

European Railway Agency Recommendation on the 1st set of Common Safety Methods (ERA-REC-02-2007-SAF)

The Director,

Having regard to the Directive 2004/49/EC¹ of the European Parliament,

Having regard to the Regulation (EC) No 881/2004 of the European Parliament and of the Council of 29 April 2004 establishing a European Railway Agency²,

Having regard to the Commission decision of 9 February 2006 (C (2006) 124 final) concerning mandates to the European Railway Agency for developing, among others, Common Safety Methods (CSM) under Directive 2004/49/EC,

Whereas

- (1) Article 6 of Regulation (EC) No 881/2004 states that with a view to the application of Article 6 of Directive 2004/49/EC the Agency shall recommend CSM to the Commission.
- (2) Article 3f of Directive 2004/49/EC defines CSM as the methods to be developed to describe how safety levels and achievement of safety targets and compliance with other safety requirements are assessed.
- (3) Article 6 (1) of Directive 2004/49/EC requires that the European Commission should adopt the first set of CSMs covering at least risk evaluation and assessment methods, mentioned in Article 6 (3) (a) of the Directive, before 30th April 2008 in accordance and having regard to the provisions of Article 8 of the Decision 1999/468/EC.
- (4) Recital 8 of Directive 2004/49/EC states that CSM should be gradually introduced to ensure that a high level of safety is maintained and, when and where necessary and reasonably practicable, improved.
- (5) Article 9 (1) of Directive 2004/49/EC requires that railway undertakings and infrastructure managers establish their safety management systems to ensure that the railway system can achieve at least the CSTs. The safety management system shall include, according to Annex III (2) (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. The criteria for deciding when a change requires risk evaluation and assessment shall be further developed in the second set of CSM.
- (6) As a consequence of the application of the Directive 91/440/EC as amended by Directive 2001/12/EC on the development of the Community's railways³ and the article

¹ JO L 220/16, 21/06/2004 on safety on the Community's railways (refer to as Safety Directive)

² JO L 220/3, 21/06/2004

9 paragraph 2 of the Directive 2004/49, particular attention shall be taken for the risk management at the interfaces between the railway actors.

- (7) Article 14 of Directive 96/48/EC⁴ and Directive 2001/16/EC⁵ both amended by Directives 2004/50/EC⁶ and 2007/37/EC⁷ referred to as Interoperability Directives in this document states that Member States shall take all appropriate steps to ensure that the structural subsystems constituting the trans-European high speed and conventional rail system may be put into service only if they are designed, constructed and installed in such a way as to meet the essential requirements concerning them when integrated into the trans-European rail system. In particular, they shall check the compatibility of these subsystems with the system into which they are being integrated.
- (8) One of the obstacles to the opening of the railway market proved to be the absence of a common approach for specifying and demonstrating compliance with safety levels and requirements of the railway system. Without this common approach, the different Member States performed in the past their own assessments in order to accept a system, or parts of it, which had been developed and proven safe in other Member States. The scope and the role of the different assessment bodies involved in such an approval process will be further defined and harmonized in the second set of CSM, in accordance with the provision of the Safety and Interoperability Directives.
- (9) To facilitate the cross-acceptance between Member States, the methods used for the identification and the management of risks have to be harmonised among each of the actors involved in the development and operation of rail systems as well as the methods to demonstrate the compliance to safety requirements of the Railway Systems in the territory of the European Union.
- (10) Article 6 (5) of Directive 2004/49/EC requires that the Member States shall make any necessary amendments to their national safety rules to comply with the CSM.
- (11) In view of the different approaches currently in use for assessing safety, such harmonization of safety methods may be allowed to take place at the latest on the first January 2010, in order to leave the applicants, where necessary, some time to gain experience in adapting to the new common approach.

³ OJ L 237, 24/8/1991, p.25. Directive as amended by Directive 2001/12/EC of the European Parliament and of the Council (OJ L 75, 15.3.2001, p. 1).

⁴ OJ L 235, 17/09/1996 P. 0006 – 0024. Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system.

⁵ OJ L 110, 20/04/2001. Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the interoperability of the trans-European conventional rail system

⁶ OJ L 220, 21/06/2004 P 40. Corrigendum to Directive 2004/50/EC of the European Parliament and of the Council of 29 April 2004 amending Council Directive 96/48/EC on the interoperability of the trans-European high-speed rail system and Directive 2001/16/EC of the European Parliament and of the Council on the interoperability of the trans-European conventional rail system (OJ L 164, 30.4.2004)

⁶ OJ L 161/60, 21/06/2007. Commission Directive 2007/37/EC of 21 June 2007 amending Annexes I and III to Council Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type approval of motor vehicles and their trailers

Has adopted the following recommendation:

1. In order to cover the basic element of their safety management system referred to in annex III (2) (d) of the Safety Directive on change management, the railway undertakings and infrastructure managers shall use the risk management process described in this recommendation in annex 1.
2. The exchange of safety relevant information, within the scope of this recommendation, between different actors of the rail sector should comply with article 13 of the annex 1 of this recommendation. This does not concern exchange of information by assessment bodies with other actors. The exchange of information for the assessment bodies shall be described in the second set of CSM.
3. The evidence resulting from the application of this recommendation should comply with article 15 of the Annex 1 of this recommendation.
4. The above three points should be transferred into a Commission regulation.

This recommendation is addressed to the Commission of the European Communities.

(signed)

Valenciennes, .. /12/2007

Marcel VERSLYPE
Executive Director

Annex 1

Chapter I Introductory provisions

Article 1. Purpose

1. This regulation covers the Common Safety Methods (CSM) as defined in Article 6 (1) of Directive 2004/49/EC which refers to the Article 6 (3) (a): “*The CSMs shall describe how the safety level, and the achievement of safety targets and compliance with other safety requirements, are assessed by elaborating and defining risk evaluation and assessment methods*”.
2. The purpose of the CSM is to maintain or, when and where necessary and reasonably practicable, improve the safety on the Community’s railway systems. The CSM should facilitate the access to the market for rail transport services by supporting cross acceptance through:
 - (a) harmonisation of the risk management processes used to assess the safety levels and the compliance with safety requirements;
 - (b) harmonisation of the exchange of safety relevant information between different actors within the rail sector in order to manage safety across the different interfaces which may exist within this rail sector;
 - (c) harmonisation of the evidence resulting from the application of a risk management process.
3. This regulation concerns all actors of the rail sector whose activities may have an impact on the safety of the railway system. The concerned actors are namely:
 - (a) the railway undertakings and infrastructure managers, generally hereafter referred to as the applicant, who shall apply the process described in this regulation;
 - (b) the manufacturers, maintenance suppliers, keepers and contracting entities, who either:
 - (1) may be involved in the process described in this regulation
 - (2) or who may be the applicant in case they require an authorisation to place in service for generic applications;
 - (c) the assessment bodies, who shall assess the correct implementation of the process described in this regulation.

Article 2. Scope

1. Referring to Annex III (2) (d) of Directive 2004/49/EC, the changes to be considered for application of this regulation shall include technical, operational as well as organisational changes.
2. The risk assessment process described in this regulation shall apply only to significant changes of the railway system in the Member States.

3. If there is no notified national rule allowing to define whether a change is significant or not in a Member State, the applicant shall decide, by expert's judgement, the significance of the change based on the following criteria:
 - (a) safety contribution: the positive impact on the safety of the considered change;
 - (b) failure consequence: the negative impact on the safety of the system in case of an unsafe implementation of the change;
 - (c) complexity of the change;
 - (d) monitoring: the possibility to monitor the implemented change throughout the system life-cycle;
 - (e) reversibility: the possibility to come back to the system before the change;
 - (f) innovation used in implementing the change.

The Applicant shall document his decision on the significance of all changes.

4. In accordance with Article 14 (2) (d) of Directive 2004/49/EC, this regulation shall also apply for the placing in service of in-use rolling stock in another Member State in order to show that the acceptance of the rolling stock does not introduce undue risks to the network.
5. Where the significant changes concern structural sub-systems to which the Interoperability Directives apply:
 - (a) this regulation shall be applicable if a risk assessment is required within the relevant TSIs;
 - (b) this regulation shall be applicable to ensure a safe integration of the structural subsystems to which the TSIs apply into an existing system, in virtue of Article 14 of the Interoperability Directives.

However, application of the CSM in the last case shall not lead to requirements contradictory to those laid down in the relevant TSIs. Nevertheless if the application of the CSM leads to a requirement non compliant with the TSI, the applicant shall:

- (1) either analyse if the system definition can be changed in order to allow compliance with the TSI
 - (2) or inform the concerned Member State who have to ask for derogation in accordance with Article 7 of the Interoperability Directives.
6. Whenever a system already in use is changed, the applicant shall assess the significance of the change taking into account all safety related changes affecting the same elements since the entry into force of this regulation or since the last safety approval delivered in accordance with Article 14 of this regulation, whichever is the latest. The purpose is to assess whether the totality of such changes does not become a significant change requiring the application of the present regulation.
7. This regulation is applicable on the same network in a Member State as defined by the transposition of the Directive 2004/49/EC into national law.

Article 3. Definitions

For the purpose of this regulation the definitions given in Article 3 of the Directive 2004/49/EC prevail.

In addition the following definitions shall apply:

- (a) 'actors' means the infrastructure managers, the railway undertakings and the other actors defined in recital 6 of the Directive 2004/49/EC;
- (b) 'applicant' means generally a railway undertaking or infrastructure manager who intends to introduce a significant change in the railway system. A manufacturer, keeper or contracting entity may also be an applicant if they require an authorisation to place in service for a generic application;
- (c) 'assessment body' means the independent organisation or entity which undertakes investigation to arrive to a judgment, based on evidence, of the suitability of a system to fulfil its requirements. In the scope of this regulation, this term covers any body which fulfils, by analogy, the minimum criteria laid down in Annex VII of the Interoperability Directives;
- (d) 'catastrophic consequence' means fatalities and/or multiple severe injuries and/or major damages to the environment resulting from an accident;
- (e) 'code of practice' means a written set of rules that, when correctly applied, can be used to close out one or several particular hazards;
- (f) 'hazard' means a condition that could lead to an accident;
- (g) 'hazard identification' means the process to find, list and characterise hazards;
- (h) 'hazard log' means the document in which safety management activities, hazards identified, decisions made and solutions adopted are recorded and referenced – The hazard log referred to in this regulation may be adapted in its extent and complexity to the needs of the system under assessment provided it addresses at least the minimum requirements of this regulation with respect to the recording of the identified hazards, their related measures, their origin and the reference to the organisation which has to manage the hazards;
- (i) 'interfaces' means all points of interaction during a system life cycle including operation and maintenance where different actors of the rail sector will have to jointly work together in order to manage the risks;
- (j) 'reference system' means a system proven in use to have an acceptable safety level and against which the acceptability of the risks from a system under assessment can be evaluated by comparison;
- (k) 'risk' means the rate of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm;
- (l) 'Risk acceptance criteria' means the terms of reference by which the acceptability of risk is assessed. These are criteria that are used to determine that the level of a risk is low enough that it is not necessary to take any immediate action to reduce it further;
- (m) 'risk acceptance principle' means the rules used in order to arrive to the conclusion that the risk related to one or several specific hazards is acceptable;
- (n) 'risk analysis' means systematic use of all available information to identify hazards and to estimate the risk;

- (o) 'risk assessment' means the overall process comprising a risk analysis and a risk evaluation;
- (p) 'risk estimation' means the process used to produce a measure of the level of risks being analysed. Risk estimation consists of the following steps: frequency, consequence analysis and their integration;
- (q) 'risk evaluation' means a procedure based on the risk analysis to determine whether the tolerable risk has been achieved;
- (r) 'risk management' means the systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risk;
- (s) 'safety' means freedom from unacceptable risk of harm;
- (t) 'safety approval' means the conclusion reached by an assessment body stating that the system under assessment can be used safely;
- (u) 'safety measures' means a set of actions either reducing the rate of occurrence of a hazard or mitigating its consequences in order to achieve and/or maintain an acceptable level of risk;
- (v) 'safety requirements' means the necessary safety characteristics (qualitative or quantitative) of a system and its operation (including operational rules) in order to meet e.g. legal or company safety targets;
- (w) 'technical system' means a product or an assembly of products including the design, implementation, and support documentation.

Notes:

- (1) The development of a technical system starts with its requirements specification and ends with its safety approval.*
- (2) It shall consider the design of relevant interfaces with human behavior. Human operators and their actions are however not included in a technical system*
- (3) Maintenance is not included in the definition, but is included in maintenance manuals*

Chapter II

General principles for the application of the CSM

Article 4. General principles and obligations

1. The risk management process covered by this regulation shall start from a definition of the system under assessment and comprise the following activities:
 - (a) the risk assessment process which shall identify the hazards, the associated safety measures and the resulting safety requirements to be fulfilled by the system under assessment;
 - (b) the demonstration of the compliance of the system with the identified safety requirements and;
 - (c) the management of all identified hazards and the associated safety measures.

This risk management process is iterative and is depicted in appendix 1. The process ends when the compliance of the system with all safety requirements necessary to accept the risks linked to the identified hazards is demonstrated.

2. This iterative risk management process:
 - (a) shall be applied for the implementation of a significant change, from the conceptual phase until its safety approval;
 - (b) shall be applied again on the related system if another significant change occurs during the system operation, maintenance or decommissioning phase;
 - (c) shall include appropriate quality assurance activities and be carried out by competent staff;
 - (d) shall be independently assessed by (an) assessment body (ies).
3. All actors whose activities may have an impact on the safety of the railway system shall apply this regulation and shall maintain a hazard log according to chapter V. The actors who already have in place methods or tools for risk assessment shall continue to apply them as far as they are compatible with the provisions of this regulation and subject to these conditions:
 - (a) the railway undertakings and infrastructure managers shall apply the risk assessment methods or tools described in their safety management system provided this safety management system is certified by a national safety authority in accordance with chapter III of Directive 2004/49/EC;
 - (b) the other actors shall apply their own risk assessment methods or tools provided they comply at least with the TSI, where applicable, or with recognised standards specified in notified national rules.
4. Without prejudice to civil liability in accordance with the legal requirements of the Member States, the risk assessment process shall fall within the responsibility of the applicant. In particular the applicant shall decide, after agreement with the concerned actors, who will be responsible for fulfilling the safety requirements resulting from the risk assessment. This decision shall depend on the type of safety measures selected to control the risks to an acceptable level. The demonstration of compliance with the safety requirements shall be done according to Chapter IV.

5. The risk management activities shall be documented at the beginning of the process clearly stating the different actors' responsibilities, as well as their activities. The applicant shall coordinate a close collaboration between the different actors involved, according to their respective responsibilities, in order to manage the hazards and their associated safety measures.
6. The evaluation of the correct application of the risk management process described in this regulation falls within the responsibility of the assessment body (ies). Each actor, for its part of the system under assessment, shall appoint assessment body (ies) without prejudice to its legal or contractual obligations.

Article 5. Interfaces management

1. For each interface relevant to the system under assessment and without prejudice to specifications of interfaces defined in relevant TSIs, the concerned actors of the rail sector shall cooperate in order to identify and manage jointly the hazards and related safety measures that need to be handled at these interfaces. The management of shared risks at the interfaces shall be co-ordinated by the applicant.
2. When in order to fulfil a safety requirement, an actor identifies the need for a safety measure that it cannot implement itself, it shall, after agreement with another actor, transfer the related hazard to the latter using the process described in Chapter V.
3. For the system under assessment, any actor who discovers a non compliance or inadequacy of a safety measure is responsible for notifying it to the applicant who shall in turn inform the actor implementing the safety measure.
4. The actor implementing the safety measure shall then inform all the actors affected by the problem either within the system under assessment or, as far as known by the actor, within other existing systems using the same safety measure.
5. When agreement cannot be found between two or more actors it is the responsibility of the applicant to find an adequate solution.

Chapter III

Common Safety Methods for risk assessment

Article 6. Risk assessment process

1. The risk assessment process is the overall iterative process that comprises:

- (a) the system definition;
- (b) the risk analysis including the hazard identification;
- (c) the risk evaluation.

The Risk assessment process shall interact with the hazard log management according to Article 12.

2. The system definition should address at least the following issues:

- (a) definition of system objective, e.g. intended purpose;
- (b) definition of system functions and elements, where relevant (including e.g. human, technical and operational elements);
- (c) definition of system boundary including other interacting systems;
- (d) definition of physical (i.e. interacting systems) and functional (i.e. functional input and output) interfaces;
- (e) definition of system environment (e.g. energy and thermal flow, shocks, vibrations, electromagnetic interference, operational use);
- (f) definition of the existing safety measures and, after iterations, definition of the safety requirements identified by the risk assessment process;
- (g) definition of the assumptions which shall determine the limits for the risk assessment.

3. A hazard identification shall be carried out on the defined system, according to Article 7

4. The risk acceptability of the system under assessment shall be evaluated by using one or several of the following risk acceptance principles:

- (a) the application of codes of practice (Article 8) or;
- (b) a comparison with similar systems (Article 9) or;
- (c) an explicit risk estimation (Article 10).

5. The applicant shall demonstrate in the risk evaluation that the selected risk acceptance principle is adequately applied. The applicant shall also check that the selected risk acceptance principles are used consistently.

6. The application of these risk acceptance principles shall identify possible safety measures which make the risk(s) of the system under assessment acceptable. Among these safety measures, the ones selected to control the risk(s) shall become the safety requirements to be fulfilled by the system. The compliance with these safety requirements shall be demonstrated in accordance with Chapter IV.

7. The iterative risk assessment process can be considered as completed when it is demonstrated that all safety requirements are fulfilled and no additional hazards have to be considered.

Article 7. Hazard identification

1. The applicant shall systematically identify, using wide-ranging expertise from a competent team, all reasonably foreseeable hazards, its functions where appropriate and its interfaces for the whole system under assessment taking into account:
 - (a) the human factors;
 - (b) the environmental conditions, and;
 - (c) all operational modes.

All identified hazards shall be recorded in the hazard log according to Chapter V.

2. To focus the risk assessment efforts upon the most important risks, the hazards shall be classified according to the estimated risk arising from them. Based on expert judgement, hazards associated with a broadly acceptable risk need not be analysed further but shall be recorded in the hazard log. Their classification shall be justified in order to allow independent assessment by an assessment body.
3. As a criterion, risks resulting from hazards may be classified as broadly acceptable when the risk is so small that it is not reasonable to implement any additional safety measure. The expert judgement shall take into account that the contribution of all the broadly acceptable risks does not exceed a defined proportion of the overall risk.
4. During the hazard identification, safety measures may be identified. They shall be recorded in the hazard log according to Chapter V.
5. The hazard identification only needs to be carried out at a level of detail necessary to identify safety measures expected to control the risks in accordance with one of the risk acceptance principles mentioned in Article 6 (4). Iteration may thus be necessary between the risk analysis and the risk evaluation phases until a sufficient level of detail is reached for the identification of hazards.

Article 8. Use of codes of practice and risk evaluation

1. The applicant, with the support of other involved actors and based on the requirements listed in paragraph 2, shall analyse whether one or several hazards are appropriately covered by the application of relevant codes of practice.
2. The codes of practice shall satisfy at least the following requirements:
 - (a) represent acknowledged rules of technology and best practice for technical systems. In case the codes of practice are not widely acknowledged in the railway application domain, they will have to be justified and be acceptable to the assessment body;
 - (b) represent the state of knowledge and best practice for operational aspects;
 - (c) be relevant for the control of the considered hazards in the system under assessment;
 - (d) be available at reasonable costs for all actors who want to use them.
3. Where applicable according to the Interoperability Directives, the compliance with the relevant TSI is mandatory. The TSIs shall then be considered as codes of practice for closing out hazards, provided requirement (c) of paragraph 2 is fulfilled.

4. Notified rules defined according to Article 8 of the Safety Directive and Article 16 of the Interoperability Directives can be considered as codes of practice provided requirements of paragraph 2 are fulfilled
5. If one or several hazards are closed out by codes of practice fulfilling the requirements of paragraph 2, then the risks associated to these hazards shall be considered as acceptable. This means that:
 - (a) these risks need not be analysed further;
 - (b) the use of the codes of practice shall be recorded in the hazard log as safety requirements for the relevant hazards.
6. In case of deviations from a relevant code of practice, the applicant shall demonstrate that the approach taken instead leads to at least the same level of safety.
7. If the risk for a particular hazard cannot be made acceptable by the application of codes of practice, additional safety measures shall be identified applying one of the two other risk acceptance principles.

Article 9. Use of reference system and risk evaluation

1. The Applicant, with the support of other involved actors, shall analyse if one or several hazards are covered by a similar system that could be taken as a reference system.
2. A reference system shall satisfy at least the following requirements:
 - (a) it has already been proven in-use to have an acceptable safety level and would still qualify for approval in the Member State where the change is to be introduced;
 - (b) it has similar functions and interfaces as the system under assessment;
 - (c) it is used under similar operational conditions as the system under assessment;
 - (d) it is used under similar environmental conditions as the system under assessment.
3. If a reference system fulfils the requirements listed in paragraph 2, then for the system under assessment:
 - (a) the risks associated with the hazards covered by the reference system shall be considered as acceptable;
 - (b) the safety requirements for the hazards covered by the reference system may be derived from the safety analyses or from an evaluation of safety records of the reference system;
 - (c) these safety requirements shall be recorded in the hazard log as safety requirements for the relevant hazards.
4. If the system under assessment deviates from the reference system, the risk evaluation shall demonstrate that the system under assessment reaches at least the same safety level as the reference system. The risks associated with the hazards covered by the reference system shall, in that case, be considered as acceptable.
5. If the same safety level as the reference system cannot be demonstrated, additional safety measures shall be identified for the deviations, applying one of the two other risks acceptance principles.

Article 10. Explicit risk estimation and evaluation

1. When the hazards are not covered by one of the two risk acceptance principles described in Articles 8 and 9, the demonstration of the risk acceptability shall be performed by explicit risk estimation and evaluation. Risks resulting from these hazards shall be estimated either quantitatively or qualitatively, taking existing safety measures into account.
2. The acceptability of the estimated risks shall be evaluated using risk acceptance criteria either derived from or based on legal requirements stated in Community legislation or in notified national rules. Depending on the risk acceptance criteria, the acceptability of the risk may be evaluated either individually for each associated hazard or globally for the combination of all hazards considered in the explicit risk estimation.

In case the estimated risk is not acceptable, additional safety measures shall be identified and implemented in order to reduce the risk to an acceptable level.

3. When the risk associated with one or a combination of several hazards is considered as acceptable, the identified safety measures shall be recorded in the hazard log.
4. Where hazards arise from failures of technical systems not covered by codes of practice or the use of a reference system, the following risk acceptance criterion shall apply for the design of the technical system:

For technical systems where a functional failure has a credible direct potential for a catastrophic consequence, the associated risk does not have to be reduced further if the rate of that failure is less than or equal to 10^{-9} per operating hour.

5. The explicit risk estimation and evaluation shall satisfy at least the following requirements:
 - (a) the methods used for explicit risk estimation shall reflect correctly the system under assessment and its parameters (including all operational modes);
 - (b) the results shall be sufficiently accurate to serve as robust decision support, i.e. minor changes in input assumptions or prerequisites shall not result in significantly different requirements.

Chapter IV

Demonstration of compliance with safety requirements

Article 11. Demonstration of compliance with safety requirements

1. Prior to the safety approval, the fulfilment of the safety requirements resulting from the risk assessment phase shall be demonstrated under the supervision of the applicant.
2. This demonstration shall be carried out by each of those actors who are responsible for fulfilling the safety requirements, as decided in accordance with Article 4 (5).
3. The approach chosen for the demonstration of compliance with the safety requirements as well as the demonstration itself shall be independently assessed by an assessment body.
4. Any inadequacy of safety measures expected to fulfil the safety requirements or any hazards discovered during the demonstration of compliance with the safety requirements shall lead to reassessment and evaluation of the associated risks by the Applicant according to Chapter III. The new hazards shall be logged in the hazard log according to Chapter V.

Chapter V

Hazard log management

Article 12. Hazard log management process

1. For significant changes, hazard log(s) shall be created or updated (where they already exist) and maintained throughout the whole life-cycle of the system under assessment. The hazard log shall track the progress on monitoring risks associated with the identified hazards.
2. The hazard log shall include all hazards, together with all related safety measures and system assumptions identified during the risk assessment process. In particular, it shall contain a clear reference to the origin, to the selected risk acceptance principles and a clear identification of the actor(s) in charge of controlling each hazard.
3. The hazard log shall be updated whenever it is relevant, in particular:
 - (a) whenever a significant change is made;
 - (b) whenever a new hazard is discovered or a new safety measure is identified;
 - (c) whenever it could be necessary to take into account accident and incident data;
 - (d) whenever the safety requirements, or the assumptions about the system, are changed.

Article 13. Exchange of information / obligations / responsibilities

1. Each actor whose activities may have an impact on the safety of the system under assessment shall have its own hazard log and shall be responsible for its management. Exceptions may be granted between co-operating actors, provided that at least one actor will have overall responsibility for the management of the hazard log covering the activities of all the involved actors. However, the responsibility for the correctness of the information to be recorded remains on the actor controlling the hazard.
2. All hazards and related safety requirements which cannot be closed by one actor alone shall be communicated to another relevant actor in order to find jointly an adequate solution. The hazards recorded in the hazard log of the actor who transfers them shall only be “closed” when the evaluation of the risks associated with these hazards is made by the other actor and the solution is agreed by all the concerned actors.

Chapter VI

Approval of CSM application

Article 14. Obligations and responsibilities

1. A significant change assessed according to this regulation shall be subject to safety approval from an assessment body.
2. A safety approval shall be based on an independent assessment of the correct application of this regulation.
3. For significant changes involving sub-systems to which the Interoperability Directives apply, a safety approval shall be taken into account by the national safety authority in its decision to authorise the placing in service of these sub-systems, in accordance with Article 16 of Directive 2004/49/EC. Care shall be taken to avoid a duplication of work between conformity assessment carried out by a notified body and any independent safety assessment carried out by the assessment body in accordance with this regulation.

Article 15. Evidence from the CSM application

1. The risk management process used to assess the safety levels and compliance with safety requirements shall be documented in such a way that all the necessary evidence showing the correct application of the risk management process is accessible to an assessment body for it to reach a conclusion about safety approval.
2. This evidence shall at least include:
 - (a) the description of the organisation and the experts put in place to carry out the risk assessment process,
 - (b) the results of the different phases of the risk assessment and the list of all the necessary safety requirements to be fulfilled in order to control the risk to an acceptable level.
3. The evidence of the risk management process described in this regulation shall be kept and updated during the system life cycle. Where relevant, the results of each system configuration used in operation shall be put into the applicant's archives at least during the system life time. Unless agreed differently in the contracts at the beginning of the project, the other actors involved shall themselves archive their respective risk and safety analysis results.

Article 16. Mutual recognition

1. Without prejudice to the provisions of Articles 9 and 15 of the Interoperability Directives, assessment bodies may apply the principles of mutual recognition on risk assessment of a system which is already approved by another assessment body. This mutual recognition is conditioned on the demonstration that the system will be used under the same functional, operational and environmental conditions as the already approved system, and that the same risk acceptance criteria have been applied.



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2. If the deviations from the already approved system can be considered as a significant change compared to the approved system, then a risk assessment on these deviations shall be performed in accordance with this regulation.

Chapter VII

Implementation of Common Safety Methods

Article 17. Entry into force

1. This regulation shall be binding in its entirety and directly applicable in all Member State. It shall enter into force at the latest on the 01 January 2010.
2. The provisions laid down in this regulation shall not apply to systems and changes at an advanced stage of development prior to the date of entry into force of the regulation.

Article 18. Risk control management/ internal and external audits

1. The railway undertakings and infrastructure managers shall include audits of application of this regulation in their recurrent auditing scheme of the safety management system as referred to in Annex III of Directive 2004/49/EC.
2. Within the tasks defined in Article 16 (2) (e) of the Directive 2004/49/EC, the national safety authority shall monitor the implementation and application of this regulation.

Article 19. Evolution of Common Safety Methods in accordance to Experiences, Technical and/or Methodological Progress

1. The national safety authority shall report in the annual safety report to the Agency the results and their experience related to the supervision of the implementation and application of the CSM.
2. The Agency shall monitor and collect feedback on the applicability of the CSM with a view to improve it.

Appendix 1

Risk management framework for the common safety methods

