requirements following experience gained with SMS assessments, with particular focus on:

- Ensuring unambiguity of those requirements that are most often misinterpreted by the stakeholders (e.g. risk assessment and change management as outlined above, but also the competency framework, role of staff and interested parties in the SMS, internal and external consultations, emergency management or management review).
- More explicit consideration in the SMS requirements of the specificities that new entrants are confronted with, as current wording is strongly oriented towards already operating companies. This should include, among others, links to business plans indicating a forecast of the planned scope of operations, the required assets and their sources and the evidence of measures taken to implement these plans.
- Finding an appropriate balance between describing on the one hand the expected outcomes of the SMS and on the other hand describing the required processes that an applicant should have in its SMS (e.g. referring to the identification of safety related requirements and interested parties instead of the list of requirements and the list of interested parties).

More explicit indication that SMS arrangements cover the entire area of operation including (where appropriate) border stations, all described in a uniform manner, and not just operations in the country of principal activity with add-ons for other countries.

Some stakeholders have highlighted the need to establish a clearer link between the risk identification process outlined in the CSM REA and the proactive monitoring activities described in the CSM MON. One potential approach could involve addressing this connection within the CSM on SMS Requirements, given its role as the overarching framework for implementing Safety Management Systems.
At the same time, other alternatives may warrant exploration, such as revising the individual CSMs to explicitly define their interactions or considering a more integrated approach. These possibilities will be further explored to ensure the revisions effectively enhance understanding and practical application across the sector.

6.3.2 Conclusion

Although the CSM SMS is quite young, the Agency has collected substantial feedback on its implementation through the safety certification activities. This has identified several opportunities for improvement. First and foremost, the risk-based approach, that is the core engine of the SMS, could be simplified by encouraging the same process to be applied whenever risk assessment is concerned. As such a process already exists in the CSM REA, a more efficient synergy could be found between the two CSMs. Secondly, the CSM SMS should consider the evolution of the EU safety regulatory framework (e.g. the ECM Regulation, the TSI OPE and the new CSM ASLP) and relevant standards (such as the ISO High Level Structure and associated management system standards, and the good practices in cyber risk management by ENISA) to ensure better consistency, to cope with new challenges in railway cybersecurity and to simplify the legal provisions wherever practicable. Interfaces with the domains of occupational health and safety, as well as the environment, can also be taken into account if deemed feasible.

The strategy to improve safety culture and to facilitate the integration of human and organisational factors is often subject to residual concerns during the safety assessment in view of granting single safety certificates. A reflection should take place on the most suitable way to improve the railway companies' understanding (e.g. guidance, training) while at the same time avoiding to create additional complexity through amendments to the legal text.

Providing greater clarity on requirements that cause interpretation difficulties, a literal indication of the required processes and not only their outputs in some requirements and taking into account the specificity of new entrants could also be an objective of this revision.

6.4 CSM SUP

6.4.1 Main Observations

The Common Safety Method on Supervision (EU)2018/761 was prepared as a continuation of the previous CSM 2012/1077. However, some elements were removed from the legal text and placed in Annex I such as the key principles and other areas were added such as the need for a supervision strategy and plan and coordination between NSAs on cross border supervision. Because supervision is a function of NSAs and not ERA the CSM is relatively speaking quite light in its direct requirements on NSAs. This has led to some misunderstandings of what is required and key concepts such as that of risk-based supervision.

Based on the feedback from NSA monitoring audits, it appears that about 70% of NSAs have had serious findings (deficiencies) relating to their supervision process. Identified issues, either classified as observations (less serious findings) or as deficiencies, related to several aspects of the supervision, such as lack of risk-based supervision, gaps in the supervision activities (not all actors / activities being supervised), lack of clarity of supervision strategies or plans (including confusion over what the difference is), ineffective use of various supervision techniques, lack of follow up of supervision activities and lack of effective use of enforcement powers leading to insufficiently effective supervision activities, lack of coordinated supervision activities, etc.

Such issues seem to have multiple and interconnected factors. These may relate to lack of understanding of the EU legislation by the national authorities – NSA, competent ministries, etc. There could be in some cases inadequate implementation as the EU legal framework could have integrated into the national legislation and subsequent approach on top of the former legislation and approach rather than superseding them. In other cases, the NSA has limited resources in terms of staff numbers, competences, budget, etc, leading to the NSA having difficulties organising its resources and competences to give effect to the EU legislation.

Furthermore, based on its experience as safety certification body, it appeared to ERA that the feedback provided from NSAs' supervision activities may vary in term of quality and frequency. In addition, it appeared that the link between SSC and VA processes - whether the NSA or ERA are the authorisation entities - and the supervision processes should be strengthened.

The NSA Network has established a subgroup on supervision to have a common reflexion including others on what risk-based supervision is. Such an initiative shows that there is a clear need and request for further clarification in the Regulation and in the related guidance.

Finally, the CSM Supervision contains an article on the competence of NSA staff. Whilst NSAs may not be covered by the potentially newly proposed CSM on Competence is essential that the current Article on the CSM SUP is aligned with what is written in the new CSM in a generic sense.

6.4.2 Conclusion

It should be further assessed whether the Common Safety Method on Supervision (EU) 2018/761 can be further clarified so that proper implementation will be more widespread among NSAs. The needed level of details of the requirements should be further discussed and assessed. Indeed, detailed requirements would leave little room for manoeuvre to NSAs in the implementation to adapt to their own specificities and the specificities of the sector in the concerned Member State.
To keep the balance between the risk of having inadequate implementation due to lack of clarity and the risk of too prescriptive and inadequate requirements, it would be recommended to have a light revision of the CSM, including such matters as risk-based supervision and the supervision strategy and plan, Annex 1 on the supervision process and Article 8 on the coordination between NSAs and with other bodies and authorities.

There will also need to be coordination with the proposal for the CSM on Competence to make sure that the two CSMs are correctly aligned on the subject.

To achieve the most workable CSM for the sector, a close consultation with them and in particular with NSAs should be set up to efficiently revise the text of the CSM and the related guidance.

6.5 CSM CST

6.5.1 *Main* Observations

The Common Safety Method for assessment of achievement of safety targets, hereafter referred as the Method or CSM CST, has been comprehensively evaluated in 2021. This section draws heavily upon the evaluation results, providing the key segments and adjusting to new developments where relevant.

The CSM CST was introduced through the Railway Safety Directive (2004/49/EC). It came into force in 2009 (Commission Decision 2009/460/EC) and aims to ensure that a high level of railway safety is maintained and, when and where necessary and reasonably practicable, improved while supporting the convergence of safety levels across the EU. It is meant to provide tools for the assessment of railway safety performance at Union level as well as for individual Member States (RSD, Recital 11).

The CSM CST and underlying CSIs are instrumental to ensuring safety monitoring in a regular and standardised way. Importantly, there has been no alternative instrument available that would meet all necessary criteria of transparency, accuracy, broad acceptance, or practicability for ensuring this task. NSAs and other railway stakeholders broadly agree on the relevance and added value of the CSM CST in that regard.

Still the reported weaknesses are several:

1) **Outdated NRVs:** The CSM CST compares safety performance of the most recent 5-year period (i.e. the Moving Weighted Average or MWA) with a set of NRVs. The Method anticipated that the reference values would be regularly updated. However, the last NRV update took place in 2012 using data from 2004 to 2009. This is problematic for several reasons.

   a) Railway safety improved considerably since 2004. Consequently, the method does not detect a possible deterioration in recent years too well, because the point of reference remains the 2004-2009 period when railway safety generally was worse. Figure 14 illustrates this evolution for all fatalities and serious injuries in the EU, Switzerland and Norway. For certain risk categories (e.g. passengers or employees), such drops can be even more striking. Yet, for some risk categories and countries the downward trend could have recently been reverted. But as the NRVs only take the period 2004-2009 into account, no deterioration would be noted. The key question therefore is if the current reference period is appropriate to determine if safety performance is maintained.

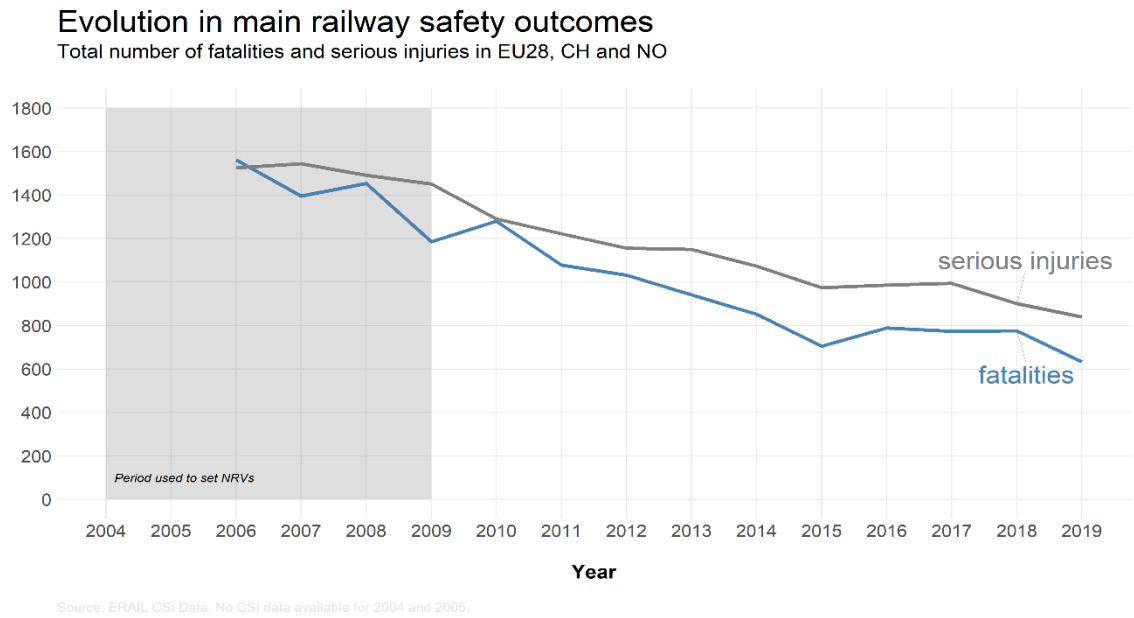

Figure 14 : Evolution in main railway safety outcomes.

b) The statistical practice in the field of railways evolved considerably since the publication of the RSD. For one, the EU expanded considerably since 2004 and the statistical practices of all MS have been largely aligned since. The railway data collected between 2004 and 2009 is however not fully harmonised. The risk categories 'Trespassers' and 'Others' are particularly affected by the changes in statistical practice. The consequence is that a possible deterioration may show up today simply because the category is more accurately monitored.

2) **Low counts:** The method is more prone to indicate a deteriorating safety performance if low counts of casualties are reported. The consequence is that countries with few accidents overall, or in a certain risk category, are more likely to be flagged for having a deteriorating performance.

   In practice, this limitation leads to discussions on the CSM CST's methodological weaknesses, rather than safety improvement actions.

3) **Delayed:** Another perceived limitation of the CSM CST concerns the delay between the data reporting and the assessment publication year. Respondents indicated that this limits the relevance of the report to influence safety improvement actions.

   It is important to consider that CSI data becomes available in October of the year following the analysed year. The CSM CST sets a deadline of 31 March of the analysed year +2 to have a sufficient buffer for any possible delays in CSI data delivery and validation. However, considering that the CSI data process has been optimised over the years, it would be possible for the Agency to start with the CSM CST assessment and publish the report by the end of the analysis year +1. This would be a time saving by three months. If the speed of publication increases, the operational relevance of the CSM CST assessment report would improve.

4) **Comparison of countries:** Another limitation of the Method is that no country specific characteristics (such as geography, utilisation rate, and quality of infrastructure) are factored in the formula to determine the reference values. Interviewees indicated that this prevents a more detailed comparison of national safety performances.

Admittedly, this was not the intended objective of the legislation and therefore can hardly be faulted. At the same time, several respondents expressed their interest in making such comparative assessments and therefore see the current country-centric and unweighted assessment formula as a limitation.

5) **Descriptive vs explanatory:** Interviewees also raised the comment that the Method does not provide any additional insights into why specific results were obtained. The CSM CST report is primarily a descriptive document which needs to be complemented by other evidence to shape safety improvement actions. This is the reason why respondents to the questionnaire answered mostly neutral on whether the CSM CST report contributed to national safety actions.

6) **Reducing variance in safety levels across Europe**: The CSM CST includes one provision to ensure that countries with risk levels that far exceed the European average do not use their past national performance as a point of reference (i.e. NRV), but rather a European CST. This CST is determined for each risk category by multiplying the average European value by 10. If the respective NRV of a MS is higher than the CST, the CST represents the maximum tolerable level of risk. In other words, if the safety performance of a country for a risk category is worse than 10 times the European average, the European average will be the benchmark.

   In practice, this provision does not have any effect. The multiplier is set too high for any NRV to be replaced by a CST. In fact, only as of a multiplying factor of 5 this method would start to have a noticeable impact. Figure 15 provides a normalised depiction of this analysis, illustrating that for all risk categories not a single country has a NRV higher than 10 times the European average (shown with the red dot). If the CST would be set at 5 times the European average, one to five countries would have a NRV higher than the CST depending on the category (i.e. country values above the orange dot).

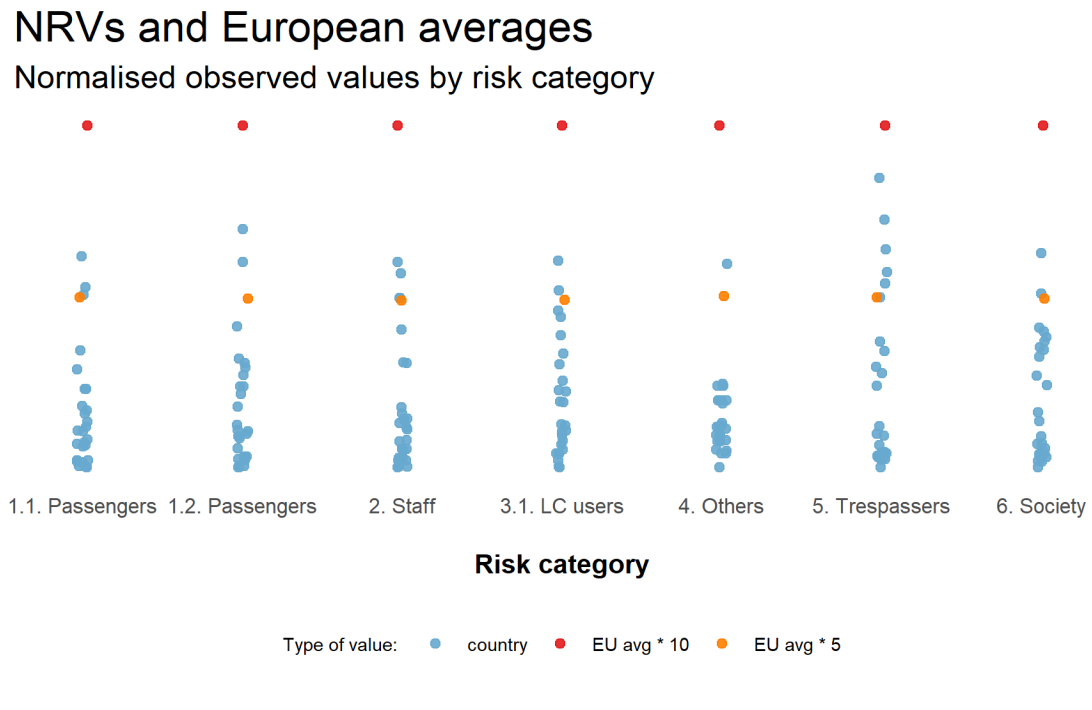

Figure 15: Overview of values used to derive the CST

Because no country exceeded the European average times 10, there was no need to provide an assessment of the estimated costs and benefits to achieve the CSTs, as set out by RSD Art. 7(3). And because the NRVs/CSTs have not been regularly updated, no priority areas for safety improvements have been identified.

This runs contrary to the provisions in the first and second RSD (2004/49/EC Art. 7(5) & EU/2016/798 Art. 7(5)) and makes that the CSM CST has not actively contributed towards reducing variance in safety levels across Europe.

The above weaknesses have lowered the relevance of the CSM CST, impacting the way how Member States perceive the CSM CST outcomes and their willingness to address issues when a deterioration has been noted.

As mentioned in section 5.4 “Vision statement 3: Future CSMs should make use of (future) CSM ASLP provided concepts / mechanisms” the concept of safety performance could also be applied also to the CSM CST. A self-assessment of the maturity of the implementation of railway safety legislation at the level of a Member State could offer valuable insights. This self-assessment could include assessing the robustness of the NSA/NIB setup, the effectiveness of rule regimes, enforcement capabilities, and more.

6.5.2 Conclusion

The evaluation concluded that the CSM CST has an important role in the EU legal framework for railway safety and it provides added value to the Member States (MS) and the European Commission. However, it suffers from poor application and enforcement.

The Method’s **relevance** is negatively affected by the lacking revisions of the National Reference Values (NRV) and Common Safety Targets (CST). This has a detrimental impact on the accuracy of the results. Furthermore, as the Method made that the CSTs are equal to the highest NRV in Europe, the CSM CST did and still does not promote the reduction of variance in safety levels. The relevance is weakened by the other mentioned points, too.

The **effectiveness** is limited due to the low compliance with enforcement actions and the absence of effective interaction with MS on safety improvements.

The **efficiency** of the Method is high as few requirements are imposed on stakeholders, and the benefits largely outweigh the associated costs.

The **coherence** between the CSM CST and other EU safety requirements is high. The Method often complements national interventions as well.

Finally, an **EU added value** exist as the CSM CST is often the only source of quantitative safety targets in MS and contributed (albeit often indirectly) to safety improvement actions.

Based on the evaluation, the following recommendations were provided to improve the CSM CST:

- Update NRVs/CSTs on the short term
- Promote the faster publication of the assessment report
- Make exclusive use of CSI data, so that misaligned historical Eurostat data is not used to determine new NRVs
- Automatically update NRVs to prevent the usage of an outdated baseline

- Ensure the application of enforcement actions as Article 5 has limited implications
- Revise the CST concept
- Adjust the statistical method so that it accounts for low casualty counts, incorporates country-specific characteristics for more nuanced comparisons, and provides explanatory insights to better support safety improvement actions.

It is noted that the CSM ASLP could resolve many of the limitations of the CSM CST if the legislation would introduce the possibility to assess safety levels and performance on a country level. It is therefore recommended to 1) Revise the NRVs of the CSM CST to increase the method's relevance will still being in use, 2) introduce requirements in the CSM ASLP to allow for country assessments, including an enforcement clause similar to article 5 of the CSM CST.

6.6 Competence management

6.6.1 Main Observations

Competence is a crucial part of the railway system performance in any type of workplace. Competence should depend on the context and the environment in which the activity is performed, and on the working culture of the organisation. A comprehensive competence management system will improve the understanding and management of human and organisational factors, of which the competence of individuals plays an important role. Thus, a well developed and managed competence management system will also be a key input for developing the maturity and safety culture of an organisation.

Competence is a key element to control safety risks on the railway, especially in degraded and emergency operations where the human's involvement is crucial. Therefore, competence has a crucial importance in the risk control measures defined and implemented by RUs and IMs, and where appropriate, by the other actors, as required by art 4.3 of the RSD.

In the current legal framework, competence is split between national rules in Member States and requirements for the development of a competence management system in the safety management system (EU Regulation 2018/762). In some Member States there are detailed national rules and in other Member States, there is a flexibility to develop a more systematic approach based on the needs and risks of the organisation. Where there are detailed national rules there is a reluctance to remove them because of a perceived lack of maturity of the sector. This has led to differing approaches which are not risk based, often outdated, and lacking the necessary flexibility to reflect the changing operational context of the organisations.

In the transition to the fourth railway package, some national rules were accepted under Appendix I. Current TSI OPE clarified the scope of application to all staff undertaking safety critical task. However, the 2023 version of TSI OPE suppresses the open points (related to point 4.6 Professional competences and to point 4.7 Health and safety conditions) for Staff with safety critical tasks other than train drivers, additional information for staff undertaking the safety critical tasks associated with accompanying a train other than train driver and additional information for staff undertaking the safety critical tasks. Reference is made to EU Regulation 2018/762 in relation to competence management system for the staff responsible for executing safety-critical tasks and safety-related functions. Therefore, the existing national rules should not apply any more.

In relation to improving marketability of the railway system, the CSM will help to develop a more systematic approach which will ensure that railway undertakings are not subject to different and sometimes confusing rules and requirements for when they operate in several Member States. Instead, the CSM will help them to adopt one framework and then adapt this to the operational context and risks from the cross-border operations and ensure that their staff are able to operate in a safe way in the range of operational needs and modes.

The EU legal framework

Since the development of the third railway package and the Railway Safety Directive (2004/49/EC), competence has been part of the requirements in the safety management system to ensure safety is maintained and where reasonably practicable improved. The fourth railway package and the revised RSD (2016/798) aimed to further improve safety through moving away from national rules and recognising that the SMS was the key tool for controlling risks. The adoption of the 4th RP confirmed that National Rules must

"comply with Union Law, including in particular TSIs, CSTs and CSMs" and not duplicate them (Art. 8(1) and (2) of RSD 2016).

Railway undertakings and Infrastructure Managers have the responsibility for ensuring that they have the necessary elements in place to adequately consider human capabilities and limitations as part of their operational safety.

Two other important EU legal instruments that also contain requirements on competence are (1) the various Decisions and Regulations on the TSI Operations and Traffic Management (the latest being EU Regulation 2019/773) and (2) Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community (TDD) which is currently being revised by the European Commission. TDD introduced the concept of licenses and certification of train drivers. In TSI OPE, the concept of minimum requirements relevant to professional qualification for the tasks associated with 'accompanying trains and with "preparing trains" was introduced in 2015. The idea was to set 'minimum' requirements so that the RU and IM could also add requirements from their risk assessments.

Analysis of National Rules

National rules are often created or updated following an accident or incident, without a proper systemic risk-based approach and are rarely updated to consider emerging good practice. The sector is often not consulted but is required to implement national rules that may not be aligned to their identified risks or effective working conditions, which may create performance and safety issues as well as difficulties in accepting and implementing the rules, from an operational perspective.

Competence is often an issue for cross border operation where Member States have different requirements on competence (from high level to very complex and detailed requirements). If a rule is not clear enough, it can be misinterpreted, which may increase the safety risks. If a rule is different across the various areas of operation between MS, then again this can lead to issues with application and can lead to higher safety risks (i.e., carrying out the same type of operation but with different risk control measures not adapted).

The SMS framework is designed to provide a basis for operators to consider the context of their organisation and then ensure that the correct competence requirements are in place, including for their contractors, partners and suppliers to manage the risks relevant to the type, extent and area of their operations.

It has been noted that there are diverging views among stakeholders regarding the description of national rules in the first paragraph of this section. While the analysis highlights challenges such as the lack of a systemic risk-based approach in creating or updating national rules, several National Safety Authorities have expressed differing perspectives. Specifically, some NSAs argue that the development and implementation of national rules often follow established risk management practices and include sector consultations.
This divergence of views underscores the complexity of addressing competence management across Member States and highlights the importance of continued dialogue to ensure that any proposed changes to the framework align with the realities faced by NSAs and the sector.

1. Identification and definition of tasks and functions

When imposing a list of safety-related and safety critical-tasks and associated competence to railway operators, the national rules do not consider the operational context and the results from the risk assessment. Having a better knowledge on their actual activities, railway operators can better assess the risks linked to each task and function and set the appropriate competence levels and criteria, based on the risk

control measures identified (in normal, degraded and emergency situations). However, some railway operators use the lists provided in national rules avoid defining any safety-related task, considering that they comply with the national rules. Railway operators also use these lists, to avoid defining any specific requirements to their contractors, partners and suppliers arguing that they are covered in the national rules. As a consequence, they do not ensure that they control all the risks posed by their activities.

In addition, as there is no harmonisation between Member States on the tasks and functions, when crossing borders RU, could be obliged to apply different requirements for the same person doing the same job (but in different countries), which may negatively impact safety and operational performance.

2. **Recognised training centres**

Some requirements on training centres could be acceptable as national rules because the recognition of training centres is the responsibility of the MS (usually the NSA). However, there should be no national rules requiring railway operators to use the one training centre recognised by the MS, because this is a barrier to interoperability. A cross border RU which has its own recognition in another Member State is required to adopt an additional requirement that is not always relevant to its operational context. This issue also generates extra costs when operating in an international context.

Article 5 of Regulation 2011/765 foresees that Member States may also permit railway operators being recognised for providing they meet the conditions. However, some national rules and NSAs practices restrict the type of entities which can and cannot be recognised as training centres.

3. **Training requirements including reassessment**

Recognised training centres could have formal training courses for drivers, and this can be permitted but not as a national rule. The railway operators should be free to choose how the training is delivered as part of their certification/authorisation process based on the outcome from their risk assessment.

Some national rules have very prescriptive requirements and do not consider technological change or innovation requiring new working practices. This can introduce new risks because the prescribed training may no longer be suitable for the operation. As an example, it is very rare to see any national rule covering training on non-technical skills. Compliance with detailed training requirements does not allow for ‘needs analyses’ and be consistent with the operational context and risk control measures.

Another issue often set out in a national rule is the number of hours of training required for tasks and functions, which varies widely across Member States. However, the number of hours is not that important whereas the continuous maintenance and assessment of staff competence is key.

Some railway operators misinterpret the rules and believe that monitoring and competence assessment is the role of the training centre whereas the training centre does not have the ability to continuously monitor the performance of the concerned staff. The railway operators will always be responsible for the continuous performance monitoring and - maintenance of competence of their staff. railway operators are also responsible to ensure that their contractors, partners and suppliers implement the necessary risk control measures.

4. Certification of staff (other than train drivers) including obligations to pass exams

Certification for train drivers is prescribed by EU law, but it is not prescribed for any other tasks. Many Member States have national rules requiring staff with safety responsibilities to be certified, without considering the operational context or results of risk assessment.

It also causes problems for cross border operation, for which railway operators face different, even sometimes contradictory, requirements between two member states. This also endangers the consistent development of their SMS and Competence Management System (CMS). The rules on certification makes difficult and sometimes impossible for railway operators to remain fully responsible for identifying, managing, and controlling the risks, as the responsibility can be shift from the railway operator to the NSA or the Member State, in this case.

The rules describing the procedures for examinations, examiners and trainers are often erroneous and based on prescriptive rules that have never been reviewed and updated (as already seen above). Therefore, they are not always based on current best practice and do not consider the development of new technologies.

In many cases, the need to have staff certified for specific tasks proves to be a barrier for foreign railway operators as they need to specially hire a person having the requested certifications or take measures to meet this requirement before being able to apply for SSC covering that Member State.

5. Documentation

Some national rules set very detailed and prescriptive documentation on exactly what a training centre or railway operator should have in relation to forms and procedures for the training and certification processes. This leads to misinterpretation from railway operators, considering that these are the only requirements applicable to them. However, some risk control measures are sometimes missing, such as recommendations for periodic assessment or processes to be implemented following an accident or for staff carrying out safety-related tasks. Back to work arrangements should not be a national rule but be part of the risk-based procedures in the railway operators' SMS. This is also linked to the necessary HOF systematic integration into the SMS processes and procedures.

6. Transposition of TDD

Many Member States transpose the requirements of the TDD into a national rule. However, transposition of Directives should not be national rules. Moreover, in some MS, the transpositions of TDD include additional constraints which are sometimes contradictory between two Member States (e.g.: experience of examiners on the national network requested, exam commission in some member states…) For example, prescriptive technical rules on train drivers' responsibilities may not consider the effect of the environment on their tasks.

The expectations and impacts of the national rules on competence are not always clearly defined. Very rarely is there any deep analysis of the benefits or improvements made following the implementation of the national rule and whether the risks are sufficiently controlled by the requirements. National rules existing for several years, often before the development of the third and fourth railway packages, are complex and cover unnecessary (or inconsistent) elements which are now mandatory in the SMS. Some national rules were created to control one risk but, due to the lack of systemic risk-based approach, inadvertently introduced (an)other risk(s).

Transposing the Train Driver Directive (TDD) through national rules can lead to unnecessary complexity and divergence between Member States, undermining harmonisation across the Single European Railway Area. National rules often become overly prescriptive, duplicating SMS requirements and creating barriers

for cross-border operations. This approach lacks flexibility and adaptability, making it difficult to align with evolving EU objectives and best practices. Transposing directives through higher-level national legislation ensures consistency, supports risk-based methodologies, and facilitates seamless interoperability. This approach helps achieve the broader goals of the EU railway safety framework while reducing administrative burdens.

Assessment of Single safety certificates

Commission Delegated Regulation (EU) 2018/762 (CSM on safety management system requirements), annexes I and II art. 4.2.1 states that: 'The organisation's competence management system (CMS) shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible…' Therefore, these cannot be covered by national laws/rules but should be part of a risk-based approach that is company specific. The railway operators define, as part of their Safety Management System, the relevant roles, tasks, competences, and training programs considering the outcome from the risk management (taking into consideration HOF, the scope, and the area of operations, …)

As mentioned previously, due to some existing the national rules, the railway operators do not fully take their responsibility which leads to a lot of confusion and inconsistency in the competence management system implementation.

Many RUs use the application of a national rule as the only way of meeting the requirements leading to a lack of ownership of competence management with the RUs believing that if they comply with the national rule there is no need to do anything more and considering all the risks are managed, which, as mentioned earlier is not true because highly dependent of the operational context.

This also contributes to a lack of understanding of a risk-based approach, which even if challenged by the Agency (residual concerns for supervision), may not be improved during the SSC validity, as some NSA will only supervise the compliance with the national rules even if they are not in line with the SMS requirements.

RUs are often confused by the SMS requirements and do not understand when asked about how they use the outcome from their risk assessment as input for the development of the CMS. They consider this requirement as confusing, duplicating and adding costs only bringing limited benefit.
Some Railway operators also consider they just have to apply the national rule and do not need to monitor the effectiveness of the requirements in controlling the identified risks, avoiding again to take full responsibility.

The competence assessment methods and training required for degraded operations, emergencies and other infrequent events may need to be different from those required for normal operations. Developing and maintaining competence in dealing with these situations is of great importance. It should be supported by the results from risk assessments, however the prescriptive training requirements prescribed in some national rules make it difficult to deliver.

The understanding of the need to consider 'back to work' arrangements following a long absence or involvement in an incident, or an accident are also poorly integrated in the CMS. Many RUs require additional training due to the blaming culture. The just culture and its subsequent focus on the care of the individual staff member is not yet sufficiently developed. More NTS may be needed.
Training requirements in national rules are very specific and do not cover issues such as training on the SMS and how this affects the delivery of safety related tasks. RUs do not always understand the benefits of consultation and engagement of staff, and this should feature as a key part of the training that they provide.

Sub-contracting activities including safety tasks should also be covered in the SMS. Some companies have no employee and use full sub contraction to cover this. Contrary to art4 of RSD, RU consider that this is the sole responsibility of the sub-contractor. It is reasonable to consider that the sub-contractor may provide the initial training, but the RU still has responsibility for ensuring (1) that staff can undertake the tasks and functions, and (2) that they can complete the task in a safe and competent way (monitoring). Among others, the RU should specify in the contractual arrangements the requirements expected from the contractor concerning competence and should appropriately check them during its monitoring activities. Moreover, there should be a continuous exchange of information between the RU and the contractor regarding key elements such as additional or refresher training, monitoring, issues which are detected, return of experience… This should also be part of the RUs monitoring process.

The operational responsibility for the safety always remains with railway operators and cannot be transferred to other parties. The railway operators using sub-contractors 'staff should develop their processes accordingly to cover correctly and fully the additional risks introduced this way.
Fatigue can also be a key concern for all staff but particularly for the staff belonging to sub-contractors. Sometimes staff can undertake several shifts for different railway operators. This is a safety risks which can lead to incidents and accidents. The railway operator should ensure that there are arrangements in place to ensure that all staff do not work excess shifts. Again, this should be at least included in the contractual arrangement with the sub-contractor or individual and should be monitored by the railway operators. This must be covered in their CMS procedures and managers responsible for the staff aware of the risks.

Non-technical skills (NTS)

Safety critical tasks require knowledge, technical skills, and non-technical skills (NTS), such as communication, awareness, concentration…. NTS underpin and enhance technical tasks and improve safety by helping people to anticipate, identify and mitigate against risks and errors.

There is often a lack of understanding about the importance of Human and Organisational Factors (HOF) and the need to consider NTS when developing competence requirements. Railway Undertakings (RUs) often treat these aspects as part of general health and safety requirements. However, while health and safety directives address occupational risks, they do not adequately cover operational risks arising from HOF. Examples of such operational risks include workload, job design, fatigue, the suitability of procedures, the working environment, and task design. This gap highlights the need to explicitly include HOF and NTS in competence management to address both occupational and operational risks effectively.

In many accidents, an indirect behavioural issue can be identified as a contributing factor leading to individual blames and in some cases, the adoption of a national rule. However, all the indirect contributing factors are almost never identified, and the latent issues remain unresolved. Therefore, HOF and NTS must be effectively implemented in the SMS procedures (as a result of the risk management process implementation) and cannot be managed via national rules. Furthermore, the implementation of HOF and NTS should not be limited to RUs and IMs alone. A wider reflection is necessary to include other actors in the safety system, such as NSAs, contractors, and suppliers, to ensure that all relevant contributors to safety are addressed as part of an integrated risk management process.

NTS are key for all staff undertaking safety critical tasks including the tasks of managers. It is rare to find a CMS that adequately considers the role of managers and the effect that they can have on the system's safety performance.

6.6.2 Conclusion

The outcome of the assessment of competence management system shows a lack of maturity. There is either an over reliance on national rules or a lack of understanding of the crucial role that the CSM procedures provide in ensuring a safe operation. The EU regulatory framework provides the parameters to deliver this, but railway operators are faced with confusion, often unnecessary bureaucracy and duplication when trying to set out their CSM requirements and procedures. The Agency assessors spend a lot of time trying to distinguish between the national rules and CSM procedures and often find that the NSAs duplicate these elements when looking at the national part. This may lead to high assessment costs with very little benefits in improving safety.

The matter of staff competences is a crucial responsibility of each railway operator of the Single European Railway Area. It should be well developed in their SMS because of the importance for the safe operation and the proper mitigation of identified risks. NSAs should use all available tools including EU Regulation 2018/761 on supervision to verify through these supervision activities the ability of the railway operators' SMS to function properly and address all relevant risks, including those arising from HOF (including staff, competence management and training)

To support sustainable safe performance, particularly across borders, railway operators need to be able to use their SMS to adapt to the different operational requirements and risks. Currently the arrangements for prescriptive national rules on issues such as competence do not allow for this.
With the suppression of open points in the 2023 version of TSI OPE, most national rules on competence will no longer remain valid and there is a need to better develop the notion of risk-based approach linked to the competence management system.

The Agency accepts that the current requirements, such as in EU Regulations 2018/762 and 2019/779, may not provide a sufficient basis to transit towards a fully risk-based CMS. Therefore, it is acknowledged that further clarification is necessary to assist railway operators and other actors.
The aim should be to work with the sector, MS and NSAs to *address and consider the following issues:*

1) The definition and role of a competence management system as part of the safety management system processes.
2) The identification of the link between the competence of staff and the task analysis for all jobs that can affect the safety of the operation. The task analysis should cover the analysis of what is needed to undertake jobs that are safety critical or have safety related functions (in normal, degraded operation and emergency situations) and then be used to select suitable staff and then train and maintain their competence. The task analysis should also be linked to the results from the risk assessment and related control measures which should identify those activities where the competence of people is linked to the effective control of risks. This should cover the competence needed for normal, degraded operations and emergency situations. This should also include the development of a process which will help railway undertakings and infrastructure managers to define safety critical risks where the human can have both a positive and negative impact and how this should be considered in the risk assessment and how to consider the results.
3) How to develop a systematic process for the management system that covers the whole cycle of competence from recruitment and selection, through to training, and maintaining, reassessment and updating competence. It should also cover the review and audit of the process (as part of the overall monitoring of the safety management system).
4) Issues in relation to human and organisational factors and the effect that this can have on staff undertaking safety critical tasks or safety related functions. This includes further describing the

role that non-technical skills can play in ensuring safe operation and controlling risks. Non-technical skills should be a key part of the selection process continuing into the development and management of the competence of staff.

5) The role and scope of both safety critical and safety related functions and how to define them. It should also include what needs to be considered when identifying such functions as part of the risk assessment and how to manage this if it is a small part of a person's overall tasks.
6) The fitness for work and the physical and psychological health of staff including identifying and managing fatigue and the abuse of alcohol and drugs.
7) The roles and responsibilities of the stakeholders, in relation to competence, who are involved in the railway market including contractual responsibilities. How this issue needs to be taken into account safety management system.
8) The roles of national safety authorities when supervising the competence management system.
9) The need to reduce the number of national rules that relate to the competence of staff and ensure that the CSM consider key aspects which will help the reduction and removal of said rules.

The current implementation of competence management within the railway sector is fraught with significant challenges, even though legal frameworks like the CSM on Safety Management Systems and the CSM on Supervision are already in place. One of the main issues is the lack of harmonisation across Member States. National rules governing competence management vary widely across Europe. While these rules may comply with EU regulations, their divergence creates inconsistencies, particularly in cross-border operations. Some of these national rules are decades old—dating back to the 1970s—and their persistence has contributed to a fragmented approach, impeding the sector's transition to a unified, risk-based framework.

Operators also face significant difficulties in translating existing legal requirements into practical applications. The CSM on SMS, specifically Annex 1, Section 4.2, and the CSM on Supervision (e.g., Article 6) include provisions for competence management, but many organizations struggle to fully understand and implement these requirements. This challenge is especially evident in critical areas like risk assessment, task analysis, and the integration of human and organizational factors, such as non-technical skills.

Another issue is the sector's over-reliance on national rules. In many cases, operators default to applying these rules, which often emphasize compliance rather than fostering a proactive safety culture or addressing competence-related risks. This approach overlooks the human element in risk management and can perpetuate a blame culture, undermining the overall effectiveness of competence management systems.

The application of competence management is inconsistent across the sector, resulting in an uneven playing field throughout the EU. While some operators excel in meeting SMS requirements, others lack the understanding and resources needed to do so effectively. Supervisory authorities, in turn, encounter difficulties promoting and monitoring compliance due to the variation in national rules and practices.

Recent changes in the TSI OPE framework have further exacerbated the challenges. The 2023 revision removed certain national rules related to safety-critical tasks, leaving operators and supervisory authorities without clear guidance on designing and implementing robust competence management systems under a harmonized framework. This has created uncertainty and increased the burden on organizations to fill the gaps left by the eliminated rules.

Finally, the lack of a cohesive approach poses significant risks for cross-border operations. Disparities in competence management frameworks, training standards, and operational procedures between countries can result in safety and operational inefficiencies, complicating efforts to ensure seamless and secure railway operations across Europe.

Despite acknowledging the challenges associated with competence management, several stakeholders expressed reservations about introducing a specific CSM dedicated to this topic. One of the primary concerns raised was that existing legal frameworks, such as the CSM on SMS and the CSM on Supervision, already include provisions for competence management. For example, Annex 1, Section 4.2 of the CSM on SMS and Article 6 of the CSM on Supervision outline requirements for managing competences. Stakeholders argued that the problem lies not in the absence of these legislative provisions but in their ineffective implementation across the sector.

Another key point of contention was the preference for detailed guidance over new legislation. Many stakeholders emphasized that the sector would benefit more from practical tools and support to help operators and supervising authorities apply existing requirements effectively. This approach, they argued, could foster greater consistency without introducing additional regulatory complexity.

Concerns were also raised about the potential risk of over-regulation. Stakeholders noted that adding a new CSM could result in duplication or overlap with existing provisions, thereby creating unnecessary administrative burdens for both operators and supervising authorities. They stressed that any new legislation should offer clear added value and avoid complicating the regulatory landscape further.

The issue of outdated national rules was another recurring theme. Many stakeholders pointed to these rules as a root cause of inconsistency and non-compliance in competence management practices. They suggested that efforts should focus on harmonizing and integrating national rules within the existing frameworks, rather than introducing new legislation that might fail to address this underlying issue.

There were also significant concerns about the capacity and readiness of operators, particularly smaller organizations, to adapt to new legislative requirements. Stakeholders highlighted the importance of improving the practical application of current rules through capacity-building initiatives and training, which they believed would better address existing gaps without imposing additional strain on operators.

Several stakeholders proposed alternative solutions to a new CSM. Suggestions included enhancing the CSM on Supervision to include specific provisions for monitoring competence management practices or leveraging tools such as the TSI OPE. These alternatives were viewed as less disruptive and more targeted toward resolving identified issues within the current framework.

Finally, questions were raised about the scope and added value of a dedicated CSM on competence management. Stakeholders emphasized that any new legislation must clearly demonstrate its capacity to improve competence management practices in ways that cannot be achieved through the existing framework or enhanced guidance. Overall, the discussion reflected a cautious approach to new legislation, prioritizing targeted and practical solutions that address the root causes of the challenges in competence management.

6.7 TSI OPE / National Rules

6.7.1 Main Observations

National rules refer to all binding rules adopted in a Member State, irrespective of the body issuing them, which contain railway safety or technical requirements, other than those laid down by Union or international rules, and which are applicable within that Member State to railway undertakings, infrastructure managers or third parties.

In order to eliminate the obstacles to interoperability, the volume of national rules, including operating rules, is expected to be reduced because of extending the scope of the TSIs to the whole of the Union rail system and of closing open points in the TSIs. The operational process should also be covered in the SMS particularly to help with cross border operation and the need to change an operational procedure.

Therefore, this should also be seen in conjunction with the Common Safety Method on SMS requirements (EU Regulation 2018/762), whose link is described in the following paragraphs. Otherwise, we will continue with the current discourse and immaturity between the two key legal frameworks (i.e. TSI OPE and CSM on SMS) that affect safe operation.

The cleaning-up of national rules is a key issue in relation to the Agency's work in removing operational barriers and helping with the effective implementation of the Fourth Railway Package (4RP) and was supposed to be delivered by 16 June 2018, according to Article 8, point 2 of Railway Safety Directive (EU) 2016/798. While some Member State progressed well, the Agency has encountered problems of inconsistent or duplication of requirements that are mandated at EU level when assessing Single Safety Certificates.

Cleaning-up of national rules is essential because:

1. National rules remain a large factor preventing effective cross border operation and harmonisation of rail target systems.
2. Many of the national rules still in existence in the Notif-IT database are redundant or otherwise not compliant with EU legislation that has evolved over the last 10 years. This includes compliance with common safety targets and indicators, CSMs and TSIs (in this case the TSI OPE).

The process of national rules cleaning up shows different areas of intervention in terms of further harmonization at Union level and in terms of moving some processes description out of the TSI OPE for the benefit of other European legislation (e.g. CSMs).

It has shown how the lack of a functional definition of the entire European railway system has led to the definition of many small national railway systems each with its own very detailed rules in a very confused overall picture. That is, there has been a strong presence of detailed operational rules at national level on certain issues, which has then led the RUs and IMs to stick to a rule-based approach rather than moving towards a risk-based approach. This seems to create two types of confusion:

- RUs and IMs are often unable to implement the CSM on SMS requirements due to the presence of national rules that are often incompatible with the CSM.
- International RUs struggle to have a clear applicable legal framework and sometimes find themselves in the situation of having to apply several national rules that not only do not comply with the TSI OPE and the CSM on SMS requirements, but also conflict with each other.

The functional link between the TSI OPE and the CSM on SMS lies mostly on criteria 4.2 on competence, 5.1 on operational planning and control and 5.5. on Emergency management.

TSI OPE application guide in Annex 1 makes the link explicit, the guidance is available on the ERA website: https://www.era.europa.eu/domains/technical-specifications-interoperability/operation-and-traffic-management-tsi_en

Stakeholders have raised concerns regarding the issue of **risk export** in the operational interface between Railway Undertakings (RUs) and Infrastructure Managers (IMs). This issue arises when differences in operational procedures, although compliant with the legal framework, create discrepancies that may lead to risks or operational inefficiencies. The challenge is particularly acute in cross-border operations, where the lack of harmonisation in rulebooks, communication tools, and digital processes exacerbates the situation.

While this concern highlights a potential gap in the current framework, it is not yet clear whether the solution lies within the scope of the Common Safety Methods (CSMs) or should be addressed through revisions to the TSI-OPE. The European Commission has suggested that areas such as harmonised rulebooks, digitalisation, and communication tools might better address these challenges under the TSI-OPE framework.

6.7.2 Conclusion

The process of cleaning up the national rules, although still ongoing, has so far revealed the following issues:

- **Competence management system**. Here, it was seen that in the different States there were detailed rules on the training and maintenance of the competences for operational staff that went beyond the risk-based approach of each operator. Furthermore, between States it might find the same rule focused on the same subject as, for example, the training programme for a specific role, which are incompatible with each other. Competence management is an element that should be taken out of the TSI OPE, due to the need to harmonise the approach among the members states while guaranteeing that the TSI remains at a functional level.
- **Safety principles**. Some safety principles are defined in the TSI OPE, e.g. in its Appendix B1, but the lack of a description of the entire railway system has led States to issue other safety principles at national level. In this case, it was found that these national principles not only did not comply with the dictates of the TSI OPE and the CSM on SMS requirements, but often the national principles of several states on the same subject matter were impossible to apply together with a clear deficit for interoperability.
- **Train composition and braking**. It can be said that this is the area where national discrepancies are most evident and create the greatest problems of interoperability. It can be said that different States have different rules on the composition of the same train, again underlining the difficulty in using a risk-based approach to operational processes. A future, more detailed functional description of those processes in the TSI OPE together with a dedicated AMOC could clearly reduce this phenomenon.
- **Operational rules concerning the use or provision of technological/mechanical devices**. Here we have seen that there are national rules that, for example, impose specific on-board equipment on locomotives to handle degraded or emergency situations. In the perspective of international transport without barriers, having national rules that without any supporting risk analysis impose different on-board equipment certainly does not help interoperability. Although the TSI OPE deals with such topics, it is necessary that the technical aspects are harmonised in the relevant structural TSIs, leaving the description of the function/process to be ensured with the relevant safety requirements to the TSI OPE. The technical part of the current version of the TSI OPE should be

deleted from the new version and can be moved into other appropriate documents, this is due to the need of keeping the new TSI at a functional level.

6.8 Human- and organisational factors

The Railway Safety directive promotes safety through safe organisations developing their Safety Management System based on risk management (taking HOF into consideration), clearly defined interfaces and respective roles and responsibilities shared between all the actors of the railway system.

Article 4.1 of Directive 2016/798, states that "*the responsibility for the safe operation of the Union rail system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings, each for its part of the system, obliging them to implement necessary risk control measures as referred to in point (a) of Article 6(1), where appropriate in cooperation with each other*".

This obligation for RUs and IMs has been reinforced by the obligations laid down in article 4.3 to implement the risk control measures (including those arising from other actors and third parties with which they have an interface). Railway undertakings and infrastructure managers shall also, where necessary, contractually oblige their contractors, partners and suppliers to implement risk control measures and monitor their implementation.

Article 4.4 also mandates all other actors of the railway system (*entities in charge of maintenance and all other actors having a potential impact on the safe operation of the Union rail system, including manufacturers, maintenance suppliers, keepers, service providers, contracting entities, carriers, consignors, consignees, loaders, unloaders, fillers and unfillers*) to implement risk controls measures.

The Safety Directive already considers the integration of HOF in the SMS (whereas 18 reinforced by article 9) of RUs and IMs and in incident and accident and investigation (whereas 41) .

These requirements in the Directive have led to integration of HOF in the SMS as follows:

- reinforcement of the obligation to integrate consistently HOF in the SMS of RUs and IMs in Regulation 2018/762 on SMS Requirements ;
- Article 3.1.1.1 on Risk assessment mandates the organisation to "*identify and analyse all operational, organisational and technical risks relevant to the type, extent and area of operations carried out by the organisation.* ***Such risks shall include those arising from human and organisational factors such as workload, job design, fatigue or suitability of procedures, and the activities of other interested parties*** *(see 1. Context of the organisation)"*;
- *Article 4.6 mandates the demonstration of " a* ***systematic approach to integrating human and organisational factors within the safety management system****. This approach shall (a) include the development of a* ***strategy*** *and the* ***use of expertise and recognised methods*** *from the field of human and organisational factors;(b)* ***address risks*** *associated with the design and use of equipment, tasks, working conditions and organisational arrangements,* ***taking into account human capabilities as well as limitations, and the influences on human performance****;*
- *Article 5.2.1 concerning asset management* mandates the organisation to "manage the safety risks associated with physical assets throughout their lifecycle (see 3.1.1. Risk assessment), from design to disposal, **and fulfil the human factors requirements** in all phases of the life cycle."

All those specific requirements aimed at RUs and IMs shall also apply to all other railway actors through compliance with articles 4.31 of Directive 2016/798 and 3.1.1.1 of Regulation 2018/762 in the IMs and RUs

contracting documents. The fulfilment of these requirements concerning HOF risk control measures can be checked by NSAs during their supervision activities.

As a consequence, the HOF requirements and their integration into the risk management including the risk control measures and the ***systematic approach to integrating human and organisational factors within the safety management system have an impact on all the CSMs.*** However, HOF requirements are not always explicitly mentioned and developed throughout the railway regulations and therefore neither systematically understood nor applied by railway stakeholders:

- CSM REA:
  - Is applicable to some of the partners, contractors and suppliers of IMs and RUs (see proposer in the definition part), therefore the provisions of RSD art 4.3 on risks and risk control measures should apply in a similar way, and there may be a reference to " *a* ***systematic approach to integrating human and organisational factors within the change management****. This approach shall include the* ***use of expertise and recognised methods*** *from the field of human and organisational factors;(b)* ***address risks*** *associated with the design and use of equipment, tasks, working conditions and organisational arrangements,* ***taking into account human capabilities as well as limitations, and the influences on human performance****;"*
  - Detailing more the Interfaces management (annex I. 1.2)
  - Make a clear reference to managing the system as a whole and that the proposer should take into account in its process the risks and risk control measures already identified within the SMS (including HOF topics);
  - Identifying HOF competence of the staff in charge of carrying out risk management process;
  - Identifying HOF competence of the AsBo (also see RFU 03)
  - Integration of HOF in the safety assessment report of the AsBo (see first bullet point and clarification note on safe integration)
  - Make a link with the CSM ASLP and contributing factors (App A part C.2) (link with HOF in change management toolkit)

- CSM on Monitoring:
  - Better develop the system and risk-based approaches (inc roles and responsibilities).
  - Art 4.3.d of RSD: RUs and IMs shall ensure that their contractors implement risk control measures through the application of the CSMs for monitoring processes set out in the CSMs on monitoring referred to in point (c) of Article 6(1), and that this is stipulated in contractual arrangements to be disclosed on request of the Agency or of the national safety authority. Consequently, similar prescriptions concerning HOF integration in risk management should apply as those stated in the RSD and CSM on SMS.
  - Art 3 of the CSM on Monitoring states that "each RU , IM and ECM shall ensure that risk control measures implemented by their contractors are also monitored in compliance with this Regulation. To this end, they shall apply the monitoring process set out in the Annex or require their contractors to apply this process through contractual arrangements." However, the process on how they ensure that the monitoring process is applied by their contractors when they use the second option, should be defined. Because they tend to use this requirement to avoid doing anything.
  - This is reinforced by the fact that the inputs to the monitoring process shall be all the processes and procedures contained in the management system, including technical, operational and organisational risk control measures. This consequently includes HOF topics.

Today, HOF requirements and indicators are not systematically explicitly included neither in the contracts neither in the monitoring activities, it therefore seems necessary to make a specific reference and develop some guidance around it.
  - Make a link with the CSM ASLP and contributing factors (App A part C.2)
  - Competence requirements for staff in charge of defining MO activities should be detailed or linked with the CSM on competence
  - Specific HOF competence/awareness of the persons in charge of carrying MO activities

- CSM SMS:
  - 3.1.1.a "*…Such risks shall include those arising from human and organisational factors such as workload, job design, fatigue or suitability of procedures, and the activities of other interested parties*" This list is not exhaustive; however, some applicants stop to the list, it would be good to make a link with the CSM ASLP and contributing factors (App A part C.2)
  - Rule-based approach to safety management contradicts the operational reality creating major inconsistencies between 'work as imagined' and 'work as done'. HOF involves taking a systemic perspective, that is, not just looking at the human, technological and organisational factors individually but understanding the interactions between the different factors and their potential impact on performance. The proposal to develop more the risk-based approach should cover this.
  - The goal is to identify how best to perform the activities in a safe and efficient way. HOF is used both as a proactive means of ensuring good design processes as well as a reactive means of identifying the key issues when something has gone wrong (through monitoring and investigations).
  - This should also cover the interfaces with partners, contractors and suppliers, which should be more detailed.
  - The strategy, which still need some improvement in annex of the SMS guide, provides a basis to better develop this concept and shows how HOF should be systematically included in the SMS processes and procedures. Examples to enrich each requirement with HOF integration can be found throughout the SMS guide.

- CSM on Supervision:
  - the obligation to specifically integrate HOF in the supervision activities of the NSA is laid down in annex I art 2.b of Regulation 2018/761, indicating that the NSA shall "*identify in the supervision strategy risk areas for targeted supervision activities, **including those emerging from the integration and management of human and organisational factors***"**;**
  - This topic should be developed to support better NSAs' understanding
  - Concerning interface management, Art 17 of RSD explicitly mentions the "supervision activities include, in particular, checking the application by railway undertakings and infrastructure managers of the individual or partial elements of the safety management system, including operational activities, the supply of maintenance and material and the use of contractors to monitor their effectiveness. This topic should be developed to better support NSA's understanding.

- CSM on competence:

- Detailing a framework for competence management will support HOF integration through the definition of roles and responsibilities, resources and competence management system, including non-technical skills;
- Clarify how to define safety critical and safety related functions using tasks analysis for all roles that can affect the safety of the operation including issues in relation to human and organisational factors and the effect that this can have on staff undertaking safety-critical tasks or safety-related functions, including for contractors, partners and suppliers (make the link with the other actors as referred to in article 4.3 and 4.4 of the RSD)
- Clarify how to develop a systematic process for the competence management system that covers the whole cycle of competence from recruitment and selection, through training to maintaining, reassessment and updating competence;
- Should cover normal, degraded and emergency situations (link with CSM ASLP contributing factors)
- Risk awareness and risk management should be included
- HOF competence will also be more detailed (see HOF competence outline)

- TSI OPE:
  - Some implicit requirements on HOF can be found in TSI OPE, this includes the communication and information exchange between the different actors (for example the necessity for the driver to repeat back to the signaller messages to confirm understanding of the information and/or instructions). There are also some more specific references to HOF concerning the monitoring and improvement processes, staff competencies (including alcohol, drugs or psychotropic medication) and safety communications.

6.9 Safety culture

In many high-risk domains, tackling organisational and cultural aspects has become paramount to enhancing safety. The success of safety culture in those industries has convinced rail leaders and law-makers to embrace this philosophy across Europe. Recommendations from the nuclear industry[4] were used to formulate the safety culture items when developing the CSM for SMS requirements in 2018. As a result, it is requested that applicants for a single safety certificate elaborate and implement a "strategy" for continually improving the safety culture of their organisations. While "strategy" is a common term in the business literature among other fields, lessons learned from the implementation of the CSM for SMS requirements reveal that the applicants are not well acquainted with the characteristics of such a strategy (e.g., design, scope, duration, safety culture framework). To support the applicants, the Agency has already developed a model, guidelines and e-learning activities. Nevertheless, additional assistance to be provided may be explored with the objective of enhancing the quality of the applications regarding the safety culture requirements.

In addition, many assessments have led to the formulation of type 2 and type 3 issues addressing the conception and implementation of the safety culture strategy. Some of those issues are to be overseen by the national safety authorities during their supervision activities. It may therefore be appropriate to explore a possible integration of the safety culture concept in the CSMs on Monitoring and Supervision.

[4] "With regard to safety culture, the regulatory body should develop general requirements and enforce them in order to ensure the authorised parties have properly considered these requirements. On the other hand, the regulatory body should avoid prescribing detailed level requirements. The regulatory body should not impose detailed requirements, should not regulate safety culture as a whole (…)" (IAEA TECDOC 1707 Regulatory Oversight of Safety Culture in Nuclear Installations, 2013, p.8)

7 Annex - Estimation of resources

The estimation of resources for the review of the Common Safety Methods considers the significance of updates required for each CSM and the need for structured collaboration with stakeholders and the European Commission. The following outlines the proposed framework for meetings, staffing, technical resources, and financial considerations to ensure effective and efficient resource allocation throughout the project.

7.1 Meeting Framework per CSM

The number of meetings for each CSM is based on the anticipated significance of updates:

- CSM on Competence Management (COMP): 10 half-day meetings.
- CSM on Safety Management System Requirements (SMS), Risk Evaluation and Assessment (REA), Supervision (SUP): 8 half-day meetings each.
- CSM on Monitoring (MON), Common Safety Targets (CST): 6 half-day meetings each.

These meetings will involve detailed discussions with key stakeholders to ensure the development of robust recommendations and alignment with project objectives.

In addition to the meetings required to revise the legal framework, an optional phase may be included to update guidance material to align with the revised legal text. This phase would ensure that stakeholders receive clear and practical instructions on implementing the updated CSMs. If undertaken, the following workshops will be organised beyond the two-year project timeframe:

- CSM on Competence Management (COMP): 5 workshops.
- CSM on Safety Management System Requirements (SMS), Risk Evaluation and Assessment (REA), Supervision (SUP): 4 workshops each.
- CSM on Monitoring (MON), Common Safety Targets (CST): 3 workshops each.

These workshops will serve as dedicated forums to clarify new provisions, discuss practical implementation challenges, and facilitate knowledge transfer between the Agency, NSAs, and railway operators.

7.2 Cross-CSM Coordination Meetings

To facilitate overarching alignment across the CSMs, additional cross-CSM meetings will be required:

- Plenary Working Party (WP) Meetings: 6 half-day meetings across the project. These will focus on sharing progress, ensuring consistency across CSMs, and addressing interdependencies.
- Steering Group (SG) Meetings: 4 meetings over the course of the project. Initially, these will occur more frequently to establish the project's strategic direction. The SG meetings will involve the sponsor, including representatives from the European Commission, and will focus on ensuring alignment with high-level objectives.

7.3 Staffing and Expertise Requirements

The review of the CSMs will require a combination of existing agency staff and external stakeholders with specialised expertise. Key roles and their contributions include:

- Project Lead: Overseeing the project, ensuring alignment with the mandate, and coordinating between working parties and steering groups.
- Technical Experts: Providing subject-matter expertise in risk-based safety management, supervision strategies, competence management, and regulatory alignment.
- Stakeholder Liaison: Facilitating communication with National Safety Authorities, railway operators, and other key stakeholders.
- Administrative Support: Managing meeting logistics, documentation, and tracking deliverables.

A key factor in the success of this review will be the time and resources available for thorough preparation of each individual workshop. Given the complexity of the revisions and the need for structured stakeholder engagement, significant effort will be required to draft materials, compile technical assessments, and ensure productive discussions. To effectively carry out these preparatory tasks—including document drafting, expert consultations, coordination with stakeholders, and post-workshop analysis—the agency will need to allocate three full-time equivalents (FTEs) per year to these activities. Over the two-year project timeframe, this equates to a total of six FTEs dedicated to the preparation and execution of meetings and workshops.

To address potential gaps in expertise, training programmes may be required for existing staff, and, if necessary, new specialists could be hired to provide additional capacity or address specific technical needs. These efforts will ensure that the review process is well-supported, efficiently managed, and effectively executed, ultimately leading to high-quality recommendations and a seamless transition to the updated framework.

7.4 Technical Resources

The successful implementation of the CSM revisions will require adequate technical resources to support a collaborative working environment for all stakeholders involved in the project. Ensuring that all participants—both from the Agency and external stakeholders—can efficiently contribute to discussions, document drafting, and data analysis will be essential for a smooth and effective review process.

The following key resources will be necessary:

- Collaborative Tools: Platforms for document drafting, project management, and stakeholder engagement will be needed to facilitate structured input from all contributors. These tools should ensure version control, clear tracking of changes, and seamless remote collaboration where required.
- Database Access: Relevant datasets, including past assessments, safety reports, and industry feedback, will need to be consulted to derive lessons learned and identify areas for improvement in the current framework. Ensuring access to structured data sources will support evidence-based decision-making throughout the project.

Having these technical resources in place from the outset will enable an efficient, well-coordinated review process and ensure that discussions and decisions are based on relevant insights and stakeholder contributions.

7.5 Financial Considerations

Key financial resources will be allocated to support the following activities:

- Organising and hosting meetings, both virtual and in-person.
- Developing new guidelines and associated documentation.
- Implementing training programmes for agency staff and external stakeholders.

- Procuring or upgrading software tools and database access.

A detailed financial estimate will be prepared in subsequent stages of the project.

7.6 Timeline and Resource Allocation

The allocation of resources will follow a phased timeline to match project milestones:

- Phase 1: Establishment of working parties, initial SG meetings to confirm the strategic direction, and detailed planning of resource needs (Months 1–6).
- Phase 2: Intensive CSM-specific discussions, ongoing WP and SG meetings, and draft recommendations (Months 7–18).
- Phase 3: Finalisation of recommendations, publication of updates, and preparation of implementation guidelines (Months 19–24).
- Phase 4 (Optional): Adaptation and development of guidance material to support the implementation of the revised CSMs. This phase would include dedicated workshops to refine guidance documents, ensuring clarity for stakeholders applying the updated framework. Phase 4 would take place beyond the initial two-year timeline and would be planned in coordination with relevant sector representatives.

7.7 Monitoring and Evaluation Plan

A robust monitoring and evaluation plan will be implemented to assess the sufficiency and effectiveness of allocated resources. Key elements include:

- Regular progress reviews during SG and WP meetings.
- Metrics for evaluating staff capacity, meeting outcomes, and stakeholder engagement.
- Agility in resource planning, allowing adjustments to address emerging challenges or opportunities.

7.8 Summary of Estimated Meetings

Meeting Type	Number of Meetings	Purpose
CSM-Specific Half-Day Meetings	Varies (6–10 per CSM)	Detailed discussions tailored to the needs of each CSM.
Plenary WP Meetings	6	Ensures cross-CSM consistency and interdependency alignment.
Steering Group Meetings	4	Strategic oversight with the sponsor and European Commission representatives.
Workshops for Application Guidance	Varies (3–5 per CSM)	Supports the adaptation and development of guidance materials to facilitate implementation of the revised CSMs.

The successful execution of this project will require a dedicated allocation of resources, particularly for the preparation and facilitation of these meetings and workshops. Given the complexity and significance of the revisions, three full-time equivalents (FTEs) per year will be needed to carry out the preparatory work, including drafting technical materials, coordinating with stakeholders, and ensuring the efficient execution of discussions. Over the two-year core project timeline, this equates to a total of six FTEs.

Additionally, should Phase 4 (optional adaptation of application guidance) be implemented, further workshops will be conducted beyond the initial two-year period, ensuring that stakeholders receive clear and practical instructions on applying the updated legal framework.

This estimation provides a structured and resource-conscious approach to the review process, ensuring effective stakeholder engagement, alignment across regulatory frameworks, and the smooth adoption of revised CSMs. By integrating staffing, technical, financial, and monitoring considerations, the project will be well-positioned to deliver impactful and well-supported regulatory improvements.

However, it is important to emphasise that this resource estimation represents an initial, high-level assessment based on the current understanding of project scope and expected activities. As the European Commission's mandate is defined and further details emerge through the subsequent project management planning phase, these estimates may require further refinement and adaptation. The final allocation of resources will be adjusted as necessary to ensure that the project remains aligned with strategic objectives while responding to evolving needs and priorities.