



EUROPEAN RAILWAY AGENCY  
Safety Unit

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

## INTERNAL AUDIT

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## Version Control

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## Introduction

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

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

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

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

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

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

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

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

Adopting a structured approach enables the identification of hazards and the continuous management of risks related to an organisations own activities, with the aim of preventing accidents. When appropriate it should take into account the interfaces with other RUs and IMs in the railway system. Implementing all relevant elements of an SMS in an adequate way can provide an organisation with the necessary trust that it controls and will continue to control all the risks associated with its activities, under all conditions.

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

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

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

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

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

## 1. Internal Audit

Internal audit, carried out by the RU or IM aims at assuring that the SMS is implemented and will continue to be delivered as foreseen in the Annex III (j).

### 1.1 Generalities

Railway Undertakings and Infrastructure managers have the obligation to perform internal audits in relation to the functioning of their SMS.

They can base their initial and ongoing internal (or “self”) audit on the assessment criteria established for the delivery and supervision of SMS by the NSAs<sup>4</sup>, using them as check-lists and deriving scoring principles.

Nonetheless, the Internal audit may go further than assessing compliance and provide elements for evaluating continuous improvement. Internal audit is a tool for encouraging reviews of objectives, practices and outcomes.

The audit activity should be delivered in an independent way and by suitably competent auditors.

Useful reference for audit principles, techniques and methods can be found in:

- ISO 19011:2002 GUIDELINES FOR QUALITY AND/OR ENVIRONMENTAL MANAGEMENT SYSTEMS AUDITING, which *“provides guidance on the principles of auditing, managing audit programmes, conducting quality management system audits and environmental management system audits, as well as guidance on the competence of quality and environmental management system auditors. The application of this International Standard to other types of audit is possible in principle, provided that special consideration is paid to identifying the competence needed by the audit team members in such cases”* [ref.: Art. 1. Scope]
- IPPF 01-2009 INTERNATIONAL STANDARDS FOR THE PROFESSIONAL PRACTICE OF INTERNAL AUDITING, issued by the Institute of internal auditors (IIA). The purpose of the IPPF standards is to:
  1. Delineate basic principles for the practice of internal auditing.
  2. Provide a framework for performing and promoting a broad range of internal auditing.
  3. Establish the basis for the evaluation of internal audit performance.

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<sup>4</sup> SMS is assessed by the NSA prior the delivery of a Safety Certificate / Safety Authorisations. It is then subject to supervision, in accordance with Regulation (s) for assessing conformity of safety certificates/authorisations [reference to be added, when available]

#### 4. Foster improved organisational processes and operations.

The standards are principles-focused, and contain basic requirements for the professional practice of internal auditing and for evaluating the effectiveness of performance, which are internationally applicable at organizational and individual levels, as well as interpretations, of terms or concepts.

### 1.2 Initial internal audit

Railway Undertakings and Infrastructure Managers operating for long or some time have already arrangements to deliver safe operation. They have, nonetheless, to demonstrate the implementation of a safety management system in conformity with Article 9 and Annex III of the Directive 2004/49/EC.

Railway Undertakings and Infrastructure Managers can check the consistency of their arrangement with the provisions of the afore mentioned Article 9 and Annex III of the Directive 2004/49/EC using the assessment criteria established for the NSAs in the Regulations containing the common safety method for assessing conformity with the requirements for obtaining railway safety certificates or authorisations. The consistency of procedure already in place with assessment criteria therein can provide a “gap analysis” that allow a revision of arrangements in place and support the process of designing a safety management system. The result of the gap analysis is expected to provide useful indications and focus on actions to be taken, summarised as shown in the following table.

RESULT OF THE GAP ANALYSIS	ACTIONS
• Existing formalised procedure consistent to requirements in the safety directive,	Use the reference in the SMS manual
• Existing process consistent to requirements in the safety directive	Formalise the procedure describing the process, then use the reference in the manual
• Existing formalised procedure partially or not consistent to requirements in the safety directive	Revise the procedure, then use the reference in the manual
• Process or procedure not established yet	Prepare the process/procedure if applicable, then use the reference in the manual. If the process or procedure is not applicable, provide justification

The actions should be allocated to the appropriate level of the organisation and their implementation should be measured, in order to achieve a consistent SMS in the due time. An internal audit would be useful before submitting application for a Part 'A' Safety Certificate or for a Safety Authorisation. RUs and IMs may choose an independent assessor to perform such audit.

New RUs/IMs that cannot rely on consolidated practices, can use the provisions of the afore mentioned Article 9 and Annex III of the Directive 2004/49/EC to design their SMS and develop the relevant documentation [see ERA SMS Application Guide - A system approach, § 8.4.1], taking into account the assessment criteria established for the NSAs in the CSM for assessing conformity of SMS to check the progress of work.

### **1.3 Ongoing internal audit**

Information relevant to the audit objectives, scope and criteria, should be prepared beforehand.

Audit objectives may refer at least to:

- periodical review of the generic system processes and procedure, in order to check the continuing effectiveness of the SMS;
- specific processes/operational areas to be investigated after weakness in operational performances (worsening trend in safety indicators) are detected;
- specific processes /operational areas where accident or repetitive incidents / dangerous events occurred

Each element to be audited should be clearly identified, with reference to the applicable rule(s) and with the appropriate level of detail to allow the desired insight of the process to be audited.

Evidence should be collected in any of the following way: interview, observation of activities, document review, sketches, photographs and documents, to be rated against relevant requirements.

Audit findings should indicate either conformity or non conformity with requirements, and/or identify opportunities for improvement. They should clearly identify the links corrective or preventive actions (e.g.: requests, addressed to the relevant part of the company).

The result of audit may consist of:

- Minor deficiencies. In these cases, some corrective measures that have no impact on the overall SMS have to be taken (like: update of documents that were found obsolete).

- Major deficiencies. In these there may be the necessity to take measures affecting the overall SMS. It is then particularly important that the senior level of management is aware of it and can, if necessary, take the responsibility to implement changes in the SMS (adopting the provisions of CSM on risk assessment).
- There are good results: actions for maintenance of good level /continuous improvement may be identified..

For all actions, allocations of responsibility, expected output and timeframe have to be set.

The audit results, after the first evaluation, can be used as a baseline for the purpose of determining future progress, allowing comparison of program performance year to year.

All these activities provide key information for management review and for risk analysis, and they should be recorded and made available for supervision of the NSA and accident investigation (audit report).

## **1.4 Audit management**

In general, the audit activities are made of the following steps

- Initial set up (the 'preparation', described below)
- Planning
- Audit delivery
- Reporting
- Follow up (to check if identified corrective actions are put in place)

### **1.4.1 Initial set up**

The preparation of audit includes:

- Audit scope and procedure to be followed
- Audit period to be considered (to define adequate programmes)
- Staff involved and qualification of auditors (internal/external)
- Identification of departments / functions / processes to be audited
- Common generic questions and specific clauses to be assigned according the rule(s) applicable to the specific department / functions / processes with evaluation method and ranking.



#### **1.4.2 Planning**

In this phase the departments / functions / processes which have to be audited are identified. Usually a specific periodical programme is drafted in order to cover all departments / functions / processes over a period, but specific audit may be arranged on the basis of safety performance data.

#### **1.4.3 Audit delivery**

This is the 'core' activity, which is review of documents, interviews, visit to workplaces, etc.

#### **1.4.4 Reporting**

This phase presents the formalization of audit findings and results. An audit report and supporting documents (e.g.: check lists) and collected evidence should be prepared, and the results communicated to the adequate level of the organisation.

#### **1.4.5 Follow up**

This additional phase is to check if identified preventive/corrective actions are put in place and if they are effective.

### **1.5 Basic audit terminology**

A selection of terms is presented in order to provide basic knowledge on audit principles. Such terminology is based on the standards ISO 9001:2008, ISO 19011:2002 and IPPF 01-2009 (the latter is available in several languages at <http://www.theiia.org/guidance/standards-and-guidance/ippf/standards/>)

#### **Audit**

An *audit* is an evidence gathering process. Audit evidence is used to evaluate how well audited criteria are being met. Audits must be objective, impartial, and independent, and the audit process must be both systematic and documented.

There are three types of audits: first-party, second-party, and third-party audits. First-party audits are internal audits. Second and third party audits are external audits.

Organizations use *first party (internal or self) audits* to audit themselves for internal purposes. However, it is not mandatory that internal audit is carried out exclusively by internal auditors. External organizations can be involved to carry out an internal audit on behalf of the auditee. First party audit can be used to declare that an organization complies with a standard (a self-declaration).

*Second party audits* are external audits. They are usually done by customers or by others on their behalf.

*Third party audits* are external audits as well. However, they're performed by independent external organizations. Third party audits are used to determine whether or not an organization complies with a standard. In quality management systems, third party auditors are referred to as registrars or certification bodies.

### **Audit criteria**

Audit criteria include policies, procedures, and requirements to be met. Audit evidence is used to determine how well such audit criteria are being met. Audit evidence is used to determine how well policies are being implemented, how well procedures are being applied, and how well requirements are being met.

### **Auditee**

An auditee is an organization, or part of it, that is being audited.

### **Audit evidence**

Audit evidence includes records, factual statements, and other verifiable information that is related to the audit criteria being used.. Audit evidence can be either qualitative or quantitative. Objective evidence is data that shows or proves that something exists or is true.

### **Audit findings**

Audit findings result from a process that evaluates audit evidence and compares it against audit criteria. Audit findings can show that audit criteria are being met (conformity) or that they are not being met (non-conformity). They can also identify improvement opportunities. Audit findings are used to assess the effectiveness of a management system and to identify opportunities for improvement.

### **Auditor**

In the context of management standards, an auditor is a person who collects evidence in order to evaluate how well the systems meet requirements. Auditors are expected to determine whether the management systems comply with standards and other planned arrangements. They must also be able to determine whether the management systems are properly implemented and maintained. And they must be able to do all of this while being independent, objective, impartial, and competent.

### **Audit plan**

An audit plan specifies how to conduct a particular audit. It describes the activities to be carried out and the arrangements to make.

## **Audit scope**

The scope of an audit is a statement that specifies the focus, extent, and boundary of a particular audit. The scope of an audit is generally defined by specifying the physical location of the audit, the organisation / organizational units that will be examined, the processes and activities that will be included, and the time period that will be covered.