
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) [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)

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ANNEX I

Supervision process as referred to in Article 3

1. GENERAL

The national safety authority shall develop a structured and auditable process for the complete activity which takes into account the elements below. This ensures that the supervision process is iterative and takes into account the need to continually improve, as shown in the diagram below in the Appendix.

2. SETTING UP THE SUPERVISION STRATEGY AND PLAN(S)

The national safety authority shall:

- (a) collect and analyse data/information from a variety of sources as an input to the strategy and the plan or plans. Sources could include information gathered during the assessment of safety management systems, outcomes of previous supervision activities, information from authorisations of subsystems or vehicles, national investigation bodies accident reports/recommendations, other accident/incident reports or data, railway undertakings' or infrastructure managers' annual safety reports to the national safety authority, annual maintenance reports from entities in charge of maintenance, complaints from members of the public and other relevant sources;
- (b) identify in the supervision strategy risk areas for targeted supervision activities, including those emerging from the integration and management of human and organisational factors, where relevant;
- (c) develop a supervision plan or plans showing how it will give effect to the supervision strategy during the lifecycle of valid single safety certificates and safety authorisations;
- (d) produce an initial estimate of resources required to give effect to the plan or plans, based on the target areas identified;
- (e) allocate resources to give effect to the plan or plans;
- (f) address in the supervision strategy and plan(s) any matters relating to cross-border operations or infrastructure(s) through coordination with other national safety authority (or authorities).

3. COMMUNICATING THE SUPERVISION STRATEGY AND PLAN(S)

The national safety authority shall:

- (a) communicate the overall objectives of the supervision strategy and overall explanation of the plan or plans to relevant railway undertakings or infrastructure managers and, where appropriate, more widely to other stakeholders;
- (b) provide relevant railway undertakings or infrastructure managers with an overall explanation on how the supervision plan or plans will be undertaken.

4. DELIVERING THE SUPERVISION ACTIVITIES

The national safety authority shall:

- (a) give effect to the plan or plans;

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- (b) take proportionate action(s) to deal with failure of a railway undertaking or an infrastructure manager to comply with its legal obligations, including issuing any urgent safety alerts and applying temporary safety measures when necessary;
- (c) evaluate how adequately a railway undertaking or an infrastructure manager has developed and implemented an action plan or plans to remedy any non-compliance or residual concern within a specified time period;
- (d) document the results of its supervision activities.

5. OUTCOMES OF SUPERVISION ACTIVITIES

The national safety authority shall:

- (a) share results of its supervision activities with the relevant railway undertaking or infrastructure manager, including identifying areas of non-compliance on the part of the railway undertaking or infrastructure manager and any areas of good practice to support safety improvement;
- (b) have an overview of the safety performance of the individual railway undertakings or infrastructure managers operating in its Member State;
- (c) publish and communicate to relevant stakeholders its views on the overall safety performance in the Member State;
- (d) publish and communicate to relevant stakeholders its views on the effectiveness of the safety regulatory framework;
- (e) use and when relevant, share information on the performance of the safety management system gathered during the supervision of railway undertakings or infrastructure managers, prior to reassessing the application for a renewal or an update of the single safety certificate or the safety authorisation, with the Agency acting as safety certification body or the relevant national safety authority, in the case of cross-border infrastructure;
- (f) where appropriate, take any enforcement actions, identify whether there is a case for restricting or revoking the single safety certificate or safety authorisation and in cases where it is not responsible for issuing the single safety certificate or safety authorisation, inform the competent authority accordingly.

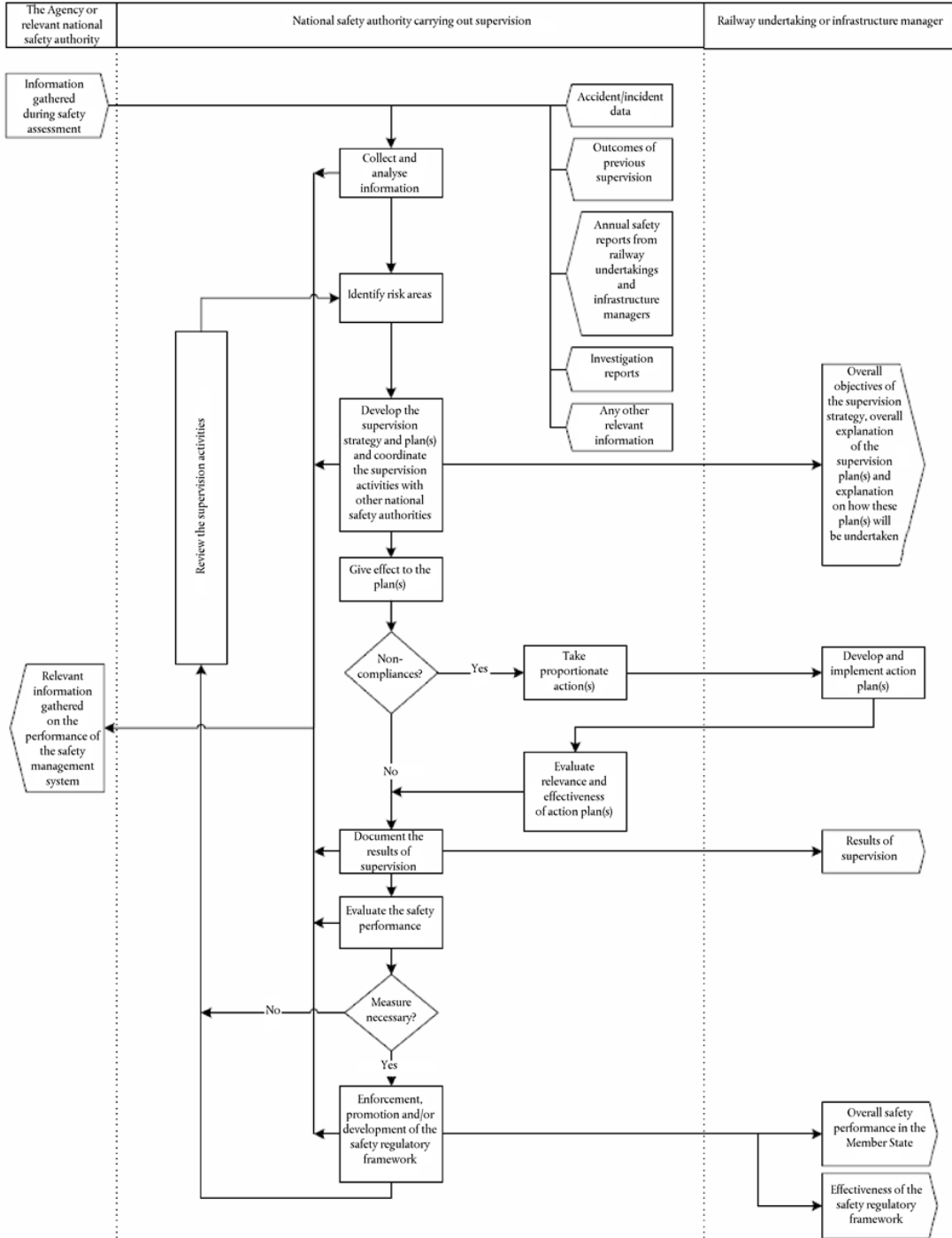
6. REVIEWING SUPERVISION ACTIVITIES

On the basis of information gathered and experience gained during supervision activities and the safety performance both at individual level and at Member State level, the national safety authority shall at regular intervals:

- (a) conduct a review of the supervision strategy and plan(s) to check that the original targeted activity, use of data/information from a variety of sources, supervision outcomes and resource allocation are appropriate, changing priorities as necessary;
- (b) revise the plan or plans if needed and consider the impact of the changes on the supervision strategy;
- (c) contribute when necessary with its views and any proposals to its Member State to overcome any deficiencies in the safety regulatory framework.

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Appendix



Changes to legislation:

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Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by [S.I. 2019/1310 reg. 11\(5\)](#)
- Signature words omitted by [S.I. 2019/1310 reg. 12\(5\)](#)
- Annex 1 para. 5(1) Annex 1 para. 5 renumbered as Annex 1 para. 5(1) by [S.I. 2019/1310 reg. 11\(6\)\(a\)\(i\)](#)
- Annex 1 para. 5(1) Annex 1 para. 5 renumbered as Annex 1 para. 5(1) by [S.I. 2019/1310 reg. 12\(6\)\(a\)\(i\)](#)
- Annex 1 Appendix flowchart substituted by [S.I. 2019/1310 Sch. 3](#)
- Annex 1 para. 5(2) inserted by [S.I. 2019/1310 reg. 11\(6\)\(a\)\(iii\)](#)
- Annex 1 para. 5(2) inserted by [S.I. 2019/1310 reg. 12\(6\)\(a\)\(iii\)](#)
- Annex 1 para. 5(1)(e) words omitted by [S.I. 2019/1310 reg. 11\(6\)\(a\)\(ii\)](#)
- Annex 1 para. 5(1)(e) words omitted by [S.I. 2019/1310 reg. 12\(6\)\(a\)\(ii\)](#)
- Annex 1 para. 5(1)(b) words substituted by [S.I. 2019/1310 reg. 11\(6\)\(a\)\(ii\)](#)
- Annex 1 para. 5(1)(c) words substituted by [S.I. 2019/1310 reg. 11\(6\)\(a\)\(ii\)](#)
- Annex 1 para. 6 words substituted by [S.I. 2019/1310 reg. 11\(6\)\(b\)\(i\)](#)
- Annex 1 para. 6(c) words substituted by [S.I. 2019/1310 reg. 11\(6\)\(b\)\(ii\)](#)
- Annex 1 para. 5(1)(b) words substituted by [S.I. 2019/1310 reg. 12\(6\)\(a\)\(ii\)](#)
- Annex 1 para. 5(1)(c) words substituted by [S.I. 2019/1310 reg. 12\(6\)\(a\)\(ii\)](#)
- Annex 1 para. 6 words substituted by [S.I. 2019/1310 reg. 12\(6\)\(b\)\(i\)](#)
- Annex 1 para. 6(c) words substituted by [S.I. 2019/1310 reg. 12\(6\)\(b\)\(ii\)](#)
- Art. 2(a) omitted by [S.I. 2019/1310 reg. 11\(3\)\(a\)](#)
- Art. 2(a) omitted by [S.I. 2019/1310 reg. 12\(3\)\(a\)](#)
- Art. 2(c) inserted by [S.I. 2019/1310 reg. 11\(3\)\(b\)](#)
- Art. 2(c) inserted by [S.I. 2019/1310 reg. 12\(3\)\(b\)](#)