



EUROPEAN RAILWAY AGENCY
Safety Unit

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

A SYSTEM APPROACH

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IMPORTANT:

The present guidelines are not binding as legal acts adopted by the European Union. It is intended to be a set of reference manuals for all actors concerned by the SMS implementation, facilitating the understanding of the system based approach and the requirements in the Railway Safety Directive. It supports further the actors by additional explanations and elements to be taken into account by the actors designing and/or implementing an SMS.

These guidelines are not mandatory but advisory documents. They contain details that can be helpful for some actors; experienced actors can continue to follow their own experience.

These guidelines need thus to be read and used only as an informative document and a help for the design and/or implementation of an SMS, without substituting the relevant applicable rules.

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Introductory provisions	General guidance	Annexes
Introduction	SMS Purpose	Scope and content

Part I – Introductory provisions

1 Introduction

The Directive 2004/49/EC¹ (the Railway Safety Directive) clearly stipulates in Article 4 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).

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 NSAs using the common safety method for assessing the conformity with the requirements for obtaining safety certificates as referred to in Article 6(3)(b) of the Directive 2004/49/EC. Such common safety method is defined in the Regulation (EU) No 1158/2010/EU².

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 NSAs using the common safety method for assessing the conformity with the requirements for obtaining safety authorisations as referred to in Article 6(3)(b) of the Directive 2004/49/EC. Such common safety method is defined in the Regulation (EU) No 1169/2010/EU³.

RUs and IMs should 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,
- renewal of safety certificates or safety authorisation.

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

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

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

Introductory provisions	General guidance	Annexes
Introduction	SMS Purpose	Scope and content

Although the CSM for assessing the conformity with the requirements for obtaining safety certificates and authorisations already give clear guidance on the adequate implementation of an SMS, with an inclusive view to Article 9 and Annex III of the Railway Safety Directive, there are no provisions specifically addressed to RUs and IMs, to be used as reference document to support the design and implementation of their SMS.

This application guide refers mainly to the afore-mentioned parts of the Railway Safety Directive, but they include also elements that give a wider scope of SMS. Such elements are put in the context, and liaise with the mandatory requirements contained therein. The present document is supplemented by the following:

- ‘**RSD and other management systems**’, providing explanations on the possibility to integrate different management system, as ‘quality’, ‘environment’, ‘occupational safety’;
- ‘**Internal audit**’, providing explanations on techniques and procedures for such activity;
- ‘**SMS related terminology**’, providing literature examples to explain terms used in the Railway Safety Directive and the guidance on SMS. Such terms are identified **in bold type and underlined**, the referenced item is provided in footnotes;
- ‘**The knowledge building texts**’, providing a list of texts to be used for develop understanding on SMS as a whole and on the single elements.

Terminology and texts refer to good practice and other documents available in the railway sector, in other **high reliability industries**⁴ (civil aviation, maritime, chemical, nuclear, etc) and in wide-spread management systems as quality, environmental protection, etc.

The guidelines are organised as follows:

- **Introductory provisions**,
- **The general guidance**. It is organised according the structure described in the Chapter 5 ‘A system approach’ and refers to the main features of the processes for design and improvement, implementation and operational activities,
- **The description of each element**. It will be complemented by information on the texts where related mandatory requirement and ERA guidance can be found (in boxed text),
- **Annexes**.

⁴ Additional explanation of the term is available in item [11] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Introduction	SMS Purpose	Scope and content

2 SMS purpose

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, introduce operational efficiencies, enhance relations with customers and regulatory authorities and build a positive **safety culture**⁵.

In addition 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 aim of preventing accidents. When appropriate it should take into account the interfaces with other RUs and IMs in the railway system. Implementing all relevant elements of an SMS in an adequate way can provide an organisation with the necessary 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 National Safety Authorities (NSAs) issue safety certificates and safety authorisations.

Mature organisations thereby recognise that an efficient control of its risks can only be achieved through a process that brings together three critical dimensions: a technical component with the used tools and equipment, a human component of front line people with their skills, training and motivation and an organisational component consisting of procedures and methods defining the relationship of tasks. Consequently, a good SMS succeeds in monitoring and improving the **risk control measures**⁶ in the three dimensions.

The implementation of a SMS is a legally binding obligation under Articles 4(3) and 9(1) of the Directive 2004/49/EC. This application guide is based on the relevant content; however RUs and IMs should consider national transposition laws 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**⁷, 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.

⁵ Additional explanation of the term is available in item [40] of the document "SMS related terminology" (in English only).

⁶ Additional explanation of the term is available in item [35] of the document "SMS related terminology" (in English only).

⁷ Additional explanation of the term is available in item [37] of the document "SMS related terminology" (in English only).

Introductory provisions	General guidance	Annexes
Introduction	SMS Purpose	Scope and content

3 SMS scope and content

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

This generic high level guidance, developed by the Agency together with relevant stakeholder, 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 companies and, at the same time, for facilitating compliance with the legal requirements set up in the Railway Safety Directive as listed in following Chapter 4 (Legal basis). This guidance is intended to be read in conjunction with the Railway Safety Directive and with all applicable railway safety related legislation.

This document reflects the effort to present an emerging view on this dynamic and important subject through this guidance in a simple and user friendly manner (see 'The big picture' in Chapter 6 and the description of single elements in chapters 7,8 and 9). It also refers to mandatory and guidance connected documents on the implementation of safety management systems.

The initially issued set of documents will be progressively complemented, as a 'living system' that will develop with the deepening of the knowledge and with the commitment to act upon identified further needs. The Agency will use the sector's feedback on the ideas presented in the document to inform a continual development of the application guide.

The Agency's intention is to complement this guidance with texts on a wide range of subjects, containing further explanation on specific elements and on cross-cutting items that are related to SMS such as: human factors, safety culture, occupational health & safety, enterprise wide risk management, duty of co-operation, organisational maturity, etc.

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

In the Guidelines, the following terms will be used with the intent described:

'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.

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements

Part II – General Guidance

4 Legal basis

The legal basis for the implementation of the RUs/IMs' SMS is the Directive 2004/49/EC. The characteristic and the essential elements of the SMS are contained in Article 2 and 9 and Annex III therein. Relevant parts of the Directive, in italics, have been abstracted:

Article 3(i) - Definitions

The Railway Safety Directive - defines a Safety Management System *"the organisation and arrangements established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations."*

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

3. Member States shall ensure that the 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.

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 CSMs⁸ 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

⁸ Additional explanation of the term is available in item [31] of the document "SMS related terminology" (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements

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 all infrastructure managers and railway undertakings shall submit to **the safety authority**⁹ 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.

ANNEX III - Safety Management Systems

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.

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**¹⁰ 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

⁹ Additional explanation of the term is available in item [38] of the document "SMS related terminology" (in English only).

¹⁰ Additional explanation of the term is available in item [x] of the document "SMS related terminology" (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements

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.*

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements

5 A system approach

5.1 Content of the SMS (as a basis for the system approach)

RUs/IMs should design their SMS in a manner to comply with requirements set out in Article 9 and Annex III of the Directive 2004/49/EC listed in following chapters.

A new RU/IM may design their safety related processes on the basis of elements described in these Guidelines.

Existing RU/IM may use the elements to check correspondence with their own organisation, in order to take decision on necessary actions to ensure compliance with the above-mentioned requirements.

An RU/IM's SMS, in common with the concept of management systems, should contain the 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/authorisations) and independent audits.

The following table shows:

- the elements that together form an SMS (**column 1**),
- their relevant reference to the Railway Safety Directive, where they are derived from, is shown in **column 2**,
- their relevant reference in the Common Safety Method for assessing conformity of safety certificate (**column 3**),

The elements from A to S are common either to railway undertakings or to infrastructure manager's SMS.

In conformity with Article 9(3) of the Railway Safety Directive, the Safety Management System implemented by 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;
- Coordination of the emergency procedures with all railway undertakings that operate on the controlled network.

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
1	2	3
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 ¹¹ 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 chief executive and communicated to all staff	Annex III(2)(a)	J
Qualitative and quantitative 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 the 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

¹¹ Additional explanation of the term is available in item [10] of the document "SMS related terminology" (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements

5.2 The 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 concept of continuous improvement, a **system-based approach**¹² and the allocation of responsibilities is 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 safety management system 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 the station car parking, shops, etc.).

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

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

However it 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 the many possibilities clustering the processes. Each process can be seen, in itself, as an operational process, because it develops an output. RUs and IMs can use them as a reference to build their process maps and a safety management system with interactions and defined responsibilities.

The following tables show how the different elements of the SMS are organised. Such tables anticipate how they will be displayed in the following Chapter 6 (Elements) and provide the following references:

- their position in the main features of the design/improvement, implementation and operation,
- their numbering,
- the relevant CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations,
- the page in the application guide.

¹² Additional explanation of the term is available in item [50] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements

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

		CSM	Page
7.1 <i>Leadership</i>	7.1.1 - Management commitment	=	21
	7.1.2 - Safety Policy	J	23
	7.1.3 - Corporate safety targets	K	24
	7.1.4 - Decision taking	=	24
	7.1.5 - Management control	G	25
7.2 <i>Risk Assessment</i>	7.2.1 - <u>Control of risks</u> ¹³ associated with the activity of the RUs/IMs	A	27
	7.2.2 - Risks arising from the activities of other parties (external to the railway system)	D	29
	7.2.3 - Procedures / methods for risk evaluation and implementation of risk control measures (change management)	M	30
	7.2.4 - Compliance with legislation, rules and standards	L	32
	7.2.5 - Co-ordination tasks for IM	Art.9(3)	33
7.3 <i>Monitoring</i>	7.3.1 - Data collection and analysis	Q	35
	7.3.2 - Accident/incident reporting and investigation	Q	37
	7.3.3 - Internal auditing	S	38

¹³ Additional explanation of the term is available in item [7] of the document “SMS related terminology” (in English only).

Introductory provisions		General guidance	Annexes	
Legal basis		System approach	Elements	
7.4 <i>Organisational learning</i>	7.4.1 - Continuous improvement		I	39
	7.4.2 - <u>Safety recommendations</u> ¹⁴		Q	40
	7.4.3 - Change management		M	41

Table 2 – Processes for implementation [Chapter 8]

		CSM	Page
8.1 <i>Structure & responsibility</i>	8.1.1 - Distribution of responsibilities	F	43
	8.1.2 - Management and supervisory accountability	G	44
	8.1.3 - Organisational structure	E	44
	8.1.4 - Workload planning	=	45
8.2 <i>Competence management</i>	8.2.1 - Competence management system (training programmes for staff)	N	46
8.3 <i>information</i>	8.3.1 - Configuration control of safety information	P	48
	8.3.2 - Involvement of staff and their representatives	H	49
	8.3.3 - Internal/external communication	O	50

¹⁴ Additional explanation of the term is available in item [43] of the document “SMS related terminology” (in English only).

Introductory provisions		General guidance		Annexes	
Legal basis		System approach		Elements	
8.4 Documentation	8.4.1 - SMS documentation			E	52
	8.4.2 - Document management			=	53
	8.4.3 - Annual <u>safety report</u> ¹⁵			Art. 9(4)	54

Table 3 – Operational activities [Chapter 9]

		CSM	Page
9.1 <i>Operational arrangements and procedures</i>	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	57
	9.1.2 - Use of contractor and control of suppliers	B/C	58
	9.1.3 - Asset management	=	59
9.2 <i>Emergency Plans</i>	9.2.1 - Emergency management	R	61
	9.2.2 - Co-ordination tasks for IM	Art. 9(3)	61

¹⁵ Additional explanation of the term is available in item [44] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

6 Elements

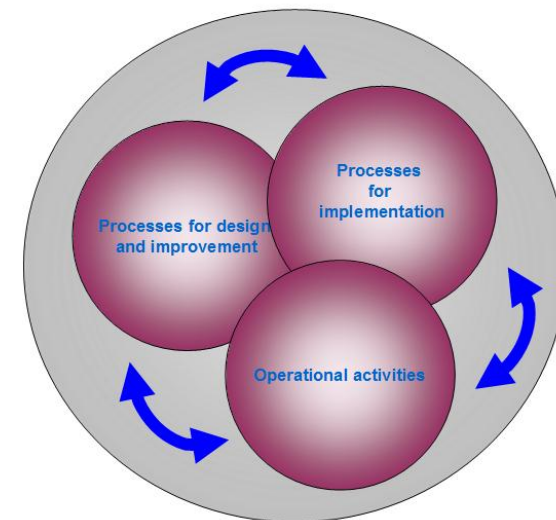
We have already stated that the Safety Management System implemented by the Railway Undertakings and by the Infrastructure Managers contains the characteristics and elements listed in Article 9 and Annex III of the Directive 2004/49/EC.

The characteristics and elements that form an SMS are then labelled throughout this guidance, on the basis of the numbering of the criteria listed in Annex II of the Regulations on assessing conformity with requirements for obtaining railway safety certificates/authorisations. 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**
[Chapter 7]
- **processes for implementation**
[Chapter 8]
- **operational activities**
[Chapter 9]

This approach is developed throughout the guidelines, as follows:

- The three groups will be described and will contain references to orient readers to the contained elements;
- Under the **main features** of the processes (design/improvement, implementation, operation) the elements of the SMS will be listed and described;
- In order to provide reference texts, distinguish texts that may contain mandatory requirements from intended to be guidance, a number of formatting styles have been used to make the 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 bright red background indicates ERA guidance texts on such requirements.



Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

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 managing some 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. There is a constant need to adjust and improve all SMS related processes. To be able to do so organisations needs that ensure 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 like new technologies, rules, standards, etc., and/or internal like 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 safety management system.

Monitoring [7.3] of both the performance of operational processes and of the 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.

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

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

Obviously, for a good performance of these processes for design and improvement as well, it is necessarily that the responsible staff/management knows 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 on 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**¹⁶.

¹⁶ Additional explanation of the term is available in item [33] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

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 aspect or programs of an organisation.

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

- 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],

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- 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],
- receiving regularly information about safety, eg 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 workforce are properly consulted on and safety matters, and that their concerns are reaching the appropriate level including, as necessary, the board ensuring that your organisation’s risks are assessed, and that appropriate control measures are established and maintained [ref. to 8.3.2 – involvement of staff],
- creating the 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.

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7.1.2 Safety policy

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: J

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

The safety policy statement should be communicated and made available to all staff using the appropriate medium (formal communication, newsletter, intranet, etc.) It should include, among others, a declaration of intent and also provides indications on the overall direction for the organisation to follow, the general objectives of the safety management system 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 contribute 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,
- enjoys 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.

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7.1.3 Corporate safety targets

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **K**

Each RU/IM, within the framework of its own SMS, is expected to include the demonstration of its capability to achieve their 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**¹⁷) 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**¹⁸);
- 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

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **none**

The safety management system's processes are fully integrated into a **railway company**¹⁹'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 decision.

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

¹⁷ Additional explanation of the term is available in item [44] of the document "SMS related terminology" (in English only).

¹⁸ Additional explanation of the term is available in item [41] of the document "SMS related terminology" (in English only).

¹⁹ Additional explanation of the term is available in item [28] of the document "SMS related terminology" (in English only).

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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**²⁰ on safety and to include safety as a key business risk in all board decisions could have catastrophic results.

7.1.5 Management control

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: G

In general, management control is a means by which an organization's resources are directed, monitored, and measured. It aims at helping the organization 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**²¹ or **corrective actions**²².

²⁰ Additional explanation of the term is available in item [22] of the document “SMS related terminology” (in English only)

²¹ Additional explanation of the term is available in item [26] of the document “SMS related terminology” (in English only)

²² Additional explanation of the term is available in item [8] of the document “SMS related terminology” (in English only)

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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 the appropriate level 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.

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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

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: A

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;

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(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, safety management 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)

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Read more on:

ERA /GUI/01-2008/SAF Guide for the application of the CSM Regulation

Risk Assessment Criteria (availability foreseen in 2011)

7.2.2 Risks arising from the activities of other parties²³

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: D

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, we can say 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 cooperating 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);

²³ Additional explanation of the term is available in item [23] of the document “SMS related terminology” (in English only).

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- (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)

Read more on:

ERA /GUI/01-2008/SAF Guide for the application of the CSM Regulation

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

*Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **M***

The level of safety is generally acknowledged good in Europe, and the set of rules currently in force in the different countries are seen as the result of the ‘historical memory’ of the 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**²⁴, taking into account also those relating to occupational safety²⁵.

²⁴ Additional explanation of the term is available in item [20] of the document “SMS related terminology” (in English only).

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Changes can apply to

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

The SMS needs to ensure that the CSMs on risk assessment, developed according to Article 6(3)(a) of the Railway Safety Directive, are 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)

Read more on:

ERA /GUI/01-2008/SAF Guide for the application of the CSM Regulation

Risk Assessment Criteria (availability foreseen in 2011)

²⁵ ref.: Directive 2004/49/EC, Recital (14)

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7.2.4 Compliance with legislation, rules and standards

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: L

Compliance with legislation and rules is not an option. 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**²⁶ 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.

²⁶ Additional explanation of the term is available in item [51] of the document “SMS related terminology” (in English only).

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7.2.5 Co-ordination tasks for the IM

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **(Art. 9(3) SD)**

The SMS of an IM is, compared to that of a 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 movement 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**²⁷ (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);

²⁷ Additional explanation of the term is available in item [29] of the document "SMS related terminology" (in English only).

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- 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, lightening and conditions of platforms. These issues are limited to areas that are functional to the core railway related activities as, for instance, access to track area, platforms for boarding and getting off trains.

c) emergency related

- Protection of passengers in case of accident;
- Exchange of information with all **interested parties**²⁸ in case of emergencies and service disruptions;
- Clearance of the affected tracks after accidents or disruptions.

²⁸ Additional explanation of the term is available in item [12] of the document “SMS related terminology” (in English only).

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7.3 Monitoring

A 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

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **Q**

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;
- Inspections 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).

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‘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 also 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.

The development of CSM on monitoring is being carried out at the time of writing. Such CSM shall provide a focused framework for RUs/IMS, including detailed guidance on the use of indicators.

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 (available in 2011)

Read more on:

ERA – Safety Reporting Sector, IMPLEMENTATION GUIDANCE FOR CSIs, ANNEX 1 AND APPENDIX TO DIRECTIVE 2004/49/EC

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

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: Q

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 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 recurrence.

Organisations should encourage 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 investigation to be carried out.

The railway companies might co-operate should an investigation involve 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 – Safety Reporting Sector, IMPLEMENTATION GUIDANCE FOR CSIs, ANNEX 1 AND APPENDIX TO DIRECTIVE 2004/49/EC

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ERA-Classification of causal factors SAF/REP/CL_CAUS_FACT – Method V2 24/04/2009

7.3.3 Internal auditing of the SMS

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **S**

As a general principle, **internal auditing**²⁹ serves the purpose of **periodically reviewing the management systems**³⁰. In particular, the **internal safety audit**³¹ 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**³², including planning of internal audits to be carried out in order to fulfil the requirements specified in Article 9(4) on reporting to the NSA.

Staff in charge of carrying out internal auditing (auditors) 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.

Read more on:

ERA – SMS GUIDELINES – INTERNAL AUDIT

²⁹ Additional explanation of the term is available in item [14] of the document “SMS related terminology” (in English only).

³⁰ Additional explanation of the term is available in item [24] of the document “SMS related terminology” (in English only).

³¹ Additional explanation of the term is available in item [15] of the document “SMS related terminology” (in English only).

³² Additional explanation of the term is available in item [13] of the document “SMS related terminology” (in English only).

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7.4 Organisational learning

The effective safety management system 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

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: I

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.

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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

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: Q

The development of organisational learning is strongly related to the analysis of accident / incident / dangerous occurrences based on external and internal reporting as well as on internal audit results. Such analysis is utterly 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 Directive 2004/49/EC is a proposal of a national investigation body to improve railway safety, based on the results of the investigation of one or more accidents or incidents.

Relevant recommendations from NSA or NIB (the latter are addressed via the NSA, to all the sector and not 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.

Read more on:

ERA- Safety Reporting Sector. GUIDANCE ON SAFETY RECOMMENDATIONS IN TERMS OF ARTICLE 25 DIRECTIVE 2004/49/EC,
ERA-Classification of causational factors SAF/REP/CL_CAUS_FACT – Method V2 24/04/2009

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Legal basis	System approach	Elements
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7.4.3 Change management

*Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **M***

The 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 the consecutive steps of the project:

- identification of the need for change (e.g.: after analysis of safety data, optimization 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 Common Safety Methods for risk assessment.

Reference to applicable legal text

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)

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

8 Processes for implementation

To make the sometimes very complex design and operational processes work effectively, there is 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 assignment, where appropriate, of functions and activities to people

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

Resource³³ management, and in particular the suitability of professional competence and health requirements to perform **safety critical or safety related tasks**³⁴ (the terms are used quite interchangeably) is a key factor for delivering safe operation.

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.

³³ Additional explanation of the term is available in item [33] of the document "SMS related terminology" (in English only).

³⁴ Additional explanation of the term is available in item [39] of the document "SMS related terminology" (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

8.1 Structure and responsibility

The safety management system 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

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **F**

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**³⁵, 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. An organisation needs to ensure that staff with delegated responsibilities has 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 a SMS by ensuring that staff at all levels takes responsibility.

³⁵ Additional explanation of the term is available in item [3] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

8.1.2 Management accountability

*Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **F***

An organisation needs to ensure that those given roles, tasks and objectives in safety management are **accountable**³⁶ for delivery of the business safety objectives for which they are responsible.

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 a proper SMS.

8.1.3 Organisational structure

*Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **F***

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

- Risk controls fits sensibly into 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.

³⁶ Additional explanation of the term is available in items [1] and [2] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

8.1.4 Workload planning

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

The SMS may benefit of 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 safety management system as a whole;
- for the preparation of plans to ensure adequate assignment and workload.

Such processes would be expected to be part the normal business planning cycle during time, and 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**³⁷ shall take into account the following:

- 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.)."

³⁷ Additional explanation of the term is available in item [16] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

8.2 Competence management

An organisation must ensure that all staff with a responsibility in the safety management system 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

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **N**

As far as 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;
- the identification of knowledge, skills and experience required to perform these processes or 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 keep under control the competence of staff;
- the ongoing training and periodical update of existing knowledge and skill, to ensure that staff is 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 at ensuring 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.

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

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

Criteria for the recognition of training centres (available in 2011)

Criteria for the recognition of examiners/examination (available in 2011)

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

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(s) of internal and external information has to be identified and acted upon.

8.3.1 Configuration control³⁸ of safety information

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **P**

Measures to control vital safety information 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 different degree of criticality for operation, as shown from the arrow's direction:

- operational urgent information concerning train movements, like late notices, temporary speed restriction, dangerous goods, hauled load, etc.;
- operational safety information/documentation, like braking sheet, train schedule, etc.;
- operational permanent information documentation like rules books or route books, permanents safety orders, etc.;
- more general SMS information (feedback of experience, **staff involvement**³⁹, 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,

³⁸ Additional explanation of the term is available in item [6] of the document “SMS related terminology” (in English only).

³⁹ Additional explanation of the term is available in item [45] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

- 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 document is to provide appropriate fields at least 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 representatives⁴⁰

*Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **H***

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

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

⁴⁰ Additional explanation of the term is available in item [47] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

Employee and representative consultation in drafting 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 ongoing 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

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: O

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 organization 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.

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

Internal communication refers to all levels of an organisation, as 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, all kind of 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.

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

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

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: E

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. An up-to-date and consolidated documentation describing the characteristics and elements of the safety management system 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

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

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 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**⁴¹ / 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 at § 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.

⁴¹ Additional explanation of the term is available in item [42] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

8.4.3 Annual safety report

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **Art. 9(4)**

The annual safety report is a summary of information that the RU/IM must provide to the NSA, 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 of 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 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 SMS is within the reporting organisation.

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

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, of course, one of 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 make it able to deliver normal operation 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 service is delivered in compliance with applicable rules.

Typical operational processes (the list is not exhaustive) refer to:

- 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 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)

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

- 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 [be careful: this document is currently under revision]

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

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

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

	Initial conformity to legal safety requirements	Maintenance of conformity	Operational management of resources
Technical equipment	Rolling stock has been put into service (= it has achieved its technical acceptance and registration) Infrastructure (track-CCS equipment) have been put into service	Rolling stock and infrastructure is duly maintained	Applicable requirement (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 refresh training is adopted for all safety related tasks	Possession of necessary competencies for the task and compliance with labour law
Operational procedures	A priori 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, instructions, safety orders, protocols, etc...) are constantly updated	Circulation of documents, ensuring that each staff member has the right documentation at the right time

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

9.1 Operational arrangements / procedures

9.1.1 Procedures to meet applicable rules – Procedures to assure compliance throughout life-cycle⁴² of equipment/operation (delivery phase)

Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: L

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

The following list (that cannot be considered exhaustive) 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 ECM,
- inspections (prior to departure and during journey).

⁴² Additional explanation of the term is available in item [18] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

The 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

ECM Certification (available in 2011)

9.1.2 Use of contractors and control of suppliers

*Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **B/C***

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:

- 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;

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

- 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're under as well as of risks they import to the railway operations.

Reference to applicable legal text

ECM Certification (available in 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 like reputation with customers, suppliers, business units, regulators, competitors, channel partners and brands,
- Information assets; digitized data, information, and knowledge about customers, processes performance, finances, information systems, etc.

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

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

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

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

9.2 Emergency plans

9.2.1 Emergency management

*Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **R***

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

*Reference to CSM on assessing conformity with requirements for obtaining railway safety certificates/authorisations: **Art. 9(3)***

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

Introductory provisions	General guidance	Annexes
Legal basis	System approach	Elements
Design and improvement	Implementation	Operation

The IM should lead the emergency procedure coordination⁴³, in order to ensure the involvement of the all involved parties (IM's appropriate department; the above mentioned entities and representatives of the railway undertakings, keepers, etc.).

IMs scenarios should take into account specific situation, like for instance:

- 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 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.

⁴³ Additional explanation of the term is available in item [10] of the document “SMS related terminology” (in English only).

Introductory provisions	General guidance	Annexes
ANNEX I	Acronyms used in the text	

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)
RSD	Railway Railway Safety Directive (Directive 2004/49/EC and relevant amendments)
RU	Railway Undertaking
SMS	Safety Management System
TSI(s)	Technical Specification(s) for Interoperability
WG	Working Group