

**COMMISSION IMPLEMENTING REGULATION (EU) No 402/2013****of 30 April 2013****on the common safety method for risk evaluation and assessment and repealing 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) <sup>(1)</sup>, and in particular Article 6(4) 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.
- (2) On 12 October 2010 the Commission issued a mandate to the European Railway Agency (the 'Agency') in accordance with Directive 2004/49/EC to revise 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 <sup>(2)</sup>. The revision should cover the results of the analysis by the Agency under Article 9(4) of the Regulation of the overall effectiveness of the CSM for risk evaluation and assessment 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) for the assessment body according to its role in the CSM, with a view to improving clarity in order to avoid differences in application across the Member States, taking into account the interfaces with existing Union authorisation/certification procedures in the railway sector. If feasible, the revision of Regulation (EC) No 352/2009 should also cover further developments in 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 revision of the CSM to the

Commission, supported by an impact assessment report to address the mandate of the Commission. This Regulation is based on that Agency recommendation.

- (3) In accordance with Directive 2004/49/EC the basic elements for the safety management system should include procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change in 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 for the system of maintenance is also 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 railways <sup>(3)</sup> 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 Community <sup>(4)</sup> 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 the scope of this Regulation.
- (7) The absence of a common approach for specifying and demonstrating compliance with safety levels and requirements of the railway system among the Member

<sup>(1)</sup> OJ L 164, 30.4.2004, p. 44.

<sup>(2)</sup> OJ L 108, 29.4.2009, p. 4.

<sup>(3)</sup> OJ L 237, 24.8.1991, p. 25.

<sup>(4)</sup> OJ L 191, 18.7.2008, p. 1.

States has proved to be one of the obstacles to liberalisation of the railway market. Such a common approach should be established through this Regulation.

- (8) To facilitate mutual recognition between Member States, the methods used for identifying and managing risks and the methods for demonstrating that the railway system in the territory of the Union conforms to safety requirements should be harmonised among the actors involved in the development and operation of the railway system. 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 in 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 for the safety in a Member State, the company or organisation in charge of implementing the change (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 set out 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 for 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, or 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 Union which require specific intervention by the national safety authority, that authority 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 actors involved, 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 within 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 wagons <sup>(1)</sup>.
- (14) Accreditation of an assessment body should normally be granted by the national accreditation body which has exclusive competence to assess if the assessment body meets the requirements set by harmonised standards. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products <sup>(2)</sup> contains detailed provisions on the competence of such national accreditation bodies.
- (15) Where harmonised Union legislation provides for the selection of conformity assessment bodies for its implementation, transparent accreditation, as provided for in Regulation (EC) No 765/2008, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of those bodies. However, national authorities may consider that they possess the appropriate means to carry out this evaluation themselves. In such cases, the Member State should provide the Commission and the other Member States with all the documentary evidence necessary for verification of the competence of the recognition body it selects for implementation of the Union legislation. In order to achieve a similar level of quality and trust as expected through accreditation, the

<sup>(1)</sup> OJ L 122, 11.5.2011, p. 22.

<sup>(2)</sup> OJ L 218, 13.8.2008, p. 30.

requirements and rules for the evaluation and surveillance of assessment bodies in the case of recognition should be equivalent to those used for 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) Recognition of internal assessment bodies in compliance with this Regulation does not require an immediate revision of already delivered safety certificates to railway undertakings, safety authorisations to infrastructure managers and certificates to entities in charge of maintenance. Their revision can be made at the next application for renewal or update of the safety certificate, safety authorisation or certificate of the entity in charge of maintenance.
- (18) In existing legislation there are no limits in the number of assessment bodies accredited or recognised in each Member State and there are no obligations to have at least one. Where the assessment body is not already designated by existing Union or national legislation, the proposer may appoint any assessment body in the Union or in a third country accredited under equivalent criteria and meeting equivalent requirements to those contained in this regulation. The Member State should be able to use accreditation or recognition or any combination of these two options.
- (19) Regulation (EC) No 352/2009 has become obsolete and should therefore be replaced by this Regulation.
- (20) In view of the new requirements introduced by the present Regulation in terms of accreditation and recognition of the assessment body, the implementation of this Regulation should be deferred in order to give sufficient time to the actors concerned to put in place and implement this new common approach.
- (21) 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

##### Subject matter

1. This Regulation establishes a revised common safety method (CSM) for risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC.
2. 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 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.

Such 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 subjected to consideration under the rules of Article 4.

2. When, on the basis of an assessment under the criteria set out in Article 4(2)(a) to (f):

(a) the change is considered significant, the risk management process set out in Article 5 shall be applied;

(b) the change is considered not significant, keeping adequate documentation to justify the decision shall be sufficient.

3. This Regulation shall apply also to 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) if the change is significant as set out in Article 4(2), the risk management process set out in Article 5 shall be applied within 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 paragraph 3(b) of this Article shall not lead to requirements contradictory to those laid down in the relevant TSIs. If such contradictions occur, the proposer shall inform the Member State concerned 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(2) of that Directive.

5. The railway systems excluded from the scope of Directive 2004/49/EC according to its Article 2(2) are excluded from the scope of this Regulation.

6. The provisions of Regulation (EC) No 352/2009 shall continue to apply in relation to projects which are at an advanced stage of development within the meaning of Article 2(t) of Directive 2008/57/EC at the date of application of this Regulation.

## Article 3

**Definitions**

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

The following definitions 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;
- (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 which implements risk control measures in accordance with Article 4 of Directive 2004/49/EC;
  - (b) an entity in charge of maintenance which implements measures in accordance with Article 14a(3) of Directive 2004/49/EC;
  - (c) a contracting entity or a manufacturer which invites a notified body to apply the 'EC' verification procedure in accordance with Article 18(1) of Directive 2008/57/EC or a designated body according to Article 17(3) of that Directive;
  - (d) an applicant for an authorisation for the 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 whereby 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/EC <sup>(1)</sup> or, Directive 2001/16/EC of the European Parliament and of the Council <sup>(2)</sup> and Directives 2004/49/EC and 2008/57/EC;
- (27) 'certification body' means a certification body as defined in Article 3 of Regulation (EU) No 445/2011;
- (28) 'conformity assessment body' means a conformity assessment body as defined in Article 2 of Regulation (EC) No 765/2008;
- (29) 'accreditation' means accreditation as defined in Article 2 of Regulation (EC) No 765/2008;
- (30) 'national accreditation body' means a national accreditation body as defined in Article 2 of Regulation (EC) No 765/2008;
- (31) 'recognition' means an attestation by a national body other than the national accreditation body that the assessment body meets the requirements set out in Annex II to this Regulation to carry out the independent assessment activity specified in Article 6(1) and (2).

#### Article 4

##### Significant changes

1. If there is no 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.

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

2. If 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 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 intervene appropriately;
- (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 changes to the system under assessment and which were not judged to be significant.

<sup>(1)</sup> OJ L 235, 17.9.1996, p. 6.

<sup>(2)</sup> OJ L 110, 20.4.2001, p. 1.

3. The proposer shall keep adequate documentation to justify its decision.

#### Article 5

##### Risk management process

1. The proposer 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 set out 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 set out in Annex I.

#### Article 6

##### Independent assessment

1. An assessment body shall carry out an independent assessment of the suitability of both the application of the risk management process as set out in Annex I and of its results. This assessment body shall meet the criteria listed in Annex II. Where the assessment body is not already designated by existing Union or national legislation, the proposer shall appoint its own assessment body at the earliest appropriate stage of the risk assessment process.

2. To perform the 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 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.

Having completed its assessment in accordance with points (a), (b) and (c), the assessment body shall deliver the safety assessment report provided for in Article 15 and Annex III.

3. Duplication of work between the following assessments shall be avoided:

- (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 as defined by Article 2(j) of Directive 2008/57/EC or a body designated in accordance with Article 17 of that Directive; and

(c) any independent assessment carried out by the assessment body in accordance with this Regulation.

4. Without prejudice to Union legislation, the proposer may choose the national safety authority as assessment body where that national safety authority offers this service and where the significant changes concern the following cases:

- (a) 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) 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) the safety certificate has to be updated due to alteration of the type or extent of the operation, as referred to in Article 10(5) of Directive 2004/49/EC;
- (d) 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) the safety authorisation has to be updated due to substantial changes to the infrastructure, signalling or energy supply, or to the principles of their operation and maintenance, as referred to in Article 11(2) of Directive 2004/49/EC;
- (f) 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.

Where a significant change concerns 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 proposer may choose the national safety authority as assessment body, where that national safety authority offers this service, unless the proposer has already given that task to a notified body in accordance with Article 18(2) of that Directive.

#### Article 7

##### Accreditation/recognition of the assessment body

The assessment body provided for in Article 6 shall be either:

- (a) accredited by the national accreditation body referred to in Article 13(1) using the criteria defined in Annex II; or
- (b) recognised by the recognition body referred to in Article 13(1) using the criteria defined in Annex II; or
- (c) the national safety authority under the requirement of Article 9(2).

#### Article 8

##### Acceptance of accreditation/recognition

1. When granting the safety certificate or the safety authorisation in accordance with Commission Regulation (EU) No 1158/2010<sup>(1)</sup> or Commission Regulation (EU) No 1169/2010<sup>(2)</sup>, a national safety authority shall accept accreditation or recognition by a Member State in accordance with

Article 7, as proof of the ability of the railway undertaking or infrastructure manager to act as an assessment body.

2. When granting the certificate to an entity in charge of maintenance in accordance with Regulation (EU) No 445/2011, the certification body shall accept such accreditation or recognition by a Member State, as proof of the ability of the entity in charge of maintenance to act as assessment body.

#### Article 9

##### Types of recognition of the assessment body

1. The following types of recognition of the assessment body may be used:

- (a) recognition by the Member State of 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 (EU) No 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 assessment and surveillance of the system of maintenance of an entity in charge of maintenance;
- (d) recognition by a recognition body designated by the Member State of the ability of an entity in charge of maintenance, an organisation or a part of it or an individual to conduct independent assessment.

2. When the Member State recognises the national safety authority as an assessment body, it is the responsibility of that Member State to ensure that the national safety authority fulfills the requirements set out in Annex II; In this case, the assessment body functions of the national safety authority shall be demonstrably independent of the other functions of the national safety authority.

#### Article 10

##### Validity of recognition

1. In the cases referred in Article 9(1)(a) and (d) and Article 9(2), the period of validity of recognition shall not exceed 5 years from the date it is granted.

2. In the case referred in Article 9(1)(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

<sup>(1)</sup> OJ L 326, 10.12.2010, p. 11.

<sup>(2)</sup> OJ L 327, 11.12.2010, p. 13.

harmonised format of safety certificates provided in Annex I to Commission Regulation (EC) No 653/2007 <sup>(1)</sup> and in an appropriate part of the safety authorisations;

- (b) the period of validity of recognition shall be limited to the validity of the safety certificate or authorisation under which it is granted. In this case, the request of recognition shall be made at the next application for renewal or update of the safety certificate or authorisation.
3. In the cases referred in Article 9(1)(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 (EU) No 445/2011;
- (b) the period of validity of recognition shall be limited to the validity of the certificate issued by the certification body under which it is granted. In this case, the request of recognition shall be made at the next application for renewal or update of that certificate.

#### Article 11

##### Surveillance by recognition body

1. By analogy to the requirements in Article 5(3) and (4) of Regulation (EC) No 765/2008 for accreditation, the recognition body shall conduct periodic surveillance in order to verify that the assessment body it recognised continues to satisfy the criteria set out in Annex II during the validity of the recognition.
2. If the assessment body no longer satisfies the criteria set out in Annex II, the recognition body shall limit the scope of application of the recognition, suspend or withdraw the recognition, depending on the degree of non-compliance.

#### Article 12

##### Relaxed criteria where a significant change is not to be mutually recognised

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.

#### Article 13

##### Provision of information to the Agency

1. Where applicable, by no later than 21 May 2015, Member States shall inform the Agency which is their national accreditation body and/or recognition body or recognition bodies for the purposes of this Regulation, as well as of the assessment bodies they recognised in conformity with Article 9(1)(a). They

shall also notify any change to that situation within one month of the change. The Agency shall make this information publicly available.

2. By no later than 21 May 2015, the national accreditation body shall inform the Agency of the assessment bodies accredited, as well as of the area of competence for which those assessment bodies are accredited as provided for in points 2 and 3 of Annex II. They shall also notify any change to that situation within 1 month of the change. The Agency shall make this information publicly available.

3. By no later than 21 May 2015, the recognition body shall inform the Agency of the assessment bodies recognised, as well as of the area of competence for which those assessment bodies are recognised as provided for in points 2 and 3 of Annex II. They shall also notify any change to that situation within 1 month of the change. The Agency shall make this information publicly available.

#### Article 14

##### Support from the Agency to accreditation or recognition of the assessment body

1. The Agency shall organise peer evaluations between the recognition bodies based on the same principles as set out in Article 10 of Regulation (EC) No 765/2008.
2. The Agency shall organise, in collaboration with the European cooperation for Accreditation (EA), training on this Regulation for the national accreditation bodies and for the recognition bodies at least at each new revision of this Regulation.

#### Article 15

##### Safety assessment reports

1. The assessment body shall provide the proposer with a safety assessment report in accordance with the requirements set out in Annex III. The proposer shall be responsible for determining if and how to take into account the conclusions of the safety assessment report for the safety acceptance of the assessed change. The proposer shall justify and document the part of the safety assessment report for which the proposer eventually disagrees.
2. In the case referred to in point (b) of Article 2(3), in accordance with paragraph 5 of this Article, the declaration referred to in Article 16 shall be accepted by the national safety authority in its decision to authorise the placing in service of structural subsystems and vehicles.
3. Without prejudice to Article 16 of Directive 2008/57/EC, the national safety authority may not request additional checks or risk analyses unless it is able to demonstrate the existence of a substantial safety risk.
4. In the case referred to in point (a) of Article 2(3), in accordance with paragraph 5 of this Article, the declaration referred to in Article 16 shall be accepted by the notified body in charge of delivering the conformity certificate, unless it justifies and documents its doubts concerning the assumptions made or the appropriateness of the results.

<sup>(1)</sup> OJ L 153, 14.6.2007, p. 9.

5. 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. Mutual recognition shall be conditional upon 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 16

##### Declaration by the proposer

Based on the results of the application of this Regulation and on the safety assessment report provided by the assessment body, the proposer shall produce a written declaration that all identified hazards and associated risks are controlled to an acceptable level.

#### Article 17

##### Risk control management and audits

1. The railway undertakings and infrastructure managers shall include audits of the application of this Regulation in their recurrent auditing scheme for 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 the application of this Regulation in their recurrent auditing scheme for the system of maintenance as referred to in Article 14a(3) of Directive 2004/49/EC.

3. As part 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 by railway undertakings, infrastructure managers and the entities in charge of maintenance that do not fall within the scope of Regulation (EU) No 445/2011 but are identified in its National Vehicle Register.

4. As part of the tasks defined in Article 7(1) of Regulation (EU) No 445/2011, the certification body of an entity in charge of maintenance of freight wagons shall perform surveillance of the application of this Regulation by the entity in charge of maintenance.

#### Article 18

##### 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 on 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 referred to 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 within 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 and with the national safety authorities.

5. The Agency shall collect all information on the experience of the application of this Regulation and shall, when necessary, make recommendations to the Commission with a view to improving this Regulation.

6. Before 21 May 2018 the Agency shall submit to the Commission a report containing:

- (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 20;
- (b) an analysis of the experience of proposers concerning decisions on the level of significance of changes;
- (c) an analysis of the cases where codes of practice have been used as set out in point 2.3.8 of Annex I;
- (d) an analysis of the experience with the accreditation and recognition of assessment bodies;
- (e) an analysis of the overall effectiveness of this Regulation.

The national safety authorities shall support the Agency in collecting such information.

#### Article 19

##### Repeal

Regulation (EC) No 352/2009 is repealed with effect from 21 May 2015.

References to the repealed Regulation shall be construed as references to this Regulation.

#### Article 20

##### Entry into force and application

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

It shall apply from 21 May 2015.

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

Done at Brussels, 30 April 2013.

*For the Commission*

*The President*

José Manuel BARROSO

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## ANNEX I

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

1.1.1. The risk management process 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 compliance of the system with all the safety requirements necessary to accept the risks linked to the identified hazards is demonstrated.

1.1.2. The risk management process shall include appropriate quality assurance activities and be carried out by competent staff. It shall be independently assessed by one or more assessment bodies.

1.1.3. The proposer in charge of the risk management process shall maintain a hazard record in accordance with point 4.

1.1.4. The actors who already have in place methods or tools for risk assessment may continue to apply them if such methods or tools 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 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 in accordance with point 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, and their risk management activities. The proposer is responsible for coordinating 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 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 coordinated by the proposer.

1.2.2. If, 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 in accordance with the process set out in point 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 reached between two or more actors it is the responsibility of the proposer to find a 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 its 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 hazard management in accordance with point 4.1.

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

- (a) system objective (intended purpose);
- (b) system functions and elements, where relevant (including human, technical and operational elements);
- (c) system boundary including other interacting systems;
- (d) physical (interacting systems) and functional (functional input and output) interfaces;
- (e) system environment (for example 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 that determine the limits for the risk assessment.

2.1.3. A hazard identification shall be carried out on the defined system, in accordance with point 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 (point 2.3);
- (b) a comparison with similar systems (point 2.4);
- (c) an explicit risk estimation (point 2.5).

In accordance with the principle referred to in point 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 that make the risk(s) of the system under assessment acceptable. Among these safety measures, those 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 point 3.

2.1.7. The iterative risk assessment process is considered to be 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 in accordance with point 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 in accordance with point 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 referred to in point 2.1.4. Iteration may 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, hazard identification may be limited to:

- (a) verification of the relevance of the code of practice or reference system;
- (b) 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) They must 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) They must 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 for it to be considered as relevant;
- (c) Upon request, they must be available to assessment bodies for them to either assess or, where relevant, mutually recognise, in accordance with Article 15(5), the suitability of both the application of the risk management process and of its 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 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 pursued 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 by 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) hazard identification in accordance with point 2.2.6;
- (b) registration of the use of the codes of practice in the hazard record in accordance with point 2.3.5;
- (c) documentation of the application of the risk management process in accordance with point 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 therefore 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. If the hazards are not covered by one of the two risk acceptance principles laid down in points 2.3 and 2.4, the demonstration of 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 requirements contained in Union 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 the combination of all hazards as a whole 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. If the risk associated with one hazard or a combination of several hazards is considered acceptable, the identified safety measures shall be registered in the hazard record.
- 2.5.4. If 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.

- 2.5.5. Without prejudice to the procedure specified in Article 8 of Directive 2004/49/EC, a more demanding criterion than the one laid down in point 2.5.4 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 laid down in point 2.5.4, the principle of mutual recognition is applicable in accordance with Article 15(5).

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 may 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. 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 in accordance with point 2. The new hazards shall be registered in the hazard record in accordance with point 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 design and implementation until acceptance of the change or delivery of the safety assessment report. A hazard record shall track the progress in monitoring risks associated with the identified hazards. Once the system has been accepted and is in operation, the hazard record shall be further maintained by the infrastructure manager or the railway undertaking in charge of 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 of the hazards and to the selected risk acceptance principles and clearly identify the actor(s) in charge of controlling each hazard.

**4.2. Exchange of information**

All hazards and related safety requirements that 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 regarded as 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 both the application of the risk management process and 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:

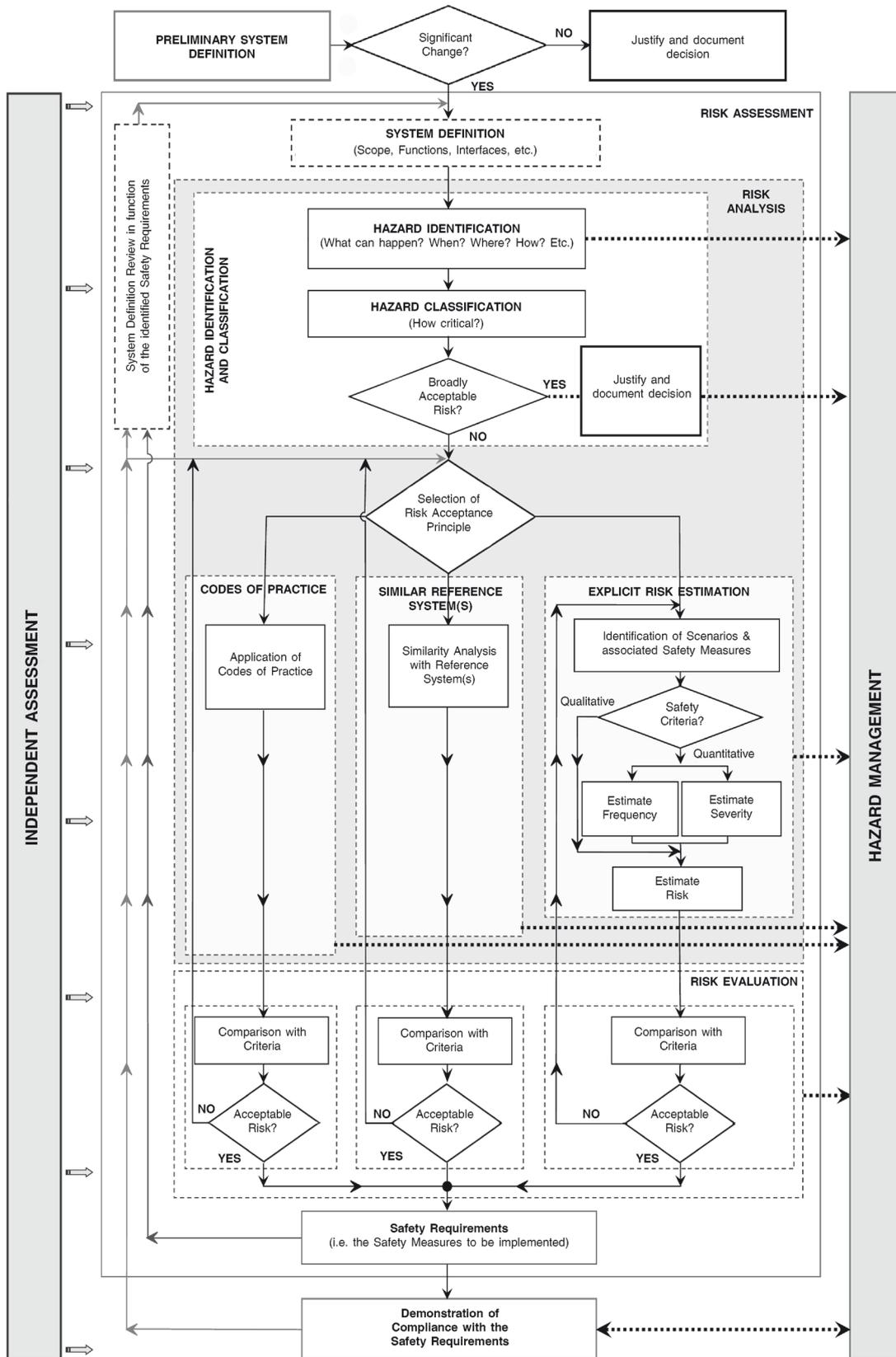
- (a) a description of the organisation and the experts appointed to carry out the risk assessment process;
- (b) results of the different phases of the risk assessment and a list of all the necessary safety requirements to be fulfilled in order to control the risk to an acceptable level;
- (c) evidence of compliance with all the necessary safety requirements;
- (d) all assumptions relevant for system integration, operation or maintenance, which were made during system definition, design and risk assessment.

5.3. The assessment body shall establish its conclusion in a safety assessment report as defined in Annex III.

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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 17020:2012 standard and of its subsequent amendments. The assessment body shall exercise professional judgement in performing the inspection work defined in that standard. The assessment body shall fulfil both the general criteria concerning competence and independence in that standard and the following specific competence criteria:
    - (a) competence in risk management: knowledge and experience of the standard safety analysis techniques and of the relevant standards;
    - (b) all relevant competences for assessing the parts of the railway system affected by the change;
    - (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 within the railway system, or parts of it for which an essential safety requirement exists, including the area of competence involving the 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) organisation, that is 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) methodology, that is evaluation of the methods and resources deployed by various stakeholders to support safety at 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 may be accredited or recognised for one, several or all of the areas of competence listed in points 2 and 3.
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*ANNEX III***SAFETY ASSESSMENT REPORT OF THE ASSESSMENT BODY**

The safety assessment report of the assessment body shall contain at least 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:
    - (i) detailed information on the independent assessment activities for checking the compliance with the provisions of this Regulation;
    - (ii) any identified cases of non-compliances with the provisions of this Regulation and the assessment body's recommendations;
  - (e) the conclusions of the independent assessment.
-