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

RSD and other management standards

Version Control

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Introduction

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

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

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

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

The purpose of the SMS is to ensure that the organisation achieves its business objectives in a safe manner. These objectives need to be fulfilled in today's ever changing and complex railway environment. In addition, the SMS should ensure that the organisation complies with all of the safety obligations that apply to it.

Adopting a structured approach enables the identification of hazards and the continuous management of risks related to an organisations own activities, with the aim of preventing accidents. When appropriate it should take into account the interfaces with other RUs and IMs in the

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[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

railway system. Implementing all relevant elements of an SMS in an adequate way can provide an organisation with the necessary trust that it controls and will continue to control all the risks associated with its activities, under all conditions.

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

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

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

Many features of the railway SMS are very similar to management practice advocated by proponents of quality, health and safety at work, environmental protection and business excellence. Therefore principles of good management can be easily integrated and may not need a complete re-design of organisations that already have those systems in place;

It has been recognised that structured management systems add value to business helping to improve overall performances, introduce operational efficiencies, enhance relations with customers and regulatory authorities and build a positive safety culture.

Integration of management systems

The integration of railway SMS with other management standards (quality / environmental protection / health and safety at work / etc.) is not a mandatory requirement, however some railway companies may wish to implement an Integrated Management System (IMS), based on the fact that the most common management standard have similar basic principles (such as management review, document control, corrective action and the requirement for training of staff).

The above mentioned management systems can be integrated into a single, joint system or a combination of any of the above.

The integration is expected to facilitate synergies in using supporting processes that may be common to them. All management systems can together pursue continuous improvement.

The IMS Manual and Procedures may be fully integrated and include relevant forms. Some useful references for the development of an IMS can be found in the document PAS[4] 99 Integrated Management.

The purpose of this document is to assist organisations to develop their SMS and/or integrating it on existing management standards, by providing:

1) a short description of the most common standards, to identify the respective scope,

2) some tables with cross reference between the requirements in the Railway Safety Directive and in the most wide-spread standards (ISO 9001, ISO 14001, OHSAS 18001).

The key to an effective Integrated Management System is designing the processes for efficiency and ease of use: all processes must be carefully thought out, well-organized, and carefully designed to work together and to lead organisations to continuous improvement.

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[4] "Publicly Available Specification" developed by British Standard Institute (BSI).

1) Management Standards

- **ISO 9000:2000 Quality management systems - Fundamentals and vocabulary**

ISO 9000:2005 contains the fundamentals of quality management systems, which form the subject of the ISO 9000 family, and defines related terms. It is not used for certification; however its principles are applicable to the following:

a) organisations seeking advantage through the implementation of a quality management system;

b) organisations seeking confidence from their suppliers that their product requirements will be satisfied;

c) users of the products;

d) those concerned with a mutual understanding of the terminology used in quality management (e.g. suppliers, customers, regulators);

e) those internal or external to the organisation who assess the quality management system or audit it for conformity with the requirements of ISO 9001 (e.g. auditors, regulators, certification/registration bodies);

f) those internal or external to the organization who give advice or training on the quality management system appropriate to that organization;

g) developers of related standards.

- **ISO 9001:2008 Quality management systems - Requirements**

ISO 9001:2008 specifies requirements for a quality management system where an organization needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All requirements of ISO 9001:2008 are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

- **ISO 14001:2004 Environmental management systems -Requirements with guidance for use**

ISO 14001:2004 specifies requirements for an environmental management system to enable an organization to develop and implement a policy and objectives which take into account legal requirements and other requirements to which the organization subscribes, and information about significant environmental aspects. It applies to those environmental aspects that the organization identifies as those which it can control and those which it can influence. It does not itself state specific environmental performance criteria.

ISO 14001:2004 is applicable to any organization that wishes to establish, implement, maintain and improve an environmental management system, to assure itself of conformity with its stated environmental policy.

All the requirements in ISO 14001:2004 are intended to be incorporated into any environmental management system. The extent of the application will depend on factors such as the environmental policy of the organization, the nature of its activities, products and services and the location where and the conditions in which it functions.

ISO 14001:2004 also provides informative guidance on its use (Annex A).

- **OHSAS 18001:2007 Occupational health and safety management systems. Specification**

OHSAS (Occupational Health and Safety Assessment Series) 18001 is the internationally recognised assessment specification for occupational health and safety management systems. This international standard provides a framework for a third party certification of organizations wishing to implement a formal procedure to reduce the risks associated with health and safety in the working environment for employees, customers and the general public, through identification and control of health and safety risks, reduction of the potential for accidents, legislative compliance and overall performance improvement. The standard is complemented by OHSAS 18002:2002, Guidelines for the Implementation of OHSAS 18001.

OHSAS 18001 has been designed to be compatible with ISO 9001 and ISO 14001.

2) Cross reference tables

The tables below are provided to assist those organisations developing and implementing an SMS by displaying the references to requirements in the most common management standards, in order to orient users in the identification of the commonalities and support the integration.

As far as the SMS in accordance with the Safety Directive, the IMS should allow prompt availability for supervision regime and investigation of accidents, incidents or other dangerous occurrences.

Dedicated cross reference may serve as a tool in each management system to identify clearly the relationship between the processes, documents and relevant responsibilities.

DIRECTIVE 2004/49/CE, Article 9	ISO 9000:2005	ISO 9001:2008	ISO 14001:2004	OHSAS 18001:2007
1. IMs and RUs shall establish their SMS to ensure that the railway system can achieve at least the CSTs**, is in** conformity with the national safety rules **described in Article 8 and Annex II and with safety requirements laid down in the TSIs, and that** the relevant parts of CSMs are applied**.**	2.3, b) - Quality Management System (QMS as follows) approach	1.1 - General	3.8 - Definition of environmental management system and notes	3 – Terms and definition
2. The SMS 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**.**	2.2 - Requirements for QMS and requirements for products 2.3, e) - QMS approach 2.4 - The process approach	1 - Scope 4.1 - General requirements	4.1 - General requirements	4.1 - General requirements
It shall ensure the control of all risks associated with the activity **of the IM/RU, including the** supply of maintenance and material and the use of contractors**.**	Not explicitly covered	4.1 – last paragraph + notes 2 and 3	4.4.6, c) - Operational control A.1, b) 1 -General requirements+ A.3.1 – Environmental aspects	4.3.1 – Planning for hazard identification, risk assessment and determining control
Without prejudice to existing national and international liability rules, the SMS shall also take into account, where appropriate and reasonable, the risks arising as a result of activities by other parties.	1, b) - Scope	4.1, b) - General requirements	4.1 - General requirements	4.1 - General requirements
3. The SMS <u>of any IM</u> **shall take into account the effects of operations by different RUs on the network and make provisions to allow all RUs to operate [...] and with the aim of coordinating the emergency procedures of the IM with all RUs that operate on its infrastructure.**	1, b) - Scope	4.1, b) - General requirements	4.1 - General requirements	4.1 - General requirements
It shall in particular describe the distribution of responsibilities within the organisation of the IM/RU	2.3, c) - QMS approach	5.5 – Responsibility, authority and communication	4.4.1 + A.4.1 – Resources, roles; responsibility and authority	4.4.1 – Resources, roles, responsibility, accountability and authority

DIRECTIVE 2004/49/CE, Annex III	ISO 9000:2005	ISO 9001:2008	ISO 14001:2004	OHSAS 18001:2007
The SMS must be documented in all relevant parts	2.7 - Documentation	4.2 - Documentation requirements -	4.2, e) 4.4.4 – Documentation A.4.4 – Documentation	4.4.4 - Documentation
It shall show how control by the management on different levels is secured,	2.3, f) - QMS approach 2.6	4.1, c) - General requirements 5.1, d) – Management commitment 5.6 Management review	4.2 + A2– Environmental policy 4.4.1, b) - Resources, roles; responsibility and authority	4.2 – OH&S policy 4.6 Management review
how staff and their representatives on all levels are involved	2.6 – Role of the top management within the QMS	5.1, a) - Management commitment 5.5.3 Internal communication	4.4.1 – Resources, roles; responsibility and authority	4.4.1 –Resources, roles, responsibility, accountability and authority 4.4.3 – Communication, participation and consultation
how continuous improvement of the SMS is ensured.	2.3, f) - QMS approach Figure 1 – Model of a process-based QMS 2.9 – Continual improvement 3.2.13 – definition	0.2, d) – Process approach Figure 1 – Model of a process-based QMS 8.5.1 Continual improvement	3.2 - Definition 4.1 – General requirements	4.3.3 – Objectives and programme(s)
(a) a safety policy approved by the organisation's chief executive and communicated to all staff;	2.5 – Quality policy and quality objectives	5.1 – Management committment 5.3 – Quality policy	4.2, b) – Environmental policy A.2 Environmental policy	4.2 – OH&S policy

DIRECTIVE 2004/49/CE, Annex III	ISO 9000:2005	ISO 9001:2008	ISO 14001:2004	OHSAS 18001:2007
(b) qualitative and quantitative targets of the organisation for the maintenance and enhancement of safety, and plans and procedures for reaching these targets;	2.5 - Quality policy and quality objectives 3.2.2 – definition of management system 3.2.5 – definition of quality objective Figure A.5 – Concepts relating to management	5.4.1 – Quality objectives 5.4.2 QMS planning	3.12 – Definition 4.3.3 – Objectives, targets and programme(s) 4.3.3 – Objectives, targets and programme(s)	4.3.3 – Objectives and programme(s)
(c) procedures to meet existing, new and altered technical and operational standards or other prescriptive conditions as laid down in TSIs, or in national safety rules referred to in Article 8 and Annex II, or in other relevant rules, or in authority decisions, and procedures to assure compliance with the standards and other prescriptive conditions throughout the life-cycle of equipment and operations;	0.1 – Introduction (second bullet point) 2.2 – Requirements for QMS and requirements for product 2.7.2, b), c), d), e), f) – Types of documents used in the quality management system	7.2.1 – Determination of requirements related to the product 7.2.2 – Review of requirements related to the product 7.3 Design and development 7.4 Purchasing 8.3 Treatment of non conformities	4.3.2 – Legal and other requirements 4.4.6, c) – Operational control A.3.2 – Legal and other requirements	4.3.2 – Legal and other requirements
(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;	Not explicitly covered	7.3.7 – Control of design and development changes	4.4.6, c) – Operational control A.1, b) 1 – General requirements A.3.1 – Environmental aspects	4.3.1 – Hazard identification, risk assessment and determining control
(e) provision of programmes for training of staff and systems to ensure that the staff's competence is maintained and tasks carried out accordingly;	1, f) – Scope 3.1.6 – Definition of competence	6.2 - Human resources. (General /Competence, awareness and training)	4.4.2–Competence, awareness and training A.4.2–Competence, awareness and training	4.4.2–Competence, training and awareness

DIRECTIVE 2004/49/CE, Annex III	ISO 9000:2005	ISO 9001:2008	ISO 14001:2004	OHSAS 18001:2007
(f) arrangements for the provision of sufficient information within the organisation and, where appropriate, between organisations operating on the same infrastructure;	2.7.2, a) – Types of documents used in the QMS Figure A.10 – Concepts relating to documentation	5.5.3 – Internal communication 7.2.3 Customer communication	4.4.3- Communication A.4.3- Communication	4.4.3 - Communication, participation and consultation
(g) procedures and formats for how safety information is to be documented and designation of procedure for configuration control of vital safety information;	2.7.2, g) – Types of documents used in the quality management system	7.1, b) - 7.1, d) planning of product realisation	4.4.6, c) – Operational control A.4.4.– Documentation A.4.5– Control of documents A.5.4 – Control of records	4.4.6 – Operational control 4.4.4.– Documentation 4.4.5– Control of documents 4.5.4 – Control of records
(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;	2.8.3 – Review of the QMS 2.8.4 – Self-assessment 2.10 - Figure A.9 – Concepts relating to conformity	5.6 – Management review 8.1 – General 8.3 Control of nonconforming product A.4 Analysis of data 8.2.4 - Monitoring and measurement of product 8.5.2 Corrective action 8.5.3 Preventive action	4.5.1 – Monitoring and measurement 4.5.2 – Evaluating of compliance A.5.1 – Monitoring and measurement A.5.2 – Evaluating of compliance	4.5.1 – Performance monitoring and measurement 4.5.2 – Evaluating of compliance 4.5.3 –Incidents investigation, nonconformity, corrective action and preventive action
(i) provision of plans for action and alerts and information in case of emergency, agreed upon with the appropriate public authorities;	Not covered	Not covered	4.4.7 - Emergency preparedness and response A.4.7 - Emergency preparedness and response	4.4.7 - Emergency preparedness and response

DIRECTIVE 2004/49/CE, Annex III	ISO 9000:2005	ISO 9001:2008	ISO 14001:2004	OHSAS 18001:2007
(j) provisions for recurrent internal auditing of the safety management system.	2.8.4 – Auditing the QMS Figure A.12 – Concepts related to audit	8.2.2 - Internal audit 8.2.3 – Monitoring and measurement of processes	4.5.5 – Internal auditing A.5.5 - Internal audit	4.5.4 – Internal audit