

EN

COMMISSION REGULATION (EC) No .../..

of [...]

**on the common safety method on risk evaluation and assessment and repealing
Commission Regulation (EC) No 352/2009****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on Safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive)¹, and in particular Article 6 thereof,

Whereas:

- (1) In accordance with Directive 2004/49/EC, common safety methods (CSMs) should be gradually introduced to ensure that a high level of safety is maintained and, when and where necessary and reasonably practicable, improved. Pursuant to Article 6(4) of that Directive, the CSMs are to be revised at regular intervals, taking into account the experience gained from their application and the global development of railway safety and the obligations on Member States laid down in Article 4(1).
- (2) On 12 October 2010² the Commission issued a mandate to the Agency in accordance with Directive 2004/49/EC to revise the Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council³. The revision should cover the results of the analysis by the Agency under Article 9(4) of that Regulation of the overall effectiveness and experience with its application as well as further developments in the roles and the responsibilities of the assessment body referred to in Article 6 of that Regulation. The revision should also include the qualification requirements (by developing a recognition/accreditation scheme) of the assessment body according to its role in the CSM, with a view to improving clarity in order to avoid differing application across the Member States,

¹ OJ L 164, 30.4.2004, p. 44.

² Commission Decision of 12.10.2010 on a mandate to the European Railway Agency for the revision of the common safety method on risk evaluation and assessment (C(2010) 6931 final)

³ OJ L 108, 29.4.2009, p. 4

taking into account the interfaces with existing EU authorisation/certification procedures in the railway sector. If feasible, the revision of Regulation (EC) No 352/2009 should also cover further developments in the risk acceptance criteria that could be used to assess the acceptability of a risk during explicit risk estimation and evaluation. The Agency submitted its recommendation on the revised CSM to the Commission, supported by an impact assessment report to address the mandate of the Commission. The present Regulation is based on that Agency recommendation.

- (3) According to point (2)(d) of Annex III to Directive 2004/49/EC, the safety management system established by railway undertakings and infrastructure managers must include 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. That basic element of the safety management system is covered by this Regulation.
- (4) Article 14a(3) of Directive 2004/49/EC requires entities in charge of maintenance to establish a system of maintenance in order to ensure that the vehicles for which they are in charge of maintenance are in a safe state of running. To manage changes in equipment, procedures, organisation, staffing or interfaces, the entities in charge of maintenance should have in place risk assessment procedures. That requirement of the system of maintenance is covered by this Regulation.
- (5) As a consequence of the application of Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways⁴ and of Article 9(2) of Directive 2004/49/EC, particular attention should be paid to risk management at the interfaces between the actors which are involved in the application of this Regulation.
- (6) Article 15 of Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community⁵ requires Member States to take all appropriate steps to ensure that the structural subsystems constituting the rail system may be placed in 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 rail system. In particular, the Member States must check the technical compatibility of these subsystems with the railway system into which they are being integrated and the safe integration of these subsystems in accordance with this Regulation.
- (7) This Regulation should address the absence of a common approach for specifying and demonstrating compliance with safety levels and requirements of the railway system. The absence of a common approach among the Member States proved to be one of the obstacles to liberalisation of the railway market.
- (8) To facilitate mutual recognition between Member States, the methods used for identifying and managing risks should be harmonised among the actors involved in the development and operation of the railway system as well as the methods for demonstrating that the railway system in the territory of the European Union conforms

⁴ OJ L 237, 24.8.1991, p. 25.

⁵ OJ L 191, 18.7.2008, p. 1.

to safety requirements. As a first step, it is necessary to harmonise the procedures and methods for carrying out risk evaluation and implementing control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations, as referred to in point (2)(d) of Annex III to Directive 2004/49/EC.

- (9) If there is no existing notified national rule for defining whether or not a change is significant in a Member State, the person in charge of implementing the change (hereinafter referred to as ‘the proposer’) should initially consider the potential impact of the change in question on the safety of the railway system. If the proposed change has an impact on safety, the proposer should assess, by expert judgement, the significance of the change based on a set of criteria that should be set out in this Regulation. This assessment should lead to one of three conclusions. In the first situation the change is not considered to be significant and the proposer should implement the change by applying its own safety method. In the second situation the change is considered to be significant and the proposer should implement the change by applying this Regulation, without the need for a specific intervention of the national safety authority. In the third situation the change is considered to be significant but there are provisions at the level of the European Union which require a specific intervention of the relevant national safety authority, such as a new authorisation for placing in service of a vehicle or a revision/update of the safety certificate of a railway undertaking or a revision/update of the safety authorisation of an infrastructure manager.
- (10) Whenever the railway system already in use is subject to a change, the significance of the change should also be assessed taking into account all safety-related changes affecting the same part of the system since the entry into force of this Regulation or since the last application of the risk management process described in this Regulation, whichever is the latest. The purpose is to assess whether or not the totality of such changes amounts to a significant change requiring the full application of the CSM on risk evaluation and assessment.
- (11) The risk acceptability of a significant change should be evaluated by using one or more of the following risk acceptance principles: the application of codes of practice, a comparison with similar parts of the railway system, an explicit risk estimation. All principles have been used successfully in a number of railway applications, as well as in other transport modes and other industries. The “explicit risk estimation” principle is frequently used for complex or innovative changes. The proposer should be responsible for the choice of the principle to apply.
- (12) When a widely recognised code of practice is applied, it should therefore be possible to reduce the impact of applying the CSM, in accordance with the principle of proportionality. In the same way, where there are provisions at the level of the European Union which require the specific intervention of the national safety authority, the latter should be allowed to act as the independent assessment body in order to reduce double checking, undue costs to the industry and time to market.
- (13) To report to the Commission on the effectiveness and application of this Regulation, and where applicable to make recommendations to improve it, the Agency should be able to gather relevant information from the various involved actors, including from the national safety authorities, from the certification bodies of entities in charge of

maintenance of freight wagons and from other entities in charge of maintenance that do not fall under the scope of Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons⁶.

- (14) Accreditation should normally be granted by the national accreditation body which has exclusive competence to assess if an assessment body meets the requirements set by harmonised standards. An accreditation body derives its authority from the State. Regulation 765/2008/EC⁷ setting out the requirements for accreditation and market surveillance relating to the marketing of products contains detailed provisions on the competence of such national accreditation bodies. Inter alia, Article 7 of that Regulation regulates cross-border accreditation in cases where accreditation may be requested from another national accreditation body.
- (15) Where harmonised legislation at the European Union level provides for the selection of conformity assessment bodies for its implementation, transparent accreditation, as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in conformity certificates, should be considered by the national public authorities throughout the European Union the preferred means of demonstrating the technical competence of those bodies. However, national authorities may consider that they possess the appropriate means of carrying out this evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, in case of recognition, by virtue of Article 5(2) of the Regulation 765/2008/EC the Member State shall provide the Commission and the other Member States with all the documentary evidence necessary for the verification of the competence of the recognition body it selects for the implementation of the European Union harmonised legislation. In order to achieve a similar level of quality and trust as expected through accreditation, the requirements and rules for the evaluation and surveillance of assessment bodies in case of recognition should be equivalent to those used for the accreditation.
- (16) An independent and competent external or internal individual, organisation or entity, a national safety authority, a notified body or a body designated according to Article 17 of Directive 2008/57/EC could act as an assessment body provided it fulfils the criteria required in Annex II.
- (17) There may be several assessment bodies, variously accredited or recognized, or no assessment bodies at all within a Member State.
- (18) Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment has become obsolete and should therefore be repealed
- (19) In view of the new requirements introduced by this Regulation in terms of accreditation and recognition of the assessment body in order to give sufficient time to

⁶ OJ L 122, 11.5.2011, p. 22.

⁷ OJ L 218, 13.8.2008, p. 30

the actors concerned to put in place and implement this new common approach, the implementation of this Regulation should be deferred.

- (20) The measures provided for in this Regulation are in accordance with the opinion of the Committee established in accordance with Article 27(1) of Directive 2004/49/EC.

HAS ADOPTED THIS REGULATION:

Article 1

Purpose

1. This Regulation establishes a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC.
2. The purpose of the Regulation is to maintain or to improve the level of safety on the railways of the European Union, when and where necessary and reasonably practicable. This Regulation shall facilitate the access to the market for rail transport services through harmonisation of:
 - (a) the risk management processes used to assess the impact of changes on safety levels and the compliance with safety requirements;
 - (b) 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 sector;
 - (c) the evidence resulting from the application of a risk management process.

Article 2

Scope

1. This Regulation shall apply to the proposer as defined in Article 3(11) when making any change to the railway system in a Member State based on the assessment of the criteria in Article 4:
 - (a) when the change is considered significant, the risk management process described in Article 5 shall be applied;
 - (b) when the change is considered not significant, keeping adequate documentation to justify the decision is sufficient.
2. The changes may be of a technical, operational or organisational nature. As regards organisational changes, only those changes which could impact the operational or maintenance processes shall be considered.
3. This Regulation shall apply also where the significant changes concern structural sub-systems to which Directive 2008/57/EC applies:

- (a) if a risk assessment is required by the relevant technical specification for interoperability (TSI). In this case the TSI shall, where appropriate, specify which parts of this Regulation apply;
 - (b) within the process of authorisation for the placing in service of structural sub-systems to ensure their safe integration into an existing system, by virtue of Article 15(1) of Directive 2008/57/EC.
4. The application of this Regulation in the case referred to in point 3(b) of Article 2(3) must not lead to requirements contradictory to those laid down in the relevant TSIs. Nevertheless if such contradictions occur, the proposer shall inform the concerned Member State which may then decide to ask for a revision of the TSI in accordance with Article 6(2) or Article 7 of Directive 2008/57/EC or a derogation in accordance with Article 9 of that Directive.
5. The railway systems excluded from the scope of Directive 2004/49/EC according to its Article 2(2) may also be excluded from the scope of this Regulation.
6. This Regulation shall not apply to systems and changes, which, on the date of entry into force of this Regulation, are projects at an advanced stage of development within the meaning of Article 2(t) of Directive 2008/57/EC.

Article 3 **Definitions**

For the purpose of this Regulation the definitions in Article 3 of Directive 2004/49/EC shall apply.

The following definitions shall also apply:

- (1) 'risk' means the frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm;
- (2) 'risk analysis' means systematic use of all available information to identify hazards and to estimate the risk;
- (3) 'risk evaluation' means a procedure based on the risk analysis to determine whether an acceptable level of risk has been achieved;
- (4) 'risk assessment' means the overall process comprising a risk analysis and a risk evaluation;
- (5) 'safety' means freedom from unacceptable risk of harm;
- (6) 'risk management' means the systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risks;
- (7) 'interfaces' means all points of interaction during a system or subsystem life cycle, including operation and maintenance where different actors of the rail sector will work together in order to manage the risks;

- (8) ‘actors’ means all parties which are, directly or through contractual arrangements, involved in the application of this Regulation pursuant to Article 2;
- (9) ‘safety requirements’ means the safety characteristics (qualitative or quantitative) of a system and its operation (including operational rules) and maintenance necessary in order to meet legal or company safety targets;
- (10) ‘safety measures’ means a set of actions either reducing the frequency of occurrence of a hazard or mitigating its consequences in order to achieve and/or maintain an acceptable level of risk;
- (11) ‘proposer’ means one of the following:
- (a) a railway undertaking or an infrastructure manager in the framework of the risk control measures they have to implement in accordance with Article 4 of Directive 2004/49/EC;
 - (b) an entity in charge of maintenance in the framework of the measures they have to implement in accordance with Article 14a(3) of that Directive;
 - (c) a contracting entity or a manufacturer when they invite a notified body to apply the “EC” verification procedure in accordance with Article 18(1) of Directive 2008/57/EC, or;
 - (d) the applicant of an authorisation for placing in service of structural sub-systems;
- (12) ‘safety assessment report’ means the document containing the conclusions of the assessment performed by an assessment body on the system under assessment;
- (13) ‘hazard’ means a condition that could lead to an accident;
- (14) ‘assessment body’ means the independent and competent external or internal individual, organisation or entity which undertakes investigation to provide a judgement, based on evidence, of the suitability of a system to fulfil its safety requirements;
- (15) ‘risk acceptance criteria’ means the terms of reference by which the acceptability of a specific risk is assessed; these criteria are used to determine that the level of a risk is sufficiently low that it is not necessary to take any immediate action to reduce it further;
- (16) ‘hazard record’ means the document in which identified hazards, their related measures, their origin and the reference to the organisation which has to manage them are recorded and referenced;
- (17) ‘hazard identification’ means the process of finding, listing and characterising hazards;
- (18) ‘risk acceptance principle’ means the rules used in order to arrive at the conclusion whether or not the risk related to one or more specific hazards is acceptable;

- (19) ‘code of practice’ means a written set of rules that, when correctly applied, can be used to control one or more specific hazards;
- (20) ‘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;
- (21) ‘risk estimation’ means the process used to produce a measure of the level of risks being analysed, consisting of the following steps: estimation of frequency, consequence analysis and their integration;
- (22) ‘technical system’ means a product or an assembly of products including the design, implementation and support documentation; the development of a technical system starts with its requirements specification and ends with its acceptance; although the design of relevant interfaces with human behaviour is considered, human operators and their actions are not included in a technical system; the maintenance process is described in the maintenance manuals but is not itself part of the technical system;
- (23) ‘catastrophic consequence’ means fatalities and/or multiple severe injuries and/or major damage to the environment resulting from an accident;
- (24) ‘safety acceptance’ means status given to the change by the proposer based on the safety assessment report provided by the assessment body;
- (25) ‘system’ means any part of the railway system which is subjected to a change. The change may be of a technical, operational or organisational nature;
- (26) ‘notified national rule’ means any national rule notified by Member States under Council Directive 96/48/EC⁸, Directives 2001/16/EC⁹, 2004/49/EC and 2008/57/EC;
- (27) ‘certification body’ means a certification body as defined in Article 3 of Commission Regulation (EU) No 445/2011;
- (28) ‘conformity assessment body’ means a conformity assessment body as defined in Article 2 of Regulation (EU) No 765/2008;
- (29) ‘accreditation’ means accreditation as defined in Article 2 of Regulation (EU) No 765/2008;
- (30) ‘national accreditation body’ means a national accreditation body as defined in Article 2 of Regulation (EU) No 765/2008.

⁸ OJ L 235, 17.9.1996, p. 6.

⁹ OJ L 110, 20.4.2001, p. 1.

Article 4
Significant changes

1. If there is no existing notified national rule for defining whether a change is significant or not in a Member State, the proposer shall consider the potential impact of the change in question on the safety of the railway system.

When the proposed change has no impact on safety, the risk management process described in Article 5 does not need to be applied.

2. When the proposed change has an impact on safety, the proposer shall decide, by expert judgement, on the significance of the change based on the following criteria:
 - (a) failure consequence: credible worst-case scenario in the event of failure of the system under assessment, taking into account the existence of safety barriers outside the system under assessment;
 - (b) novelty used in implementing the change: this concerns both what is innovative in the railway sector, and what is new just for the organisation implementing the change;
 - (c) complexity of the change;
 - (d) monitoring: the inability to monitor the implemented change throughout the system life-cycle and take appropriate interventions;
 - (e) reversibility: the inability to revert to the system before the change;
 - (f) additionality: assessment of the significance of the change taking into account all recent safety-related modifications to the system under assessment which were not judged as significant.

The proposer shall keep adequate documentation to justify his decision.

Article 5
Risk management process

1. The proposer as defined in Article 3(11) shall be responsible for applying this Regulation, including the assessment of the significance of the change based on the criteria in Article 4, and for conducting the risk management process described in Annex I.
2. The proposer shall ensure that risks introduced by its suppliers and its service providers, including their subcontractors, are also managed in compliance with this Regulation. To this end, the proposer may require through contractual arrangements that its suppliers and its service providers, including their subcontractors, participate in the risk management process in Annex I.

Article 6
Independent assessment

1. An assessment body shall carry out an independent assessment of both the suitability of the application of the risk management process described in Annex I and of the appropriateness of its results. This assessment body shall meet the criteria listed in Annex II. Where the assessment body is not already identified by European Union or existing national legislation, the proposer shall appoint its own assessment body at the earliest appropriate stage of the risk assessment process.
2. To perform this independent assessment, the assessment body shall:
 - (a) ensure it has a thorough understanding of the significant change based on the documentation provided by the proposer;
 - (b) conduct an assessment of the processes used for managing the safety and quality during the design and implementation of the significant change, if those processes are not already certified by a relevant conformity assessment body;
 - (c) conduct an assessment of the application of those safety and quality processes during the design and implementation of the significant change. This assessment shall end up with the delivery of the safety assessment report defined in Article 8.
3. Duplication of work shall be avoided between the following assessments:
 - (a) the assessment of conformity of the safety management system and of the system of maintenance of entities in charge of maintenance as required by Directive 2004/49/EC, and;
 - (b) the conformity assessment carried out by a notified body or a body designated according to Article 17 of Directive 2008/57/EC, and;
 - (c) any independent assessment carried out by the assessment body in accordance with this Regulation.
4. The national safety authority may act as the assessment body where the significant changes concern the following cases:
 - (a) where a vehicle needs an authorisation for placing in service, as referred to in Articles 22(2) and 24(2) of Directive 2008/57/EC;
 - (b) where a vehicle needs an additional authorisation for placing in service, as referred to in Articles 23(5) and 25(4) of Directive 2008/57/EC;
 - (c) where the safety certificate has to be updated due to an alteration of the type or extent of the operation, as referred to in Article 10(5) of Directive 2004/49/EC;
 - (d) where the safety certificate has to be revised due to substantial changes to the safety regulatory framework, as referred to in Article 10(5) of Directive 2004/49/EC;

- (e) where the safety authorisation has to be updated due to substantial changes to the infrastructure, signalling or energy supply, or to the principles of its operation and maintenance, as referred to in Article 11(2) of Directive 2004/49/EC;
 - (f) where the safety authorisation has to be revised due to substantial changes to the safety regulatory framework, as referred to in Article 11(2) of Directive 2004/49/EC.
5. Where the significant change concern a structural subsystem that needs an authorisation for placing in service as referred to in Article 15(1) or Article 20 of Directive 2008/57/EC, the national safety authority may act as the assessment body unless the proposer already gave that task to a notified body in accordance with Article 18(2) of that Directive.

Article 7

Accreditation/Recognition of the assessment body

1. The assessment body carrying out the activities in Article 6 shall be either:
 - (a) accredited by the national accreditation body using the criteria defined in Annex II, or;
 - (b) recognised by the recognition body using the criteria defined in Annex II.
2. By analogy to the requirements in Article 5(3) and 5(4) of Regulation (EC) 765/2008/EC for accreditation, the recognition body shall ensure the following:
 - (a) conduct periodic surveillance in order to verify that the assessment body it recognised still satisfies the criteria set out in Annex II during the validity of the recognition;
 - (b) if the assessment body no longer satisfies the criteria set out in Annex II, limit the scope of application of the recognition, suspend or withdraw the recognition, depending on the degree of non-compliance.
3. In case of recognition, the following types of recognition of the assessment body may be used:
 - (a) recognition directly by the Member State of a national safety authority, an entity in charge of maintenance, an organisation or a part of it or an individual;
 - (b) recognition by the national safety authority of the ability of an organisation or a part of it or an individual to conduct independent assessment through the assessment and supervision of the safety management system of a railway undertaking or an infrastructure manager;
 - (c) when the national safety authority is acting as certification body in conformity with Article 10 of Regulation 445/2011, recognition by the national safety authority of the ability of an organisation or a part of it or an individual to

conduct independent assessment through the assessment and surveillance of the system of maintenance of an entity in charge of maintenance.

4. When granting the safety certificate or the safety authorisation according to Regulation 1158/2010/EC¹⁰ or Regulation 1169/2010/EC¹¹, a national safety authority shall accept the accreditation or the recognition by a Member State, as proof of the ability of the railway undertaking or infrastructure manager to act as assessment body.
5. The Agency shall organise peer evaluations between the recognition bodies based on the same principles as the ones described in Article 10 of Regulation 765/2008/EC.
6. The Agency shall organise, in collaboration with the European cooperation for Accreditation (EA), trainings on this Regulation for the national accreditation bodies and for the recognition bodies at least at each new revision of this Regulation.
7. In the case of Article 7(3)(a), the validity of recognition shall not exceed 5 years from the date it is granted.
8. In the case of Article 7(3)(b):
 - (a) the statement of recognition for a railway undertaking or an infrastructure manager shall be displayed on the relevant safety certificate in field 5 '*Additional Information*' of the harmonised format of safety certificates provided in Annex I of Regulation 653/2007/EC¹² and in an appropriate part of the safety authorisations;
 - (b) the validity of recognition shall be 5 years from the date it is granted or, equal to the validity of the safety certificate or authorisation. In this case, the request of recognition shall be made at the next application for renewal or update of the safety certificate or authorisation.
9. When granting the certificate to an entity in charge of maintenance according to Regulation (EU) No 445/2011, the certification body shall accept the accreditation or the recognition by a Member State, as proof of the ability of the entity in charge of maintenance to act as assessment body.
10. In the case of Article 7(3)(c):
 - (a) the statement of recognition for an entity in charge of maintenance shall be displayed on the relevant certificate in field 5 '*Additional Information*' of the harmonised format of certificates for entities in charge of maintenance provided in Annex V, or in Annex VI where relevant, of Regulation 445/2011;
 - (b) the validity of recognition shall be 5 years from the date it is granted or, equal to the validity of the certificate issued by the certification body. In this case, the

¹⁰ OJ L 326, 10.12.2010, p. 11

¹¹ OJ L 327, 11.12.2010, p. 13

¹² OJ L 153, 14.6.2007, p. 9

request of recognition shall be made at the next application for renewal or update of that certificate.

11. Where the risk assessment for a significant change is not to be mutually recognised, the proposer shall appoint an assessment body meeting at least the competency, independency and impartiality requirements of Annex II. The other requirements of paragraph 1 in Annex II may be relaxed in agreement with the national safety authority in a non-discriminatory way.
12. If applicable, by no later than [specific date to be inserted by OPOCE - *one year after the date of entry into force*], Member States shall inform the Agency which is their national accreditation body and/or recognition body or recognition bodies carrying out the activities in Article 7(1), as well as of the assessment bodies they recognised in conformity with Article 7(3)(a). They shall also notify any change to that situation within 1 month of the change. The Agency shall make this information publicly available.
13. By no later than [specific date to be inserted by OPOCE - *18 months after the date of entry into force*], the national accreditation body shall inform the Agency of the assessment bodies accredited, as well as of the area of competence in points 2 and 3 of Annex II those assessment bodies are accredited. They shall also notify any change to that situation within 1 month of the change. The Agency shall make this information publicly available.
14. By no later than [specific date to be inserted by OPOCE - *18 months after the date of entry into force*], the recognition body shall inform the Agency of the assessment bodies recognised, as well as of the area of competence in points 2 and 3 of Annex II those assessment bodies are recognised. They shall also notify any change to that situation within 1 month of the change. The Agency shall make this information publicly available.

Article 8

Safety assessment reports

1. The assessment body shall provide the proposer with a safety assessment report according to the requirements defined in Annex III. The proposer shall be responsible for determining if and how to take into account the recommendations of the safety assessment report for the safety acceptance of the assessed change.
2. In the case referred to in point (b) of Article 2(3), in accordance with Article 8(4) the safety assessment report shall be accepted by the national safety authority in its decision to authorise the placing in service of structural subsystems and vehicles. The national safety authority may not request additional checks or risk analyses unless it is able to demonstrate without prejudice to Article 16 of Directive 2008/57/EC the existence of a substantial safety risk.
3. In the case referred to in point (a) of Article 2(3), the independent assessment shall be part of the task of the notified body, unless otherwise prescribed by the TSI.

If the independent assessment is not part of the task of the notified body, in accordance with Article 8(4) the safety assessment report shall be accepted by the

notified body in charge of delivering the conformity certificate or by the contracting entity in charge of drawing up the EC declaration of verification, unless it justifies and documents its doubts concerning the assumptions made or the appropriateness of the results.

4. When a system or part of a system has already been accepted following the risk management process specified in this Regulation, the resulting safety assessment report shall not be called into question by any other assessment body in charge of performing a new assessment for the same system. The mutual recognition shall be conditional on demonstration that the system will be used under the same functional, operational and environmental conditions as the already accepted system, and that equivalent risk acceptance criteria have been applied.

Article 9

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 Article 9 of Directive 2004/49/EC.
2. The entities in charge of maintenance shall include audits of application of this Regulation in their recurrent auditing scheme of the system of maintenance as referred to in Article 14a(3) of Directive 2004/49/EC.
3. Within the framework of the tasks defined in Article 16(2)(e) of Directive 2004/49/EC, the national safety authority shall supervise the application of this Regulation.

Article 10

Feedback and technical progress

1. Each infrastructure manager and each railway undertaking shall, in its annual safety report referred to in Article 9(4) of Directive 2004/49/EC, report briefly on its experience with the application of this Regulation. The report shall also include a synthesis of the decisions related to the level of significance of the changes.
2. Each national safety authority shall, in its annual safety report referred to in Article 18 of Directive 2004/49/EC, report on the experience of the proposers with the application of this Regulation, and, where appropriate, its own experience.
3. The annual maintenance report of entities in charge of maintenance of freight wagons set out in point I(7)(4)(k) in Annex III to Regulation (EU) No 445/2011, shall include information about the experience of entities in charge of maintenance in applying this Regulation. The Agency shall gather this information in coordination with the respective certification bodies.
4. The other entities in charge of maintenance that do not fall under the scope of Regulation (EU) No 445/2011 shall also share their experience with the Agency on the application of this Regulation. The Agency shall coordinate the sharing of experience with these entities in charge of maintenance.

5. The Agency shall collect all information on the experience of the application of this Regulation and, when necessary, shall make recommendations to the Commission with a view to improving this Regulation.
6. Before [specific date to be inserted by OPOCE - *four years after the date of entry into force*] the Agency shall submit to the Commission a report which shall include:
 - (a) an analysis of the experience with the application of this Regulation, including cases where the CSM has been applied by proposers on a voluntary basis before the relevant date of application provided for in Article 12;
 - (b) an analysis of the experience of the proposers concerning the decisions related to the level of significance of the changes;
 - (c) an analysis of the cases where codes of practice have been used as described in section 2.3.8 of Annex I;
 - (d) an analysis of the experience with the accreditation and recognition of assessment bodies;
 - (e) an analysis of overall effectiveness of this Regulation.

The national safety authorities shall assist the Agency by identifying cases of application of this Regulation.

Article 11

Repeal

1. Commission Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council shall be repealed with effect from [specific date to be inserted by OPOCE - *one year after the date of entry into force*]
2. References to the repealed Regulation No 352/2009 shall be construed as references to this Regulation.

Article 12

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.
2. This Regulation shall apply from [specific date to be inserted by OPOCE - *one year after the date of entry into force*].

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

Done at Brussels, [...]

For the Commission
The President
[...]

ANNEX I**1. GENERAL PRINCIPLES APPLICABLE TO THE RISK MANAGEMENT PROCESS****1.1. General principles and obligations**

1.1.1. 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 risks, the associated safety measures and the resulting safety requirements to be fulfilled by the system under assessment;
- (b) demonstration of the compliance of the system with the identified safety requirements; and
- (c) management of all identified hazards and the associated safety measures.

This risk management process is iterative and is depicted in the diagram of the Appendix. 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.

1.1.2. This iterative risk management process:

- (a) shall include appropriate quality assurance activities and be carried out by competent staff;
- (b) shall be independently assessed by one or more assessment bodies.

1.1.3. The proposer in charge of the risk management process required by this Regulation shall maintain a hazard record according to section 4.

1.1.4. The actors who already have in place methods or tools for risk assessment may continue to apply them as far as they are compatible with the provisions of this Regulation and subject to the following conditions:

- (a) the risk assessment methods or tools are described in a safety management system which has been accepted by a national safety authority in accordance with Article 10(2)(a) or Article 11(1)(a) of Directive 2004/49/EC; or
- (b) the risk assessment methods or tools are required by a TSI or comply with publicly available recognised standards specified in notified national rules.

1.1.5. 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 proposer. In particular the proposer shall decide, with agreement of the actors concerned, who will be in charge of fulfilling the safety requirements resulting from the risk assessment. The safety requirements assigned by the proposer to those actors shall not go beyond the scope of their responsibility and domain of control. 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 conducted according to section 3.

- 1.1.6. The first step of the risk management process shall be to identify in a document, to be drawn up by the proposer, the different actors' tasks, as well as their risk management activities. The proposer shall coordinate close collaboration between the different actors involved, according to their respective tasks, in order to manage the hazards and their associated safety measures.
- 1.1.7. Evaluation of the correct application of the risk management process described in this Regulation falls within the responsibility of the assessment body.

1.2. Interfaces management

- 1.2.1. For each interface relevant to the system under assessment and without prejudice to specifications of interfaces defined in relevant TSIs, the rail-sector actors concerned 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 proposer.
- 1.2.2. 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 management of the related hazard to the latter using the process described in section 4.
- 1.2.3. For the system under assessment, any actor who discovers that a safety measure is non-compliant or inadequate is responsible for notifying it to the proposer, who shall in turn inform the actor implementing the safety measure.
- 1.2.4. 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.
- 1.2.5. When agreement cannot be found between two or more actors it is the responsibility of the proposer to find a reasonably practicable solution.
- 1.2.6. When a requirement in a notified national rule cannot be fulfilled by an actor, the proposer shall seek advice from the relevant competent authority.
- 1.2.7. Independently from the definition of the system under assessment, the proposer is responsible for ensuring that the risk management covers the system itself and the integration into the railway system as a whole.

2. DESCRIPTION OF THE RISK ASSESSMENT PROCESS

2.1. General description

2.1.1. 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 management according to section 4.1.

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

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

2.1.3. A hazard identification shall be carried out on the defined system, according to section 2.2.

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

- (a) the application of codes of practice (section 2.3);
- (b) a comparison with similar systems (section 2.4);
- (c) an explicit risk estimation (section 2.5).

In accordance with the general principle referred to in section 1.1.5, the assessment body shall refrain from imposing the risk acceptance principle to be used by the proposer.

- 2.1.5. The proposer shall demonstrate in the risk evaluation that the selected risk acceptance principle is adequately applied. The proposer shall also check that the selected risk acceptance principles are used consistently.
- 2.1.6. 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. Compliance with these safety requirements shall be demonstrated in accordance with section 3.
- 2.1.7. The iterative risk assessment process can be considered as completed when it is demonstrated that all safety requirements are fulfilled and no additional reasonably foreseeable hazards have to be considered.

2.2. Hazard identification

- 2.2.1. The proposer shall systematically identify, using wide-ranging expertise from a competent team, all reasonably foreseeable hazards for the whole system under assessment, its functions where appropriate and its interfaces.

All identified hazards shall be registered in the hazard record according to section 4.

- 2.2.2. 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 registered in the hazard record. Their classification shall be justified in order to allow independent assessment by an assessment body.
- 2.2.3. 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.
- 2.2.4. During the hazard identification, safety measures may be identified. They shall be registered in the hazard record according to section 4.
- 2.2.5. The hazard identification only needs to be carried out at a level of detail necessary to identify where safety measures are expected to control the risks in accordance with one of the risk acceptance principles mentioned in point 2.1.4. 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.
- 2.2.6. Whenever a code of practice or a reference system is used to control the risk, the hazard identification can be limited to:
- (a) the verification of the relevance of the code of practice or of the reference system;
 - (b) the identification of the deviations from the code of practice or from the reference system.

2.3. Use of codes of practice and risk evaluation

- 2.3.1. The proposer, with the support of other involved actors, shall analyse whether one, several or all hazards are appropriately covered by the application of relevant codes of practice.
- 2.3.2. The codes of practice shall satisfy at least the following requirements:
- (a) be widely recognised in the railway domain. If this is not the case, the codes of practice will have to be justified and be acceptable to the assessment body;
 - (b) be relevant for the control of the considered hazards in the system under assessment. Successful application of a code of practice for similar cases to manage changes and control effectively the identified hazards of a system in the sense of this Regulation is sufficient to be considered as relevant;
 - (c) upon request, be available to assessment bodies who shall either assess or, where relevant, mutually recognise, in accordance with Article 8(4) of this Regulation, the suitability of the application of the risk management process and the appropriateness of the results.
- 2.3.3. Where compliance with TSIs is required by Directive 2008/57/EC and the relevant TSI does not impose the risk management process established by this Regulation, the TSIs may be considered as codes of practice for controlling hazards, provided requirement (b) of point 2.3.2 is fulfilled.
- 2.3.4. National rules notified in accordance with Article 8 of Directive 2004/49/EC and Article 17(3) of Directive 2008/57/EC may be considered as codes of practice provided the requirements of point 2.3.2 are fulfilled.
- 2.3.5. If one or more hazards are controlled by codes of practice fulfilling the requirements of point 2.3.2, then the risks associated with 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 registered in the hazard record as safety requirements for the relevant hazards.
- 2.3.6. Where an alternative approach is not fully compliant with a code of practice, the proposer shall demonstrate that the alternative approach taken leads to at least the same level of safety.
- 2.3.7. 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.
- 2.3.8. When all hazards are controlled by codes of practice, the risk management process may be limited to:
- (a) the hazard identification in accordance with section 2.2.6;

- (b) the registration of the use of the codes of practice in the hazard record in accordance with section 2.3.5;
- (c) the documentation of the application of the risk management process in accordance with section 5;
- (d) an independent assessment in accordance with Article 6.

2.4. Use of reference system and risk evaluation

- 2.4.1. The proposer, with the support of other involved actors, shall analyse whether one, several or all hazards are appropriately covered by a similar system that could be taken as a reference system.
- 2.4.2. 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.
- 2.4.3. If a reference system fulfils the requirements listed in point 2.4.2, 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 registered in the hazard record as safety requirements for the relevant hazards.

- 2.4.4. 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, applying another reference system or one of the two other risk acceptance principles. The risks associated with the hazards covered by the reference system shall, in that case, be considered as acceptable.
- 2.4.5. If at least 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 risk acceptance principles.

2.5. Explicit risk estimation and evaluation

- 2.5.1. When the hazards are not covered by one of the two risk acceptance principles described in sections 2.3 and 2.4, 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.
- 2.5.2. The acceptability of the estimated risks shall be evaluated using risk acceptance criteria either derived from or based on legal requirements stated in EU 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.

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

- 2.5.3. When the risk associated with one or a combination of several hazards is considered as acceptable, the identified safety measures shall be registered in the hazard record.
- 2.5.4. 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 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.

- 2.5.5. Without prejudice to the procedure specified in Article 8 of Directive 2004/49/EC, a more demanding criterion may be requested, through a notified national safety rule, in order to maintain a national safety level. In the case of additional authorisations for placing in service of vehicles, the procedures of Articles 23 and 25 of Directive 2008/57/EC shall apply.
- 2.5.6. If a technical system is developed by applying the 10^{-9} criterion defined in point 2.5.4, the principle of mutual recognition is applicable in accordance with Article 8(4) of this Regulation.

Nevertheless, if the proposer can demonstrate that the national safety level in the Member State of application can be maintained with a rate of failure higher than 10^{-9} per operating hour, this criterion can be used by the proposer in that Member State.

- 2.5.7. 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.

3. DEMONSTRATION OF COMPLIANCE WITH SAFETY REQUIREMENTS

- 3.1. Prior to the safety acceptance of the change, fulfilment of the safety requirements resulting from the risk assessment phase shall be demonstrated under the supervision of the proposer.
- 3.2. This demonstration shall be carried out by each of the actors responsible for fulfilling the safety requirements, as decided in accordance with point 1.1.5.
- 3.3. The approach chosen for demonstrating compliance with the safety requirements as well as the demonstration itself shall be independently assessed by an assessment body.
- 3.4. 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 proposer according to section 2. The new hazards shall be registered in the hazard record according to section 4.

4. HAZARD MANAGEMENT

4.1. Hazard management process

- 4.1.1. Hazard record(s) shall be created or updated (where they already exist) by the proposer during the design and the implementation and till the acceptance of the change or the delivery of the safety assessment report. The hazard record shall track the progress in monitoring risks associated with the identified hazards. once the system has been accepted and is operated, the hazard record shall be further maintained by the infrastructure manager or the railway undertaking in charge with the operation of the system under assessment as an integrated part of its safety management system.
- 4.1.2. The hazard record shall include all hazards, together with all related safety measures and system assumptions identified during the risk assessment process. it shall contain a clear reference to the origin and to the selected risk acceptance principles and shall clearly identify the actor(s) in charge of controlling each hazard.

4.2. Exchange of information

All hazards and related safety requirements which cannot be controlled by one actor alone shall be communicated to another relevant actor in order to find jointly an adequate solution. The hazards registered in the hazard record of the actor who transfers them shall only be “controlled” when the evaluation of the risks associated with these hazards is made by the other actor and the solution is agreed by all concerned.

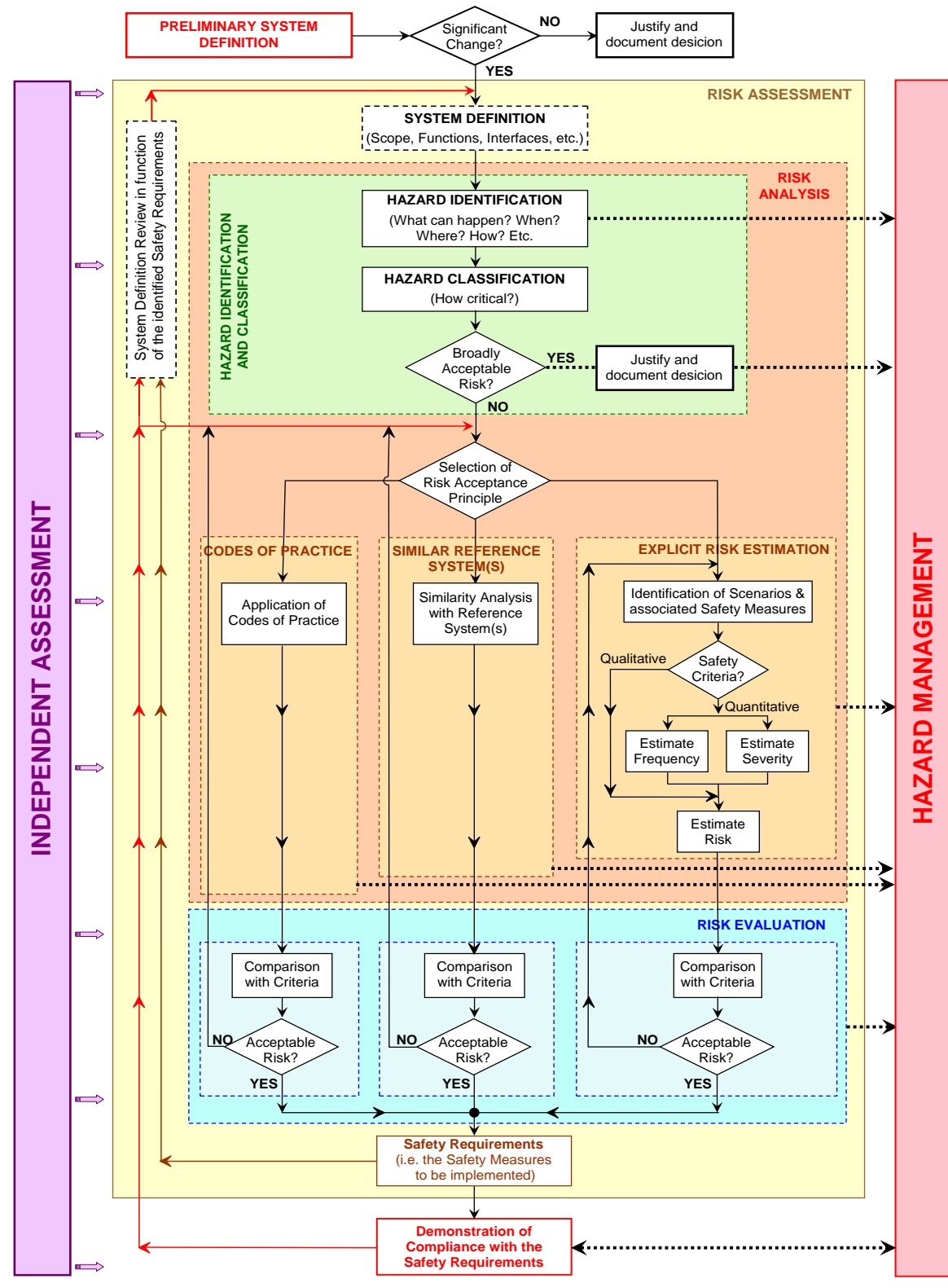
5. EVIDENCE FROM THE APPLICATION OF THE RISK MANAGEMENT PROCESS

- 5.1. The risk management process used to assess the safety levels and compliance with safety requirements shall be documented by the proposer in such a way that all the

necessary evidence showing the suitability of the application of the risk management process and of the appropriateness of its results are accessible to an assessment body.

- 5.2. The documentation produced by the proposer under point 5.1. shall at least include:
- (a) description of the organisation and the experts appointed to carry out the risk assessment process;
 - (b) results of the different phases of the risk assessment and a list of all the necessary safety requirements to be fulfilled in order to control the risk to an acceptable level;
 - (c) evidence of compliance with all the necessary safety requirements;
 - (d) all assumptions relevant for the system integration, operation or maintenance, which were made during the system definition, design and the risk assessment.
- 5.3. The assessment body shall establish its conclusion in a safety assessment report as defined in Annex III.

Appendix
Risk management process and independent assessment



ANNEX II**CRITERIA FOR ACCREDITATION OR RECOGNITION OF THE ASSESSMENT BODY**

1. The assessment body shall fulfil all requirements of the ISO/IEC 17020:1998 standard and of its subsequent amendments. The assessment body shall provide professional judgement in performing the inspection work defined in that standard. The assessment body shall fulfil both the general criteria on competence and independence from that standard and the following specific competence criteria:
 - (a) competence in risk management process: knowledge and experience of the standard safety analysis techniques and of the relevant standards;
 - (b) all relevant competences for assessing the system under assessment;
 - (c) competence in the correct application of safety and quality management systems or in auditing management systems.
2. By analogy to Article 28 of Directive 2008/57/EC concerning the notification of notified bodies, the assessment body shall be accredited or recognised for the different areas of competence of the railway system, or parts of it for which an essential requirement of safety exists, including the area of competence in operation and maintenance of the railway system.
3. The assessment body shall be accredited or recognised for assessing the overall consistency of the risk management and the safe integration of the system under assessment into the railway system as a whole. This shall include competence of the assessment body in checking the following:
 - (a) the organisation, i.e. the arrangements necessary to ensure a coordinated approach to achieving system safety through a uniform understanding and application of risk control measures for subsystems;
 - (b) the methodology, i.e. evaluation of the methods and resources deployed by various stakeholders to support safety at the subsystem and system level, and;
 - (c) the technical aspects necessary for assessing the relevance and completeness of risk assessments and the level of safety for the system as a whole.
4. The assessment body can be accredited or recognised for one, several or all of the area of competences listed in paragraphs 2 and 3 above.

ANNEX III

SAFETY ASSESSMENT REPORT OF THE ASSESSMENT BODY

1. The safety assessment report of the assessment body shall at least contain the following information:
 - (a) Identification of the assessment body;
 - (b) The independent assessment plan;
 - (c) The definition of the scope of the independent assessment as well as its limitations;
 - (d) The results of the independent assessment including in particular:
 - 1) Detailed information on the independent assessment activities for checking the compliance with the provisions of this Regulation;
 - 2) The identified non compliances with the provisions of this Regulation and the assessment body recommendations;
 - (e) The conclusions of the independent assessment