

APPLYING THE COMMON SAFETY METHOD ON CONFORMITY ASSESSMENT – A GUIDE FOR NATIONAL SAFETY AUTHORITIES

The main focus of this guide is to provide practical help for NSAs on effectively conducting the assessment phase of their activities prior to awarding safety certificates or safety authorisations. It is meant to be a living document regularly updated to reflect NSA concerns, problems and good practice. As such the Agency would welcome any feedback from NSAs based on their experience during SMS assessment.

In the first instance, could you please email any suggestions for issues to be covered or feedback on the usefulness of the guide to:

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Introduction

The Common Safety Method for Conformity Assessment (CSM CA) is addressed to national safety authorities (NSAs). The CSM CA is based on two Commission Regulations – one (Commission Regulation (EU) 1158/2010)¹ for railway undertakings (RUs) seeking a safety certificate and another (Commission Regulation (EU) 1169/2010)² for infrastructure managers (IMs) seeking a safety authorisation. The CSM CA sets out legally the harmonised way in which all NSAs should approach assessments prior to the award of safety certificates and safety authorisations and establishes principles they need to apply to supervision after the award of the safety certificate or safety authorisation. The Commission Regulations were published in the Official Journal of the European Union on 10 and 11 December 2010 and became binding on Member States twenty days after its publication.

The CSM CA is an important building block in harmonisation of decision-making principles amongst NSAs. The two Regulations set out a unified and coherent framework both for the assessment and award of safety certificates/authorisations but also a common framework of principles for supervision after the award of the certificate/authorisation. Day to day application of the CSM CA should help develop mutual trust amongst NSAs in reassuring them that decisions are being taken within a common framework of principles.

We need more work on developing understanding and application of these tools. To help in this process, the Agency will play an educational and facilitating role to raise awareness and understanding of the content of the CSM CA and its day to day application.

In addition, this activity on CSM CA links to other workstreams underway within the Agency, there is a need to have a wider understanding about the core functions of an NSA (which includes application of the supervision principles) and how they might be developed. These workstreams are:

- (a) The development of a programme for cross-auditing of NSAs; and
- (b) The development of a Common Safety Method to help NSAs in their post-award supervision and the detailed application of the supervision principles in the CSM CA.

¹ OJ L326, 10.12.2010, p, 11

² OJ L327, 11.12.2010, p.13

Structure of Application Guide

This document is split into seven sections

1. General Introduction to Management Systems and how SMS fits into overall structure – educational tool for NSAs and for RUs and IMs.
2. Summary of the Legal Texts making up the CSM CA.
3. Framework Application Principles and Procedures for NSAs to use in the assessment process.
4. SMS Requirements and Assessment Criteria for obtaining a Part A safety certificate for RUs or safety authorisation for IMs.
5. Requirements and Assessment Criteria for Part B safety certificates for RUs.
6. Requirements and Assessment Criteria for network specific part of safety authorisation for IMs
7. Principles of Supervision Regime

This document offers practical guidance on any issues of interest to NSAs during assessment. However, we do not feel it is appropriate to comment on every single criterion based on the assumption that the purpose is self-explanatory.

Section 1 - SAFETY MANAGEMENT SYSTEMS

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.

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.

The Agency has produced a detailed set of guidelines for RUs and IMs on developing a SMS in a variety of languages. This set of documents set out good practice for the development and content of an SMS. All the language versions are available to download via the Agency's website.

Section 2 - SUMMARY OF PROVISIONS OF COMMISSION REGULATIONS (EU) 1158/2010 1 1169/2010 on CSM on CONFORMITY ASSESSMENT

Article 1

Subject matter

This Regulation establishes a common safety method (CSM) for assessing conformity with requirements in safety certificates as referred to in Article 6(3) (b) of the Railway Safety Directive.

The CSM includes:

- (a) a procedure and criteria for assessing applications by railway undertakings for safety certificates under Article 10(2) of the Railway Safety Directive, as set out in Annexes I, II and III to this Regulation,
- (b) principles for supervising compliance with the requirements of the Railway Safety Directive after the national safety authority has granted the certificate, as set out in Annex IV to this Regulation (Annex III for safety authorisation for IMs).

Article 2

Definitions

For the purposes of this Regulation, the following definition shall apply: 'supervision' means the arrangements put in place by the national safety authority to oversee safety performance after it has granted a safety certificate/safety authorisation.

Article 3

Procedures for assessing applications

1. When examining applications for both Part A and Part B safety certificates submitted after the entry into force of this Regulation, national safety authorities shall apply the procedure set out in Annex I to this Regulation for assessing their conformity with requirements in the Railway Safety Directive. National safety authorities shall use the assessment criteria set out in Annex II to this Regulation for safety certificates issued in accordance with Article 10(3) and those contained in Annex III to this Regulation for safety certificates issued in accordance with Article 10(4) of the Railway Safety Directive. These criteria shall also be used in case of renewal of safety certificates in accordance with Article 10(5) of the Railway Safety Directive.

2. During assessment, national safety authorities may accept commitments by applicants that they will manage risks through the use of contracts between parties. The contracts shall also specify the exchange of information needed to ensure the safe operation of vehicles, especially in the areas relating to managing maintenance.

3. Products or services provided by contractors or suppliers to railway undertakings shall be presumed to conform to safety requirements if the contractors, suppliers or products are certified in accordance with relevant certification schemes established under EU legislation, for the provision of such products and services.

The provisions of the proposed Commission Regulation on ECM is a good example of these types of schemes. Railway undertakings and infrastructure managers need to describe the processes they use to manage the interfaces with an entity in charge of maintenance and to monitor the results delivered by an entity in charge of maintenance, certified under this system. This shall be accepted by a national safety authority as proof of the ability of a railway undertaking or infrastructure manager to meet the relevant requirements on maintenance and control of contractors and suppliers specified in both Regulations on the common safety method on conformity assessment, unless the NSA can demonstrate the existence of a substantial safety risk.

Supervising the management of the interfaces between RUs/IMs and the ECMs become the main focus of NSA activity in this area. This is on the basis of using the principles for supervision activity in the CSM on Conformity Assessment and targeting supervision activity on the area with the greatest risk to operation of the railway.

Article 4 Supervision

After granting a safety certificate, national safety authorities shall, for both Part A and Part B safety certificates, supervise railway undertakings' continued application of their safety management system and shall apply the principles for supervision set out in Annex IV.

In the course of 2010/2011 the Agency will develop and recommend to the Commission a CSM providing a framework for how NSAs should undertake supervision activities. This will be alongside the development of a CSM for RUs/IMs on how they should monitor safety performance.

Article 5

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

SECTION 3 (ANNEX I OF LEGAL TEXT)

Procedure for assessing conformity with requirements for obtaining safety certificates to be issued in accordance with Article 10(2) (a) and (b) of the Railway Safety Directive

1. The procedures that a national safety authority puts in place to receive and assess applications and to award safety certificates shall be built upon the following framework principles.

(a) Setting up and reviewing the assessment process

National safety authorities shall develop structured and auditable processes to be undertaken by suitably competent persons. They shall scrutinise applications against the assessment criteria for safety management systems set out in Annex II and III. They shall record and give reasons for all decisions. The national safety authority's overall assessment process shall be periodically internally reviewed and continuously improved to secure its continued effectiveness and efficiency.

The exact detail of the assessment process needs to be set by each NSA on its own but common features of the process should be:

- acknowledgment of receipt of an application ;
- an initial screen of the application to ensure the documentation is sufficient for the formal assessment to begin ;
- application of structured and auditable processes, such as the use of project management techniques, to deliver the assessment, including the allocation of appropriate resources to assessment activity ;
- use of the CSM CA Assessment Criteria;
- formally record decisions at each stage of the process ;
- ensuring that staff involved in the assessment process are competent to deliver their assigned roles ;
- monitoring and auditing of decision making and use of process by line management in the NSA ;
- providing feedback to the applicant at all stages of the process of the application including meeting with the applicant to resolve any queries ;
- the creation of a complaints and an appeals process.
- the creation of an issues log to inform post-award supervision activities
- developing a proportionate approach to applications for upgrades and renewals of existing safety certificates/safety authorisations based on safety performance of RU/IM

(b) Quality of the assessment process

National safety authorities shall monitor the quality of their own performance at key stages in the processing of applications for safety certificates.

NSAs need to adopt quality management principles in their approach to assessing applications. This does not mean that an NSA need be certified to ISO 9000 standards. It does mean however that;

- the NSA needs to document its procedures on handling applications, starting at the receipt stage, proceeding to an assessment phase including reviewing the decision made and finishing at either the award or rejection stage.
- the NSA needs to document management oversight of the process within the NSA and how the objective of continuous improvement is pursued.
- the NSA need to develop provisions to measure and control the effectiveness of the processes put in place;
- the NSA should be prepared to adopt innovations and ways to optimise the use and functioning of existing processes;
- the NSA needs to develop and document a complaints procedure as a first step to resolving disputes.
- as a matter of good practice the NSA might decide to create a User Group, involving RUs and IMs in order to provide a forum for feedback by stakeholders on the working of the assessment process put in place by the NSA.
- the NSA should also develop a formal link between the SMS assessment phases and post-award supervision phases of its activities so that information gathered from one phase can inform the other phase - the development of an issues log for example.

(c) Scope of the assessment

The assessment shall be at management-system level and process-driven. Where scrutiny reveals shortcomings, the national safety authority may exercise discretion and, depending on the nature and seriousness of the non-conformity, shall outline the points which need to be enhanced. Ultimately, the national safety authority shall exercise its power to reject an application.

The assessment shall be:

- appropriate to the risks, character and extent of operations of the applicant;
- based on judgments of the railway undertaking's overall ability to operate safely as described in its safety management system (SMS).

The main purpose is to assess the capability of the RU/IM to operate safely, based on an holistic assessment of its SMS and not the individual elements of the SMS on their own. This approach allows for equality of treatment between new entrants to the rail market without any operational experience and existing entrants in the market with a lot of operational experience. Assessment of the SMS should be based on the following elements:

- a summary of the SMS (describing the functioning of the SMS) or the entire SMS documentation if it is a concise;
- the SMS documentation should signpost other documents supporting the detailed processes put in place ;
- NSA assessment is based on forming a professional judgement by the assessor or assessment team whether the RU/IM is capable of operating safely and not based on the elimination of all risks, prior to operation ;
- the assessment of the appropriateness of the SMS needs to be conducted using the assessment criteria in the CSM CA ;
- the assessor(s) needs to reach a view on whether the documentation outlining the SMS meets the assessment criteria or whether there is a need to request supplementary information or a meeting to allow a decision to be reached.
- the assessors(s) also need to form a view as to whether the degree of non-compliance with any assessment criterion is significant enough to show that the RU/IM is not capable of operating safely or whether it is a point to be recorded in the issues log and closed out during post-award supervision . This distinction is a decision for the assessor(s) and for the line management chain responsible for scrutinising the process.
- when assessing an RU's ability to perform ECM activity at the same time as assessing its SMS, the NSA should only check how the RU explains its procedures for meeting the specific requirements for operational maintenance functions – maintenance development,

(d) Timing of the assessment

National safety authorities shall complete the assessment within the time required by Article 12 of the Railway Safety Directive whilst ensuring that the evidence provided by the applicant is sufficiently examined. The national safety authority shall inform railway undertakings of issues of major concern as early as practically possible during the assessment phase.

To help the NSA meet the four month deadline for awarding the certificate, it will be useful to firstly conduct a quick screen of the information provided to see it is complete before beginning the formal assessment process. This will give both the NSA and the applicant the opportunity to request and provide further information at an early stage of the process and to discuss any areas of doubt on the documentation prior to the start of the formal assessment procedure and deadline. This process is only to ensure that all the documentation is in place to allow the formal assessment process to begin. The four month deadline starts when the formal assessment process begins.

(e) Decision making during the assessment

A decision to accept or reject an application for a safety certificate or authorisation shall be based on the evidence provided by the applicant and on whether compliance with the relevant requirements has been shown or not.

In this context, evidence can come in two main forms – either documents submitted in support of a safety certificate/safety authorisation application showing how the SMS meets the assessment criteria in the CSM CA or responses given to questions in telephone or other contacts or face-to-face meetings between the NSA and the RU in the course of the assessment. Where there has been a telephone conversation/ other contact/ face-to face meeting, there needs to be a formal record of the information collected /decisions taken.

2. The national safety authority shall assess whether the application for a safety certificate complies with Commission Regulation (EC) No 653/20073.
3. In particular, the national safety authority shall assess whether the attached summary of the safety management system manual allows an initial judgment on the quality and appropriateness of the safety management system and shall decide in which areas further information is necessary. The national safety authority may, as part of this request for more information, seek as much detailed information as it deems reasonably necessary to help its assessment of the application.
4. When granting a safety certificate, compliance of the applicant's safety management system with the assessment criteria shall be documented in relation to each assessment criterion.
5. When identifying a point of query or possible non-compliance, the national safety authority shall be specific and help the applicant to understand the level of detail expected in the response. To do this it shall:
 - refer accurately to the relevant criteria and ensure that the applicant has understood clearly the identified areas of non-compliance;
 - identify the relevant part of related regulations, rules, and standards;
 - state why the assessment criterion is not met;
 - agree on further commitments, information and any supporting evidence to be provided, as required by the level of detail of the criterion, and specify both the action required by the applicant to rectify the deficiency and the timeframe for compliance;
 - specify areas which could be subject to further scrutiny through supervision after the award of the certificate.
6. If a railway undertaking applies for both Part A and Part B certificates at the same time, the national safety authority shall ensure that the Part A certificate is granted first or that both certificates are granted together as provided for in Commission Regulation (EC) 653/2007. Nevertheless, National safety authorities shall define a procedure for how to use the application form (in particular, the front page for the Annexes) if a new application is made for both certificates at the same time.
7. The general framework procedures in place for assessing applications for safety certificates shall also apply to applications for safety certificates under Article 10(2) (b) of the Railway Safety Directive.
8. An national safety authority's assessment of an application for a safety certificate under Article 10(2) (b) of the Railway Safety Directive shall only apply to a railway undertaking's ability to comply with the requirements needed to operate on the

specific network for which it is seeking a certificate by using the procedures it has established to obtain a Part A certificate.

9. These assessment criteria are based on showing that the results of applying the procedures or processes to manage operation on a specific network have been documented and the commitment to implement them has been made. Hence in order to check whether the criteria have been met, the national safety authority may request submission of a sample of the documentation planned to be used by the railway undertaking.

10. National safety authorities shall cooperate to address issues of non-compliance with the Part B assessment criteria or to deal with queries on the Part B application. A national safety authority assessing a Part B application shall liaise with the national safety authority that issued Part A to discuss and agree what action, if any, each one will take to ensure compliance with the Part B assessment criteria.

It is important that NSAs develop good co-operation arrangements to deal with the award of Part B safety certificates and their assessment. Firstly, an NSA should not assess an application for a Part B certificate if the RU has not obtained a Part A in its own country. In such circumstances the NSA who has received the Part B application will need to inform the NSA of the country where the RU is established.

Where an NSA assessing a Part B certificate application, has some queries or doubts about the contents of the Part B application, it should not request any supporting information relating to the Part A certificate directly from the RU. Instead, it should speak to the NSA who issued the Part A certificate and raise their queries or concerns with that NSA. Both NSAs should then try and resolve any queries together.

It is important that the detailed nature of co-operation between NSAs is left to the NSAs themselves to develop, possibly on a case by case basis, as there are so many variables surrounding each Part B application in the different Member States.

SECTION 4(ANNEX II OF LEGAL TEXT)

Criteria for assessing conformity with the requirements for obtaining safety certificates to be issued in accordance with Article 10(2)(a) of the Railway Safety Directive related to the railway undertaking's safety management system as described in Article 9 and Annex III of the Railway Safety Directive

A. RISK CONTROL MEASURES FOR ALL RISKS ASSOCIATED WITH THE ACTIVITY OF THE RAILWAY UNDERTAKING

A.1 There are procedures put in place to identify risks associated with railway operations, including those directly arising from work activities, job design or workload and the activities of other organisations/persons.

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

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

A.4 There are procedures in place to recognise the need to work together with other entities (such as the infrastructure manager, railway undertakings, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on issues where they have shared interfaces that are likely to affect the putting in place of adequate risk control measures in accordance with Article 4(3) of the Railway Safety Directive.

A.5 There are procedures for agreed documentation and communication with the relevant entities including the identification of roles and responsibilities of each participating organisation and the specifications for information exchanges.

A.6 There are procedures to monitor the effectiveness of these arrangements and to implement changes when required.

These criteria provide a practical interpretation of the general risk identification requirements contained in Article 9 of the Safety Directive. They require the RU/IM to identify the risks associated with its operations and put in place measures to control all these identified risks. It is important to remember that these criteria do not deal with managing the risks from changes (this is dealt with under Assessment Criteria N).

In criterion A.1, the reference to « work activities » means that unless the NSA has been given the legal powers to deal with matters of occupational health and safety of workers by national legislation, then the NSA should in this instance simply check that procedures for dealing with railway worker health and safety is referred to in the applicant's SMS. The precise manner for how this information is organised and communicated is a matter for the applicant to describe in the application. In terms of job design, it is important to avoid an excessive volume of tasks and a conflict between different safety related duties. It is also important that job design maintains or improves the existing level of safety. Further details for how the SMS can deal with these issues is included in the relevant parts of the Agency's SMS guidelines.

Criterion A. 4 is important because due to the institutional changes in the functions, roles and responsibilities of RUs and IMs, it is important to develop co-operation arrangements to address interface risks or risks which are shared between concerned parties. The precise nature of these arrangements and the responsibility for end decision making and appeals will normally be left up to each Member State at this stage

B. RISK CONTROL RELATED TO THE SUPPLY OF MAINTENANCE AND MATERIAL

B.1 There are procedures to derive maintenance requirements/standards/processes from safety data and from the assignment of rolling stock.

B.2 There are procedures to adapt maintenance intervals according to the type and extent of service performed and/or data from rolling stock.

B.3 There are procedures to ensure that the responsibility for maintenance is clearly defined, to identify the competencies required for maintenance posts and to allocate appropriate levels of responsibility.

B.4 There are procedures to collect information on malfunctions and defects arising from day-to-day operation and to report them to those responsible for maintenance.

B.5 There are procedures to identify and report risks arising from defects and construction non-conformities or malfunctions throughout the lifecycle to interested parties.

B.6 There are procedures to verify and control the performance and results of maintenance to ensure that they comply with corporate standards.

The main risk arising from maintenance activities is that vehicles become unsafe because of degradations, damages, wear and tear appearing during operations. This risk is shared between entities in charge of maintenance (ECMs) and RUs/IMs, keepers and shipping forwarders as the users.

According to Article 14(a) of the Railway Safety Directive, the system of maintenance of the ECM allows to vehicles to be in a safe state of running. The degradations and damage (not always visible) may lead to an unsafe state of running. The ECM has to put in place the necessary maintenance measures to assure RUs/IMs that risks of unsafe state of running are under control and to come back to a safe state when necessary. The use of process which include details of how information is exchanged between the parties involved is an accepted way of managing these risks. In particular the ECM has to assure that the vehicles are in a safe state when going out of maintenance and returning to operation and in practice during an appropriately defined time after return to operation.

The certification of ECM under the proposed ECM certification scheme aims at providing appropriate assurance to RUs/IMs that ECMs are able to put in place a maintenance system to ensure that vehicles are in a safe state when returning to operations and during a reasonable time. Consequently, an NSA can accept that an RU/IM who uses vehicles under the control of a certified ECM has met the requirements of Assessment Criteria B1, B2, B3, C1 and the performance part of B6. An RU/IMs SMS should explain how it identifies the certified ECM for the freight vehicles it includes in its trains and how it selects certified ECMs for its own freight vehicles and exchanges information either directly or indirectly with the ECM.

Nevertheless, RUs/IMs still have to take measures to address day to day operational risk of unsafe state of running. This is regularly done through pre-departure checks and monitoring en route by operational staff (commonly referred to as first level maintenance) and should be described in the RU/IM's SMS.

C. RISK CONTROL RELATED TO THE USE OF CONTRACTORS AND CONTROL OF SUPPLIERS

- C.1 There are procedures to verify the competence of contractors (including subcontractors) and suppliers.
- C.2 There are procedures to verify and control the safety performance and results of all contracted services and products supplied either by the contractor or supplier to ensure that they comply with the requirements set out in the contract.
- C.3 Responsibilities and tasks relating to railway safety issues are clearly defined, known and allocated between the contracting partners and among all other interested parties.
- C.4 There are procedures to ensure traceability of safety-related documents and contracts.
- C.5 There are procedures to ensure that safety tasks, including the exchange of safety-related information, are performed by the contractors or the supplier according to relevant requirements set out in the contract.

The use of contracts is a generally accepted way to manage risks. However, the prime responsibility for managing contractors and checking their delivery against the set specifications originally rests with the RU/IM. The use of contractors or sub-contractors does not mean that the RU/IM delegates any of their responsibilities for ensuring that the contracted services are carried out to the standards specified before operation.

The main objective of the NSA in the assessment process is to satisfy itself that the process for managing contractors exists and is described in the SMS. The checking of whether these arrangements work in practice is part of the NSA supervision activities after the award of the certificate/authorisation.

D. RISKS ARISING FROM THE ACTIVITIES OF OTHER PARTIES EXTERNAL TO THE RAILWAY SYSTEM

- D.1 There are procedures to identify potential risks from parties external to the railway system where appropriate and reasonable.
- D.2 There are procedures to establish control measures to mitigate the risks identified under D1 insofar as the responsibilities of the applicant are concerned.
- D.3 There are procedures to monitor the effectiveness of the measures identified under D2 and implement changes where appropriate.

E. DOCUMENTATION OF THE SAFETY MANAGEMENT SYSTEM

E.1 There is a description of the activity that makes clear the type, extent and risk of operation.

E.2 There is a description of the structure of the safety management system, including the allocation of roles and responsibilities.

E.3 There is a description of safety management system procedures required by Article 9 and Annex III consistent with the type and extent of services operated.

E.4 Safety-critical processes and tasks relevant to the type of activity/service are listed and briefly described.

Documentation of the SMS means that descriptions of the procedures and processes developed should be in writing. This practice helps the RU/IM initially to judge the adequacy of its procedures to manage the identified risk, to monitor their ongoing effectiveness in managing the identified risks and to be able to audit whether the procedures meet the original objectives of managing the risks identified. It also helps in providing for the traceability of safety related decisions.

F. DISTRIBUTION OF RESPONSIBILITIES

F.1 There is a description of how coordination of safety management system activities across the organisation is ensured, based on proven knowledge and lead responsibility at management level.

F.2 There are procedures to ensure that staff with delegated responsibilities within the organisation have the authority, competence and appropriate resources to fulfil their duty.

F.3 Safety-related areas of responsibility, and the distribution of responsibilities to specific functions associated with them, together with their interfaces, are clearly defined.

F.4 There is a procedure to ensure that safety tasks are clearly defined and delegated to staff with appropriate competence.

G. SECURING CONTROL BY THE MANAGEMENT ON DIFFERENT LEVELS

G.1 There is a description of how responsibilities are allocated for each safety-related process throughout the organisation.

G.2 There is a procedure for regular monitoring of task performance assured by the line management chain that must intervene if the tasks are not being properly performed.

G.3 There are procedures to identify and manage the impact of other management activities on the safety management system.

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

G.5 There are procedures to allocate resources to deliver the tasks under the safety management system.

H. INVOLVING STAFF AND THEIR REPRESENTATIVES ON ALL

H.1 There are procedures in place to ensure that staff and staff representatives are adequately represented and consulted in defining, proposing, reviewing and developing the safety aspects of operational procedures that may involve staff.

H.2 Staff involvement and consultation arrangements are documented.

I. ENSURING CONTINUOUS IMPROVEMENT

There are procedures in place to ensure, where reasonably practicable, the continuous improvement of the safety management system; these shall include:

- (a) procedures for periodic reviews of the safety management system, as found to be necessary
- (b) procedures for describing arrangements to monitor and analyse relevant safety data
- (c) procedures for describing how identified shortcomings are rectified
- (d) procedures for describing the implementation of new safety management rules based on development and lessons learnt.
- (e) procedures for describing how internal audit findings are used to bring about improvement in the safety management system.

In assessing against these criteria, NSAs should remember that requirements for continuous improvement should be built into all phases of safety management development and not just the end phase. All elements of the SMS should be subject to auditing at various phases such as their introduction, ongoing monitoring of their effectiveness or an end year review of how they functioned. The extent of monitoring and auditing will vary depending on the proximity of the SMS process to the risk it is being used to control.

J. SAFETY POLICY APPROVED BY THE ORGANISATION'S CHIEF EXECUTIVE AND COMMUNICATED TO ALL STAFF

A document describing the organisation's safety policy exists and is:

- (a) communicated and made available to all staff, e.g. via the organisation's intranet;
- (b) appropriate to the type and extent of service;
- (c) approved by the organisation's chief executive.

K. QUALITATIVE AND QUANTATIVE TARGETS OF THE ORGANISATION FOR MAINTAINING AND ENHANCING SAFETY, AND PLANS AND PROCEDURES FOR REACHING THESE TARGETS

K.1 There are procedures to determine relevant safety targets in line with the legal framework, and there is a document stating these targets.

K.2 There are procedures to determine relevant safety targets consistent with the type and extent of the railway operations covered and the relevant risks.

K.3 There are procedures to regularly assess overall safety performance in relation to its corporate safety targets and to those established on member state level.

K.4 There are procedures in place to regularly monitor and review operational arrangements by:

(a) collecting relevant safety data to derive trends in safety performance and assess compliance with targets;

(b) interpreting relevant data and implementing necessary changes.

K.5 There are procedures in place by the infrastructure manager to develop plans and procedures for reaching its targets.

L. PROCEDURES TO MEET EXISTING, NEW AND ALTERED TECHNICAL AND OPERATIONAL STANDARDS OR OTHER PRESCRIPTIVE CONDITIONS

L.1. For safety related requirements relevant to the type and extent of operations, there are procedures for:

(a) identifying these requirements and updating relevant procedures to reflect changes made to them (change control management);

(b) implementing them;

(c) monitoring compliance with them;

(d) taking actions when non-compliance is identified.

L.2 There are procedures in place to ensure that the right staff, procedures, specific documents, equipment and rolling stock are used for the purpose intended.

L.3 The safety management system has procedures in place to ensure that maintenance is carried out according to the relevant requirements.

M. 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

M.1 There are management procedures for changes in equipment, procedures, organisation, staffing or interfaces.

M.2 There are risk assessment procedures to manage changes and to apply the common safety method on risk evaluation and assessment as set out in Commission Regulation (EC) No 352/2009 when required.

M.3 The railway undertaking has procedures in place to feed the results of risk assessment into other processes within the organisation and make them visible to relevant staff.

Guidance on the use of the CSM on Risk Assessment, which provides for a formal process to manage significant risks arising from changes, has been provided by the Agency and is available via the Agency's website at: <http://www.era.europa.eu/Document-Register/Pages/guide-for-application-common-safety-method-risk-assessment.aspx>

N. PROVISION OF STAFF TRAINING PROGRAMMES AND SYSTEMS TO ENSURE THAT THE STAFF COMPETENCE IS MAINTAINED AND TASKS CARRIED OUT ACCORDINGLY

N.1 There is a competence management system that includes at least:

- (a) identification of the knowledge and skills required for safety related tasks;
- (b) selection principles (basic educational level, mental aptitude and physical fitness required);
- (c) initial training and certification of acquired competence and skills;
- (d) ongoing training and periodical update of existing knowledge and skills;
- (e) periodic checks of competence where appropriate;
- (f) special measures in case of accidents/incidents or long absence from work, as required/where appropriate;
- (g) specific safety management system training for staff directly involved in ensuring that the safety management system works.

N.2 There are procedures within the competence management system providing for:

- (a) the identification of posts that perform safety tasks;
- (b) the identification of posts that entail responsibilities for taking operational decisions within the safety management system;
- (c) staff to have the necessary knowledge, skills and aptitude (medical and psychological) appropriate to their tasks and periodically refreshed/updated;
- (d) allocating staff with the competence appropriate to relevant tasks;
- (e) monitoring how tasks are performed and implementing corrective actions where required.

O. ARRANGEMENTS FOR THE PROVISION OF SUFFICIENT INFORMATION WITHIN THE ORGANISATION AND, WHERE APPROPRIATE, BETWEEN ORGANISATIONS OPERATING ON THE SAME INFRASTRUCTURE

O.1 There are procedures to ensure that:

- (a) staff have knowledge and understanding of the safety management system and information is easily accessible; and
- (b) appropriate documentation on the safety management system is given to relevant safety personnel.

O.2 There are procedures to ensure that:

- (a) key operational information is relevant and valid;
- (b) staff are aware of its existence before it must be applied;
- (c) it is available to staff and where required copies are formally given to them.

O.3 There are arrangements in place for the sharing of information between railway organisations.

P. PROCEDURES AND FORMATS FOR DOCUMENTING SAFETY INFORMATION, AND DESIGNATION OF A PROCEDURE FOR CONFIGURATION CONTROL OF VITAL SAFETY INFORMATION

P.1 There are procedures to ensure that all relevant safety information is accurate, complete, consistent, easy to understand, appropriately updated, and duly documented.

P.2 There are procedures to:

- (a) format, generate, distribute and manage control of changes to all relevant safety documentation;
- (b) receive, collect and store all relevant documentation/information on paper or by other registration systems.

P.3 There is a procedure for configuration control of vital safety information.

Q. PROCEDURES TO ENSURE THAT ACCIDENTS, INCIDENTS, NEAR MISSES AND OTHER DANGEROUS OCCURRENCES ARE REPORTED, INVESTIGATED AND ANALYSED AND THAT NECESSARY PREVENTIVE MEASURES ARE TAKEN

Q.1 There are procedures to ensure that accidents, incidents, near misses and other dangerous occurrences:

- (a) are reported, logged, investigated and analysed;
- (b) are reported, as required by relevant legislation, to national bodies.

Q.2 There are procedures to ensure that:

- (a) recommendations from the national safety authority, from the national investigating body, and from industry/internal investigations are evaluated and implemented if appropriate or mandated;
- (b) relevant reports/information from other railway undertakings, infrastructure managers, entities in charge of maintenance and keepers are considered and taken into account.

Q.3 There are procedures for relevant information relating to the investigation and causes of accidents, incidents, near misses and other dangerous occurrences to be used to learn and, where required, to adopt preventive measures.

R. PROVISION OF PLANS FOR ACTION AND ALERTS AND INFORMATION IN CASE OF EMERGENCY, AGREED UPON WITH THE APPROPRIATE PUBLIC AUTHORITIES

R.1 A document identifies all types of emergency, including degraded operations, and there are procedures in place to identify new ones.

R.2 There are procedures in place to ensure that, for each identified type of emergency:

- (a) the emergency services can be promptly contacted;

(b) the emergency services are provided with all relevant information both in advance, to prepare their emergency response, and at the time of an emergency.

R.3 The roles and responsibilities of all parties are identified and set out in a document.

R.4 Plans for action, alerts and information exist and include:

(a) procedures to alert all staff with responsibility for emergency management;

(b) arrangements to communicate these to all parties, including emergency instructions for passengers;

(c) arrangements for contacting competent staff immediately so they can take any decisions required.

R.5 There is a document describing how resources and means have been allocated and how training requirements have been identified.

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

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

R.8 There are procedures to ensure that competent staff in charge (particularly relating to dangerous goods services), with adequate language skills, can be contacted easily and without delay by the infrastructure manager.

R.9 There is a procedure to contact the entity in charge of maintenance or the keeper in the event of an emergency.

S. PROVISIONS FOR RECURRENT INTERNAL AUDITING OF THE SAFETY MANAGEMENT SYSTEM

S.1 There is an internal auditing system which is independent and impartial and which acts in a transparent way.

S.2 There is a schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance.

S.3 There are procedures in place to identify and select suitably competent auditors.

S.4 Procedures are in place to:

(a) analyse and evaluate the results of the audits,

(b) recommend follow-up measures,

(c) follow up the effectiveness of measures,

(d) document the execution of audits and the results of audits.

S.5 There are procedures to ensure that senior levels of the management chain are aware of the results of audits and take overall responsibility for implementation of changes to the safety management system. S.6 There is a document showing how audits are planned in relation to routine monitoring arrangements to ensure compliance with internal procedures and standards

SECTION 5 (ANNEX III OF LEGAL TEXT FOR SAFETY CERTIFICATES)

CRITERIA FOR ASSESSING CONFORMITY WITH THE REQUIREMENTS FOR OBTAINING SAFETY CERTIFICATES TO BE ISSUED IN ACCORDANCE WITH ARTICLE 10(2) (B) OF THE RAILWAY

GENERAL

The service for which a Part B certificate is being sought is outlined and there is a description of how the railway undertaking's generic procedures devised in support of its certificate issued under Article 10(2)(a) of the Railway Safety Directive are applied to develop all the arrangements (including allocation of resources) put in place to deliver the service.

A. COMPLIANCE WITH NETWORK-SPECIFIC RULES

A.1 There are documents containing results to show that the specific rules and specific risks associated with operating on the network for which a Part B application is being submitted have been considered and to show that the railway undertaking can comply with any network-specific rules and any exceptions to or derogations from those rules.

A.2 Network interfaces with other parties involved in railway operation on the network concerned are identified.

A.3 There are documents showing how the railway undertaking will interact with the infrastructure manager (IM) for the network and other railway undertakings operating on the network, including details on how information is shared.

A.4 There are documents showing how the railway undertaking will deal with emergency situations, including coordination with the infrastructure manager and the relevant public authorities.

A.5 There are documents identifying any specific accident/incident investigation rules and showing that the applicant can comply with them.

B. COMPLIANCE WITH NETWORK-SPECIFIC REQUIREMENTS FOR STAFF COMPETENCE

B.1 The documentation demonstrates that the applicant's safety management system contains a competence management system to:

(a) identify the categories of staff (employed or contracted) involved in providing the service and

(b) deliver competent staff for the network concerned, especially for those staff who are asked to undertake a variety of tasks and assure certification where appropriate.

B.2 The documentation demonstrates that there are arrangements put in place to organise the day-to-day work of the staff to ensure that safety-related tasks are carried out and that staff are assigned to appropriate tasks.

B.3 The documentation demonstrates the applicant's ability to produce documents to be used in training the relevant staff and its ability to ensure that the documents will be accurate, be kept up to date and be in a language and terminology understood by the staff who need to use them.

C. COMPLIANCE WITH NETWORK-SPECIFIC REQUIREMENTS FOR MANAGEMENT OF ROLLING STOCK²⁵

C.1 In the documentation, the types of rolling stock to be used on the specific network and the type of operations to be conducted are clearly indicated.

C.2 The documentation outlines how the railway undertaking complies with any operational restrictions placed on the type of rolling stock used on the network.

C.3 In the documentation, any additional maintenance requirements for the network concerned are identified and appropriate arrangements for maintenance are in place.

C.4 In the documentation, any additional requirements to manage rolling stock incidents for the network concerned are identified and appropriate arrangements are put in place.

SECTION 6 (ANNEX I OF LEGAL TEXT ON SAFETY AUTHORISATION)

CRITERIA FOR ASSESSING CONFORMITY WITH THE REQUIREMENTS FOR OBTAINING SAFETY AUTHORISATIONS TO BE ISSUED IN ACCORDANCE WITH ARTICLE 11(2) (B) OF THE RAILWAY SAFETY DIRECTIVE

T. SAFE DESIGN OF THE RAILWAY INFRASTRUCTURE

T.1 There are procedures to ensure the safe design of the infrastructure throughout the life-cycle of the infrastructure, covering design and installation.

T.2 There are procedures which take into account technical change of the infrastructure and the management of that change.

T.3 There are procedures which show that relevant rules covering the design of the infrastructure and any national safety methods have been identified and that the applicant can comply with them.

U. SAFE OPERATION OF THE INFRASTRUCTURE

U.1 There are procedures to ensure that the infrastructure is managed and operated safely, taking into account the number, type and extent of operators running services on the network including all necessary interactions depending on the complexity of the operation.

U.2 There are procedures which show how safety is managed at the physical and/or operational borders of the infrastructure.

U.3 There are procedures which show how effective cooperation and coordination is managed, both in normal and emergency situations.

U.4 There are procedures which show that rules covering the safe operation and management of infrastructure/vehicle interfaces have been identified and that the applicant can comply with them.

V. PROVISION OF MAINTENANCE & MATERIAL

V.1 There are procedures to ensure that maintenance of the infrastructure is undertaken safely, including clear management control and documented audit and inspection.

V.2 There are procedures which ensure that the maintenance of the infrastructure meets the specific needs of the network.

V.3 There are procedures which show that rules covering the supply of maintenance and material have been identified and that the applicant can comply with them.

W. MAINTENANCE AND OPERATION OF THE TRAFFIC CONTROL AND SIGNALLING SYSTEM

W.1 There are procedures to ensure that the traffic control and signalling system is operated and maintained so as to ensure the safe operation of the railway.

W.2 There are procedures to comply with existing, new and altered technical and operational standards.

W.3 There are procedures which set out how safety is managed at the physical and/or operational borders of the traffic control and signalling system, including how cooperation, if necessary, is managed.

W.4 There are procedures which show that rules covering the safe operation and maintenance of the traffic control and signalling system have been identified and that the applicant can comply with them.

SECTION 7 - FRAMEWORK PRINCIPLES FOR SUPERVISION AFTER THE AWARD OF A SAFETY CERTIFICATE OR SAFETY AUTHORISATION

1. The approach of national safety authorities to supervision of railway undertakings' compliance under Article 4(1) and 16(2) (e) of the Railway Safety Directive shall be based on the following principles. These principles apply to the framework of supervision activities as a whole and to individual cases within that framework.

2. National safety authorities shall apply the principle of proportionality between enforcement and risk. Action taken by a national safety authority to achieve compliance or bring railway undertakings to account for not meeting their legal obligations shall be proportionate to any risks to safety or to the potential seriousness of any non-compliance, including any actual or potential harm.

Proportionality means relating enforcement action to the risks. Action taken by an NSA to achieve compliance or bring RUs/IMs to account for non-compliance should be proportionate to any risks to safety or to the seriousness of any breach, which includes any actual or potential harm arising from a breach of the SMS or wider legal provisions. In practice, applying the principle of proportionality means that NSAs will take particular account of how far an RU/IM holder has fallen short of what the SMS or law requires and the extent of the risks to people arising from the breach. Some duties are specific and absolute whilst others require action as far as is reasonably practicable. NSAs need to apply the principle of proportionality in relation to both kinds of duty.

Deciding what is reasonably practicable to control risks involves the exercise of judgement. Where RUs/IMs must control risks in accordance with the provisions of Article 4 of Directive 2004/49/EC, NSAs will, when considering the protective measures taken, take account of the degree of risk on the one hand, and on the other the sacrifice, whether in money, time or trouble, involved in the measures necessary to avert the risk. Unless it can be shown that there is gross disproportion between these factors and that the risk is insignificant in relation to the cost, the RU/IM must take measures and incur costs to reduce the risk.

3. National safety authorities shall apply the principle of consistency of approach to ensure that a national safety authority takes a similar approach in similar circumstances to achieve similar ends.

Consistency is not a simple matter. NSAs are faced with many variables, including the degree of risk, the attitude and competence of management, any history of incidents or breaches involving the RU/IM, previous enforcement action and the seriousness of any breach, which includes any potential or actual harm arising from a breach of the SMS or wider legal provisions. Decisions on enforcement action are discretionary, involving the judgment of individual NSA inspectors. Each NSA should have arrangements in place to promote consistency in the exercise of discretion, including effective arrangements for liaison with other NSAs through the NSA Network.

4. National safety authority supervision activity shall be targeted primarily at those activities which an national safety authority believes give rise to the most serious risks or where the hazards are least well controlled. To do so, the national safety authority shall have methods and power to assess the day-to-day performance of the railway undertaking.

5. National safety authorities shall decide on priorities to use their resources effectively but the decision on how best to do that should rest with each individual national safety authority. Action shall be focused on those who are responsible for the risk and who are best placed to control it.

Targeting means making sure that NSA supervision activity is targeted primarily on those whose activities give rise to the most serious risks or where the hazards are least well controlled and that action is focused on those who are responsible for the risk and who are best placed to control it, whether employers, manufacturers, suppliers or others. Any enforcement action will be directed against RUs/IMs responsible for a breach. Where several RUs/IMs have responsibilities, the NSA may take action against more than one when it is appropriate to do so in accordance with this policy. This work is closely linked to the NSA's responsibilities for promoting, enforcing and developing the regulatory framework.

NSAs should develop an intervention strategy to help in deciding which inspections, audits, investigations or other regulatory activity should take priority according to the nature and extent of risks posed by a duty holder's operations. An RU/IM's management competence is important, because a relatively low hazard activity poorly managed can entail greater risk to workers or the public than a higher hazard activity where proper and adequate risk control measures are in place.

6. National safety authorities shall apply the principle of transparency to help railway undertakings understand what is expected of them (including what they should or should not do) and what they should expect from the national safety authority.

Transparency means helping RUs/IMs to understand what is expected of them and what they should expect from NSAs. It also means making clear to RUs/IMs not only what they have to do but, where this is relevant, what they don't. That means distinguishing between statutory requirements and advice or guidance about what is desirable but not compulsory.

RUs/IMs, employees, their representatives and others also need to know what to expect when an NSA visits and what rights of complaint are open to them. NSAs should document their decision-making processes and what RUs/IMs and their employees and their representatives can expect when an NSA conducts an audit/inspection activity. NSA staff will provide guidance to the RU/IM what to do to comply with the law. They will, if asked, write to confirm any guidance, and to distinguish legal requirements from best practice advice.

7. National safety authorities shall be accountable for their decisions in accordance with Article 17(3) of the Railway Safety Directive. National safety authorities shall therefore have policies and principles against which they can be assessed. Moreover, National safety authorities shall also have an effective and easily accessible mechanism for dealing with comments and handling complaints — a complaints procedure.

NSAs are accountable to the public for their actions. This means that NSAs should have policies and standards (such as the supervision principles here) against which they can be judged, and an effective and easily accessible mechanism for dealing with comments and handling complaints.

In particular, these policies should:

- *describe a complaints procedure in the case of decisions by officials, or if procedures have not been followed; and*
- *explain about the right of appeal (where national law requires this) in the case of formal enforcement action*

8. National safety authorities shall develop cooperation arrangements between each other in order to share information with each other and to coordinate action on breaches. This is particularly important for Part B Safety Certificates. In addition, National safety authorities shall develop cooperation arrangements with other competent authorities in order to share information and to develop unified approaches to issues that impinge on railway safety.

To help provide a coherent approach, especially for RUs operating in other Member States, it is important that NSAs co-operate with each other in order to share information on safety performance by RUs and to develop holistic cross border approaches to supervision. If an NSA spots a problem with an RU's inability to comply with the requirements in a Part B certificate, then it is important that it discusses it with the NSA who issued the Part A certificate to establish jointly if the problem is a fundamental failure of the whole SMS established by the company or just the network specific part. It is also important for each NSA to discuss and agree what type of joint action might be feasible. Whilst, IMs do not operate across borders, it is also important that NSAs share information on IM performance in order to disseminate best practice or to discuss whether any problems in safety performance are isolated. Further elaboration of this type of co-operation will be given in the CSM on Supervision currently under development.

There is also a need for co-operation requirements between NSA and other Competent Authorities (such as Labour Inspectorates) to be developed to deal with potential breaches of railway safety legislation and worker health and safety legislation. Where a railway NSA has concerns over worker health and safety issues and does not have the legal competence to address the problem itself, then it should raise the matter with the relevant worker protection Competent Authority. Similarly, it should make arrangements with the worker protection Competent Authority for it to raise more general concerns over railway safety with the relevant NSA.

Similar arrangements also need to be put in place between the NSA, accident National Investigation Bodies (NIBs) and the Competent Authority for dangerous goods transport.