

**COMMISSION DELEGATED REGULATION (EU) No ..../....**

**of**

**on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation and repealing Regulation (EU) 1169/2010**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast)<sup>1</sup>, and in particular Article 6(1) thereof,

Whereas:

- (1) One of the purposes of Directive (EU) 2016/798 is to improve access to the market for rail transport services by defining common principles for the management, regulation and supervision of railway safety. Directive (EU) 2016/798 also requires all infrastructure managers to apply to competent national safety authorities for a safety authorisation.
- (2) Article 6(1)(b) of Directive (EU) 2016/798 provides a framework for authorities issuing single safety certificates and safety authorisations to harmonise their decision-making process and criteria across the European Union, through the application of common safety methods (CSMs). This Regulation sets out a CSM for assessing conformity with the requirements for obtaining a railway safety authorisation.
- (3) The CSMs have been gradually introduced to describe how the safety levels, the achievement of safety targets and compliance with other safety requirements are assessed.
- (4) 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 with the objective of generally maintaining and, where reasonably practicable, continuously improving safety, in accordance with Article 6(5) of Directive (EU) 2016/798.
- (5) On 1 September 2016 the Commission issued a mandate to the European Union Agency for Railways (the ‘Agency’) in accordance with Directive (EU) 2016/798 to revise the common safety method for assessing conformity with the requirements for obtaining railway safety certificates referred to in Commission Regulation (EU) No 1158/2010 of 9 December 2010<sup>2</sup>, the common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation referred to in Commission Regulation (EU) No 1169/2010 of 10 December 2010<sup>3</sup> and the common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation referred to in Commission Regulation (EU) No

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<sup>1</sup> OJ L 138, 26.05.2016, p. 102.

<sup>2</sup> OJ L 326, 10.12.2010, p. 11.

<sup>3</sup> OJ L 327, 11.12.2010, p.13.

1077/2012 of 16 November 2012<sup>4</sup>. This mandate to the Agency is aimed at further harmonising conformity assessment approaches among Member States. The Agency submitted its recommendation on the revision of the CSMS to the Commission, supported by an impact assessment report to address the mandate of the Commission. This Regulation is based on that Agency recommendation.

- (6) In accordance with article 12 of Directive (EU) 2016/798, the safety authorisations issued by the national safety authorities give evidence that the infrastructure managers have established their safety management systems as provided for in Article 9 of Directive (EU) 2016/798 and are capable of complying with the relevant requirements thereof.
- (7) The purpose of the safety management system is to ensure that the railway undertakings and infrastructure managers achieve their business objectives in a safe manner. The safety management system is often integrated with other management systems to increase the overall performance of the organisation and reduce costs while mutualising the efforts at all levels of the organisation. To this end, the common framework of the ISO High Level Structure<sup>5</sup> is used to functionally cluster the requirements of the safety management system, as referred to in Article 9 of Directive (EU) 2016/798. This framework also facilitates the understanding and application of a process approach by the railway undertakings and infrastructure managers when developing, implementing, maintaining and continually improving their safety management system.
- (8) Once issued with a safety authorisation the applicant should continue to use its safety management system as referred to in Article 9 of Directive (EU) 2016/798.
- (9) The human plays a central role in the safe and efficient operation of the railway. Therefore, it is essential that the railway undertakings and infrastructure managers take a systematic approach to supporting human performance and managing human factors within the safety management system.
- (10) The way safety is perceived, valued and prioritised in an organisation reflects the real commitment to safety at all levels in the organisation. Therefore, it is also important for railway undertakings and infrastructure managers to identify the actions and behaviours that can positively shape a safety culture through their safety management system.
- (11) Article 12 of Directive (EU) 2016/798 assigns the role and responsibilities for the safety authorisation to the national safety authorities. In order to facilitate a consistent understanding on how to implement a competence management system and to reinforce the mutual trust between them, a minimum set of uniform competency requirements for staff undertaking conformity assessment activities and a sequence of activities to implement a competence management system are set out in this Regulation.
- (12) The safety management system should take into account the fact that Council Directive 89/391/EC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work<sup>6</sup> and its relevant individual directives are fully applicable to the protection of the health and safety of workers engaged in railway transport. It does not create any additional responsibilities or tasks for the national safety authority other than to check if health and safety risks have been taken into account by the applicant for a safety authorisation. Responsibility for checking the compliance with

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<sup>4</sup> OJ L 320, 17.11.2012, p. 3.

<sup>5</sup> ISO/IEC Directives, Part 1, consolidated supplement 2015, Annex SL Appendix 2.

<sup>6</sup> OJ L 183, 26.06.1989, p.1.

Council Directive 89/391/EC may still be allocated on other competent authorities appointed by the Member State.

- (13) The safety management system should where relevant take into consideration the potential additional risks generated by carrying dangerous goods containments and thereby, should also take account of Council Directive 2008/68/EC of 24 September 2008 on the inland transport of dangerous goods<sup>7</sup>.
- (14) Infrastructure Managers may need to use, within the limit of their activities, trains, infrastructure inspection vehicles, on-track machines or other special vehicles for different purposes, such as the transport of materials and/or staff for construction or infrastructure maintenance, the maintenance of its infrastructure assets or the management of emergency situations. In that case, the infrastructure manager should be deemed to do so in the capacity of a railway undertaking under its safety management system. Therefore, any cross-border agreement, as referred to in Article 10(8) of Directive (EU) 2016/798, could also apply.
- (15) In the case of cross-border infrastructure, as referred to in Article 12(5) of Directive (EU) 2016/798, the relevant national safety authorities should cooperate in order to avoid, as far as reasonably practicable, any duplication of assessment.
- (16) Without prejudice to the responsibilities set out in Article 4(3) of Directive (EU) 2016/798 for the safe operation of trains, infrastructure managers may play different roles within the Union rail system such as providing specific products or services (e.g. the provision of services by training centres recognised in accordance with Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community<sup>8</sup>). Alternatively, these products or services may also be partly or wholly provided by contractors, partners or suppliers.
- (17) In assessing conformity with safety requirements of products or services provided by infrastructure managers or their contractors, partners or suppliers, authorisations, recognitions or certificates granted in accordance with relevant Union law to infrastructure managers or their contractors, partners or suppliers should be considered as valid evidence of compliance with the relevant assessment criteria (or parts of them) defined in this Regulation.
- (18) In the cases provided for in Article 14(4) of Directive (EU) 2016/798, the certification of entities in charge of maintenance and of maintenance workshops as appropriate provide sufficient evidence that infrastructure managers are capable, through their safety management system, to control the risks related to the maintenance of vehicles, including the use of contractors.
- (19) Training centres should be recognised by the competent authority for providing training courses for train drivers and train candidate drivers in accordance with Directive 2007/59/EC. Training centres play an important role to ensure that train drivers are competent for the safety-related tasks assigned to them. In that respect, training centres should be competent in regard to the training they carry out and their recognition by a competent authority should where relevant be taken into account by the national safety authority when carrying out an assessment of the competence management system.
- (20) Commission Regulation (EU) No 1169/2010 has become obsolete and should therefore be replaced by this Regulation.

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<sup>7</sup> OJ L 260, 30.09.2008, p.13.

<sup>8</sup> OJ L 315, 3.12.2007, p. 51.

HAS ADOPTED THIS REGULATION:

*Article 1*

**Subject matter**

This Regulation establishes a common safety method (CSM) for assessing conformity with requirements for obtaining safety authorisations as referred to in Article 6(1)(b) of Directive (EU) 2016/798.

*Article 2*

**Scope**

1. National safety authorities shall use this Regulation in order to assess compliance with the legal obligation in Article 12(1) of Directive (EU) 2016/798 on an infrastructure manager to provide documentary evidence that it has established its safety management system in accordance with Article 9 of Directive (EU) 2016/798 and that it meets the requirements laid down in the relevant national rules notified in accordance with Article 8 of Directive (EU) 2016/798.

2. The applicant for a safety authorisation shall demonstrate compliance with the assessment criteria set out in Annex II in order to provide the documentary evidence referred to in paragraph 1.

3. The assessment of the infrastructure manager's capacity to operate trains, infrastructure inspection vehicles, on-track machines or other special vehicles, including the use of contractors where relevant, shall be part of its assessment for a safety authorisation under Article 12 of Directive (EU) 2016/798. To that end, the national safety authority shall assess conformity with the relevant requirements and assessment criteria set out in this Regulation and Commission Regulation (EU) No ..../.. of .. on a common safety method for assessing conformity with the requirements for obtaining a railway single safety certificate<sup>9</sup>.

*Article 3*

**Definitions**

For the purposes of this Regulation, the following definitions shall apply:

- (a) 'human factors' means all of the people or human performance issues that must be considered to assure the lifelong safety and effectiveness of a system or organisation;
- (b) 'safety culture' means the combination of values, beliefs, vision, purpose, policies, objectives and leadership styles that impact on an organisation's safety. A positive safety culture is characterised by awareness, assessment and action on safety matters in all these areas, and is supported by an open communications style throughout the whole organisation;
- (c) 'human-centred approach' means a philosophy for considering the needs, capabilities and behaviours of people first and then designing to accommodate those needs, capabilities and behaviours;

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<sup>9</sup> OJ: Please insert the number of the revised CSM Regulation on conformity assessment for single safety certificates.

- (d) ‘dangerous goods’ means those substances and articles the carriage of which is prohibited by RID, or authorised only under the conditions prescribed therein;
- (e) ‘RID’ means the Regulations concerning the International Carriage of Dangerous Goods by Rail, as adopted under Directive 2008/68/EC;
- (f) ‘residual concern’ means a minor issue identified during the assessment of an application for a safety authorisation which does not prevent the issue of it and can be used to inform later supervision.
- (g) ‘character’ in relation to an operation means the characterisation of operation by its scope, including infrastructure design and construction, infrastructure maintenance, traffic planning, traffic management and control, and by the use of the railway infrastructure, including conventional and/or high speed lines, transport of passengers and/or goods;
- (h) ‘extent’ in relation to an operation means the extent characterised by the length of railway track and the estimated size of the infrastructure manager in terms of number of employees working in the railway sector.

#### *Article 4*

##### **Safety assessment process**

1. National safety authorities shall apply the process set out in Annex I to this Regulation and the assessment criteria set out in Annex II to this Regulation for assessing new, update or renewal applications for safety authorisations in accordance with Article 12 of Directive (EU) 2016/798.
2. The national safety authority shall coordinate with the applicant, upon its request, before the submission of its application for a safety authorisation in order to help it understand what is expected of it and what it should expect from the national safety authority.
3. Products or services provided by contractors, partners or suppliers to infrastructure managers shall be accepted as proof of the ability of the infrastructure managers to conform to the relevant assessment criteria (or parts of them) specified in Annex II if such products or services are authorised, recognised or certified in accordance with relevant Union law.

#### *Article 5*

##### **Assessment of compliance with relevant notified national rules**

1. The assessment of the elements referred to in Article 12(1) of Directive (EU) 2016/798 shall cover for the relevant network those notified national rules that relate to operational requirements not yet mandated in the Technical Specification for Interoperability relating to the operation and traffic management subsystem or in any other applicable European legislation.
2. In the case of cross-border infrastructure, as referred to in Article 12(5) of Directive (EU) 2016/798, the relevant national safety authorities shall cooperate to ensure that the relevant national rules, as referred to in paragraph 1, notified in their respective Member State, are met before the issuing of the safety authorisation.

#### *Article 6*

##### **Interface with supervision**

1. The national safety authority shall use information gathered during the assessment of the application for safety authorisation for the purposes of its supervision for the duration of that safety authorisation in accordance with Article 17(11) of Directive (EU) 2016/798.

2. In the case of cross-border infrastructure, the national safety authority shall exchange information referred to in paragraph 1 with relevant national safety authority (or authorities), including a description of any residual concern and agreed action to be followed up during supervision activities.

#### *Article 7*

##### **Competence of the persons involved in conformity assessment activities**

1. The national safety authority responsible for conformity assessment shall have a competence management system in place to ensure that the conformity assessment activities are undertaken by competent persons, which shall include:

- (a) The development of competence profiles for each job, position or role;
- (b) The selection and/or recruitment of staff, assessing them against the established competence levels;
- (c) The maintenance of competence by training, development and assessment of staff against the established competence levels.

2. The competence management system shall ensure through its processes (e.g. training, mentoring, shadowing, on-the-job training) that staff involved in conformity assessment demonstrate the appropriate level of competence for the performance of their tasks. The competencies listed below must be held by the individual carrying out the conformity assessment or, in the case of team work, must be shared amongst the team members:

- (a) Knowledge of the relevant regulatory framework as it applies to conformity assessment;
- (b) Knowledge of the functioning of the railway system;
- (c) Appropriate level of critical analysis to enable them to carry out assessment tasks;
- (d) Experience of the assessment of a safety or similar management system in the railway sector or a safety management system in a sector with equivalent operational and technical challenges;
- (e) Relevant non-technical competencies, including but not limited to, problem solving, communication and team working that enable them to carry out their tasks.

3. In cases where during the conformity assessment, the national safety authority undertakes on-site visits, inspections and audits of the infrastructure manager(s), competencies set out in Article 7 of Commission Delegated Regulation (EU) No ..../.. of .. on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation<sup>10</sup> shall apply equally to staff carrying out the on-site visits, inspections and audits.

#### *Article 8*

##### **Repeal**

Commission Regulation (EU) No 1169/2010 is repealed with effect from 16 June 2019.

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

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<sup>10</sup> OJ: Please insert the number of the revised CSM Regulation on supervision.

*Article 9*

**Entry into force**

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 16 June 2019.

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

Done at

*For the Commission*

*The President*

DRAFT

**PROCESS FOR ASSESSING CONFORMITY WITH REQUIREMENTS FOR  
OBTAINING SAFETY AUTHORISATIONS TO BE ISSUED IN ACCORDANCE  
WITH ARTICLE 12 OF DIRECTIVE (EU) 2016/798**

**1. General**

1.1. The national safety authority shall develop a structured and auditable process for the complete activity which takes into account the elements below. This ensures that the process for assessing conformity with the requirements for obtaining a safety authorisation is iterative, as shown in the diagram below (see Figure 1 in the Appendix), where the national safety authority may make reasonable requests for further information or re-submission in accordance with this Regulation.

**2. Receipt of application**

2.1. The national safety authority shall require in its application guidance document, as referred to in Article 12(1) of Directive (EU) 2016/798, that the applicant indicates where in its safety management system documentation each of the CSM assessment criteria, including the requirements of the applicable Technical Specification for Interoperability relating to the operation and traffic management subsystem, and relevant notified national rules are met.

2.2. After receiving the application for a safety authorisation, the national safety authority shall set up the registered file. It shall formally and promptly acknowledge receipt of the application.

2.3. The national safety authority shall assign competent resources to deliver the assessment process.

2.4. Document control shall be exercised through the registered file which shall contain the records made of the inputs and outputs at each stage of the assessment process, including the final decision over issue of safety authorisation and the original safety authorisation.

**3. Initial screen**

3.1. The national safety authority shall undertake promptly on receipt of the application an initial screen to check that:

- (a) the applicant has provided the basic information which is either required by the legislation or needed for it to be processed effectively;
- (b) the safety management system documentation contains sufficient evidence and is structured and internally cross-referenced so that it can be properly assessed against the CSM assessment criteria and relevant notified national rules. The national safety authority shall conduct an initial review of the actual content of the evidence contained in the application to make an initial judgement on the quality, sufficiency and appropriateness of the safety management system;
- (c) the current status of the action plan (or plans) established by the infrastructure manager to resolve any major non-compliance and any other area of concern identified during supervision activities since the previous assessment is included;
- (d) the current status of the action plan (or plans) established by the infrastructure manager to resolve residual concerns from previous assessment is included.

3.2. Following the check referred to in paragraph 3.1, the national safety authority shall decide if there are any areas in which further information is necessary. Where relevant, the national

safety authority shall promptly seek only the information that it deems reasonably necessary to support its assessment.

3.3. The national safety authority shall read a sufficient sample of the application to check that its content is understandable. If it is clearly not, the national safety authority shall decide whether it shall be returned, with a request for an improved version.

3.4. If the application is fundamentally deficient, such that it clearly could not lead to the issue of a safety authorisation without major revision, irrespective of whether the linguistic quality referred to in paragraph 3.3 is satisfactory or not, the national safety authority shall discuss this without delay with the applicant and if the conclusion is confirmed, the national safety authority shall reject the application, stating the reasons in writing, and request the applicant to make a re-submission.

3.5. Where the application has minor deficiencies, but is otherwise of sufficient quality to allow the main assessment to proceed, the national safety authority shall request the necessary further information promptly, including justifications and details of the timescale for the applicant's response. The timeframe for providing supplementary information shall be reasonable, proportionate to the difficulty of providing the information requested and agreed with the applicant as soon as it is informed that its file is not complete. If the applicant does not provide the required information within the given timescale, the national safety authority may decide to extend the timescale for the applicant's response or in the last resort, to reject the application without prior notice.

3.6. Any supplementary information sent as part of the application shall be kept on file and where relevant, shared with whom it may concern within the national safety authority.

#### **4. Detailed assessment**

4.1. After the completion of the initial screen stage, the national safety authority shall proceed to the detailed assessment of the application file (see Figure 2 in the Appendix), using the CSM assessment criteria and relevant notified national rules.

4.2. In undertaking the detailed assessment referred to in paragraph 4.1, in accordance with Article 18(1) of Directive (EU) 2016/798, the national safety authority shall exercise professional judgment, be impartial and proportionate, and provide documented reasons for conclusions reached.

4.3. The national safety authority shall have arrangements in place within their respective organisation to ensure that the assessment is completed in a timely manner and in any case, within a timescale allowing the national safety authority to take its final decision not more than four months following the acknowledgement of the completeness of the application file.

4.4. In the case of cross-border infrastructure, the relevant national safety authorities shall coordinate their assessment to avoid as far as possible duplication of costs and effort and to ensure consistency of decisions to be taken for the rail infrastructure located in their respective Member State.

4.5. The assessment shall determine whether the CSM assessment criteria and relevant notified national rules are complied with and in the case of identified instances of non-compliance, whether further information shall be requested. During the assessment, the national safety authority shall also seek evidence that the CSM assessment criteria and relevant notified national rules have been met from the outputs of the safety management system processes, using sampling methods where appropriate, to ensure that the applicant has understood and can meet the requirements according to the character and extent of the railway operations.

4.6. Any identified instances of non-compliance that are considered major or unacceptable shall be resolved to the satisfaction of the national safety authority and lead to an update of the application file where appropriate before the safety authorisation can be issued. If it is a residual concern only, the matter can be deferred for consideration to supervision and/or actions can be agreed upon with the applicant, based on its proposal for updating the application file. In such a case formal resolution of the issue will take place after the issue of the safety authorisation.

4.7. The national safety authority shall be transparent on how it judges the severity of each identified instance of non-compliance.

4.8. When identifying a point of query or a possible instance of non-compliance, the national safety authority shall be specific and help the applicant understand the level of detail expected in the response. To that end, the national safety authority shall:

- (a) refer accurately to the relevant CSM assessment criteria and notified national rules and help the applicant to understand the identified areas of non-compliance;
- (b) identify the relevant part of related regulations, rules and standards;
- (c) state why the individual CSM assessment criterion or notified national rule, including any related legislation, is not met;
- (d) agree with the applicant on further commitments, documents and any other supporting information to be provided, as required by the level of detail of the CSM assessment criterion or the notified national rule; and
- (e) specify and agree with the applicant on a timeframe for compliance, reasonable and proportionate to the difficulty of providing the information requested.

4.9. If the applicant significantly delays providing the requested information, the national safety authority might need to suspend the assessment (or extend the time in which it reaches a final decision) or in the last resort, reject the application, which could have implications for the operation either starting at a specified date, or continuing after expiry of the existing safety authorisation, if the application is for a renewal.

4.10. The timeframe for the assessment may only be suspended (or extended), upon decision of the national safety authority and with the agreement of the applicant in the following cases:

- (a) major deficiencies or multiple minor deficiencies that, considered collectively, may raise the category to a major deficiency of evidence are identified, such that they prevent the assessment or parts of it to continue, or;
- (b) major non-conformities or multiple minor non-conformities that, considered collectively, may raise the category to a major non-conformity with the CSM assessment criteria and/or relevant notified national rules are found, such that if they were not corrected they would prevent the issuing of the safety authorisation.

4.11. To be satisfactory, the applicant's written responses shall be sufficient to allay the concerns expressed and to demonstrate that its proposed arrangements will meet the relevant criteria or notified national rules.

4.12. Where a response is considered unsatisfactory, it shall be explained precisely why, identifying the further information or demonstration required of the applicant to make it satisfactory.

4.13. If for whatever reason, a final resolution of any issue looks like becoming protracted such that the agreed timeframe for compliance may be exceeded, and deferment of concerns to a later supervision plan is not appropriate, the national safety authority shall promptly discuss it with the applicant. If concerns emerge that the application could be refused, or that it will take

a longer time to reach a final decision than the timeframe allowed for the assessment, the national safety authority may consider possible contingency procedures.

4.14. To aid its assessment, the national safety authority may also decide to undertake on-site audits and inspections. If so, in the case of cross-border infrastructure, the relevant national safety authorities shall coordinate the organisation of such on-site audits and inspections in order to plan efficiently their individual or joint initiatives without causing unnecessary inconvenience to the applicant. The assessment may also be suspended if the applicant is not able to promptly arrange an audit or inspection within its organisation.

4.15. When it is concluded that either the application meets all requirements or that further progress is unlikely in securing satisfactory responses to outstanding matters, the national safety authority shall complete its assessment by:

- (a) stating whether all criteria have been complied with or whether there are still matters outstanding;
- (b) identifying any residual concern not fully resolved during the assessment to be scrutinised during later supervision;
- (c) identifying any limitation or condition of use to be included in the safety authorisation;
- (d) reporting on the follow-up of major non-compliances identified during supervision activities, as referred to in Article 6 of Commission Delegated Regulation (EU) No ...<sup>11</sup>, where appropriate;
- (e) ensuring that the assessment process has been correctly applied; and
- (f) providing the outcome of the assessment, including summary conclusions and an opinion over the issue of the safety authorisation where appropriate.

4.16. The national safety authority shall record and justify in writing all findings and judgments in order to facilitate both the assurance process and the final decision, as well as to assist with any appeal against the final decision.

## **5. Decision-making**

5.1. Based on the conclusions of the completed assessment, a decision shall be made on whether to issue a safety authorisation or to refuse the application. Where a safety authorisation is to be issued, some residual concerns for consideration in later supervision may be identified. A safety authorisation shall not be issued where any major non-compliance with the CSM assessment criteria is identified and not resolved during the assessment.

5.2. Once the decision has been taken and if the decision is to award the safety authorisation, the national safety authority shall prepare a safety authorisation in the standard format set out in Annex III of this Regulation.

5.3. Safety authorisations shall be valid for five years and renewed upon application by the applicant at intervals not exceeding five years.

5.4. The national safety authority may decide to restrict the scope of the safety authorisation, by identifying limitations or conditions of use, if it is concluded in coordination with other relevant national safety authority (or authorities) in the case of cross-border infrastructure that these limitations or conditions of use address any major non-compliance that would prevent the issue of the safety authorisation. The safety authorisation shall be updated on request of the applicant after all residual concerns have been addressed in its application file.

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<sup>11</sup> OJ: Please insert the number of the revised CSM Regulation on supervision.

5.5. The applicant shall be informed about the final decision and a safety authorisation shall be issued as appropriate.

5.6. If the decision is for refusal or contains limitations or conditions of use other than those defined in the application, the national safety authority shall inform the applicant, giving the reasons for the decision, and notify it of the procedure to request for a review of or to appeal against its decision.

5.7. The national safety authority shall inform the Agency of each individual decision to issue, renew, update or revoke safety authorisations in accordance with Article 12(4) of Directive (EU) 2016/798.

## **6. Closing assessment**

6.1. The national safety authority shall complete the administrative closure by ensuring that all documents and records are reviewed, organised and archived. To continually improve its process, the national safety authority shall identify historic information and lessons learned for use by future assessments.

## **7. Specific provisions for the renewal of a safety authorisation**

7.1. A safety authorisation shall be renewed upon the request of the applicant before the expiry of its validity to ensure continuity of authorisation.

7.2. In the case of a renewal application, the national safety authority in cooperation with other relevant national safety authority (or authorities) in the case of cross-border infrastructure shall check details of changes to the evidence submitted in the previous application and consider the results of past supervision activities as referred to in Article 6 of Commission Delegated Regulation (EU) No ...<sup>12</sup> to prioritise or target the relevant CSM assessment criteria and notified national rules upon which to assess the renewal application.

7.3. The national safety authority shall take a proportionate approach to re-assessment, based on the degree of changes proposed. If significant matters of concern are raised during supervision activities, the national safety authority shall decide whether the whole application file needs to be re-assessed.

## **8. Specific provisions for the update of a safety authorisation**

8.1. A safety authorisation shall be updated (or revised) whenever there is a substantial change proposed to the infrastructure, the signalling, any energy supply used in connection with the infrastructure or the principles of operation and maintenance of such infrastructure, signalling or energy supply in accordance with Article 12(2) of Directive (EU) 2016/798.

8.2. Where it proposes to make a substantial change in accordance with paragraph 8.1, the infrastructure manager holding the safety authorisation shall notify the national safety authority without delay.

8.3. Following the notification by the infrastructure manager referred to in paragraph 8.2, the national safety authority shall:

- (a) check firstly that the substantial change(s) relating to any potential application is (are) clearly described; and
- (b) discuss with the infrastructure manager the need for an update of the safety authorisation.

8.4. The national safety authority may need to make further enquiries with the applicant before coming to a conclusion, but if the national safety authority considers the proposed change not

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<sup>12</sup> OJ: Please insert the number of the revised CSM Regulation on supervision.

to be substantial it shall inform the applicant in writing that a revision is not required, keeping a record of the decision for the registered file.

8.5. In the case of an update application, the national safety authority in cooperation with other relevant national safety authority (or authorities) in the case of cross-border infrastructure shall:

- (a) check details of changes to the evidence submitted in the previous application whereby the current safety authorisation was issued;
- (b) consider the results of past supervision activities as referred to in Article 6 of Commission Delegated Regulation (EU) No ..../..<sup>13</sup> (in particular, issues relating to the ability of the applicant to effectively implement and monitor its change management process);
- (c) prioritise or target the relevant CSM assessment criteria and notified national rules in order to assess the update application.

8.6. The national safety authority shall take a proportionate approach to re-assessment, based on the degree of changes proposed. If significant matters of concern are raised during supervision activities, the national safety authority shall decide whether the whole application file needs to be re-assessed.

8.7. An application to update a safety authorisation shall not lead to the extension of its validity period.

8.8. The national safety authority shall decide at the request of the applicant whether the safety authorisation needs to be updated where the conditions under which the safety authorisation was issued are to be changed without any impact on the infrastructure, the signalling, any energy supply used in connection with the infrastructure or the principles of operation and maintenance of such infrastructure, signalling or energy supply.

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<sup>13</sup> OJ: Please insert the number of the revised CSM Regulation on supervision.

Safety assessment process

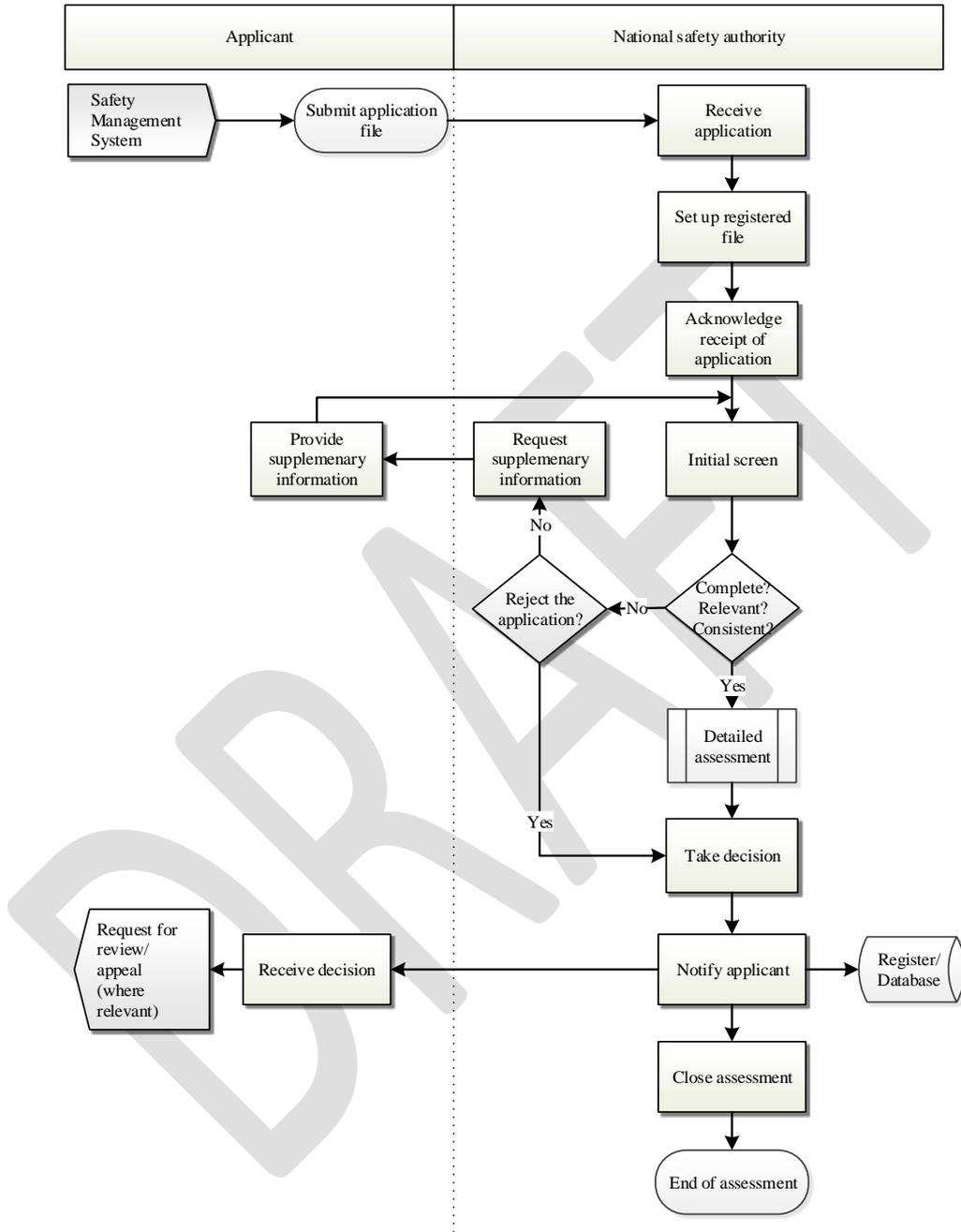


Figure 1: Safety assessment process.

## Detailed assessment process

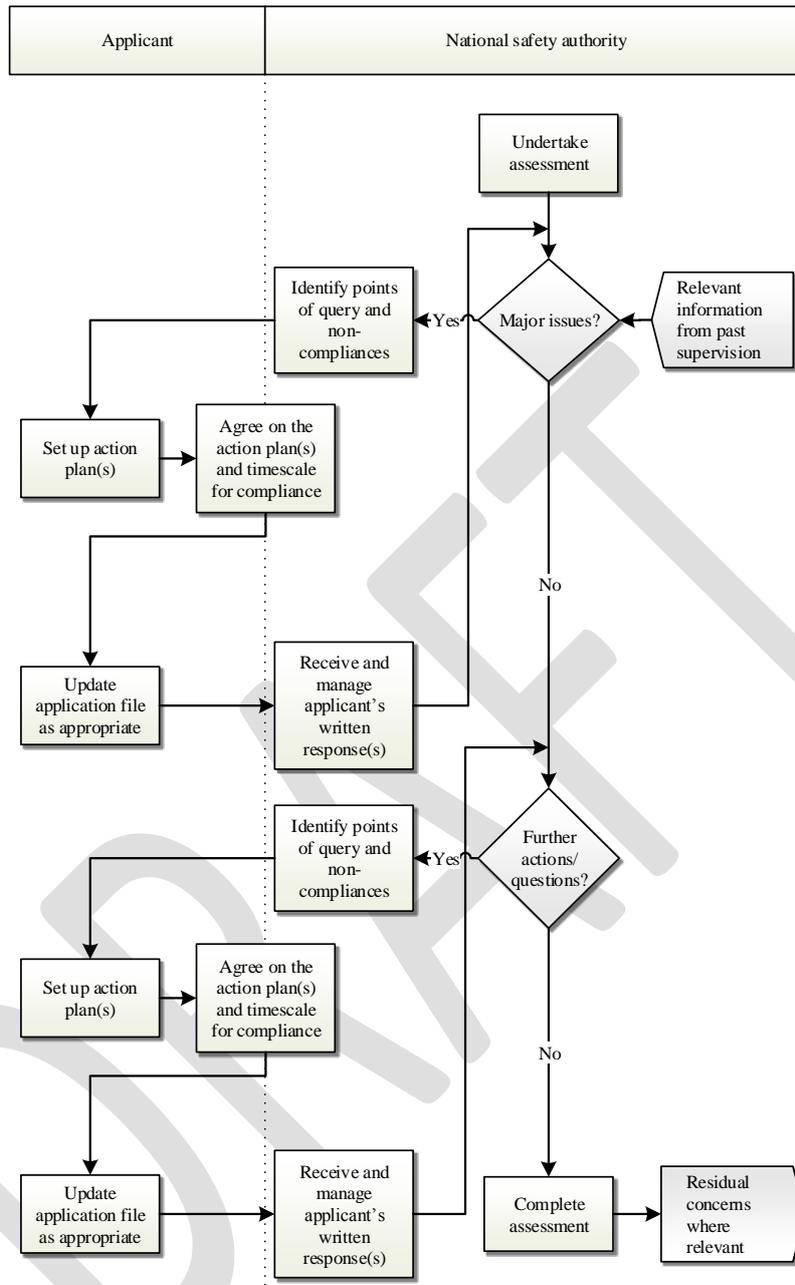


Figure 2: Detailed assessment process

## ANNEX II

### **CRITERIA FOR ASSESSING CONFORMITY WITH THE REQUIREMENTS FOR OBTAINING SAFETY AUTHORISATIONS TO BE ISSUED IN ACCORDANCE WITH ARTICLE 12 OF DIRECTIVE (EU) 2016/798 RELATED TO THE INFRASTRUCTURE MANAGER'S SAFETY MANAGEMENT SYSTEM AS DESCRIBED IN ARTICLE 9 OF THAT DIRECTIVE**

#### *1. CONTEXT OF THE ORGANISATION*

##### 1.1. Organisation, context and scope of the safety management system

###### 1.1.1. The organisation shall:

- (a) describe the character and extent of its operations;
- (b) identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself, or by contractors under its control;
- (c) identify interested parties (e.g. regulatory bodies, authorities, railway undertakings, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;
- (d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);
- (e) ensure that the requirements referred to in point (d) are taken into account in developing, implementing and maintaining the safety management system;
- (f) describe the scope of the safety management system, indicating which part of the business is included or not in its scope and taking into account the requirements referred to in point (d).

##### 1.2. Human factors

###### 1.2.1. The organisation shall demonstrate a systematic approach to integrating and managing human factors within the safety management system. This shall include the use of recognised methods from the field of human factors to address risks associated with the design and use of equipment, tasks and working conditions, taking into account human capabilities as well as limitations, and the influences on human performance.

#### *2. LEADERSHIP*

##### 2.1. Leadership and commitment

###### 2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:

- (a) taking overall accountability and responsibility for safety;
- (b) ensuring commitment to safety by management at different levels within the organisation through their activities and in their relationships with staff and contractors;
- (c) ensuring that the safety policy and safety objectives are established, understood and are compatible with the strategic direction of the organisation;
- (d) ensuring the integration of the safety management system requirements into the organisation's business processes;

- (e) ensuring that the resources needed for the safety management system are available;
- (f) ensuring that the safety management system is effective in controlling the safety risks posed by the organisation;
- (g) encouraging staff to support compliance with the safety management system requirements;
- (h) promoting continual improvement of the safety management system;
- (i) providing a strategy to ensure that human factors knowledge, methods and a human-centred approach are consistently applied;
- (j) ensuring that safety is considered when identifying and managing the organisation's business risks and explaining how conflict between safety and other goals will be recognised and resolved;
- (k) promoting a positive safety culture in which staff (e.g. front line operators) are not punished for actions, omissions or decisions taken by them that are commensurate with their experience and training, but where gross negligence, wilful violations and destructive acts are not tolerated.

## 2.2. Safety policy

2.2.1. A document describing the organisation's safety policy is established by the top management and is:

- (a) appropriate to the organisation's character and extent of railway operations;
- (b) approved by the organisation's chief executive (or a representative(s) of the top-management);
- (c) communicated and made available to all staff.

2.2.2. The safety policy shall:

- (a) include a commitment to conform with all legal and other requirements related to safety;
- (b) include a commitment to establish and evaluate the organisation's safety performance against identified safety objectives;
- (c) include a commitment to continual improvement of the safety management system;
- (d) be maintained in accordance with the business strategy and the evaluation of the safety performance of the organisation.

## 2.3. Organisational roles, responsibilities, accountabilities and authorities

2.3.1. The responsibilities, accountabilities and authorities of staff having a role that affects safety (including management and other staff involved in safety-related tasks) shall be defined, documented, assigned and communicated at all levels within the organisation.

2.3.2. The organisation shall ensure that staff with delegated responsibilities for safety-related tasks shall have the authority, competence and appropriate resources to perform their tasks without being adversely affected by the activities of other business functions.

2.3.3. Delegation of responsibility for safety-related tasks shall be documented and communicated to the relevant staff, accepted and understood.

2.3.4. The organisation shall describe the allocation of roles referred to in paragraph 2.3.1. to business functions within and where relevant, outside the organisation (see 5.3. Contractors, partners and suppliers).

## 2.4. Consultation of staff and other parties

2.4.1. Staff, their representatives and external interested parties, as appropriate and where relevant, shall be consulted in developing, maintaining and improving the safety management system in the relevant parts they are responsible for, including the safety aspects of operational procedures.

2.4.2. The organisation shall facilitate the consultation of staff by providing the methods and means for involving staff, recording staff's opinion and providing feedback on staff's opinion.

## 3. PLANNING

### 3.1. Actions to address risks

#### 3.1.1. Risk assessment

##### 3.1.1.1. The organisation shall:

- (a) identify and analyse all operational (including human performance), organisational and technical risks relevant to the character and extent of operations carried out by the organisation. Operational risks shall include at least those arising from work activities, job design or fatigue and the activities of other interested parties (see 1.1. Organisation, context and scope of the safety management system);
- (b) evaluate the risks referred to in point (a) by applying appropriate risk assessment methods;
- (c) develop and put in place safety measures, with identification of associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);
- (d) develop a system to monitor the effectiveness of safety measures (see 6.1. Monitoring);
- (e) recognise the need to collaborate with other interested parties (such as railway undertakings, infrastructure managers, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on shared risks and the putting in place of adequate safety measures;
- (f) communicate risks to staff and involved external parties (see 4.4. Information and communication).

3.1.1.2. When assessing risk, an organisation shall take into account the need to determine, provide and sustain a safe working environment which conforms to applicable legislation, in particular Council Directive 89/391/EEC.

#### 3.1.2. Planning for change

3.1.2.1. The organisation shall identify potential safety risks and appropriate safety measures (see 3.1.1. Risk assessment) before the implementation of a change (see 5.4. Management of change) in accordance with the risk management process set out in the applicable Common Safety Method as referred to in Article 6(1)(a) of Directive (EU) 2016/798, including consideration of the safety risks from the change process itself.

### 3.2. Safety objectives and planning

3.2.1. The organisation shall establish safety objectives for relevant functions at relevant levels to maintain and, where reasonably practicable, improve its safety performance.

- 3.2.2. The safety objectives shall:
- (a) Be consistent with the safety policy and the organisation's strategic objectives (where applicable);
  - (b) Be linked to the priority risks that influence the safety performance of the organisation;
  - (c) Be measurable;
  - (d) Take into account applicable legal and other requirements;
  - (e) Be reviewed as regards their achievements and revised as appropriate;
  - (f) Be communicated.
- 3.2.3. The organisation shall have plan(s) to describe how it will achieve its safety objectives.
- 3.2.4. The organisation shall describe the strategy and plan(s) used to monitor the achievement of the safety objectives (see 6.1. Monitoring).

#### 4. SUPPORT

##### 4.1. Resources

- 4.1.1. The organisation shall provide the resources, including competent staff and effective and useable equipment, needed for the establishment, implementation, maintenance and continual improvement of the safety management system to ensure the safe operation and maintenance of its railway operations.

##### 4.2. Competence

- 4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:

- (a) identification of the competencies (including knowledge, skills, non-technical behaviours and attitudes) required for safety-related tasks;
  - (b) selection principles (basic educational level, psychological and physical fitness required);
  - (c) initial training, experience and qualification;
  - (d) ongoing training and periodic update of existing competencies;
  - (e) periodic checks of competence, psychological and physical fitness, where appropriate.
- (f) specific training in relevant parts of the safety management system for staff at all levels within the organisation.
- 4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:
- (a) the training programme is delivered according to the identified competency requirements and individual needs of the staff;
  - (b) where applicable, the training ensures that staff can operate under all operating conditions (normal, degraded and emergency);
  - (c) the duration of the training and the frequency of the refresher training are appropriate for the training objectives;

- (d) records are kept for all staff (see 4.5.3. Control of documented information);
  - (e) the training programme is regularly reviewed and audited (see 6.2. Internal auditing) and changes made when necessary (see 5.4. Management of change).
- 4.2.3. Back to work arrangements shall be in place for staff following accidents/incidents or long absences from work, including providing additional training where such a need is identified.
- 4.3. Awareness
- 4.3.1. Top management shall ensure that they and their staff having a role that affects safety are aware of the relevance, importance and consequences of their activities and how they contribute to the correct application and the effectiveness of the safety management system, including the achievement of safety objectives (see 3.2. Safety objectives and planning).
- 4.4. Information and communication
- 4.4.1. The organisation shall define adequate communication channels to ensure that safety-related information is exchanged among the different levels of the organisation and with external interested parties including contractors, partners and suppliers.
- 4.4.2. To ensure that safety-related information reaches those making judgements and decisions, the organisation shall manage the identification, receipt, processing, generation and dissemination of safety-related information.
- 4.4.3. The organisation shall ensure that safety-related information is:
- (a) relevant, complete and understandable for the intended users;
  - (b) valid;
  - (c) accurate;
  - (d) consistent;
  - (e) controlled (see 4.5.3. Control of documented information);
  - (f) communicated before it takes effect;
  - (g) received and understood.
- 4.5. Documented information
- 4.5.1. Safety management system documentation
- 4.5.1.1. There is a description of the safety management system including:
- (a) the identification and description of the processes and activities related to safety of rail operations, including safety-related tasks and associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);
  - (b) the interaction of these processes;
  - (c) the procedures or other documents describing how these processes are implemented;
  - (d) the identification of contractors, partners and suppliers with a description of the type and extent of services delivered;
  - (e) the identification of contractual arrangements and other business agreements, concluded between the organisation and other parties identified under (d),

necessary to control the safety risks of the organisation and those related to the use of contractors;

(f) reference to documented information required by this Regulation.

4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:

- (a) a synthesis of the decisions on the level of significance of the safety-related changes, including an overview of significant changes, in accordance with Article 18(1) of the applicable Common Safety Method as referred to in Article 6(1)(a) of Directive (EU) 2016/798;
- (b) the organisation's safety objectives for the following year(s) and how serious risks for safety influence the setting of these safety objectives;
- (c) the results of internal accident/incident investigation (see Learning from accidents and incidents) and other monitoring activities (see 6.1. Monitoring, 6.2. Internal auditing and 6.3. Management review), in accordance with Article 5(1) of the applicable Common Safety Method for monitoring as referred to in Article 6(1)(c) of Directive (EU) 2016/798;
- (d) details of progress on addressing outstanding recommendations from the national investigation bodies (see 7.1. Learning from accidents and incidents);
- (e) the organisation's safety indicators set out to evaluate the organisation's safety performance (see 6.1. Monitoring);
- (f) where applicable, the conclusions of the annual report of the safety advisor on the activities of the organisation relating to the transport of dangerous goods.

4.5.2. Creating and updating

4.5.2.1. The organisation must ensure that when creating and updating documented information related to the safety management system an adequate format and media are used.

4.5.3. Control of documented information

4.5.3.1. The organisation must control documented information related to the safety management system, in particular its storage, distribution and the control of changes, to ensure its availability, suitability and protection where appropriate.

## 5. OPERATION

5.1. Operational planning and control

5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:

- (a) risk acceptance criteria and safety measures are applied (see 3.1.1. Risk assessment);
- (b) plan(s) to achieve the safety objectives are delivered (see 3.2. Safety objectives and planning);
- (c) information is collected to measure the correct application and effectiveness of the operational arrangements (see 6.1. Monitoring).

5.1.2. The organisation shall ensure that its operational arrangements conform to the safety-related requirements of applicable Technical Specifications for Interoperability and

relevant national rules (see 1.1. Organisation, context and scope of the safety management system).

- 5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:
  - (a) identification of the safe boundaries of transport for traffic planning and control based on the design characteristics of the infrastructure;
  - (b) traffic planning, including timetable and train path allocation;
  - (c) real-time traffic management in normal mode and in degraded modes with the application of traffic restrictions of use and the management of traffic disruptions;
  - (d) setting of conditions for running exceptional consignments.
- 5.1.4. To control the allocation of responsibilities where relevant for the safety of operational activities, the organisation shall identify responsibilities for planning and operating the rail network and define how relevant tasks affecting the safe delivery of all services are allocated to competent staff within the organisation (see 2.3. Organisational roles, responsibilities, accountabilities and authorities) and to other external qualified parties when appropriate (see 5.3. Contractors, partners and suppliers).
- 5.1.5. To control information and communication where relevant for the safety of operational activities (see 4.4. Information and communication), relevant staff (e.g. signallers) shall be informed about specific routing requirements for trains and movements of vehicles including relevant changes which may result in a hazard, temporary or permanent operational restrictions (e.g. due to track maintenance) and conditions for exceptional consignments where these are required.
- 5.1.6. To control competence where relevant for the safety of operational activities (see 4.2. Competence), the organisation shall ensure, in accordance with applicable legislation (see 1.1. Organisation, context and scope of the safety management system), for its staff:
  - (a) compliance with their training and work instructions, and corrective actions are taken where required;
  - (b) specific training in case of anticipated changes affecting the running of operations or their task assignment;
  - (c) adoption of adequate measures following accidents and incidents.
- 5.2. Asset management
  - 5.2.1. The organisation shall manage the safety risks associated with physical assets throughout their lifecycle (see 3.1.1. Risk assessment), from design to disposal, and fulfil the human factors requirements for use.
  - 5.2.2. The organisation shall:
    - (a) ensure that the assets are used for the purpose intended while maintaining their safe operational state and their expected level of performance;
    - (b) manage the assets in normal and degraded operations;
    - (c) detect as soon as reasonably practicable instances of non-compliance with operating requirements before or during the operation of the asset, including the application of restrictions of use as appropriate to ensure a safe operational state of the asset (see 6.1. Monitoring).

- 5.2.3. The organisation shall ensure that its asset management arrangements, where applicable, conform to all essential requirements as set out in the relevant Technical Specifications for Interoperability (see 1.1. Organisation, context and scope of the safety management system).
- 5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:
- (a) the identification of the need for maintenance to keep the infrastructure in a safe operational state, based on the planned and real use of the infrastructure and its design characteristics;
  - (b) the management of the removal of the asset from operation for maintenance, when defects have been identified or when asset condition degrades outside the limits of a safe operational state as referred to in point (a);
  - (c) the management of the return to operation of the asset with eventual restrictions of use after maintenance has been delivered to ensure it is in a safe operational state;
  - (d) the management of calibrated or verified monitoring and measurement equipment.
- 5.2.5. To control information and communication where relevant for the safety of asset management (see 4.4. Information and communication), the organisation shall take into account:
- (a) the exchange of relevant information within the organisation or with external entities responsible for maintenance (See 5.3. Contractors, partners and suppliers), in particular on safety-related malfunctions, accidents, incidents as well as on eventual restrictions of use of the asset;
  - (b) the traceability of all necessary information including the information related to point (a) (see 4.4. Information and communication and 4.5.3. Control of documented information);
  - (c) the establishment and maintenance of records of all assets including the management of the configuration of all changes affecting the safe integrity of the assets (see 5.4. Management of change).
- 5.3. Contractors, partners and suppliers
- 5.3.1. The organisation shall identify and control safety risks arising from outsourced activities, including operations or cooperation with contractors, partners and suppliers.
- 5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation must define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:
- (a) the competence requirements (see 4.2. Competence);
  - (b) the responsibilities for the tasks performed;
  - (c) the achievement of the expected results and safety performance;
  - (d) the obligations relating to the exchange of safety-related information (see 4.4. Information and communication);
  - (e) the traceability of safety-related documents (see 4.5. Documented information).
- 5.3.3. In accordance with the process set out in the applicable Common Safety Method for monitoring as referred to in Article 6(1)(c) of Directive (EU) 2016/798, the organisation must monitor:

- (a) the safety performance and results of all activities and operations of contractors, partners and suppliers to ensure that they comply with the requirements set out in the contract;
  - (b) the awareness of contractors, partners and suppliers of safety risks they entail to the organisation's operations.
- 5.4. Management of change
- 5.4.1. The organisation shall implement and control changes to the safety management system to maintain or improve the safety performance, including the decision points that shall determine the continuation on this course and the review of potential changes to the safety risks (See 3.1.1. Risk Assessment).
- 5.4.2. The organisation shall notify the relevant authority about any substantial change in accordance with Article 12 of Directive (EU) 2016/798 and identify the need to apply for a new authorisation for placing in service/on the market of an asset or for an update of the safety authorisation when required.
- 5.5. Emergency management
- 5.5.1. There are procedures in place to identify the emergency situations and associated measures to be taken to manage them (see 3.1.1. Risk assessment) and to re-establish normal operating conditions in accordance with the applicable Technical Specification for Interoperability relating to the operation and traffic management subsystem.
- 5.5.2. There are procedures in place to ensure that, for each identified type of emergency:
- (a) the emergency services can be promptly contacted;
  - (b) the emergency services are provided with all relevant information both in advance, to prepare their emergency response, and at the time of an emergency;
  - (c) first aid is provided internally.
- 5.5.3. The roles and responsibilities of all parties are identified and documented in accordance with the applicable Technical Specification for Interoperability relating to the operation and traffic management subsystem.
- 5.5.4. Plans for action, alerts and information in case of emergency exist and include arrangements to:
- (a) alert all staff with responsibility for emergency management;
  - (b) communicate information to all parties (e.g. railway undertakings, contractors, authorities, emergency services), including emergency instructions for passengers;
  - (c) take any decisions required in accordance with the type of emergency.
- 5.5.5. The organisation shall describe how resources and means for emergency management have been allocated (see 4.1. Resources) and how training requirements have been identified (see 4.2. Competence).
- 5.5.6. The emergency arrangements are regularly tested in cooperation with other interested parties and updated when appropriate.
- 5.5.7. The organisation shall coordinate emergency plans with all railway undertakings that operate on the organisation's infrastructure, with the emergency services, so as to facilitate their rapid intervention, and with any other party that could be involved in an emergency situation.

- 5.5.8. There are arrangements in place to halt operations and railway traffic promptly, if necessary, and to inform all interested parties of the action taken.
- 5.5.9. For cross-border infrastructure, the cooperation between the relevant infrastructure managers shall facilitate the necessary coordination and preparedness of the competent emergency services on both sides of the border.

## 6. PERFORMANCE EVALUATION

### 6.1. Monitoring

- 6.1.1. The organisation shall perform monitoring in accordance with the applicable Common Safety Method for monitoring as referred to in Article 6(1)(c) of Directive (EU) 2016/798:
- (a) to check the correct application and the effectiveness of all the processes and procedures in the safety management system, including the operational, organisational and technical safety measures;
  - (b) to check the correct application of the safety management system as a whole, and if it achieves the expected outcomes;
  - (c) to investigate whether the safety management system conforms to the requirements in this Regulation;
  - (d) to identify, implement and evaluate the effectiveness of the corrective measures (see 7.2. Continual improvement), as appropriate, if any relevant instance of non-compliance to points (a), (b) and (c) is detected.
- 6.1.2. The organisation shall regularly monitor at all levels within the organisation the performance of safety-related tasks and intervene if these tasks are not being properly performed.

### 6.2. Internal auditing

- 6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:
- (a) A schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance;
  - (b) The identification and selection of competent auditors (see 4.2. Competence);
  - (c) The analysis and evaluation of the results of the audits;
  - (d) The identification of the need for corrective or improvement measures;
  - (e) The verification of the completion and effectiveness of these measures;
  - (f) The documentation pertaining to the execution and results of audits;
  - (g) The communication of the results of audits to the top management.

### 6.3. Management review

- 6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:
- (a) details of progress on addressing outstanding actions from previous management reviews;
  - (b) changing internal and external circumstances (see 1.1. Organisation, context and scope of the safety management system);

- (c) the organisation's safety performance related to:
    - (i.) the achievement of its safety objectives;
    - (ii.) the results from its monitoring activities, including the internal audit findings, and internal accident/incident investigations and status of their respective actions;
    - (iii.) the relevant outputs from supervisory activities conducted by the national safety authority;
  - (d) recommendations for improvement.
- 6.3.2. Based on the outputs of its management review, the top management shall take overall responsibility for the planning and implementation of needed changes to the safety management system.

## *7. IMPROVEMENT*

### 7.1. Learning from accidents and incidents

#### 7.1.1. Accidents and incidents related to the organisation's railway operations shall be:

- (a) reported, logged, investigated and analysed to determine their causes;
- (b) reported to national bodies as appropriate.

#### 7.1.2. The organisation shall ensure that:

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

#### 7.1.3. The organisation shall use information relating to the investigation to review the risk analysis and evaluation (see 3.1.1. Risk assessment), to learn and, where required, to adopt corrective measures (see 5.4. Management of change).

### 7.2. Continual improvement

#### 7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in the applicable Common Safety Method for monitoring as referred to in Article 6(1)(c) of Directive (EU) 2016/798 and at least the outputs of the following activities:

- (a) Monitoring (see 6.1. Monitoring);
- (b) Internal auditing (see 6.2. Internal auditing);
- (c) Management review (see 6.3. Management review);
- (d) Learning from accidents and incidents (see 7.1. Learning from accidents and incidents).

#### 7.2.2. The organisation shall provide means to motivating staff and other interested parties to be active in improving safety as part of its organisational learning.



## SAFETY AUTHORISATION

Safety Authorisation confirming acceptance of the safety management system within the European Union in conformity with Directive (EU) 2016/798 and applicable national legislation

**EU IDENTIFICATION NUMBER:** \_\_\_\_\_

### 1. AUTHORISED INFRASTRUCTURE MANAGER

Legal denomination:	
Infrastructure manager name:	Acronym:
National registration number:	VAT No:

### 2. AUTHORITY ISSUING AUTHORISATION

Organisation:
Country:

### 3. AUTHORISATION INFORMATION

This is a	- new authorisation <input type="checkbox"/>	EU Identification Number of the previous authorisation: _____
	- renewed authorisation <input type="checkbox"/>	
	- updated authorisation <input type="checkbox"/>	
Validity from: _____		to: _____
Particulars of Infrastructure(s): _____		

### 4. APPLICABLE NATIONAL LEGISLATION

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### 5. LIMITATIONS AND CONDITIONS OF USE

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**6. ADDITIONAL INFORMATION**

Date issued

Internal reference number

Signature and/or  
stamp

DRAFT