Changes to legislation: *Commission Delegated Regulation (EU) 2018/761 is up to date with all changes known to be in force on or before 18 December 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Commission Delegated Regulation (EU) 2018/761 of 16 February 2018 establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012 (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2018/761

of 16 February 2018

establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012

(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[(1)], and in particular Article 6(6) thereof,

Having regard to Recommendation ERA-REC-115-REC from the European Union Agency for Railways delivered to the Commission on 9 March 2017, on the revision of the common safety methods on conformity assessment and the common safety method on supervision,

Whereas:

(1) The common safety methods ('CSMs') describe how the safety levels and the achievement of safety targets and compliance with other safety requirements are assessed.

(2) In accordance with Article 6(5) of Directive (EU) 2016/798, 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.

(3) By its Implementing Decision of 1 September 2016[(2)], the Commission gave a mandate to the European Union Agency for Railways ('the Agency') in accordance with Article 6(2) of Directive (EU) 2016/798 to revise Commission Regulations (EU) No 1158/2010[(3)], (EU) No 1169/2010[(4)] and (EU) No 1077/2012[(5)]. On 9 March 2017, the Agency issued its recommendation, enclosing a report on the results of the consultation of national safety authorities, social partners and users and a report assessing the impact of the amended CSMs to be adopted, to address the mandate of the Commission. The Commission examined the recommendation issued by the Agency to verify that the mandate was fulfilled as referred to in Article 6(4) of Directive (EU) 2016/798.

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(4) After a single safety certificate or a safety authorisation is issued, the national safety authority should conduct supervision activities to check whether the safety management system arrangements are effectively used during operation and that all the necessary requirements are complied with on a continuous basis.

(5) In accordance with Article 17(1) and (8) of Directive (EU) 2016/798, in cases where railway undertakings and infrastructure managers are also entities in charge of maintenance that are not certified in accordance with Article 14(4) of Directive (EU) 2016/798, supervision activities carried out by national safety authorities with the aim of checking the application of the relevant CSMs referred to in Article 6 of Directive (EU) 2016/798 by entities in charge of the maintenance are justified means for supervising the effectiveness of the safety management systems of these railway undertakings and infrastructure managers.

(6) A supervision process should be set out for the national safety authorities with the aim of improving mutual trust in their approaches to, and decision-making during, supervision activities.

(7) National safety authorities should be accountable for their decisions and therefore, should have internal arrangements or procedures against which they can be held to account.

(8) Supervision should be targeted primarily at those activities which a national safety authority believes give rise to the most serious risks or where the risks are least well-controlled. For that purpose, the national safety authority should develop and implement a risk-based supervision strategy and plan(s) outlining how it targets its activities and sets its priorities for supervision.

(9) Enforcement actions taken by national safety authorities to ensure that railway undertakings and infrastructure managers achieve legal compliance as referred to in Article 17(1) of Directive (EU) 2016/798 should be proportionate to any risks to safety or to the potential seriousness of any non-compliance with their legal obligations.

(10) To be able to perform its tasks under point (i) of Article 16(2) of Directive (EU) 2016/798, the national safety authority should form a judgement, based on the outcomes of its supervision activities, on the effectiveness of the safety regulatory framework.

(11) The audit and inspection techniques for supervision should commonly include interviews with people at various levels in an organisation, reviewing documents and records related to the safety management system and examining the safety outcomes of the management system revealed by inspections or related activities.

(12) In accordance with Article 17(13) of Directive (EU) 2016/798, the Agency, acting as safety certification body, and the national safety authorities should coordinate when and where appropriate to ensure the full exchange of information between assessment and supervision activities, including any notices addressed to railway undertakings. Similarly, the relevant national safety authorities should coordinate in the case of cross-border infrastructures.

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(13) In order to ensure that supervision is carried out effectively by national safety authorities and to reinforce mutual trust between them, those authorities should ensure that staff involved in supervision have the necessary competencies. To that end, those competencies should be identified.

(14) National safety authorities involved in the supervision of an infrastructure manager with cross-border infrastructure or of a railway undertaking operating in more than one Member State should cooperate with each other to avoid any duplication of supervision and coordinate their approach to supervision to ensure that any key information on the infrastructure manager or railway undertaking, particularly on known risks and its safety performance, is shared and used to target supervision activities on the areas of greatest risk for the whole operation.

(15) National safety authorities should cooperate, where necessary, with other competent authorities or bodies that interact in the railway sector, such as the regulatory bodies and the licensing authorities within the meaning of Directive 2012/34/EU of the European Parliament and of the Council[(6)], or the competent authorities for monitoring compliance with applicable working, driving and rest-time rules for train drivers, to deliver their respective mandates, share information, resolve any conflicts in approach, prevent related adverse effects in the railway system and coordinate their response to any failure to comply with the safety regulatory framework.

(16) According to Article 31(3) of Directive (EU) 2016/798, the new safety certification regime will start from 16 June 2019. However, Member States have the possibility to notify the Agency and the Commission pursuant to Article 33(2) of Directive (EU) 2016/798 that they have extended the transposition period and may in consequence continue to issue certificates in accordance with Directive 2004/49/EC of the European Parliament and of the Council[(7)] until 16 June 2020. It is therefore necessary to align the application dates of this Regulation with the dates set out in Directive (EU) 2016/798 in order to allow smooth transition to the new certification regime.

(17) Regulation (EU) No 1077/2012 has become obsolete and should be replaced by this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes common safety methods (‘CSMs’), referred to in point (c) of Article 6(1) of Directive (EU) 2016/798, for the supervision of the management of safety by national safety authorities after the railway undertakings have been granted a single safety certificate and infrastructure managers after they have been granted a safety authorisation.

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Article 2

Definition

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

(a) 'safety certification body' means the body responsible for issuing a single safety certificate, either the Agency or a national safety authority;

(b) 'residual concern' means a minor issue identified during the assessment of an application for a single safety certificate or for a safety authorisation which does not prevent their issuing and can be deferred for later supervision.

Article 3

Supervision process

1 National safety authorities shall apply the supervision process set out in Annex I.

2 National safety authorities shall establish internal arrangements or procedures for managing the supervision process.

3 For the purposes of supervision, the national safety authorities shall accept the authorisations, recognitions or certificates of products or services provided by railway undertakings and infrastructure managers, or their contractors, partners or suppliers, granted in accordance with relevant Union law, as proof of the ability of railway undertakings and infrastructure managers to fulfil the corresponding requirements defined in Commission Delegated Regulation (EU) 2018/762[8].

Article 4

Techniques for supervision

National safety authorities shall adopt suitable techniques, such as audits and inspections, and select the most appropriate ones when planning their supervision activities.

Article 5

Links between supervision and assessment

1 The national safety authority carrying out supervision shall use and, where relevant, share information gathered on the performance of the safety management system during its supervision activities for the purpose of renewing or updating single safety certificates or safety authorisations.

2 In cases where the national safety authority referred to in paragraph 1 is not responsible for issuing the single safety certificate or safety authorisation, it shall coordinate promptly with the Agency acting as safety certification body or the relevant national safety authority, in the case of cross-border infrastructure, on its request, after the receipt of an application for renewal or update.

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Based on the outcome of the coordination referred to in the first subparagraph, the national safety authority shall identify and target the information which is relevant to assessing whether the railway undertaking's or infrastructure manager's safety management system is effectively working, including at least:

a a description of major non-compliances, which may affect safety performance or create serious safety risks, and any other area of concern identified during supervision activities since the previous assessment;

b the status of the action plan (or plans) established by the railway undertaking or infrastructure manager to resolve major non-compliances and any other area of concern referred to in point (a) and relevant actions that have been taken by the national safety authority to supervise resolution of these issues;

c an overview of the safety performance of the railway undertaking or infrastructure manager operating in its Member State;

d the status of the action plan (or plans) established by the railway undertaking or infrastructure manager to resolve residual concerns from previous assessment.

Article 6

Competence of the staff involved in supervision

1 The national safety authorities shall ensure that staff involved in supervision have the following competencies:

a knowledge of the relevant regulatory framework as it applies to supervision;

b knowledge of the functioning of the railway system;

c appropriate level of critical analysis;

d experience in the supervision 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 knowledge of and experience in interviewing skills;

f problem solving, communication and teamworking.

2 In the case of teamwork, the competencies may be shared amongst the team members.

3 With a view to ensuring the correct application of paragraph 1, the national safety authorities shall put in place a competence management system which shall include:

a the development of competence profiles for each job, position or role;

b the recruitment of staff in accordance with the established competence profiles;

c the maintenance, development and assessment of staff competence in accordance with the established competence profiles.

Article 7

Decision-making criteria

1 The national safety authority shall establish and publish decision-making criteria on how it evaluates the correct application of a safety management system by a railway undertaking or an infrastructure manager and the effectiveness of the safety management system in controlling safety risks associated with the activities of the railway undertaking or infrastructure manager.