Railway Safety Commission

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Guideline for the Development of an SMS for Railway Undertakings and Infrastructure Managers

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Preface

Purpose

The purpose of this document is to provide guidance to Railway Organisations (Railway Undertakings and Infrastructure Managers) in Ireland on requirements for obtaining Safety Certification or Safety Authorisation from the Railway Safety Commission (RSC) based on assessment of their Safety Management System (SMS).

Scope

This document applies to the requirements for submitting documented evidence of a Railway Organisation's SMS to the RSC for conformity assessment as a pre-requisite to obtaining a Safety Certificate or Safety Authorisation.

Responsibility

The RSC Principal Inspector Assessment & Authorisation is responsible for the drafting, review and updating of this document.

This document will be updated on an as-required basis.

Revision History

Issue	Version	Section Number and Reason for Change

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1 Introduction

Article 4 of Directive 2004/49/EC (the Railway Safety Directive) clearly stipulates that the Railway Undertakings (RU) and Infrastructure Managers (IM) shall be made responsible for safe operation and, to fulfil this responsibility, it requires that they establish a Safety Management System (SMS).

It is a requirement under the Railway Safety Act 2005 (Section 39) that railway organisations "shall implement a safety management system and shall prepare a document describing the components of such safety management system."

The SMS implemented by the Railway Undertakings, and containing the characteristics and elements listed in Article 9 and Annex III of the Railway Safety Directive, must be assessed by the National Safety Authority (NSA), in this case the Railway Safety Commission (RSC) using the Common Safety Method (CSM) for assessing the conformity with the requirements for obtaining Safety Certificates as referred to in Article 6(3)(b) of the Railway Safety Directive. This particular CSM is defined in Regulation (EU) No 1158/2010/EU.

The SMS implemented by Infrastructure Managers, and containing the characteristics and elements listed in Article 9 and Annex III of the Railway Safety Directive, must be assessed by the RSC using the CSM for assessing the conformity with the requirements for obtaining Safety Authorisations as referred to in Article 6(3)(b) of the Railway Safety Directive. This particular CSM is defined in Regulation (EU) No 1169/2010/EU.

RUs and IMs must therefore document their procedures and arrangements in a manner that allows

- assessment prior to the delivery of the Safety Certificate or Safety Authorisation,
- supervision after the granting of the Safety Certificate or Safety Authorisation, and
- renewal of Safety Certificates or Safety Authorisation.

The respective CSMs for assessing conformity with the requirements for obtaining Safety Certificates and Safety Authorisations provide clear guidance on the adequate implementation of an SMS, with an inclusive view of Article 9 and Annex III of the Railway Safety Directive. In order to satisfy the requirement for a reference document that may be used by RUs and IMs to support the design and implementation of their SMS, the European Railway Agency (ERA) has published guidelines. The ERA guidelines are supplemented by the following:

'**Integration of management systems**', which provides explanations on the possibility to integrate different management system, such as 'quality', 'environment', 'occupational safety',http://www.era.europa.eu/tools/sms/Pages/Integration-of-management-systems.aspx

'**Internal audit**', which provides explanations on techniques and procedures for such activity, http://www.era.europa.eu/tools/sms/Pages/Internal-Audit.aspx

'**Railway experience literature**', which provides a list of texts to be used in developing an understanding of SMS as a whole and on the various elements, http://www.era.europa.eu/tools/sms/Pages/Railway-experiences-literature.aspx

'**SMS related terminology**' [*see* Annex II *to this document*], which provides literature examples to explain terms used in the Railway Safety Directive and the guidelines. Such terms are identified **in bold type and underlined** throughout this document

Terminology and texts refer to good practice and other documents available in the railway sector, in other **high reliability industries** (civil aviation, maritime, chemical, nuclear, etc.) and in wide-spread management systems such as quality, environmental protection, etc.

This guidance document, which the RSC has prepared based on the ERA guidelines, refers mainly to the afore-mentioned parts of the Railway Safety Directive, but also includes elements that give a wider scope of SMS. Such elements are put in the context, and liaise with the mandatory requirements contained therein. The document is organised as follows:

In addition to this Section, further introductory information is provided in Sections 2 and 3 which outline the purpose of an SMS and its scope and content. General guidance is provided in Section 4 which describes the legal basis, Section 5 outlines the basis of a system approach, and Section 6 explains the elements that form an SMS. These elements are elaborated in Section 7, processes for design and improvement; Section 8, processes for implementation; and Section 9, operational activities, and the description of each element is complemented by information on the texts where related mandatory requirement and ERA guidance can be found.

2 Purpose of the SMS

The overall 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, giving evidence that the organisation complies with all of the safety obligations that apply to it.

It is recognised that there are wide benefits of managing business in a structured way. It adds value helping to improve overall performances, introduces operational efficiencies, enhances relations with customers and regulatory authorities, and builds a positive **safety culture**.

For safety, adopting a structured approach enables the identification of hazards and the continuous management of risks related to an organisations own activities, with the objective of preventing accidents. When appropriate the SMS 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 assurance that it controls and will continue to control all the identified risks associated with its activities, under all conditions.

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 RSC issue Safety Certificates and Safety Authorisations.

Mature organisations recognise that efficient control of their 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, a good SMS succeeds in monitoring and improving the **risk control measures** in the three dimensions.

The implementation of an SMS is a legally binding obligation under Articles 4(3) and 9(1) of the Railway Safety Directive. This guidance document is based on the relevant content; however RUs and IMs must also consider all applicable national legislation when implementing their SMS. Nonetheless, there are also 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, **safety and health at work**, environmental protection and business excellence. Therefore principles of good management can be easily integrated and should not need a complete re-design of organisations that already have those systems in place.

3 SMS scope and content

Designing and implementing an adequate SMS is a challenging task and there are no simple answers.

This guidance, based on the guideline developed by ERA, is intended to support, through practical advice and suggestions, the design, implementation and delivery of a structured and organisation-wide railway SMS. The overall aim is to provide a tool for the ease of use by railway organisations and, at the same time, facilitate compliance with the legal requirements laid down in the Railway Safety Directive as listed in Section 4 (Legal basis). It is intended to be read in conjunction with the Railway Safety Directive and with all applicable railway safety related and national legislation.

NOTE: This document in itself is not mandatory; however requirements stipulated by the Railway Safety Directive are to be complied with.

In this guidance document, the following terms are used with the intent described, below:

'shall' indicates that a statement is mandatory. It is used only for direct quotation of the legal text.

'should' indicates a recommendation.

'may' indicates the existence of an option.

4 Legal basis

The legal basis for the implementation of an SMS by RUs and IMs is the Railway Safety Directive. The characteristic and the essential elements of the SMS are contained in Articles 2 and 9 and Annex III therein. Relevant parts of the Directive, in italics, have been abstracted:

4.1 Article 3(i) - Definitions

Safety Management System is defined as "the organisation and arrangements established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations."

4.2 Article 4(3) - Development and improvement of railway safety

Member States shall ensure that responsibility for the safe operation of the railway system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings,

obliging them to implement necessary risk control measures, where appropriate in cooperation with each other, to apply national safety rules and standards, and to establish safety management systems in accordance with this Directive.

4.3 Article 9 - Safety management systems

1. Infrastructure managers and railway undertakings shall establish their safety management systems to ensure that the railway system can achieve at least the CSTs, is in conformity with the national safety rules described in Article 8 and Annex II and with safety requirements laid down in the TSIs, and that the **relevant parts of CSMs** are applied.

2. The safety management system shall meet the requirements and contain the elements laid down in Annex III, adapted to the character, extent and other conditions of the activity pursued. It shall ensure the control of all risks associated with the activity of the infrastructure manager or railway undertaking, including the supply of maintenance and material and the use of contractors. Without prejudice to existing national and international liability rules, the safety management system shall also take into account, where appropriate and reasonable, the risks arising as a result of activities by other parties

3. The safety management system of any infrastructure manager shall take into account the effects of operations by different railway undertakings on the network and make provisions to allow all railway undertakings to operate in accordance with TSIs and national safety rules and with conditions laid down in their safety certificate. It shall furthermore be developed with the aim of coordinating the emergency procedures of the infrastructure manager with all railway undertakings that operate on its infrastructure.

4. Each year infrastructure managers and railway undertakings shall submit to **the safety authority** before 30 June an annual safety report concerning the preceding calendar year. The safety report shall contain:

(a) information on how the organisation's corporate safety targets are met and the results of safety plans;
(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;
(c) the results of internal safety auditing;
(d) observations on deficiencies and malfunctions of railway operations and infrastructure management that might be relevant for the safety authority.

4.4 Annex III - Safety Management Systems

4.4.1 Requirements on the safety management system

The safety management system must be documented in all relevant parts and shall in particular describe the distribution of responsibilities within the organisation of the infrastructure manager or the railway undertaking. It shall show how control by the management on different levels is secured, how staff and their representatives on all levels are involved and how continuous improvement of the safety management system is ensured.

4.4.2 Basic elements of the safety management system

The basic elements of the safety management system are:

(a) a safety policy approved by the organisation's chief executive and communicated to all staff;
(b) qualitative and quantitative targets of the organisation for the maintenance and enhancement of safety, and **plans** and procedures for reaching these targets;
(c) procedures to meet existing, new and altered technical and operational standards or other prescriptive conditions as laid down
- in TSIs, or
- in national safety rules referred to in Article 8 and Annex II, or
- in other relevant rules, or
- in authority decisions,
- and procedures to assure compliance with the standards and other prescriptive conditions throughout the life-cycle of equipment and operations;

(d) procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations;
(e) provision of programmes for training of staff and systems to ensure that the staff's competence is maintained and tasks carried out accordingly;
(f) arrangements for the provision of sufficient information within the organisation and, where appropriate, between organisations operating on the same infrastructure;
(g) procedures and formats for how safety information is to be documented and designation of procedure for configuration control of vital safety information;
(h) procedures to ensure that accidents, incidents, near misses and other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken;
(i) provision of plans for action and alerts and information in case of emergency, agreed upon with the appropriate public authorities;
(j) provisions for recurrent internal auditing of the safety management system.

5 A system approach

5.1 Content of the SMS

RUs/IMs should design their SMS in a manner to comply with requirements set out in Article 9 and Annex III of the Railway Safety Directive, as listed in following Sections.

A new RU/IM may design their safety related processes on the basis of elements described in this guidance document. An existing RU/IM may use the elements described in this guidance document to check correspondence with their own organisation, in order to inform decisions on necessary actions to ensure compliance with the above-mentioned requirements.

A railway organisation’s SMS, in common with the concept of management systems, should contain a description of safety related processes and procedures, all of which shall be capable of assessment

(on the basis of the CSM on assessing conformity with requirements for obtaining railway Safety Certificates / Safety Authorisations) and independent audits.

The table below shows the elements that together form an SMS. The elements **A** to **S** inclusive are common either to Railway Undertakings' or to Infrastructure Mangers' SMS.

Element	*RSD reference*	CSM ref
Risk control measures for all risks associated with the activity of the railway undertakings/infrastructure managers	***Article 9(2)***	**A**
Risk control related to the supply of **maintenance** and material	***Article 9(2)***	**B**
Risk control related to the use of contractor and control of suppliers	***Article 9(2)***	**C**
Risks arising from the activities of other parties external to the railway system	***Article 9(2)***	**D**
Documentation of the SMS	***Annex III(1)***	**E**
Distribution of responsibilities	***Annex III(1)***	**F**
Securing control by the management on different levels	***Annex III(1)***	**G**
Involving staff and their representatives on all levels	***Annex III(1)***	**H**
Ensuring continuous improvement	***Annex III(1)***	**I**
Safety policy, approved by the organisation's Board, accepted by the chief executive, and communicated to all staff	***Annex III(2)(a)***	**J**
Qualitative and quantative targets of the organisation for maintaining and enhancing safety, and plans and procedures for reaching these targets	***Annex III(2)(b)***	**K**
Procedures to meet existing, new and altered technical and operational standards or other prescriptive conditions	***Annex III(****2)(c)*	**L**
Procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operation	***Annex III(****2)(d)*	**M**
Provision of staff training programmes and systems to ensure that the staff competence is maintained and tasks carried out accordingly	***Annex III(****2)(e)*	**N**
Arrangements for provision of sufficient information within the organisation and, where appropriate, between organisations operating on the same infrastructure	***Annex III(****2)(f)*	**O**
Procedures and formats for documenting safety information, and designation of a procedure for configuration control of vital safety information	***Annex III(****2)(g)*	**P**
Procedures to ensure that accidents, incidents, near misses and other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken	***Annex III(****2)(h)*	**Q**
Provision of plans for action and alerts and information in case of emergency, agreed upon with the appropriate public authorities	***Annex III(****2)(i)*	**R**
Provisions for recurrent internal auditing of the safety management system	***Annex III(****2)(j)*	**S**

In conformity with Article 9(3) of the Railway Safety Directive, the SMS implemented by railway Infrastructure Managers shall contain some additional information that is required in order to relate to the following elements:

- effects of operations by different railway undertakings on the network;
- provisions to allow all railway undertakings to operate in accordance with TSIs and national safety rules and with conditions laid down in their safety certificate;
- co-ordination of the emergency procedures with all railway undertakings that operate on the controlled network.

5.2 Adoption of a system approach

The main purpose of an SMS, in accordance to Article 3(i) is "to ensure the safe management of operations of an RU/IM" in order to deliver the general requirements of Article 4 of the Railway Safety Directive, where the general concepts of continuous improvement, a **system-based approach** and the allocation of responsibilities are introduced. The system-based approach, also known as 'process-based approach' in the domain of management systems engineering, consists of:

- processes as interrelated activities which transform inputs into outputs,
- map of processes, including interactions, and
- a detailed description of processes and sub-processes.

Thus, the railway SMS can be identified as the sum of processes that contributes to the design, planning, delivery and control of operation, as part of a company business. It means that the SMS covers only core railway activities outlined by the Railway Safety Directive (for instance, it should not include activities like safety in station car parking areas, shops, etc.).

This Section describes a way to represent the processes according to their function:

- **design and improvement,**
- **implementation,**
- **operational activities**.

However, this Section is only for guidance and it is not intended to give a presumption of conformity with SMS requirements. The proposed model describes only one of many possible ways of clustering the processes. Each process can be seen, in itself, as an operational process, because it develops an output. RUs and IMs can use the above clusters as a reference to build their process maps and an SMS with interactions and defined responsibilities.

The following tables show how the different elements of an SMS are organised, and indicate their position in the main features of the design and improvement, implementation, and operational activities functions. The characteristics and elements that form an SMS are labelled throughout this guidance document on the basis of the numbering of the criteria listed in Annex II of the CSM on assessing conformity with requirements for obtaining Safety Certificates or Safety Authorisations.

Table 1 –Processes for design and improvement [Section 7]

		CSM ref
7.1 Leadership	7.1.1 - Management commitment	
	7.1.2 - Safety Policy	**J**
	7.1.3 - Corporate safety targets	**K**
	7.1.4 - Decision taking	
	7.1.5 - Management control	**G**
7.2 Risk Assessment	7.2.1 - **Control of risks** associated with the activity of the RUs/IMs	**A**
	7.2.2 - Risks arising from the activities of other parties (external to the railway system)	**D**
	7.2.3 - Procedures / methods for risk evaluation and implementation of risk control measures (change management)	**M**
	7.2.4 - Compliance with legislation, rules and standards	**L**
	7.2.5 - Co-ordination tasks for IM	**Art.9(3)**
7.3 Monitoring	7.3.1 - Data collection and analysis	**Q**
	7.3.2 - Accident/incident reporting and investigation	**Q**
	7.3.3 - Internal auditing	**S**
7.4 Organisational learning	7.4.1 - Continuous improvement	**I**
	7.4.2 - **Safety recommendations**	**Q**
	7.4.3 - Change management	**M**

Table 2 –Processes for implementation [Section 8]

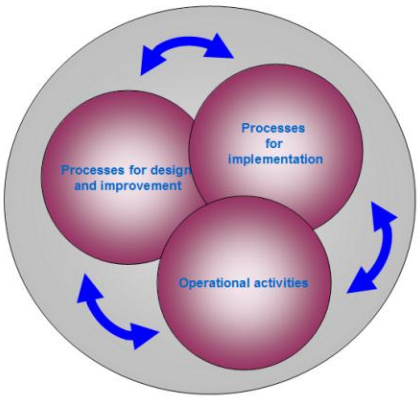
		CSM ref
8.1 Structure & responsibility	8.1.1 - Distribution of responsibilities	**F**
	8.1.2 - Management and supervisory accountability	**G**
	8.1.3 - Organisational structure	**E**
	8.1.4 - Workload planning	
8.2 Competence management	8.2.1 - Competence management system (training programmes for staff)	**N**
8.3 information	8.3.1 - Configuration control of safety information	**P**
	8.3.2 - Involvement of staff and their representatives	**H**
	8.3.3 - Internal/external communication	**O**
8.4 Documentation	8.4.1 - SMS documentation	**E**
	8.4.2 - Document management	
	8.4.3 - Annual **safety report**	**Art.9(4)**

Table 3 –Operational activities [Section 9]

		CSM ref
9.1 Operational arrangements and procedures	9.1.1 - Procedures to meet applicable rules for type of service delivered; Procedures to assure compliance throughout life-cycle of equipment and operation (delivery phase)	**L**
	9.1.2 - Use of contractor and control of suppliers	**B/C**
	9.1.3 - Asset management	
9.2 Emergency Plans	9.2.1 - Emergency management	**R**
	9.2.2 - Co-ordination tasks for IM	**Art.9(3)**

6 Elements

The system approach is represented here as a "big picture" encompassing all elements of the SMS in an interrelation of processes, grouped according to their function:



- processes for design and improvement [**Section 7**]
- processes for implementation [**Section 8**]
- operational activities [**Section 9**]

This approach is developed throughout this guidance document, as follows:

- The 3 groups are described and contain references to orient readers to the contained elements;
- Under the main features of the processes (design and improvement, implementation, operational activities) the elements of the SMS are listed and described;
- In order distinguish texts that contain mandatory requirements and to provide reference texts, a number of formatting styles have been used to make this document easier to use:
    - Boxed text at the end of specific elements, displayed on a grey background indicates related texts, containing mandatory requirements;
    - Boxed text displayed on a blue background indicates ERA guidance texts on such requirements.

7 Processes for design and improvement

Railway Undertakings and Infrastructure Managers need to ensure the control of the part of railway system that they are responsible for, mainly by setting arrangements in their organisations to:

- comply with safety requirements applicable to the railway system as a whole (TSIs, national requirements, etc.),
- identify specific risks related to their activity,
- identify, and manage future and local risks.

The governance of such organisations should be made of consistent arrangements, adoption of ad hoc policies, structured implementation and operational processes, and allocation of responsibilities for areas of activity.

Furthermore, organisations are dynamic and continuously evolving. Therefore there is a constant need to adjust and improve all SMS related processes to take account of experience and cater for future developments. To be able to do so, organisations need to ensure the design and control of the implementation and operational processes through effective **leadership [7.1]** and the involvement of staff.

Risk assessment [7.2] can help to anticipate future developments and threats such as potential disruptions, pressures and their consequences.

Unforeseen events, not identified when designing the risk control measures, may take place. Risk control measures can, because of a changing environment (external, e.g. new technologies, rules, standards, etc.; and/or internal, e.g. new or changing techniques, operational procedures, organisational structure, etc.), no longer fulfil the intended purpose. Additionally, changes in the general management arrangements and structure may impact on the SMS.

Monitoring [7.3] of both the performance of operational processes and of the business environment is necessary to identify latent system failures, which are those system elements that are or could become a threat in the near term. Monitoring supports the return of experience, which is an important complement for the continual reflection upon risks.

Furthermore, **lessons should be learned [7.4]** from operational incidents. This and the findings of audits, inspections, and all other relevant sources of information can be used to improve the system.

Finally, all these processes together are needed to provide the management of a company with the necessary input to take informed decisions about structural or functional changes of the SMS so that it is better prepared for what may happen in the future.

Obviously, for a good performance of these processes for design and improvement, it is necessary for the responsible staff and management also to know what to do, how to do it, and with timely knowledge of all relevant information to do so. This means that some processes for implementation also apply to all the processes for improvement, just like the principles of monitoring.

Processes for design and improvement:

- are intended to assure that desired objectives are met, to prevent problems from occurring or re-occurring and to adapt and improve in line with changing external and internal requirements,
- define how to accomplish tasks and how to evaluate and adapt them to the changing environment, allocating adequate **resources**.

7.1 Leadership

Strong and effective leadership ensures that safety objectives are set and prioritised (Plan), that practices are implemented to meet safety targets (Do), that the system effectiveness is constantly checked (Check) and that corrective and/or proactive measures are taken (Act).

7.1.1 Management commitment

The responsibility for leadership and for creating the environment of continuous improvement belongs to all levels of management, but particularly to the highest.

Senior management should be aware of how the success of the organisation, with respect to the safe operation of the railway system in a continuously changing internal and external environment, depends largely on the ability to monitor and continuously improve the effectiveness of risk control measures.

If senior management does not express informed, sustained commitment to safety as one of the primary business objectives, the commitment for safety in the field can easily shift towards other, sometimes conflicting, business objectives, particularly in less mature organisations.

Management commitment implies the direct participation by the highest level management in all specific and important safety aspects or programmes of an organisation.

The list below shows examples on how management commitment is delivered in practice, through a sequel of safety aspects and, in each case, the relevant connection to other elements of SMS that are dealt with in this guidance document:

- showing passion and interest for safety,
- formulating and establishing safety policy and objectives [ref. to **7.1.1** – safety policy],
- setting targets to improve or maintain safety and benchmarking performance against others in railway sector or other industries [ref. to **7.1.3** – corporate safety targets],
- providing resources and training [ref. to **7.2.1** – risk control and to **8.2.1** – competence management system],
- ensuring that all staff – including the Board – are sufficiently trained and competent in their safety responsibilities [ref. to **8.2.1** – competence management system],
- ensuring control at all levels of the organization [ref. to **7.1.5** – management control],
- regularly receiving information about safety, e.g. performance data (accidents, incidents, dangerous occurrences), and evaluating and reviewing the SMS in light of results achieved [ref. to **7.3** – monitoring],
- being aware of what is happening on the ground, and what audits or assessments are undertaken, receiving results related to the activities carried out internally or by contractors [ref. to **7.3.3** – internal auditing],
- ensuring appropriate Board level review of SMS,
- ensuring that all levels of the organisation, including the board, receives relevant safety information [ref. to **8.3.3** – internal external communication],
- being confident that the workforce are properly consulted on safety matters, and that their concerns are reaching the appropriate level including, as necessary, the Board ensuring that the organisation's risks are assessed, and that appropriate control measures are established and maintained [ref. to **8.3.2** – involvement of staff],
- creating an environment of continuous improvement [ref. to **7.4.1** – continuous improvement],
- bringing to the attention of the Board the changes in working arrangements that may have significant implications for safety [ref. to **7.4.3** – Change management],
- promoting safety culture.

Strong and active leadership is reinforced by visible, active commitment from the top:

- establishing effective 'downward' and 'upward' communication systems,
- establishing effective management structures,
- integrating of safety management with business decisions.

7.1.2 Safety policy

The safety policy expresses and reflects an organisation's commitment, obligation (mission) and strategic view (vision) on safety.

The Board's safety policy should be communicated and made available to all staff using the appropriate medium (formal communication, newsletter, intranet, etc.). It should include, *inter alia*, a declaration of intent and also provides indications on the overall direction for the organisation to follow, the general objectives of the SMS, as well as the necessary resources and activities required to deliver these objectives.

The safety policy should also reflect the following characteristics, thus giving evidence of the organisation's management commitment and providing staff with clear guidance for action to consolidate safety culture and safety awareness within the organisation:

- is developed by management and staff and signed by the highest level of the organisation,
- is appropriate to the nature and scale of the organisation's risks and contributes to all aspects of business performance as part of a demonstrable commitment to continuous improvement,
- outlines the principles and core values according to which the organisation and staff operate,
- pursues the development and improvement of working ethics,
- has the commitment and involvement of all staff,
- is aligned with other operational policies,
- states the responsibilities and accountabilities for directors, managers and employees.

In addition, the safety policy should aim at being reflected in the actions and decisions of all staff, and is expected to be reviewed periodically.

7.1.3 Corporate safety targets

Each RU/IM, within the framework of its own SMS, is expected to include the demonstration of its capability to achieve the organisation's corporate safety targets, which may require maintaining or enhancing its level of safety, in line with the other business objectives.

The corporate safety targets are to be considered as part of a continuous loop:

- they are set on the basis of past performance assessment (that may be the achievement of the previous organisation's corporate safety targets). They should be credible and achievable. Measurement of safety performance (collecting relevant safety data through routine checks arrangements, internal auditing and **safety reporting**) is part of monitoring [see Chapter **7.3** on monitoring];
- specific actions are planned and implemented, broken down to be managed at all relevant levels of the organisation (**safety planning**);
- the actions are monitored and their effectiveness is measured, (again, through routine checks arrangements, internal auditing and safety reporting) , focussing not only on the safety outcome but also on the effective performance of safety management activities;
- corporate targets are revised according the result of monitoring.

7.1.4 Decision taking

The SMS's processes are fully integrated into a **railway company's** business context. It is important that such companies can rely on robust decision making processes, in order to justify and trace operational safety related decisions.

Management decisions should take into account the direct or indirect impact on safety.

Processes should be transparent in order to understand how the final decision affecting safety was made. They are more effective when they include an understanding of:

- identification of safety issues within the business context (examples as 'budget reduction'),
- setting priorities,
- responsibilities at different level,
- methods available to address problems (analysis tools),
- the value of involving specialists, knowledge, skills and experience required,
- extent of consultation,
- output,
- related actions (plans, timescale, responsibilities for completion).

Therefore, failure to identify the impact of **other management activities** on safety, and to include safety as a key business risk in all Board decisions, could have catastrophic results.

7.1.5 Management control

In general, management control is a means by which an organisation's resources are directed, monitored, and measured. It aims at helping the organisation to accomplish, in the specific area of safety, its specific targets or objectives.

Control on all levels of the organisation, proportionately put over the appropriate delegated functions/staff, allows for the identification of flaws/faults in the SMS processes and therefore the possibility to implement **preventive** or **corrective actions**.

Therefore safety has to be effectively taken into account at every level of the organisation of the company, and any instances of malfunctioning must be detected and dealt with in good time.

For the top management it is therefore crucial, not only to ensure safety but also to fulfil its commitment and legal obligations to improve railway safety, to be aware of the results of performance monitoring and audits, and to take overall responsibility for implementation of changes to the risk control measures and relevant SMS processes.

The following activities may represent examples of how the management control is put into practice:

- Design, implementation and monitoring of the delivery of the SMS activities, including the necessary risk assessment and management of changes,
- Design of the organisational structure, in order to comply with regulatory framework and all applicable rules, and allocation of resources,
- Delegation of responsibilities, functions and tasks to appropriate levels of the organisation,

- Delegation of control tasks to the appropriate level of the organisation and development of a feedback loop,
- Development and monitoring of a safety policy,
- Development and monitoring of safety measures and projects that allows continuous improvement (taking into account costs),
- Promotion of continuous education and training for all level of the organisation, to foster employee attitudes, management beliefs and value system,
- Usage of management tools to address safety issues (i.e. problem solving tools and techniques),
- Benchmarking of performance results and processes,
- Balance between safety requirements and accessible resources,
- Improvement of managerial and technical processes,
- Integrating the customers' and suppliers' expectations,
- Carrying out internal audits and reviews on a continuous basis.

The above listed activities show how processes for design and improvement are strictly connected: management commitment, monitoring and control ensure a continuous loop for input and delivery of safe operation.

7.2 Risk assessment

Risk could impact basically three areas which are financial, time, or quality. Safety risks could appear, in shapes of hazardous events in all three areas, which could be connected to technical systems, human or organisational factors.

The responsibility for the safe operation of the railway system and the control of risks associated with it belongs to the infrastructure manager and the railway undertakings, obliging them to implement necessary control measures and to apply national safety rules and standards.

To achieve this, risk assessment (which is the overall process of risk analysis and risk evaluation) is a key element in any effective SMS.

7.2.1 Control of risks associated with the activity of the RU/IM

1. Risks related to activities carried out solely by RUs or IMs

To be able to control, under all conditions, the risks associated with their railway operations, RUs and IMs need to set up a framework to systematically analyse all risks directly arising from work activities, job design or workload and implement appropriate controls to protect the safety of those undertaking and or affected by the tasks.

This requires an identification of risks in a methodical way to ensure that all significant activities within the organisation have been identified and all the risks flowing from these activities defined. By estimating the consequence and probability of each of the identified risks, it should be possible to prioritise the key risks that need to be analysed in more detail.

When analysing such risks, the following elements should be considered:

(a) have a clear understanding of what work is involved;

(b) identify, analyse and evaluate the risks that are related to that work to be undertaken;
(c) identify ways of eliminating, mitigating or controlling those risks;
(d) set or approve specifications which detail the conditions to be fulfilled, including competencies of staff, exchange of safety related information (configuration, accessibility for review at all times, retention), data recording, etc.;
(e) implementation of a monitoring system to ensure that desired performance is achieved.

2. Shared risks (related to activities at interface)

An RU or IM should also recognise the need and have the commitment to co-operate, where appropriate, with other entities (RU, IM, manufacturer, maintenance supplier, entity in charge of maintenance, vehicle keepers, service provider, procurement entity, sidings, etc.) on issues where they have shared interfaces that are likely to affect the putting in place of adequate risk control measures.

When analysing such interfaces the following elements should be considered:

(a) have a clear view of the processes and interfaces between parties;
(b) have a clear understanding of what work the each party will undertake;
(c) identify, analyse and evaluate the risks that are related to that work to be undertaken;
(d) identify ways of eliminating, mitigating or controlling those risks (merely passing them onto others should not be a solution);
(e) set or approve specifications which detail the conditions that each party must ensure, including competencies of staff, exchange of safety related information(configuration, accessibility for review at all times retention), data recording, etc.;
(f) implementation of a monitoring system to ensure agreed performance is achieved. Such monitoring can be part of, or be integrated in an already existing to quality anagement system and should ensure that appropriate monitoring of performance is performed, corrective or preventive measures are identified and acted upon.

During the risk analysis process it is necessary to compare the estimated risks against risk criteria which the organisation has established.

Risk evaluation therefore, is used to make decisions about the significance of risks to the organisation and whether each single risk should be accepted or treated, by selecting and implementing measures (be it technical, human, organisational or any possible combination of these) to control the risk.

Reference to applicable legal text:
CSM on risk assessment: 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 (Official Journal of the European Union L 108/4 of 29/4/2009)

7.2.2 Risks arising from the activities of other parties

It is possible that **other parties**, external to the railway system, import risks onto a railway company (i.e. level crossing, pedestrian and bicycle crossings, road network, non-railway constructions, etc.).

In general, it can be said that for operating trains at level crossings, there are rules to be complied with at national and local level, and that is sufficient for RUs to operate in normal and degraded situations. However, there may be unexpected events that need to be analysed for ensuring that safety is maintained or improved.

It is more a task for IMs to consider the safety impact of activities carried out at the interface with other transport modes (roads, waterways) when designing or upgrading infrastructure.

In addition, working sites (either temporary or permanent) adjacent to controlled infrastructure may have impact on operation, and require the implementation of specific measures to ensure that safety is not lowered (see **7.2.5** on 'co-ordination tasks for IM).

In these cases, when analysing the interfaces with such external parties the following elements should be considered:

(a) have a clear understanding of what activity is undertaken by such party and how it may impact on the railway operation;
(b) identify, analyse and evaluate the risks that are related to that activities;
(c) identify ways of co-operating with the relevant stakeholders in order to eliminate, mitigate or control those risks (for instance, setting specific separations or establishing safe working procedures for workers and protection of customers);
(d) set or approve specifications which detail the conditions that the other party must ensure, including competencies of staff, exchange of safety related information (configuration, accessibility for review at all times retention), data recording, etc.;
(e) implementation of a monitoring system to ensure agreed performance is achieved. Such monitoring can be part of or be integrated into an already existing management system and should ensure that appropriate monitoring of performance is performed. As and when necessary, corrective or preventive measures are identified and acted upon.

Reference to applicable legal text:
CSM on risk assessment: 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 (Official Journal of the European Union L 108/4 of 29/4/2009)

7.2.3 Procedures and methods for carrying out risk evaluation and implementing risk control measures (change management)

Generally, a good level of safety is acknowledged across Europe, and the set of rules currently in force in the different countries are seen as the result of the 'historical memory' of the railway sector in the treatment of risks. Consequently, the fulfilment of safety requirements in force allow the

railway companies to operate without having to re-start risk assessment for the whole activity they perform.

However, compliance with requirements does not ensure safe operation forever: railway organisations must have a system in place to control changes/new projects and **manage related risks**, taking into account also those relating to occupational safety.

Changes can apply to

- technique/technologies;
- operational procedures/rules/standards (either internal and/or involving interfaces);
- organisational structure.

The SMS needs to ensure that the CSM on risk assessment, developed according to Article 6(3)(a) of the Railway Safety Directive, is applied where appropriate.

The procedures and methods are the tools to carry out risk evaluation; therefore they can be configured as key in the whole risk management process.

The involvement of different levels of the organisation and of the different expertise (economical, technical, and organisational) within a railway company is bound to provide an important source of organisational learning [see also **7.4.3**].

Reference to applicable legal text:
CSM on risk assessment: 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 (Official Journal of the European Union L 108/4 of 29/4/2009)

7.2.4 Compliance with legislation, rules, and standards

Compliance with legislation and rules is not optional. RUs and IMs must identify and understand the applicable laws and all other relevant standards and prescriptive conditions and must implement a system of controls to achieve compliance.

The regulatory framework may include different documents such as TSIs and linked technical standards, national safety rules, as referred to in Article 8 and Annex II of the Railway Safety Directive, and other relevant rules, applicable at national level.

Therefore, it is crucial that all safety related procedures and processes of the SMS are:

- designed to comply with the regulatory framework and updated to take into account any variation or addition;
- consistent with **type and extent of services** operated by the organisation;
- consistent with relevant organisation changes.

To ensure this, an SMS should have a process/procedure in place to promptly identify, gather and list, relevant requirements contained in TSIs, national safety and technical rules and internal rules/procedures for:

- each individual category of staff,
- each type of rolling stock,
- safety equipment (personal protection equipment – PPE - and collective protection equipment –CPE),
- other equipment (on board, on the ground, devices used for rolling stock and track maintenance).

Variations/additions in this regulatory framework should be promptly detected and recognised.

For maintenance processes, organisations must comply with all legal requirements and relevant specifications, standards and requirements throughout the entire life cycle of equipment and operations.

7.2.5 Co-ordination tasks for the IM

The SMS of an IM is, compared to that of an RU, more sensitive to number, type and extent of operators running services on its network. As interactions between railway partners increase, the SMS of an IM should reflect the appropriate and updated level of complexity of services it provides. Some examples of infrastructure related and operation related activities that should be considered as interfaces to be managed by the IM are listed below:

a) Infrastructure related

- infrastructure maintenance (tracks, signalling, telecommunications, overhead lines), ensuring that train movements and maintenance activities can be performed without endangering passengers, workers, third persons and assets (either carried out internally or outsourced);
- protection from other transport modes' interfaces (crossings, bridges, sidings);
- safety of tunnels;
- safety of persons working (for track, signalling or overhead lines maintenance) on or adjacent to **railway premises** (for construction sites or other reasons);
- communication of infrastructure related information that may affect traffic: requirements, permanent / temporary restrictions, adoption of degraded mode procedures, alerts, etc.).

b) Operation related

- train movement control or authorisation, in normal and degraded situation for all RUs operating on the controlled infrastructure;
- interface with neighbouring IMs (to ensure continuity of service at national and international level);
- access to marshalling yards, freight terminals, private sidings;
- shunting (operating directly or supervising undertakings operating on the controlled infrastructure);

- exchange of operational information with RUs in case of rolling stock failures that may have an impact on the scheduled operation;
- control of activities in the passengers stations, including the control of passengers and public access, specific provision for persons with reduced mobility and availability, lighting and conditions of platforms. These issues are limited to areas that are functional to the core railway related activities such as, access to the track area, platforms for boarding and alighting from trains.

c) Emergency related

- protection of passengers in case of an accident;
- exchange of information with all **interested parties** in case of emergencies and service disruptions;
- clearance of the affected tracks after accidents or disruptions.

7.3 Monitoring

Systematic monitoring should provide assurance to managers and stakeholders that all identified risks are effectively controlled and evidence that the SMS requirements are being met. It provides the basis for defining any action needed to improve or maintain the targeted level of safety.

7.3.1 Safety data collection and analysis

In order to ensure that risk controls are applied and work in practice, an organisation needs to measure the level of application of these controls and their results. The collection of safety data and the subsequent analysis allow the organisation to measure its overall performance, understanding where there are deficiencies in all SMS arrangements.

The collection of safety data is based on monitoring and should consider the following elements:

- structured reporting of accidents / incidents / near misses / dangerous occurrences;
- inspection findings (it could be for detecting non-compliance with operational arrangements and/or concerning the state of infrastructure or equipment);
- audit results (mainly at design and implementation process level).

To make this data collection possible, an organisation must ensure that the information or the unit of measurement for the specified indicator is available or can be established. In addition, a periodic evaluation of the scope and viability of indicators and tolerance levels is required.

The scope of data analysis should include the detection of:

- any deviance from expected outcomes (using lagging indicators);
- process anomalies (using leading indicators).

'Lagging' indicators measure the final outcomes that result from an activity. Lagging indicators like the number of accidents and incidents, demonstrate if a "safe" result is delivered. In a performance measuring system they allow the comparison with historical data, demonstrating at the same time the quality of results (e.g. improvement or worsening) and the possibility to be used in a predictive sense (e.g. the increasing number of signals passed at danger may be the precursor of a collision).

However, to have a complete picture on the effectiveness of the risk control measures a selection of leading indicators needs to be compared with set levels of tolerance. These leading indicators are mainly based on proactive monitoring of the critical elements of risk control measures (i.e. those actions or processes which must function correctly to deliver the desired outcome), but also elements of the environment and/or assumptions made when designing the risk control measures (mainly during the risk assessment process) could be part of these critical elements.

'Leading' indicators are used to monitor the effectiveness of control systems and give advance warning of any developing weaknesses before problems occur.

Some examples of leading indicators are:

- % of inspections completed to plan,
- % of maintenance actions identified by inspections carried out to timescale,
- % of staff carrying out actions without required competency,
- % of safety critical processes reviewed to timescales.

Reference to applicable legal text:
Commission Directive 2009/149/EC of 27 November 2009 amending Directive 2004/49/EC of the European Parliament and of the Council as regards Common Safety Indicators and common methods to calculate accident costs

CSM on monitoring: Commission Regulation (EU) No 1078/2012 of 16 November 2012 on the adoption of a common safety method for monitoring to be applied by railway undertakings and infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance (Official Journal of the European Union L 320/8 of 17/11/2012)

7.3.2 Accident and incident reporting / investigation / analysis / preventive and corrective measures

Internal accident and incident investigation provides the organisation with a reactive review of the performance of risk control measures and related processes of the SMS (lagging indicators). Therefore not only the immediate causes but also underlying causes are to be systematically investigated.

Standardised arrangements for when and how an investigation is carried out include:

- procedures for internal and external accident and incident notification and reporting;
- procedures, formats and approaches (e.g., site protocol) for investigations, eventually differentiated according to the nature of the accident (e.g., environmental, employee injuries, transportation of dangerous goods);
- procedures for reporting and documenting findings, conclusions and recommendations;
- procedures for reviewing risk control measures after an accident or incident, and for ensuring implementation of recommendations and preventive or corrective actions in order to prevent a recurrence.

Organisations should encourage the reporting of incidents and dangerous occurrences and also establish accountability during its investigation. The scope of incidents investigated includes process anomalies (leading indicators) and deviance from expected outcomes (lagging indicators) where appropriate.

The railway companies should ensure that the staff appointed for internal investigation is competent and duly trained for the scope of the investigation to be carried out.

The railway companies should co-operate if an investigation involves more than one organisation.

Reference to applicable legal text:
Commission Directive 2009/149/EC of 27 November 2009 amending Directive 2004/49/EC of the European Parliament and of the Council as regards Common Safety Indicators and common methods to calculate accident costs

Read more on:
ERA - Classification of causational factors SAF/REP/CL_CAUS_FACT – Method V2 24/04/2009

7.3.3 Internal auditing of the SMS

As a general principle, **internal auditing** serves the purpose of **periodically reviewing the management systems**. In particular, **the internal safety audit** should assess if the procedures described within the SMS ascertain that the services of the RU/IM comply with relevant requirements and that all SMS processes are still effective.

RUs/IMs should establish an **internal auditing system**, including planning of internal audits to be carried out in order to fulfil the requirements specified in Article 9(4) on reporting to the RSC.

Auditors carrying out internal SMS auditing must be competent and experienced in the field/matter they are assessing and also skilled and adequately prepared and trained to perform audit activity.

Audits should be carried out in an impartial, independent and transparent way: auditors should be independent from the organisational unit being audited and conflict of interest between the assessing and the assessed party should be avoided.

Reference to applicable legal text:
CSM on monitoring: Commission Regulation (EU) No 1078/2012 of 16 November 2012 on the adoption of a common safety method for monitoring to be applied by railway undertakings and infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance (Official Journal of the European Union L 320/8 of 17/11/2012)

7.4 Organisational learning

The effective SMS should rely on a continual, structured and documented reflection upon practice through monitoring performance, analysing data and results and establishing a feedback system to continuously improve its safety performance, culture and attitude.

7.4.1 Continuous improvement

Continuous improvement is mainly related to activities where ideas from improvements have been suggested and acted upon, e.g.

- auditing results,
- outputs from inspections,
- output from accident reports,
- research,
- ad hoc ideas contributed from personnel,
- new legislation, etc.

In order to be effective and support decision-making, a continuous improvement process must cover and extend to all relevant phases of an organisation's SMS, e.g.:

- planning of preventive/corrective actions,
- their implementation on an adequate scale,
- assessment/monitoring/verification of their effectiveness,
- enforcement, review and revision of plans and risk control arrangements.

In combination with appropriate statistical tools to analyse data, this must ensure that all processes are periodically revised in a systematic way. The most common representation of this cyclic activity is the 'Plan–Do–Check–Act' management circle, or 'Deming' cycle.

Improvements should be assessed to ensure they are reasonable to be carried out. The assessment should take into account wider operational and business benefits.

7.4.2 Safety recommendations

The development of organisational learning is strongly related to the analysis of an accident / incident / dangerous occurrences based on external and internal reporting as well as on internal audit results. Such analysis is important for the review of unsafe conditions and process disruption, and is part of the basic elements to derive planning of reactive or proactive measures.

A safety recommendation in terms of the Railway Safety Directive (Directive 2004/49/EC) is a proposal of a National Investigating Body (NIB), in this case the Railway Accident Investigation Unit (RAIU), to improve railway safety, based on the results of the investigation of one or more accidents or incidents.

Relevant recommendations from the RSC or RAIU (the latter are addressed via the RSC, to all of the sector and not the individual actor) following accident investigations should be evaluated, in the context of the monitoring system, and implemented if appropriate. Also relevant reports/information from RUs/IMs and keepers or other relevant sources should be considered and taken into account.

7.4.3 Change management

Change management is the process to control changes in existing and new projects by identifying potential hazards and defining appropriate control measures before the implementation of a change.

This process should be carried out during consecutive steps of the project:

- identification of the need for change (e.g.: after analysis of safety data, optimisation of resources, obsolescence of equipment, etc.);
- determining feasibility;
- design;
- planning.

The above mentioned elements of the process are expected to support the implementation of changes: the identification of the need for change, the determination of feasibility and the design of the change are mainly management driven activities, whilst planning is more a process for implementation. The final aim is to give evidence that such changes do not decrease the level of safety in the system, and enabling traceability of implemented changes.

The organisation as a whole should rely on the change management process to identify changes within the organisation which may affect established safety related processes and services:

- to describe the arrangements to ensure safety performance before implementing changes;
- to eliminate or modify safety risk controls that are no longer needed or effective due to changes in the operational environment.

When additional risk control measures are to be implemented, relevant intermediate steps need to be identified and the level of implementation needs to be measured. In each case, the change management has to be carried out taking into account the CSM for risk assessment.

Reference to applicable legal text:
CSM on risk assessment: 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 (Official Journal of the European Union L 108/4 of 29/4/2009)

8 Process for implementation

To make the sometimes very complex design and operational processes work effectively, there is a need for a set of processes for implementation. They should serve to implement activities and to assure that such activities are being carried out and that results are obtained.

In this context, people need to know what their role in the system is and what they're responsible for. Therefore, the **structure [8.1]** has to include identification of responsibilities and, where appropriate, the assignment of functions and activities to staff.

They also need to have the **knowledge and skills [8.2]** to know what to do in all circumstances and at all times they need to have all relevant **information [8.3]** available in an adequate form.

Resource management, and in particular the suitable professional competence and health requirements to perform **safety critical or safety related tasks** (the terms are used quite interchangeably) is a key factor for delivering safe operations.

Processes for implementation underlie and ensure **documentation [8.4]** of all operational and processes for design and improvement, since they are necessary to implement them efficiently and therefore to run the business.

8.1 Structure and responsibility

The SMS should be based on a clear distribution of responsibilities and on adequate human and technical resources, in order to deliver safe operations.

8.1.1 Distribution of responsibilities

Each RU/IM should clearly identify and define the areas of responsibility related to railway safety, in order to allocate them at the **appropriate level**, within their organisational structure, to associated staff and/or specific functions.

Delegation of responsibilities and safety tasks should be formal and approved by the senior/top management and by the staff member responsible for the specific function and safety task [i.e. Safety Responsibility Statements]. An organisation needs to ensure that staff with delegated responsibilities have the authority, competence and appropriate resources to fulfil their function. Therefore, responsibility and competence should be coherent and compatible with the given role/task.

Clear authorities, roles, tasks and objectives for safety at all levels in the railway company have an important part in the design and implementation of an SMS by ensuring that staff at all levels take responsibility.

8.1.2 Management accountability

An organisation needs to ensure that those given roles, tasks and objectives in safety management are **accountable** for delivery of the business safety objectives for which they are responsible (i.e. Job Descriptions).

Adequate supervision in line with monitoring mechanisms compliments the provision of information, instruction and training to ensure that the safety policy of an organisation is effectively implemented and developed. Good supervision regimes can form a powerful part of an SMS.

8.1.3 Organisational structure

The organisational structure of RUs/IMs should be appropriate to deliver the safety policy and safety approach of the organisation, so that:

- risk controls fit sensibly into the management structure (the design of the structure should cover all internal and external interfaces);

- responsibility for and delivery of (possibly conflicting) business objectives in a safe manner are transparent and effectively deal with interfaces;
- resources are effectively allocated;
- safety related information reaches the highest level of the organisation, so that they can be considered when decisions are taken.

8.1.4 Workload planning

Good planning of activities will significantly improve the way that organisations manage safety, by providing sufficient and right (human and technical) resources to complete tasks.

The SMS may benefit by having procedures for estimating the necessary resources that the company will need:

- to operate and maintain its railway operations;
- to implement, manage and maintain its SMS as a whole;
- for the preparation of plans to ensure adequate assignment and workload.

Such processes would be expected to be part of the normal business planning cycle over time, and should be subsequently reviewed to ensure that resources are being appropriately managed. This will lead to effective risk control as well as to efficient operation.

When work to be assigned to each staff category includes execution of safety-critical tasks, the **job-design** shall take into account the following:

- that the volume of tasks to be completed is not excessive at times when a safety-critical task is being carried out;
- where safety-critical tasks are combined the RU is able to demonstrate that there is no worsening of safety. For example:
    - there is no requirement for independence of the tasks,
    - the combination is permitted by national safety rules,
    - the combination contains no “functional” contradictions;
- there are no contradictions between execution of safety-critical tasks and other objectives assigned to staff (for example: systematic conflict between safety and production, lack of resources, etc.).

8.2 Competence management

A railway organisation must ensure that all staff with a responsibility in the SMS is competent to ensure a safe, effective and efficient delivery of its objectives, in all circumstances, and that staff skills and knowledge are maintained.

8.2.1 Programmes for training of staff – competence management system

As far as is not covered by specific legislation, a competence management system should include:

- the identification of posts that have responsibilities for performing operational, implementation and processes for design and improvement in the SMS, including those posts that perform safety tasks;
- identification of knowledge, skills and experience required to perform these processes / tasks;

- the selection principles (required basic educational level, attitude, psychological welfare and physical fitness);
- the initial training;
- the certification of acquired competence and skills;
- the necessary measures to maintain the competence of staff;
- the on-going training and periodical update of existing knowledge and skills, to ensure that staff are constantly competent for performing the assigned tasks;
- proficiency checks, as required;
- specific measures in case of long absence from work, as required.

It is also important that the competence management system aims to ensure that all staff are aware of the relevance and importance of their activities and how they contribute to the achievement of the safety objectives. Senior management/top team and, in general, supervisory roles should be trained in understanding their safety responsibilities.

Reference to applicable legal text:

DIRECTIVE 2007/59/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community

Commission Decision 2008/231/EC - Technical specification of interoperability relating to the operation subsystem of the trans-European high-speed rail system adopted referred to in Article 6(1) of Council Directive 96/48/E and repealing Commission Decision 2002/734/EC of 30 May 2002

Commission Regulation 36/2010/EU of 3 December 2009 on Community models for train driving licences, complementary certificates, certified copies of complementary certificates and application forms for train driving licences, under Directive 2007/59/EC of the European Parliament and of the Council.

Commission Decision of 29 October 2009 on the adoption of basic parameters for registers of train driving licences and complementary certificates provided for under Directive 2007/59/EC of the European Parliament and of the Council (2010/17/EC)

Commission Decision 2006/920/EC of the 11 August 2006 concerning the technical specification of interoperability relating to the subsystem traffic operation and management of the trans-European conventional rail system

8.3 Information

Organisations must define information control procedures, based on existing management systems. Safety information must be readily available for consultation and/or verification. The necessary flow of internal and external information have to be identified and acted upon.

8.3.1 Configuration control of safety information

Measures to control vital safety information (**configuration control**) are important to maintain and improve safety performance within an organisation. The availability of correct information enables awareness and allows for corrective actions to be taken promptly and efficiently.

There are several types of information to be managed, with a different degree of criticality for operations:

- operational urgent information concerning train movements, such as late notices, temporary speed restriction, dangerous goods, hauled load, etc.;
- operational safety information/documentation, such as braking sheet, train schedule, etc.;
- operational permanent information documentation such as rules books or route books, permanents safety orders, etc.;
- more general SMS information (feedback of experience, **staff involvement**, minutes of meetings, etc.).

The elaboration, transmission, archiving requirement and processes may be different for the listed types of information. As a general principle, organisations should ensure that key operational information is:

- relevant and valid,
- accurate,
- complete,
- appropriately updated,
- controlled,
- consistent and easy to understand (incl. the language used),
- staff are aware of its existence before it must be applied,
- easily accessible to staff and where required copies are formally given to them.

A method to format and generate controlled documents which provides appropriate fields for:

- unique identification number,
- date,
- responsible person for preparation,
- responsible person for authorising the release (of the original document and of the following revisions),
- list of revisions.

8.3.2 Involvement of staff and staff representatives

Within any organisation, involvement of staff is a key element in developing a safety culture, gaining staff confidence and encouraging cooperation, support and acceptance.

The involvement of staff in the implementation of an SMS is crucial for the development, maintenance, and improvement of a strong safety culture within the organisation.

Employee and **staff representative** consultation during drafting of the company safety policy is recommended. A collaborative approach will help ensure that significant employee concerns are

addressed in the policy and will provide an additional vehicle for communicating the railway's commitment to safety to employees.

Employees and their representatives should also be consulted in setting annual safety targets and identifying the associated safety initiatives.

Consulting with employees and linking the target-setting process with the risk management process will help ensure that the most significant outstanding safety issues and concerns are addressed.

Employees and their representatives can make important contributions to each step of the risk assessment process that should include mechanisms for employees to identify safety issues and concerns on a routine and on-going basis. These mechanisms should have a high level of visibility and participation to ensure that all risks are captured. Employees and their representatives should also be involved in the development of risk control strategies, particularly for risks that they have identified.

Employees should be informed of actions that are being taken or that are planned to address the safety issues and concerns they have identified. Feedback is essential to ensure continued participation.

8.3.3 Internal / external communication

Organisations cannot operate without communication. Communication can take various forms but all forms involve the transfer of information from one party to others.

Communication processes in place within the organisation allow the SMS to function effectively. The exchange of relevant safety information is crucial within and among organisations.

It is therefore important that defined reporting channels and interfaces exist, within a structured process, to ensure that knowledge and understanding of the SMS is ensured and all safety relevant information [ref. to **8.3.1** on configuration control of safety information] is conveyed to or available for the right person/role/function in a prompt and clear way.

Internal communication refers to all levels of an organisation, for instance:

- staff involved in SMS design, implementation and delivery,
- staff involved in operational and organisational arrangements and changes,
- operational staff.

There are three interrelated methods for communication within an organisation:

(i) Visible Behaviour
(ii) Written Communication
(iii) Face - to - face discussion

Managers may wish to acknowledge and, if possible, remove barriers to communication. Examples of obstacles or barriers include illiteracy, language differences, reprisals (supervisory and/or peer), or other forms of discrimination. Incentive programs, drug testing programs, and disciplinary mechanisms should be carefully designed and implemented to ensure that employees are not discouraged from reporting job-related injuries, illnesses, hazards, and risks.

External communication refers to safety aspects that may be relevant, but not limited, to:

- other companies operating on the same infrastructure (RUs, IMs, maintenance providers, service providers, etc.),
- suppliers / contractors,
- customers,
- regulatory agencies (e.g.: NSAs),
- other stakeholders (users, neighbours, other authorities).

Information may especially pertain to known hazards that need to be controlled by others.

Good two way communication is also essential because it supports the development of a positive safety culture.

8.4 Documentation

Processes and procedures describing activities, having direct and indirect effects on railway safety, are relevant parts of the SMS, both at an organisational and operational level and should be duly documented to ensure traceability.

8.4.1 SMS Documentation

SMS documents must be promptly and accordingly updated in case of relevant technical, operational and organisational changes, even if they do not affect operational safety directly.

The documentation needs to ensure the traceability of SMS processes. Up-to-date and consolidated documentation describing the characteristics and elements of the SMS should exist.

A formal document on SMS is to be submitted by Railway Undertakings applying for a Safety Certificate Part A (new, renewed or updated/amended): the 'Summary of the Safety Management System (SMS) manual'. The document underlines the main elements of the railway undertaking's SMS. It must detail and give supporting information and evidence of the different processes or company standards/rules implemented (or in the phase of implementation), cross referencing or linked to the items identified in Article 9 and Annex III.

Similarly, the IM should submit its SMS manual when applying for a safety authorisation [see Regulation on CSM for assessing conformity of safety authorisation, Annex I, 3(e)].

In addition to the manual, a set of procedures is requested. A procedure is the specified way to perform a task.

Reference to applicable legal text:
Commission Regulation (EC) No 653/2007 of 13 June 2007 on the use of a common European format for safety certificates and application documents in accordance with Article 10 of Directive 2004/49/EC of the European Parliament and of the Council and on the validity of safety certificates delivered under Directive 2001/14/EC

8.4.2 Document management

Processes and procedures describing activities, having direct and indirect effects on railway safety, should be considered as relevant parts of the SMS, both at an organisational and operational level.

The following documents pertaining to an SMS need to be considered:

- safety manual referred to in Regulation 653/2007/EC;
- procedures listed in Annex III of the Directive 2004/49/EC and other procedures applicable at company level;
- **safety plans** / reports;
- audit and monitoring results;
- documents related to implementation of corrective/preventive actions;
- any other operational document that is necessary to ensure compliance with applicable rules (rule books, route books, safety orders, etc.), including all operational information described in **8.3.1** "configuration control of safety information";
- applicable standards;
- any other technical document that is related to life-cycle of equipment and operation and with risk analysis.

For SMS documentation the following principles should be applied:

- format, preparation, distribution and control of changes should be defined beforehand,
- the documents should be regularly monitored and updated,
- all relevant documentation should be collected and stored/archived.

8.4.3 Annual safety report

The annual safety report is a summary of information that the RU/IM must provide to the RSC, in conformity with Article 9(4) of the Directive 2004/49/EC.

The annual safety report includes:

(a) information on how the organisation's corporate safety targets are met and the results of safety plans;
(b) the development of national safety indicators, and of the CSIs , as far as it is relevant to the reporting organisation;
(c) the results of internal safety auditing;
(d) observations on deficiencies and malfunctions of railway operations and infrastructure management that might be relevant for the safety authority.

It is important to note that:

- "organisation's corporate safety targets" are not directly connected to 'Common Safety Target' that are set at Member State level. The corporate targets may tend to improvement or maintaining safety performance, resulting from the analysis of past performances;
- "safety plans" are documents containing a list of actions with expected result, relevant timeframe and allocation of responsibilities, identified in order to pursue improvement in performance or maintaining of an adequate level of safety;

- "national safety indicators and the Common Safety Indicators (CSIs)" are the set of data to be collected in order to evaluate a railway company's safety performance. CSIs are established at EU level, gathered by the NSAs and transferred yearly to ERA on the basis of Article 18 of the Directive 2004/49/EC. National indicators are collected at Member State level and may complement CSIs. Railway companies collect data according to their area of activities (freight/passengers, only freight, only passengers) and the relevance to it.

Information submitted is relevant both for NSAs and RUs/IMs to evaluate how effective an SMS is within the reporting organisation.

9 Operational activities

Operational activities form the core of a company by creating, producing and delivering the products and services that customers want - taking into account primary business objectives like safety, from initial planning to conform to applicable requirement to maintenance and operation. Safety is one of the primary objectives and so safety and safety measures should be embedded in operational related processes.

The risk control measures - be it technical, human, organisational or every possible combination of these - are an integral part of the operational activities. They are built into the system to enable it to deliver normal operations and respond adequately to regular and irregular disruptions and disturbances, e.g. by adjusting its functioning to better match the new conditions, by mitigating the effects of an adverse event, by preventing a further deterioration or spreading of events, by restoring the state that existed before the event, etc.

Operational activities should ensure that the service is delivered in compliance with applicable rules.

Typical operational processes include:

- traffic planning,
- traffic management in normal and degraded situation (it includes control-command system and equipment),
- train preparation,
- train driving in normal and degraded situation,
- infrastructure (track and signalling) maintenance,
- rolling stock fitness for operation.

Such operational arrangements and procedures [**9.1]** should take into account normal and degraded situations, as well as emergencies [**9.2**].

Although the Technical Specifications for Interoperability (TSIs) are applicable only to a limited part of the European railway network, they can provide detailed reference for the description of operational processes:

- Commission Decision of 1 February 2008 concerning the technical specification of interoperability relating to the operation subsystem of the trans-European high-speed rail

system adopted referred to in Article 6(1) of Council Directive 96/48/EC and repealing Commission Decision 2002/734/EC of 30 May 2002 (2008/231/CE)

- Commission Decision of 11 August 2006 concerning the technical specification of interoperability relating to the subsystem 'Traffic Operation and Management' of the trans-European conventional rail system(2006/920/EC) and relevant amendments [this document is currently under revision]

Important: such technical specifications do not cover all ranges of operational arrangement. Sole compliance with them does not ensure safe operation.

The use of processes for implementation on a continuous basis ensures that each operational activity is performed as it was intended to.

The following table shows that operational processes need processes for implementation to implement their key activities concerning: technical equipment, staff, and operational procedures.

	Initial conformity to legal safety requirements	**Maintenance of conformity**	**Operational management of resources**
Technical equipment	Infrastructure (structures, track, and CCS equipment) have been put into service. Rolling stock has been put into service (it has achieved technical acceptance and registration).	Infrastructure and rolling stock is duly maintained.	Applicable requirements (e.g. route book) are fulfilled on a day by day basis. Rolling stock is fit for operation and trains are prepared for running.
Staff	Staff is adequately trained and, when necessary, certified (initial training). Medical & psychological requirements have been checked.	A continuous follow-up, (including evaluation of knowledge, skills, and competence, and medical condition) and refresher training is adopted for all safety related tasks.	Possession of the necessary competencies for the task and compliance with labour law.
Operational procedures	A prior identification of applicable requirements with respect to the IM's/RU's field of activities is carried out. Documents are exhaustive and support compliance.	Documents (Rule books, route books, instructions, safety orders, protocols, etc.) are constantly updated.	Circulation of documents, ensuring that each staff member has the right documentation at the right time.

9.1 Operational arrangements / procedures

9.1.1 Procedures to meet applicable rules – Procedures to assure compliance throughout life cycle of equipment / operation (delivery phase)

RUs / IMs should carefully reflect upon the elements that are to be considered when delivering safe operation, as far as compliance with applicable rules, suitability of rolling stock and professional competence of staff is concerned.

The following list contains some operational processes in the railway sector:

- processes related to train movements,
- processes related to operation of safety installations and equipment,
- processes related to operation of power supply installations,
- track and equipment maintenance,
- control command system and telecommunication maintenance,
- power supply installations maintenance,
- maintenance of civil engineering,
- management of infrastructure and equipment,
- assignment and use of rolling stock and equipment,
- rolling stock and equipment maintenance,
- exchange of information with keeper or Entity in Charge of Maintenance (ECM),
- inspections (prior to departure and during journey).

Staff performing safety related tasks should receive instructions with the following characteristics:

- Exhaustiveness: all the rules and requirements relevant to safety tasks relevant to the operation of the RU are identified and transcribed in the document,
- Preciseness: each of the rules and requirements are correctly transcribed without error (for example: behaviour to adopt before a signal, safety related communication texts, etc.),
  Consistency: the requirements applying to a single person or a single team from different sources are compatible and consistent. They do not come into conflict."

Reference to applicable legal text:
Commission Regulation (EU) No 445/201 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 (Official Journal of the European Union L 122/22 of 11/5/2011)

9.1.2 Use of contractors and control of suppliers

Where suppliers, partners and subcontractors are relied upon to undertake activities relating to operating safety, the railway company must control the delivery of safe supplies and services provided by these suppliers, partners and subcontractors.

This means, in particular, that in regard to criteria for selection and accreditation:

- suppliers, partners and subcontractors must satisfy the same requirements as the railway undertaking itself is required to meet: the corresponding contracts shall cover all the relevant requirements, including at least: responsibilities and tasks relating to railway safety issues, the obligations related to the transfer of relevant information between both partners and the traceability of safety related documents;
- the RU/IM must ensure, through appropriate monitoring, that the supplies and services offered consistently meet safety requirements;
- the RU/IM must ensure that its suppliers, partners and subcontractors undertake to accept the checks, inspections and audits called for by the regulations;
- the RU/IM must ensure, that preventive or corrective measures are implemented after checks, inspections and audits.

It is equally important suppliers and/or contractors have a clear understanding of the railway risks they are under as well as the risks they import to the railway operations.

Reference to applicable legal text:
Commission Regulation (EU) No 445/201 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 (Official Journal of the European Union L 122/22 of 11/5/2011)

9.1.3 Asset management

Asset management is the systematic and co-ordinated activities and practices undertaken by a company to manage assets that are a key or critical factor in achieving effective service delivery and their associated risks in an optimum manner to achieve its strategic and regulatory objectives.

Successful asset management involves identification of the assets owned or managed by a company. In general, the following types of assets are identified:

- physical assets; e.g. buildings, networks, infrastructures, equipment,
- human assets; e.g. people skills, career paths, training, reporting, mentoring, competencies,
- financial assets; e.g. cash, investments, liabilities, cash flow, receivables, etc.,
- intangible assets; intellectual property assets and relationship assets e.g. reputation with customers, suppliers, business units, regulators, competitors, channel partners and brands,
- information assets; digitised data, information, and knowledge about customers, processes performance, finances, information systems, etc.

The focus for the railway sector is mainly on the first group, and the physical asset to be considered should be track and related equipment (mainly for IMs) and rolling stock (mainly for RUs).

Asset management refers to the policies, strategies, information, plans and resources, which integrate to deliver efficient operation, and the putting in place of the above-mentioned activities and practices to ensure that assets remain in a condition to allow the operation to deliver its business objectives safely, effectively and efficiently during all of its life-cycle.

The outcome of competent asset management is asset integrity, i.e. assets that are fit for their purpose and whose risk of failure is managed to meet an appropriate standard of performance, however the management of assets can also plan for safety hazards brought into the organisation during asset renewal and disposal.

Asset management can therefore support the procedures to assure compliance throughout the life-cycle of equipment referred to in **9.1.1**.

9.2 Emergency plans

9.2.1 Emergency management

Each railway organisation must set up an emergency plan identifying and specifying the different types and levels (critical, non-critical, etc.) of emergencies that might occur. Each plan should be periodically reviewed and detail the actions, alerts and information to be given in case of an emergency.

All foreseeable emergencies need to be identified, and for each emergency situation the plan should clearly identify and define:

- the different parties/staff interested/involved (including periodic participation of management);
- the interfaces between RU, IM and relevant public authorities;
- the references for emergency related activities and actions;
- processes and procedures to be set in place according to the type of emergency.

Periodically testing of the emergency plans, including joint exercises with other involved parties, is good practice in order to monitor the effectiveness and update of the emergency plans.

9.2.2 Co-operation tasks for IM

Emergency procedures should be agreed with appropriate entities and should be adequate and anticipate different operational scenarios that may occur in a disruption, involving the intervention of public authorities, emergency and rescue services.

The IM should lead the **emergency procedure coordination**, in order to ensure the involvement of all concerned parties (IM's appropriate department; the above mentioned entities and representatives of the railway undertakings, keepers, etc.).

IMs scenarios should take into account specific situations, such as:

- language issues that may arise in case of events involving foreign language speaking drivers and onboard staff;
- transport of dangerous goods (specific knowledge of substance labelling and flow of information to relevant entities in conformity with the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) provisions and with national applicable rules);
- all internal and external entities to be informed in relation to emergency management and recovery;
- involvement of all parties concerned in testing phases.

Annex I

Acronyms used in the text

CCS	Control – Command System
CSI	Common Safety Indicators
CSM	Common Safety Method(s)
ECM	Entity in Charge of Maintenance
EN(s)	European Standard(s)
ERA	European Railway Agency
IM(s)	Infrastructure Manager(s)
NIB(s)	National Investigation Body(ies)
NSA(s)	National Safety Authority(ies)
RAIU	Railway Accident Investigation Unit
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
RSC	Railway Safety Commission
RSD	Railway Safety Directive (Directive 2004/49/EC and relevant amendments)
RU(s)	Railway Undertaking(s)
SMS	Safety Management System
TSI(s)	Technical Specification(s) for Interoperability
WG	Working Group

SMS related terminology

Annex II

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.

Accountable (roles)	Person or post liable to be called to account (accountable, responsible).
Appointed person	A person designated by a company, on the basis of his or her qualifications, for the purpose of performing a certain task.
Appropriate levels of responsibility	The hierarchical level in the organisation will usually be explicitly recognized by distinct levels with different management activities as well as different functional activities. For example, many organisations may be separated into the following four levels: 1. Decision-making – makes all decisions in the organisation (many decisions will be assigned to managers at other levels in the organisation) and interacts with stakeholders. 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. 3. Supervision and Monitoring – The monitoring of operations to identify the degree of achievement of the organisation's plans and other determined performance criteria. (This level may be combined with either the Policy Analysis level or the Operational level). 4. Operations – the production and delivery of goods or services to meet the organisation's mandate and goals. For safety related organisations, these operations will result in reduction of risk through the implementation of regulations or risk treatment and control measures. There is a flow of information between all levels of an organisation. 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 organisation is generally related to output measures of the operations, cost effectiveness of the program, costs to modify the operations, human resources status reporting, etc. [Adapted from: Network for environmental risk assessment and management (NERAM):Benchmark Framework for Risk Management, August 2000]

Assessor	Person in charge for assessing the possession of requirements or the compliance with specified rules (belonging to NSA or to qualified bodies).
Character and extent of activity	"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. "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).
Configuration control (of documentation)	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). '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. [Adapted from: Index for the Project Management System, http://sparc.airtime.co.uk/users/wysywig/]
Control of all risks	Selection and application of suitable measures to reduce (all) risks [Adapted by BS 88:2004-Occupational health and safety management systems - Guide]
Corrective action	Action to eliminate or mitigate the cause or reduce the effects of a detected nonconformity or other undesirable situation. [FAA Advisory Circular 120-92]
Effectiveness of control measures	Effectiveness of control measures is the expected output of an implementation plan following risk management decision process. Monitoring is the action that allows the effectiveness of control measures. [Adapted from "Risk management: guidelines for decision-makers" (Canadian Standards Association – CAN/CSA-Q850-97), July 1997]
Emergency procedure co-ordination	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. 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.
Entity in Charge of Maintenance (ECM)	Entity in Charge of Maintenance (ECM) means an entity in charge of maintenance of a vehicle, and registered as such in the National Vehicle Register. All Vehicles on the interoperable network are required to have an ECM. [Reg. 2001/445/EC]

High reliability industries	Organisations that consistently operate under trying and hazardous conditions, and manage to have relatively few accidents. These organisations 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 organisations: nuclear aircraft carriers, nuclear power generating plants, power grid dispatching centres, air traffic control systems, aircraft operations, hospital emergency departments, hostage negotiating teams, fire-fighting crews, continuous processing firms. High reliability characteristics include: a. personal technical excellence and commitment to continuous training; b. sustained, high levels of operational performance, encompassing both productivity and safety objectives; c. robust technical systems and structures, and organisational processes that provide redundancy and flexibility; d. decentralised authority patterns, including deference to capable individuals with the most technical expertise and individuals closest to the problem; e. a committed workforce where every individual understands and accepts their roles and responsibilities for safe mission performance; f. a deep commitment to continuous performance improvement, openness and trust, and cultivation of a continuous learning environment; g. the use of systems of checks and audits to build reliability. [Integrated Safety Management System Manual, U.S. Department of Energy, Office of Health, Safety and Security]
Infrastructure Manager (IM)	Infrastructure Manager means any body or undertaking that is responsible in particular for establishing and maintaining railway infrastructure on the rail system, or a part thereof, as referred to in Article 3 of Directive 91/440/EEC and defined in Annex I (A) of Commission Regulation (EC) No. 851/2006, which may also include the management of infrastructure control and safety systems. The functions of the infrastructure manager on its network or part of its network may be allocated to different bodies or undertakings;
Interested parties	In general, an interested party is a person or group that has a stake in the success or performance of another organisation. Interested parties may be directly affected by the organisation or actively concerned about its performance. Interested parties can come from inside or outside of the organisation. Examples of interested parties can include customers, suppliers, owners, partners, employees, unions, or members of the general public. [Adapted from ISO 9000:2005, http://www.praxiom.com/iso-definition.htm] Persons or group concerned with, affecting or affected by (railway) safety performance of the organisation. [Adapted from BS 88:2004-Occupational health and safety management systems - Guide]

Internal auditing system	The arrangement established by a company in order to perform internal audits. The companies may entrust specific departments, however, they can appoint independent assessors to carry out internal audits.
Internal audits	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. [EN ISO 19011]
Internal safety auditing	An audit (*) 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. Internal audits 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. [http://www.praxiom.com/iso-definition.htm] 'Provisions for the recurrent internal audits' are one of the basic elements of the safety management system [ref. to Annex III(2)(j)]. (*)AUDIT: A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled [EN ISO 19011]
Job design	"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" (Michael Armstrong, Amstrong's handbook of human resources management practice, 2009 - ISBN 978 0 7494 5242 1).
Learning Organisation (see also Organisational learning)	One that values continuous learning. An organisation that is deeply committed to continuous performance improvement and develops and sustains organisational 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 on-going 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. [INTEGRATED SAFETY MANAGEMENT SYSTEM MANUAL, U.S. Department of Energy, Office of Health, Safety and Security]
Lifecycle of equipment and operation	'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: - Acquisition - Development - Implementation - Operations and Maintenance - Termination - There are, anyway, different ways to figure life-cycles, for different purposes.

	The CENELEC standard EN50126:1999 – "Railway applications. The specification and demonstration of reliability, availability, maintainability and safety (RAMS)" contains a figure for life cycle in railway technical application: - Concept - System Definition and Application - Conditions - Risk Analysis - System Requirements - Apportionment of System Requirements - Design and Implementation - Manufacture - Installation - System Validation - System Acceptance - Operations and Maintenance - Modification and Retrofit - Performance Monitoring - Decommissioning and Disposal
Maintenance	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]
Manage related risks / Interface risks introduced by changes	When a change of technical, operational or organisational nature is introduced in a railway company, it may have a potential impact on safety. Railway companies have then to identify and manage risks arising from such changes, applying the methodology of Regulation 352/20094. 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".
Monitoring	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: - It refers to the type and extent of activity of the railway company, - It covers all necessary topics (railway companies should identify appropriate indicators within the on-going activity, including operational arrangement, staff performance, rolling stock performance, progress in training and maintenance programmes, etc.), - It includes the following elements: o 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, safety tours and audit findings), o the methods to record data (automatic data recording in a database, manual feeding), o the storage medium (i.e.: excel table, IT customised database, etc.),

	○ the output (figures, reports, etc.) and the reporting flow. - Milestones have to be set for the first monitoring period and for the following, in order to review the monitoring arrangements. - 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.).
National Safety Authority	National Safety Authorities (NSAs) are the designated "competent" authorities for the regulation of railway safety.
Organisational learning	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 organisation and to make it adaptive towards changes. Organisational learning is an organisation-wide continuous process that enhances its collective ability to accept, make sense of, and respond to internal and external change. Organisational 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]
Other management activities	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.
Other parties	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.
Periodical reviews of SMS	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: - At regular intervals, to verify continued legislative compliance and that the safety management system is achieving its objectives. - In case of modification(s), in order to verify that such modifications do not impair compliance with relevant legislation.
Plans	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). [ISO 9001:2005 Quality management systems - Fundamentals and vocabulary (3.7.5)] 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.

Preventive action	Action to eliminate or mitigate the cause or reduce the effects of a potential nonconformity or other undesirable situation. [FAA Advisory Circular 120-92]
Qualified body	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.
Railway company	The terms designate both Railway Undertakings and Infrastructure Managers, when they are expected to fulfil the same requirements.
Railway premises	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. 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 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. Annex I(A) specifies that railway infrastructure "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: - ground area, - track and track bed, in particular embankments, cuttings, drainage channels and trenches, masonry trenches, culverts, lining walls, planting for protecting side slopes etc., passenger and goods platforms, 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 network as follows: - lines intended for passenger services, - lines intended for mixed traffic (passengers and freight), - lines specially designed or upgraded for freight services, - passenger hubs, - freight hubs, including intermodal terminals, - lines connecting the abovementioned elements. 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: "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. The infrastructure structural subsystem also includes: - structure supporting or protecting the track - line side structures and civil engineering works that could affect the interoperability of the railway - passenger platforms and other station infrastructure that could affect the interoperability of railway - arrangements necessary within the subsystem to protect the environment - arrangements to safeguard passenger safety in the event of degraded operations".
Railway Undertaking	Railway Undertaking means 'railway undertaking' as defined in Directive 2001/14/EC, and any other public or private undertaking, the activity of which is to provide transport of goods and/or passengers by rail on the rail system on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only;
Reasonably practicable	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' e.g., maintenance schedules appropriate for vehicle specific manufacturer and types. 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. [A glossary of words and phrases used in the management of safety by European railways, UIC Safety Platform, 22 December 2005]

Relevant parts of CSM	The relevant part of CSM 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. The CSMs 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). The CSM on monitoring as in Article 6.3(c) of Directive 2004/49/EC, covers the monitoring to be applied by railway undertakings and infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance. The CSM on supervision, as in Article 6.3(c) of Directive 2004/49/EC, is addressed to NSAs. A SMS can only remain effective in managing the risks if it is continually monitored/reviewed to ensure that it is achieving its objectives.
Relevant safety data	The term refers to the sentences in the CSM on assessing conformity of safety certificates, concerning: - 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). - 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 appropriate indicators, to be collected automatically or during safety inspections, audits, etc.
Resources	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]
Risk analysis	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 5, Article 3.10]
Risk control measures = safety measures	'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/EC7, Annex I, 1.1.5]

Routine monitoring arrangements	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: - It refers to the type and extent of activity of the railway company, - It covers all necessary topics (railway companies should identify appropriate indicators within the on-going activity, including operational arrangement, staff performance, rolling stock performance, progress in training and maintenance programmes, etc.), - It includes the following elements: o 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, safety tours and audit findings), o the methods to record data (automatic data recording in a database, manual feeding), o storage medium (i.e. excel table, IT customised database, etc.) o the output (figures, reports, etc.) and the reporting flow - Milestones have to be set for the first monitoring period and for the following, in order to review the monitoring arrangements. - 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.).
Safety and health at work	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. [DIRECTIVE 1989/391/EEC6, Article 1] Factors and conditions that: - affect health and safety in the workplace, or - could affect health and safety in the workplace. Occupational health and safety factors affect employees (permanent and temporary), contractors, visitors, and anyone else who is in the workplace. [Adapted from OHSAS 18001:2007] International Labour Organisation (ILO) and World Health Organisation (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 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."
Safety authority	National Safety Authorities (NSAs) 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. They are otherwise designated as “competent” authorities to perform the

	tasks contained in the Directive 2007/59/EC on train drivers certification.
Safety critical tasks	The only EU-wide available identification for safety critical tasks is in TSI Operation and Traffic Management (4.2.1.1 General requirements) 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. Railway Undertaking staff: - undertaking the task of driving trains and forming part of the "train crew", - undertaking tasks on-board (other than driving) and forming part of the "train crew", - undertaking the task of preparing trains, - Infrastructure Manager's staff undertaking the task of authorising the movement of trains. Work performed by staff when they control or affect the movement of a vehicle, which could affect the health, and safety of persons. 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". Different definitions are used at national level. "Safety relevant" may be used with the same meaning.
Safety culture	"The safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety management." [Advisory Committee on the Safety of Nuclear Installations (ACSNI)]
Safety planning	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 procedures for safety management. 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.
Safety plans	A safety plan 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. Safety plans also specify who will do what and when, (to be checked with activities in Safety Regulation Sector) [Adapted by ISO 9000:2005, in http://www.praxiom.com/iso-definition.htm] The results of safety plans should allow the development of safety reports as required in Article 9(4)(a) of the Directive 2004/49/EC.
Safety recommendation	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.
Safety report	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: - information on how the organisation's corporate safety targets are met and the results of safety plans; - 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;

	- the results of internal safety auditing; - observations on deficiencies and malfunctions of railway operations and infrastructure management that might be relevant for the safety authority.
Safety reporting	In addition to legal requirements (afore-mentioned Article 9.4), safety reporting is a management tool for reviewing the SMS. 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.
Staff involvement	We detect two converging view on understanding the concept of staff involvement, that subsume the principles of engaging support, understanding, commitment and contribution; 1. The legal perspective, that is represented by the Directive 2002/14/EC: - 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) 2. The human resources management perspective: - 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 organisation - rather than being ignored by over-confident and unwise managers. [http://www.hrmguide.co.uk/employee_relations/employee-involvement.htm]
Staff representatives	Equivalent to "employees' representatives" defined in Dir. 2002/14/EC, Art. 2 as 'the employees' representatives provided for by national laws and/or practices'. "Person chosen or appointed to represent and defend employee s and their interests, especially those which operate at enterprise level". [European Foundation for the Improvement of Living and Working Conditions, Third European Survey on Working Conditions, Dublin 2001]
Suitably competent person	Person with the appropriate combination of skill, knowledge qualification and experience [source BS 8800:2004]
System	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, procedures, facilities, services, and other support facets. [FAA Advisory circular 120-92]
System-based approach	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 (e.g., 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. 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. [S2S _ BASIC PRINCIPLES OF SAFETY MANAGEMENT SYSTEM] Available at: http://www.safety-s2s.eu/ 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. [ISO N544R2, “Guidance on the Concept and Use of the Process Approach for management systems”]
Type and extent of service	Character or ‘Type’ of service refers to: - passenger transport, including and excluding high-speed services, - freight transport, including and excluding dangerous goods services, - shunting services. ‘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). [Regulation 653/2007/EC]
Validation procedure	Validation 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 validated status is achieved. The process of validation can be carried out under realistic use conditions or within a simulated use environment. A procedure is a way of carrying out a process or activity. Procedures may or may not be documented. However, Annex III(1) of RSD expects SMS is documented in all relevant parts. Documented procedures can be very general or very detailed, or anywhere in between. While a general procedure could take the form of a simple flow diagram, a detailed procedure could be a one page form or it could be several pages of text. [Adapted from ISO 9000:2005, http://www.praxiom.com/iso-definition.htm]

(Verification of) competence of contractors or suppliers	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: - to ensure that legal safety related requirements are met, - to ensure that products and services meet the standards and specification for the safety of railway operation. A railway company using contractors or suppliers should and carefully consider clearly identify: - safety critical product(s) and service(s) to be procured, as well as relevant specifications, - expected technical and/or operational performance; - the requirements that contractors/suppliers have to meet, like for instance: o specific associated competencies; o tools to used; o reference laws, standards, rules, instructions, etc., o adequate and documented management system, o awareness of risks imported on the company's SMS. The derived applicable requirements should be included in the contracts between the two parties. Such contracts should also include: - responsibilities and tasks, relating to railway safety issues - the obligations related to the transfer of relevant information between both parties (including the reporting of non-conformities), - the traceability of safety related documents, - monitoring, audit and review arrangements, - management of sub-contractors. 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: - at the time of selection, - on a continuous basis (monitoring), - periodically, during the validity of the contract (audit).