European Railway Agency

Safety Management System

Assessment Criteria
for Railway Undertakings and Infrastructure Managers

to be used by National Safety Authorities when assessing conformity with requirements in
safety certificates and safety authorisations issued in accordance with Articles 10(2)(a) and
11(1)(a) of Directive 2004/49/EC

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Reference documents

Ref.	Document Title	Document ref.
/1/	Directive 2004/49/EC (Railway Safety Directive – SD)	
/2/	ILLGRI/UIC Safety Platform paper "SMS assessment criteria" including comments made by the Safety Platform from 09/11/2005	August 2006
/3/	DB/SBB/OeBB brochure "Safety Management in European Railway Companies"	Final version, January 2005
/4/	SAMRAIL deliverable D2.2.2 "Guidelines for the Safety Management System of European Railways"	SAMRAIL/SM/D 2.2.2/V4.0
/5/	UIC Safety Platform working paper "Benchmarking the procedures for awarding Safety Certificates" (09/08/2004), including the annex "Mapping of national procedures" (16/08/2004)	

Contents

1   Introduction

Article 16(2)(e) of Directive 2004/49/EC (Safety Directive) entrusts the National Safety Authorities (NSAs) to issue safety certificates and safety authorisations in accordance with Articles 10 and 11 thereof. Therefore, the NSAs need to assess that conditions and requirements laid down in these articles are met. To support the NSAs, the Safety Directive in Article 6(3)(b) foresees the Agency drafting a common safety method (CSM) for assessing conformity with requirements in safety certificates and safety authorisations issued in accordance with Articles 10 and 11. In September 2009, the Agency has to submit the recommendation containing this CSM to the Commission.

The Agency's SafeCert Team, in charge of developing this CSM, has split the work into four parts: 1) SMS assessment criteria and 2) SMS assessment procedures (both for safety certificates and safety authorisations issued in accordance with Articles 10(2)(a) and 11(1)(a)), 3) assessment criteria and procedures for safety certificates issued in accordance with Article 10(2)(b), and 4) assessment criteria and procedures for safety authorisations issued in accordance with Article 11(1)(b). All parts will be developed in cooperation with the ERA Working Group on Safety Certification and Authorisation (ERA WG SafeCert) and the NSA Network. The documentation of each milestone constitutes the common agreement. The final recommendation for the CSM in total will comprise of all four papers.

This present proposal deals with the first step, the SMS Assessment Criteria to be used by the NSAs for assessing conformity of Part A – Certificates for railway undertakings (RUs) and Safety Authorisations for infrastructure managers (IMs). As the requirements for the safety management system (SMS) are described in Article 9 and Annex III of the Safety Directive, this document follows that structure. It gives for each paragraph or even sentence a short abstract or description, which represents the common understanding agreed upon in the working group. This is followed by commonly agreed assessment criteria linked to the specific issue. The level of detail of the assessment criteria tries to find the right balance between a common approach for the equal treatment of RUs in each Member State and enough freedom for the Member States to still use well-developed current practices.

The position paper deals entirely and exclusively with the planning, realisation and verification of safety of railway operations/services within a RU/IM and does not deal with issues relating to the implementation and assessment of other types of management systems (environmental, health and safety at work, etc.) which are specifically regulated through other parts of the Treaty[1].

The papers mentioned under 2) to 4) will be available during the course of 2008, at the latest in spring 2009. Additionally, two other documents complete the work on the CSM for conformity assessment:

- A so-called "SMS Survey", giving an introduction to the concept of system, system based approach and safety management system, and an overview on the historical reasons that have determined the necessity to give evidence of an organisations' structure for the management of safety in the railway as well as in other safety critical sectors, together with abstracts of legislative and/or regulating documents, containing reference to the implementation of a safety management system (available since April 2007);
- Guidelines for RUs and IMs on how to design and implement an SMS according to the Safety Directive, which is the complementary side to the NSA-view of the CSM (available during 2009).

All quotations from the Safety Directive are written in italics.

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[1] Consolidated versions of the Treaty on European Union and of the Treaty establishing the European Community, OJ 26.12.2006

2 The concept of Safety Management Systems as defined in Directive 2004/49/EC

> *Recitals:*
>
> *(13) In carrying out their duties and fulfilling their responsibilities, infrastructure managers and railway undertakings should implement a safety management system, fulfilling Community requirements and containing common elements. Information on safety and the implementation of the safety management system should be submitted to the safety authority in the Member State concerned.*
>
> *(14) The safety management system should take into account the fact that Council Directive 89/391/EC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (2) and its relevant individual directives are fully applicable to the protection of the health and safety of workers engaged in railway transport. The safety management system should also take account of Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail (3).*
>
> *Article 3(i) SD: 'safety management system' means the organisation and arrangements established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations;*

ABSTRACT/DESCRIPTION

The main purpose of an SMS is "*to ensure the safe management of operations of an RU/IM*" (Article 3(i) SD) in order to deliver the general requirements of Article 4 of the Safety Directive, where the general concept of continuous improvement, a system-based approach and the allocation of responsibilities is introduced.

An SMS, in common with the concept of management systems, should be process-orientated and contain, for the RU/IM, the description of safety related processes and procedures, all of which shall be capable of independent audits.

The *system based* or *process-orientated approach*[2] is recognized as the means for Member States "*to develop and improve railway safety*".

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[2] For the interpretation of *system based* or *process orientated approach*, refer to the relevant Guidelines

3   Article 9 – Safety management systems

3.1 Article 9(1)

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

ABSTRACT/DESCRIPTION

I.0 An SMS is a means established by an RU or an IM to ensure the safe management of its operations on a continuous basis.

The *relevant parts of the CSMs* applicable to the SMS are those derived under point (a) and (c) of Article 6(3) of Directive 2004/49/EC. Issues relating to Article 6(3)(a) are developed under Annex III (2)(d), those relating to Article 6(3)(c) are linked to the methods developed under National Safety Rules, in accordance with Article 10(2)(b) and Annex III(2)(c).

Annex III of the Safety Directive is the main reference for safety management systems, listing the basic elements and requirements. Article 9 of the Safety Directive introduces and anticipates some of the requirements laid down in Annex III.

ASSESSMENT CRITERIA

Article 9(1) serves as a general introduction to the objectives an SMS should ensure and therefore does not require any assessment criteria.

3.2 Article 9(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.

ABSTRACT/DESCRIPTION

II.0 This paragraph of Article 9 introduces issues and specific requirements relating to processes which are not explicitly dealt with in Annex III, but explains further elements contained in the general concepts introduced in Article 4, e.g. the concept of "*shared risks*"[3]. This term is not explicitly used in the Safety Directive, but the SMS needs to contain requirements for addressing this type of risk.

An RU/IM should be able to identify all risks associated with its activity and put in place adequate measures to control and mitigate them. These include:

- Risks, which exist as a direct result of the activities carried out by the RU/IM or other organisations, and for which it is possible to put into place risk control measures under their direct and sole control.

- *Shared risks*, which are residual interface risks arising from a separation of activities or functions between the various players involved in the operation of the railway system (IMs/RUs/contractors for example), and which require co-operation between the players to ensure that the interface risks are addressed in a coherent way. The IM in particular has a key role to play in this process, in that it manages the wider environment in which trains operate[4].

Assessment criteria for processes regarding *shared risks, the use of contractors*, and *risks arising as a result of activities by other parties* are listed in this section, but, for complete reference, point 2(f) of Annex III should also be consulted.

Risks arising as a result of activities by other parties refer to those risks associated to interfaces with third parties not directly related to the railway system activities.

Maintenance issues are also dealt with under point 2(c) of Annex III in relation to *compliance with standards and other prescriptive conditions throughout the lifecycle of equipment and operations*. For the scope of this assessment, an SMS should give evidence of having processes to ensure that maintenance is managed according to all relevant rules and standards.

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[3] ref.: Directive 2004/49/EC, Article 4(3) 1st paragraph *"…where appropriate in cooperation with each other…"*

[4] ref.: Directive 2004/49/EC, Recital 17

ASSESSMENT CRITERIA

1) *RISKS ASSOCIATED WITH THE ACTIVITY OF THE INFRASTRUCTURE MANAGER OR RAILWAY UNDERTAKING (including SHARED RISKS)*

II.1 There are processes and procedures in place to identify risks associated with railway operations, including those directly arising from the activities of other organisations/persons.

II.2 There are processes and procedures in place to develop and put in place risk control measures.

II.3 There are processes and procedures in place to monitor the effectiveness of risk control arrangements and to implement changes when required.

II.4 There are compatible processes and arrangements in place to identify RUs/IMs whose activity is likely to affect the safety of the organisation's railway services.

II.5 There are compatible processes and arrangements in place to identify and manage shared risks and to recognise the need and commitment to collaborate.

II.6 There are agreements in place documenting how co-operation will be achieved and how shared risks will be addressed, including identifying the role and responsibility of each individual organisation in the process.

II.7 There are agreements in place to cooperate in monitoring the effectiveness of the existing agreed arrangements for dealing with shared risks and to agree and implement changes when required.

2) *SUPPLY OF MAINTENANCE AND MATERIAL*

II.8 There are procedures to derive maintenance requirements/standards/processes from safety and/or reliability data and from the assignment of rolling stock to their services, where appropriate.

II.9 There are processes to adjust/adapt maintenance intervals according to type and extent of service performed by the RU/IM, where appropriate.

II.10 There are processes to ensure that the responsibility for maintenance is clearly defined in the organisation, to identify the competencies for maintenance posts and to allocate appropriate levels of responsibility.

II.11 There are processes to gather information on experience/feedback, maintenance, malfunctions, defects and repairs and use it to learn and adopt corrective measures to improve the level of safety.

II.12 There are processes to identify, recognise and report risks linked to construction deficiencies/non-conformities or malfunctions and faulty functioning conditions throughout the lifecycle (even though fulfilling factory and other requirements and product approval and certification had been already granted).

II.13 There are processes to verify and control that performance and results of maintenance done either by the RU/IM or third parties, comply with standards set by the RU/IM.

3) USE OF CONTRACTORS AND CONTROL OF SUPPLIERS

II.14 There are processes to verify beforehand the competence of contractors (including subcontractors) and suppliers.

II.15 Responsibilities and tasks, relating to railway safety issues, are clearly defined, known and allocated between the contracting partners and among all other interested parties.

II.16 The RU/IM has a process to ensure traceability of relevant documents and contracts.

II.17 There is a validation process to ensure that supplied and contracted services meet required standards.

II.18 There are processes in place to safeguard that safety tasks are conducted within the required schedule and according to required standards and criteria.

II.19 There are processes in place to safeguard day to day management of safety tasks.

4) RISKS ARISING FROM THE ACTIVITIES OF OTHER PARTIES (WHERE APPROPRIATE AND REASONABLE)

II.20 The RU/IM has:

- identified potential risks from other parties external to the railway system;
- established adequate control measures to mitigate the relevant risks.

3.3 Article 9(3)

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

ABSTRACT/DESCRIPTION

III.0 The safety management system 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.

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

ASSESSMENT CRITERIA

1) *IM's SMS AND THE EFFECTS OF DIFFERENT OPERATIONS BY THE RUs IN ACCORDANCE TO TSIs, NATIONAL SAFETY RULES AND CONDITIONS IN THE SAFETY CERTIFICATE*

Refer to the document on assessment criteria and procedures for that part of safety authorisations issued in accordance with Article 11(1)(b) of the Safety Directive.

2) *COORDINATION OF EMERGENCY PROCEDURES BETWEEN THE IM AND ALL RUs OPERATING ON ITS INFRASTRUCTURE*

Refer to point 2(i) of Annex III.

3.4 Article 9(4)

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

(a) information on how the organisation's corporate safety targets are met and the results of safety plans;

(b) the development of national safety indicators, and of the CSIs laid down in Annex I, as far as it is relevant to the reporting organisation;

(c) the results of internal safety auditing;

(d) observations on deficiencies and malfunctions of railway operations and infrastructure management that might be relevant for the safety authority.

ABSTRACT/DESCRIPTION

IV.0 The annual safety report is a summary of relevant information that the RU/IM must provide to the NSA.

Information submitted is relevant both for NSAs and RUs/IMs to evaluate how strong and sound safety culture and the SMS are within the reporting organisation.

ASSESSMENT CRITERIA

IV.1 There are processes in place to manage effectively and in time all relevant information/data that must be collected to submit the annual safety report to the competent NSA.

4 ANNEX III

4.1 Annex III(1) – SMS General requirements

(A) The safety management system must be documented in all relevant parts […]

ABSTRACT/DESCRIPTION

A.0 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.

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.

ASSESSMENT CRITERIA

A.1 There is a description of the types of activity that are or will be undertaken by the railway organisation that give clarity to type, extent and risk of operation.

A.2 The RU/IM has provided a description of the SMS structure showing the allocation of roles and responsibilities.

A.3 The RU/IM has a document that describes all main SMS processes required by Annex III (2) consistent with type and extent of services operated.

A.4 Safety critical processes and tasks relevant to the type of activities/services carried out by the RU/IM are listed and briefly described.

A.5 The documentation listed in A.1 to A.4 provides sufficient information that can be used to plan/set up internal audits.

> *(B) The safety management system [...] shall in particular describe the distribution of responsibilities within the organisation of the infrastructure manager or the railway undertaking.*

ABSTRACT/DESCRIPTION

B.0 Each RU/IM should clearly identify and define the areas of responsibility related to railway safety, in order to allocate them, within an organisational procedural system, to associated staff and/or specific functions. Each area of responsibility should be described and documented in detail (this point is developed further under Annex III (1) section C).

Delegation of responsibilities and safety tasks should be formal and approved either by the senior/top management or by the staff member responsible for the specific function and safety task.

ASSESSMENT CRITERIA

B.1 The RU/IM has an appointed person, employed by the organisation and with proven knowledge of its railway system, with direct access to the management board and/or chief executive, coordinating the railway safety management system at management level (not process level).

B.2 Those in the organisation with delegated responsibilities have the authority, competence and appropriate means to perform and fulfil their duty, i.e. function, responsibility and competence should be coherent and compatible with the given role/task.

B.3 Safety related areas of responsibility and the distribution of responsibilities to specific functions associated with them are clearly defined.

B.4 Interfaces between the different responsibilities are clearly defined.

B.5 There is a process to ensure that safety tasks are clearly defined and delegated to staff competent for the function, task and type of responsibility.

> *(C) The safety management system […] shall show how control by the management on different levels is secured, […]*

ABSTRACT/DESCRIPTION

C.0 Control on all levels of the organisation and over the different delegated functions/staff allows for the identification of flaws/faults in the SMS processes and therefore the possibility to implement preventive/corrective actions. It is therefore crucial not only to ensure safety, but also, for the top management, to fulfil its commitment and legal obligations to improve railway safety.

Delegation of safety tasks and responsibilities does not absolve or exonerate an organisation's management from its legal responsibilities and duties relating to railway safety.

ASSESSMENT CRITERIA

C.1 All safety related processes and areas of responsibilities have identified and qualified posts, responsible for them throughout the whole operating cycle (i.e. on call duty, permanence and replacements are identified).

C.2 Regular monitoring of task performances is assured by the line management chain who must intervene if the tasks aren't being properly performed.

C.3 There are procedures to integrate the SMS with other management activities.

C.4 There are procedures to hold those with a role in the management of safety accountable for their performance.

C.5 There are processes to allocate adequate resources to deliver the safety tasks.

> ***(D) The safety management system […] shall show how staff and their representatives on all levels are involved …***

ABSTRACT/DESCRIPTION

D.0 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.

Safety-related processes are usually linked to other cross-cutting organisational processes and extend to different levels and functional areas making staff involvement easy, natural and consequential.

ASSESSMENT CRITERIA

D.1 There are processes in place in the SMS to ensure that staff and staff representatives are adequately represented and that staff representatives are consulted (committees/groups) and involved in defining, proposing, reviewing and developing the safety aspects of operational processes that may involve staff[5].

D.2 There are processes in place in the SMS to ensure that staff involvement and consultation arrangements are documented.

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[5] ref.: Directive 2004/49/EC, Recital (16); Directive 95/18/EC, Article 12

(E) The safety management system shall show […] how continuous improvement of the safety management system is ensured.

ABSTRACT/DESCRIPTION

E.0 The continuous improvement model must be applied, where reasonably practicable, to all relevant systems/processes within an organisation and therefore also to its SMS and safety performances.

Continuous improvement of the SMS and railway safety should consider combining both processes with the improvement of safety performance to ensure, where reasonably practicable, that the level of safety performances is maintained.

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 in an adequate scale;

- assessment/monitoring/verification of their effectiveness;

- enforcement, review and revision of plans.

In combination with appropriate statistical tools to analyse data, this must ensure that all processes are periodically revised and completed in a management cycle.

ASSESSMENT CRITERIA

E.1 The RU/IM has processes and/or procedures in place to ensure, where reasonably practicable, the continuous improvement of the SMS; these should include periodical reviews of the SMS, as found to be necessary[6].

E.2 There are processes in place describing arrangements to monitor and analyse relevant safety data.

E.3 There are processes in place describing how identified shortcomings are rectified.

E.4 There are processes in place describing how new safety developments, lessons learnt are implemented.

E.5 There are processes in place describing how internal audit findings are used to bring about improvement in the SMS.

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[6] Criteria to assess the existence of process/es ensuring, where reasonably practicable, the improvement of safety performances, are defined according to, and therefore under, Annex III (2)(b)

4.2 Annex III(2) – Basic elements of the SMS

> **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;**

ABSTRACT/DESCRIPTION

a.0 The safety policy expresses and reflects an organisation's commitment, obligation (mission) and strategic view (vision) on railway safety; it includes, among others, a declaration of intent and also provides indications on the overall direction and the general objectives of the safety management system.

The safety policy should also outline the principles and core values according to which the organisation and staff operate, thus giving evidence of the organisation's management commitment to the development and improvement of working ethics and providing staff with clear guidance for action to consolidate safety culture and safety awareness within the organisation.

ASSESSMENT CRITERIA

a.1 The organisation's safety policy is:

- available to all staff;
- appropriate to the RU/IM's type and extent of service;
- approved by the organisation's chief executive.

> **b) …qualitative and quantitative targets of the organisation for the maintenance and enhancement of safety, and plans and procedures for reaching these targets;**

ABSTRACT/DESCRIPTION

b.0 Railway Safety performances are generally assessed evaluating the achievement of the organisation's corporate safety targets, which need to be set and broken down to be managed at all relevant levels of the organisation.

Each Railway Undertaking/Infrastructure Manager, within the framework of its own Safety Management System, must include the demonstration of its capability to maintain or improve its level of safety, by

- measuring its safety performances (monitoring, internal auditing);
- identifying the most suitable and feasible measures using the resources available (safety planning);
- putting in place the planned measures (acting);
- evaluating the effectiveness of measures (monitoring, internal auditing, safety reporting).

ASSESSMENT CRITERIA

b.1 The RU/IM has processes and procedures to derive relevant safety targets in line with the legal framework.

b.2 The RU/IM has processes and procedures to derive relevant safety targets consistent with type, extent and relevant risks of the RU/IM.

b.3 The RU/IM has processes and procedures to regularly assess its overall safety performance in relation to its own safety targets and to those established on member state level.

b.4 The RU/IM has processes and procedures in place to monitor and review operational arrangements by:

- collecting relevant safety data to derive trends in safety performance and assess compliance with targets;
- assessing past performances (does not apply for first time applicants) in relation to their safety targets;
- interpreting relevant data and implementing necessary changes.

b.5 The RU/IM has processes in place to develop plans and procedures for reaching its targets.

c) …procedures to meet existing, new and altered technical and operational standards or other prescriptive conditions as laid down
- *in TSIs, or*
- *in national safety rules referred to in Article 8 and Annex II, or*
- *in other relevant rules, or*
- *in authority decisions,*
and procedures to assure compliance with the standards and other prescriptive conditions throughout the lifecycle of equipment and operations;

ABSTRACT/DESCRIPTION

c.0 All safety related procedures and processes of the safety management system must be:

- designed to comply with the regulatory framework and updated to take into account any variation or addition;

- consistent with type and extent of services operated by the organisation;

- consistent with relevant organisation changes.

The safety management system should have a process/procedure in place to promptly identify, gather and list, for each individual category of staff, requirements contained in EU-rules, TSIs, national safety rules and internal rules/procedures.

Organisations should have a process/procedure in place to promptly detect/recognize variations/additions in the regulatory framework. 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, and other relevant rules.

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.

ASSESSMENT CRITERIA

c.1 The SMS has processes and procedures in place to identify all necessary safety related requirements, relevant for the type and extent of operations carried out by the RU/IM, and ensure that they are updated and accordingly implemented (change control management).

c.2 The SMS has processes and procedures in place to monitor implementation of all necessary safety related requirements.

c.3 The SMS has processes and procedures in place to implement corrective actions, when needed, to ensure compliance of the railway system with standards and other prescriptive conditions throughout the lifecycle of equipment and operations.

c.4 The SMS has processes and procedures in place to ensure that the right staff, procedures, specific documents, equipment and rolling stock are used for the purpose intended[7].

c.5 The SMS has processes and procedures in place to ensure that maintenance is carried out according to the relevant requirements.

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[7] Staff, procedures and rolling stock are all considered as elements of operation in this context.

> *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;*

ABSTRACT/DESCRIPTION

d.0 Railway organisations must have a system in place to control changes/new projects and manage related risks, taking into account also those relating to occupational safety[8].

Changes can apply to

- technique/technologies;
- operational procedures/rules/standards;
- organisational structure.

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

ASSESSMENT CRITERIA

d.1 The RU/IM has processes and criteria in place to recognise changes in equipment, procedures, organisation, staffing or interfaces.

d.2 The RU/IM has processes to assess the level of impact of changes to decide whether to apply the CSMs on risk assessment.

d.3 The RU/IM has processes to ensure risk assessment and identification of control measures.

d.4 The RU/IM has processes to monitor the implementation and effectiveness of control measures.

d.5 There are processes/measures in place to assess with other organisations (IM, other RUs, third parties, etc) interface risks introduced by changes.

d.6 The results of the risk analysis are visible to all relevant staff and there are processes in place to feed these results into other processes within the organisation.

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[8] ref.: Directive 2004/49/EC, Recital (14)

e) …provision of programmes for training of staff and systems to ensure that the staff's competence is maintained and tasks carried out accordingly;

ABSTRACT/DESCRIPTION

e.0 An organisation must ensure that all staff with a responsibility in the safety management system are competent to perform their tasks and that staff skills and knowledge are maintained, in all circumstances.

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

- the selection principles (required basic educational level, mental aptitude and physical fitness);
- the initial training and certification of acquired competence and skills;
- the ongoing training and periodical update of existing knowledge and skills;
- proficiency checks, as required;
- specific measures in case of long absence from work, as required;
- specific SMS training for staff directly involved in the implementation and enforcement of an organisation's SMS, e.g. safety manager, those responsible for safety-related processes/functions, etc.

ASSESSMENT CRITERIA

e.1 The RU/IM has set up a competence management system providing for:

- the identification of posts that have responsibilities for taking operational decisions within the system;
- the identification of posts that perform safety-critical tasks;
- linking posts to the requirements they must meet for their task in national and cross-border traffic;
- allocating staff with the appropriate competence to relevant tasks.

e.2 The competence management system complies with:

- TSI Operations as far as within the control of the RU/IM and where applicable;
- national requirements that implement or elaborate relevant items of the TSI Operations in national rules;
- national requirements for issues/elements not covered or left open by the TSI;
- its own internal rules and principles for staff qualification.

e.3 There are procedures in place to ensure that the necessary knowledge, skills and aptitude (medical and psychological) of staff are refreshed/updated to retain the level required to safely perform each task.

f) *…arrangements for the provision of sufficient information within the organisation and, where appropriate, between organisations operating on the same infrastructure;*

ABSTRACT/DESCRIPTION

f.0 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 all information is conveyed to the right person/role/function in a prompt and clear way.

All necessary safety-related information needs to be traceable, documented, complete and available when required.

ASSESSMENT CRITERIA

f.1 The SMS has adequate processes to ensure that all relevant and valid safety information, including day-to-day operational information, is available to staff before they must enforce/apply it.

f.2 Appropriate access and accessibility to the document/information is ensured for all interested staff.

f.3 To ensure knowledge and understanding of the SMS there is an information process in place to provide all staff, involved in safety related processes, with relevant documents and to show how and where to find, within them, the parts they need to know.

f.4 There is a process ensuring that SMS information is distributed to all safety relevant personnel (management and staff performing safety critical tasks) and that all other staff are informed of its existence and purpose.

f.5 It is ensured that there are adequate arrangements in place for the sharing of information between railway organisations.

> **g) …procedures and formats for how safety information is to be documented and designation of procedure for configuration control of vital safety information;**

ABSTRACT/DESCRIPTION

g.0 Organisations must define document and data control procedures, based on existing management systems; documents and records must be readily available for consultation and/or verification.

Measures to control vital safety information are important to maintain and improve safety performance within an organisation and also to allow for corrective actions to be taken promptly and efficiently.

RUs and IM, operating on a same network system, should have arrangements in place to ensure the correct exchange, duly documented, of all relevant safety information. They should develop and support the use of standardised protocols for formal communications concerning operation (train logs, traffic/operating restrictions etc.) as a useful means of harmonisation.

ASSESSMENT CRITERIA

g.1 The SMS has adequate processes to ensure that all relevant safety information are accurate, complete, appropriately updated and duly documented.

g.2 The SMS has adequate processes to:
- format, generate, distribute and manage the control of changes to all relevant safety documentation;
- receive, collect and store/archive all relevant documentation/information on paper or by other means/registration systems;
- ensure that staff are formerly given all relevant and updated documentation and act upon it as necessary.

g.3 The SMS has adequate processes to ensure consistency, coherence and comprehension of language/content.

g.4 RUs and IMs have arrangements in place to ensure that communication barriers don't arise, or are minimised; evidence should be provided of the use of standardised protocols/formats for safety related information and to document all relevant data.

> **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;**

ABSTRACT/DESCRIPTION

h.0 Railway organisations should rely on a structured monitoring system and the management decision process. This would promote and encourage the reporting of faults, dangerous events/occurrences, near misses, including events/cases where employees have made mistakes or failed to comply or follow correct safety procedures, etc. Root cause analysis should be usefully performed in relevant cases, results included in training programs as lessons learned and relevant information made available to all interested/related staff and, if deemed necessary, to other interested parties.

Staff directly or indirectly involved in safety related events should actively participate in the problem-solving process to search for and develop preventive measures.

ASSESSMENT CRITERIA

h.1 The SMS has adequate processes and someone competent responsible for each, to ensure that:

- accidents, incidents, near misses and other dangerous occurrences are reported, logged, investigated and analysed;
- accidents, incidents, near misses and other dangerous occurrences are reported, as required by relevant legislation, to national bodies;
- recommendations from the NSA, NIB, from industry/internal investigations are evaluated and implemented if appropriate or mandated;
- relevant reports/information from other RUs and IMs are considered and taken into account.

h.2 The SMS provides that

- relevant information relating to the investigation and causes of accidents, incidents, near misses and other dangerous occurrences is used to learn and adopt corrective measures to improve the level of safety;
- the investigation processes take into account the effects of the operation of other RUs/IMs;
- the allocation of resources and training is provided for the investigation process.

i) …provision of plans for action and alerts and information in case of emergency, agreed upon with the appropriate public authorities;

ABSTRACT/DESCRIPTION

i.0 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.

For each type of emergency the plan should clearly identify and define:

- the different parties/staff interested/involved;
- 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.

ASSESSMENT CRITERIA

i.1 The RU/IM has identified all types of emergency and has procedures in place to identify new ones.

i.2 There are processes in place to ensure that the RU/IM can

- promptly contact emergency services;
- provide the emergency services with all relevant information both to prepare in advance for their emergency response, and at the time of the emergency.

FOR EACH IDENTIFIED TYPE OF EMERGENCY:

i.3 The roles and responsibilities of all parties (IM, RU, emergency services, etc.) are identified and defined.

i.4 Plans for action, alerts and information exist and includes:

- procedures to alert all staff with responsibility for emergency management;
- arrangements to communicate these to all parties, including emergency instructions for passengers.

i.5 Resources, means and training requirements have been identified and allocated.

i.6 There are procedures in place to re-establish normal operating conditions as soon as possible.

i.7 There are procedures for testing emergency plans in cooperation with other parties to train staff, test emergency procedures, identify weak points and verify how potential emergency situations are managed.

i.8 In the case of degraded operations:

- interfaces between RU/IM/third parties are clearly defined and duties, responsibilities unambiguously assigned to competent staff;
- competent staff can be contacted immediately to take any required decisions.

For the assessment of RUs

i.9 Procedures ensure that competent staff or a responsible person (particularly relating to services of dangerous goods), with adequate language skills, can be contacted easily and without delay by the infrastructure manager.

For the assessment of IMs

i.10 All emergency plans and procedures of the IM are coordinated with RUs which operate on its infrastructure and any other infrastructure with which it has an interface.

i.11 There are arrangements in place to halt operations and railway traffic promptly, if necessary, and to inform all interested parties of the action taken.

j) …provisions for recurrent internal auditing of the safety management system.

ABSTRACT/DESCRIPTION

j.0 Internal auditing serves the purpose of reviewing and verifying if the SMS is still effective, i.e. if the procedures described within the SMS ensure that the services of the RU/IM comply with relevant requirements.

RUs/IMs should establish a calendar of internal audits to be carried out in order to fulfil the requirements specified in Article 9(4) on reporting to the NSA (audit planning).

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 audits.

Audits should be carried out in an impartial and independent 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.

ASSESSMENT CRITERIA

j.1 The RU/IM has a internal auditing system which is independent, impartial and acts in a transparent way.

j.2 The RU/IM has a schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance.

j.3 Audits are carried out by suitably competent persons.

j.4 Procedures and/or processes are in place to

- identify and select auditors,
- analyse and evaluate the results of the audits,
- propose and implement specific corrective measures/actions,
- verify the effectiveness of previous measures/actions.

j.5 Senior management is aware of the results of audits and take overall responsibility for implementation of changes to the SMS.

j.6 The RU/IM shows how the audit process is planned in relation to routine monitoring arrangements to ensure compliance with internal procedures and standards.