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

of

on a common safety method for assessing conformity with the requirements for obtaining a railway single safety certificate

(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)[[1]](#footnote-1), 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 provides equal treatment for all railway undertakings by applying the single safety certification requirements throughout the European Union.

(2) Article 6(1)(b) of Directive (EU) 2016/798 provides a framework for authorities issuing single safety certificates or safety authorisations to harmonise their decision-making process and criteria across the European Union, through the application of common safety methods (CSMs).

(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[[2]](#footnote-2), 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[[3]](#footnote-3) 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 1077/2012 of 16 November 2012[[4]](#footnote-4). 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 10 of Directive (EU) 2016/798, the single safety certificates issued by the Agency or by the national safety authorities (NSAs) as appropriate, give evidence that the railway undertakings have established their safety management system as provided for in Article 9 of Directive (EU) 2016/798 and are capable to comply 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[[5]](#footnote-5) 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 single safety certificate the applicant shall 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) In assessing conformity with safety requirements of products or services provided by contractors or suppliers of railway undertakings, such as 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[[6]](#footnote-6), authorisations or certificates granted in accordance with relevant Union law to contractors or suppliers may be considered valid evidence. Certification of entities in charge of maintenance in accordance with Article 14(4) of Directive (EU) 2016/798 may also be regarded valid evidence.

(12) Commission Regulation (EC) No 653/2007 of 13 June 2007 on the use of a common European format for safety certificates and application documents in accordance with Article 10 of Directive 2004/49/EC of the European Parliament and of the Council and on the validity of safety certificates delivered under Directive 2001/14/EC[[7]](#footnote-7) provides standard format for safety certificates. Annex I to Regulation (EC) No 653/2207 is replaced by Annex VI 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 and amending Regulation (EC) No 653/2007[[8]](#footnote-8). Article 10 of Directive (EU) 2016/798 sets out a new safety certification regime for the issuing of single safety certificates. In addition, certificates issued to entities in charge of maintenance in accordance with Regulation (EU) No 445/2011 and single safety certificates issued to railway undertakings being also entities in charge of maintenance for their own vehicles should be managed independently in order to avoid additional burdens and costs resulting from their renewal, update or revocation. Annex I and Annex II of Regulation (EC) No 653/2007 and Annex IV of Regulation (EU) No 445/2011 should therefore be repealed by this Regulation. A new format of single safety certificates is included in this Regulation.

(13) Article 10 of Directive (EU) 2016/798 assigns the role and responsibilities for the safety certification either to the Agency in accordance with Article 10(5) of Directive (EU) 2016/798 or to a NSA in accordance with Article 10(8) of Directive (EU) 2016/798. In order to facilitate a consistent understanding amongst these bodies 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.

(14) 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[[9]](#footnote-9) and its relevant individual directives are fully applicable to the protection of the health and safety of workers engaged in railway transport.

(15) The safety management system should duly 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[[10]](#footnote-10).

(16) Training centres shall be recognised by the competent authority for providing training courses for train drivers and train candidate drivers 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[[11]](#footnote-11). When the railway undertaking exclusively provides training to staff of the company it belongs to, the recognition of the training centres can be managed in combination of the safety assessment process. In this case, the statement of recognition can be displayed on the relevant single safety certificate.

(17) Commission Regulation (EU) No 1158/2010 has become obsolete and should therefore be replaced by this Regulation.

HAS ADOPTED THIS REGULATION:

Article 1

**Subject-matter**

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

Article 2

**Scope**

1. Safety certification bodies shall use this Regulation in order to assess compliance with the legal obligation in Article 10(3) of Directive (EU) 2016/798 on a railway undertaking to provide documentary evidence that it has established its safety management system in accordance with Article 9 of Directive (EU) 2016/798 and, in collaboration with relevant NSA(s) as appropriate, that it meets the requirements laid down in the relevant national rules notified in accordance with Article 8 of Directive (EU) 2016/798.

2. Pursuant to Article 9(1) of Directive (EU) 2016/798, the applicant for a single safety certificate shall demonstrate compliance with the assessment criteria set out in Annex II in order to provide the documentary evidence referred to in paragraph 1.

Article 3

**Definitions**

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

1. ‘safety certification body’ means the body responsible for the issuing of single safety certificates, either the Agency in accordance with Article 10(5) of Directive (EU) 2016/798 or a NSA in accordance with Article 10(8) of Directive (EU) 2016/798;
2. ‘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;
3. ‘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;
4. ‘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;
5. ‘dangerous goods’ means those substances and articles the carriage of which is prohibited by RID, or authorised only under the conditions prescribed therein.
6. ‘RID’ means the Regulations concerning the International Carriage of Dangerous Goods by Rail, as adopted under Directive 2008/68/EC.

Article 4

**Process for assessing applications**

1. When examining applications for a single safety certificate submitted after the entry into force of this Regulation, the safety certification body in collaboration with relevant NSA(s) as appropriate 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 single safety certificates in accordance with Article 10 of Directive (EU) 2016/798.

2. The safety certification body and relevant NSA(s) as appropriate shall coordinate with the applicant, upon its request, before the submission of its application for a single safety certificate in order to help it understand what is expected of it and what it should expect from the safety certification body and relevant NSA(s) as appropriate.

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

Article 5

**Assessment of relevant notified national rules**

1. The assessment of the elements referred to in Article 10(3)(b) of Directive (EU) 2016/798 shall cover for the intended area of operation 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 case of cross-border operations without an extension of the area of operation of the single safety certificate, as referred to in Article 10(8) of Directive (EU) 2016/798, the relevant NSAs 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 single safety certificate.

Article 6

**Interface with supervision**

1. The safety certification body shall exchange information gathered during the assessment of the application for a single safety certificate with the relevant NSA(s) for the purposes of its (their) continuous supervision in accordance with Article 17(11) of Directive (EU) 2016/798.

2. The information referred to in paragraph 1 shall include a description of any minor non-compliances or residual concerns and agreed actions to be followed up during supervision activities.

Article 7

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

1. The safety certification body 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 a team assessment, must be shared amongst the team members:

1. Knowledge of the relevant regulatory framework as it applies to conformity assessment;
2. Knowledge of the functioning of the railway system;
3. Appropriate level of critical analysis to enable them to carry out assessment tasks;
4. 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;
5. 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 safety certification body or the relevant NSA(s) as appropriate undertakes on-site visits, inspections and audits of the railway undertakings, as referred to in Article 10(5) of Directive (EU) 2016/798, 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[[12]](#footnote-12) shall apply equally to staff carrying out the on-site visits, inspections and audits.

Article 8

**Repeal**

Commission Regulation (EU) No 1158/2010 is repealed with effect from 16 June 2019 in respect of areas of operation in the Member States that have not notified the Agency or the Commission in accordance with Article 33(2) of Directive (EU) 2016/798. It is fully repealed with effect from 16 June 2020.

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

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 in respect of areas of operation in the Member States that have not notified the Agency or the Commission in accordance with Article 33(2) of Directive (EU) 2016/798. It shall fully apply from 16 June 2020.

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

Done at

*For the Commission*

*The President*

*ANNEX I*

Process for assessing conformity with requirements for obtaining safety certificates to be issued in accordance with Article 10 of Directive (EU) 2016/798

1. **General**

1.1. The process for assessing conformity with the requirements for obtaining a single safety certificate is iterative, as shown in the diagram below (see Figure 1 in the Appendix), where the safety certification body and as appropriate relevant NSA(s) may make reasonable requests for further information or re-submission in accordance with this Regulation.

2. **Receipt of application**

2.1. The safety certification body and as appropriate relevant NSA(s) shall require in their respective application guidance document that the applicant indicates where in its application file each of the CSM assessment criteria are met.

2.2. After receiving the application dossier, the safety certification body shall formally acknowledge receipt of the application.

2.3. During the receipt of application stage, the safety certification body and as appropriate relevant NSA(s) shall assign competent resource to deliver the assessment process.

3. **Initial screen**

3.1. In accordance with the one month timescale, as referred to in Article 10(6) or where applicable in Article 10(8) of Directive (EU) 2016/798, for making an initial response to the applicant, the safety certification body in coordination with relevant NSA(s) as appropriate 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 application file 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 in accordance with Article 5 of this Regulation. The safety certification body in coordination with relevant NSA(s) as appropriate 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.

3.2. The relevant NSA(s) shall also check that the evidence for the type, extent and intended area of operation is clearly identified.

3.3. Following the checks referred to in paragraph 3.1 and paragraph 3.2, the safety certification body and as appropriate relevant NSA(s) shall decide if there are any areas in which, for their respective part, further information is necessary. Where relevant, the safety certification body and as appropriate relevant NSA(s) shall promptly seek only the information that they deem reasonably necessary to support their assessment.

3.4. The different parts of the application shall be submitted in the language(s) permitted by the safety certification body and as appropriate relevant NSA(s) in accordance with their respective language policy. The safety certification body and as appropriate relevant NSA(s) shall read a sufficient sample of the application, each for their own part, to check that the language is understandable. If it is clearly not, the safety certification body and the relevant NSA(s) shall decide, each for their own part, whether it should be returned, with a request for an improved version.

3.5. If the application is fundamentally deficient, such that it clearly could not lead to the issue of a single safety certificate without major revision, irrespective of whether the linguistic quality referred to in paragraph 3.4 is satisfactory or not, the safety certification body and as appropriate relevant NSA(s) shall discuss this without delay and if the conclusion is confirmed, the safety certification body shall reject the application, stating the reasons in writing, and request the applicant to make a re-submission.

3.6. Where the application has minor deficiencies, but is otherwise of sufficient quality to allow the main assessment to proceed, the safety certification body in coordination with the relevant NSA(s) as appropriate shall request the necessary further information promptly, including details of the timescale for the applicant’s response. If the applicant does not provide the required information within the given timescale, the safety certification body may decide to extend the timescale for the applicant’s response or to reject the application without prior notice.

3.7. 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 safety certification body and as appropriate relevant NSA(s).

4. **Assessment**

4.1. After the completion of the initial screen stage, the safety certification body and as appropriate relevant NSA(s) shall proceed, each for their own part, to the detailed assessment of the application file (see Figure 2 in the Appendix), using the CSM assessment criteria and relevant notified national rules in accordance with Article 5 of this Regulation.

4.2. In undertaking this, the safety certification body and as appropriate relevant NSA(s) shall exercise professional judgment, be impartial and proportionate, and provide documented reasons for conclusions reached.

4.3. The safety certification body and as appropriate relevant NSA(s) 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 safety certification body to take its final decision not more than four months following receipt of the complete application file.

4.4. The assessment shall determine whether the CSM assessment criteria and relevant notified national rules are complied with and in the case of instances of identified non-compliance, whether further information shall be requested. During the assessment, the safety certification body and as appropriate relevant NSA(s) shall also seek evidence of fulfilment of the CSM assessment criteria and relevant notified national rules 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 type and extent of the railway operations and the intended area of operation.

4.5. Any identified instances of non-compliance that are considered major or unacceptable shall be resolved and lead to an update of the application file where appropriate before the single safety certificate can be issued. If it is a minor concern only, the matter can be deferred for resolution 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 single safety certificate.

4.6. The safety certification body and as appropriate relevant NSA(s) shall be transparent on how they judge the severity of each identified instance of non-compliance.

4.7. When identifying a point of query or a possible instance of non-compliance, the safety certification body and as appropriate relevant NSA(s) shall be specific and help the applicant understand the level of detail expected in the response. To do this it shall:

(a) refer accurately to the relevant CSM assessment criteria and notified national rules and ensure that the applicant has understood clearly 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 specify a timeframe for compliance proportionate to the difficulty of providing the information requested.

4.8. If the applicant delays significantly providing the requested information, the safety certification body and as appropriate relevant NSA(s) might need to suspend the assessment (or extend the time in which it reaches a decision) or reject the application, which could have implications for the operation either starting at a specified date, or continuing after expiry of the existing single safety certificate, if the application is for a renewal.

4.9. If the applicant agrees, the timeframe for the assessment may only be suspended (or extended) upon decision of the safety certification body in coordination with relevant NSA(s) as appropriate in the following cases:

(a) major deficiencies of evidence are identified, such that they prevent the assessment or parts of it to continue, or;

(b) major non-conformities 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 single safety certificate.

4.10. 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.

4.11. 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. Where there are significant inadequacies in the responses, the safety certification body and/or as appropriate relevant NSA(s) shall raise this as soon as possible with the applicant, if necessary arranging to meet them again or undertaking an inspection or audit of the relevant part(s) of its application.

4.12. If for whatever reason, a final resolution of any issue looks like becoming protracted such that the time limit may be exceeded, and deferment of concerns to a later supervision plan is not appropriate, the safety certification body shall promptly discuss it together with the relevant NSA(s) as appropriate. If concerns emerge that the application could be refused, or that it will take a longer time to reach a decision than the timeframe allowed for the assessment, the safety certification body may consider possible contingency procedures.

4.13. To aid its assessment, the safety certification body and/or as appropriate relevant NSA(s) may also decide to undertake on-site audits and inspections. If so, the safety certification body and as appropriate relevant NSA(s) 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.

4.14. When it is concluded that either the application meets all requirements or that no further progress is likely with securing satisfactory responses to outstanding matters, the safety certification body and relevant NSA(s) as appropriate shall complete their assessment by:

(a) stating whether all criteria have been complied with or whether there are still matters outstanding;

(b) identifying any minor non-compliances or residual concerns not fully resolved during the assessment to be scrutinised during later supervision;

(c) reporting on the follow-up of major non-compliances identified during supervision activities, as referred to in Article 6(2) of Commission Delegated Regulation (EU) No ../.., where appropriate;

(d) conducting an independent (i.e. by someone not involved in the assessment) quality assurance process to ensure that the assessment process has been correctly applied and to monitor the quality of its (their) own performance at key stages in the processing of the application; and

(e) making a recommendation for the issuing (or not) of the single safety certificate, each for their respective part of the assessment as appropriate.

4.15. The safety certification body and as appropriate relevant NSA(s) 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 single safety certificate or to refuse the application. Where a single safety certificate is to be issued, some minor non-compliances or residual concerns for consideration in later supervision may be identified. A single safety certificate shall not be issued where serious 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 single safety certificate, the safety certification body shall prepare a single safety certificate in the standard format set out in Annex III of this Regulation.

5.3. The safety certification body may decide to restrict the scope of the single safety certificate, by identifying specific limitations or conditions of use, if it is concluded in coordination with relevant NSA(s) as appropriate that these limitations or conditions of use address any residual concerns that would prevent the issue of the single safety certificate. The single safety certificate shall be updated on request of the applicant after all residual concerns have been addressed in its application file.

5.4. The applicant shall be informed about the final decision and a single safety certificate shall be issued as appropriate.

5.5. If the decision is for refusal or contains limitations or conditions of use other than those defined in the application, the safety certification body shall inform the applicant, giving the reasons for the decision, and notify it of the procedure to appeal against its decision.

5.6. If a NSA identifies a serious risk for safety during its supervision and decides to take enforcement action in accordance with Article 17(6) of Directive (EU) 2016/798, it should (where it is not also the safety certification body) consult with the Agency as to what implications the proposed action may have for the single safety certificate and whether there is a case for restricting or revoking it. In such cases the NSA shall provide to the safety certification body the evidence supporting its decision. The safety certification body shall decide whether or not the single safety certificate needs updating with restrictions or is to be revoked.

5.7. The safety certification body (if not the Agency) shall notify the Agency, as the system authority for registers and databases of each individual decision to issue, renew, update or revoke single safety certificates in accordance with Article 10(16) of Directive (EU) 2016/798 and Articles 12 and 37(6) of Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004[[13]](#footnote-13).

6. **Closing assessment**

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

7. **Specific provisions for the renewal of a single safety certificate**

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

7.2. In the case of a renewal application, the safety certification body and relevant NSA(s) as appropriate 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 Regulation (EU) No ../.. to prioritise or target the relevant CSM assessment criteria and notified national rules upon which to assess the renewal application.

7.3. The safety certification body and as appropriate relevant NSA(s) 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 safety certification body and as appropriate relevant NSA(s) shall decide whether the whole application file needs to be re-assessed.

8. **Specific provisions for the update of a single safety certificate**

8.1. A single safety certificate shall be updated whenever there is a substantial change proposed to the type or extent of operation in accordance with Article 10(13) of Directive (EU) 2016/798, or in case of extension of the area of operation in accordance with Article 10(14) of Directive (EU) 2016/798.

8.2. Where it proposes to make a substantial change in accordance with paragraph 8.1, the railway undertaking holding the single safety certificate shall notify the safety certification body without delay.

8.3. Following a notification by the railway undertaking as referred to in paragraph 8.2, the safety certification body shall:

(a) check that the substantial change(s) relating to any potential application is (are) clearly described; and

(b) discuss with the railway undertaking and the relevant NSA(s) as appropriate the need for an update of the single safety certificate.

8.4. The safety certification body in coordination with the relevant NSA(s) as appropriate may need to make further enquiries with the applicant before coming to a conclusion, but if the safety certification body considers the proposed change not to be substantial it shall inform the applicant in writing that an update is not required, keeping a record of the decision for the registered file.

8.5. In the case of an update application, the safety certification body and relevant NSA(s) as appropriate shall:

(a) check details of changes to the evidence submitted in the previous application whereby the current certificate was issued;

(b) consider the results of past supervision activities as referred to in Article 6 of Regulation (EU) No ../.. (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 safety certification body and as appropriate relevant NSA(s) 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 safety certification body and as appropriate relevant NSA(s) shall decide whether the whole application file needs to be re-assessed.

8.7. An application to the safety certification body to update a single safety certificate shall not lead to the extension of its validity period.

*Appendix*

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 certificates to be issued in accordance with Article 10 of Directive (EU) 2016/798 related to the railway undertaking’s safety management system as described in Article 9 of that Directive.

1. CONTEXT OF THE ORGANISATION

1.1. The organisation shall:

(a) describe the type, extent and area of its operations;

(b) identify the serious risks for safety posed by its railway operations;

(c) identify interested parties (e.g. regulatory bodies, authorities, 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. The safety management system shall demonstrate a systematic approach to integrating and managing human factors and use 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) ensuring that the safety policy and safety objectives are established, understood and are compatible with the strategic direction of the organisation;

(b) ensuring the integration of the safety management system requirements into the organisation’s business processes;

(c) ensuring that the resources needed for the safety management system are available;

(d) ensuring that the safety management system is effective in controlling the safety risks posed by the organisation;

(e) encouraging staff to support compliance with the safety management system requirements;

(f) promoting continual improvement of the safety management system;

(g) providing a strategy to ensure that human factors knowledge, methods and a human centred approach are consistently applied;

(h) ensuring that safety is considered when identifying and managing the organisation’s business risks;

(i) promoting a positive safety culture in which front line operators or others 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 type 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) provide a framework for setting 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 and authorities

2.3.1. Top management shall ensure that the responsibilities and authorities are described, assigned and communicated to those having a role within the safety management system.

2.3.2. Safety-related tasks are described based on the organisation’s activities (see 1. Context of the organisation) and assigned to competent staff (see 4.2. Competence).

2.3.3. The organisation shall ensure that those having a role within the safety management system are held responsible for their performance.

2.3.4. 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.

2.3.5. Delegation of responsibility for safety-related tasks must be communicated to the relevant staff and formally accepted.

2.3.6. There is a description of the structure of the organisation (see 4.5.1. Safety management system documentation), including the allocation of relevant roles within the safety management system to positions and functions within the organisation.

2.4. Involvement 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 have risk assessment procedures for:

(a) identifying and analysing all operational (including human performance), organisational and technical risks relevant to the type, extent and area of operations carried out by the organisation. Operational risks shall include at least those arising from work activities, job design or workload and the activities of other interested parties (see 1. Context of the organisation);

(b) evaluating the risks referred to in point (a) in accordance with appropriate risk assessment methods set out in the applicable Common Safety Method as referred to in Article 6(1)(a) of Directive (EU) 2016/798;

(c) developing and putting in place safety measures, with identification of associated responsibilities (see 2.3. Organisational roles, responsibilities and authorities);

(d) developing a system to monitor the effectiveness of safety measures (see 6.1. Monitoring);

(e) recognising 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) communicating 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 an appropriate 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 control measures (see 3.1.1. Risk assessment) before the implementation of a change (see 5.4. Management of change), 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 at relevant functions and 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 within the safety management system are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities 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 safety management system training for staff directly involved in ensuring that the safety management system works.

4.2.2. The organisation shall provide a training programme, as referred to in points 1(c), 1(d) and 1(f), 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 and complementary to internal training, the recognised training centre(s) delivers the training in accordance with the competence requirements;

(c) where applicable, the training ensures that staff can operate under all operating conditions (normal, degraded and emergency);

(d) the identification of the duration of the training and the frequency of the refresher training;

(e) records are kept for all staff;

(f) 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 staff having a role within the safety management system 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 safety management processes and related activities;

(b) the interaction of these processes;

(c) the descriptions and/or procedures that implement these safety management processes;

(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) an overview of the changes that have an impact on the safety management system, including the decisions on the level of significance of these 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 (see 3.2. Safety objectives and planning);

(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 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. Context of the organisation).

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) planning of existing or new train routes and new train services, including the introduction of new types of vehicles, the need to lease vehicles and/or to hire staff from external parties and the exchange of information on the maintenance for operational purposes with entities in charge of maintenance;

(b) fatigue risk management;

(c) development and implementation of train timetables;

(d) preparation of trains or vehicles before movement, including pre-departure checks and train composition;

(e) running trains or movement of vehicles in the different operating conditions (normal, degraded and emergency);

(f) adaptation of the operation to requests for removal from operation and notification of return to operation issued by entities in charge of maintenance;

(g) authorisations for movements of vehicles.

5.1.4. To control the allocation of responsibilities where relevant for the safety of operational activities, the organisation shall identify responsibilities for coordinating and managing the safe running of trains and movements of vehicles 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 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. train crews) shall be advised of the details of any specified conditions of travel, including relevant changes which may result in a hazard, temporary or permanent operational restrictions (e.g. due to specific type of vehicles or to specific routes) and conditions for exceptional transport/consignment, 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. Context of the organisation), for staff undertaking safety-related tasks:

(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, in accordance with Article 14(2) of Directive (EU) 2016/798 where relevant, 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 related to safety as set out in the relevant Technical Specifications for Interoperability (see 1. Context of the organisation).

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 asset in a safe operational state, based on the planned and real use of the asset 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);

(d) 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.

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 and operations of or cooperation through contractual arrangements with contractors, partners and suppliers.

5.3.2. To control the safety risks referred to in point 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 tasks responsibilities and quality of the expected results;

(c) the obligations relating to the exchange of safety-related information (see 4.4. Information and communication);

(d) 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 20016/../EU, 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:

(a) Identify the need to notify the relevant authority about the change and to apply for a new authorisation for placing on the market of a vehicle or for an update of the single safety certificate when required;

(b) Notify the relevant national safety authority (or authorities) before starting any new rail transport operation, including a breakdown of the categories of staff and the types of vehicles (see 4.4. Information and communication) and the use of contractors, partners and suppliers as appropriate (see 5.3. Contractors, partners and suppliers).

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 Specifications 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.

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 exist and include:

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

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

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

5.5.5. The organisation shall describe how resources and means 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. There are procedures to ensure that competent staff in charge, with adequate language skills, can be contacted easily and without delay by the infrastructure manager and provide the latter with the right level of information.

5.5.8. There is a procedure to contact the entity in charge of maintenance or the railway vehicle keeper in the event of an emergency.

5.5.9. Following a serious accident, the railway undertaking shall provide guidance to victims helping them in complaints procedures under Union legislation, in particular Regulation (EC) No. 1371/2007, without prejudice to the obligations of other parties. Such assistance shall use channels for communicating with victims’ families and include psychological support for accident victims and their families.

6. PERFORMANCE EVALUATION

6.1. Monitoring

6.1.1. The organisation shall apply 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 identify, implement and evaluate the effectiveness of the preventive and corrective measures (see 3.1.1. Risk assessment and Continual improvement respectively), as appropriate, if any relevant instance of non-compliance to points (a) and (b) 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, preventive 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. Context of the organisation);

(c) the organisation’s safety performance related to:

(i.) the achievement of its safety objectives;

(ii.) the results from its monitoring activities, internal auditing and internal 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;

(b) reported to national bodies as appropriate;

(c) controlled, and in case non-conformities occurred, these are corrected.

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, to learn and, where required, to adopt corrective or preventive measures (see 3.1.1. Risk assessment and 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.

*ANNEX III*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **SINGLE SAFETY CERTIFICATE** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Single Safety Certificates confirming acceptance of the railway undertaking's safety management system including the provisions adopted by the railway undertaking to meet specific requirements necessary for safe operation on the relevant network in conformity with Directive (EU) 2016/798 and applicable national legislation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **EU IDENTIFICATION NUMBER:** | | | | | | | | |  |  |  | |  |  | |  | | |  | |  | | |  | | |  | | |  | | | |  | |  |
| **1. CERTIFIED RAILWAY UNDERTAKING** | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
| Legal denomination: | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
| Railway undertaking name: | | | | | | | | | | | | | | | | | | Acronym: | | | | | | | | | | | | | | | | | | |
| National registration number: | | | | | | | | | | | | | | | | | | VAT No: | | | | | | | | | | | | | | | | | | |
| **2. AUTHORITY ISSUING CERTIFICATE** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Organisation: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Country: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **3. CERTIFICATE INFORMATION** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | |  |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| This is a | - new certificate | | | |  |  | EU Identification Number  of the previous certificate: | | | | | | | |  | | | | | | | | | | | | | | | | |  | | | | |
|  | | | |  |  |  | |  | |  |  | |  |  | |  |  | |  |  | |  | |  | |  | |
| - renewed certificate | | | |  |  |  | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| - updated certificate | | | |  |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | |  |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Validity from: | | | | | | | | to: | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Type of operation[[14]](#footnote-14): | | | |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  | including high-speed services | | |  |  |  | | | |  | |  |  | |  |  |  | | Passenger transport |  |  |  |  |  | |  |  | excluding high-speed services | | |  |  |  | | | |  | |  |  | |  |  |  | |  |  |  |  |  |  | |  |  |  | including dangerous goods services | | |  |  |  | | | |  | |  |  | |  |  |  | | Freight transport |  |  |  |  |  | |  |  | excluding dangerous goods services | | |  |  |  | | | |  | |  |  | |  |  |  | |  |  |  |  |  |  | | Shunting only | |  |  |  |  |  |  |  |  |  |  |  | |  | |  |  |  |  |  |  |  |  |  |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Other operations[[15]](#footnote-15): | | | |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  | | |  |  | | |  |  | | | |  |  |  |  |  |  |  |  |  |  |  |  | |  |  | | |  |  | | |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **4. APPLICABLE NATIONAL LEGISLATION**[[16]](#footnote-16) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **5. AREA OF OPERATION AND EXCLUSIONS**[[17]](#footnote-17)[[18]](#footnote-18) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **6. LIMITATIONS AND CONDITIONS OF USE** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **7. ADDITIONAL INFORMATION** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Date issued | | | | Signature | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | |
| Internal reference number | | | | Authority’s stamp | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | | | | | | |
|  | | | |  | | | | | | | |

1. OJ L 138, 26.05.2016, p. 102. [↑](#footnote-ref-1)
2. OJ L 326, 10.12.2010, p. 11. [↑](#footnote-ref-2)
3. OJ L 327, 11.12.2010, p.13. [↑](#footnote-ref-3)
4. OJ L 320, 17.11.2012, p. 3. [↑](#footnote-ref-4)
5. ISO/IEC Directives, Part 1, consolidated supplement 2016, Annex SL Appendix 2. [↑](#footnote-ref-5)
6. OJ L 315, 3.12.2007, p. 51. [↑](#footnote-ref-6)
7. OJ L 153, 14.6.2007, p.9. [↑](#footnote-ref-7)
8. OJ L 122, 11.5.2011, p.22. [↑](#footnote-ref-8)
9. OJ L 183, 26.06.1989, p.1. [↑](#footnote-ref-9)
10. OJ L 260, 30.09.2008, p.13. [↑](#footnote-ref-10)
11. OJ L 315, 3.12.2007, p. 51 [↑](#footnote-ref-11)
12. OJ… [↑](#footnote-ref-12)
13. OJ L 138, 26.5.2016, p. 1. [↑](#footnote-ref-13)
14. For each Member State concerned by the intended area of operation. [↑](#footnote-ref-14)
15. For each Member State concerned by the intended area of operation. [↑](#footnote-ref-15)
16. For each Member State concerned by the intended area of operation. [↑](#footnote-ref-16)
17. Exclusions of part(s) of the network in accordance with Article 10(7) of Directive (EU) 2016/798. [↑](#footnote-ref-17)
18. For each Member State concerned by the intended area of operation. [↑](#footnote-ref-18)