

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)

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.

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⁽¹⁾.

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Changes to legislation: There are outstanding changes not yet made to Commission Delegated Regulation (EU) 2018/761. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

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.

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;

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- 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.

These criteria shall include information on how the national safety authority manages and deals with non-compliances identified in the safety management system of the railway undertaking and infrastructure manager.

2 The national safety authority shall adopt and publish a procedure detailing how railway undertakings, infrastructure managers and any other interested party may submit a complaint on decisions taken during supervision activities.

Article 8

Coordination among national safety authorities and cooperation with other authorities or bodies

1 National safety authorities involved in the supervision of an infrastructure manager with cross-border infrastructure(s) or of a railway undertaking operating in more than one Member State shall coordinate their approach to supervision in accordance with Article 17(7) and (9) of Directive (EU) 2016/798.

After the granting of the safety authorisation or single safety certificate, national safety authorities shall promptly decide which of them is to have a leading role for coordinating the supervision of the correct application and effectiveness of the safety management system, without prejudice to the obligations of the national safety authorities under points (d) and (j) of Article 16(2) and Article 17 of Directive (EU) 2016/798.

2 For the purposes of paragraph 1, the national safety authorities shall develop arrangements based on the framework for coordinated and joint supervision set out in Annex II.

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3 National safety authorities shall also develop cooperation arrangements with the national investigation bodies, certification bodies for entities in charge of maintenance and other competent authorities or bodies.

Article 9

Repeal

Regulation (EU) No 1077/2012 is repealed with effect from 16 June 2019.

Article 10

Entry into force and application

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

[^{F1}It shall apply from 16 June 2019.

However, Article 5(2) and paragraphs (1) and (2) of Article 8 shall apply from 16 June 2020 in the Member States that have notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798 that they have extended the transposition period of that Directive, and that have not notified the Agency and the Commission in accordance with Article 33(2a) of Directive (EU) 2016/798 that they have further extended that transposition period.

Article 5(2) and paragraphs (1) and (2) of Article 8 shall apply from 31 October 2020 in the Member States that have notified the Agency and the Commission in accordance with Article 33(2a) of Directive (EU) 2016/798 that they have further extended the transposition period of that Directive.]

Textual Amendments

- F1** Substituted by [Commission Delegated Regulation \(EU\) 2020/782 of 12 June 2020 amending Delegated Regulations \(EU\) 2018/761 and \(EU\) 2018/762 as regards their dates of application following the extension of the transposition deadline of Directive \(EU\) 2016/798 of the European Parliament and of the Council \(Text with EEA relevance\).](#)

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

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- (1) Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010 (See page 26 of this Official Journal).

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