



EUROPEAN RAILWAY AGENCY  
Safety Unit

Application guide for the design and implementation  
of a Railway Safety Management System

# SMS RELATED TERMINOLOGY

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## Version Control

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## Introduction

The Directive 2004/49/EC<sup>1</sup> (hereinafter referred to as 'the Railway Safety Directive' if not otherwise specified) clearly stipulates in Article 4 that the responsibility for safe operation is with the railway undertakings (RU) and infrastructure managers (IM) and, to fulfil this responsibility, it requires that they establish a safety management system (SMS), in accordance with Articles 9 and Annex III of the Directive itself.

The adequate implementation of an SMS by all RUs/IMs is a key element for success for the entire safety regulatory framework as foreseen by the Railway Safety Directive, since it forms the basis on which the National Safety Authorities (NSAs) issue safety certificates and safety authorisations. For the assessment of an SMS, NSAs can rely on the Regulations 1148/2010/EU<sup>2</sup> and 1169/2010/EU<sup>3</sup>.

Such Regulations contain the framework principles for assessing an SMS, the criteria to be used for this assessment and principles for supervision after the award of Safety certificates or authorisations.

Although these CSM can already give clear guidance on the adequate implementation of an SMS, with a view to Article 9 and Annex III of the Railway Safety Directive, there are no provisions specifically addressed to RUs and IMs, to be used as reference document to support the design and implementation of their SMS. The Agency has the intention to provide this practical guidance through a set of complementary SMS guidelines of which this document is a part of deliverables.

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<sup>1</sup> DIRECTIVE 2004/49/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive)

<sup>2</sup> Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates. OJ L 326, p.11

<sup>3</sup> Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety authorisations. OJ L 327, p.13

The purpose of the SMS is to ensure that the organisation achieves its business objectives in a safe manner. These objectives need to be fulfilled in today's ever changing and complex railway environment. In addition, the SMS should ensure that the organisation 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 organisations own activities, with the aim of preventing accidents. When appropriate it should take into account the interfaces with other RUs and IMs in the railway system. Implementing all relevant elements of an 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 thereby recognise that an efficient control of its risks 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.

**The implementation of a SMS is legally binding after Articles 4(3) and 9(1) of the Directive 2004/49/EC.**

Nonetheless, there are other good reasons for implementing and delivering an effective SMS:

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 easily integrated and 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 helping to improve overall performances, introduce operational efficiencies, enhance relations with customers and regulatory authorities and build a positive safety culture.

## SMS related terminology

### UNDERSTANDING OF TERMS AND CONCEPTS

The following terms and concepts have been selected from the content of the Railway Safety Directive, during the development of the CSM on conformity assessment or suggested by the stakeholders, because they seem to require some explanation.

Some explanation has been found in dictionaries, literature, good practice or standards, either in railway related documents or in similarly regulated fields.

Such explanation is reputed to provide, at a sufficient degree of appropriateness, the basic information to build knowledge on the managements systems, safety management systems and the relevant elements.

<b>1</b>	<b>Accountable (roles)</b>	Person or post liable to be called to account (accountable, responsible)
<b>2</b>	<b>Appointed person</b>	A person designated by a company, on the basis of his or her qualifications, for the purpose of performing a certain task
<b>3</b>	<b>Appropriate levels of responsibility</b>	<p>The hierarchical level in the organization will usually be explicitly recognized by distinct levels with different management activities as well as different functional activities.</p> <p>For example, many organizations may be separated into the following four levels:</p> <ol style="list-style-type: none"><li>1. Decision-making – makes all decisions in the organization (many decisions will be assigned to managers at other levels in the organization) and interacts with stakeholders.</li><li>2. Policy Analysis – the review of monitoring and supervisory results, the analysis of operations and programs to develop new programs and operations as well as modifications to meet desired criteria.</li><li>3. Supervision and Monitoring – The monitoring of operations to identify the degree of achievement of the organization’s plans and other determined performance criteria. (this level may be combined with either the Policy Analysis level or the Operational level).</li><li>4. Operations – the production and delivery of goods or services to meet the organization’s mandate and goals. For safety related organizations, these operations will result in reduction of risk through the implementation of regulations or risk treatment and control measures.</li></ol>

		<p>There is a flow of information between all levels of an organization. Generally, the flow of information from the top down is related to decisions on programs to be operated and targets for budgets and production. The flow of information upwards in the organization is generally related to output measures of the operations, cost effectiveness of the program, costs to modify the operations, human resources status reporting, etc.</p> <p>[adapted from: Network for environmental risk assessment and management (NERAM):Benchmark Framework for Risk Management, August 2000</p>
<b>4</b>	<b>Assessor</b>	<p>Person in charge for assessing the possession of requirements or the compliance with specified rules.(belonging to NSA or to qualified bodies)</p>
<b>5</b>	<b>Character and extent of activity</b>	<p>"Type" of service is characterised by passenger transport, including and excluding high-speed services, freight transport, including and excluding dangerous goods services, and shunting services only.</p> <p>"Extent" of service and of the railway undertaking is characterised by volume of passenger/goods and the estimated size of the railway undertaking in terms of employees working in the railway sector (micro, small, medium sized, large enterprise).</p>
<b>6</b>	<b>Configuration control (of documentation)</b>	<p>In general 'configuration' identifies the functional and/or physical characteristics of hardware/software as set forth in technical documentation and achieved in a product. (as stated in U.S. military standard MIL-STD-973). The same principle is adopted for items other than hardware/software (e.g.: documentation).</p> <p>'Configuration control' is the systematic evaluation, co-ordination, approval or disapproval and dissemination of proposed changes and implementation of all approved changes in the configuration of any item after formal establishment of its configuration baseline.</p> <p>[adapted from: INDEX for the Project Management System, available in <a href="http://sparc.airtime.co.uk/users/wysywig/">http://sparc.airtime.co.uk/users/wysywig/</a>]</p>
<b>7</b>	<b>Control of all risks</b>	<p>Selection and application of suitable measures to reduce (all) risks</p> <p>[Adapted by BS 88:2004-Occupational health and safety management systems - Guide]</p>
<b>8</b>	<b>Corrective action</b>	<p>Action to eliminate or mitigate the cause or reduce the effects of a detected nonconformity or other undesirable situation.</p> <p>[FAA Advisory Circular 120-92]</p>

9	<b>Effectiveness of control measures</b>	<p>Effectiveness of control measures is the expected output of an implementation plan following risk management decision process.</p> <p>Monitoring is the action that allows the effectiveness of control measures.</p> <p>[adapted from “Risk management: guidelines for decision-makers” (Canadian Standards Association – CAN/CSA-Q850-97), July 1997]</p>
10	<b>Emergency procedure coordination</b>	<p>An emergency procedure is a response plan which allows for all predicted uncontrolled events to be described and measures to be acted upon to eliminate or mitigate the consequences.</p> <p>Coordination of emergency procedures should allow all internal (identified contact persons and departments) and external responders (e.g.: identified contact persons and departments in other companies, rescue services, police, etc.) to act effectively if such events occur.</p>
11	<b>High reliability industries</b>	<p>Organizations that consistently operate under trying and hazardous conditions, and manage to have relatively few accidents. These organizations operate in settings where the potential for error and disaster is very high. They have no choice but to function reliably because failure results in severe consequences. HRO theory holds that significant accidents can be prevented through proper management of prevention and mitigation activities. Examples of high-reliability organizations: nuclear aircraft carriers, nuclear power generating plants, power grid dispatching centers, air traffic control systems, aircraft operations, hospital emergency departments, hostage negotiating teams, firefighting crews, continuous processing firms. High reliability characteristics include:</p> <ol style="list-style-type: none"> <li>(1) personal technical excellence and commitment to continuous training;</li> <li>(2) sustained, high levels of operational performance, encompassing both productivity and safety objectives;</li> <li>(3) robust technical systems and structures, and organizational processes that provide redundancy and flexibility;</li> <li>(4) decentralized authority patterns, including deference to capable individuals with the most technical expertise and individuals closest to the problem;</li> <li>(5) a committed workforce where every individual understands and accepts their roles and responsibilities for safe mission performance;</li> <li>(6) a deep commitment to continuous performance improvement, openness and trust, and cultivation of a</li> </ol>

		<p>continuous learning environment</p> <p>(7) the use of systems of checks and audits to build reliability.</p> <p>[INTEGRATED SAFETY MANAGEMENT SYSTEM MANUAL, U.S. Department of Energy, Office of Health, Safety and Security]</p>
<b>12</b>	<b>Interested parties</b>	<p>In general, an interested party is a person or group that has a stake in the success or performance of another organization. Interested parties may be directly affected by the organization or actively concerned about its performance. Interested parties can come from inside or outside of the organization. Examples of interested parties can include customers, suppliers, owners, partners, employees, unions, or members of the general public.</p> <p>[Adapted from ISO 9000:2005]</p> <p>Persons or group concerned with, affecting or affected by (railway) safety performance of the organisation</p> <p>[Adapted from BS 88:2004-Occupational health and safety management systems - Guide]</p>
<b>13</b>	<b>Internal auditing system</b>	<p>The arrangement established by a company in order to perform internal audits.</p> <p>The companies may entrust specific departments, however, they can appoint independent assessors to carry out internal audits.</p>
<b>14</b>	<b>Internal audits</b>	<p><i>Audit conducted by, or on behalf of, the organisation itself for management review and other internal processes, and may form the basis for an organisation's self-declaration of conformity</i></p> <p>[EN ISO 19011]</p>
<b>15</b>	<b>Internal safety auditing</b>	<p>An <i>audit(*)</i> is an evidence gathering process. Audit evidence is used to evaluate how well audit criteria related to the delivery of safety management system are being met. Audits must be objective, impartial, and independent, and the audit process must be both systematic and documented.</p> <p><i>Internal audits</i> have to be carried out by companies to evaluate internally the delivery of safety management system. However, they can appoint independent assessors to carry out internal audits.</p> <p>'Provisions for the recurrent internal audits' are one of the basic elements of the safety management system (ref. to Annex III(2)(j))</p> <p>(*)AUDIT: <i>A systematic, independent and documented process for obtaining audit evidence and evaluating it</i></p>



		<p>objectively to determine the extent to which the audit criteria are fulfilled</p> <p>[EN ISO 19011]</p>
16	Job design	<p><i>“Job Design is the process of deciding on the contents of a job in terms of its duties and responsibilities, on the methods to be used in carrying out the job, in terms of techniques, systems and procedures, and on the relationships that should exist between the job holder and his superior subordinates and colleagues”</i>(Michael Armstrong, <i>Amstrong’s handbook of human resources management practice, 2009 - ISBN 978 0 7494 5242 1</i>) .</p> <p>Job Design is affected by 3 categories of factors: organisational, environmental and behavioural.</p> <p>The <b>organizational factors</b> that affect job design are characteristics of task, work flow, ergonomics and work practices.</p> <ul style="list-style-type: none"> <li>- Characteristic of task: Each task consist of 3 elements, namely, planning, executing and controlling. Job design involves the assembly of a number of task into a job or a group of jobs. A job may require an employee to perform a variety of connected task. All these characteristics of jobs are taken into consideration for job design.</li> <li>- Workflow: The flow of work in an organization is strongly influenced by the nature of the product. This product usually suggests the sequence and balance between jobs if the work is to be completed efficiently.</li> <li>- Ergonomics: Ergonomics is concerned with the designing and shaping of jobs as per the physical abilities and characteristics of individuals so that they can perform their jobs effectively.</li> <li>- Work Practices: Work practices are the set methods of performing work. This can affect the job design as there is little flexibility in designing the job especially if the work practices are approved by employee unions.</li> </ul> <p><b>Environmental factors</b> affect job design. Environmental factors include employee abilities &amp; availability and Social &amp; Cultural expectations.</p> <ul style="list-style-type: none"> <li>- Employee Abilities &amp; Availability: Abilities and availability of people plays an important role while designing jobs. Due attention needs to be given to the employee who will actually perform the job.</li> <li>- Social And Cultural Expectations:</li> </ul>

		<p>Jobs should be designed keeping the employees in mind. Due to increase in literacy rate and knowledge, employees are now more aware and only perform jobs that are to their liking and matches their profile.</p> <p><b>Behavioral factors</b> are related to human needs and they need to be satisfied properly. Behavioral elements include the following:</p> <ul style="list-style-type: none"> <li>- Feedback: Employee should be given proper feedback about his job performance. This will enable the employee to improve his performance and complete the job in a proper manner.</li> <li>- Autonomy: Employee should be given proper autonomy required to perform the work. The absence of autonomy may lead to poor performance on the part of employees.</li> <li>- Use Of Abilities: The job should be designed in such a manner that an employee will be able to use his abilities fully and perform the job effectively.</li> <li>- Variety: Absence of variety in the job assigned may lead to boredom. Adequate scope to variety factor should be given while designing a job.</li> </ul> <p>[<a href="http://hubpages.com/hub/Job-Design">http://hubpages.com/hub/Job-Design</a>]</p>
17	<p><b>Learning Organisation</b> (see also <b>Organisational learning</b>)</p>	<p>One that values continuous learning. An organization that is deeply committed to continuous performance improvement and develops and sustains organizational processes, such as incident critiques, that facilitate continuous improvement; encourage openness and trust so that problems are reported; cultivate an environment that encourages and rewards ongoing efforts to learn from experience, learn from others, and from self-directed studies; aggressively seek to know what it doesn't know; demonstrate excellence in performance monitoring, problem analysis, solution planning, and solution implementation; systematically eliminate or mitigate error-likely situations; and remain obsessed with the liabilities of success.</p> <p>[INTEGRATED SAFETY MANAGEMENT SYSTEM MANUAL, U.S. Department of Energy, Office of Health, Safety and Security]</p>
18	<p><b>Lifecycle of equipment and operation</b></p>	<p>'Life-cycle', in system engineering, identifies a sequence of stages in which the output of each stage becomes the input for the next. It is possible to identify broadly 5 stages:</p>

		<ul style="list-style-type: none"> <li>– Acquisition</li> <li>– Development</li> <li>– Implementation</li> <li>– Operations and Maintenance</li> <li>– Termination</li> </ul> <p>There are, anyway, different ways to figure life-cycles, for different purposes. The CENELEC standard EN 50126:1999 – “Railway applications. The specification and demonstration of reliability, availability, maintainability and safety (RAMS)” contains a figure for life cycle in railway technical application:</p> <ul style="list-style-type: none"> <li>– Concept</li> <li>– System Definition and Application</li> <li>– Conditions</li> <li>– Risk Analysis</li> <li>– System Requirements</li> <li>– Apportionment of System Requirements</li> <li>– Design and Implementation</li> <li>– Manufacture</li> <li>– Installation</li> <li>– System Validation</li> <li>– System Acceptance</li> <li>– Operations and Maintenance</li> <li>– Modification and Retrofit</li> <li>– Performance Monitoring</li> <li>– Decommissioning and Disposal</li> </ul>
<b>19</b>	<b>Maintenance</b>	Combination of all technical, administrative and managerial actions during the life-cycle of an item intended to retain it in, or restore it to, a state in which it can perform the required function.

		[BS EN 13306:2001, Maintenance terminology]
<b>20</b>	<b>manage related risks / Interface risks introduced by changes</b>	<p>When a change of technical, operational or organisational nature is introduced in a railway company, it may have a potential impact on safety.</p> <p>Railway companies have then to identify and manage risks arising from such changes, applying the methodology of Regulation 352/2009<sup>4</sup></p> <p>Risks to be managed may refer to interfaces, defined by the afore-mentioned Regulation as “all points of interaction during a system or subsystem-life-cycle, including operation and maintenance where different actors of the rail sector will work together to manage the risks”.</p>
<b>21</b>	<b>Organisational learning</b>	<p>As a principle, organisational learning is part of the knowledge management system. In organisational engineering, organisational learning is seen as tool to improve the performance of an organization and to make it adaptive towards changes.</p> <p>Several theories explain what organisational learning means. Some of them have been selected:  “the process of "detection and correction of errors." Organizations learn through individuals acting as agents for them: "The individuals' learning activities, in turn, are facilitated or inhibited by an ecological system of factors that may be called an organizational learning system" (p. 117).</p> <p>Chris Argyris, Organizational learning and management information systems. Accounting, Organizations, and Society, 2(2), 113-123 (1977)</p> <p>Organizational learning is related to four constructs: knowledge acquisition, information distribution, information interpretation, and organizational memory. [...] An entity learns if, through its processing of information, the range of its potential behaviours is changed.</p> <p>G.P. Huber, “Organizational Learning: The Contribution Process and the Literatures“, Organization Science, 2 (1), pp.88-115(1991)</p> <p>Quoted in, “Organizational Learning and Learning Organizations, Malhotra Yogesh. (1996). Available at <a href="http://www.brint.com/papers/orglrng.htm">http://www.brint.com/papers/orglrng.htm</a></p>

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<sup>4</sup> COMMISSION REGULATION (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council, OJ L108 p.4

		<p>"the process of improving actions through better knowledge and understanding"  C.M. Fiol, &amp; M.Lyles: <i>Organizational Learning. Academy of Management Review</i>, 10:4, 803-813. (1985).  Organization-wide continuous process that enhances its collective ability to accept, make sense of, and respond to internal and external change. Organizational learning and is more than the sum of the information held by employees. It requires systematic integration and collective interpretation of new knowledge that leads to collective action and involves risk taking as experimentation.  [www.businessdictionary.com]</p>
<b>22</b>	<b>Other management activities</b>	<p>Those management positions whose responsibility is in the accomplishment of organisation's mission(s), as distinguished from those related to management, support and operational processes of the organisation's SMS.</p>
<b>23</b>	<b>Other parties</b>	<p>The safety management system is expected to take into account, where appropriate and reasonable, the risks arising as a result of activities by other parties.  Other parties are not directly related to the railway system activities, so they may be: road infrastructures (e.g.: bridges), freight terminals, sidings. The list is not exhaustive.</p>
<b>24</b>	<b>Periodical reviews of SMS</b>	<p>After initial compliance assessment to ensure that a safety management system is put into effect, it is necessary that the system is periodically reviewed and validated against relevant legislation.  In particular, the safety management system needs to be reviewed:</p> <ul style="list-style-type: none"> <li>– At regular intervals, to verify continued legislative compliance and that the safety management system is achieving its objectives.</li> <li>– In case of modification(s), in order to verify that such modifications do not impair compliance with relevant legislation</li> </ul>
<b>25</b>	<b>Plans</b>	<p>To determine what a plan may mean, it is useful to use the ISO definition for 'Quality plan'.  document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract  NOTE 1 These procedures generally include those referring to quality management processes and to product realization processes.  NOTE 2 A quality plan often makes reference to parts of the quality manual (3.7.4) or to procedure documents.  NOTE 3 A quality plan is generally one of the results of quality planning (3.2.9).</p>

		<p>[ISO 9001:2005 Quality management systems - Fundamentals and vocabulary (3.7.5)]</p> <p>We may assume that ‘safety’ plans are document specifying which procedures and associated resources shall be applied by whom and when to a specific safety related project, product, process or contract.</p>
26	<b>Preventive action</b>	<p>action to eliminate or mitigate the cause or reduce the effects of a potential nonconformity or other undesirable situation.</p> <p>[FAA Advisory Circular 120-92]</p>
27	<b>Qualified body</b>	<p>Qualified bodies are entities other than railway undertakings and infrastructure managers, requested by the NSAs to provide technical assistance when they are carrying out the tasks referred to in Article 16 of Directive 2004/49/EC.</p>
28	<b>Railway company</b>	<p>The terms designate both Railway Undertakings and Infrastructure Managers, when they are expected to fulfil the same requirements.</p>
29	<b>Railway premises</b>	<p>There are several definitions that may guide on the identification of railway premises. Each document refers to a specific scope, however they have a basic commonality.</p> <p>COMMISSION REGULATION (EC) No 851/2006 of 9 June 2006 specifying the items to be included under the various headings in the forms of accounts shown in Annex I to Council Regulation (EEC) No 1108/70 contains a detailed description of railway infrastructure</p> <p>ANNEX I “Definition and scope of the term ‘Transport Infrastructure’”, specifies that for the purposes of Article 1 of Regulation (EEC) No 1108/70, ‘transport infrastructure’ means all routes and fixed installations of the three modes of transport “(rail, road, inland waterways) being routes and installations necessary for the circulation and safety of traffic.</p> <p>Annex I(A) specifies that railway infrastructure “<i>consists of the following items, provided they form part of the permanent way, including service sidings, but excluding lines situated within railway repair workshops, depots or locomotive sheds, and private branch lines or sidings:</i></p> <ul style="list-style-type: none"> <li>— <i>ground area,</i></li> <li>— <i>track and track bed, in particular embankments, cuttings, drainage channels and trenches, masonry trenches,</i></li> <li><i>culverts, lining walls, planting for protecting side slopes etc.,</i></li> <li><i>passenger and goods platforms,</i></li> </ul>

*four-foot way and walkways,  
 enclosure walls, hedges, fencing,  
 fire-protection strips,  
 apparatus for heating points, crossings, etc.,  
 snow protection screens,*

- *engineering structures:  
 bridges, culverts and other overpasses, tunnels, covered cuttings and other underpasses,  
 retaining walls, and structures for protection against avalanches, falling stones, etc.,*
- *level crossings, including appliances to ensure the safety of road traffic,*
- *superstructure, in particular:  
 rails, grooved rails and check rails,  
 sleepers and longitudinal ties, small fittings for the permanent way, ballast including stone chippings and  
 sand,  
 points, crossings, etc.,  
 turntables and traversers (except those reserved exclusively for locomotives),*
- *access way for passengers and goods, including access by road;*
- *safety, signalling and telecommunications installations on the open track, in stations and in marshalling  
 yards,  
 including plants for generating, transforming and distributing electric current for signalling and  
 telecommunications,  
 buildings for such installations or plants,  
 track brakes,*
- *lighting installations for traffic and safety purposes,*
- *plants for transforming and carrying electric power for train haulage: sub-stations, supply cables between  
 substations and contact wires, catenaries and supports; third rail with supports,*
- *buildings used by the infrastructure department, including a proportion in respect of installations for the  
 collection of transport charges.”*

The Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the  
 interoperability of the rail system within the Community describes the European conventional railway

		<p>network as follows:</p> <ul style="list-style-type: none"> <li>- <i>lines intended for passenger services,</i></li> <li>- <i>lines intended for mixed traffic (passengers and freight),</i></li> <li>- <i>lines specially designed or upgraded for freight services,</i></li> <li>- <i>passenger hubs,</i></li> <li>- <i>freight hubs, including intermodal terminals,</i></li> <li>- <i>lines connecting the abovementioned elements.</i></li> </ul> <p>The Commission Decision of 20 December 2007 concerning a technical specification for interoperability relating to the ‘infrastructure’ sub-system of the trans-European high-speed rail system contains the description of infrastructure sub-system:</p> <p><i>“The infrastructure structural subsystem of the trans-European high-speed rail system includes the tracks and switches and crossings of the high-speed lines within the scope set out in Chapter 1. These tracks are those defined in the Infrastructure Register of the section of line concerned.</i></p> <p><i>The infrastructure structural subsystem also includes:</i></p> <ul style="list-style-type: none"> <li>— <i>structure supporting or protecting the track</i></li> <li>— <i>line side structures and civil engineering works that could affect the interoperability of the railway</i></li> <li>— <i>passenger platforms and other station infrastructure that could affect the interoperability of railway</i></li> <li>— <i>arrangements necessary within the subsystem to protect the environment</i></li> <li>— <i>arrangements to safeguard passenger safety in the event of degraded operations”.</i></li> </ul>
30	<b>Reasonably practicable</b>	<p>Reasonably practicable’ reflects the fact that the requirements of the law vary with the degree of risk associated with a particular activity or environment, and must be balanced against the time, trouble and cost of taking measures to control the risk. It allows the person who owes the duty to choose the most efficient means for controlling a particular risk from the range of feasible possibilities preferably in accordance with the ‘hierarchy of control’ eg, maintenance schedules appropriate for vehicle specific manufacturer and types.</p> <p><i>A safety measure is reasonably practicable if its cost, in terms of money, inconvenience or impact on services, is justified by the safety benefits that it provides</i></p> <p>[A glossary of words and phrases used in the management of safety by European railways, UIC Safety Platform, 22 December 2005</p>



31	<b>Relevant parts of CSM</b>	<p>The relevant part of CMS to be applied by railway undertakings and infrastructure managers is basically the CSM on risk evaluation and assessment methods, as in Article 6.3(a) of Directive 2004/49/EC.</p> <p>A CSM on monitoring will cover the supervision and monitoring of the RUs and IMs sub-systems to ensure that they continue to be operated and maintained in accordance with the essential requirements, as in the Article 6.3(c) of Directive 2004/49/EC. However, whilst the essential requirements cover safety these only relate to those needed to provide for the interoperability of the sub-system. The safe operation and maintenance of the vehicle and infrastructure will go wider than the essential requirements laid down in the Interoperability Directive and are more akin to the need to ensure that safety is generally maintained, and where reasonably practicable, continuously improved as set out in Article 4 of the RSD, which is a fundamental part of the RUs/IMs SMS.</p> <p>A SMS can only remain effective in managing the risks if it is continually monitored/reviewed to ensure that it is achieving its objectives.</p> <p>CSM on conformity assessment with requirements in safety certificates and safety authorisations, as in as in Article 6.3(b) of Directive 2004/49/EC are addressed to NSAs. Nonetheless, the assessment criteria therein contained can be used by railway undertakings and infrastructure managers to carry out self assessment of their own safety management system (see section 1.5 of this document).</p>
32	<b>Relevant safety data</b>	<p>The term refers to the sentences in the CSM on assessing conformity of safety certificates, concerning:</p> <ul style="list-style-type: none"> <li>– Criteria I – Ensuring continuous improvement. The use of safety data that are relevant to the monitoring and measurement of continuous improvement. The RU/IM can use applicable Common Safety Indicators (CSIs) as a baseline, complemented with identified performance indicators, derived from the type of service delivered and the arrangements in place (including outsourced activities).</li> <li>– Criteria K – Qualitative and quantitative targets of the organisation for maintaining and enhancing safety, and plans and procedures for reaching these targets. The use of safety data to measure performance, in order to check the effectiveness of risk control measures and the attainment of corporate safety targets is linked to the compliance to applicable rules and it is also connected to the concept of measuring performance with the aim of enhancing (or improving) safety. Relevant data are again the CSIs, complemented by data identified by the company as</li> </ul>

		appropriate indicators, to be collected automatically or during safety inspections, audits, etc.
<b>33</b>	<b>Resources</b>	Human, financial, physical, and knowledge factors that provide a firm the means to perform its business processes [Business Dictionary (businessdictionary.com)] Resources may be people, infrastructure, work environment, information, suppliers and partners, natural resources and financial resources. [Quality management systems - Guidelines for performance improvements (ISO 9004:2000), § 6.1.1]
<b>34</b>	<b>Results of the risk analysis</b>	Type of safety measure selected to control the risk to an acceptable level, that leads to the definition of safety requirements to be fulfilled by the relevant company or part of a company [Adapted from Regulation 352/2009/EC <sup>5</sup> , Article 3.10]
<b>35</b>	<b>Risk control measures = safety measures</b>	‘safety measures’ means a set of actions either reducing the rate of occurrence of a hazard or mitigating its consequences in order to achieve and/or maintain an acceptable level of risk; [Regulation 352/2009/EC <sup>7</sup> , Annex I, 1.1.5]
<b>36</b>	<b>Routine monitoring arrangements</b>	Monitoring is crucial to effective control of the system. Routine monitoring arrangements should be suited to the (safety related) business processes and set up to check performance over a period of time. A routine monitoring system should be set up based on the following principles: <ul style="list-style-type: none"> <li>– It refers to the type and extent of activity of the railway company</li> <li>– It covers all necessary topics (railway companies should identify appropriate indicators within the ongoing activity, including operational arrangement, staff performance, rolling stock performance, progress in training and maintenance programmes, etc...),</li> <li>– It includes the following elements: <ul style="list-style-type: none"> <li>- the methods to collect data (automatic data capturing from equipment as hot box detector or on-board equipment, manual data collecting on accidents, incidents and other dangerous occurrences,</li> </ul> </li> </ul>

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<sup>5</sup> COMMISSION REGULATION (EC) No 352/2009<sup>5</sup> of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council, OJ L108, p.4

		<p>safety tours and audit findings)</p> <ul style="list-style-type: none"> <li>- the methods to record data (automatic data recording in a database, manual feeding)</li> <li>- the storage medium (i.e.: excel table, IT customised database, etc.)</li> <li>- the output (figures, reports, etc.) and the reporting flow</li> </ul> <p>– Milestones have to be set for the first monitoring period and for the following, in order to review the monitoring arrangements.</p> <p>– Resource requirements for monitoring have to be identified and allocated at the appropriate level of organisation (skills and training needs of staff, support tools, etc.).</p>
37	<b>Safety and health at work</b>	<p><i>Prevention of occupational risks, the protection of safety and health, the elimination of risk and accident factors, the informing, consultation, balanced participation in accordance with national laws and/ or practices and training of workers and their representatives.</i></p> <p>[DIRECTIVE 1989/391/EEC<sup>6</sup>, Article 1]</p> <p>Factors and conditions that:</p> <ul style="list-style-type: none"> <li>– affect health and safety in the workplace, or</li> <li>– could affect health and safety in the workplace.</li> </ul> <p>Occupational health and safety factors affect employees (permanent and temporary), contractors, visitors, and anyone else who is in the workplace.</p> <p>[Adapted from OHSAS 18001:2007]</p> <p>International Labour Organization (ILO) and World Health Organization (WHO) shared definition of occupational health (1995): "Occupational health should aim at: the promotion and maintenance of the highest degree of physical, mental and social well-being of workers in all occupations; the prevention amongst workers of departures from health caused by their working conditions; the protection of workers in their employment from risks resulting from factors adverse to health; the placing and maintenance of the worker in</p>

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<sup>6</sup> COUNCIL DIRECTIVE of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, as amended by Regulation (EC) No 1882/2003 , Directive 2007/30/EC of the European Parliament and of the Council of 20 June 2007 and Regulation (EC) No 1137/2008.

		an occupational environment adapted to his physiological and psychological capabilities; and, to summarize, the adaptation of work to man and of each man to his job."
38	<b>Safety authority</b>	<p><b>National Safety Authorities (NSAs)</b> are the entities set under the Directive 2004/49/EC, defined at Article 3(g), and required to fulfil the tasks described in Article 16.</p> <p>They are otherwise designated as “competent” authorities to perform the tasks contained in the Directive 2007/59/EC on train drivers certification.</p>
39	<b>Safety critical tasks</b>	<p>The only EU-wide available identification for <i>safety critical tasks</i> is in TSI Operation and Traffic Management (4.2.1.1 General requirements)</p> <p>This section deals with the staff who contributes to the operation of the subsystem by performing safety critical tasks involving a direct interface between a Railway Undertaking and an Infrastructure Manager.</p> <p>Railway Undertaking staff:</p> <ul style="list-style-type: none"> <li>– undertaking the task of driving trains and forming part of the “train crew”,</li> <li>– undertaking tasks on-board (other than driving) and forming part of the “train crew”,</li> <li>– undertaking the task of preparing trains.</li> <li>– Infrastructure Manager’s staff undertaking the task of authorising the movement of trains</li> </ul> <p>Work performed by staff when they control or affect the movement of a vehicle, which could affect the health, and safety of persons.</p> <p>The directive 2007/59/EC implicitly considers ‘safety critical tasks’ those who contribute to “ensure the safety of the train and of the passengers and goods being transported”.</p> <p>Different definitions are used at national level. “Safety relevant” may be used with the same meaning.</p>
40	<b>Safety culture</b>	<p>“The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization’s health and safety management.”</p> <p>[Advisory Committee on the Safety of Nuclear Installations (ACSNI)]</p>
41	<b>Safety planning</b>	At the early stages of SMS design, an SMS implementation plan is necessary to ensure a consistent, focused and comprehensive approach to the development of the necessary organisational structure, processes and

		<p>procedures for safety management.</p> <p>In the delivery phase, plans enable the setting of organisation's safety objective and targets, as well as the identification of the necessary means and resources for their achievement.</p>
<b>42</b>	<b>Safety plans</b>	<p>A <i>safety plan</i> is a document that is used to specify the procedures and resources that will be needed to carry out a project, perform a process, realize a product, or manage a contract. <i>Safety plans</i> also specify who will do what and when. <i>(to be checked with activities in Safety Regulation Sector)</i></p> <p>[Adapted by ISO 9000:2005]</p> <p>The results of <i>safety plans</i> should allow the development of safety reports as required in Article 9(4)(a) of the Directive 2004/49/EC.</p>
<b>43</b>	<b>Safety recommendation</b>	<p>A proposal of the National Investigation Body of the State conducting the investigation, based on information derived from the investigation, made with the intention of preventing accidents or incidents.</p>
<b>44</b>	<b>Safety report</b>	<p>Legal requirement set by Article 9.4 of Directive 2004/49/EC. The safety report must be submitted yearly by railway undertakings and infrastructure managers and contains:</p> <ul style="list-style-type: none"> <li>(a) information on how the organisation's corporate safety targets are met and the results of safety plans;</li> <li>(b) the development of national safety indicators, and of the CSIs laid down in Annex I, as far as it is relevant to the reporting organisation;</li> <li>(c) the results of internal safety auditing;</li> <li>(d) (d) observations on deficiencies and malfunctions of railway operations and infrastructure management that might be relevant for the safety authority.</li> </ul>
<b>45</b>	<b>Safety reporting</b>	<p>In addition to legal requirements (afore-mentioned Article 9.4), safety reporting is a management tool for reviewing the SMS.</p> <p>Safety reporting allows the evaluation of the effectiveness of arrangements, through safety performance indicators (relevant CSIs plus others specifically identified), results of internal and external audit, analysis of events like accident / incident / dangerous occurrences</p>
<b>46</b>	<b>Staff involvement</b>	<p>We detect two converging view on understanding the concept of staff involvement, that subsume the principles of engaging support, understanding, commitment and contribution</p>

		<p>1. <u>The legal perspective, that is represented by the Directive 2002/14/EC:</u></p> <p><i>There is a need to strengthen dialogue and promote mutual trust within undertakings in order to improve risk anticipation, make work organisation more flexible and facilitate employee access to training within the undertaking while maintaining security, make employees aware of adaptation needs, increase employees' availability to undertake measures and activities to increase their employability, promote employee involvement in the operation and future of the undertaking and increase its competitiveness. (Whereas 7)</i></p> <p>2. <u>The human resources management perspective</u></p> <p><i>There are sound practical reasons for taking account of employee views before making significant decisions. They include an acknowledgement of the greater and more detailed knowledge that experienced employees may have of specific processes when compared with a manager who may be relatively new or who has never been involved at a working level with those processes. Changes may seem perfectly reasonable and desirable to the manager, operating at a distance from the activity to be changed. But skilled workers may be aware of implications that are invisible to the manager. [...] the concept of knowledge management is based on the value of individual expertise and experience which need to be harnessed and used for the benefit of the organization - rather than being ignored by over-confident and unwise managers.</i></p> <p>[<a href="http://www.hrsguide.co.uk/employee_relations/employee-involvement.htm">http://www.hrsguide.co.uk/employee_relations/employee-involvement.htm</a>]</p>
47	<b>Staff representatives</b>	<p>Equivalent to "employees' representatives" defined in Dir. 2002/14/EC, Art. 2 as '<i>the employees' representatives provided for by national laws and/or practices</i>'.</p> <p>"person chosen or appointed to represent and defend employees and their interests, especially those which operate at enterprise level".</p> <p>[European Foundation for the Improvement of Living and Working Conditions, Third European Survey on Working Conditions, Dublin 2001]</p>
48	<b>Suitably competent person</b>	<p>Person with the appropriate combination of skill, knowledge qualification and experience</p> <p>[source BS 8800:2004]</p>
49	<b>System</b>	<p>An integrated set of constituent elements that are combined in an operational or support environment to accomplish a defined objective. These elements include people, hardware, software, firmware, information,</p>

		<p>procedures, facilities, services, and other support facets.</p> <p>[FAA Advisory circular 120-92]</p>
50	<b>System-based approach</b>	<p>Industry has traditionally treated quality problems and errors as failings on the part of individual providers, perhaps reflecting inadequate knowledge or skill levels. The "systems approach," by contrast, takes the view that most errors reflect predictable human failings in the context of poorly designed systems (eg, expected lapses in human vigilance in the face of long work hours or predictable mistakes on the part of relatively inexperienced personnel faced with cognitively complex situations). Rather than focusing corrective efforts on reprimanding individuals or pursuing remedial education, the systems approach seeks to identify situations or factors likely to give rise to human error and implement "systems changes" that will reduce their occurrence or minimize their impact on workers. This view holds that efforts to catch human errors before they occur or block them from causing harm will ultimately be more fruitful than ones that seek to somehow create flawless providers.</p> <p>This "systems focus" includes paying attention to human factors engineering (or ergonomics), including the design of protocols, schedules, and other factors that are routinely addressed in other high-risk industries but have traditionally been ignored .</p> <p>[S2S _ BASIC PRINCIPLES OF SAFETY MANAGEMENT SYSTEM] Available at: <a href="http://www.safety-s2s.eu/">http://www.safety-s2s.eu/</a></p> <p>The term "System based approach", more commonly named "process based approach", refers to the possibility to manage and control the interaction between processes and the interfaces between the functional hierarchies of organisations.</p> <p>[ISO N544R2, "Guidance on the Concept and Use of the Process Approach for management systems"]</p>
51	<b>Type and extent of service</b>	<p>Character or 'Type' of service refers to:</p> <ul style="list-style-type: none"> <li>– passenger transport, including and excluding high-speed services,</li> <li>– freight transport, including and excluding dangerous goods services,</li> <li>– shunting services.</li> </ul> <p>'Extent' of service and of the railway undertaking is characterised by volume of passenger/goods and the estimated size of the railway undertaking in terms of employees working in the railway sector (micro, small,</p>

		medium sized, large enterprise). [Regulation 653/2007/EC]
52	<b>Validation procedure</b>	<p><i>Validation</i> is a process. It uses objective evidence to confirm that the requirements which define an intended use or application have been met. Whenever all requirements have been met, a <i>validated status</i> is achieved. The process of <i>validation</i> can be carried out under realistic use conditions or within a simulated use environment.</p> <p>A <i>procedure</i> is a way of carrying out a process or activity. <i>Procedures</i> may or may not be documented. However, Annex III(1) of RSD expects SMS is documented in all relevant parts.</p> <p><i>Documented procedures</i> can be very general or very detailed, or anywhere in between. While a <i>general procedure</i> could take the form of a simple flow diagram, a <i>detailed procedure</i> could be a one page form or it could be several pages of text.</p> <p>[Adapted from ISO 9000:2005]</p>
53	<b>(Verification of) competence of contractors or suppliers</b>	<p>The railway company should have procedures in place to manage contracts with contractors or suppliers providing products and services entirely through each phase, from the selection to the end:</p> <ul style="list-style-type: none"> <li>– to ensure that legal safety related requirements are met</li> <li>– to ensure that products and services meet the standards and specification for the safety of railway operation.</li> </ul> <p>A railway company using contractors or suppliers should and carefully consider clearly identify:</p> <ul style="list-style-type: none"> <li>– safety critical product(s) and service(s) to be procured, as well as relevant specifications</li> <li>– expected technical and/or operational performance;</li> <li>– the requirements that contractors/suppliers have to meet, like for instance: <ul style="list-style-type: none"> <li>– specific associated competencies;</li> <li>– tools to used;</li> <li>– reference laws, standards, rules, instructions, etc..</li> <li>– adequate and documented management system</li> <li>– awareness of risks imported on the company’s SMS</li> </ul> </li> </ul>



		<p>The derived applicable requirements should be included in the contracts between the two parties. Such contracts should also include:</p> <ul style="list-style-type: none"><li>a) responsibilities and tasks, relating to railway safety issues</li><li>b) the obligations related to the transfer of relevant information between both parties (including the reporting of non conformities)</li><li>c) the traceability of safety related documents</li><li>d) monitoring, audit and review arrangements</li><li>e) management of sub-contractors</li></ul> <p>Monitoring is the key activity for the continuous verification of competence of contractors/suppliers. The railway company should be able to verify the fulfilment of requirements:</p> <ul style="list-style-type: none"><li>– at the time of selection</li><li>– on a continuous basis (monitoring)</li><li>– periodically, during the validity of the contract (audit).</li></ul>
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