

**Guidance for safety
certification and
supervision**



Safety management system requirements for safety certification or safety authorisation

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Guidance for safety certification and supervision

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0 Introduction

An applicant for a single safety certificate or a safety authorisation shall demonstrate compliance with the relevant safety management system requirements set out in [Regulation \(EU\) 2018/762](#). To that end, it shall provide documentary evidence to the national safety authority or, where relevant, the European Union Agency for Railways (also named hereafter the 'Agency'), that it has established its safety management system (SMS) in accordance with Article 9 of [Directive \(EU\) 2016/798](#).

This guidance document is a living document which has been developed in collaboration with national safety authorities and sector representatives and is intended to be continually improved based on the feedback of users and taking into account the experience gained during the implementation of [Directive \(EU\) 2016/798](#), related common safety methods (CSMs) and any other relevant EU Regulations.

0.1 Purpose of the guide

This guidance document is aimed at giving:

- ▶ *The purpose behind each of the assessment requirements set out in Annex I and II of the above CSM complemented where necessary by explanatory notes providing specific details on particular terms or ideas used in the requirements;*
- ▶ *An indication of what evidence an organisation might provide to demonstrate the compliance required by the above CSMs;*
- ▶ *An illustrative list of examples of evidence that can be observed in applications for a single safety certificate or safety authorisation when carrying out assessment, or that can be used by the applicant as reference material for their application;*
- ▶ *Illustrative references and standards that can be used to help in assessing, developing, implementing or continually improving a safety management system; and*
- ▶ *Some indication of what issues might need to be considered by a national safety authority during its supervision of a railway undertaking or infrastructure manager.*

For the purpose of the assessment of an application for a single safety certificate involving the Transport of Dangerous Goods by Rail an NSA may have a direct role as the competent authority in assessing the relevant parts of the application. Alternatively, it may have a co-ordinating role liaising as necessary with any other transport of dangerous goods competent authority seeking their advice for the relevant parts of the assessment as necessary.

0.2 Who is this guide for?

The present document is addressed to:

- ▶ *The national safety authorities and the European Union Agency for Railways when assessing the compliance of the railway undertakings' safety management system with the relevant SMS requirements and when NSAs are conducting supervision;*

- ▶ The national safety authorities when assessing the compliance of the infrastructure managers' safety management system with the relevant SMS requirements and when conducting post-award supervision; and
- ▶ The railway undertakings and infrastructure managers (also named hereafter the 'applicant') to assist them in developing, implementing, maintaining and continually improving their safety management system in compliance with the relevant SMS requirements (and other applicable safety requirements) and to know what to expect during supervision.

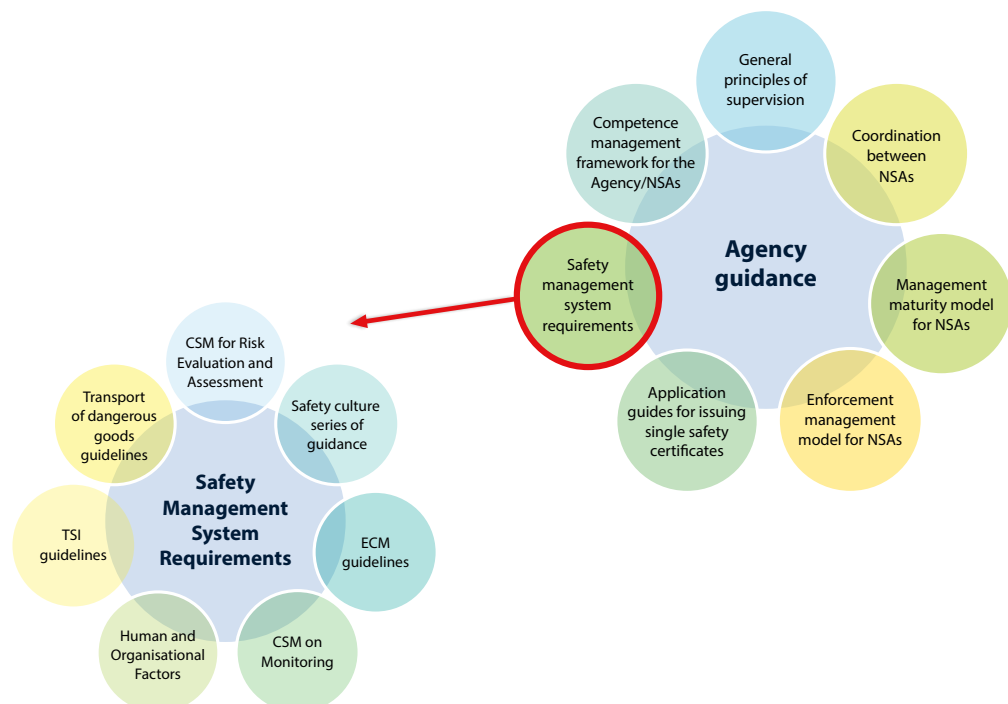
0.3 Scope

What this guidance does not do is prescribe what evidence an applicant should present. The fundamental reason for this is that each organisation's SMS should be tailored to the specific risks that organisation needs to control. So each SMS is a unique system of documented information, providing an indication of the specific risk control measures and systems in place within an individual organisation which evolves over time as the organisation changes. It would be incorrect, therefore, to provide a prescriptive list of information which an applicant should provide. Doing this would render the assessment process a pointless exercise as all applications would look the same when the corresponding SMSs were not.

0.4 Guidance structure

This document is part of the Agency compendium of guidance supporting the railway undertakings, infrastructure managers, national safety authorities and the Agency, in fulfilling their roles and undertaking their tasks in accordance with [Directive \(EU\) 2016/798](#).

Figure 1: Compendium of Agency guidance



The information provided for in this guide shall be supplemented by specific national safety authorities' guidance, describing and explaining the notified national rules that are valid for the intended area of operation and the documents which shall be supplied in the application for a single safety certificate in order to comply with the provisions of Article 10(3)(b) and Article 10(8) of [Directive \(EU\) 2016/798](#) (see also *Agency application guide for issuing single safety certificates*). For Infrastructure Managers this guide should be supplemented by guidance produced by National Safety Authorities on the requirements for safety authorisations as prescribed in Article 12(1) of [Directive \(EU\) 2016/798](#).

Notified national rules means only those rules which have been notified by a Member State to the Commission. In accordance with Recital 12 of [Directive \(EU\) 2016/798](#) it is expected that the number of notified national rules will decline over time. These will either be replaced by measures set out in Technical Specifications for Interoperability (TSIs), other EU Regulations or company rules. Company rules or standards will be assessed as appropriate through compliance with the TSI relating to the operation and traffic management subsystem of the railway network in the European Union, (hereafter also called the TSI OPE) as reflected through the safety management system requirements explained in this guide.

The present guidance is structured in accordance with the requirements set out in Annex I and Annex II of Regulation (EU) 2018/762. In the following sections, each requirement is captured in a yellow box for ease of reference. Where there are differences between the requirements applicable to railway undertakings and those applicable to infrastructure managers, the relevant text for the latter appears in the yellow boxes showing the requirements in [blue](#).

Side by side comparison or correlation tables between the assessment criteria of the former Regulations (EU) 1158/2010 and (EU) 1169/2010, and the requirements of [Regulation \(EU\) 2018/762](#), are provided in Annex 1 of this guide. The tables also include cross-referencing to the clauses of the ISO High Level Structure where applicable. These are provided to help applicants demonstrate compliance of their safety management system with the new requirements, in particular in the cases where the applicant has already been granted a safety certificate or safety authorisation and/or the applicant has already another ISO management system (e.g. ISO 9001, 14001 or 45001) in place, (so that they can be integrated together) or has plans to develop one using that model. Using this table does not provide a systematic presumption of conformity with the requirements set out in [Regulation \(EU\) 2018/762](#) for those organisations holding an ISO certificate.

0.5 ISO/IEC Directives Part 1 and Consolidated ISO Supplement

ISO has developed official procedures to be followed when developing and maintaining an international standard. In Annex SL Appendix 2 of [ISO/IEC Directives Part 1 and Consolidated ISO Supplement](#), a High Level Structure (HLS) is adopted to use core text in every management system standard.

Annex I and Annex II of Regulation (EU) 2018/762 ensure a structure consistent with the ISO HLS, facilitating the integration of different management systems, where applicable, which share the same core organisational principles and requirements but where legal compliance

and risk domains are specific to each discipline (e.g. occupational safety, environment, quality).

ISO standards and relevant guidance may assist railway undertakings and infrastructure managers in developing their SMS (e.g. ISO 31000 is a generic document for better understanding risk management, ISO 31010 supplies information as to the selection and application of risk assessment techniques like FMECA, FTA, ETA, HAZOP, ISO 55000 provides requirements for asset management). However, these can contribute only if a sound knowledge of the context of the railway related risks are known.

If the use of the HLS ensures a consistent stance with ISO management system standards, it must be underlined that the above CSMs are regulations which primarily serve the purpose of national safety authorities or the Agency in assessing applications for the granting of safety certificates or safety authorisations. As such, assessments for single safety certificates or safety authorisations will be against the SMS requirements and not the ISO HLS per se. In other words, the ISO standards are based on voluntary certification, but some legal frameworks provide for them to give presumption of conformity with the applicable rules governing a specific domain. There is no provision conferring on ISO standards the presumption of conformity with requirements contained in [Directive \(EU\) 2016/798](#) or with [Regulation \(EU\) 2018/762](#).

Clauses 4 to 10.2 taken from ISO/IEC Directives Part 1 and consolidated supplement 2016, Annex SL Appendix 2, are reproduced or adapted with the permission of the International Organisation for Standardization, ISO. Please refer to the source document for the original text. This document can be obtained from the [website of the ISO Central Secretariat](#). Copyright remains with ISO.

0.6 Purpose of the safety management system

The purpose of the SMS is to ensure that the organisation controls risks that arise as a consequence of business objectives in a safe manner and complies with all of the safety obligations that apply to it.

Adopting a structured approach enables the identification of hazards and the continuous management of risks related to an organisation's own activities, with the aim of preventing accidents. This approach takes into account shared risks at the interfaces with other actors in the railway system (mainly railway undertakings, infrastructure managers and entities in charge of maintenance but also any other actors having a potential impact on the safe operation of the rail system, such as manufacturers, maintenance suppliers, keepers, service providers, contracting entities, carriers, consignors, consignees, loaders, unloaders, training centres, as well as passengers and other people interacting with the rail system etc). Implementing all relevant elements of a SMS in an adequate way can provide an organisation with the necessary trust that it controls and will continue to control all the risks associated with its activities, under all conditions.

Mature organisations recognise that efficient control of risk can only be achieved through a process that brings together three critical dimensions: a technical component with the used

tools and equipment, a human component of front line people with their skills, training and motivation and an organisational component consisting of procedures and methods defining the relationship of tasks.

Consequently, an adequate SMS succeeds in monitoring and improving all three dimensions of its risk control measures. Many features of the railway SMS are very similar to management practice advocated by proponents of quality, health and safety at work, environmental protection and business excellence. Therefore, principles of good management can be more easily integrated as specified above, through the use of a CSM that is based on the ISO HLS and therefore may not need a complete re-design of organisations that already have those systems in place.

It has been recognised that structured management systems add value to business through the effective management of interfaces. This helps to improve overall performance, introduce operational efficiencies, enhance relations with contractors and sub-contractors, customers and regulatory authorities as well as helping to build a positive safety culture.

An applicant must design its SMS in a manner to comply with the requirements set out in Article 9 of [Directive \(EU\) 2016/798](#) in order to ensure the safe management of its operations. To that end, it has to demonstrate compliance with the requirements set out in Annex I and II of [Regulation \(EU\) 2018/762](#). These requirements are arranged to give a complete picture of the organisation's safety management system following a Plan, Do, Check, Act (PDCA) cycle. The applicant will need to consider each individual requirement as well as how they fit together to form a coherent SMS which controls the relevant risks.

0.7 Safety management system and process approach

An SMS is a means of drawing together the various strands which need to come together to be able to run a safe and successful organisation. These elements will comprise the mechanisms in place to comply with international and national regulations and standards, sector and business level requirements, the outcomes of risk assessment and good practice across the range of company activities. For this reason the SMS should be integrated into the business processes of the organisation and in addition, should not become a paper-based system specifically developed for demonstrating compliance with the regulatory framework. The SMS should be a living set of arrangements, which grows in maturity and develops as the organisation, which it serves, does so. Constructing an SMS requires an organisation to understand the risks it must control, the legal framework in which it is operating and to have a clear idea of what 'good' performance looks like. This Guide indicates the elements of the SMS which will need to be satisfied in order for the assessing authority to grant a single safety certificate. However, it should be borne in mind that the quality of the SMS goes beyond the sum of its parts. The SMS must also function as a coherent whole where compliance with each part works to ensure the whole system functions correctly.

The requirements by which the assessment of an SMS will be judged can be satisfied by a documented process (or procedure etc.) but it should also be integrated within and across the various business areas of the organisation. For example, the NSA can check that a policy statement exists but it has also to check the organisation's commitment to

apply it. A practical way to do this is for the NSA to check how the SMS is monitored and reviewed at senior management level, how staff are involved in this and how the results are communicated to them. Likewise, the organisation may not have a specific procedure or procedures to manage safety relevant information but it has to describe how the relevant parts of the business manage it adequately (e.g. communication of safety-relevant information to the train driver).

An important development in Annex I and Annex II of [Regulation \(EU\) 2018/762](#) is the introduction of a process approach. This is also promoted in ISO management system standards, where the different processes of the management system are closely linked and their consistent operation contributes to the achievement of the organisation's objectives. Annex I and Annex II of [Regulation \(EU\) 2018/762](#) identify some important links between processes to facilitate the understanding of the process approach but this does not mean that only those links exist or that they should be demonstrated for compliance purposes. The ability that an organisation has to present how the processes of its management system link together is a good indicator of its understanding of how its management system works effectively.

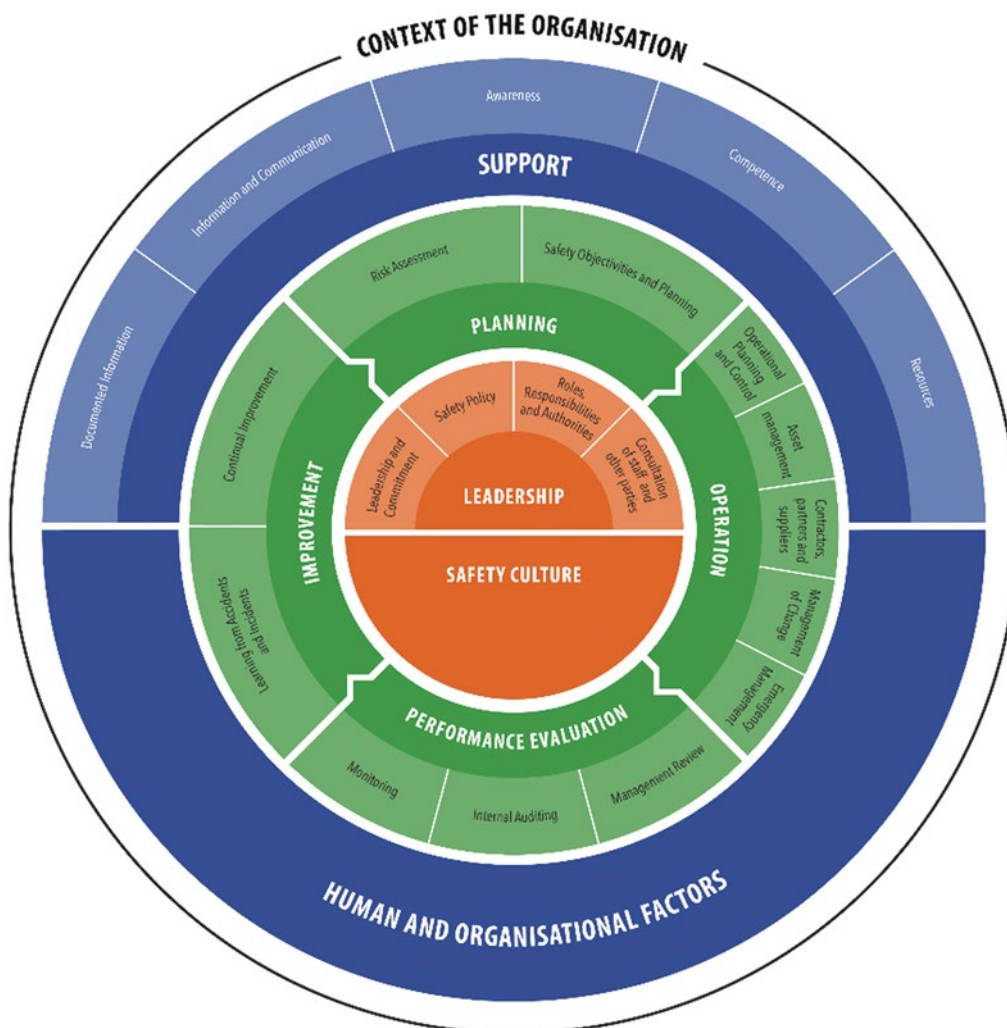
The elements of the SMS can be observed to apply a Plan-Do-Check-Act (PDCA) cycle (see [Figure 2](#)). The PDCA concept reflects the functional relations between the main SMS elements:

- ▶ **Planning:** *identify risks and opportunities, establish safety objectives and identify processes and measures necessary to deliver results in accordance with the organization's safety policy;*
- ▶ **Operation:** *develop, implement and apply the processes and measures as planned;*
- ▶ **Performance evaluation:** *monitor and evaluate the realized performance of the implemented processes and measures with regard to the objectives and the planning, and report the results;*
- ▶ **Improvement:** *take actions to continually improve the safety management system and the safety performance to achieve the intended outcomes.*

This core PDCA process is complemented by other SMS elements:

- ▶ **'Context of the organisation'** *that provides input to the planning phase;*
- ▶ **'Leadership'** *as the driving force for the PDCA-cycle;*
- ▶ **Various 'Support' functions** *that are supportive to all the SMS elements.*

Figure 2: Railway safety management system



0.8 Safety management system, human and organisational factors and safety culture

Human and organisational factors (HOF) integrates knowledge in social sciences such as Management Science, Psychology, Sociology, Design Science, Political Science, to enlarge the scope of study and investigation while considering organisational, institutional, cultural or political contributors to safety. Indeed, according to the International Ergonomics Association, ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data, and other methods to design in order to optimise human well-being and overall system performance (see also the definition in Annex 6).

The term ‘organisational’ has been introduced to highlight the overarching organisational level of analysis and not only the individual level although obviously organisations are composed of individuals.

The investigation of human and organisational factors is part of the safety management process, whereby a (positive) safety culture is part of the outcome (or output) of this process.

Safety culture is a set of patterns of behaviour and thinking, largely shared within an organisation, regarding the management of major risks related to their activities. This of course implies that there might be multiple cultures at play within an organisation based on issues such as job role, geography or other shared values. As such, safety culture is developed on a daily basis, through the interactions between actors, in the context of an organisation that needs both to adapt to its environment (see also the definition in Annex 6).

That said, a direct way to describe safety culture, is to look at the factors that contribute to behaviour. The SMS provides the foundation: in defining the supposed working conditions and the expected outcome, an organisation will define a preferred way of working and the technical means to support the activity. In order to perform safely, the organisation will anticipate adverse situations, and will implement rules and the means to deal with them. In addition, there is the 'human world' of the organisation: qualities, feelings, meanings and the relationships that condition patterns of interaction among individuals within the organisation in such a way as to affect the way they think and act. This cultural side mainly refers to the 'unwritten rules guiding the behaviour and decisions of a group of people'. Together, the structural and cultural part of the organisation facilitate (or inhibit) organisational performance.

A high risk exists, however, that an overly bureaucratic approach to safety management contradicts the operational reality and results in a safety management system taking on a life of its own, i.e. all the effort is put into designing, maintaining and even proving the existence of a documented system, ignoring the operational input that is needed to actually make it work as intended, and creating major inconsistencies between 'work as imagined' and 'work as done'.

On the other hand, there is the possibility to deploy the safety management system as an instrument to exert a positive influence on an organisation's safety culture and impact the physical environment as well as the behaviour of employees in a manner that promotes and facilitates safety. It is the match between the structural and cultural part of the organisation that ultimately creates safety. This is where human and organisational factors should play a significant role. In order to assist people in carrying out their task, an organisation needs to understand how humans, (with their capabilities and limitations) use assets (e.g. train drivers' cab equipment, or any man-machine interface) and specifications to solve problems and take this knowledge into account when designing their work environment. The same goes for rules and regulations: as long as the workers implementing them are not considered when designing working procedures, they will be forced to break rules in order to get work done whenever contradictions or conflicts occur.

The Agency, together with representatives of the sector, has developed the European Railway Safety Culture Model (ERSCM) which is illustrated in Annex 4 (translations of the Guidance on the ERSCM can be found in all EU languages on the European Railway Agency website the link to which can be found in Annex 4). Throughout this document, the human and organisational factors and the basic characteristics that are known to contribute to a positive safety culture are explained as appropriate. Furthermore, Annex 4 and Annex 5 provide the reader with other useful information for the organisation to develop its own strategies. Readers are reminded that they are free to use their own Safety Culture models to support their legal obligations.

0.9 Supporting evidence and documented information

The present document provides some indication of the evidence that the applicant (i.e. the railway undertaking or the infrastructure manager) needs to provide when applying for a safety certificate or safety authorisation without indicating exactly what should be provided, for the reasons stated above. For each requirement, an indication of the evidence that the applicant should supply is given along with the appropriate reference to that requirement. Beneath this, some examples are provided of what this evidence might look like in practice. It should be recognised that the examples are given as an aid to understanding and are not the only means of demonstrating compliance nor do they represent a complete list of possible alternatives. Moreover, it must be understood that when the applicant makes an application they describe how they meet each requirement. The assessor or the applicant may ask for or provide as evidence the kind of information suggested to clarify or reinforce how it is met. For the applicant and the assessor the most important point for each requirement is to make sure that the statements concerning compliance are linked to references, which explain where further evidence can be found to support the points made. The examples section for each of the requirements attempts to indicate what this referenced material might look like.

References, which should be helpful to applicants in preparing their applications, are listed after this section. Finally, the last section under each element attempts to establish the necessary link to Supervision. Here is given an indication of issues that an assessor may wish to highlight to the NSA Supervision teams as areas of interest which can be used to test the comprehensiveness of the SMS.

Likewise the approach enacted in ISO management system standards, Annex I and Annex II of Regulation (EU) 2018/762 are not prescriptive, except for specific cases, about the nature of evidence (e.g. procedure) to be expected of the applicant. The flexibility left to the applicant aims at allowing the organisation to present its safety management system arrangements in a manner which reflects the nature of the business and is proportionate to its scale. In addition, it will assist in moving away from a paper-based test of compliance to an assessment of a living evolving system which properly reflects a business' safety management arrangements, as they exist in practice.

The term 'documented information' was introduced as part of the ISO HLS and common terms for management system standards. The definition of 'documented information' can be found in *ISO 9000 clause 3.8*. Documented information can be used to communicate a message, provide evidence of what was planned, has actually been done, or knowledge sharing. It includes but is not limited to documents and records such as procedures, minutes of meetings, reports, formal communication of objectives, results, agreements, contracts, etc. Further explanation can be found in the *Guidance on the requirements for Documented Information of ISO 9001:2015* available on the [ISO website](#).

The term 'procedure' should not be intended to imply the existence of a stand-alone document, covering exclusively and extensively the management of each single element of the SMS, or to request the development of a specific set of new documents. Where reference is made in this document to a procedure it means documented information (e.g. paper documents) setting out the steps to be applied. Where reference is made to a process this refers to the means of achieving a task or goal which may or may not be set out in a procedure.

0.10 Cross-referencing other EU Regulations and applicable legal requirements

References to other EU Regulations reinforce consistency between the different legal texts while acknowledging the links between them. The SMS arrangements should always comply with the legal text in force, unless stated otherwise (e.g. specific transitional provisions, delayed application). When an EU Regulation is repealed, usually all references are construed as references to the new Regulation (if specified therein).

All railway undertakings and infrastructure managers must comply with a range of legal obligations which extend beyond those that solely deal with safety matters. Some of these other obligations will directly or indirectly have an impact on how the organisation addresses its safety responsibilities through its SMS, for example compliance with legislation deriving from [Directive \(EU\) 2016/797](#) (Interoperability Directive) or safety relevance of the service provided by the infrastructure managers to the railway undertakings under the framework of the [Directive \(EU\) 2012/34](#). Therefore, the SMS that the railway undertakings and infrastructure managers use to address safety risks must be organised to ensure compliance with such other legal obligations as appropriate.

1. Context of the organisation

1.1 Regulatory requirement

1.1	The organisation shall: <ul style="list-style-type: none">(a) describe the type, character, extent and area of its operations;(b) identify the serious risks for safety posed by its railway operations whether they will be carried out by the organisation itself, or by contractors, partners and suppliers under its control;(c) identify interested parties (e.g. regulatory bodies, authorities, railway undertakings, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;(d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);(e) ensure that the requirements referred to in point (d) are taken into account in developing, implementing and maintaining the safety management system;(f) describe the scope of the safety management system, indicating which part of the business is included or not in its scope and taking into account the requirements referred to in point (d).
1.2	For the purpose of this Annex the following definitions are applied: <ul style="list-style-type: none">(a) 'character' in relation to railway operations carried out by infrastructure managers means the characterisation of operation by its scope, including infrastructure design and construction, infrastructure maintenance, traffic planning, traffic management and control, and by the use of the railway infrastructure, including conventional and/or high speed lines, transport of passengers and/or goods;(b) 'extent' in relation to railway operations carried out by infrastructure managers means the extent characterised by the length of railway track and the estimated size of the infrastructure manager in terms of number of employees working in the railway sector.

1.2 Purpose

The applicant should be as precise as possible in demonstrating to the authority that its SMS covers its full operation. The assessing authority should be able to see clearly what the nature of the operation is and how this is managed through the SMS. The applicant should show that it has a clear understanding of its relationships with interested parties and the serious risks it faces, who is affected and how these matters are dealt with in the SMS.

1.3 Explanatory notes

In point 1.1 of the legal text above where the requirement concerns infrastructure managers 'type' is replaced by 'character' and 'area' is deleted.

The requirement “organisation”, its context and the scope of the safety management system **(1.1)** aims at better understanding from the assessors perspective of the organisation’s business, stakeholders’ expectations and the environment in which the organisation operates. The nature of the organisation is the starting point for the assessment; having this information at the start of the application will enable an applicant to describe what they do and how their organisation is structured, and this in turn will allow the assessor to make decisions on how to plan the assessment. For example if the organisation is centralised or runs disparate operations with extensive local freedom to plan and organise their activities or if the organisation employs more or less contractors there will be a corresponding expectation that the applicant’s organisation and its SMS is structured to deal with the issues created. The organisation should clearly explain who its contractors are, what monitoring of them is carried out (see also Section 6.1) and how the responsibilities for different aspects of the operation are managed by the applicant. It should also be clear where the responsibility lies between the Safety Management System of the applicant and those of any other organisation with whom there are interfaces. The explanation of the overall context of the organisation can also indicate how human and organisational factors are managed. The structure set out in clause 4 of the ISO High Level Structure may help understand the preparation work needed before establishing the SMS. It is critical that the assessor understands the scope of the operation if s/he is going to be able to conduct a proper assessment.

The type of operations **(1.1 (a))** covers by definition the transport of passengers (with or without high speed services) and goods (with or without dangerous goods), and shunting services. It may also include other special types of operation such as the testing of vehicles, the operation of vehicles for the maintenance of the rail infrastructure or operations on privately owned sidings. More information on the type, extent and area of operation can be found in the *Agency application guide for issuing single safety certificates*. Further information on siding operations can be found in Annex 3.

For an infrastructure manager the character and extent **(1.2)** the nature of the business and its geographical size and complexity. The character reflects the kind of infrastructure in use, how modern it is, whether it is high speed or conventional or both whilst the extent addresses the kind of business that is being run.

Identifying serious risks in this case means that the applicant should show that they are aware from their analysis of the risks they face which are the most important. Identification of serious risks also means that the applicant has established a risk management system (or is preparing to establish it), and from this they can:

- ▶ *analyse dangerous occurrences and assess risks,*
- ▶ *become aware of the most important (in terms of consequences and frequency) and*
- ▶ *give priorities to measures aiming at the prevention of accidents.***(1.1 (b))**

This helps to set the context of the organisation and shows the assessing authority that they understand the environment in which they operate. The activities of other actors or other parties external to the railway system **(1.1 (c))** may affect the safety of operations and in that respect, have also to be considered for the risk assessment. Further information on contractual arrangements and partnerships can be found in Annex 3.

1. Context of the organisation

The applicant should also provide enough information so that the safety certification body can understand what kind of operation the company carries out and where; for example, the freight the company will provide transport for i.e. timber, containers, combined transport, semi-trailers in pocket-wagons, goods inside wagons or on open wagons etc and the routes covered. For different types of goods the company may need to have different types of management arrangements referred to in the SMS (loading, training etc.)

The context of the organisation must also describe how the railway undertaking or infrastructure manager plans to handle maintenance of all the vehicles they will use. For example will the organisation use a certified Entity in Charge of Maintenance (ECM), or does the organisation want to become a ECM and maintain vehicles exclusively for its own operation and fulfil for itself the relevant ECM requirements (see annex II of [Regulation \(EU\) 2019/779](#) and its associated Guide), inside the SMS. The applicant needs to specify the relationship between different contracting parties for maintenance for example if the Railway undertaking rents vehicles which are maintained by a third party ECM, this should be specified. Further information on the management of maintenance activities can be found in the ERA Guide on Entities in Charge of Maintenance.

The identification of applicable requirements related to safety **(1.1 (d))** ranges from the provisions of applicable EU Regulations (e.g. relevant CSM on safety management systems and in particular its Annex I and Annex II, CSM for risk evaluation and assessment , CSM on monitoring, relevant TSIs, Implementing Act on the practical arrangements for safety certification and where applicable, Implementing Act on the practical arrangements for vehicle authorisation and ECM Regulation) and national legislation (e.g. notified national rules, national law) to any other requirements to which the organisation subscribes (e.g. sector or industry level rules for train operation or management system and technical standards such as ISO, CEN/CENELEC, UIC).

In this section the organisation identifies those legal provisions it must comply with along with those sector and other requirements which it will need to observe in order to be able to run trains safely. There may be different requirements in different Member States (MS) and the SMS must be capable of managing any conflicts between these and the legal framework. Further information relevant to these requirements may be found in documents such as Network Statements.

If the railway undertaking plans to transport dangerous goods or the infrastructure manager plans to allow dangerous goods transport on their infrastructure they both need to fulfil the specific requirements set out in the regulation on the international transport of dangerous goods, (RID) as well as any national rules which apply. RID has specific requirements for the training of staff involved in dangerous goods transport such as the safety advisor as well as for example requirements for emergency plans and these should be covered in the SMS (see also UIC – IRS 40471-3).

For the purposes of this document, the terms ‘staff’, ‘employees’ and ‘workers’ have the same meaning, that is to say people who work under the direct control of the applicant’s organisation.

1.4 Evidence

- ▶ *For railway undertakings: Information about the nature of the operation, e.g. passenger and/or freight, transport of dangerous goods, geographical coverage, (by including a map or route plan) and scale of the operation, the use of subcontractors, partnerships with other operators (name), the different actors involved (name and type of actor), the choice of certified ECM with a copy of the valid certificate. It should also identify the types of rolling stock, number of staff directly employed and give an indication of where extra staff are contracted from and where the application is a renewal of a certificate any changes made since the last assessment;***(1.1 (a))**
- ▶ *For infrastructure managers: Information about the nature of the operations they cater for, e.g. freight and or passenger, shunting, or other facility services (as referred to in Annex II of the Directive 2012/34/EU) having an impact on railway safety, geographical coverage (by including a map or route plan) and scale of the Railway Undertakings' operations taking place on the network. The infrastructure manager should also include information on its use of subcontractors (name), partnership with other operators (name), different actors involved (name and type), choice of certified ECM with a copy of a valid certificate. They should also indicate any rolling stock (including plant for infrastructure maintenance or measurement) they may operate, and indicate the number of staff they employ and in the case of renewals any changes to the staffing arrangements since the last assessment;***(1.1(a))**
- ▶ *The applicant has to indicate what the most serious safety risks are which affect their business;***(1.1(b))**
- ▶ *The applicant for a safety certificate or a safety authorisation has to show how it has identified the relevant regulatory requirements e.g. the CSM assessment requirements, the Technical Specifications for Interoperability, in particular the one relating to the operation and traffic management subsystem (TSI OPE), the applicable national rules and other requirements (sector rules, other rules) which it will need to follow in order to be able to run trains safely as well as how it maintains compliance with these (the SMS processes which support compliance);***(1.1 (c)-(d))**
- ▶ *The applicant has to identify interested parties who are relevant for the successful implementation of their SMS (i.e. their actions have an impact or potential impact on the SMS for example contractors, or partners) with an indication of why they are needed for the successful operation of the SMS;***(1.1 (c) (d))**
- ▶ *For both: The applicant should indicate where in its safety management system documentation each of the SMS requirements, including the relevant requirements of the applicable Technical Specifications for Interoperability, in particular the (TSI OPE), and relevant notified national rules and other requirements are met;***(1.1(e))**
- ▶ *The applicant needs to provide information concerning the scope of the SMS (including what the boundaries are with other parts of the business such as the maintenance of vehicles).***(1.1(f))**

1.5 Examples of evidence

A map showing the geographical area of operation. Information on the rolling stock authorised for operation (including where relevant any proposed rolling stock which it is proposed to have in operation during the life of the certificate or authorisation and any limitations on the

1. Context of the organisation

area of use). Information on the types of services it intends to operate (passenger and /or freight) is included.

When the applicant is an infrastructure manager, this information can be provided by reference to, for example:

- ▶ *The information contained in the Register of Infrastructure (RINF) set up in conformity with Directive (EU) 2016/797 (Art. 49);*
- ▶ *The content of the Network Statement (in particular, in Section I) set up in conformity with Directive 2012/34/EU; and*
- ▶ *The route book set up in conformity with Regulation (EU) 2019/773 (TSI OPE).*

The information provided for obtaining a safety authorisation or safety certificate is properly referenced and is sufficiently documented to prove compliance with relevant EU legislation.

An indication of current and proposed staffing within the lifespan of the single safety certificate as far as this is known.

A railway undertaking provides information on the operational interfaces it has, including with the infrastructure manager(s), other railway undertakings, contractors and the emergency services. This information includes any specific requirements of the infrastructure manager which impact on the railway undertaking's SMS.

For railway undertakings, a mapping table submitted through the one-stop shop as part of the application file for a safety certificate could be used to explain how regulations and other relevant requirements are complied with.

Similarly an infrastructure manager should provide a similar list of those with whom it has operational interfaces, such as railway undertakings operating on the controlled infrastructure, its contractors, neighbouring IMs, construction sites, local authorities (for road interfaces) and the Emergency Services.

Information on the legal provisions (both national and European) that it will comply with.

A description (including an organogram) which sets out how the SMS is structured and managed inside the organisation which also contains links to the different sections of the SMS where more detailed information such as operating rules can be found.

A recent copy of the Annual Report which details the most serious risks that the organisation deals with and the objectives to control these, the methodology used to assess them and how they are prioritised.

A statement whether you use a certified ECM or maintain vehicles exclusively for your own operation.

An overview of the maintenance process and the type and level carried out.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

A risk register or an overview where operational safety risk scenarios are documented, including consideration of human and organisational factors:

- ▶ *Individuals (e.g. human error);*
- ▶ *Workplace (e.g. physical environment, such as noise, darkness, weather); and*
- ▶ *Organisation (e.g. workload, competence management, task design, resources, shifts).*

Defining the most serious risks, risk scenarios are evaluated in order to allow for a risk prioritisation (this is found in the risk assessment process, see 3.1.1). The risk register covers risks linked to the organisation's activities as well as activities executed by contractors, partners or suppliers under its control. For each serious risk the risk owner is clearly defined within the SMS.

The SMS containing a description of the stakeholders that are relevant for safety management and describes how the relationship with these stakeholders will be managed. The means sharing the most serious risks with the concerned third parties are indicated and some examples provided (e.g. contracts, minutes of meetings).

1.6 References and standards

- ▶ *TSI OPE application guide*
- ▶ *ECM guidelines*
- ▶ *UIC – IRS 40471-3 Inspections of Dangerous Goods Consignments*

1.7 Supervision issues

Check the accuracy of the information provided against known information about existing operations in the case of a certificate renewal application or against other available information in the case of a new entrant.

Check that the SMS as described does deliver the arrangements to manage safety in practice.

Check that all the interfaces that the organisation has with others are reflected in the arrangements in the SMS for controlling risk.

2. Leadership

2.1 Leadership and Commitment

2.1.1 Regulatory requirement

- 2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:
- (c) taking overall accountability and responsibility for safety;
 - (d) ensuring commitment to safety by management at different levels within the organisation through their activities and in their relationships with staff and contractors;
 - (e) ensuring that the safety policy and safety objectives are established, understood and are compatible with the strategic direction of the organisation;
 - (f) ensuring the integration of the safety management system requirements into the organisation's business processes;
 - (g) ensuring that the resources needed for the safety management system are available;
 - (h) ensuring that the safety management system is effective in controlling the safety risks posed by the organisation;
 - (i) encouraging staff to support compliance with the safety management system requirements;
 - (j) promoting continual improvement of the safety management system;
 - (k) ensuring that safety is considered when identifying and managing the organisation's business risks and explaining how conflict between safety and other goals will be recognised and resolved;
 - (l) promoting a positive safety culture.

2.1.2 Purpose

Setting a clear and positive direction for safety management will have an important effect on how risk is managed. The assessing authority needs to be confident that the applicant is committed to allocating resources to allow the organisation to operate safely, to allow it to manage its risks effectively and that the leadership within the applicant's organisation is there to ensure that this happens. Management commitment to human and organisational factors is demonstrated in policies and objectives and in management and leadership behaviours. Furthermore, a human and organisational factors approach taken by leadership will also ensure that training and procedure development is based on the task to be performed within its natural setting, which will help optimise both risk control and performance as it will be based on an accurate description of the task ("work as done").

The safety policy states the importance and prioritisation of safety including the integration of human and organisational factors and the promotion of the safety culture.

The organisation fosters a constant and collective vigilance, fighting complacency (“everything is under control”) and over-simplification (“respecting procedures is sufficient to deliver safety”) and developing a questioning attitude. Furthermore, all actors in the organisation are aware that, whatever the quality of planning and organisation, technical barriers and procedures, there may always be a gap between what was anticipated and what really happens. All possible sources are used to detect and collectively analyse those situations that have not been anticipated adequately.

In addition, the organisation’s communication on safety is in line with the reality of managerial decisions.

For an SMS to work effectively and improve in the future it is essential that those in leadership roles demonstrate to their staff and interested parties that they are setting a positive agenda within which safety can be managed. It is those in leadership positions who have the largest influence on the organisational culture and it is therefore essential that they can communicate the right message to those that work under their responsibility. The behaviour of managers at all levels in the organisation and the importance they attribute to safety in their day-to-day decisions, influence greatly the behaviour of other actors in fulfilling their tasks safely. Also, managers should create the physical and social work environments within which frontline work is done safely.

2.1.3 Explanatory notes

‘Top management’ (2.1.1) in this context means those who make decisions as the directing mind of the organisation. Typically, it would include the Chief Executive, members of the top management group, Chairman and Board Members. As a group and as individuals, ‘top management’ is required to demonstrate leadership and commitment through the safety management system.

How are human and organisational factors and safety culture integrated?

Enough weight is to be given to safety risks (2.1.1 (i)) to balance other business risks, to avoid a situation where management prioritise business needs in such a manner that safety performance is weakened. The top management must ensure that objectives are dealt with in such a way that safety performance is maintained and risks are managed as far as reasonably practicable. Conflicting objectives should not result in conflicting tasks for individuals which could lead to safety issues.

An integrated human and organisational factors approach to leadership and management means setting goals, expectations and accountabilities in relation to safety behaviours at all levels of the organisation and ensuring timely feedback and communication.

2.1.4 Evidence

- ▶ *There is a safety policy, objectives and there is evidence that these are available to and understood by all staff and it is made clear how these fit into other business processes and are linked to continual improvement;(2.1.1 (a)(b)(g)(e)(h))*

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- ▶ *The safety policy states the importance of applying a human and organisational factors approach in all safety-related processes to accomplish a high level of safety in the organisation. The organisation shows how human and organisational factors issues in organisational processes are managed;***(2.1.1 (c))**
- ▶ *The relationship between the SMS and other business activities is clearly set out in a procedure or organogram;***(2.1.1 (e),(i))**
- ▶ *There is information available in the safety policy or in other processes to indicate that the management are committed to providing and maintaining sufficient resources to allow the SMS to function effectively and improve over time;***(2.1.1 (e), (h))**
- ▶ *There is evidence showing that the leadership are promoting a positive safety culture;***(2.1.1 (j), (h))**
- ▶ *Evidence to show how it is ensured that staff understand their safety roles and responsibilities and how what they do impacts on the ability of the organisation to control risk through the SMS;***(2.1.1 (d)(f)(i))**
- ▶ *There is evidence within the Safety Policy or other documentation that the organisation seeks to inform its staff of the important role they play in ensuring that the SMS works in practice to deliver meaningful risk control;***(2.1.1 (e))**
- ▶ *There are processes stating how human and organisational factors should be addressed and communicated within the organisation related to the organisations business objectives and organisational processes, e.g projects, investigations of incidents and accidents, risk analyses and other safety-related activities for the organisation's own personnel, contractors, partners and suppliers;***(2.2.1 (c)(d)e))**
- ▶ *There is evidence that the leadership has put in place processes to ensure that human and organisational factors are properly addressed by the organisation's subcontractors;***(2.2.1 (c) (d)(e))**

2.1.5 Examples of evidence

A Safety policy is provided signed and dated by the Chief Executive which clearly states the commitment of the management to safety and safety improvement and how the staff are involved in managing safety risk. The Safety Policy also indicates how it will be reviewed.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

A clear set of safety objectives being set for the organisation which are Specific, Measurable, Achievable, Realistic and Time bound (SMART) and there is a clear methodology set out in a procedure for creating these and for analysing the success or failure to achieve them. The SMS contains evidence that management has objectives linked to operational safety (next to objectives linked to occupational health and safety).

A clear statement by the leadership on how they promote a positive safety culture and how staff are involved and engaged in the process.

An overview of the meetings and their frequency that the top management has where safety is a standard reporting item.

A clear statement as to the commitment of the organisation to provide sufficient resources to allow the SMS to function efficiently to control risks.

An organogram setting out clearly how the SMS functions and who is responsible for what.

That a human and organisational factors approach is taken in the design of new equipment, e.g. new trains. This includes using the presents users' experience in producing design requirements, analysing tasks to identify cognitive and physiological challenges, reducing the potential for erroneous performance through design by applying human factors guidelines such as internationally recognised standards, making workload and fatigue management analysis to ensure the personnel is capable of task performance, making risk analyses to identify potential problems and identifying mitigating actions for these. Environmental factors such as snow, heat, rain etc. are considered as well as socio-economic factors such as organisational priorities, procurement and national culture.

Safety leadership training being organised for managers in safety positions. There is evidence of periodic management training. There is evidence that management training takes into account the safety vision, how it was integrated in the safety policy as well as how to communicate and apply it.

The leadership demonstrating through records of safety tours or visits to site its commitment to the promotion of a positive safety culture and its desire to lead by example.

2.1.6 References and standards

► [*Safety Culture \(ERA web-page\)*](#)

2.1.7 Supervision issues

The extent of the disconnect between any policies and procedures provided as part of the evidence above and the observed reality during supervision and to what extent the organisation is aware of the gap are key issues for supervision.

The extent of leadership's true commitment to the SMS and safety culture promotion as well as that of the employees to the organisation should be tested during supervision through the examination of the organisation's own mechanisms for understanding and developing that culture and the SMS.

Check that the organisation can demonstrate sufficient resources are being provided to the development, implementation, maintenance and continual improvement of the safety management system.

Check, by interviewing the top management and other staff, how the management express their commitment to safety improvement. Find out how often and in what ways they are in

2. Leadership

contact with staff on safety issues and/or for promoting safety culture (workshops, forums, dedicated safety days, etc...).

Check if there are communications from the top management, concerning objectives, either in the sense of encouraging all staff to contribute to their attainment or to thank all for improved performance.

2.2 Safety policy

2.2.1 Regulatory requirement

- 2.2.1. A document describing the organisation's safety policy is established by the top management and is:
- (m) appropriate to the organisation's type, **character** and extent of railway operations;
 - (n) approved by the organisation's chief executive (or a representative(s) of the top-management);
 - (o) actively implemented, communicated and made available to all staff.
- 2.2.2. The safety policy shall:
- (a) include a commitment to conform with all legal and other requirements related to safety
 - (b) provide a framework for setting safety objectives and evaluating the organisation's safety performance against these objectives;
 - (c) include a commitment to control safety risks which arise both from its own activities and those caused by others;
 - (d) include a commitment to continual improvement of the safety management system;
 - (e) be maintained in accordance with the business strategy and the evaluation of the safety performance of the organisation.

2.2.2 Purpose

The safety policy is an important document for showing how the organisation manages its safety responsibilities and its leadership and commitment for the proper management of safety. The applicant should be able to show that they have a safety policy which meets the requirements above and describes in summary the basic structure of risk control.

2.2.3 Explanatory notes

The safety policy is an expression of the leadership's philosophy and therefore this section is linked closely with section 3.1.

In point **2.2.1 (a)** of the legal text above where the requirement concerns infrastructure managers 'type' is replaced by 'character'.

How are human and organisational factors and safety culture integrated?

The safety policy expresses the safety vision, even if the regulatory requirement above does not directly mention human and organisational factors there is a clear focus on human factors issues within the organisation and a recognition of the important role that humans play in delivering a safe and efficient organisation and delivering business objectives. The role of the human is considered at each review of operational and business development.

2.2.4 Evidence

- ▶ *For a Railway Undertaking: A written safety policy signed by the Chief Executive that reflects the type and extent of operation, supports conformity with legislative and other requirements, continual safety improvement and provides a framework for setting safety objectives.(2.2.1 (a),(b)), (2.2.2 (a-c))*
- ▶ *For an Infrastructure Manager: A written safety policy signed by the Chief Executive that reflects the character and extent of railway operations and infrastructure development, supports conformity with legislative and other requirements, continual safety improvement and is used for setting safety objectives;(2.2.2 (a-c))*
- ▶ *For both: Information to indicate that the safety policy has been communicated to all staff;(2.2.1 (c))*
- ▶ *Information that the safety policy is maintained so that it is always aligned with the business strategy and the evaluation of the safety performance of the organisation;(2.2.2 (d), (e))*
- ▶ *Evidence that the safety policy has a commitment to monitor safety performance and is periodically reviewed following analysis of the safety performance amended after reviewing the safety performance of the organisation against the set objectives.(2.2.2(b), (d), (e))*

2.2.5 Examples of evidence

A safety policy signed and dated by the Chief Executive which accurately reflects the type, extent and character of the operation. The document gives a commitment to continual improvement of the SMS

The safety policy is current and has a defined review cycle aligned with the business strategy.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in.

The safety policy contains information or references in which the process is set out for reviewing it. This is to identify if it needs amendment following the monitoring of the safety performance of the organisation against the set objectives.

The safety policy and other associated policies being used as a focus for managers, which results in them being interpreted in the same way by all staff.

Employees being actively involved in reviewing and revising the safety policy and how it is applied.

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The safety policy referring to a process/methodology for risk-based evaluation of proposed decisions (in line with the safety vision). This process explains how safety is taken into account as a primary objective.

The safety policy or other provisions in the SMS mandating every member of staff to stop when work conditions become unsafe.

A baseline evaluation of the organisation in terms of safety culture having been conducted. Weak points have been identified by the organisation, communicated to staff and measures for improvement are stated in the safety policy.

There a process for communicating the safety policy via the organisation's intranet and for displaying it in strategic/operational locations.

The organisation being outward looking and seeking external learning opportunities to develop its efficiency and effectiveness and considers human factors issues in doing so.

2.2.6 Supervision issues

During supervision it will be important to test how well the safety policy has been communicated to and is understood by all staff and what role it plays in setting the safety framework within which the organisation operates. A key question is whether the document is helping to set the agenda or is there simply because it is a legal requirement.

Check that changes in organisational safety performance have triggered a review of the safety policy.

Check that the safety policy reflects the reality of the organisation.

2.3 Organisational roles, responsibilities, accountabilities and authorities

2.3.1 Regulatory requirement

- 2.3.1. The responsibilities, accountabilities and authorities of staff having a role that affects safety (including management and other staff involved in safety-related tasks) shall be defined at all levels within the organisation, documented, assigned and communicated to them.
- 2.3.2. The organisation shall ensure that staff with delegated responsibilities for safety-related tasks shall have the authority, competence and appropriate resources to perform their tasks without being adversely affected by the activities of other business functions.
- 2.3.3. Delegation of responsibility for safety-related tasks shall be documented and communicated to the relevant staff, accepted and understood.
- 2.3.4. The organisation shall describe the allocation of roles referred to in paragraph 2.3.1. to business functions within and where relevant, outside the organisation (see 5.3. Contractors, partners and suppliers).

2.3.2 Purpose

The aim of this requirement is to get the applicant to provide a clear picture of the structure of the organisation and how roles and responsibilities are allocated and maintained over time from those in front line positions to top management. This is key to understanding how well the organisations safety management system controls risk. The applicant should demonstrate how they assign competent staff to activities, how they ensure that those staff have a clear understanding of their roles and responsibilities and how people are held accountable for their performance.

2.3.3 Explanatory notes

There may exist a gap in the understanding between the safety management provisions at an operational level and the management processes that are supposed to run the safety management system (e.g. risk assessment, monitoring). The identification of roles relevant within the safety management system (2.3.1) is not limited to those being accountable or responsible for the management of safety processes, such as the safety manager or the safety team, but extends to any role involved in safety-related tasks, such as the operational staff and this is independent of their managerial or non-managerial positions within the organisation (i.e. senior managers, line managers, other staff/employees/workers).

‘Delegation’ (2.3.3) means the transfer of responsibility to a lower from a higher position of authority usually for the purpose of speeding up the organisation’s response to matters which arise. Safety responsibility can be delegated, i.e. cascaded down, within the scope of the defined job responsibilities, provided such delegation is documented. Safety accountability cannot be delegated it legally remains with the senior management. It defines the obligation of the person who is held to account if something is not done, does not work, or fails to achieve its objective, to demonstrate the satisfactory discharge of his/her safety responsibilities.

The allocation of roles (2.3.4) can be demonstrated through the provision of an appropriate organisation chart or organogram.

How are human and organisational factors and safety culture integrated?

Within roles, responsibilities, accountabilities and authorities (2.3.1) the exchange of safety-related information should be covered. For example who is responsible for issuing late change notices for train drivers. (see also 4.4.1 and 4.4.2).

The SMS should conform to the CSM SMS requirements (1.1 (d)) and top management is accountable for ensuring that its SMS meets them. Top management may delegate some of its responsibilities to relevant staff. Performance reporting is conducted in accordance with the requirements of management review (6.3), where relevant staff have a responsibility to report on the safety management system’s performance to top management.

‘Safety-related tasks’ (2.3.1) are not limited to those tasks that directly manage safety (i.e. safety-critical tasks, that are performed by staff when they control or affect the movement of a train, which could affect the health, and safety of persons, as stated in the TSI OPE). It

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also includes non-operational tasks that influence safety, linked to the risk assessment (e.g. planning operation, rostering staff, assigning vehicles). Where new or changed roles and responsibilities are being considered there is an analysis of human factors matters in relation to the change and the way that duties are actually carried out within the organisation.

There are criteria to delegate and allocate responsibilities and tasks where the necessary competence and skills are identified. These criteria are applied and therefore safety tasks are clearly allocated and the staff carrying them out have the appropriate competence, authority and resources to deliver them, and they are aware of the risks linked to their tasks.

The communication and acceptance of tasks **(2.3.3)**, including safety-related tasks, is part of the normal business process for how staff are allocated to functions and this should be auditable. Where delegation of responsibilities is carried out there is a systematic approach to how this is done.

Management should possess sufficient knowledge and understanding of human and organisational factors issues to ensure that specialists are engaged when needed. The roles, responsibilities and accountabilities of human and organisational factors specialists should be defined according to the tasks to be carried out. **(2.3.3)**.

There should be a process to ensure that individuals can report near misses, incidents and accidents without fear of repercussion. The policy supports individual rights and responsibilities to raise safety concerns, and does not tolerate harassment, intimidation, retaliation or discrimination for doing so. The key to the success of a just culture is trust and openness in the organisation. This is built-up over time and depends on management's willingness to make comprehensive analyses when incidents and accidents have occurred, as well as to listen and learn before reacting. Consistency in handling safety issues is important in establishing a just culture.

2.3.4 Evidence

- ▶ *An organogram and relevant explanatory text giving the structure of the organisation relevant safety responsibilities and the way that the safety management system is set out and how it links to the context of the organisation;***(2.3.1), (2.3.4)**
- ▶ *A list of other information detailing safety responsibilities within the organisation's structure;***(2.3.1), (2.3.3)**
- ▶ *Evidence that a competence management system is in place and maintained for all staff which assesses the adequacy of the tasks with assigned responsibilities, competence and resources;***(2.3.2)**
- ▶ *Evidence from the competence management system or other HR procedures such as performance management that the organisation ensures that roles and responsibilities are communicated to, accepted and clearly understood by staff and that they will be held accountable for performing them;***(2.3.3)**
- ▶ *A description of responsibilities for operation and maintenance, including a definition of the requirements that staff and contractors as appropriate should comply with;***(2.3.4)**

- ▶ *The strategy for human and organisational factors should demonstrate requirements for when and how human and organisational factors expertise is engaged and what their roles and responsibilities are.* **(2.3.1), (see also 4.6)**

2.3.5 Examples of evidence

An organogram supported by additional text which allows the assessor to see how the SMS is structured and how its different parts relate to each other.

Reference to the Competence Management System (CMS) with information on how this is structured and links to where the detail can be found including descriptions of the HR processes supporting it such as performance management.

A feedback process is provided that is used to ensure that information that has passed down through the organisation is clearly understood.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

The organisational structure being consistent with responsibilities clearly allocated across the organisation.

The overall policies and procedures covering roles and responsibilities are consistent all across the organisation.

The process covering how safety responsibilities are allocated and where powers of delegation are allowed with some examples to show how the process has worked with a clear link to the risk assessment arrangements.

Examples of role descriptions of safety-related tasks, also those not directly involved in operations and which indirectly affect the delivery of operation (i.e. assigning roles, planning operation and providing operational information to staff, supervising operation) are available and reviewed as and when necessary (for example, in case of changing timetables).

The SMS containing evidence that the responsibilities and the risks linked to the tasks are included in the competence management system and in training programmes. There is evidence (for example, the person to whom the responsibility has been delegated has confirmed this in writing) that the responsibilities have been formally accepted.

The procedure(s) for working out what competence and resourcing is required to support safety tasks and responsibilities for all levels of the hierarchy.

The strategy for human and organisational factors showing how human and organisational factors is an integrated part of processes and projects. The expertise and activities related to human and organisational factors is appropriate for the size of the process or project. The roles and responsibilities, and accountabilities as well as the stages where it is necessary to use a human factors specialist is defined in the process or project plan.

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2.3.6 References and standards

► *Safety Accountabilities and Responsibilities (SKYbrary)*

2.3.7 Supervision issues

For supervision, the key issues here will be matters of degree. The question that will need to be answered is 'how far does the information supplied reflect the reality of the situation in practice'?

An examination of the functioning of the competence management system will be the route to answering most of the questions in this section.

2.4 Consultation of staff and other parties

2.4.1 Regulatory requirement

- 2.4.1. Staff, their representatives and external interested parties, as appropriate and where relevant, shall be consulted in developing, maintaining and improving the safety management system in the relevant parts they are responsible for, including the safety aspects of operational procedures.
- 2.4.2. The organisation shall facilitate the consultation of staff by providing the methods and means for involving staff, recording staff's opinion and providing feedback on staff's opinion.

2.4.2 Purpose

The applicant should provide evidence that they actively involve their own staff (or their representatives) as well as external interested parties in using and developing the safety management system to control risks over time. This will also give an indication to the assessing authority what the safety culture is like within the organisation and how actively they involve relevant third parties in managing safety in areas where the risk is shared.

The organisation acknowledges that no single individual has on his own all the information that is needed to manage safety in a sustainable way. Process experts, safety experts, supporting services, front line staff, management and supervisors, trade unions, external contractors, all hold and use knowledge and information that is essential for safety. They need to be given the opportunity to meet, discuss and express their point of view in order to gain the best possible understanding of the reality of the workplace. Particular attention is needed at the organisational interfaces between services, departments and organisations. The exchange of ideas and information on the analysis and treatment of risk, accidents and incidents should be fostered.

Involvement in reporting safety critical information and participating in the analysis of dangerous situations and incidents is supported by a climate of trust. In addition, the early input of operational staff is actively sought when performing risk assessment, designing or transforming technical installations and writing new procedures.

2.4.3 Explanatory notes

External parties (2.4.1) means organisations which have an interface with the applicant such as contractors, partners, suppliers, relevant government agencies, local authorities or the emergency services.

How are human and organisational factors and safety culture integrated?

These external parties (2.4.1) can be consulted on matters pertinent to the management system. For instance, contractors can be responsible for some safety-related tasks such as train preparation or infrastructure maintenance. When the train preparation procedure or infrastructure maintenance are risk assessed, it is good practice that those contractors be involved in the process.

The expertise of end users is important to ensure a good understanding of working conditions and procedures, processes, tools and documentation consistent with their purpose. Consulting frontline workers from risk assessment on the choice and testing of documentation or equipment will help develop sustainable and safe performance (with better compliance by staff).

The development of a positive safety culture is fostered by good quality and timely communication of relevant information to those who need to receive it.

2.4.4 Evidence

- ▶ *The applicant should provide details of the process for consulting staff (or their representatives) and relevant external interested parties, including how those consultations translate into changes to the safety management system or specific operational procedures;(2.4.1), (2.4.2)*
- ▶ *The applicant should provide information about the system in place to feedback to staff the outcomes of consultation.(2.4.2)*

2.4.5 Examples of evidence

The process or procedure for consulting staff (and, as applicable, their representatives) and interested parties in developing the SMS.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

Examples of minutes of consultation meetings held with staff (and/or their representatives) with the records of outcomes.

Examples of how opinions and suggestions from staff are collected during change management (i.e. on a draft/amended/new operational procedure) and how they are dealt with.

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A document/procedure being provided showing how the operational staff, that will deal with a new or developed technical system are involved at an early stage (planning and developing) of the work, in order to collect inputs e.g. concerning the man-machine interface.

Procedures stating how human and organisational factors should be addressed and the results communicated within the organisation related to the organisation's business objectives and processes, e.g. projects, investigations of incidents and accidents, risk analyses and other safety-related activities for own personnel, contractors, partners and suppliers.

The organisation clearly defining safety expectations and required behaviours. Organisational priorities are aligned to avoid conflicting goals. A process for planning, risk assessing and controlling activities to ensure that safety is not compromised by other business interests is described, for example by using conservative decision-making. Safety goals are linked to the safety culture. Management takes an active role in planning and implementing needed changes to the safety culture.

2.4.6 Supervision issues

Consultation with and involvement of relevant personnel both internally and externally is an important part of making sure that those with relevant experience are able to have a positive impact on the safety management system of the organisation.

Supervision in this area should target the records of how staff and external parties are consulted and their comments taken on board as well as covering records of changes to the SMS which originated in this field

Particular attention should be paid to how feedback is given and learning derived from this.

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3.1 Actions to address risk

3.1.1 Regulatory requirement

3.1.1. Risk assessment

3.1.1.1. The organisation shall:

- (f) identify and analyse all operational (including human performance), organisational and technical risks relevant to the type (*character*), 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);
- (g) evaluate the risks referred to in point (a) by applying appropriate risk assessment methods;
- (h) develop and put in place safety measures, with identification of associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);
- (i) develop a system to monitor the effectiveness of safety measures (see 6.1. Monitoring);
- (j) recognise the need to collaborate with other interested parties (such as railway undertakings, infrastructure managers, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on shared risks and the putting in place of adequate safety measures;
- (k) communicate risks to staff and involved external parties (see 4.4. Information and communication).

3.1.1.2 When assessing risk, an organisation shall take into account the need to determine, provide and sustain a safe working environment which conforms to applicable legislation, in particular Council Directive 89/391/EEC.

3.1.2. Planning for change

3.1.2.1. The organisation shall identify potential safety risks and appropriate safety measures (see 3.1.1. Risk assessment) before the implementation of a change (see 5.4. Management of change) in accordance with the risk management process set out in the Regulation (EU) No 402/2013, including consideration of the safety risks from the change process itself.

3.1.2 Purpose

This requirement goes to the heart of the SMS, it is aimed at getting the applicant to show how their systems identify and control the risks they face. It also requires the applicant to show how they use the results of the risk assessment in practice to improve risk control and how they check this over time. It is important to remember that this requirement does not deal

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directly with managing the risks from changes (which is another requirement) but it is related to it. It should also be noted that there is a specific requirement to address via risk assessment issues related to human performance such as job design and fatigue risk management.

How this information is organised and communicated as part of the SMS is a matter for the applicant to describe in the application and the content should reflect the risks encountered by the organisation bearing in mind the type, extent and area of its operation (see the context of the organisation). It is appropriate to deal both with the risks for which the responsibility rests on the applicant and the risks arising from the activities of third parties.

A common understanding, throughout the organisation, on how to prevent major risks is seen as a priority for good safety management. The low frequency of a scenario should not lead to it being ignored. Moreover, to ensure the realism of a chosen scenario for risk assessment compared to real operations, both safety management experts and operators at the sharp end of the business contribute to safety analysis and risk assessment. The results of these assessments are communicated in an accessible and understandable format to all actors contributing to safety. Management fosters discussions on major risks to be managed, in order to assure a common understanding and awareness. Furthermore, the existence of major risks is stressed throughout the life cycle of the system.

3.1.3 Explanatory notes

For the purposes of assessment of an application, the applicant should show how they comply with Council Directive 89/391/EEC and associated regulations. The assessment will focus on the demonstration of the management of these issues and not the issues themselves. Issues like fatigue or stress management, as well as the testing of physical and psychological fitness may be dealt with as a legal issue within the framework of occupational health and safety, however they have an interface with the competence management system (e.g. for training after long absence) and with job assignment (staff should be assigned to certain jobs only if ascertained that they are fit for them), as stated in the TSI OPE.

In point **3.1.1.1 (a)** of the legal text above where the requirement concerns infrastructure managers 'type' is replaced by 'character' for the purpose of assessment.

'Activities' (**3.1.1.1 (a)**) here means both the action that the interested parties (contractors, suppliers and others) are carrying out on behalf of or in conjunction with an applicant and also the assets that are used in support of those actions. The key point being that the applicant has to demonstrate that they have a robust process for the assessment of risk and all relevant risks are addressed. Some risks (e.g. hydrogeological risks, risks at level crossings, stones thrown at trains, trespassers) need also to be taken into account by the organisation when this is appropriate and reasonable. However, these issues are related to operational risks (since they all affect the train operations) and may not be related to human performance only.

'Other interested parties' designates both organisations and individuals. These parties can be external to the railway system (**1.1 (c)**).

A change may be safety-related or not (3.1.2.1). The impact of any safety-related changes should be assessed and appropriate safety measures identified to reduce the related risks to an acceptable level. The implementation of the change management process may also lead to safety risks, in particular when it is decided to postpone the implementation of a change when it will be necessary to avoid, partly or wholly the creation of another safety risk. However, risk management (3.1.1.1) is not exclusive to change management. In general, the organisation should ensure that the safety risks relating to its operations are adequately managed. The need for identifying, managing and controlling these safety risks, as part of the applicant's SMS, goes therefore beyond change management and the application of the CSM for risk evaluation and assessment.

The CSM for risk evaluation and assessment applies to all technical, operational or organisational changes (for the latter those that have an operational or maintenance consequence). For each safety-related change, the applicant/proposer has first to decide whether the change is significant (or not). If it is deemed that it is, it has to demonstrate that the risks related to the change are acceptable using the principles described in the CSM and that the requirements issuing from this demonstration have been implemented effectively in the system under change. The risk assessment carried out is then assessed by an independent assessment or recognised body which will write a report on the acceptability or not of the analysis. NSAs will consider such reports in their supervision activities but cannot challenge the results of the report unless they have reason to believe that the process of assessing the risk assessment has not been followed correctly. When the change is safety-related but not significant, the applicant/proposer has to document its decision and it will still need to risk assess the change under the risk management process of the SMS. In that case, it is the responsibility of the applicant to choose the appropriate risk assessment methods for justifying that the risk control measures it puts in place are appropriate to control the associated risks to an acceptable level. It should be noted that whilst the trigger for the application of the CSM for risk evaluation and assessment is whether a change is significant or not an organisation could choose to apply that CSM in any event, for example if it felt that for commercial or societal reasons the change merited an independent assessment of the work that the organisation had done. Further information on how to manage significant changes can be found in the ERA Guide on the Common Safety Method for Risk Evaluation and Assessment.

The CSM for risk evaluation and assessment contains six criteria which should be examined to determine 'significance'. These are:

- ▶ **failure consequence:** *credible worst-case scenario in the event of failure of the system under assessment, taking into account the existence of safety barriers outside the system;*
- ▶ **novelty used in implementing the change:** *this concerns both what is innovative in the railway sector, and what is new just for the organisation implementing the change;*
- ▶ **complexity of the change;**
- ▶ **monitoring:** *the inability to monitor the implemented change throughout the system life cycle and take appropriate interventions;*
- ▶ **reversibility:** *the inability to revert to the system before the change; and*

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- ▶ **additionality:** *assessment of the significance of the change taking into account all recent safety-related modifications to the system under assessment and which were not judged as significant.*

These elements should be used to assess how decisions on 'significance' under the CSM for risk evaluation and assessment made by organisations have been reached.

Although the risk management process set out in the CSM for risk evaluation and assessment applies in the case of safety-related and significant changes, the principles underpinning the risk management process enacted in that Regulation are common practice for risk management and therefore, can apply in all other situations where risk assessment is needed.

How are human and organisational factors and safety culture integrated?

Human and organisational factors are applied consistently, from the outset, when designing (new) systems. All levels of the organisation, including frontline operators, are involved in a proactive manner in the risk assessment, anticipating the occurrence of errors through a user-centred approach where the company's organisational structure, availability/use of equipment, design of safety tasks, competence management system and procedures are considered for the assessment of safety risks and identification of safety measures.

The risk assessment procedure will contain approaches or methods to take systematically human and organisational factors into account and aim to remove risks at source in all SMS processes and procedures, when if possible. If not possible, human and organisational factors strategy should aim at minimising the consequences of the risks.

There is a systematic approach for identifying the safety-related tasks and processes, and methods from the human and organisational factors domain are used for analysing safety critical tasks, e.g. task analysis, HTA (hierarchical task analysis), TTA (tabular task analysis). Professional human and organisational factors expertise should be used to select and apply appropriate methods.

The risk assessment process should describe the involvement of human and organisational factors specialists and the relevant competencies, for users and other interested parties. This could for example include a description of the extent to which human and organisational factors specialists should be involved in risk analysis and what level of human and organisational factors competence is needed.

Appropriate methods for integrating human and organisational factors in risk assessment are described, e.g. task analysis, usability analysis, simulation, human HAZOP, bow-tie.

3.1.4 Evidence

- ▶ *The applicant should supply evidence that it has a risk assessment process (including a description of the methodologies used, personnel involved and any validation or verification undertaken), which encompasses both risks identified as significant changes under the CSM for risk evaluation and assessment, (Commission Implementing Regulation (EU) 402/2013) and*

risks considered not-significant which should nevertheless be controlled and the process covers all operational, organisational and technical risks;(3.1.1.1.(a),(b))

- ▶ *Evidence that risks associated with human and organisational factors issues are considered in the risk assessments. The strategy for human and organisational factors should show how and when human and organisational factors are an integrated part of the risk assessment process and demonstrate the use of appropriate methods and expertise;(3.1.1.1(a))*
- ▶ *Evidence of a means of involving where appropriate third parties in the risk assessment process, including how risks from third parties which affect the operations of the railway undertaking or infrastructure manager are managed;(3.1.1.1(a)), (3.1.1.1(e)), (3.1.1.1(f))*
- ▶ *Evidence that the applicant has a process in place to develop and put in place risk control measures, including who is responsible for ensuring that they are completed ;(3.1.1.1 (c)).*
- ▶ *The applicant should indicate how they involve and communicate the results of risk assessment and the associated control measures to the relevant staff;(3.1.1.1(f))*
- ▶ *The applicant should demonstrate how they monitor the effectiveness of their risk control measures including how processes or procedures are updated as required;(3.1.1.1 (d))*
- ▶ *Within the evidence provided the applicant should indicate how they take account of the need to comply with other applicable legislation such as that made under Council Directive 89/391/EEC;(3.1.1.2)*
- ▶ *The applicant provides evidence to demonstrate as part of its change management process that the impact of any change is systematically evaluated. This will mean the use of risk assessment including the use of the CSM for risk evaluation and assessment to identify the risks and the control measures necessary. The applicant also provides evidence that the control measures identified during the change management process have been implemented;(3.1.2.1)*

3.1.5 Examples of Evidence

A risk assessment process or procedure including as necessary how and when Failure Modes and Effects Analysis (FMEA), Hazard and Operability Study (HAZOP) or other techniques are used to support the implementation of control measures to address risk.

Evidence such as a hazard register which shows that the organisation has a process for systematically evaluating hazards as the first step in managing risk, fed by the results of monitoring, promptly updated when new risks are detected, complemented with appropriate information on the safety measures adopted to keep the risk under control (e.g. technical equipment, lists of safety critical components, operational procedures, staff training).

Procedure for complying with other relevant EU legislation such as Council Directive 89/391/EEC, as far as risks related to staff (death, temporary or permanent injuries, near misses) may be covered by the occupational health and safety legal framework, but the control measures should be included in, or complement operational rules.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

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An overview of the process elements for how human and organisational factors are taken into account in the risk assessment process and how and where necessary third parties are involved. Minutes of meetings show that end-users and human and organisational factors experts attended and that their opinions were taken into account.

Examples of analyses carried out which consider the number and nature of tasks to be executed, their complexity, their repetitiveness, the delegation of duties, the workload (including schedule, shifts, use of machinery and relevant instructions, etc.), the clarity and exhaustiveness of rules and working instructions, feedback from staff and the way corrective actions are taken.

The procedure for communicating the outcomes of risk assessments to staff with illustrative examples as necessary.

An indication of the process to ensure the safety-related tasks delegated to each staff category is designed in such a way that:

- ▶ *The volume of tasks to be completed is not excessive at times when a safety-related task is being carried out;*
- ▶ *Where safety-related tasks are combined the organisation is able to demonstrate that the level of safety is maintained;*
- ▶ *There are no contradictions between the delivery of safety-related tasks and other objectives assigned to staff (consistent with 2.1.1 (j)).*

A human and organisational factors strategy linked to the risk assessment processes. This demonstrates that the results from risk analyses are being used and safety-enhancing measures are implemented and evaluated.

Some human and organisational factors elements being dealt with within the occupational health and safety legal framework, and important topics such as fatigue, work-related stress and physical working environment (e.g. cleanness, temperature, light) , in this case, the occupational health and safety documentation should be managed through the SMS.

3.1.6 References and standards

- ▶ *Agency guide for the application of the CSM on risk assessment*
- ▶ *Risk acceptance criteria for technical systems and operational procedures used in various industries*
- ▶ *Guideline supporting the implementation of Regulation (EU) 2015/1136 on harmonised design targets (CSM DT) in the scope of the CSM on risk assessment*
- ▶ *ISO 31000:2018 Risk Management*
- ▶ *ISO 31010:2019 Risk management - Risk assessment technique*
- ▶ *ISO45001:2018 Occupational Health and Safety Management Systems – A Practical Guide For Small Organisations*

- ▶ *CENELEC - EN50126 Railway Applications – The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) Part 1:Basic, Requirements and Generic, Process*
- ▶ *Office of the National Rail Safety Regulator - Asset management guideline (2019)*

3.1.7 Supervision issues

The risk assessment process should be at the heart of the safety management system when carrying out supervision, therefore it should be possible from interviews and checks of documentation and processes to discover whether this is in fact the reality. Of key importance here are any findings from supervision which will be relevant for the future renewal of a single safety certificate or safety authorisation. In addition, any findings from the supervision of risk assessment processes should as necessary form an input into the supervision strategy of the NSA.

The following information can serve as inputs for later supervision:

- ▶ *Hazard list;*
- ▶ *Results of risk analysis, including reports of the risk assessment body or bodies where appropriate;*
- ▶ *Justification about the use of risk assessment methods (e.g. FMECA, FTA, ETA, HAZOP), including how risk assessment criteria are set and how hazard severity and likelihood of occurrence are determined;*
- ▶ *As appropriate, a classification of hazardous events by subject, effects or causes (e.g. preliminary hazard list).*

Staff with responsibilities associated with risk assessment should be aware of their role and the importance of the process and be competent to carry it out effectively.

It is particularly important that a range of examples of risk assessments are examined as these will show whether risks are properly considered using an appropriate methodology. Field observation should then demonstrate that the identified control measures are in place.

3.2 Safety objectives and planning

3.2.1 Regulatory requirement

- 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:
 - (l) Be consistent with the safety policy and the organisation's strategic objectives (where applicable);
 - (m) Be linked to the priority risks that influence the safety performance of the organisation;
 - (n) Be measurable;
 - (o) Take into account applicable legal and other requirements;
 - (p) Be reviewed as regards their achievements and revised as appropriate;
 - (q) Be communicated.
- 3.2.3. The organisation shall have plan(s) to describe how it will achieve its safety objectives.
- 3.2.4. The organisation shall describe the strategy and plan(s) used to monitor the achievement of the safety objectives (see Monitoring).

3.2.2 Purpose

To ensure that the organisation meets legal requirements and ensures that the concept of continual improvement in safety is communicated to staff and believed in by the management.

The applicant needs to demonstrate that they have meaningful objectives and a process to implement and monitor them during their lifetime.

3.2.3 Explanatory notes

Safety performance here means the performance of the organisation against its safety objectives and the performance of the safety management system and all the processes and procedures which support this.

The term 'safety objectives' is interchangeable with the term 'safety targets', although the latter usually has a numerical meaning. Safety objectives or safety targets are different from the Common Safety Targets (CSTs) set at the Member State level, however some companies may use the latter as objectives to be attained, in order to maintain or improve their safety performance.

Using a plan-do-check-act approach, objectives should be reviewed on a regular basis and should consider the results of risk assessment and past monitoring and accident and incident investigation in setting priorities in order to maintain and where practicable improve safety performance.

The setting and monitoring of safety performance indicators that support the organisation's decision-making on risk control and whether these are effective are inputs for setting up and reviewing safety objectives.

How are human and organisational factors and safety culture integrated?

Safety objectives are linked to risks, as the latter will influence the safety performance of the organisation (i.e. the intended outcomes of the safety management system and therefore the success in meeting the objectives). Safety objectives may be quantitative, represented by a reduction of the number of events as an absolute value or in percentage terms. Safety objectives may be also qualitative, expressed as a generic value, like "safety at level crossings will be improved" or "the current level of safety will be maintained". In this case however, the level of improvement or the level at which safety will be maintained will need to be defined and monitored according to some defined criteria in order to determine whether the Safety Objectives are being met.

The organisation defines SMART objectives and communicates them to staff to develop their awareness of the relevance and importance of their activities and how they contribute to the achievement of safety objectives and planning to manage safety risks. Staff are also aware that the achievement of the objectives are monitored and reviewed when necessary.

The objectives are prioritized according to the risk assessment, in line with each other and with the safety policy.

3.2.4 Evidence

- ▶ *There is a set of SMART safety objectives which fit in with the organisation's wider business needs;(3.2.1), (3.2.2 (a),(b)),(c))*
- ▶ *A statement indicating the legal requirements and how they are complied with;(3.2.2 (d))*
- ▶ *Description of how these objectives can be achieved and are communicated to relevant staff;(3.2.2 (f)), (3.2.3)*
- ▶ *There is a monitoring process, consistent with the requirements set out in the CSM on Monitoring (Regulation (EU) 1078/2012), for the objectives to ensure that they are consistently fit for purpose and that the organisation achieves its goals.(3.2.2 (e)), (3.2.4)*

3.2.5 Examples of evidence

The process by which safety objectives are set prioritised and monitored and how conflicts with other objectives are avoided and if not avoided, resolved. This should include the level the objectives are set at and how they contribute to other objectives at other levels where this is appropriate. It should also include the interfaces, the timing and any necessary supporting qualitative or quantitative data.

The safety objectives and the plan for delivering them together with the process to be followed when it appears the safety objectives are going to be missed.

3. Planning

Safety objectives are consistent with the mission and vision statements set out in the safety policy and from this it can be seen that they are valued by staff and there is reinforcement of their commitment to achieving them.

The process or procedure to turn the outcomes from monitoring activities into safety objectives, the planning of actions to achieve them and related indicators of achievement.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

The organisation's strategic plan putting forward safety as a primary objective.

Provisions present within the SMS (risk management process) that explain how conflicts between objectives should be handled.

A process for consulting staff on safety objectives and the process for defining and communicating individual safety objectives, and how they are formally accepted by staff. The process explaining where the objectives can be found by staff, how they know their expected level of contribution to the achievement of these objectives and how they are reviewed/measured as to success, constructed and planned to be achieved is necessary.

A procedure for the communication of objectives to staff shows how awareness is developed and understanding is checked.

In a reporting procedure in which staff indicate the achievement of safety objectives.

3.2.6 Supervision issues

A key question for supervision will be how achievable are the set objectives in practice and what happens in reality if it starts to become clear that they are unlikely to be met.

How the safety objectives are set and reviewed – that the objectives focus on vulnerable or critical activities/controls and utilise outcome and activity indicators

How is the organisation demonstrating continuous improvement in risk control through its' safety objectives.

How does the organisation effectively monitor its safety performance and therefore, use the CSM on monitoring to assess performance against safety objectives and related safety performance indicators.

How do objectives (e.g. one defined some years before), develop from creation to final achievement (or failure).

4. Support

4.1 Resources

4.1.1 Regulatory requirement

4.1.1. The organisation shall provide the resources, including competent staff and effective and useable equipment, needed for the establishment, implementation, maintenance and continual improvement of the safety management system..

4.1.2 Purpose

The purpose of this requirement is to make sure that the organisation has processes in place to provide adequate resources such as technical equipment or systems or competent staff to allow its SMS to control risk in accordance with its objectives.

4.1.3 Explanatory notes

Allocating adequate resources is a pre-requisite for achieving an appropriate level of safety.

How are human and organisational factors and safety culture integrated?

The company ensures that the necessary resources are provided to staff to carry out their tasks safely. This includes staffing, equipment and documentation. This requirement is also linked to the risk assessment and the safety measures identified.

4.1.4 Evidence

- ▶ *Information concerning the competence management system (CMS) or in the event that a CMS does not exist evidence how the organisation ensures that it has sufficient competent staff in place;(4.1.1)*
- ▶ *Information concerning how the organisation goes about making sure that it has enough effective and useable equipment in place to allow it to fulfil its service obligations and to maintain an effective safety management system which controls risk;(4.1.1)*
- ▶ *Information concerning the organisation of maintenance functions (see also Annex II of ECM Regulation 2019/779) and how this relates to the provision of sufficient resource to allow the organisation to fulfil its service obligations.(4.1.1)*

4.1.5 Examples of evidence

The competence management procedure or details of the process which seeks to make sure that the organisation has in place competent staff in relevant roles, with detailed assessment and training programmes as appropriate (**see also 4.2**).

4. Support

A statement setting out the process for resource allocation so as to fulfil operational needs along with relevant references to supporting documents.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

A statement as to how staffing requirements are decided so that the SMS runs efficiently, together with details of relevant reference procedures or processes where further information can be found.

A process explaining how resources are allocated as a result of the risk assessment and the safety measures decided for carrying out a task: including time, staffing, competencies (including non-technical skills), procedures, tools and equipment.

The results of task analyses showing that the appropriate time and staffing is defined considering workload. The process is similarly carried out for all safety tasks in all business units ('long distance'/'short distance' transport service, train drivers, shunting, maintenance activities...).

A document setting out the allocated resources for planned changes in the organisation (including staffing and the supply of necessary equipment).

4.1.6 Supervision issues

Check that the competence framework and equipment requirements are clearly linked back to the outputs from risk assessment

In checking the CMS the national safety authority should check that the organisation has in place the means to identify and maintain staff with the correct skills to allow them to carry out their tasks in a safe manner. Of key concern will be how the CMS is kept up to date.

When looking at the maintenance activities which relate to this requirement those carrying out supervision should seek to ensure that where these activities are contracted out, the railway undertaking or infrastructure manager exercises its oversight function to ensure that contractors deliver the appropriate safe-to-use product.

Checking vacancy gaps in selected areas of the SMS can be used as an indicator of the adequacy or not of human resources.

Similarly the way equipment is used e.g. how many spares are taken to site can be an indication of the quality of the equipment provided and hence the adequacy of resources.

4.2 Competence

4.2.1 Regulatory requirement

- 4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:
- (r) identification of the competencies (including knowledge, skills, non-technical behaviours and attitudes) required for safety-related tasks;
 - (s) selection principles (basic educational level, psychological and physical fitness required);
 - (t) initial training, experience and qualification;
 - (u) ongoing training and periodic update of existing competencies;
 - (v) periodic assessment of competence and checks of psychological and physical fitness, to ensure that qualifications and skills are maintained over time.
 - (w) specific training in relevant parts of the safety management system in order to deliver their safety-related tasks.
- 4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:
- (a) the training programme is delivered according to the identified competency requirements and individual needs of the staff;
 - (b) where applicable, the training ensures that staff can operate under all operating conditions (normal, degraded and emergency);
 - (c) the duration of the training and the frequency of the refresher training are appropriate for the training objectives;
 - (d) records are kept for all staff (see 4.5.3. Control of documented information);
 - (e) the training programme is regularly reviewed and audited (see 6.2. Internal auditing) and changes made when necessary (see 5.4. Management of change).
- 4.2.3. Back to work arrangements shall be in place for staff following accidents/incidents or long absences from work, including providing additional training where such need is identified.

4.2.2 Purpose

The purpose of this requirement is to ensure that the organisation has in place appropriate structures and resources to control the risks it faces and allow it to deploy staff who are competent to fulfil the safety functions and in particular those of a safety critical nature that they undertake. The competence management system will also allow the organisation to maintain the skill, knowledge and experience of their staff over time.

Competence plays a pivotal role in ensuring that activities are carried out satisfactorily. The need to have competent staff extends to both front-line support (including contractors, consultants and suppliers of safety-related services) and management personnel. Management competence requirements are frequently overlooked; however, managers make important decisions that can have fundamental and wide-ranging effects on health

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and safety. These should include provisions for training all staff to the required safety standards, for maintaining competency, irrespective of circumstances, including issues like staff availability and for monitoring levels of competency in relation to required standards.

In this context, safety is seen as an integrated component of professional behaviour and professionalism – and not as an “additional layer” to be added to the professional skills. Also the capacity of an organisation to deal in real time with non-anticipated events highly relies on the competence of front line staff and their supervisors. These competences can be, for example, developed simulations and regular training of complex scenarios.

4.2.3 Explanatory notes

A training programme (4.2.2) can be provided via a third party training centre. In this case, the organisation should ensure that the training centre is competent to provide the relevant services either because it has been certified or recognised under a national or European scheme, or through direct monitoring of the training activities and the outcomes from it. Training Centres may provide all the training needs of an organisation or only a few of them based on their competences in the various fields. Where a third party training centre provides an organisation with training then that organisation must check that the training covers the necessary elements and where they do not they should supplement such external training with internal training as necessary.

How are human and organisational factors and safety culture integrated?

Competencies are an integral part of the competence management system, including non-technical skills, attitudes and behaviours. The necessary levels of the required competencies to carry out a task are defined with a link to the risk assessment and task analyses.

‘Attitude’ (4.2.1 (a)) is used to describe how people react to certain situations and how they behave in general (e.g. being proactive, being able to get along with other people). This is very important in making the interconnections within the SMS work.

There is a systematic approach ensuring that human and organisational factors competence is accessible in relevant roles based on risk assessment and task analyses.

Human and organisational factors competence can for example be used in risk assessment, in projects in relation to new or modified designs, in performance evaluation and improvement to provide a non-technical perspective or regarding human performance issues. Specific human and organisational factors training to increase awareness is given to management and staff carrying out safety tasks.

4.2.4 Evidence

- ▶ *The applicant should provide information about their competency management system and how it works to fulfil the matters set out in the requirements;(4.2.1),(4.2.2(a) –(e))*
- ▶ *The evidence shall include details of the training programmes that are in place for staff (including where necessary information concerning the organisations requirements for the*

competence of trainers) and how this is kept up to date and reviewed (including when necessary for the Safety Advisor role under RID or when applicable for the competence of maintenance staff according to the requirements of Annex I and Annex II of Regulation (EU) 2019/779 on ECMS; **(4.2.2 (a)-(e))**;

- ▶ The evidence shall include the back to work arrangements in place for staff following accidents and incidents or long absence from work including how any additional training needs are identified; **(4.2.3)**
- ▶ If the applicant uses a recognised training centre which has been certified under EU Regulations, a copy of the relevant certificate will provide a presumption of conformity with the elements above to the extent that they are covered by that certification process; **(4.2.1 (a), (c) –(f), (4.2.2)**
- ▶ The applicant should indicate how it ensures that for the same tasks there is no difference between the competence of its own staff and those of any contractors, suppliers and consultants it employs; **(4.2.1 (a) –(f))**
- ▶ Appropriate human and organisational factors and awareness training is given to management and staff carrying out safety tasks; **(4.2.1), (4.2.2)**
- ▶ The applicant should indicate how Human and organisational factors competence needs are assessed, which includes defining in what roles and in what processes human and organisational factors competence is needed and what level of competence is required. The human factors capability available (e.g. formal human factors qualifications i.e. academic degree, internal/externally recognised competences and experience) is tailored and proportionate to the maturity and complexity of the company. **(4.2.1 (a)-(f))**
- ▶ The applicant should provide information about the process for authorising staff to undertake key roles including the ongoing management of staff competencies **(4.2.1 (a)-(f), 4.2.2(d))**.

4.2.5 Examples of Evidence

The competence management system with an explanation of how it works over time including for non-frontline staff where appropriate as well as links to the documentation which supports it including the various training programmes and how sub-contracted training centres are managed.

The contractual arrangements (including Terms of Reference) with any certified training centres along with evidence of their certification are provided.

Examples of training programmes for groups of staff.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

The process showing how the requirements and the qualifications, including psychological or physical fitness, deemed necessary for particular safety-related-roles are managed and complied with, including a link to risk assessment and task analyses.

A process showing how staff requirements and qualifications are managed, both in terms of:

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- ▶ *Complying with applicable requirements concerning physical and psychological fitness;*
- ▶ *Defining professional competencies deemed necessary for each safety-related role.*

Processes for periodical re-examination of requirements and training programmes show an up-to-date situation and are constantly aligned with technical, operational and organisational changes.

In a procedure or process for ensuring staff have specific and refresher training for the following:

- ▶ *Anticipated changes affecting internal regulations, infrastructure, organisational structure etc.;*
- ▶ *Updates of the assigned tasks (e.g. for train drivers, new routes, new locomotive types, new type of service).*

The SMS describing how training needs for safety tasks have been identified and implemented according to the specific roles. The process-related information is used to create training material and the provisions guarantee that involved staff get acquainted with the risks linked to their activities.

An accident and incident investigation procedure, to the extent that it addresses actions to modify training programmes in the light of accidents and incidents, past supervision etc.

A process for allowing staff to question procedures and decisions and to report routine and abnormal deviations.

The SMS describing what mechanisms for knowledge sharing are present within the organisation.

The process ensuring that:

- ▶ *Competence is maintained by sufficient practice in the field (e.g. for train drivers, knowledge of operating conditions, categories of trains, traction units, lines and stations) and/or by scheduling specific training, in particular where there has been a long absence from work (e.g. illness) or accident/incident;*
- ▶ *Competence is periodically evaluated to ensure the acquired competency is maintained;*
- ▶ *Necessary action is taken where there are identified non-conformities or unsuitable behaviours, such as withdrawal of a person or piece of equipment from service for a period, restrictions with regard to recognised skills where a non-conformity was identified, specific training etc.;*
- ▶ *Suitable measures are taken for staff following accidents and incidents (e.g. for train drivers passing a signal, an accident involving a person, etc. For example the organisation ensures that the train driver is fit to resume service or is replaced with another who is competent to operate the service to be provided);*
- ▶ *Lessons learned following serious accidents, or any other significant event, are shared, in particular when new risks are detected and need to be managed at operational level;*

- ▶ *That there is a monitoring process for the Competence Management System, including for how its effectiveness is measured.*

The SMS explaining how management is trained to be able to conduct pre-decision risk assessments, includes human and organisational factors in their daily activities (risk assessment, performance evaluation, improvement...)

A process for ensuring business continuity and the process for back to work arrangements with a link to the competence management system.

The training programme showing that specific training methods are identified according to the training objectives and training criteria:

- ▶ *mentoring;*
- ▶ *on the job training;*
- ▶ *simulators;*
- ▶ *emergency training;*
- ▶ *team resource management training.*

The process for ensuring that staff have appropriate competencies including that the identification of the necessary competencies is linked to risk assessment. This established process shows that there is a systematic approach using human and organisational factors competencies for staff carrying out risk assessment and determining the consequent safety roles and competencies to ensure that the necessary resources and competencies are allocated.

Safety culture competence being based on a needs analysis. Safety culture competence needs are assessed and strategies to ensure the right competencies and resources are demonstrated. Basic knowledge of safety culture and its importance is shown to be promoted by management.

A process for ensuring that contractors, partners and suppliers meet the same competency requirements. The contractual arrangements (or partnership agreements) addressing these requirements and the monitoring of the contract (or partnership) performance.

4.2.6 References and Standards

- ▶ *ISO10015:2019 'Quality Management Guidelines for Competence Management and People Development'*
- ▶ *ISO10018:2020 'Quality Management – Guidance for people management'*

4.2.7 Supervision issues

How the outputs from risk assessment are linked to a review of the CMS.

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When looking at the competence management system it is important to remember that there will be competence requirements which extend beyond the staff of the organisation but also impact upon contractors and others.

The CMS should be checked to see how up-to-date it is and whether the training activities made under it reflect the organisation's current needs.

The organisation should have some means of ensuring that contracted staff carrying out activities are competent to do so. This is a particular issue where labour only contractors are concerned where checks on competence may not be as thorough.

The competence level required for similar activities between directly employed staff and contractors should be the same.

There is a system in place which ensures that tasks and posts with a safety element, including safety critical tasks, are identified.

There is a robust and effective competence management system including, identification of the knowledge and skills needed, training, maintenance and resources for competence; the processes for recruitment, training, assessment, competence monitoring and record-keeping, indicating how all these contribute to achieving and maintaining competence in place.

Focusing on human factors – how does the organisation go about assessing physical and psychological fitness (e.g. train drivers and for other staff performing safety critical tasks).

4.3 Awareness

4.3.1 Regulatory requirement

4.3.1. Top management shall ensure that they and their staff having a role that affects safety are aware of the relevance, importance and consequences of their activities and how they contribute to the correct application and the effectiveness of the safety management system, including the achievement of safety objectives (see Safety objectives and planning).

4.3.2 Purpose

Awareness means making the staff aware of the safety policy of the organisation and how they contribute to safety within the organisation, the hazards and risks that they need to be aware of and the outcomes of accident and incident investigation. It also covers making staff aware of the implications of not contributing towards the implementation of the SMS both from their point of view and that of the organisation. The purpose of this requirement is to address issues of safety culture within the organisation. It is for top management to set the agenda and direction of the organisation and to set out how business is done. Staff operating within the organisation will take their cue from management. The applicant will need to demonstrate how they address such issues within their processes and procedures.

4.3.3 Explanatory notes

This requirement is linked to human and organisational factors. Further information on human and organisational factors can be found in Annex 5.

4.3.4 Evidence

- ▶ *The applicant should indicate where within their Human Resources or other processes the key role that staff have in delivering the objectives of the organisation is reflected, how they seek to measure this and what steps they are putting in place to maintain and improve it;(4.3.1) (see also 2.3)*
- ▶ *Information on the functioning of the competence management system.(4.3.1)*

4.3.5 Examples of evidence

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

A statement in the safety policy or elsewhere as to the commitment of the 'directing minds' of the organisation to the promotion of the safety culture of the organisation in order to ensure the control of risks through a management system approach. The document will also indicate the role of all staff in promoting the safety policy through their actions and through achieving the safety objectives that are set. Links are provided to the specific procedures which seek to promote these ideas throughout the organisation.

The monitoring process includes an item on understanding across the organisation of the safety management system and the importance and risk awareness of each individual task.

That there are regular staff engagement surveys with a focus on safety showing staff understand how their role fits into the organisation's overall safety objectives.

The training programmes including explanations of risks, safety measures and safety objectives for carrying out the tasks and sub-tasks.

A procedure that staff, contractors or other stakeholders can follow to report the risks they are exposed to.

A statement including an indication of how the organisation promotes its approach on safety awareness, human and organisational factors and safety culture to its contractors, partners and suppliers.

In the communications from the top management, concerning objectives, either in the sense of encouraging all staff to contribute to their attainment or for example in congratulatory messages for improved performance.

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In information showing that middle management and operational staff are involved in frontline safety initiatives (workshops, forums, dedicated safety days, training programmes oriented to develop awareness of their role within the SMS, etc.).

A description of the communication channels and the channels used, and how they integrate human and organisational factors.

In a process for designing procedures explaining how concerned staff are involved and how risks and safety measures are taken into account, as well as the potential impact of non-compliance on operational activities.

4.3.6 Supervision issues

In interviewing staff on this issue, it is important to establish the nature of the understanding that people have of the roles and responsibilities which apply to them. This will indicate if the organisation is able to understand the importance of an effective organisational culture or awareness in delivering safety through the SMS.

How the organisation has baselined its current culture and what steps are in place for improving and developing it are key questions for supervision.

Check the monitoring of the delivery of health and safety responsibilities / objectives, risk awareness, reporting culture - looking for lapses, errors, violations and other incongruences.

4.4 Information and communication

4.4.1 Regulatory requirement

- 4.4.1. The organisation shall define adequate communication channels to ensure that safety-related information is exchanged among the different levels of the organisation and with external interested parties including contractors, partners and suppliers.
- 4.4.2. To ensure that safety-related information reaches those making judgements and decisions, the organisation shall manage the identification, receipt, processing, generation and dissemination of safety-related information.
- 4.4.3. The organisation shall ensure that safety-related information is:
 - (a) relevant, complete and understandable for the intended users;
 - (b) valid;
 - (c) accurate;
 - (d) consistent;
 - (e) controlled (see Control of documented information);
 - (f) communicated before it takes effect;
 - (g) received and understood.

4.4.2 Purpose

Compliance with these requirements is designed to show that the applicant has demonstrated within their application that they have in place the appropriate means to identify safety-related information at different levels and to communicate it at the right time and to the right people. That they horizon scan to ensure current risk controls remain relevant and up-to-date and can identify new threats and opportunities from external influences (political, social, environmental, technological, economic and legal). That they are able to make sure that it reaches the appropriate staff (particularly safety critical staff) within their organisation who need to react to it. This will include how they supply relevant safety-related information to other interested parties with whom they interface.

4.4.3 Explanatory notes

The organisation specifies what type of safety-related information needs to be communicated, how it will communicate (**see also 4.5**), to whom and under which conditions this will be initiated and processed (**4.4.1**). Safety-related information is exchanged between staff carrying out tasks within the organisation, with sub-contractors, partners or suppliers, between railway undertakings and infrastructure managers and where relevant, between infrastructure managers.

Different types of information can be distinguished:

- ▶ *The SMS documentation (**see also 4.5**);*
- ▶ *Static information required from the infrastructure manager to design the rail operations such as operational rules and characteristics of the rail infrastructure (e.g. gauge, train length, gradients and axle load);*
- ▶ *Information required for the planning of rail operations such as station working timetables, lists of routes, temporary speed restrictions, changes to the rail infrastructure, ongoing track works, limitations in railway gauge, trains to be diverted from the planned route, sections of line to be worked as single track, train running forecasts (including any changes to the train routes and/or commuter services);*
- ▶ *Information concerning the train traffic management (between railway undertakings and infrastructure managers and where relevant, between infrastructure managers) including the identification of competent staff within each organisation that can be contacted in case of degraded operations or emergency situations (**see also 5.5**), during and outside core working hours.*

Basic requirements for the purposes of the exchange of information (**4.4.2**) are identified in the TSI OPE between the railway undertaking and the infrastructure manager, in the ECM Regulation between the railway undertaking and the ECM, in the CSM on Safety Management System Requirements between the railway undertaking/infrastructure manager and the authorities (the Agency, NSA).

There are arrangements in place for the exchange of information with relevant parties concerning safety risks relating to defects and construction non-conformities or malfunctions

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of technical systems, including those of structural sub-systems including information on any corrective actions taken for example through the SAIT (Safety Alert Tool) system which the Agency has promoted with the railway Sector. Using the SAIT fulfils the obligation set out in the Railway Safety Directive (Article 4(5)) and the requirement in the CSM on Monitoring (Article 4) and the Regulation on Entities in Charge of Maintenance (Article 5(5) to exchange such information).

'Valid' in the context above **(4.4.3 (b))** means up-to-date.

'Consistent' in the context above **(4.4.3 (d))** means not conflicting if coming from different sources.

'Understood' in the context above **(4.4.3 (g))** means that the applicant demonstrates that they have taken steps to ensure that safety critical information has been taken in by those who it is aimed at. This can be delivered by ad-hoc training, by questions, to check the correct understanding at briefings or in safety critical communications by adopting protocols which require the repeating of important messages, e.g. between signaller and driver to confirm that they have been absorbed correctly, or by any other means which meets the requirement.

This requirement is linked to human and organisational factors. More information on human and organisational factors can be found in Annex 5.

4.4.4 Evidence

- ▶ *The applicant identifies the various communication channels which exist in the organisation and their purpose;***(4.4.1)**
- ▶ *The applicant needs to supply evidence for example of any internal safety alert system, any system for supplying staff with relevant but routine information and any system for supplying staff with relevant but ad hoc information;***(4.4.2)**
- ▶ *The applicant indicates how it satisfies itself that the information which has been disseminated has reached those it is intended to reach (particularly those in safety critical roles) and has been understood by them.***(4.4.3)**

4.4.5 Examples of evidence

The process/procedure for ensuring external parties, such as the infrastructure manager(s), (other) railway undertakings, authorities etc. are provided with a contact who is able to communicate with them (e.g. language skills) and has access to the right level of information.

The process or procedure for confirmation of delivery of safety-related documents.

For the roles entrusted to manage the interfaces: evidence as to whom the safety alert is sent, depending on the area of operation (e.g. the safety alerts appear in the Route Book or Late Notices information).

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

In a clear statement as to how communication both up and down for different types and levels of information works, including links to the specific procedures on safety alerts and routine communications.

In a process or procedure which indicates what steps are taken for different types of communications to ensure that they reach the staff that they are intended for and that those personnel understand what is being communicated e.g. safety critical information.

The process or procedure which ensures each staff member involved in a safety-related task is supplied with the correct version of documents at the right time, to ensure involvement and ability to promptly act or react in normal, degraded and in emergency situations.

The TSI OPE contains requirements concerning various documents, including some referring to communications between the railway undertakings' and infrastructure managers' staff. There is an awareness of all those documents (rulebook, route book, timetables, books of forms...), and they contain the set of communication protocols or media for clearly and promptly exchanging formalised information affecting operation, in particular for train movements in degraded mode.

The safety alerts to be exchanged within the organisation or with other interested parties. Some typical examples are:

- ▶ *The railway undertaking provides information to the infrastructure manager of any occurrences that may have an impact on train movements (faults of rolling stock, e.g. hot axle boxes, in order that the infrastructure manager can take risk control measures such as blocking traffic on the adjacent track);*
- ▶ *The infrastructure manager provides information on infrastructure faults and eventual temporary safety measures like speed reduction to all railway undertakings operating in the relevant area.*

The process or procedure for disseminating information about changes to the organisational structure of the organisation both micro and macro.

The copies of the instructions given to staff undertaking safety-related tasks and addressing the operating rules relevant for the network(s) which are:

- ▶ *Complete: all the rules and requirements relevant to safety tasks relevant to the operation of the railway undertaking are identified and transcribed in the relevant documents;*
- ▶ *Accurate: each of the rules and requirements are correctly transcribed without error (e.g. behaviour to adopt before a signal, safety-related communications);*
- ▶ *Consistent: The requirements applying to a single person or a single team from different sources are compatible and consistent and they do not conflict.*

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The process for recording information is established in the relevant internal rules, using the appropriate communication channel.

The training programmes identify how communication is managed and how communication skills are integrated in the competence management system.

The reporting process enabling staff to report on safety issues within the just culture policy explains how this feedback is analysed and valued so that latent system failures can be seen and considered in the risk management process. The process also includes the way the feedback on reporting is given to staff.

The procedure explaining the different type of meetings and relevant outcomes (e.g. minutes of meetings, notes, ...) show how safety communication is managed both up and down throughout the company.

4.4.6 Supervision issues

Check that there are techniques and process used to keep up to date in risk control, horizon scanning for opportunities or threats.

Check that there is a process for monitoring the use of formalized information.

In supervision key issues are how up to date the information is and whether it reaches **all** the relevant staff e.g. those on night shift or those who work remote from the organisations main bases in good time.

4.5 Documented information

4.5.1 Regulatory requirement

4.5.1. Safety management system documentation

4.5.1.1. There is a description of the safety management system including:

- (a) the identification and description of the processes and activities related to safety of rail operations, including safety-related tasks and associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);
- (b) the interaction of these processes;
- (c) the procedures or other documents describing how these processes are implemented;
- (d) the identification of contractors, partners and suppliers with a description of the type and extent of services delivered;
- (e) the identification of contractual arrangements and other business agreements, concluded between the organisation and other parties identified under (d), necessary to control the safety risks of the organisation and those related to the use of contractors;
- (f) reference to documented information required by this Regulation.

4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:

- (a) a synthesis of the decisions on the level of significance of the safety-related changes, including an overview of significant changes, in accordance with Article 18(1) of the applicable Article 18(1) of Regulation (EU) No 402/2013;
- (b) the organisation's safety objectives for the following year(s) and how serious risks for safety influence the setting of these safety objectives;
- (c) the results of internal accident/incident investigation (see 7.1 Learning from accidents and incidents) and other monitoring activities (see 6.1 Monitoring, 6.2 Internal Auditing and 6.3 Management Review), in accordance with Article 5(1) of Regulation (EU) No 1078/2012;
- (d) details of progress on addressing outstanding recommendations from the national investigation bodies (see 7.1 Learning from accidents and incidents);
- (e) the organisation's safety indicators set out to evaluate the organisation's safety performance (see 6.1 Monitoring);
- (f) where applicable, the conclusions of the annual report of the safety advisor as referred to in RID on the activities of the organisation relating to the transport of dangerous goods.

4.5.2. Creating and updating

4.5.2.1. The organisation shall ensure that when creating and updating documented information related to the safety management system adequate formats and media are used.

4.5.3. Control of documented information

4.5.3.1. The organisation shall control documented information related to the safety management system, in particular its storage, distribution and the control of changes, to ensure its availability, suitability and protection where appropriate.

4.5.2 Purpose

The applicant has to demonstrate that the overall safety management system is adequate for the type and extent of services operated and is capable of managing the risks generated. This requires:

- ▶ *An explanation of the applicant's safety policy, organisation and high level arrangements of the SMS; and*
- ▶ *The more detailed arrangements as set out in the requirements above paragraphs 4.5.1.1 (a) to (f) and 4.5.1.2 (a) to (f).*

The applicant has also to show how its SMS documentation is managed, i.e. the identification, creation, maintenance, management, storage and retention of documented information (i.e. documents and records/data), to make sure that it is up to date and the correct versions are available to relevant staff when required.

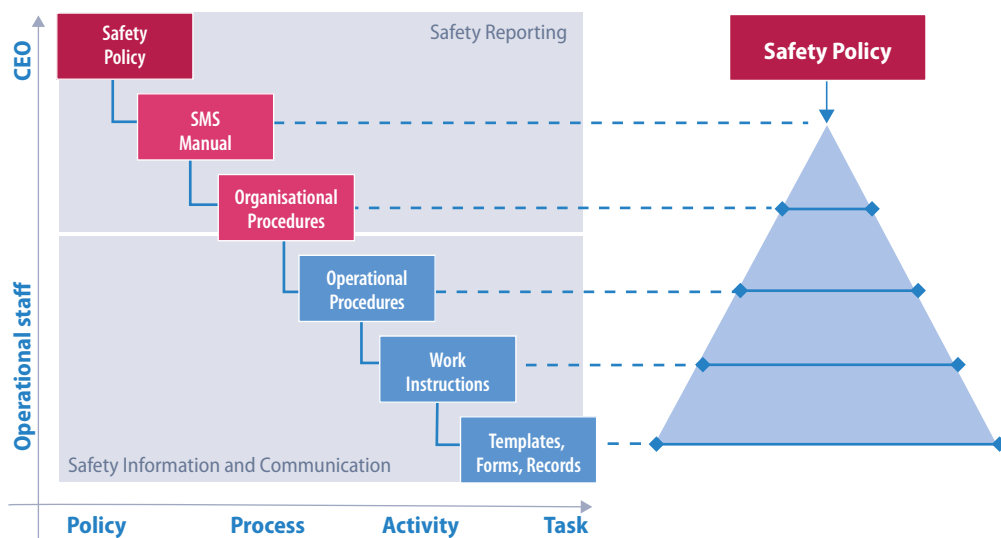
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4.5.3 Explanatory notes

Any documents where the applicant demonstrates the compliance of its SMS against the applicable requirements **(4.5.1.1 (f))** are part of the documented information of the SMS.

The following [Figure 3](#) shows a typical documentation structure:

Figure 3: Typical documentation structure



Depending on the area of operation, railway undertakings may submit different reports **(4.5.1.2)** to the NSAs of the Member States where they have their operations. In general, the scope of the report only relates to the part of the operation in the respective Member State. The Agency however recommends that the same report covers the whole area of operation, this should facilitate the sharing of information between NSAs supervising the same railway undertaking.

Annual report of the safety advisor **(4.5.1.2 (f))**, in the case of the transport of dangerous goods, as required by Directive 2008/68/EC as amended and RID, the annual report of the dangerous goods safety advisor is also an input for the annual safety report. The safety advisor is required to fulfil specified functions including advising the undertaking who appointed it as to health, safety and environmental matters in connection with the transport of dangerous goods and the preparation of necessary reports.

The identification, format (e.g. language, software version and graphics) and medium (e.g. paper, electronic) used for documented information **(4.5.2.1)** are left to the discretion of the organisation. It does not need to be in a written paper manual.

How are human and organisational factors and safety culture integrated?

The document control **(4.5.3.1)** designates the process (or procedure) specifying the internal controls, in particular the review and approval for adequacy prior to issue and use, that need to be considered and implemented for information that is required to be documented. It

aims at identifying the current revision status of documents to preclude the use of invalid or obsolete documents. In particular, it ensures that:

- ▶ *The pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the safety management system are performed;*
- ▶ *Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;*
- ▶ *Any obsolete documents retained for legal or knowledge preservation purposes are suitably identified.*

4.5.4 Evidence

- ▶ *The applicant should provide a description of the safety management system and how it works with appropriate signposts to relevant procedures where necessary;(4.5.1.1 (a) – (c))*
- ▶ *The applicant should set out who its contractors, suppliers and partners are and how the relationships are controlled and monitored to make sure that safety risks both of the applicant and those with whom it has contractual relationships are properly managed to ensure safety(4.5.1.1 (d), (e)).*
- ▶ *The applicant should provide the relevant procedure(s) which demonstrate that it can control documented information (4.5.1.1 (f))*
- ▶ *The applicant should identify the roles and responsibilities that are in place in relation to safety-related tasks and how the risks from the activities of the applicant and others are managed;(4.5.1.1 (a))*
- ▶ *The applicant shall provide evidence that they have (or have arrangements in place to produce) an annual safety report covering the items listed in 4.5.1.2 above;(4.5.1.2(a)-(f))*
- ▶ *The applicant should indicate how the document management system works, including how information is made available and is suitable for use where and when it is needed, how it is changed in a controlled manner within the system and how it is stored and maintained in such a way that it is readily retrievable.and the document management system should allow for information to be kept in facilities which provide a suitable environment to minimise deterioration or damage and to prevent loss.(4.5.2.1), (4.5.3.1)*

4.5.5 Examples of evidence

A description of the safety management system, its overall structure and the links to the documents which support the processes therein (e.g. manual, organisational and operational procedures, work instructions). Notwithstanding the new concept of documented information, introduced by ISO, the organisation may preserve the traditional architecture of documentation, if it is fit for purpose.

An outline of how the different documents are structured, published, made available, filed, maintained/revised and repealed with reference to the relevant document control procedures.

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The procedure for drafting its annual report along with a copy of a previous version, if the applicant is new the procedure indicates the proposed layout of the report.

Retention periods for documents and records are established, documented and complied with.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

The document management process or procedure addresses how documents are updated after regular reviews and after accidents or incidents. The process or procedure addresses the escalation process in cases where agreed updates have not taken place within the required timeframe or where there is no agreement on how to update the document.

that there is a controlled language (i.e. using short, clear sentences, and avoiding jargon) is used to encourage shared understanding and good data quality.

Where practicable, the nature of the changes are identified in the document or appropriate attachments to facilitate their review and approval as well as their understanding by staff.

The process for designing procedures explains how it takes human and organisational factors into account, for example:

- ▶ *Content and relevance: relevance to the task carried out by the person/people, including how the front line operators are actively involved in the design of these procedures;*
- ▶ *Flow: how the e description of processes and relevant responsibilities (who does what) is defined, supported by flow- charts;*
- ▶ *Scope: integrating broader operating scenarios in order to ensure the understanding of the input and output for the task to be carried out;*
- ▶ *Interfaces: contains exhaustive identification and description of interfaces. It is clear when the procedure should be used and when it is no longer applicable because of changes to the task or work situation. Clear purpose and scope rules for the application of the procedure;*
- ▶ *Validity: updated and provided in time for enforcement;*
- ▶ *Adequacy and comprehensiveness: adequate for how work should be done and comprehensive of all details that are necessary*
- ▶ *Awareness: staff have a good understanding of the existing procedures/ rules/requirements, staff have an understanding of the safety reasons for the procedures and the potential impact of non-compliance on operational activities.*
- ▶ *Act upon/Response: procedures show clearly which action is consequent to each communication and the expected response*
- ▶ *Performance under stress/emergency: procedures are easy to perform under the stress of an emergency*

- ▶ *Flexibility: processes allow flexibility for the employees to react in case of emergency to minimize the negative consequences.*
- ▶ *Staff consultation: staff are consulted during the development of the procedures – they know best how to get the job done - and can provide comments or alternative solutions.*
- ▶ *Testing period: the procedure undergoes a testing period, with a review of the outcome before entry into force.*
- ▶ *Revision : the effectiveness of the procedure is subject to periodic review, and the review takes into account the results of monitoring, audits and lessons learned from past events. It is oriented to continuous improvement spirit and organisational learning.*
- ▶ *Change management: Procedures are reviewed in case new equipment or processes come in. The management of change in procedures is important because it allows for them to be aligned with the companies' objectives and arrangements and to ensure that the relevant risks are managed.*

The staff authorised to approve documents for issue ensuring that the contents are accurate and can be understood by all end users (or recipients) to whom they apply.

4.5.6 References and standards

- ▶ *Guidance on the requirements for Documented Information of ISO 9001:2015, ISO/TC 176/SC2/N1286*

4.5.7 Supervision issues

Check the contractual arrangements provide for effective oversight and control of risks by the organisation (i.e. when contracting out services).

Of critical importance when conducting supervision is to establish what the relationship between those in control of the document management system and those with responsibility for updating information and liaising with the former is like in practice. It is at this level that a breakdown in the control of documentation can often occur since it is likely the two parts of the process are in two different management chains. This could lead for example to the importance of the work to update documentation being perceived differently leading to time lags developing in updating of documentation with the associated risks.

Staff ability to access up to date information/documentation.

The SMS structure and mode of operation should reflect the reality of the way that work is conducted and not be an artificial overlay on top of custom and practice.

4.6 Integration of human and organisational factors

4.6.1 Regulatory requirement

- 4.6.1. The organisation shall demonstrate 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.

4.6.2 Purpose

The applicant shows that the use of a systematic human and organisational factors approach in targeting risk is an integral part of the SMS. Satisfying these elements is important for demonstrating that the applicant is competent to run a railway operation and has the risk control systems embedded in its SMS to manage the risks it faces.

4.6.3 Explanatory notes

Human and organisational factors involves taking a systemic perspective where the interactions between human, technological and organisational factors are considered. The organisation should consider human and organisational factors through a life cycle approach. This means identifying and addressing human and organisational factors in safety management activities related to business objectives, management, operations, human performance, task and workplace design in all stages of the system life cycle, e.g. from commissioning to decommissioning. A strategy for human and organisational factors specifies a systematic approach to integrating human and organisational factors within safety management activities.

The organisation should develop the necessary competence in terms of human and organisational factors it needs to support its business activities, especially for safety roles. This also covers staff in charge of integrating human and organisational factors in risk assessment. Human and organisational factors expertise means that the staff involved have received dedicated training as defined in the competence management system. Professional human and organisational factors expertise means either having staff trained at an appropriate level to meet the requirement or having access to someone qualified to some defined national and/or international standard in the subject. Large organisations may have a human factors department with professional human factors experts supporting the organisation. A small organisation may give responsibility to managers at all levels to identify the need for outside professional human factors expertise when appropriate.

This requirement is linked to human and organisational factors. More information on a strategy for human and organisational factors can be found in Annex 5.

4.6.4 Evidence

- ▶ *The applicant details in a strategy how human and organisational factors are systematically integrated so that the risks associated with the interaction between human behaviour, organisational conditions and technology are properly taken into account within the processes of the SMS. In doing so, the applicant should make clear where further detail on the relevant procedures can be found or to action plans for progressive integration/development, indicating the activities, who will be in charge of them and the timeframe;***(4.6.1)**
- ▶ *Available human and organisational factors design standards and best practices are used. Relevant standards are for example ISO Series 11064 Ergonomic design of control centres and ISO Series 9241 Ergonomics of human-system interaction;*
- ▶ *A user-centred design process, based on human and organisational principles and methods as well as involvement of users, is applied in relation to for example new or modified design, procedures, training, workload and work environment to ensure the lifelong safety and effectiveness of a system. End users are involved in the design process, for example in the requirements definition, subsequent development and testing process.*
- ▶ *A user centred design process is an iterative process that involves several phases. Analyses are made to understand and specify the context of use (for example staffing and competence analysis, task analysis and risk analysis). User requirements are defined based on these analyses. Design solutions, including design of interfaces, workplaces, training, procedures and organisation, are produced to meet the user requirements. Evaluations of the designs are made using formal methods, such as for example task analysis, simulation, risk assessment, expert evaluations, user evaluations, verification and validation. More specifically this covers human and organisational factors integration in risk assessment, information and communication and documented information;***(3.1, 4.4 and 4.5)**
- ▶ *Manufacturers and suppliers are involved and aware of human factors in the design of vehicles, equipment (man-machine interface) and IT systems, and the necessary requirements derived from process detailed in the bullet point above are included in the specifications and the contracts;***(5.2)**
- ▶ *Partners, suppliers and contractors are involved in the promotion and integration of human and organisational factors;***(5.3)**
- ▶ *The performance evaluation processes include human and organisational factors principles and methods, cascaded from the risk assessment;***(6)**
- ▶ *The improvement processes, including accident investigation include analysis of human and organisational factors.***(7)**

4.6.5 Examples of evidence

A copy of the human and organisational factors strategy which details how the use of human and organisational factors expertise and techniques are taken into account. The safety policy refers to the human and organisational factors strategy.

The organisation performs a risk analysis, using evidence-based methods of the operational and support processes in all stages of the life cycle, from design to disposal. The analysis

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identifies all human and organisational factors and the performance influencing factors that will impact railway safety and the safety management activities needed to control the identified risks.

The strategy for human and organisational factors demonstrates the safety management activities in place as well as an approach to monitor and improve its effectiveness. The strategy is based on a proactive approach but also includes reactive activities as necessary.

Human factors methods, e.g. task analyses and usability analysis, are used as an input into the design, structure and content of procedures, and full scale simulations involve current operational staff to optimise procedures. Safety management activities related to support functions, task design, staffing levels, training, design and use of equipment, procedures and communication protocols, are identified and linked to the results of the risk assessment.

The strategy includes how human and organisational factors are integrated in the change management process. Human factors integration means the process to integrate human factors and ergonomics into the systems engineering process. The human factors integration plan provides a systematic approach to defining the relationship between all the project activities and the human factors domain. Human factors engineering means the integration of human characteristics into system definition, design, development, and evaluation to optimise human-machine performance under operational conditions.

As the operational processes involve complex working patterns the strategy for human and organisational factors includes a fatigue risk management program.

There is a clear link between the results of risk assessment, the human and organisational factors strategy and the safety objectives. The latter includes the progressive integration of human and organisational factors, e.g.: mapping the real situation of the company, identifying gaps, developing plans for integration or improvement of human and organisational factors in their SMS, so that the process and relevant documentation are controlled over time.

There is an explanation of how the strategy or part of it is communicated to staff, through different processes such as communication of the safety policy, the raising of awareness or safety objectives.

4.6.6 References and Standards

- ▶ *Wickens, C.D., Lee, J.D., Liu, Y & Gordon Becker, S.E (2004). An Introduction to Human Factors Engineering. New Jersey: Pearson Education. ISBN-13: 978-0131837362*
- ▶ *ISO Standard series, e.g.*
- ▶ *ISO Series 6385:2004 Ergonomic principles in the design of work systems*
- ▶ *ISO Series 11064 Ergonomic design of control centres*
- ▶ *ISO Series 9241 Ergonomics of human-system interaction*
- ▶ *ISO Series 10075 Ergonomic principles related to mental work-load*

- ▶ *CENELEC - EN 50126-1 Railway Applications - The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) – Part 1: Generic RAMS Process, Chapter 5.6 (in particular § 5.6.4)*
- ▶ *EEMUA 191. Alarm systems, a guide to design, management and procurement*
- ▶ *UIC 651 Layout of drivers' cabs in locomotives, railcars, multiple unit trains and driving trailers*
- ▶ *Rail Safety & Standards Board (2008). Understanding Human Factors, a guide for the railway industry*

4.6.7 Supervision issues

Check to make sure that human factors issues are taken into account in the decision making processes for management of risks through risk assessment, change management and asset management.

Check that operational documents reflect the commitment to manage human factors through ergonomic design (e.g.: user friendly design, plain language, graphics to support instructions, easy management of updates), to support the management of risks.

Check that in monitoring the performance, the Railway Undertaking/Infrastructure Manager focus their analysis on human factors as a primary or underlying cause of accidents, incidents or dangerous occurrences.

Check if there are documented examples of corrective measures taken which are designed to remove factors affecting the human performance and impairing safety.

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5.1 Operational planning and control

5.1.1 Regulatory requirement

- 5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:
- (a) risk acceptance criteria and risk control measures are applied (see 3.1.1 Risk assessment);
 - (b) plan(s) to achieve the safety objectives are delivered (see 3.2 Safety objectives and planning);
 - (c) information is collected to measure the correct application and effectiveness of the operational arrangements (see 6.1 Monitoring).
- 5.1.2. The organisation shall ensure that its operational arrangements conform to the safety-related requirements of applicable Technical Specifications for Interoperability and relevant national rules and any other relevant requirements (see 1. Context of the Organisation).
- 5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1 Risk assessment), at least the following shall be taken into account:
- (a) planning of existing or new train routes and new train services, including the introduction of new types of vehicles, the need to lease vehicles and/or to hire staff from external parties and the exchange of information on the maintenance for operational purposes with entities in charge of maintenance;
 - (b) development and implementation of train timetables;
 - (c) preparation of trains or vehicles before movement, including pre-departure checks and train composition;
 - (d) running trains or movement of vehicles in the different operating conditions (normal, degraded and emergency);
 - (e) adaptation of the operation to requests for removal from operation and notification of return to operation issued by entities in charge of maintenance;
 - (f) authorisations for movements of vehicles.
 - (g) usability of interfaces in train driving cabs and train control centers and with equipment used by maintenance staff.
- 5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:
- (a) identification of the safe boundaries of transport for traffic planning and control based on the design characteristics of the infrastructure;
 - (b) traffic planning, including timetable and train path allocation;
 - (c) real-time traffic management in normal mode and in degraded modes with the application of traffic restrictions of use and the management of traffic disruptions;
 - (d) setting of conditions for running exceptional consignments.

- 5.1.4. To control the allocation of responsibilities where relevant for the safety of operational activities, the organisation shall identify responsibilities for coordinating and managing the safe running of trains and movements of vehicles and define how relevant tasks affecting the safe delivery of all services are allocated to competent staff within the organisation (see 2.3 Organisational roles, responsibilities, accountabilities and authorities) and to other external qualified parties when appropriate (see 5.3 Contractors, partners and suppliers).
- 5.1.4 To control the allocation of responsibilities where relevant for the safety of operational activities, the organisation shall identify responsibilities for planning and operating the rail network and define how relevant tasks affecting the safe delivery of all services are allocated to competent staff within the organisation (see 2.3. Organisational roles, responsibilities, accountabilities and authorities) and to other external qualified parties when appropriate (see 5.3. Contractors, partners and suppliers).
- 5.1.5. To control information and communication where relevant for the safety of operational activities (see 4.4 Information and communication), relevant staff (e.g. train crews) shall be advised of the details of any specified conditions of travel, including relevant changes which may result in a hazard, temporary or permanent operational restrictions (e.g. due to specific type of vehicles or to specific routes) and conditions for exceptional consignments, where these are required.
- 5.1.5 To control information and communication where relevant for the safety of operational activities, (see 4.4 Information and communication), relevant staff (e.g. signallers) shall be informed about specific routing requirements for trains and movements of vehicles including relevant changes which may result in a hazard, temporary or permanent operational restrictions (eg due to track maintenance) and conditions for exceptional consignments.
- 5.1.6. To control competence where relevant for the safety of operational activities (see 4.2 Competence), the organisation shall ensure, in accordance with applicable legislation (See 1. Context of the organisation), for its staff:
- (a) compliance with their training and work instructions, and corrective actions are taken where required;
 - (b) specific training in case of anticipated changes affecting the running of operations or their task assignment;
 - (c) adoption of adequate measures following accidents and incidents.

5.1.2 Purpose

The applicant should demonstrate that they have the relevant processes in place to manage operational risks through the SMS including making sure that staff understand their roles, the operational risks they face, and what the control measures are, and that they have the appropriate competence and training to manage these in accordance with the safety management system documentation.

The applicant should ensure that the vehicles or the infrastructure is/are operated safely in accordance with the applicable requirements under different operating conditions (i.e. normal, degraded and emergency), including also the use of assets for testing purposes (e.g. testing of running behaviours of vehicles before authorisation is granted) and in exceptional circumstances (e.g. unusual consignments such as the transport of big indivisible pieces that

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cannot be transported by other transport means such as concrete beams/girders for bridges, etc.).

5.1.3 Explanatory notes

In points 5.1.3, 5.1.4 and 5.1.5 of the legal text above where the requirement concerns infrastructure managers the clauses in black are replaced by those in blue.

Directive (EU) 2016/798 requires the railway undertakings and infrastructure managers to establish an SMS to manage the safety risks inherent in their railway operations. The general consensus in safety management is that safety should be integrated within normal business processes as much as possible. The reason for this is that the business focus is then as much on safety as on any other business process which will reduce the conflicts between different processes.

ISO states in its guidance document (N360) supporting Annex SL that the intent of clause 8 (Operation) is to specify the elements that need to be implemented within the organisation's operations to make sure that the management system requirements are fulfilled, as well as ensuring that the priority risks and opportunities are being addressed. In addition, it is stated that additional requirements (discipline specific) related to operational planning and control can be prescribed. In particular, that they are not deleterious to the company's business but provide a sufficient framework to control how key safety issues will be managed within the organisation's business processes.

Explicit links have been added between operational requirements and other management system requirements (similar to the approach adopted in Annex II of Regulation (EU) 2019/779) to make clear that specific operational requirements are to be considered with respect to the relevant management system requirements (e.g. planning of routes for railway undertakings is an activity that should be subject to risk assessment). This approach is not intended to be exhaustive but aims at identifying particular issues authorities believe are significant (based on their experience) and which therefore should be examined during their assessment or supervision activities. Railway undertakings and infrastructure managers should not only focus on these specific requirements when developing and implementing their safety management system arrangements (disregarding other safety risks for instance). In any event, railway undertakings and infrastructure managers have to apply safety management system requirements (e.g. risk assessment, monitoring, competence, information and communication) to all of their relevant business processes so as to demonstrate that the safety risks are adequately controlled.

The integration of the SMS into the business/operational processes is of prime importance and to achieve that goal, the organisation has to conform to applicable TSIs (**5.1.2**), such as the TSI OPE, and to notified national rules when the interface requirements are not fully mandated in the TSIs. Acceptable means of compliance may also be published by the Member State or its authority to facilitate compliance with their national rules. At least the following operational processes should be considered where relevant:

- ▶ *Operating infrastructure (controlling infrastructure routes and equipment, authorising vehicle movements in all conditions and ensuring infrastructure maintenance: track and control-command and signalling system(s)),*
- ▶ *Operating train (developing routes and relevant timetables, managing train preparation, ensuring train driving, accompanying, testing, maintaining and repairing vehicles)*
- ▶ *Shunting (moving vehicles in order to assemble or disassemble a train).*

The TSI-OPE is key here because it sets out 'Fundamental Operating Principles' (FOP) which should be reflected in the relevant parts of the SMS and therefore compliance with the TSI-OPE can be used to demonstrate compliance with the relevant SMS requirements above.

The infrastructure manager should identify and provide conditions and measures to use a vehicle for tests on the network within the given timeframe as specified in Article 21(3) and 21(5) of Directive (EU) 2016/797 **(5.1.2)**.

Records of route compatibility checks include the characteristics of vehicle/train considered against the intended routes of operation including the possible deviation route(s) identified by the infrastructure managers (see clause 4.2.2.5 of TSI OPE)

Characteristics of routes of operation are on the basis of register of infrastructure (RINF) and/or the information provided by the Infrastructure manager.

If problems are identified by either party a joint resolution by the railway undertaking and the infrastructure manager should be undertaken.

New train service **(5.1.3 (a))** may include new types of goods to be transported.

'Safe boundaries' **(5.1.3 (a))** for infrastructure managers means both safe physical infrastructure limits where this is necessary and safety limits for infrastructure and command and control where these are required by the design limits of that infrastructure.

Movement of vehicles **(5.1.3 (d))** has a wider meaning than movement of trains (i.e. scheduled movement of vehicles) and authorisations given before train departure. It may also include recovery of a broken down train, movement of track maintenance machines or the unplanned replacement of a damaged vehicle in a train before departure of a train.

In accordance with Article 1.1 of UIC leaflet 502-1, the following definition of the term 'exceptional consignments' **(5.1.5)** is proposed: '*A consignment is considered as exceptional if its external dimensions, its weight or its features in relation to the fixed equipment or wagon of a RU involved in the transport cause particular difficulties, and therefore, it can only be accepted under special technical or operating conditions*'. TSI OPE defines exceptional transport as: "*A vehicle and/or the load carried which because of construction/design, dimensions or weight does not meet the parameters of the route and requires special authority for the movement and may require special conditions over part or its entire journey.*"

How are human and organisational factors and safety culture integrated?

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The exchange of information for operational purposes on vehicle maintenance **(5.1.3 (a))** with ECMs and keepers is identified in Article 5(3) of [Regulation \(EU\) 2019/779](#). It includes the maintenance schedule and any restrictions issued by ECM during maintenance (short term planning).

Where reference is made to the development and implementation of train timetables **(5.1.3 (b))**, this means that the applicant should demonstrate how via risk assessment they have managed the risk posed by the activity within their organisation and at the interface with other actors. For example that they have taken into account

- ▶ *The additional workload to signalling staff when increasing the number of trains at certain times;*
- ▶ *The appropriate operational agreements with the relevant infrastructure manager(s) for stopping traffic, recovery, exchange of information and all other services that are deemed necessary;*
- ▶ *Managing the risks associated with track maintenance when trains are being run 24 hours a day.*

The organisation applies a proactive risk assessment process, which allows the identification of risks applicable to its railway operations, including the shared interface risks and those arising from human and organisational factors (see also 3.1). It also reduces the risk of an overreliance on inherited procedures or rules.

The organisation applies risk acceptance criteria to determine if existing actions are sufficient to keep or reduce the risks to an acceptable level or if new actions are to be identified otherwise. The organisation then integrates its operational activities and compliance with the TSIs as far as these relate to operations in its monitoring process (see section **6 Performance evaluation** below).

Human and organisational factors should be considered in operational planning for the continuous improvement of safety culture in connection with for example work schedules, fatigue management, stress, work environment (physical and psychosocial), workplaces and work processes etc. This is to ensure that the consequences of the changes or arrangements don't have a negative impact on human performance or organisational safety.

5.1.4 Evidence

- ▶ *Information to indicate that when planning, developing, implementing and reviewing its operational processes it plans to achieve safety objectives, applies risk assessment measures and monitors the outcomes, including the appropriate signposts to where additional information on procedures can be found;***(5.1.1 (a)-(c))**
- ▶ *Evidence that the organisation is aware of and actually implements all categories of mandatory safety requirements which apply to its operation and outlines how the SMS ensures compliance with them;*
- ▶ *Information that the applicant makes sure that its operational arrangements are compliant with the applicable requirements (legislation, standards, etc.);***(5.1.2)**

- ▶ *In the framework of vehicle type authorisation and/or vehicle authorisation for placing on the market, the infrastructure manager is able to identify and provide (5.1.2):*
 - *operational conditions to be applied for the use of the vehicle for tests on the network, based on the information provided by the applicant for the authorisation;*
 - *any necessary measures to be taken on the infrastructure side to ensure safe and reliable operation during the tests on the network, and/or*
 - *any necessary measures in the infrastructure installations to perform the tests on the network.*
- ▶ *For the check before the use of authorised vehicles (Article 23.1 of Directive (EU) 2016/797) and especially route compatibility check (Article 23.1(a) of Directive (EU) 2016/797) the railway undertaking, within its SMS, is able to identify and provide (5.1.3 (a)) evidence procedures and records showing that the vehicle is compatible with the route where it is intended to operate and is properly integrated in the composition of the train (see also clause 4.2.2.5 of TSI OPE).*
- ▶ *Evidence of compliance of operational documentation with the requirements for managing operation (and maintenance) at organisational and physical boundaries, e.g. organisational, technical and operational interfaces with neighbouring infrastructure, border stations, interactions with other RUs or IMs etc;(5.1.2)*
- ▶ *Information on how the risks of operational activities are managed through the risk assessment process and cover the elements set out in the requirements above including for human and organisational factors;(5.1.3 (a) – (g))*
- ▶ *Evidence that Article 14(2) of Directive (EU) 2016/798 is being complied with by the body responsible for maintenance;(5.1.3(f))*
- ▶ *Information on how the responsibilities including the responsibility for fatigue risk management are managed for the safety of operational activities;(5.1.4)*
- ▶ *Information on how the organisation manages information and communications for the safety of operational activities;(5.1.5)*
- ▶ *Information concerning the competence management system and associated procedures and how these link to specific work or task instructions to maintain the safety of operational activities; (5.1.6)*
- ▶ *Evidence that operational documentation (procedures, work instructions, etc.) is updated when and where necessary.(see also 4.5.3)*

5.1.5 Examples of evidence

A list of the mandatory requirements (including TSIs) and how it is complying with them (**see also 2**).

An explanation of how operational risks are managed through the risk assessment process and how it is ensured that operational safety objectives are met. Links are provided to where relevant procedures are to be found.

A statement as to how the CMS contributes to the control of operational risks and how the information and communication flow is managed to ensure that risks are properly controlled.

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Details of the maintenance system for rolling stock .

Details of the procedure for pre-departure checks (TSI OPE) that are in place to ensure a conformity check of:

- ▶ *Braking performance (preparing the braking sheet),*
- ▶ *Train composition;*
- ▶ *Front and rear signals;*
- ▶ *Load and hauled vehicle condition.*

A copy of the process for identifying non conformities and how it is ensured that any necessary action is taken, such as those leading to the removal of the vehicle from operation, replacement of broken /defective component/equipment/vehicle or implementation of operational restrictions.

A document giving the types of vehicles to be used on each specific route and the type of operations to be conducted and in particular any:

- ▶ *Operational restrictions due to specific types of vehicles;*
- ▶ *Restrictions due to the operation of specific types of vehicles on specific routes;*
- ▶ *Additional maintenance requirements for specific routes (**see also 5.2**).*

In relation to compliance with the Fundamental Operational Principles (FOP) of the TSI OPE, evidence is provided showing that the railway undertaking can ensure that (only for illustrative purposes):

- ▶ *A train can only operate over a portion of line if the train composition is compatible with the infrastructure (FOP 3)*

This relates to confirmation of train compatibility with the infrastructure of the route over which it is planned to operate, before its movement is authorised. Compatibility between a train and infrastructure is affected primarily by the dimensions of a vehicle and any load placed on it; the clearances between the train and the infrastructure or trains on adjacent tracks (gauging); the minimum required braking capacity of the train; the weight and length of a train and the capacity and capability of the infrastructure.

There is evidence that:

- ▶ *Pre-departure checks take place to ensure that, before a train begins or continues its journey, its passengers, staff and goods are carried safely (FOP 4)*

This concerns the train and its readiness for movement. It includes as examples: the braking capacity of the train, the speed which the train is permitted to travel, the formation and coupling of the train, identification, loading and securing of freight, the provision of adequate information to train preparation and operational staff. The aim is to prevent collisions and derailments due to a number of risks.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

In a document describing any additional requirements to manage degraded situations (e.g. incidents with a vehicle) for the network(s) concerned by the area of operation.

The persons in charge of planning and delivering the operational activities are trained to take human and organisational factors into account, to both integrate human performance capabilities and limitations, including identified risks and safety measures.

Safety information being identified and following human and organisational factors principles (see section **4.4 Information and communication** below).

In a process for fatigue management applicable to staff members with irregular work hours. The process is based on evidence-based methods and professional expertise. The process takes into account that a range of factors must be considered in taking a comprehensive approach to fatigue risk management. The fatigue management program includes planning and control of the work environment and work tasks, in order to minimise as far as reasonably practical, the effects of fatigue on work-force alertness and performance, in a manner appropriate to the level of risk exposure and the nature of operation.

5.1.6 References and standards

- ▶ *ISO N360 JTTCG concept document to support Annex SL*
- ▶ *UIC leaflet 502-1*
- ▶ *Annex II to Directive 2008/68/EC (RID)*
- ▶ *Guidance on the TSI OPE*

5.1.7 Supervision issues

The supervision of operational activity should be conducted by focusing on discrete areas and examining these in detail to see how they are reflected in the safety management system of the organisation being supervised and whether they have the right staff in the right place doing the right thing. This will allow the NSA to see whether the activities are covered within the SMS as a coherent whole or are managed separately with weak links to safety objectives and the overall strategy.

In particular supervision should check:

- ▶ *How higher level SMS documents translate into consistent local instructions which are used to manage risk at the operational level;*
- ▶ *Management of emergency circumstances or non-routine situations;*
- ▶ *How boundaries of operation/ limits of operation are managed, including the interface arrangements with other parties;*
- ▶ *Fatigue management arrangements;*

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- ▶ *Management of hazardous substances;*
- ▶ *Arrangements for the transport of dangerous goods, including training, roles and responsibilities for the organisation's staff, as in Chapters 1.3, 1.4 and 1.8 of RID liaising as necessary with any other transport of dangerous goods competent authority.;*
- ▶ *Compliance with the Fundamental Operating Principles set out in the TSI OPE.*

5.2 Asset management

5.2.1 Regulatory requirement

- 5.2.1. The organisation shall manage the safety risks associated with physical assets throughout their life cycle (see 3.1.1. Risk assessment), from design to disposal, and fulfil the human factors requirements for use.
- 5.2.2. The organisation shall:
 - (a) ensure that the assets are used for the purpose intended while maintaining their safe operational state, in accordance with Article 14(2) of Directive (EU) 2016/798 where relevant, and their expected level of performance;
 - (b) manage the assets in normal and degraded operations;
 - (c) detect as soon as reasonably practicable instances of non-compliance with operating requirements before or during the operation of the asset, including the application of restrictions of use as appropriate to ensure a safe operational state of the asset (see 6.1. Monitoring).
- 5.2.3. The organisation shall ensure that its asset management arrangements, where applicable, conform to all essential requirements as set out in the relevant Technical Specifications for Interoperability (see 1.Context of the organisation).
- 5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:
 - (a) the identification of the need for maintenance to keep the asset in a safe operational state, based on the planned and real use of the asset and its design characteristics;
 - (b) the management of the removal of the asset from operation for maintenance, when defects have been identified or when asset condition degrades outside the limits of a safe operational state as referred to in point (a);
 - (c) the management of the return to operation of the asset with eventual restrictions of use after maintenance has been delivered to ensure it is in a safe operational state;
 - (d) the management of monitoring and measurement equipment to ensure that it is fit for its intended purpose.
- 5.2.5. To control information and communication where relevant for the safe management of assets (see 4.4. Information and communication), the organisation shall take into account:
 - (a) the exchange of relevant information within the organisation or with external entities responsible for maintenance (See 5.3. Contractors, partners and suppliers), in particular on safety-related malfunctions, accidents, incidents as well as on eventual restrictions of use of the asset;

- (b) the traceability of all necessary information including the information related to point (a) (see 4.4. Information and communication and 4.5.3. Control of documented information);
- (c) the establishment and maintenance of records of all assets including the management of changes affecting the safety of assets (see 5.4. Management of change).

5.2.2 Purpose

The applicant should demonstrate how it manages the life cycle of its assets from design to disposal through the procedures and arrangements set out in the SMS. The applicant should demonstrate that it has applied a human centred approach at each stage of the life cycle. It should detail where the management of its assets interfaces with different elements of its safety management system such as competence management, operational planning and monitoring. The objective of the applicant should be to demonstrate that it has a robust system in place for asset management which reflects the risks that are posed by the type and extent of its operations.

5.2.3 Explanatory notes

'Asset' (5.2) means any equipment (fixed or mobile), structure, software or any other component which requires maintenance over time provided for the purposes of running a railway operation. Assets will be divided into those managed by the railway undertaking (mainly vehicles but also including other equipment eg wheel lathes, safety protection equipment and computer programmes provided for the safe maintenance of assets) and those managed by an infrastructure manager (all the infrastructure components, such as track, equipment for control-command/signalling, switching from one track to another, power supply, level crossings, civil engineering, such as bridges, viaducts, tunnels, platforms, lifts, escalators, etc. A complete list is provided in Annex I of the [Directive \(EU\) 2012/34](#)).

The life cycle of an asset entails the following phases:

- (a) *Design;*
- (b) *Implementation (construction/manufacturing, installation, testing and commissioning);*
- (c) *Operation and maintenance;*
- (d) *Repair, modification and retrofit, involving the management of changes;*
- (e) *Renewal, decommissioning and disposal.*

It is important for an organisation to demonstrate how it captures and maintains (system and) safety requirements for assets, and how these will be verified, validated, and tracked.

If maintenance is contracted to a third party, it is the organisation's responsibility to specify and monitor that the performance of the asset complies with the organisation's established standards.

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Once processes are in place to manage the risk associated with safety critical assets, the organisation should monitor asset performance against these risks and its own expectations.

Where assets are likely to be renewed, decommissioned, or disposed of, the organisation establishes and documents processes to manage any risks associated with such activities.

These processes are only relevant to organisations that are carrying out such activities or are likely to do so

For the renewal of an asset that is approaching its end of life, the organisation ensures that the replacement asset meets established safety performance criteria. As part of this process, all safety analyses are reviewed.

Requirements relating to maintenance **(5.2.4)** are derived from the ECM Regulation, the rolling stock being an asset that a railway undertaking and possibly an infrastructure manager should manage. These requirements in Annex II to [Regulation \(EU\) 2019/779](#) are more specific and prescriptive whereas the above requirements mainly address the interface between the railway undertaking or infrastructure manager's SMS and the ECM's maintenance system with the aim of ensuring that the assets are safe to operate and maintain. Further details can be found in the ECM Regulation and the accompanying guide. The risk assessment should also address the potential safety impact of any substitution in the course of maintenance (which is part of the life cycle of the asset) in accordance with the requirements of [Directive \(EU\) 2016/797](#) and relevant TSIs.

All assets are not regulated by TSIs **(5.2.3)** and even if a TSI applies (e.g. TSI INF), only what is necessary for interoperability is regulated which means that other safety requirements might still be needed. Compliance with the essential requirements of relevant TSIs, (not only the essential requirements for safety) is to be maintained in the case of substitution, renewal or upgrading.

The term 'safe operational state' **(5.2.4 (a))** means that the asset is to be operated within its safe limits of use. The safe limits of use can evolve throughout the lifespan of the system but are to be defined bearing in mind the interoperability parameters. Defects can be identified **(5.2.4 (b))** and based on a root cause analysis, the safe limits of use can be adapted accordingly. For vehicles, safe operational state means a safe state of running in accordance with Article 14(2) of [Directive \(EU\) 2016/798](#).

Asset configuration **(5.2.5 (c))** includes the unique identification of the assets, their location, any maintenance carried out, etc. (and not only the configuration management of changes). The configuration management of (technical) changes applies to substitution.

An ECM is to be appointed in accordance with Article 14(1) of [Directive \(EU\) 2016/798](#) to ensure that vehicles for the maintenance of which it is in charge are in a safe state of running. It is not necessary to describe in detail the activities carried out by an ECM which has been certified in accordance with [Regulation \(EU\) 2019/779](#). On the other hand, it is necessary to indicate which elements and which aspects are covered by the ECM certificate and how the interface with the ECM is managed, in particular what information is exchanged between the applicant and the ECM and how this is done. If the ECM is not directly contracted by the railway undertaking but is a third party to a contract between a vehicle owner (or keeper) and

the railway undertaking the information exchange may be conducted via an intermediary but must still be efficient and timely in both directions.

In the case of a partnership between railway undertakings, each railway undertaking remains fully responsible for operating safely and therefore controlling risks related to its activities. The use by one railway undertaking of the safety certificate of its partner railway undertaking as a means of controlling the risks associated with the supply of maintenance is not sufficient if it is not supported by contractual arrangements between the partner railway undertakings. Those contractual arrangements have to be commonly developed and monitored by each partner and are also part of each SMS, therefore subject to supervision by respective NSAs. The respective NSAs should coordinate to address any cross border interface issues which may have been created by the contracting entities.

How are human and organisational factors and safety culture integrated?

Human factors are integrated through the life cycle of all systems and subsystems, based on the results of risk assessment that already included human and organisational factors and the defined safety measures.

This includes a user-centered approach in the design phase of the system which can be composed of function allocation (human/machine), interviews and task analyses (for each sub-task). Specifications for the assets are based on the users needs, including user performance and limitations.

Safety measures are defined taking into consideration the work environment, the organisation and staffing, teams and communications, the design of procedures (including operations and maintenance of the asset), and adequate resources in relation to the asset ensuring that human and organisational factors are considered and appropriately addressed. This may include specifications concerning e.g. workplace layout, the ergonomic design of equipment (tools, machinery, materials), the usability of equipment, the feedback expected from it, the quality of equipment, the inspection/maintenance schedule and the tolerance for errors.

5.2.4 Evidence

► *Information concerning the asset management system within the organisation's SMS including relevant links to other areas such as risk assessment, operational planning, change management etc. (5.2.1), (5.2.2), (5.2.5 (a)-(b)):*

Design phase

- *Evidence of processes and consultation to determine asset requirements;*
- *Evidence of risk management strategies in relation to the procuring and putting into service of new or modified assets;*
- *Documentation of all relevant processes for designing and delivering assets;*
- *Processes for managing risks in the design phase;*
- *Evidence of the tools used for ensuring safety;*

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- *Details of the standards or other safety information relied upon for the design and maintenance of the asset and any tests used to confirm compliance;*
- *The existence of a manual, or similar, that includes the processes for operating and maintaining assets and for managing risks in the operation and maintenance phase;*

Implementation phase

- *Evidence of safety risk management, testing, and validation processes covering construction/ manufacturing and commissioning of the asset and its operational readiness;*

Operation and maintenance phase

- *Evidence of ongoing compliance with the standards and processes, and management of identified risks;*
- *Asset maintenance plans and procedures;*
- *Evidence of the activities of the organisation in relation to identifying and eliminating risks;*
- *Evidence of the processes used to report on and manage any safety performance issues and corrective actions;*
- *Evidence of the use of trending performance against the predicted strategic life of an asset for tracking performance and planning for renewals;*
- *Processes for identifying faults and failures and undertaking corrective action;*
- *Management of emergency circumstances or non routine situations which may affect asset safety;*
- *Evidence of the consideration of asset management for notifiable occurrences, and management of shared risks at the interfaces;(see also 3.1)*

Renewal, decommissioning and disposal

- *Evidence of processes to manage risks associated with the renewal, decommissioning, or disposal of assets which are appropriate to the scale and nature of the organisation;*
- ▶ *Evidence of a systematic approach to address human and organisational factors in all life cycle stages of asset management;(5.2.1)*
- ▶ *Evidence of the compliance of operational documentation with the requirements for managing (operation) and maintenance at organisational and physical boundaries, e.g. organisational, technical and operational interfaces with neighbouring infrastructures, border stations, interactions with other railway undertakings or infrastructure managers;(5.2.3)*
- ▶ *Information showing that the applicant demonstrates that its maintenance arrangements are compliant with the relevant requirements (legislation, standards, etc.);(5.2.3)*
- ▶ *In the case of vehicles a copy of the ECM certificate (this could be held by the railway undertaking or by an entity that the railway undertaking relies on to provide vehicle maintenance, or even outsourced as regards maintenance functions) or (until 16th June 2022) evidence that Articles 14(2), 14(3) and Annex III of Directive (EU) 2016/798 is being complied with by the entity responsible for maintenance;(5.2.4 (a)-(d))*

In the case of partnerships between railway undertakings where the vehicle is maintained by the partner:

Evidence that contractual arrangements are in force between the partners, including:

- *The exchange of information as described in Article 5 of [Regulation \(EU\) 2019/779](#);*
 - *Technical support when appropriate in particular for CCS legacy systems;*
 - *The control of capabilities of contracted maintenance workshops to deliver maintenance;*
 - *The monitoring of vehicles and the exchange of relevant information resulting from this monitoring;(see also 6.1)*
- ▶ *In the case of assets for which a certificate of conformity is required under EU law or national rules a copy of such a certificate along with an explanation of the extent to which it is relied upon as part of the SMS;(5.2.4 (a)-(d))*
- ▶ *Information on how the document management part of the SMS works in relation to asset management, including evidence that maintenance documentation (procedures, work instructions, etc.) is updated when and where necessary;(5.2.5 (a)-(c))*
- ▶ *Evidence of the configuration management of assets through their life cycle, including any change management processes in place to deal with baseline reconfigurations;(5.2.5 (c))*

5.2.5 Examples of evidence

Design phase

The organisation documents all relevant safety-related processes and information relating to the design and delivery of the assets through the use of configuration management processes (or a configuration management system). These outline the technical and organisational activities that establish and maintain control of the asset throughout its life cycle.

The organisation establishes and documents a process to manage the risks associated with the design of the asset solution by:

- ▶ *Determining requirements for any new and/or modified assets (see also 1) and it consults on them with relevant stakeholders (see also 2.4);*
- ▶ *Managing the risks associated with implementing such changes (see also 3.1); and*
- ▶ *Managing the risks associated with asset procurement and contract management where relevant (see also 3.1 and 5.3).*

These include hazard safety analyses to identify areas most at risk of failure, reviewed against the organisation's hazard log. This is achieved by identifying safety critical systems and establishing key performance objectives through the use of appropriate risk identification techniques, for example:

- ▶ *Reliability, availability, maintainability & safety (RAMS) analysis of the design of assets (where key safety performance criteria are communicated to designers to ensure that the asset is fit for purpose); and*
- ▶ *Failure modes, effects and criticality analysis (FMECA) and/or reliability centred maintenance (RCM) to manage risks during the design phase and to support establishing a maintenance plan.*

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These requirements are managed against the specific standards and processes used for the design, maintenance, and operation of rail infrastructure and rolling stock, as identified by the organisation. The organisation demonstrates that:

- ▶ *Safety critical systems are designed to functional specifications;*
- ▶ *There is a validation and commissioning test plan to confirm that the asset is fit for purpose and safe to operate and maintain; and*
- ▶ *Operation and maintenance documentation has been prepared, which outlines processes for updating, reviewing, and maintaining assets (see also 4.5).*

The organisation demonstrates that it uses appropriate systems engineering processes and safety assurance processes (e.g. EN50126/8/9 for complex systems) in their design and procurement approach. This might be achieved through the creation of a 'Systems Engineering Management Plan' (SEMP), which would specify the procedure to identify and record stakeholders, system requirements, and safety needs.

Implementation phase

In order to ensure the successful and safe implementation of the asset, the organisation establishes processes to manage the risks associated with its construction, testing, and commissioning, in line with the processes of the SMS.

It also implements a process to manage:

- ▶ *The testing, verification, and validation of system and safety requirements of the asset, which might be achieved by way of a 'Testing and Commissioning Management Plan' or equivalent; and*
- ▶ *The operational readiness of the asset, which can be achieved with an operational readiness checklist.*

Operation and maintenance phase

The organisation has developed an asset operation and maintenance documentation that outlines the safety management processes it uses to update, review, and maintain their assets. It describes the scope of the operations and, where applicable, the risk management strategies they have in place to cover all relevant activities.

This documentation:

- ▶ *Ensures that the asset is operated and maintained in accordance with the asset design;*
- ▶ *Identifies and incorporates all safety-related conditions, which specify how the use of the asset might be restricted, and the conditions that are in place for its use; and*
- ▶ *Specifies the ongoing checks to be carried out.*

The process for configuring the design and delivery of proposed assets (described in the design phase) is extended to cover the whole of its life cycle by:

- ▶ *Establishing and maintaining records of all assets through the creation of an asset register. This contains information such as the unique identification of the assets, their location, any maintenance carried out, , etc.;*
- ▶ *Managing documents and information about the assets in accordance with the organisation's SMS (see also 4.4 and 4.5); and*
- ▶ *Determining the criticality of assets, based on the results of a safety risk assessment. Safety critical assets are identified within the asset register.*

The organisation shows how asset information is developed, maintained, and integrated within their hazard log.

The organisation monitors ongoing compliance with their nominated standards and processes in order to ensure that their railway operations continue to be safe and perform efficiently. To this end, the organisation establishes processes to ensure that:

- ▶ *Assets are operated and maintained in accordance with the relevant manuals;*
- ▶ *The condition of the assets is monitored;*
- ▶ *Equipment needed to test or inspect assets is appropriately controlled, calibrated, and maintained;*
- ▶ *Any risks associated with operating and maintaining the assets are being managed in accordance with the risk management processes and all workplace health and safety laws; and*
- ▶ *Spare parts are available for maintenance, especially for the safety critical assets. This might be achieved by determining spare part needs for the assets based on the asset criticality, as identified through the use of 'Reliability Centred Maintenance' (RCM).*

The organisation demonstrates that it has asset maintenance planning to:

- ▶ *Address competency, capacity, and resource requirements;*
- ▶ *Provide for information management and record keeping needs;*
- ▶ *Deliver detailed plans that have been established through a risk-based process and which define the different maintenance levels and established standard organisational structures, procedures and responsibilities for the maintenance of assets; and*
- ▶ *Ensure calibration of the tools and equipment that will be used for maintenance.*

This may specifically include:

- ▶ *A 'Technical Maintenance Plan' (TMP); and*
- ▶ *Work instructions developed from and audited against the TMP.*

Planning is documented and controlled, using a computer maintenance management system (see also 4.5).

The organisation has processes in place to ensure that:

- ▶ *When a vehicle or equipment is assigned to a task that:*

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- *Compliance with the task/mission to be performed (e.g. technical compatibility of each type of rolling stock with the routes) is checked when rostering and before departure;*
 - *Maintenance of at least safety-critical components is delivered according to the plan (preventive maintenance with the frequency and type of interventions);*
 - *Maintenance interventions are defined when defects are identified or when they exceed their safe limits of use (corrective maintenance), unless operational restrictions are implemented;*
 - *Necessary action is taken as soon as possible following identification of the need for change, such as the removal from operation or the setting of operational restrictions.*
- ▶ *Work instructions are available for all safety critical activities;*
 - ▶ *All tasks are signed-off for compliance;*
 - ▶ *Documentation about maintenance carried out is controlled (**see also 4.5**); and*
 - ▶ *Competency based training is available on all safety critical systems (**see also 4.1**).*

There is a process/procedure for ensuring that operational restrictions, whether temporary or permanent (e.g. due to specific vehicle type or to specific routes) are:

- ▶ *Taken into account when the vehicle or an equipment is assigned to a task/mission;*
- ▶ *Communicated in due time to staff operating the vehicle or equipment (e.g. train driver, train manager).*

The organisation demonstrates that it:

- ▶ *Understands the performance of its' safety critical assets by identifying what needs to be monitored, measured, and reported;*
- ▶ *Establishes and records the method and frequency of monitoring, measurement, analysis, and evaluation of the performance of safety critical assets;*
- ▶ *Monitors trending performance against the predicted strategic life of an asset (**see also 6.1**);*
- ▶ *Reports on performance issues based on the level of safety risk and escalates safety performance issues so that that they are adequately addressed;*
- ▶ *The results of monitoring are used to adapt the maintenance plan where relevant;*
- ▶ *Establishes channels to communicate any results (**see also 4.4**);*
- ▶ *Improves the conformance of safety critical assets with standards by:*
 - *reviewing operational and maintenance controls, and assessing the risk of assets not meeting the predetermined standards;*
 - *identifying the root cause(s) of safety performance issues; and*
 - *identifying actions that might be needed for return the assets to safe operating condition;*
- ▶ *Improves the SMS continuously by identifying potential risks and taking corrective action (**see also 7.2**); and*
- ▶ *Documents where opportunities have been taken to reduce or eliminate risk and how this was achieved.*

The organisation has processes for identifying any faults or failures that might occur with their assets and ensuring the appropriate corrective actions are carried out. These are in line with the provisions and maintenance programmes or plans and:

- ▶ *Ensure appropriate recording of failures and the resultant corrective actions;*
- ▶ *Address safety critical failures;*
- ▶ *Ensure the appropriate reporting of notifiable occurrences; and*
- ▶ *coordinate unscheduled repairs for safety-related assets.*

The organisation:

- ▶ *Documents the failure management process;*
- ▶ *Uses appropriate analysis techniques for safety critical features, such as 'Root Cause Analysis' (RCA);*
- ▶ *Implements failure recording, which may include fault codes, failure mode, effect, criticality and corrective action;*
- ▶ *Develops procedures to manage common repair activities; and*
- ▶ *Introduces a feedback process for the engineering or technical teams to review and improve systems and minimise the risk of future failures.*

This is achieved through the use of fault reporting, analysis, and corrective actions (FRACAS), which:

- ▶ *Records faults that were detected and recorded during testing and commissioning, as well as any that occurred during operation or maintenance; and*
- ▶ *Manages the subsequent corrective actions taken to address them.*

The organisation documents all faults and corrective actions and requires a technically competent person to check any unscheduled repairs.

There is a process/procedure governing the management of degraded or emergency circumstances in asset management.

The organisation has established processes to manage interface risks that occur during the operation and maintenance of its assets (**see also 3.1.1**). These cover interfaces between assets and between the actors using them.

Renewal, decommissioning and disposal phase

The organisation understands the condition of their assets and, when they are deteriorating, responds accordingly by replacing or maintaining them.

The organisation has established a validation and commissioning test plan to confirm that a new asset is fit for purpose and safe to operate and maintain. If the organisation extends the life of an existing asset, it seeks appropriate safety information, such as historical data, to ensure that it remains safe to use.

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Monitoring of trends against expected performance is carried out (see operation and maintenance phase).

When disposing of any rail infrastructure or rolling stock, the organisation appropriately manages the risks of taking the asset out of service.

Managing changes to safety critical assets

In situations where the organisation seeks to change the configuration baseline of safety critical assets, it implements a change management process to ensure the effective management of safety risks, establishing configuration baselines for all safety critical assets with associated software (whether they are embedded in existing systems or standalone programs). If an operator is changing the configuration baseline of safety critical assets, it, where possible:

- ▶ *Manages the risks arising from changes to these assets;*
- ▶ *Tracks serial and model numbers;*
- ▶ *Validates functional requirements against specifications and risk control measures;*
- ▶ *Controls the release of configuration items; and*
- ▶ *Ensures that the status of any assets under configuration management is up to date.*

The organisation's changes to established baselines, operating conditions, or the maintenance schedule of safety critical assets do not in any way diminish the safety of the rail operations.

Application of common safety methods

There is a process/procedure for monitoring that the entities responsible for maintenance (e.g. ECMs) use for checking the application of the CSM for risk evaluation and assessment and CSM on monitoring as applicable (i.e. either required by law and/or by contractual arrangements).

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

The organisation's risk register containing safety risks linked to all phases that are part of the asset management life cycle and identifies underlying human and organisational factors related root causes for each risk scenario related to asset life cycle management.

The organisation's programme specifies a framework for how identified human and organisational risks will be reviewed, agreed, and progressed to achieve resolutions throughout the design or change management process. The programme specifies the relationship with other parties related to the design or change activity.

For example:

- ▶ *End-users are part of the need analysis, this can include task analyses and interviews, some representatives of staff are involved from the design to the testing phases;*
- ▶ *There are procedures and dedicated means to ensure a clear communication between operational and maintenance teams, as well as with ECM(s);*
- ▶ *End-users are also involved in the change management processes, including automation. Feedback can be provided by staff to the project team, and this feedback is analysed and improvement actions are taken. The minutes of meetings and reports on change management clearly show their engagement and the consideration of their concerns;*
- ▶ *All concerned users are identified as part of the risk assessment and training is provided to them as part of the competence management system, to ensure staff remain competent;*
- ▶ *Manufacturers and suppliers are involved in the process of design and change management in order to ensure appropriate consideration of human factors.*

Information is provided on the use of the Safety Alert Information Tool (SAIT) (**see 5.4.3**).

5.2.6 References and standards

- ▶ *ECM guidelines*
- ▶ *ERA Clarification note on safe integration*
- ▶ *CENELEC - EN50126 Railway Applications – The Specification and Demonstration of Reliability, Availability, Maintainability and Safety (RAMS) Part 1:Basic, Requirements and Generic, Process*
- ▶ *Office of the National Rail Safety Regulator - Asset management guideline (2019)*
- ▶ *ISO 55000:2014 Asset management – Overview, principles and terminology*
- ▶ *ISO 55001:2014 Asset management – Management Systems – Requirements*

5.2.7 Supervision issues

From a supervision perspective, it is important that the concentration is on the management of the asset over its life cycle from design to disposal not on individual failures of the management of the asset unless these have direct safety implications.

Supervision should consider how existing assets which pre-date current standards are managed and maintained.

Supervision should consider whether and how the organisation uses the SAIT.

5.3 Contractors, partners and suppliers

5.3.1 Regulatory requirement

- 5.3.1. The organisation shall identify and control safety risks arising from outsourced activities, including operations or cooperation with contractors, partners and suppliers.
- 5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:
- (a) the legal and other requirements related to safety (see 1. Context of the organisation,);
 - (b) the level of competence required to deliver the tasks set out in the contract (see 4.2. Competence);
 - (c) the responsibilities for the tasks to be performed;
 - (d) the expected safety performance to be maintained during the contract ;
 - (e) the obligations relating to the exchange of safety-related information (see 4.4. Information and communication);
 - (f) the traceability of safety-related documents (see 4.5. Documented information).
- 5.3.3. In accordance with the process set out in Article 3 of Regulation (EU) No 1078/2012, the organisation shall monitor:
- (a) the safety performance of all activities and operations of contractors, partners and suppliers to ensure that they comply with the requirements set out in the contract;
 - (b) the awareness of contractors, partners and suppliers of safety risks they entail to the organisation's operations.

5.3.2 Purpose

The applicant has to demonstrate that it has the ability to identify, assess and control risks which arise from the activities of contractors and other suppliers which it has a working relationship with. This is not simply a question of risk assessment and neither does it require a list of all risks or categories of relevant risk, but it requires the applicant to show how its systems and procedures as a whole are designed and organised to facilitate the identification, assessment and control of these risks. This includes the need for the contract to set out how safety-related information is exchanged. The use of well-written contracts is a generally accepted way to manage risks. However, the prime responsibility for managing contractors and checking their delivery against the set specifications rests with the organisation. The use of contractors or sub-contractors does not mean that the RU/IM delegates any of their responsibilities for ensuring that the contracted services are carried out to the standards specified before operation.

The applicant should demonstrate that it has processes in place to determine the competence of contractors and other suppliers and to assess their safety performance as part of its procurement process.

Each organisation is responsible for, carrying out the monitoring process set out in the CSM on monitoring and ensuring that, through contractual arrangements, risk control measures

implemented by their contractors are also monitored in compliance with the CSM. If organisations identify any relevant safety risk concerning defects or malfunctions of technical equipment they are required under the CSM on monitoring to report those risks to the other parties involved so that they can take any necessary corrective actions to ensure system safety.

5.3.3 Explanatory notes

Further information on contractual arrangements and partnerships can be found in Annex 3.

How are human and organisational factors and safety culture integrated?

The processes set out by the company to control its risks include the activities of contractors, partners and suppliers. Risks and the safety measures defined by the company are communicated to contractors, suppliers and partners and included in the specifications for each type of outsourced activity. This may also cover monitoring of performance of the outsourced activity (see section **6.1 Monitoring** below).

The human and organisational factors strategy may cover relevant issues concerning contractors, partners and suppliers.

Roles, responsibilities and competencies necessary to carry out the outsourced tasks are clearly defined in the contracts. These competencies are the same as those described in the competence management system for internal staff.

The contracts contain provisions on how safety information and communication is managed to ensure the same level of safety described for internal information and communication. This also includes knowledge-sharing.

5.3.4 Evidence

- ▶ *Evidence of how the SMS of the organisation interfaces with the management systems of contractors and suppliers to control risks;(5.3.1)*
- ▶ *Evidence that contractual arrangements are developed based on the results of risk assessment;(5.3.1)(see also 3.1)*
- ▶ *There are processes stating how human and organisational factors should be addressed and communicated to subcontractors as well as the management of them;(5.3.1)*
- ▶ *Evidence of how the organisation manages documentation concerning contractors and suppliers;(5.3.2(a) –(d))*
- ▶ *Evidence of how the organisation selects contractors and suppliers in order to ensure that they are competent and that safety risks are properly managed;(5.3.2(a)-(e))*
- ▶ *The process in place to ensure important safety information is shared with the contractors and suppliers or reported by them;(5.3.2 (d))*
- ▶ *Evidence of how the document control procedure ensures the management of safety related documents which are relevant to contractors and suppliers (5.3.2(f)).*

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- ▶ *The process or procedure for monitoring that the organisation has in place for making sure that contractors partners and suppliers with whom it has a working relationship are able to manage the risks that they face;(5.3.3 (a)-(b))*
- ▶ *Evidence that contractors, partners or suppliers are regularly monitored in accordance with the CSM on monitoring (Regulation (EU) 1078/2012) to ensure that the product or service meets specified requirements and safety objectives.(5.3.3 (a))(see also 6.1)*

5.3.5 Examples of evidence

Evidence of the safety objectives (or targets) that contractors, partners and suppliers are expected to achieve and the indicators that will be used to measure them is supplied.

The document management procedure which deals with the organisations standards to be applied by the contractors, partners and suppliers (see also 4.5.1.1 (e) Document Management.

A list/overview of its contractors, partners and suppliers for internal or external use, with specification of the products and/or services provided by them (**see also 4.5.1.1 (d) and (e)**) and an indication of what impacts on safety there are, together with the measures to control the identified risks (e.g. exchange of information, clarification of responsibilities, training) (**see also 3.1.1.1 (a)**).

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

The appropriate audit/inspection planning process for its contractors, partners and suppliers with some example records of these activities, such as audit/inspection reports or findings and the related action plans.

The human and organisational factors strategy details how these issues are covered with contractors, partners and suppliers.

In a procedure by which contractors, partners and suppliers are selected and monitored. The procedure makes it clear that the standards to be applied by the contractors are the same as those for directly employed staff and what the roles and responsibilities are. The procedure documents the information exchange necessary between the SMS systems to the applicant and the contractors, partners and suppliers.

The competence management system procedure which links with that of their contractors, partners and suppliers.

The process/procedure for managing contractors, partners and suppliers including how interface risks arising from the activities of contractors, partners or suppliers are managed, and shared with them and where relevant how these are included in contractual arrangements and how the exchange of information is integrated within the SMS.

The process or procedure by which relevant requirements applicable to the contractors, partners or suppliers are identified and shared with them and where relevant, how they are

included in contractual arrangements which are properly documented within the document management system so ensuring traceability of information.

The documentation management system procedure for managing the certificates, authorisations, recognitions or any other type of evidence demonstrating compliance with the requirements applicable to contractors, partners or suppliers and which controls their validity over time (e.g. through monitoring activities).

5.3.6 Supervision issues

When supervising an organisation it may be necessary in order to get a complete picture of the extent of the control and monitoring to conduct supervision activities with a contractor or supplier working for that organisation. It may also be necessary to access the documentation that the contractor or supplier is working to and examine how this relates to the procedures set out in the SMS of the organisation.

Arrangements to ensure that contractor and supplier safety performance and competence is an integral part of the procurement process.

5.4 Management of change

5.4.1 Regulatory requirement

5.4.1. The organisation shall implement and control changes to the safety management system to maintain or improve the safety performance. This shall include decisions at the different stages of the change management and the subsequent review of safety risks (See 3.1.1. Risk Assessment).

5.4.2 Purpose

It is important for the applicant to be able to identify and respond to new risks which may arise in its operation by applying the CSM for Risk Evaluation and Assessment ([Regulation \(EU\) 402/2013](#)) as appropriate. The SMS should demonstrate it has procedures for evaluating these risks and implementing new risk control measures where appropriate. This should cater for all types and levels of change: significant and minor, permanent and temporary, immediate and long term. It should apply to changes of a technical, operational or organisational nature.

5.4.3 Explanatory notes

Not all changes are subject to risk assessment (**5.4.1**). Where changes are actively managed through other processes in the SMS, such as day-to-day operations, they should not be seen as a change requiring management through the formal change process.

Roles, responsibilities, accountabilities and authorities to be defined (**see also 2.3**) include the management of change (**5.4.1**), e.g. assignment of roles to a change control board.

How are human and organisational factors and safety culture integrated?

5. Operation

The change management process allows for risks to be assessed in a proportionate and robust manner, including human and organisational factors (HOF) where appropriate, and for reasonable control measures to be adopted.

Staff are consulted during the change management process **(see also 2.4)**.

Safety risks arising from downsizing or the outsourcing of activities, including operations or cooperation with contractors, partners and suppliers are managed and prioritised as equal to internal risks.

5.4.4 Evidence

- ▶ *A description of the change management process;(5.4.1)*
- ▶ *A description of the procedures and methods used to evaluate new or changed risks and implement new;(5.4.1)*
- ▶ *Control measures including sign posts to where detailed processes can be found;(5.4.1)*
- ▶ *Information on how the organisation identifies significant changes and decisions on when to apply the processes in the CSM for risk evaluation and assessment or when to carry out risk assessment under the SMS procedures ;(5.4.1)*
- ▶ *Information on the arrangements within change management that the organisation has in place for managing vehicle authorisations and changes to the single safety certificate or safety authorisation;(5.4.1)*
- ▶ *Information on the process for notification of the relevant National Safety Authority of changes before starting a new rail transport operation.(5.4.1)*

5.4.5 Examples of evidence

A copy of the change management procedure as part of their application. This document covers the need for risk assessment of all changes according to differing legal requirements. An example of an issue and assumptions log which is regularly reviewed as the change progresses is provided. Finally, the procedure also covers the process by which relevant NSA(s) are notified of changes.

The change management process refers to use of the risk assessment process and the outcomes are considered when developing, implementing and reviewing operational processes.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

Changes to roles, responsibilities, tools and equipment, work environments, processes and procedures are supported by an analysis of human and organisational factors which identifies possible safety risks related to the change. Methods used include for example, task analysis, usability analysis, simulation, risk assessment, HAZOP and safety survey. There are examples of changes to be preceded by risk assessment applying a human and organisational

factors approach. In particular, this applies for change of work procedures due to modified equipment, changes of work schedules or reallocation of responsibilities.

In examples of projects showing how human and organisational factors have been taken into account as part of the management of change process, from the beginning, through the analysis of the company's needs: technical changes, as new equipment(s) or upgrades, organisational or operational changes, with expected impact on the existing situation, etc., thereby avoiding poor design that would have impaired the company's performance. There are minutes of meetings analysing the effect the change will have on the organisation's culture, and how this has been communicated to the management.

Roles and responsibilities for managing change and the associated safety risks being sufficiently defined, and the competence management system shows that people in charge have been trained to integrate human and organisational factors.

The project hazard log created during each project identifying underlying human and organisational factors-related root causes for each safety-related risk scenario. It also includes the potential impacts on contractors, partners and suppliers, who are involved when needed.

Project risk assessments being conducted in the early stages of the project and these involve end-users. Risk assessment is seen as an ongoing process that addresses ongoing issues during the change process (e.g. evolving assumptions and updating new identified risks).

In administrative processes/arrangements between various organisations, providing plans and project details etc. to different parties. Unions and other stakeholders are involved early in the process for any big decisions or changes.

The tools used being the same as those set out in the risk assessment chapter, i.e. task analysis, usability analysis, simulation, risk assessment, HAZOP, safety survey.

5.4.6 Supervision issues

To establish whether the management of change arrangements in the SMS are sufficiently robust it will be necessary to follow a number of changes of different types through the defined process to see whether they have (a) been managed appropriately and the risks arising from changes properly considered, and (b) whether any lessons learnt have been incorporated into revisions to the SMS procedures.

Assessing the compliance of the management of change arrangements with CSM for risk evaluation and assessment.

The organisation has processes for implementing, and on-going monitoring of relevant TSIs, national rules and other standards, where appropriate showing how these are applied throughout the life cycle of any equipment or operation.

5.5 Emergency management

5.5.1 Regulatory requirement

- 5.5.1. The organisation shall identify the emergency situations and associated timely measures to be taken to manage them (see 3.1.1. Risk assessment) and to re-establish normal operating conditions in accordance with Regulation (EU) No 2015/995.
- 5.5.2. The organisation shall ensure that, for each identified type of emergency:
 - (a) the emergency services can be promptly contacted;
 - (b) the emergency services are provided with all relevant information both in advance, to prepare their emergency response, and at the time of an emergency;
 - (c) first aid is provided internally.
- 5.5.3. The organisation shall identify and document the roles and responsibilities of all parties in accordance with Regulation (EU) No 2015/995.
- 5.5.4. The organisation shall have plans for action, alerts and information in case of emergency including arrangements to:
 - (a) alert all staff with responsibility for emergency management;
 - (b) communicate information to all parties (e.g. infrastructure manager, [railway undertakings](#), contractors, authorities, emergency services), including emergency instructions for passengers;
 - (c) take any decisions required in accordance with the type of emergency.
- 5.5.5. The organisation shall describe how resources and means for emergency management have been allocated (see 4.1. Resources) and how training requirements have been identified (see 4.2. Competence).
- 5.5.6. The emergency arrangements are regularly tested in cooperation with other interested parties and updated when appropriate.
- 5.5.7. The organisation shall ensure that competent staff in charge, with adequate language skills, can be contacted easily and without delay by the infrastructure manager and provide the latter with the right level of information.
- 5.5.7. [The organisation shall coordinate emergency plans with all railway undertakings that operate on the organisation's infrastructure, with the emergency services, so as to facilitate their rapid intervention, and with any other party that could be involved in an emergency situation.](#)
- 5.5.8. There is a procedure to contact the entity in charge of maintenance or the railway vehicle keeper in the event of an emergency.
- 5.5.8. [The organisation shall have arrangements to halt operations and railway traffic promptly, if necessary, and to inform all interested parties.](#)
- 5.5.9. [For cross-border infrastructure, the cooperation between the relevant infrastructure managers shall facilitate the necessary coordination and preparedness of the competent emergency services on both sides of the border.](#)

5.5.2 Purpose

Robust systems for emergency planning are essential for any duty holder and should cover the information that needs to be supplied to the emergency services to enable them to draw up their major incident response plans. Also important are those aspects of the SMS that are directly relevant to the emergency response arrangements, e.g. training for emergencies and testing of emergency plans.

5.5.3 Explanatory notes

Emergency situations (5.5.1) links with results of the organisation's risk assessment although TSI OPE (see clause 4.2.3.7) provides a non-limitative list of emergency situations.

First Aid provided internally (5.5.4 (c)) means that the company is capable of managing the provision of first aid for the emergency situations identified in clause 5.5.1.

Clauses 5.5.7 and 5.5.8 in the legal text above are replaced by the clauses in blue text where the assessment relates to the Infrastructure manager. **Clause 5.5.9** in blue above relates only to the Infrastructure Manager.

How are human and organisational factors and safety culture integrated?

Emergency management is linked to resource management, roles and responsibilities, and the competence management system, to ensure staff awareness and training (including maintenance of competence). This includes the development of competencies (including non-technical skills such as resistance to stress, resilience...) for the actors concerned with the emergency plans and procedures.

5.5.4 Evidence

The applicant is expected to provide an overview of:

- ▶ *The types of emergency covered, including degraded operations and the procedures in place to manage them;(5.5.1)*
- ▶ *The information supplied by the applicant to enable the Emergency Services to plan their response to a major accident on the railway, where appropriate referring to duties under applicable EU legislation and any relevant cross-border arrangements;(5.5.2 (a) and (b))*
- ▶ *It is expected that companies identify within their risk assessment what first aid they can provide themselves and what would need to be provided by the emergency services (5.5.2 (c)).*
- ▶ *The plans, roles and responsibilities, (including for those with designated skills assigned to assist the Infrastructure Manager or vice versa), training and arrangements to maintain competence, and the arrangements for effective communications with emergency services, relevant staff and communication with those affected by incidents such as passengers or affected third parties (this should include a document which sets out the roles and responsibilities of all parties, how resources and means have been allocated and training requirements have been identified); the procedures to return to normal operations after an emergency;(5.5.1), (5.5.3), (5.5.4 (a)-(c)), (5.5.5), (5.5.7) (5.5.8 and 5.5.9 from infrastructure manager regulatory requirements only)*
- ▶ *Those specific aspects of the SMS that are directly relevant to the emergency response arrangements, e.g. training for emergencies and testing of emergency plans to identify any weaknesses; (5.5.6)*
- ▶ *The procedure to contact the relevant entity in charge of maintenance or the keeper in the event of an emergency affecting one of their vehicles;(5.5.8 from railway undertaking regulatory requirements only)*

5.5.5 Examples of evidence

A copy of the Emergency Management Procedure(s) and the plans (e.g. recovery procedures) associated with it. The procedure covers the whole network operated, with specific arrangements as necessary for tunnels and other high risk locations and for cross-border co-operation, staffing and roles and responsibilities and includes links to the emergency arrangements of the infrastructure manager and how to contact other relevant parties such as the ECM where relevant. When the area of operation of a railway undertaking contains several infrastructure managers, the railway undertaking should take into account the differences between the emergency arrangements (and the user-agreements) with these infrastructure managers.

The emergency procedure includes the process by which victims of incidents and their families are given guidance on complaints procedures.

The procedure (where relevant) includes information on what happens in an emergency situation where dangerous goods are involved, the organisation (railway undertaking) has a process to ensure that:

- ▶ *The loader, the tank wagon owner where privately owned, the owner or keeper and the operator in the case of a tank container, the consignee etc. can be promptly contacted.*
- ▶ *The infrastructure manager is provided with relevant information as soon as possible (e.g. registration number of the wagons, position of the wagons in the train, UN number, RID classification code and hazard identification number of the dangerous goods in conformity with RID provisions);*
- ▶ *The organisation (infrastructure manager) has a process to ensure that authorities (e.g. rescue services, police, other emergency services, and authorities) are provided with relevant information on dangerous goods (see examples above).*

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

The procedure which establishes the scenarios of identified potential emergency situations, assessing the risks linked to the different situations (with the identified interfaces), including those arising from human and organisational factors. The safety measures identified to mitigate these risks are integrated in the concerned plans, processes and procedures (including operating procedures).

The procedures describing the link between emergency planning and risk management.

References in the procedure to the competence management system requirements for staff who have to respond to emergencies as well as making sure that contracted staff are capable of meeting the same standards.

There being a procedure which describes the management of emergency drills (theoretical and practical) on a regular basis with all parties concerned (both internal and external), how feedback from emergency drills is collected by means of monitoring activities (see section **6.1**

Monitoring below) in order to take actions/measures to improve the emergency plans and procedures and the competence of all the actors concerned (see **7.2. Continual improvement** below).

There being a procedure which contains information on how emergency drills are used for competence management and to improve the process.

There being a procedure describing the business continuity management to be put in place in order to avoid deviations of standards/procedures when exposed to an unexpected impact on operations.

There being a procedure describing how the emergency plans are put into place in order to guarantee an efficient and fast intervention in order to save lives following an accident.

The provisions guaranteeing that the organisation's staff and emergency services have easy access to documentation related to emergency and business continuity plans to avoid further degrading the situation.

There being a procedure describing how recommendations expressed by other parties (authorities, emergency services) and best practices are considered for the review of the emergency plans and procedures.

5.5.6 Supervision issues

In order to properly assess the procedures in the SMS for emergency management it may be necessary to cross-check the SMS procedures with those of relevant interface actors (in particular the relationship between the key players such as the RU, IM and the emergency service) to ensure that the processes in place for the management of such incidents represent a coherent whole.

Check that all foreseeable emergencies have plans in place.

Arrangements for testing of emergency plans and coordinated arrangements with emergency services and not limited to table top exercises.

Interface arrangements with other interested parties exist and include, testing, control, communication, coordination and competence.

6. Performance evaluation

6.1 Monitoring

6.1.1 Regulatory requirement

- 6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:
- (a) to check the correct application and the effectiveness of all the processes and procedures in the safety management system, including the operational, organisational and technical safety measures;
 - (b) to check the correct application of the safety management system as a whole, and if it achieves the expected outcomes;
 - (c) to investigate whether the safety management system conforms to the requirements in this Regulation;
 - (d) to identify, implement and evaluate the effectiveness of the corrective measures (see 7.2. Continual improvement), as appropriate, if any relevant instance of non-compliance to points (a), (b) and (c) is detected.
- 6.1.2. The organisation shall regularly monitor at all levels within the organisation the performance of safety-related tasks and intervene if these tasks are not being properly performed.

6.1.2 Purpose

The organisation should provide evidence that it has in place a process for monitoring the application and effectiveness of the safety management system and that this process is appropriate to the size, extent and type of its operation. The organisation should demonstrate that the process can identify, evaluate and correct any defects in the functioning of the SMS.

6.1.3 Explanatory notes

Effectiveness of the control measures means that the organisation has a process in place to check that once a risk assessment has been carried out and appropriate control measures applied that these are reviewed after a period of time to ensure that the expected reduction in safety risk from their application has been achieved **(6.1.1 (d))**.

How are human and organisational factors and safety culture integrated?

Self-critical and objective assessments of the organisation's safety culture programmes, practices and performance are routinely conducted. Safety information from for example, the corrective action program, human performance, incident and accident analysis, surveys and relevant internal and external operating experience, is systematically collected and evaluated to identify trends and avoid organisational and individual drifting or complacency.

A successful assessment is able to provide input into the improvement of safety performance by providing a clear picture of how the organisation's safety culture influences safety. The assessment seeks to identify strengths and weaknesses of the safety culture by comparing what the culture is to what it should be aiming to be. This allows for prioritisation of areas for improvement and the implementation of changes for example, to process, training and behaviour. Safety culture assessment is a means of working proactively to improve safety performance and to increase safety margins. Independent safety culture assessments are recommended to be applied every three to five years, organisational self-assessments yearly or every second year.

6.1.4 Evidence

- ▶ *Information on how the applicant has implemented the CSM on monitoring (Regulation (EU) 1078/2012);(6.1.1 (a))*
- ▶ *Information on how the monitoring process identifies the success or otherwise of meeting the expected safety outcomes;(6.1.1 (b))*
- ▶ *Evidence that the SMS has been altered as a consequence of the correction of defects in the SMS processes identified during monitoring;(6.1.1 (c))*
- ▶ *Evidence that there is a review of the effectiveness of corrective measures put in place following evidence of non-compliance with the SMS processes;(6.1.1 (d))*
- ▶ *The organisation should have a process for setting performance standards and indicators for monitoring related to operational processes as well as for implemented changes. There should be a program for continuously assessing the performance of processes related to human and organisational factors as well as the result of these processes, e.g. staff adherence to implemented procedures as well as the use of new equipment.(6.1.2)*
- ▶ *Safety performance is assessed systematically in light of the safety culture improvement strategy. This means that the organisation should be looking to see how safety culture improvement fits into and is part of the goal of safety improvement.(6.1.2)*

6.1.5 Examples of evidence

A statement that the CSM on monitoring (Regulation (EU) 1078/2012) is applied and that there is a procedure which covers this activity. The procedure details how performance against safety objectives is measured and corrected through the change management and risk assessment process and how defects in the SMS will be corrected.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

The organisation having processes and procedures to systematically evaluate that the arrangements for including human and organisational factors are adequate and that the results achieved are according to performance standards.

6. Performance evaluation

The organisation having processes and procedures for systematically evaluating staff performance in safety critical work tasks. These processes are based on a proactive approach, setting standards for performance and systematic evaluation. Evidence based methods are used, e.g. crew resource management.

The monitoring process including provisions on resources allocated, including staffing and competencies for the staff involved in monitoring activities.

The monitoring undertaken integrating the check of the implementation and effectiveness of processes and procedures that integrates human and organisational factors safety measures derived from the risk assessment process. The monitoring therefore integrates specific human and organisational factors items, including in operational activities. This also covers assessment and maintenance of competencies (technical and non-technical skills, attitudes, behaviours...) for staff (internal or external) carrying out safety tasks (as see section **4.2 Competence** above).

The monitoring undertaken including the analysis of the success of the human and organisational factors strategy.

The monitoring process including the analysis of the reporting made by staff. The SMS contains a just culture process, in which gross negligence, wilful violations and destructive acts are addressed. The aim is to develop a reporting culture in which staff feel comfortable to report because they won't be blamed for unintended errors or omissions. This also explains how safety-related issues/incidents can be reported by staff members, contractors or other relevant stakeholders.

The monitoring process being an element to improve the organisational learning. The analysis of the reporting from staff is analysed as part of the monitoring process with a view to improve the safety measures and the SMS processes and procedures.

The monitoring results being analysed from a safety culture perspective and included in the process for safety culture assessment.

6.1.6 References and standards

- ▶ *[CSM on Monitoring application guide](#)*

6.1.7 Supervision issues

Examination of the monitoring process and the findings and actions arising from it is critical for establishing whether the SMS is a 'living' and evolving document as experience generates improvement, or it is a fixed document which does not change over time.

Examination of a number of key risk areas and controls and testing their correct application and effectiveness through the SMS is critical so that the NSA can establish compliance with CSM on monitoring.

6.2 Internal auditing

6.2.1 Regulatory requirement

- 6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:
- (a) A schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance;
 - (b) The identification and selection of competent auditors (see 4.2. Competence);
 - (c) The analysis and evaluation of the results of the audits;
 - (d) The identification of the need for corrective or improvement measures;
 - (e) The verification of the completion and effectiveness of these measures;
 - (f) The documentation pertaining to the execution and results of audits;
 - (g) The communication of the results of audits to the top management.

6.2.2 Purpose

The applicant should demonstrate that they have an internal auditing system which involves competent staff and produces meaningful outputs which are considered by management and ensures that the Safety Management System complies with legal provisions.

6.2.3 Explanatory notes

Internal audits **(6.2.1)** are monitoring tools in the meaning of the CSM on monitoring ([Regulation \(EU\) 1078/2012](#)). Although it is a separate requirement, it is meant to contribute to the achievement of the objectives of monitoring in accordance with the CSM on monitoring.

Internal audits **(6.2.1)** aim at providing information as to whether the safety management system conforms to the applicable requirements **(6.1.1 (c))** and is effectively implemented and maintained **(6.1.1 (a), (b) and (d))**. The applicable requirements refer to the requirements in Annex I (or Annex II) of [Regulation \(EU\) 2018/762](#) and thereby, to any other applicable requirements to which the organisation subscribes **(see also 1.1)**.

Auditors have the responsibility for verifying the completion and effectiveness of the corrective or improvement measures **(6.2.1 (c))** to be taken to address audit findings.

6.2.4 Evidence

- ▶ *Evidence that there is an internal audit process or framework which provides for planned audits and additional targeted audits in response to safety performance data;***(6.2.1 (a))**
- ▶ *Evidence of a competence management system which includes elements which address the competence of internal auditors;***(6.2.1 (b))**
- ▶ *Evidence of findings from audits both internal and external which have been acted upon;***(6.2.1 (c), (d), (e), (f))**

- ▶ *Evidence that the results of audits have been discussed at top management level and relevant actions taken as a result.***(6.2.1 (g))**

6.2.5 Examples of evidence

An internal audit procedure is in place for planned and additional audits including discussion of the outcomes at senior management level.

Examples of audit reports and a log of the findings from internal audits which indicates what action has been taken to address them.

Results of the audit activities carried out throughout the organisation are collected, analysed and make recommendations to be used for the periodic management review.

The procedure references the competence management system. The CMS demonstrates that the auditors have followed appropriate auditor training (e.g. ISO).

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

The internal audit process including provisions on resources allocated, including staffing and competencies for the staff involved. Competence requirements for staff carrying out internal audits are integrated in the competence management system, including for the specific human and organisational factors competencies. Training examples show that human and organisational factors were included.

The internal audit integrating the check of the implementation and effectiveness of processes and procedures that integrate human and organisational factors safety measures derived from the risk assessment process (see above **6.1 monitoring**).

The organisation having processes and procedures to systematically integrate human and organisational factors in its internal audits. The aim is to check the effectiveness of the human and organisational factors safety measures and evaluate the achievements of the safety objectives including human and organisational factors.

Examples of internal audits showing that human and organisational factors are taken into account while analysing the results of the audits, identifying the need for corrective or improvement measures and communicating them to top management.

The organisation having processes and procedures for systematically integrating the evaluation of staff performance carrying out safety critical work tasks and operational activities.

The process describing the management of communication regarding the results, recommendations/measures which points towards a shared and transparent approach.

6.2.6 References and standards

- ▶ *ISO 19011:2018 - Guidelines for auditing management systems*
- ▶ *CSM on Monitoring application guide*

6.2.7 Supervision issues

When carrying out supervision it is essential that the planning and the findings of audits are examined. This will reveal whether the audits target the right areas, whether the outcomes are reasonable and whether the staff carrying out the audits are competent and independent.

Check that the areas selected for audit are aligned with the risk profile of the organisation.

There is a mechanism for triggering non-planned audits and this is used by reviewing a number of examples.

6.3 Management review

6.3.1 Regulatory requirement

- 6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:
- (a) details of progress on addressing outstanding actions from previous management reviews;
 - (b) changing internal and external circumstances (see 1.Context of the organisation);
 - (c) the organisation's safety performance related to:
 - (i.) the achievement of its safety objectives;
 - (ii.) the results from its monitoring activities, including the internal audit findings, and internal accident/incident investigations and status of their respective actions;
 - (iii.) the relevant outputs from supervisory activities conducted by the national safety authority;
 - (d) recommendations for improvement.
- 6.3.2. Based on the outputs of its management review, the top management shall take overall responsibility for the planning and implementation of needed changes to the safety management system.

6.3.2 Purpose

Strong safety leadership from management is essential for the efficient and effective working of an organisation's safety management system as well as its continued development over time. The organisation should demonstrate that the management are actively involved in reviewing the performance of the safety management system and developing it for the future.

How are human and organisational factors and safety culture integrated?

The management review is linked to all the safety management system processes and procedures, it may then integrate human and organisational factors, with a view to improving them.

6.3.3 Evidence

- ▶ *Processes for management meetings covering the review of the safety management system and progress on internal recommendations from audits and reviews;(6.3.1 (a)-(d))*
- ▶ *Records of how the organisation has performed against its safety objectives;(6.3.1(c),(i))*
- ▶ *Evidence that the recommendations of the relevant NSA have been taken into account in the safety management system;(6.3.1 (c),(iii))*
- ▶ *The organisation can demonstrate it has processes for determining and setting targets consistent with the type, extent and relevant risks, it regularly assesses performance against targets, compliance with procedures and uses safety data to monitor, review and implement changes to operational arrangements.(6.3.1)*
- ▶ *Evidence that the management is taking an active role in planning and implementing needed changes to the safety management system;(6.3.2)*
 - *There are processes and tools to systematically report all types of identified risks, errors, near misses, deficiencies and incidents, as well as for categorizing and analysing what is reported from a human and organisational factors perspective to be able to find underlying causes and effective measures;*
 - *Human and organisational factors expertise is used in the accident investigation process;*
 - *There are systematic processes for feeding back lessons learnt on human and organisational factors issues into training and design;*
 - *Lessons learnt from accident and incident investigations are communicated to employees in the organisation, and are fed back into training, design and other areas to reduce the likelihood of reoccurrence;*
 - *Results from accident investigations are reported at management meetings and are regarded as an important tool for learning and improvement;*
- ▶ *There is a assurance process in place for accident investigations.*

6.3.4 Examples of evidence

The procedure which covers the review and progress on internal recommendations from audits and reviews conducted by senior management, along with minutes from selected meetings.

The issues log showing recommendations which have been made and progress on rectifying defects tracked by management.

The procedure for the management review of the outcomes from internal accident investigation and the relevant outputs from NSA supervision.

Information is supplied on which indicators are followed up by top management and at what frequency.

The examples of evidence referred to above should show how human and organisational factors are integrated in the management review.

6.3.5 Supervision issues

During supervision, it is essential to observe that the process for ensuring that management reviews the effectiveness of the SMS, results in real change at the operational level.

Management awareness of changing internal and external circumstances. Are the management carrying out for example– horizon scanning or other techniques such as PESTLE ((political, economic, social and technological, legal and environmental) analysis to inform the development of their SMS.

The connection/link between the results of the management review and how they are an input of the annual safety report.

7. Improvement

7.1 Learning from accidents and incidents

7.1.1 Regulatory requirement

- 7.1. Learning from accidents and incidents
- 7.1.1. Accidents and incidents related to the organisation's railway operations shall be:
 - (a) reported, logged, investigated and analysed to determine their causes;
 - (b) reported to national bodies as appropriate.
- 7.1.2. The organisation shall ensure that:
 - (a) recommendations from the national safety authority, the national investigating body and industry/ internal investigations are evaluated and implemented if appropriate or mandated;
 - (b) relevant reports/information from other interested parties such as railway undertakings, infrastructure managers, entities in charge of maintenance and railway vehicle keepers are considered and taken into account.
- 7.1.3. The organisation shall use information relating to the investigation to review the risk analysis and evaluation (see 3.1.1. Risk assessment), to learn with the aim of improving safety and, where applicable, to adopt corrective measures and/or improvement measures (see 5.4. Management of change).

7.1.2 Purpose

The organisation should demonstrate that it investigates accidents and incidents to learn and improve risk controls, that the staff doing so are competent to undertake investigation including into human and organisational factors issues, accidents are reported to the relevant authorities and recommendations and reports are made and acted upon by management.

In addition, the organisation applies “double-loop learning”: not only the reality of events is the focus of learning but also the organisations capacity to improve, by focussing on those elements that either foster or inhibit the transfer of knowledge and information throughout the organisation.

7.1.3 Explanatory notes

The terms ‘near misses’ and ‘other dangerous occurrences’ are included in the definition of ‘incident’ in accordance with [Directive \(EU\) 2016/798](#). It is equally important to investigate near misses and other dangerous occurrences in order to proactively manage safety.

Learning from accidents and incidents should support the sharing of information with other interested parties (infrastructure manager, other railway undertakings, ECMs, in order to develop the cooperation and foster the overall improvement of performance of the SMS).

For investigations requiring a human and organisational factors perspective investigators should either be trained or have access to suitable expertise to examine the issues in question.

How are human and organisational factors and safety culture integrated?

The analysis of accidents/incidents is not about blaming an individual, or a department that is “more responsible than another”, but rather aims at understanding and improving the organisational weaknesses that made them possible. The most important challenge when analysing events is to prevent also “neighbouring” events. If the analysis stops with identifying the immediate causes, it will only be possible to prevent the next similar event. If, on the other hand, the analysis enables the identification of technical and organisational “root causes”, the improvement actions will allow the prevention of another type of accident that shares the same mechanisms. If for example the analysis makes it clear that a procedure was not updated, and that the corrective action only aims at correcting this procedure, the effect will be limited. If the analysis looks further and identifies weaknesses in the process for updating procedures, the positive effect of an improvement action can be much wider.

The company can use the reporting structure set out in Article 4 of [Regulation \(EU\) 2020/572](#) “on the reporting structure to be followed for railway accident and incident investigation reports” to identify the elements on human and organisational factors that are to be investigated and integrate them in their reports. Note: however that this is just one of the reference models that exists, and can be used.

Reporting dangerous situations and “high potential” incidents is encouraged and made easy. If needed, mechanisms exist that keep the reporting anonymous. If the reporting is nominative, staff members and teams that sent the reports assist with analysis and the finding of short term responses. Team discussions are organised and actions taken are communicated to concerned staff members and throughout the organisation as appropriate.

7.1.4 Evidence

- ▶ *Information concerning the accident/incident report process including how root causes are identified and analysed, including reporting within the organisation and to other competent authorities and other parties;(7.1.1)*
- ▶ *Information on the method that the organisation uses relating to the investigation including the human and organisational factors element to review the risk analysis and evaluation process following an event;(7.1.3)*
- ▶ *Evidence that recommendations from the competent authorities have been acted upon from accident and incident reports and any necessary identified changes have been acted upon;(7.1.2 (a), (b))*
- ▶ *Reviewing past incidents to identify relevant factors relative to a current incident(s).There is evidence of wider organisational learning from incidents and experience, nationally and internationally.(7.1.3)*
- ▶ *There is a methodology for conducting investigations based on human and organisational factors knowledge and state of the art methods.*

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- ▶ *There is a training program for accidents and incident investigators applying a human and organisational factors perspective.*
- ▶ *A “just culture” is fostered, recognising and reinforcing positive safety initiatives (reporting of incidents, the involvement of staff in analysis and continuous improvement, support for colleagues etc.). This “just culture” should take away any fear of blame, by defining a largely accepted limit between what is and what isn’t accepted. The right to make a mistake is accepted.*

7.1.5 Examples of evidence

The procedure for accident investigation which describes the investigation methods and includes reference to the competence management requirements for accident and incident investigators.

A sample of accident and incident reports of different types which indicate that the investigations were carried out by a competent person, the findings are based on the evidence and the recommendations have been acted upon.

A copy of the procedure/process which tracks the corrective/mitigation measures identified following an accident/incident.

Information is provided on the use of the Safety Alert Information Tool (SAIT) to keep on top of and to advise other organisations of matters affecting particular assets.

There are trained investigators available.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

Competence requirements for staff carrying out investigations being included in the competence management system of the company. There is a training program for accidents and incident investigators, including how to systematically integrate human and organisational factors.

The reports showing an in-depth analysis of occurrences that lead to consistent action plans at any level of the safety management system, fostering a willingness to learn from incidents through changes to behaviours across the business. Minutes of meetings and exchange of communications show that when incidents include external parties, there is evidence that the results of analysis and actions are openly shared.

The Management recognising that incidents and accidents are caused by multiple factors some originating from management decisions, and minutes of Board meetings show that the results of accident/incident investigation and associated recommendations (i.e. corrective and/or improvement actions) are reported back to the management and how they feed the review of the SMS (**see also 6.3**).

A human and organisational factors approach being taken in investigations of incidents and accidents, and referred to in the human and organisational factors and safety culture

strategies and in all related processes (risk assessment, performance evaluation, continual improvement...)

The initial and continuous training programmes of staff showing that actions from lessons learnt are integrated, with a particular focus on human and organisational factors risks and how to mitigate them.

The investigations taking a systematic perspective, that is, not just to look at the human, technological and organisational factors in their own right but also to emphasise the interactions between the factors. For example, if a train driver has been involved in a Signal Passed At Danger (SPAD) incident, the suggested factors to investigate include the relevant issues e.g. fatigue, cognitive overload, competence, etc. (Human), the technology's influence on performance, such as human-system interfaces, layout, signal placing (Technology), the organisation's influence on performance, such as training, SMS, organisational priorities (Organisation) as well as the interaction between the three areas such as the influence of procurement on design or management of change with the introduction of new design.

The analysis of dangerous events being done in a crosscutting way, using a diverse set of skills and taking into account the points of view of all concerned parties (including external parties as necessary).

A "just culture" policy and existing reporting tools fostering a reporting culture and a questioning attitude among staff. All routine and abnormal deviations reported by staff are analysed and lead to implementing improvement actions where necessary. Communication to the concerned staff on what actions were taken is systematically carried out.

7.1.6 References and Standards

- ▶ *[ERA safety culture webpage](#)*
- ▶ *[ERA human and organisational factors webpage](#)*
- ▶ *[Commission Implementing Regulation \(EU\) 2020/572 of 24 April 2020 on the reporting structure to be followed for railway accident and incident investigation reports](#)*
- ▶ *IAEA (2002) - Safety culture in nuclear installations: Guidance for use in the enhancement of safety culture. IAEA TECDOC-1529. International Atomic Energy Agency, Vienna (2002).*
- ▶ *Mathis, T.L. & Galloway, S.M. (2013) - Steps to safety culture excellence.*
- ▶ *Kecklund, L., Lavin, M. & Lindvall, J. (2016) - Safety culture: A requirement for new business models. Lessons learned from other High-Risk Industries. In proceeding presented of The International Conference on Human and Organisational Aspects of Assuring Nuclear Safety – Exploring 30 Years of Safety Culture, Vienna, 22 to 26 February 2016*
- ▶ *RSSB (2015) - Safety Culture and behavioural development: Common factors for creating a culture of continuous development (www.sparkrail.org)*

7.1.7 Supervision issues

The competence of accident/incident investigators is critical for identifying meaningful recommendations and securing appropriate preventive measures. Those carrying out supervision should look for management interference in the outcomes of accident and incident reports which could affect the quality of the report and any outcomes which derive from it.

The results of an internal investigation have led to organisational learning, that is tracked in documents, reports or other information channels (i.e.: intranet, company internal magazine, etc.)

The organisation culture relating to incident and close call reporting.

7.2 Continual Improvement

7.2.1 Regulatory requirement

- 7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:
- (a) Monitoring (see 6.1. Monitoring);
 - (b) Internal auditing (see 6.2. Internal auditing);
 - (c) Management review (see 6.3. Management review);
 - (d) Learning from accidents and incidents (see 7.1. Learning from accidents and incidents).
- 7.2.2. The organisation shall provide means to motivating staff and other interested parties to be active in improving safety as part of its organisational learning.
- 7.2.3. The organisation shall provide a strategy to continually improve safety culture, relying on the use of expertise and recognised methods to identify behavioural issues affecting the different parts of the safety management system and to put in place measures to address these.

7.2.2 Purpose

Continual improvement is a major part of having an effective SMS. The purpose of this requirement is to get the applicant to show that they are committed to improve and their SMS supports this.

Top management engages in a **collective reflexion** to continually improve the safety culture of the organisation.

This collective reflexion is embodied in a strategy which targets **cultural traits** that significantly influence the safety performance and that deserve to be better valued or subject to change.

7.2.3 Explanatory notes

Continual improvement (7.2.1) focuses on the SMS elements that evaluate and lead to improvement actions but not to those elements already being subject to improvement since they are already part of the scope of the monitoring activities.

How are human and organisational factors and safety culture integrated?

Organisational learning (7.2.2) means the process of improving actions through better knowledge and understanding.

Safety culture (7.2.3) here has the definition referred to in 2.1.1 (j). A positive safety culture motivates and enables organisations and individuals to strive to improve safety and performance. It increases job satisfaction, job retention and provides cost benefits. It can also help meet regulatory expectations, as safety authorities and regulators are increasingly recognising the role safety culture plays in effective safety management. More specifically a positive safety culture can lead to:

- ▶ *Reduction in operational risk through more comprehensive risk assessment and improved understand of risk within the workforce;*
- ▶ *Reduction in workforce injuries by removing hazards identified through increased near miss reporting;*
- ▶ *Reduction in unsafe acts and conditions through improved workforce engagement and leadership development;*
- ▶ *Reduction in costs related to workforce injuries, unsafe actions and conditions;*
- ▶ *Improved performance through enhancing staff training, engagement and reductions in injuries, unsafe acts and conditions.*
- ▶ *Improved and more efficient SMS, with procedures and rules to better match reality*

Due to the fundamental properties of culture, which is created through daily interactions and difficult to change, this strategy is considered long term, owned and encouraged by the top management.

There are many ways to improve the safety culture:

- ▶ *Developing a system for sharing concerns. This can depend on the maturity of the organisation be anonymous but with growing trust be open and accessible for all. It is important that feedback is built into the system to ensure that employees feel a sense of involvement and belonging;*
- ▶ *Change procurement and contract terms to encourage a good safety culture for suppliers. Safety culture could be a criterion for selecting suppliers;*
- ▶ *Visibly reward safe behaviours. The reward can take many forms from increased annual pay via bonuses to weekly safety rewards for outstanding performance;*
- ▶ *Create specific objectives for managers on safety leadership, for example encouraging management to take a more visible role in the field setting standards by example;*

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► *Etc.*

The results of assessments should be communicated at all levels in the organisation. They should be acted upon to foster and sustain a positive safety culture, to improve the safety leadership and to promote a learning attitude within the organisation.

Identification and selection of relevant cultural traits is often a complex task¹ that should be carefully conducted.

Indeed this task should involve staff at all levels across the whole organisation and often beyond (e.g. contractors).

While the perceptions and beliefs of the staff may be collected through a questionnaire survey, such a method is generally considered as insufficient to establish cultural traits that influence safety. Possibly guided by the survey results, experts should conduct observations, individual interviews and focus groups to establish a more accurate diagnosis.

Note: A focus group gathers a small number of people (usually between 4 and 15) with a moderator to focus on a specific topic. Focus groups aim at a discussion instead of individual responses to formal questions, and produce qualitative data.

Based on this diagnosis, an action plan that aims at better valuing or contributing to changing cultural traits can be defined and supported by the top management. Top management monitors the implementation of the identified actions and revises it accordingly.

To ensure sustainability of the strategy, the diagnosis should be revised every 2-5 years with the same approach. Frequency depends on the results of the initial exercise.

In several high-risk industries, this diagnosis is often performed within a *safety culture assessment*. Assessing safety culture may be conducted independently or by self-assessment. The advantage of an independent assessment is that the organisation gets a more objective picture of the safety culture but it carries the risk that the organisation can be misunderstood or have difficulty in accepting the conclusions. The advantage of a self-assessment is that it is conducted in-house with the organisation's own personnel, who have in-depth knowledge of the organisation. The disadvantage is that status and hierarchies may interfere. Some characteristics of a safety culture assessment are listed below:

- *Includes a 2/3-week assessment process and a preparatory stage;*
- *Involves a multi-disciplinary review team;*
- *Data collection relies on social sciences methods (including interviews, focus groups, observations);*
- *Assessment scope is the whole organisation and its interfaces;*
- *Based on a safety culture model or framework;*
- *Top management is committed and considers the assessment as a learning opportunity;*

¹ Diversity of activities and size of the organisation are simple examples of parameters that go with the complexity of this task.

- ▶ *Results are disseminated throughout the organisation;*
- ▶ *Results are acted upon to design/revise a strategy to continually improve the selected traits to safety culture.*

The improvement of the human and organisational factors strategy and processes is an integrated part of continuous improvement of the SMS.

A systematic approach is defined as a step-by-step process to deal with the issues related to safety culture. For example, to have a process for risk observation, incident and accident reporting and how the information is used as well as lessons learned for continuous improvements.

More information on safety culture and human and organisational factors can be found in Annex 4 and Annex 5 respectively.

7.2.4 Evidence

- ▶ *Information on the process for collating evidence to demonstrate continual improvement of the SMS;(7.2.1)*
- ▶ *Procedures which detail how the organisation takes into account the results from monitoring, internal audit, management review and learning from accidents and incidents to improve the SMS;(7.2.1)*
- ▶ *Information on how the organisation seeks to engage staff and others in improving the SMS;(7.2.2)*
- ▶ *The applicant should in a strategy detail how the safety culture is developed so that the risks associated with the safety culture are properly taken into account within the relevant processes of the SMS. In doing so the applicant should make clear where further detail on relevant procedures can be found;(7.2.3)*
- ▶ *The safety culture is assessed continually to identify improvements;(7.2.3)*
- ▶ *Safety culture improvements are applied using the PDCA cycle to ensure the actions have an impact. Lessons learned are implemented and systematically evaluated for impact.(7.2.3)*

7.2.5 Examples of evidence

The procedure that covers monitoring, internal audit, management review and accident and incident investigation specifically the sections which concentrate on the lessons to be learnt for the safety management system.

The 'Close Call' initiative in Network Rail where staff are encouraged to be active in notifying the organisation on weaknesses/gaps or situations where there is a safety or health risk.

Taking into account human and organisational factors and improving safety culture will have a positive impact on compliance with the relevant SMS requirement and the evidence of this will be found in:

7. Improvement

Examples of the minutes of the periodic trade union/management health and safety meetings, showing where situations deemed uncertain/unsafe or in need of further consideration have been discussed.

The results from accident investigations being reported at management meetings and are regarded as an important tool for learning and improvement, taking into account human and organisational factors in a systemic and systematic way.

A copy of the safety culture improvement strategy and how this links into the different parts of the SMS.

The strategy providing adequate evidence that there is professional competence and, as necessary, training and experience in the field of safety culture amongst the staff assigned to deliver and develop the strategy.

The type of training and competence required relating to understanding the concept of safety culture and the means and ways to measure and work for continuous improvements. The critical aspect is that there is an understanding of safety culture as a holistic concept that influences all parts of the SMS and that safety culture cannot be treated as an element in its own right.

There being a process for continually evaluating safety enhancing measures. The effects of the safety enhancing measures are identified and put into practice so that they can be evaluated.

Minutes of management review show that management recognise that incidents, accidents, and deviations are caused by multiple factors some originating from procedures and management decisions .

The minutes of management review meetings show how corrective action from monitoring activities, internal audits, and incident and accident investigation process takes human and organisational factors into account and are defined at any level of the safety management system and the organisation. They also show how the results are used to improve risk assessment (**see 3.1**).

The procedures that cover monitoring, internal audit, management review and accident and incident investigation being linked with the awareness process (**see 4.3**) and competence management system (**see 4.2**).

7.2.6 Supervision issues

During supervision, management commitment to continual improvement of the SMS should be tested through interviews as well as through an analysis of documentation. Is there a risk-based approach to targeting improvement, i.e. associated with vulnerable and critical controls?

The organisation's use of maturity models to examine the performance of the SMS should be examined where these exist.

ANNEX 1 – Correlation tables

The tables below provide a side by side comparison between the assessment requirements set out in Annex II of former Regulations (EU) 1158/2010 and (EU) 1169/2010, and the requirements set out in Annex I and Annex II of Regulation (EU) 2018/762. It aims at facilitating the transition from the old safety certification regime under Directive 2004/49/EC to the new one introduced by Directive (EU) 2016/798.

Having a correspondence with Regulation (EU) 2018/762 does not provide a proof of the ability of railway undertakings or infrastructure managers to meet the relevant SMS requirements in accordance with Article 9 of Directive (EU) 2016/798. The level of detail between former and new assessment requirements may still differ although they share to some extent common principles. In addition, not all assessment requirements in Annex I and Annex II of Regulation (EU) 2018/762 have a correspondence to the former Regulations. Further demonstration is then required from the railway undertakings and infrastructure managers to comply with the new assessment requirements (or parts of them).

The SMS requirements of Regulation (EU) 2018/762 that do not have any correspondence to those of Regulation (EU) 1158/2010 and/or Regulation (EU) 1169/2010 are to be considered as new requirements and in that respect, additional evidence is to be provided by the applicant to demonstrate compliance with them. In most cases, it is not possible to have a perfect match between the criteria of the former and requirements of the new CSM Regulation. Therefore, in such circumstances, the comparison is based on the intent of the requirements. It may also happen that the requirements have been made more explicit in Regulation (EU) 2018/762 while sharing the same intent. In such a case, the requirements in that Regulation are not to be considered new but can be used by the different parties to help them understand what evidence is to be expected of the applicant.

A correspondence to the ISO High Level Structure (HLS)² is also provided for railway undertakings and infrastructure managers wanting to develop an integrated management system. Likewise, having a management system certified against one or several ISO management system standards (e.g. ISO 9001, ISO 14001 or ISO 45001) does not provide a proof of the ability of railway undertakings or infrastructure managers to meet the relevant SMS requirements in accordance with Article 9 of Directive (EU) 2016/798.

² ISO/IEC Directives, Part 1, consolidated supplement 2016, Annex SL Appendix 2.

Table 1: Side by side comparison – Assessment criteria/requirements common to railway undertakings and infrastructure managers

Regulation (EU) 1158/2010 & 1169/2010 Criterion ID	Regulation (EU) 2018/762 Requirement ID	ISO HLS Clause N°	Commentary
A.1	3.1.1.1	6.1	
A.2	3.1.1.1	6.1	
A.3	6.1.1	9.1	
A.4	3.1.1.1 (e)	N/A	
A.5	4.4 4.5.1.1	7.4	
A.6	6.1.1 5.4.1	9.1 8.1	
B.1	5.2.4	N/A	Maintenance is a phase of the asset life cycle.
B.2	5.2.4	N/A	Maintenance is a phase of the asset life cycle.
B.3	2.3.1 4.2.1	5.3 7.2	Definition and allocation of responsibilities for maintenance is largely found in 2.3.1. Identification of competencies required for maintenance is largely found in 4.2.1.
B.4	6.1.1 5.2.5	9.1 7.4	Data collection (malfunctions, defects) and analysis is part of the monitoring process. Exchange of data between those responsible for the day-to-day operations and those responsible for maintenance is part of the information and communication process applied to asset management.
B.5	6.1.1	N/A	Referred to in Art. 4(2) of CSM on monitoring.
B.6	6.1.1	9.1	Evaluation of the performance and results of maintenance is part of the monitoring process applied to maintenance.
C.1	5.3.2 (a) 5.3.3 (a)	8.1	
C.2	5.3.3 (a)	8.1	
C.3	5.3.2 (b)	N/A	
C.4	5.2.5 (b) 5.3.2 (c)	N/A	
C.5	5.3.2 (c) 5.3.3 (a)	N/A	
D.1	3.1.1.1 (a)	N/A	
D.2	3.1.1.1 (c)	N/A	
D.3	6.1.1	N/A	
E.1	1.1.1 (a) 1.1.1 (b)	4.1	
E.2	4.5.1.1 (a)	4.4	
E.3	4.5.1.1 (c)	7.5.1	

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Regulation (EU) 1158/2010 & 1169/2010 Criterion ID	Regulation (EU) 2018/762 Requirement ID	ISO HLS Clause N°	Commentary
E.4	4.5.1.1 (a) 4.5.1.1 (b)	7.5.1	
F.1	4.5.1.1 (a)	4.4	
F.2	2.3 4.5.1.1 (a)	5.3 4.4	
F.3	2.3.1 2.3.4	N/A	
F.4	4.5.1.1 (a) 4.2.1 2.3.1 2.3.2 2.3.3	4.4 5.3	Definition of safety-related tasks is part of the description of the safety management system, including the allocation of responsibilities. Responsibilities are defined for each relevant role within the safety management system.
G.1	4.5.1.1 (a) 2.3.1	4.4 5.3	Definition of safety-related tasks is part of the description of the safety management system, including the allocation of responsibilities. Responsibilities are defined for each relevant role within the safety management system.
G.2	6.1.1 6.2.1	9.1 9.2	Internal audit aims at checking that the organisation conforms to the applicable requirements.
G.3	2.1.1 (d)(i) 2.3.2	N/A	
G.4	2.3.1	5.3	
G.5	4.1.1	7.1	Note that there is a link here to the Criterion in 1158/2010 N2(d)
H.1	2.4.1	N/A	
H.2	(removed)	N/A	Staff performing safety-related tasks should be involved in developing, maintaining and improving the SMS. It is left to the organisation to implement req. 2.4.1 in such a way that conformance to it is traceable.
I	7.2.1	10.1 10.2	
J	2.2.1	5.2	
K.1	3.2.1 3.2.2 (d)	6.2	
K.2	3.2.2 (a)	6.2	The safety objectives should be consistent with the safety policy which should be appropriate to the type and extent of rail operations.
K.3	3.2.4	6.2	Safety objectives are not limitative to Common Safety Targets established at Member State level.
K.4	6.1.1 5.4	9.1 8.1	
K.5	3.2.4 (adapted)	9.1	Reference to monitoring strategy and plan(s) in accordance with CSM on monitoring.
L.1	6.1.1 5.4	9.1 8.1	

Regulation (EU) 1158/2010 & 1169/2010 Criterion ID	Regulation (EU) 2018/762 Requirement ID	ISO HLS Clause N°	Commentary
L.2	4.2 4.4 4.5 5.2.2 (a)	N/A	Use of competent staff, procedures, specific documents and rolling stock is respectively managed in competence, information and communication and documented information and asset management.
L.3	1.1.1 (e) 6.1.1 6.1.2	4.3 9.2	Compliance with applicable requirements is rooted in 3.1.2.2 at large (not specific to maintenance). Monitoring ensures the correct application of the procedures. Internal auditing ensures the conformance of the procedures to the applicable requirements.
M.1	3.1.2.1 5.4.1	6.1 8.1	In accordance with ISO, there is first a planning of the change, including the risk identification and assessment, and then, the implementation of the change.
M.2	3.1.2.1	N/A	
M.3	5.4.1	8.1	
N.1	4.2.1 4.2.3	7.2	
N.2	4.5.1.1 (a) 2.3.1 2.3.2 2.3.4 6.1.1	N/A	
O.1	4.4.1 4.4.2 4.4.3	7.4	
O.2	4.4.3	7.4	
O.3	4.4.1	N/A	
P.1	4.4.3	N/A	
P.2	4.5.2 4.5.3	7.5.2 7.5.3	
P.3	4.5.3	7.5.3	
Q.1	7.1.1	10.1	
Q.2	7.1.2	N/A	
Q.3	7.1.3	10.2	
R.1	5.5.1	N/A	
R.2	5.5.2	N/A	
R.3	5.5.3	N/A	
R.4	5.5.4	N/A	
R.5	5.5.5	N/A	
R.6	5.5.1	N/A	
R.7	5.5.6	N/A	
S.1	6.2.1	9.2	

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Regulation (EU) 1158/2010 & 1169/2010 Criterion ID	Regulation (EU) 2018/762 Requirement ID	ISO HLS Clause N°	Commentary
S.2	6.2.1 (a)	9.2	
S.3	6.2.1 (b)	9.2	
S.4	6.2.1 (c) to (f)	9.2	
S.5	6.2.1 (g) 6.3.1	9.3	
S.6	6.2.1	9.2	

The table below provides a side by side comparison between the former assessment criteria and the new SMS requirements only applying to railway undertakings.

Table 2: Side by side comparison – Assessment criteria/requirements specific to railway undertakings

Regulation (EU) 1158/2010 Criterion ID	Regulation (EU) 2018/762 Annex I Requirement ID	ISO HLS Clause N°	Commentary
R.8	5.5.7	N/A	
R.9	5.5.8	N/A	

The table below provides a side by side comparison between the former assessment criteria and the new SMS requirements only applying to infrastructure managers.

Table 3: Side by side comparison – Assessment criteria/requirements specific to infrastructure managers

Regulation (EU) 1169/2010 Criterion ID	Regulation (EU) 2018/762 Annex II Requirement ID	ISO HLS Clause N°	Commentary
R.8	5.5.7	N/A	
R.9	5.5.8	N/A	
T.1	5.2.1	N/A	The safe design and installation of the infrastructure are part of the asset life cycle.
T.2	3.1.2 5.4.1	N/A	Identification of technical change of the infrastructure is largely found in 3.1.2. Management of technical change of the infrastructure is largely found in 5.4.1.
T.3	3.1.2	N/A	Compliance with applicable rules covering the design of the infrastructure is largely found in 3.1.2.
U.1	5.1.1 5.1.3	N/A	Management of safety of the infrastructure is largely found in 5.1.1.
U.2	5.1.1	N/A	Management of safety at the physical and/or operational borders of the infrastructure is largely found in 5.1.1.
U.3	5.1.3 (c) 5.5.7	N/A	Management of normal and degraded operations is largely found in 5.1.3 (c).

Regulation (EU) 1169/2010 Criterion ID	Regulation (EU) 2018/762 Annex II Requirement ID	ISO HLS Clause N°	Commentary
U.4	5.1.2 5.2.3	N/A	
V.1	5.2.4 6.1.1	N/A	Maintenance of the infrastructure is largely found in 5.2.4. Audits and inspections (when relevant) are part of the monitoring activities.
V.2	5.2.4	N/A	Maintenance of the infrastructure is largely found in 5.2.4.
V.3	5.2.3	N/A	
W.1	5.1.3	N/A	
W.2	5.1.1	N/A	Management of safety at the physical and/or operational borders of the traffic control and signalling system is largely found in 5.1.1.
W.3	5.1.2 5.2.3	N/A	

The table below provides a side by side comparison between the ISO HLS and the new SMS requirements.

Table 4: Side by side comparison – ISO High Level Structure

ISO HLS Clause N°	Regulation (EU) 2018/762 Requirement ID	Commentary
4.1	1.1.1 (a) 1.1.1 (b)	
4.2	1.1.1 (c) 1.1.1 (d)	
4.3	1.1.1 (e) 1.1.1 (f)	
4.4	4.5.1.1 (a)	
5.1	2.1	
5.2	2.2	
5.3	2.3	
6.1	3.1.1 3.1.2	The CSM for risk evaluation and assessment is applied to determine whether a change is safety-related (or not) and then, whether it is significant (or not). The 'virtual' separation made by ISO between the strategic level (ISO HLS Clause 6) and the tactical level (ISO HLS Clause 8) of the planning is re-evaluated considering the EU regulatory framework and in particular, the application of the above CSM (regardless the nature of the changes).
6.2	3.2.1 3.2.2 (a) 3.2.2 (d) 3.2.4	

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ISO HLS Clause N°	Regulation (EU) 2018/762 Requirement ID	Commentary
7.1	4.1	
7.2	4.2	
7.3	4.3	
7.4	4.4	
7.5.1	4.5.1	
7.5.2	4.5.2	
7.5.3	4.5.3	
8.1	5.1 5.2 5.3 5.4 5.5	In accordance with ISO guidance document (N360), the intent of clause 8 of ISO HLS is to specify the requirements that need to be implemented within the organisation's operations to make sure the management system requirements are fulfilled, and the priority risks and opportunities are being addressed. In addition, it is stated that additional requirements (discipline specific) related to operational planning and control can be prescribed. In that sense, the requirements at 5.X are coherent with the ISO approach. In particular, they are not intrusive to the company's business but provide a sufficient framework to control how key safety issues will be managed within the company's business processes.
9.1	6.1	The concept of "monitoring" refers to the monitoring framework defined in the CSM on monitoring and has therefore a broader meaning than the concept of monitoring, measurement, analysis and evaluation defined in clause 9.1 of ISO HLS.
9.2	6.2	Internal audits are monitoring tools in the meaning of the CSM on monitoring. Although it is a separate requirement, it is meant to achieve the objectives of the monitoring in accordance with the CSM on monitoring.
9.3	6.3	
10.1	7.1	
10.2	7.2	

ANNEX 2 –

Cross-acceptance of authorisations, recognitions or certificates of products or services granted in accordance with Union law

The issuing authority for the single safety certificate or safety authorisation can consider certificates granted by other bodies, such as ISO conformity assessment bodies, to avoid any duplication of assessment and additional costs being borne by the applicant. The final decision always lies with the issuing authority.

However, in accordance with Article 3(12) of [Regulation \(EU\) 2018/763](#), for the purposes of the assessment of applications for single safety certificates, the issuing authority shall accept the authorisations, recognitions or certificates of products or services provided by railway undertakings, or their contractors, partners or suppliers, granted in accordance with relevant Union law, as proof of the ability of railway undertakings to fulfil the corresponding safety management system requirements for the type of product or service concerned. Although there is no equivalent provision in EU law for the assessment of applications for safety authorisations, the national safety authorities are also encouraged to apply the same principle.

The following table identifies the different cases existing so far in the EU regulatory framework and provides illustrative examples of types of products or services that may be covered by each case.

Table 5: Authorisations, recognitions or certificates of products or services granted in accordance with Union law

Case	Type of products or services	Applicable Union law	Regulation (EU) 2018/762 Requirement ID	Commentary
ECM certificate	Maintenance of vehicles	Article 14(4) of Directive (EU) 2016/798 Regulation (EU) 2019/779	5.2 5.3	In the cases provided for in Article 14(4) of Directive (EU) 2016/798, the certification of entities in charge of maintenance provides sufficient evidence that railway undertakings and infrastructure managers are capable, through their safety management system, to control the risks related to the maintenance of vehicles, including the use of contractors.

GUIDANCE FOR SAFETY CERTIFICATION AND SUPERVISION

Safety management system requirements for safety certification or safety authorisation

Case	Type of products or services	Applicable Union law	Regulation (EU) 2018/762 Requirement ID	Commentary
Recognition	Training of train drivers	Directive 2007/59/EC Decision 2011/765/EU	4.2.2	<p>Training centres should be recognised by the competent authority for providing training courses for train drivers and train candidate drivers in accordance with Directive 2007/59/EC.</p> <p>Training centres play an important role to ensure that train drivers are competent for the safety-related tasks assigned to them. In that respect, training centres should be competent in regard to the training they carry out and their recognition by a competent authority should where relevant be taken into account by the safety certification body and the national safety authority when carrying out an assessment of the competence management system.</p>
Train driver licence and certificate	Competence and fitness of train drivers	Directive 2007/59/EC	4.2.1	Licences and certificates issued in accordance with Directive 2007/59/EC provide sufficient evidence of fitness and competence of train drivers. This does not preclude the organisation to demonstrate that their arrangements for competence and fitness are adequate.
Single Safety certificate	Maintenance and inspection of infrastructure Shunting Testing of rolling stock	Article 10 of Directive (EU) 2016/798	5.3	<p>Infrastructure managers may subcontract the maintenance or inspection of their infrastructure to companies operating special vehicles on the track.</p> <p>Likewise, shunting or testing operators may be requested to hold a safety certificate.</p> <p>In the above cases, the single safety certificate provides sufficient evidence that railway undertakings and infrastructure managers are capable, through their safety management system, to control the risks related to the use of contractors and suppliers.</p>
Authorisation for placing on the market / vehicle type authorisation	Vehicle (type) authorisation	Directive (EU) 2016/797	5.2	The vehicle (type) authorisation ensures, through its design, manufacture, verification and validation, conformity with the essential requirements of all applicable legislation (including safety) so that it may be used safely on the railway networks for which it is intended to be used according to the limits and conditions of use specified within the technical file for the vehicle/vehicle type.

In specific cases, the holding of a certificate (or equivalent) granted in accordance with Union Law may not be sufficient to control all the safety risks pertaining to the products delivered to, or the services used by railway undertakings and infrastructure managers.

For example, railway undertakings, in partnership, remain fully responsible to operate safely and therefore to control the risks related to their activities including the supply of maintenance to vehicles. The use by one railway undertaking of the single safety certificate of its partner as a means of controlling the risks associated with the supply of maintenance is not sufficient if it is not supported by strong effective contractual arrangements between the partners. Those contractual arrangements have to be commonly developed and monitored in the application of the SMS procedures of each partner and are also part of each SMS, therefore subject to supervision by respective NSAs.

Therefore, the single safety certificate may be used as a means for controlling the risks associated with the supply of maintenance and as a means of compliance for fulfilling the requirements related to the control of risks associated with the maintenance of vehicles when the three following conditions are met:

1. *There must be contractual arrangements in force between partner railway undertakings that include aspects related to maintenance of vehicles such as:*
 - (a) *Exchange of information as described in Article 5 of [Regulation \(EU\) 2019/779](#);*
 - (b) *Technical support when appropriate in particular for control-command legacy systems;*
 - (c) *Control of the capability of contracted maintenance workshops to deliver maintenance;*
 - (d) *Effective monitoring of vehicles and the exchange of information resulting from this monitoring.*
2. *Those contractual arrangements are developed as result of risk assessment and must be regularly monitored by each railway undertaking against the CSM on monitoring ([Regulation \(EU\) 1078/2012](#)). The outcome of this monitoring is then formally exchanged between both partner railway undertakings.*
3. *The SMS of both partners contains adequate processes and procedures to achieve the conditions 1 and 2 above.*

In other cases, national law may require for a specific type of product or service the holding of a national certificate (or equivalent) to be issued by a competent body (e.g. the national safety authority), which could also be used as proof of the ability of the railway undertakings or infrastructure managers to fulfil the relevant requirements of [Regulation \(EU\) 2018/762](#). For example, national certificates granted to ECMs and/or maintenance workshops of vehicles other than freight wagons may also provide reasonable assurance, similar to the ECM certificate, that the vehicles for which they are in charge of maintenance are in a safe state of running.

ANNEX 3 –

Siding operations, contractual arrangements and partnerships

Siding operations

In this document, 'siding' means railway infrastructure connected to a railway network which is under the responsibility of an infrastructure manager (i.e. the infrastructure part of the rail system falling under the scope of [Directive \(EU\) 2016/798](#)). Sidings may or may not be part of this rail network depending on the transposition of the above Directive in each Member State.

Activities performed in sidings such as the loading of wagons are industrial activities which then interface with specific railway activities such as the composition, preparation and movement of rakes of vehicles that can be trains or will be used in trains. This includes the coupling of different vehicles to form rakes of vehicles or trains and moving them.

Those sidings may be (but are not limited to):

- ▶ *Infrastructure used to park railway vehicles between operations.*
- ▶ *Intermodal terminals;*
- ▶ *Infrastructure used for services on passenger vehicles such as cleaning or light maintenance;*
- ▶ *Infrastructure belonging to and managed by a maintenance workshop for railway vehicles;*
- ▶ *Industrial areas or plants where the industrial activities of loading/unloading of freight wagons are performed.*

The activities performed in sidings are performed by a 'siding operator'. A siding operator may be a railway undertaking, an infrastructure manager, a service provider (e.g. cleaning of passenger vehicles), an industrial organisation (e.g. a chemical plant loading/unloading tank wagons) or even a subcontractor of this industrial organisation. In the former case, the organisation has taken the business decision to become a railway undertaking or is a railway undertaking that plans to manage sidings in addition to its current railway activities. In the latter case, the infrastructure manager is the infrastructure manager for the sidings or is acting as a railway undertaking under its safety authorisation.

The 'siding operator' controls the risks associated with occupational health and safety through its health and safety management system in place according to international and national legislation. When the 'siding operator' is not a railway undertaking, this management system takes into account the health and safety obligations related to external workers in particular those of railway undertakings, for instance when train drivers enter the siding. In parallel, the railway undertaking controls the risks associated with occupational health and safety through its health and safety management system according to international and national legislation.

Case 1: The siding operator is a railway undertaking “Y”

This railway undertaking controls, through its SMS, the risks associated with its railway operations in its siding infrastructure and on the railway network under the responsibility of an infrastructure manager. This control of risks includes risks associated with damage to vehicles caused by all activities performed in the siding including also composition, preparation and the running of trains.

In practice it is sometimes difficult to determine the responsible railway undertaking. For example, a train of a railway undertaking “X” arrives at a siding (driver and locomotive are hired) and a railway undertaking “Y”, which operates the siding, takes it over as a new train (driver and locomotive are hired) and in the meantime, siding operations need to be carried out. In such a case, the above safety principle applies. There are shared interface risks that must be considered in the railway undertaking “Y”’s SMS (e.g. damage to vehicles caused by siding operations such as loading). In addition, the transfer of information about the vehicles from the railway undertaking “X” to the railway undertaking “Y” must also be considered. This includes the assurance that the vehicle is in a safe state of running when the railway undertaking “X” transfers it to the siding operator and similarly, when it is transferred onwards via the railway undertaking “Y”. The railway undertaking “Y” responsible for the siding operations remains fully accountable for the control of risks inherent in the maintenance activities carried out thereon.

Case 2: The siding operator is not a railway undertaking

Four subcases can be considered:

- ▶ **Subcase 2.1** when the siding operator is the infrastructure manager.
- ▶ **Subcases 2.2 and 2.3** when the siding operator, not being an infrastructure manager, performs activities only on its own infrastructure but not on the rail network under the responsibility of the infrastructure manager.
- ▶ **Subcase 2.4** includes railway operations performed by a siding operator, not being an infrastructure manager, on the rail network under the responsibility of the infrastructure manager.

Subcase 2.1: When activities in the sidings are shared between railway undertaking(s) and an infrastructure manager (or any organisation acting on its behalf), each railway undertaking must be informed of all safety events that have taken place during the activities of the infrastructure manager through contractual arrangements. That includes damage, accidents and incidents involving vehicles.

Those contractual arrangements are managed respectively by the SMS of each railway undertaking and the SMS of the infrastructure manager.

Through its SMS, the railway undertaking controls the risks associated with its own operations in relation to the information received.

Subcase 2.2: Train composition and preparation is made by the railway undertaking (coupling, preparation) on the siding infrastructure. The railway undertaking must be informed of all

(safety) events that have taken place during the activities of the siding operator (e.g. loading or cleaning) through contractual arrangements. This includes damage, accidents and incidents involving vehicles.

Those contractual arrangements are managed by the SMS of the railway undertaking.

Through its SMS, the railway undertaking controls the risks associated with its own following operations in relation to the information received.

Subcase 2.3: Train composition is fully/partially performed by the siding operator or by an organisation working on behalf of the siding operator.

After a train is composed, it is transferred to one railway undertaking.

Likewise subcase 2.2, the railway undertaking must be informed of all events that have taken place during the activities of the siding operator (e.g. loading or cleaning) and during train composition through contractual arrangements. Events include damage, accidents and incidents involving vehicles.

Those contractual arrangements are managed by the SMS of the railway undertaking.

Through its SMS, the railway undertaking controls the risks associated with its own operations in relation to the information received.

Subcase 2.4: This subcase supplements subcase 2.3. Therefore hereafter only the additional duty of the railway undertaking is introduced.

The siding operator runs trains or moves rakes of vehicles from its rail infrastructure onto the railway network under the responsibility of an infrastructure manager.

For example:

- ▶ *Moves the train or rakes of vehicles from a service yard to the platforms of a passenger station or to a parking yard attached to a passenger station;*
- ▶ *Moves the train or rakes of vehicles from an industrial plant to an interchange point (exchange siding) attached to a freight station.*

The siding operator is neither a railway undertaking nor an infrastructure manager but those operations performed on the network of an infrastructure manager must be covered by a single safety certificate or a safety authorisation.

The railway operations made by the siding operator on the rail network under the responsibility of an infrastructure manager are covered either by the single safety certificate of a railway undertaking or by the safety authorisation of an infrastructure manager. This means that the railway undertaking or the infrastructure manager must control the risks associated with the operations performed by the siding operator through the arrangements for the management of subcontractors in their SMS.

In all cases, the railway undertakings and the infrastructure manager must accurately describe the scope of all their railway operations and of their activities which interface with other railway operations to make the supervision of the SMS by NSAs effective. The capability of railway undertakings and infrastructure managers to describe clearly and completely their operations as well as other activities interfacing with railway operations is essential for ensuring the effectiveness of the SMS and the effectiveness of the NSA supervision.

The contractual arrangements in all the above subcases must include clearly (but are not limited to):

- ▶ *What has to be done by each contracting party;*
- ▶ *The expected quality of the outputs/services;*
- ▶ *Assignment of roles and responsibilities;*
- ▶ *What, when and how information will be exchanged between the contracting parties. Information includes reporting on events as described in all subcases above and the particularly characteristics of the infrastructure of the siding such as speed limits, weight limits or gradient conditions;*
- ▶ *Competence requirements;*
- ▶ *Health and safety requirements (deriving from risk assessment, national requirements, etc.).*

Contractual arrangements and partnerships

The railway undertaking is responsible for ensuring the safe running of the train by coordinating and managing train operations. Contractual agreements (usually consisting of framework agreements, special agreements and annexes) constitute the basis for effective cooperation between different railway undertakings, be it new entrants or incumbents, and must comply with the provisions of European and national legislation and any other applicable requirements.

Therefore, the railway undertaking has to control the risks of its operations, including cooperation with partners and the use of (sub) contractors. The NSA then supervises that the railway undertaking fulfils its legal obligations in a transparent and diligent manner.

Railway undertakings cannot outsource their safety responsibility for coordinating and managing the safe running of trains. This is however not detrimental to the existence of cooperation regimes between railway undertakings. The basic principles above also apply to cooperation between railway undertakings. The railway undertaking responsible for ensuring the safe running of trains must be clearly identified in all agreements between involved parties and must hold a single safety certificate. Either this railway undertaking directly manages the resources (personnel, vehicles) through its SMS or it may decide to subcontract (partly or wholly) the use of the resources (e.g. leasing of vehicles, hiring of train drivers) to another party. In the latter case, the railway undertaking still has the responsibility for controlling the risks relating to the use of (sub)contractors by monitoring through its SMS the contract performance in accordance with [Regulation \(EU\) 1078/2012](#) and therefore, has to check that these resources comply with the legal and other applicable safety requirements (e.g. vehicles

in a safe state of running, route compatibility, staff training, train drivers with a valid licence and certificate for a specific route).

A single safety certificate delivered by a safety certification body (and supervised accordingly by an NSA) to the contracting party (i.e. the partner or subcontractor) can provide sufficient assurance to the railway undertaking responsible for the safe operation that the SMS arrangements meet the relevant requirements. The contractual arrangements include the transfer of information relevant to safety (e.g. previous rest time of the train drivers) between the contracting parties.

The principles underpinning cooperation between railway undertakings remain the same irrespective of cooperation regimes, i.e. partnership or subcontracting (partly or wholly) railway activities in domestic or cross-border operations. However, the nature and extent of measures to be implemented by railway undertakings and the extent to which the NSA has to supervise these cooperation arrangements are proportionate to the degree of cooperation between railway undertakings.

For example, cross-border cooperation between railway undertakings (i.e. use of external vehicles and/or staff) is likely to require more controls than any other cooperation regimes because the operation is handed over to another railway undertaking with different languages and operating rules for rolling stock that may differ from one Member State to another. In contrast, hiring external train drivers or vehicles only would obviously require less monitoring and consequently, less supervision activities by the NSA.

ANNEX 4 – Safety culture

Introduction to safety culture and a safety culture improvement strategy

Culture arises from the interactions of people in their everyday lives and helps define the behavioural expectations and norms of society. Culture is a complex concept involving numerous factors, which develops over time depending on the circumstances, environment and experiences of a nation, state, society and/or organisation.

Safety culture refers to the elements of the culture that specifically address safety. Whereas it is possible to give a description of some of the contributors to a safety culture, it is impossible to collect all the information that encapsulates a safety culture. There is no single scientific objective measurement of safety culture. This is because the contributing factors vary, not just between organisations but also within them. Different departments have different safety requirements and needs, for example operational and financial, and the prevailing safety culture will develop from these. External factors such as regulatory requirements, levels of education, societal structures as well as the national culture will also contribute to shape an organisation's safety culture.

Safety culture is an established concept. It, however, lacks an agreed definition. In this context, the Agency, together with representatives of the sector, has developed the following understanding applicable to any railway organisation: *'Safety culture refers to the interaction between the requirements of the safety management system, how people make sense of them, based on their attitudes, values and beliefs and what they actually do, as seen in decisions and behaviours'*.

That said, a simple way to describe safety culture is to look at the factors that contribute to behaviour. The SMS provides the foundation by defining and prescribing through policies and procedures what is required. In a utopia, the SMS would be perfect and all management and personnel will comply. Unfortunately, a utopia is a utopia, and what happens is that management and personnel try to make sense of the content of the SMS based on their values, attitudes and beliefs derived from personal experience combined with the behavioural norms of the work place and society. If the SMS makes sense and there is a culture of compliance the correct behaviours will follow. If not individual interpretations will be made and alternative solutions will be applied. These will be based on an individual risk assessment weighing up factors that impact on the decisions made. The risk assessment will not only focus on the actual risk but also include factors related to convenience, the risk of getting caught, management's words and actions etc. The interdependence between the SMS, sense making and behaviour therefore defines the safety culture.

Assessing safety culture requires an insight into the three factors and their interdependence. As stated earlier there is no single scientific objective measurement of safety culture. Instead characteristics that impact on the development of safety culture can be analysed in the light of the three factors.

For example, a policy statement such as ‘Safety first’ can be followed up by investigating what it means to the employees – do they actually believe in it, does management ‘walk the walk’, how are decisions made and on what grounds, how does the organisation react when under pressure etc. Similar investigations can be made about other factors such as continuous learning and a questioning attitude. Combining the results of the analysis will provide a picture of the present state of the culture. Over time a more comprehensive picture can be built allowing for stronger conclusions.

The European railway safety culture model (see [Figure 4](#)) was developed as a conceptual and evaluation framework that may be used to better understand the concept of safety culture, and to assess and improve the safety culture of any railway organisation.

Figure 4: the European Railway Safety Culture Model

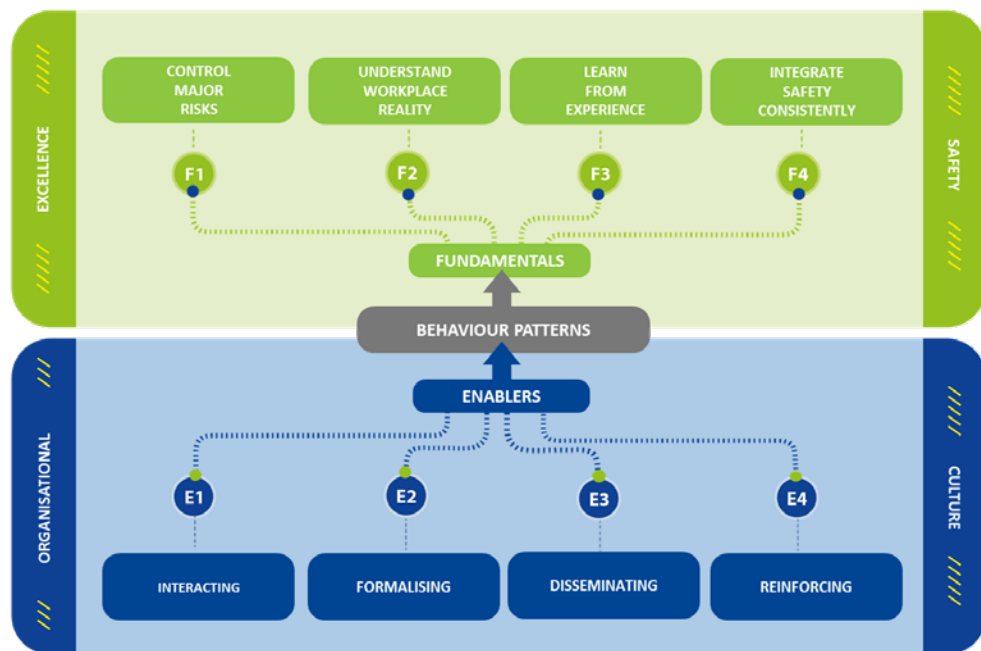
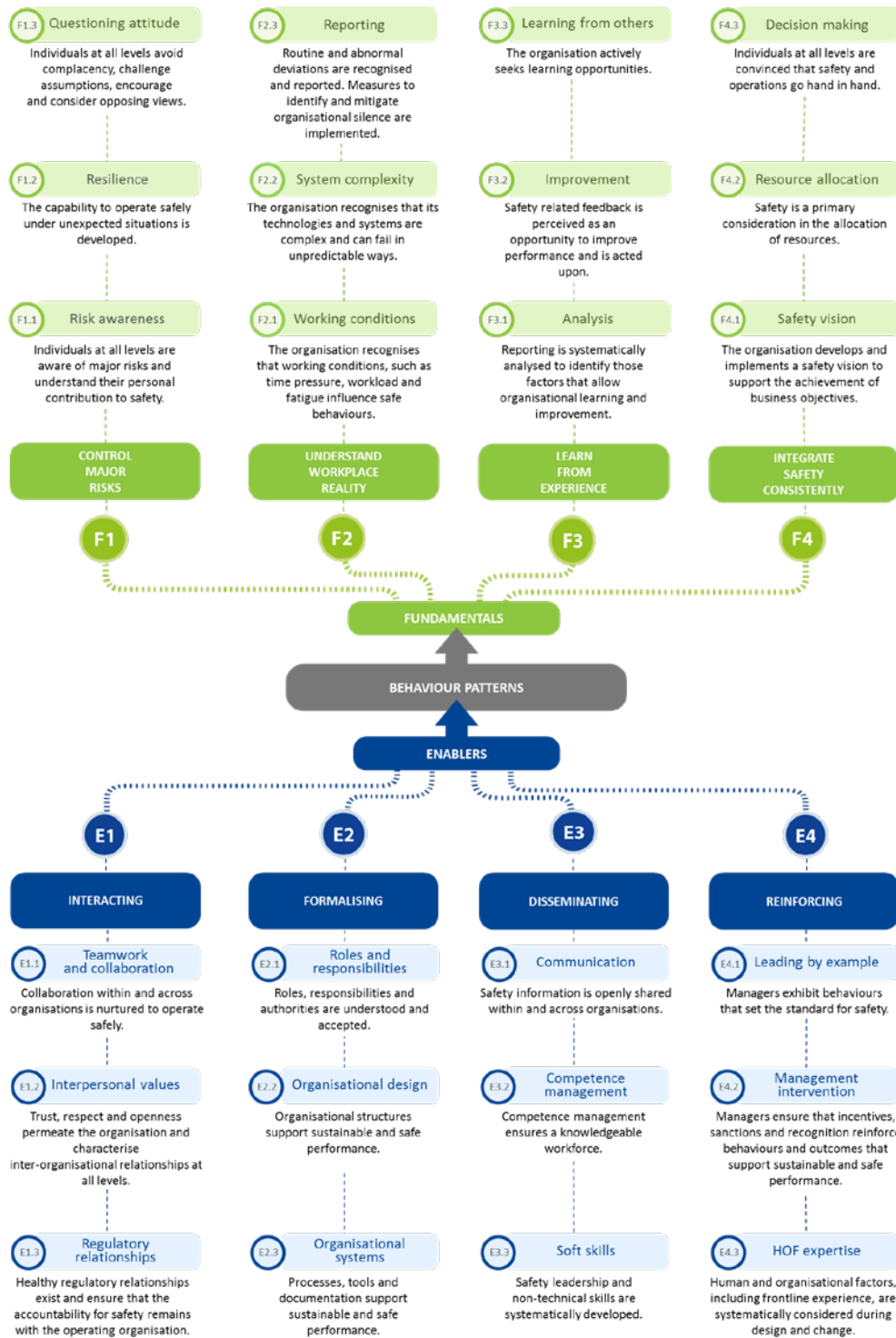


Figure 5: Attributes of the European Railway Safety Culture Model



Side by side comparisons between the SMS requirements and the European Railway Safety Culture Model

The tables below provide a side by side comparison between the European Safety Culture Model Fundamentals and Enablers, and the SMS requirements set out in [Regulation \(EU\) 2018/762](#).

Careful use of the tables, along with the [guidance on the European Safety Culture Model](#), should allow the organisation to see which of the SMS requirements have strong links with the attributes of the European Safety Culture Model and therefore allow them to devise processes and procedures which better take into account the desired organisational behaviours.

Table 6: Side by side comparison – SMS Requirements/European Railway Safety Culture Model

SMS Requirement	Link to the European Railway Safety Culture Model attributes
1. Context of the organisation	F1.1, F2.2, F3.3 F4.1 E1.1, E2.1, E2.2, E3.1, E4.3
2.1 Leadership and Commitment	F1.1, F2.1, F2.2, F4.1 E1.1, E2.1, E3.1
2.2 Safety policy	F1.1, F2.1, F2.2, F4.1 E1.1, E3.1
2.3 Organisational roles, responsibilities, accountabilities and authorities	F1.1, F2.1, F2.2, F2.3, F3.1, F 3.2, F4.1, F4.2 E1.1, E2.1, E2.2, E3.1, E3.2, E4.3
2.4 Consultation of staff and other parties	F1.1, F2.1, F2.2, F2.3, F3.1, F3.2, F4.1, F4.2, E1.1, E2.2, E2.3, E3.1, E4.3
3.1 Actions to address risk	F1.1, F2.1, F2.2, F2.3, F3.1, F3.2 F3.3, F4.1, F4.3 E1.1, E2.1, E2.2, E2.3, E3.1, E3.2, E4.3
3.2 Safety objectives and planning	F1.1, F2.1, F2.2, F2.3, F3.1, F 3.2, F4.1, F4.2 E1.1, E2.2, E2.3, E3.1, E4.3
4.1 Resources	F1.1, F2.1, F2.2, F4.1, F4.2, E1.1, E1.2, E2.1, E2.2, E2.3, E3.1, E3.2, E3.3, E4.3
4.2 Competence	F1.1, F1.2, F1.3, F2.1, F2.2, F2.3, F3.1, F3.2, F4.1, F4.2, F4.3 E1.1, E2.1, E2.2, E2.3, E3.1, E3.2, E3.3, E4.1, E4.2, E4.3
4.3 Awareness	F1.1, F1.2, F2.2, F2.3, F3.1, F3.2, F4.1, F4.3 E1.1, E1.2, E2.1, E3.1, E3.2, E3.3, E4.1, E4.2
4.4 Information and communication	F1.1, F1.2, F2.2, F2.3, F3.1, F3.2, F4.1, F4.3 E2.1, E3.1, E3.2, E3.3, E4.2
4.5 Documented information	F1.1, F1.2, F2.2, F2.3, F3.1, F3.2, F4.1, F4.3 E2.1, E2.2, E2.3, E3.1, E3.2, E3.3, E4.2
4.6 Integration of human and organisational factors	F1.1, F1.2, F2.2, F2.3, F3.1, F3.2, F4.1, F4.3 E2.1, E2.2, E2.3, E3.1, E3.2, E3.3, E4.3
5.1 Operational planning and control	F1.1, F2.1, F2.2, F3.1, F3.2, F4.1, F4.2 E2.1, E2.3, E3.1, E3.2, E3.3, E4.3
5.2 Asset management	F2.1, F2.2, F4.1, F4.2, F4.3, E1.1, E2.3, E3.1, E3.2, E4.3

SMS Requirement	Link to the European Railway Safety Culture Model attributes
5.3 Contractors, partners and suppliers	F1.1, F2.1, F2.2, F4.1, F4.2, F4.3 E1.1, E2.3, E3.1, E3.2, E4.3
5.4 Management of change	F1.1, F2.1, F2.2, F4.1, F4.2, F4.3 E1.1, E2.3, E3.1, E3.2, E4.3
5.5 Emergency management	F1.1, F1.2, F1.3, F2.1, F2.2, F3.1, F3.2, F3.3, F4.1, F4.2, F4.3 E1.1, E2.3, E3.1, E3.2, E3.3, E4.1, E4.2, E4.3
6.1. Monitoring	F1.1, F1.2, F1.3, F2.1, F2.2, F3.1, F3.2, F4.1, F4.2, F4.3 E1.1, E1.2, E2.1, E2.3, E3.1, E3.2, E3.3, E4.1, E4.2, E4.3
6.2 Internal auditing	F1.1, F1.2, F1.3, F2.1, F2.2, F3.1, F3.2, F4.1, F4.2, F4.3 E1.1, E2.1, E2.3, E3.1, E3.2, E3.3, E4.1, E4.2, E4.3
6.3. Management review	F1.1, F1.2, F1.3, F2.1, F2.2, F3.1, F3.2, F4.1, F4.2, F4.3 E1.1, E2.1, E2.3, E3.1, E3.2, E3.3, E4.1, E4.2, E4.3
7.1. Learning from accidents and incidents	F1.1, F1.3, F2.1, F2.2, F2.3, F3.1, F3.2, F4.1, F4.3 E1.3, E2.1, E2.3, E3.1, E3.2, E3.3, E4.2, E4.3
7.2. Continual improvement	F1.1, F1.3, F2.1, F2.2, F2.3, F3.1, F3.2, F4.1, F4.3 E2.1, E2.3, E3.1, E3.2, E3.3, E4.2, E4.3

Table 7: Side by side comparison – European Railway Safety Culture Model/SMS Requirements

European Railway Safety Culture Model attribute	Link to SMS Requirement
F 1.1 Risk awareness	1, 2.1, 2.2, 2.3, 2.4, 3.1, 3.2, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2
F1.2 Resilience	4.1, 4.2, 4.3, 4.5, 4.6, 5.5, 6.1, 6.2, 6.3
F1.3 Questioning attitude	5.5, 6.1, 6.2, 6.3, 7.1, 7.2
F2.1 Working conditions	2.1, 2.2, 2.3, 2.4, 3.1, 3.2, 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2
F2.2 System complexity	1, 2.1, 2.2, 2.3, 2.4, 3.1, 3.2, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2
F2.3 Reporting	2.3, 2.4, 3.2, 4.2, 4.3, 4.4, 4.5, 4.6, 7.1, 7.2
F3.1 Analysis	2.3, 2.4, 3.2, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2
F3.2 Improvement	2.3, 2.4, 3.2, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2
F3.3 Learning from others	3.1, 5.5
F4.1 Safety vision	1, 2.1, 2.2, 2.3, 2.4, 3.1, 3.2, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2
F4.2 Resource allocation	2.3, 2.4, 3.2, 4.1, 4.2, 5.1, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3
F4.3 Decision-making	3.1, 3.2, 4.2, 4.3, 4.4, 4.5, 4.6, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2, 7.3
E1.1 Teamwork and collaboration	1, 2.1, 2.2, 2.3, 2.4, 3.1, 3.2, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2
E1.2 Interpersonal value	4.1, 4.3, 6.1
E1.3 Regulatory relationship	7.1
E2.1 Roles and responsibilities	1, 2.1, 2.3, 3.1, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 6.1, 6.2, 6.3, 7.1, 7.2
E2.2 Organisational design	1, 2.1, 2.3, 2.4, 2.4, 3.1, 3.2, 4.1, 4.2, 4.4, 4.5

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E2.3 Organisational systems	2.4, 3.1, 3.2, 4.1, 4.2, 4.5, 4.6, 5.1, 5.2, 5.3, 5.4, 5.56.1, 6.2, 6.3, 7.1, 7.2
E3.1 Communication	2.1, 2.2, 2.3, 2.4, 3.1, 3.2, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2
E3.2 Competence management	3.1, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2
E3.3 Soft skills	4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 6.1, 6.2, 6.3, 7.1, 7.2
E4.1 Leading by example	4.2, 4.3, 5.5, 6.1, 6.2, 6.3
E4.2 Management intervention	4.2, 4.3, 4.4, 4.5, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2
E4.3 HOF expertise	1, 2.3, 2.4, 3.1, 3.2, 4.1, 4.2, 4.6, 5.1, 5.2, 5.3, 5.4, 5.5, 6.1, 6.2, 6.3, 7.1, 7.2

Further information on safety culture can be found on the [ERA website](#).

ANNEX 5 –

Human and organisational factors

Introduction to human and organisational factors

Human and organisational factors (HOF) is a multidisciplinary field focusing on how to increase safety, enhance performance as well as increase user satisfaction. HOF is a user-centred approach, that is, the design is based upon an explicit understanding of users, tasks and environments. The starting point is always the user's capabilities and limitations and how these are influenced and interact with the systems encountered during task performance. The goal is to identify how best to perform the task in a safe and efficient way. Emphasis is on usability. 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.

When for example designing new vehicles, it is insufficient just to apply the design standards. The train drivers, conductors and maintenance personnel should be involved to add their experiences and understanding of how to perform the tasks safely and efficiently. This can, for example, be related to specific station or line issues, accessibility and access for maintenance workers, task priorities in the cab, communication requirements or passenger behaviour at stations.

Including the knowledge and experience of different operators is best achieved through an iterative process where the user evaluates the design and development of the train on a continual basis as design and development progresses. This helps prevent a common error in the design process, that is, to focus on the human's interaction with individual systems instead of task performance in general. For example, different suppliers have different ideas of how alarms should be prioritised and without a holistic perspective the user frequently ends up being overloaded with information of limited relevance for task performance. Just because the technical design provides the opportunity to display the information but the user may have no need for it. HOF analysis helps distinguish between the need to know and the nice to have.

HOF involves taking a systemic perspective, that is, not just looking at the human, technological and organisational factors in their own right but also emphasising the interactions between the different factors. For example, if a train driver has been involved in an incident such as a signal passed at danger, the suggested factors to investigate (not a comprehensive list) relate to fatigue, cognitive overload, competence, etc. (Human), the technology's influence on performance, such as human-system interfaces, layout, signal placing (Technology), the organisation's influence on performance, such as training, SMS, organisational priorities (Organisation) as well as the interaction between the three areas such as the influence of procurement on design or management of change with the introduction of new design.

Methods are drawn from many different fields, for example experimental psychology, industrial engineering, organisational psychology, sociology, management science, cognitive engineering, ergonomics, computer science and safety engineering.

Since the emphasis of HOF is on the user, a task analysis is a commonly applied method. A task analysis provides the designer with an understanding of the tasks to be performed and how these relate to systems the user interacts with and the organisational conditions that impact on performance. Based on the task analysis, further analysis such as human-system interaction, workload, human reliability/risk, anthropometry and biometric analysis can be performed. The key is to ensure that the user has the best achievable work situation for safe and efficient performance.

Further information on human and organisational factors can be found on the [ERA website](#).

Strategy to support the integration of human and organisational factors within the safety management system

The organisation should provide a strategy to ensure that human factors knowledge, methods and a human-centred approach are systematically and consistently applied to all relevant processes within the organisation. Such an approach means considering the needs, capabilities and behaviours of people first and then designing to accommodate those needs, capabilities and behaviours.

The human and organisational factors (HOF) strategy may contain elements linking to:

Leadership

▶ *Leadership and commitment*

- *Management commitment to HOF is clearly stated in policies and objectives;*
- *There is a process/guideline showing how HOF should be applied in projects;*
- *HOF is an integrated part of the design process and of project management.*

▶ *Safety policy*

- *The safety policy states clearly that a HOF perspective should be applied in all safety-related processes.*

▶ *Organisational roles, responsibilities, accountabilities and authorities*

- *Clearly defined roles, responsibilities and accountabilities of the HOF specialist;*
- *There is a process for how HOF experts participate in projects and processes on a regular basis.*

Planning

▶ *Actions to address risk*

- *A description of how the HOF perspective is considered in risk analyses;*
- *Involvement of HOF specialists and frontline workers including those having interfaces in risk analyses.*

Support

▶ *Resources and competence*

- *Systematic approach of using human and organisational factors competence to ensure that safety relevant roles have sufficient resources based on the risk assessment.*
- *Link between the risk assessment, the safety-related tasks and the competence management system to ensure that staff continuously demonstrate the identified competencies;*
- *Time and resources are allocated to ensure HOF requirements are fulfilled.*

▶ *Awareness*

- *Systematic use of human and organisational factors competence in the organisation to ensure that staff in relevant roles are aware of the part they play in safety.*

Operation

▶ *Operational planning and control*

- *HOF is considered in operational planning.*

▶ *Asset management*

- *The organisation has guidelines for applying a human centred approach at each stage of the life cycle.*

▶ *Management of change*

- *HOF shall always be assessed as part of the management of change process.*

Performance evaluation

▶ *Monitoring*

- *Safety performance is assessed systematically in light of the HOF strategy.*

Improvement

▶ *Learning from accidents and incidents*

- *HOF expertise and methods are used in the accident investigation process;*
- *There is a methodology for conducting investigations based on HOF knowledge and methods;*
- *There is a training program for accidents and incident investigators, applying a HOF perspective.*

▶ *Continual improvement*

- *Process for continuous improvement of the organisations processes for managing HOF.*

ANNEX 6 – Definitions

Use of the words or terms throughout the document such as ‘must’, ‘should’ or ‘shall’ indicates a legal requirement exists, with which compliance is necessary. Definitions found in related railway safety legislation such as the Railway Safety Directive (EU) 2016/798, the CSM for Risk Evaluation and Assessment (EU) 402/2013 and in the relevant Technical Specifications for Interoperability apply to this document but are not reproduced below.

Accident	An unwanted or unintended sudden event or a specific chain of such events which have harmful consequences; accidents are divided into the following categories: collisions; derailments; level crossing accidents; accidents to persons involving rolling stock in motion; fires and others (Directive (EU) 2016/798).
Area of operation	A network or networks within one or more Member States where a railway undertaking intends to operate (Directive (EU) 2016/798).
Asset management	The approach used by an organisation to ensure that physical assets remain safe, fit-for-purpose, and commercially viable from design and construction, throughout its life cycle, to decommissioning.
Audit	Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled (ISO 9000).
Business unit	A business unit is a department or functional area within an organisation. It may concern different roles and purposes, e.g. human resources, production, long distance transport, logistics, shunting.
Character of operation	The characterisation of operation by its scope, including infrastructure design and construction, infrastructure maintenance, traffic planning, traffic management and control, and by the use of the railway infrastructure, including conventional and/or high speed lines, transport of passengers and/or goods
Competence	Ability to apply knowledge and skills to achieve intended results (ISO 9000).
Continual improvement	Recurring activity to enhance performance (i.e. measurable result) (ISO 9000).
Document management	The process (or procedure) for the identification, creation, maintenance, management, storage and retention of documented information.
Extent of operation	In relation to railway operations carried out by railway undertakings, the extent characterised by the number of passengers and/or volume of goods and the estimated size of a railway undertaking in terms of number of employees working in the railway sector (i.e., as a micro, small, medium-sized or large enterprise) (Directive (EU) 2016/798). In relation to railway operations carried out by infrastructure managers, the extent characterised by the length of railway track and the estimated size of the infrastructure manager in terms of number of employees working in the railway sector (Regulation (EU) 2018/762).
Hazard	A condition that could lead to an accident (Regulation (EU) 402/2013).
Human and organisational factors	All human performance characteristics and organisational aspects that must be considered to ensure the lifelong safety and effectiveness of a system or organisation.
Human-centered approach	An approach considering the needs, capabilities and behaviours of people first and then designing to accommodate those needs, capabilities and behaviours.
Incident	Any occurrence, other than an accident or serious accident, affecting the safety of railway operations (Directive (EU) 2016/798). This includes near misses.

Infrastructure manager	Any body or firm responsible in particular for establishing, managing and maintaining railway infrastructure, including traffic management and control-command and signalling; the functions of the infrastructure manager on a network or part of a network may be allocated to different bodies or firms (Directive 2012/34/EU).
Interested party	Person or organisation that can affect, be affected by, or perceive itself to be affected by a decision or activity (ISO 9000) related to the safety management system.
Investigation	A process conducted for the purpose of accident and incident prevention which includes the gathering and analysis of information, the drawing of conclusions, including the determination of causes and, when appropriate, the making of safety recommendations (Directive (EU) 2016/798).
Management system	A set of interrelated or interacting elements of an organisation to establish policies and objectives, and the processes to achieve those objectives (ISO 9000).
Monitoring	The arrangements put in place by railway undertakings, infrastructure managers or entities in charge of maintenance to check their management system is correctly applied and effective (Regulation (EU) 1078/2012).
National rule	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 (Directive (EU) 2016/798).
Process	Set of interrelated or interacting activities which transforms inputs into outputs (ISO 9000).
Rail infrastructure	The facilities that are necessary to enable a railway to operate, including: <ul style="list-style-type: none"> ▶ Railway tracks and associated track structures; ▶ Service roads, signalling systems, communications systems, rolling stock; ▶ Control systems, train control systems, and data management systems; ▶ Notices and signs; ▶ Electrical power supply and electric traction systems; ▶ Associated buildings, workshops, depots, and yards; and ▶ Plant, machinery, and equipment.
Railway undertaking	A railway undertaking as defined in point (1) of Article 3 of Directive 2012/34/EU, and any other public or private undertaking, the activity of which is to provide transport of goods and/or passengers by rail on the basis that the undertaking is to ensure traction, including undertakings which provide traction only (Directive (EU) 2016/798). Any public or private undertaking licensed according to this Directive, the principal business of which is to provide services for the transport of goods and/or passengers by rail with a requirement that the undertaking ensure traction; this also includes undertakings which provide traction only (Directive 2012/34/EU).
Risk	The frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm (Regulation (EU) 402/2013).
Risk analysis	Systematic use of all available information to identify hazards and to estimate the risk (Regulation (EU) 402/2013).
Risk assessment	The overall process comprising a risk analysis and a risk evaluation (Regulation (EU) 402/2013).
Risk evaluation	A procedure based on the risk analysis to determine whether an acceptable level of risk has been achieved (Regulation (EU) 402/2013).
Risk management	The systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risks (Regulation (EU) 402/2013).
Safety culture	The interaction between the requirements of the safety management system, how people make sense of them, based on their attitudes, values and beliefs and what they actually do, as seen in decisions and behaviours. A positive safety culture is characterised by a collective commitment by leaders and individuals to always act safely, in particular when confronted with competing goals (Regulation (EU) 2018/762).
Objective	Result to be achieved. A safety objective must be specific, measurable, achievable, realistic and time-based. It must also be set at relevant functions and levels within the organisation.

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Partner	A commercial entity with which another commercial entity has some form of alliance. This relationship may be a contractual, exclusive bond in which both entities commit not to ally with third parties.
Partnership	An arrangement where parties, known as partners, agree to cooperate to advance their mutual interests.
Safety management system	The organisation, arrangements and procedures established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations (Directive (EU) 2016/798).
Top management	Person or group of people who directs and controls an organisation at the highest level (ISO 9000).
Type of operation	The type characterised by passenger transport, including or excluding high-speed services, freight transport, including or excluding dangerous goods services, and shunting services only (Directive (EU) 2016/798).



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Guidance for Safety certification:

- ▶ Application guide for the granting of single safety certificates — A guide for the applicants
- ▶ Application guide for the granting of single safety certificates — A guide for the authorities
- ▶ **Safety management system requirements for safety certification or safety authorisation**
- ▶ Supervision guide
- ▶ Management maturity model
- ▶ Enforcement management model
- ▶ Coordination between national safety authorities – A common approach to supervision
- ▶ Competence management framework for authorities