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*Status: Point in time view as at 31/12/2020.*

*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)*

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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

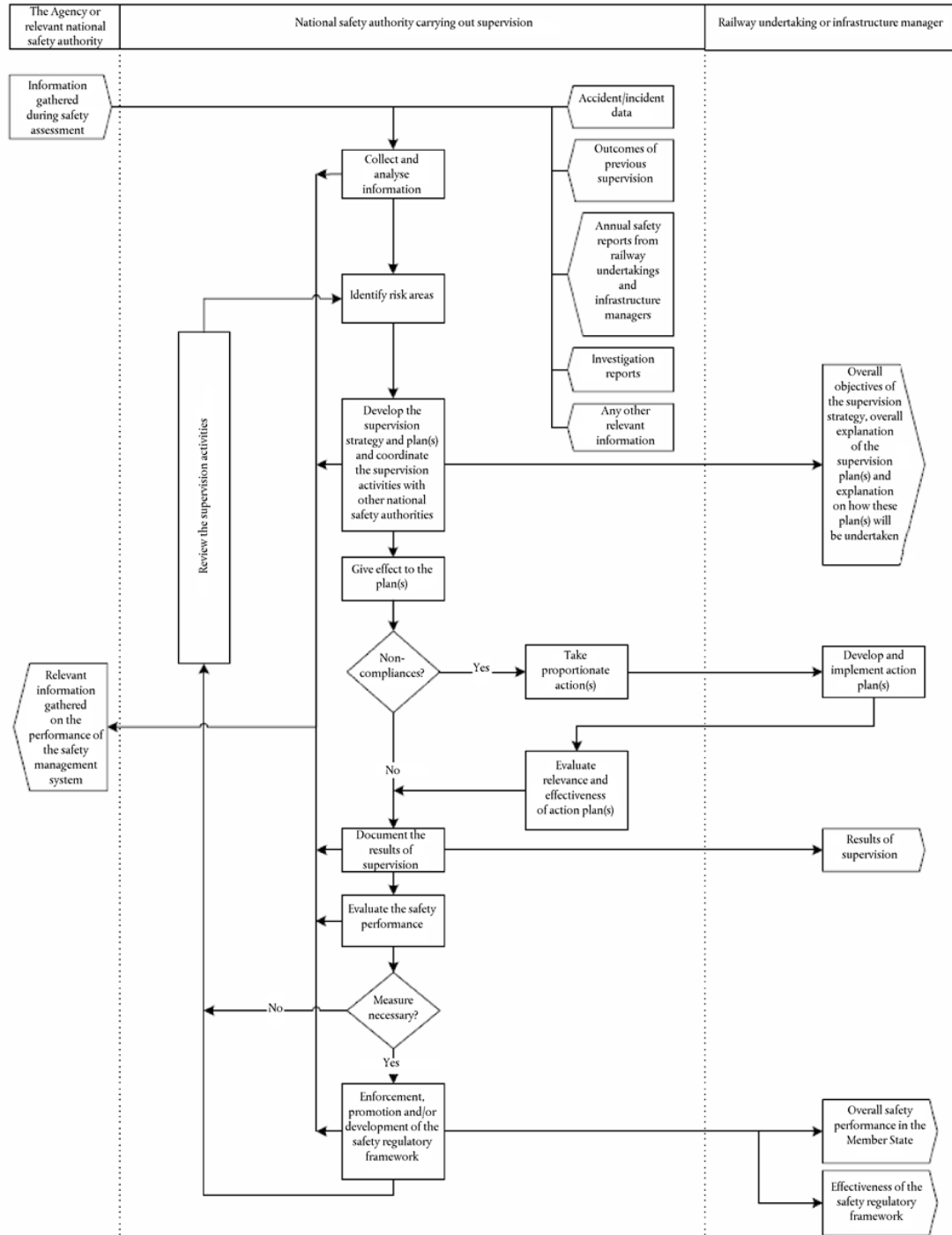
On the basis of information gathered and experience gained during supervision activities and the safety performance both at individual level and at Member State level, the national safety authority shall at regular intervals:

- (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



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## ANNEX II

### **Framework for coordinated and joint supervision as referred to in Article 8(2)**

The relevant national safety authorities shall develop arrangements based on the following principles and specific elements:

1. Agree which railway undertakings and infrastructure managers are operating in such a manner as to require coordinated or joint supervision.
2. Agree on common language(s) and the level of confidentiality of the information to be used for the purposes of their coordination arrangements.
3. Agree what information to exchange and a timetable for the exchange:
  - (a) exchange relevant information on railway undertakings and infrastructure managers identified under point 1 and share results from their assessment activities;
  - (b) provide copies of safety authorisations where appropriate;
  - (c) share results from related supervision activities, including enforcement decisions and actions, where relevant;
  - (d) share information on the safety performance of railway undertakings and infrastructure managers identified under point 1 in each Member State.
4. Share decision-making criteria:
  - (a) share information on how each national safety authority targets its activities for each railway undertaking and infrastructure manager concerned as part of the supervision plan;
  - (b) establish a dialogue between relevant national safety authorities on the proposed response to dealing with major compliance gaps.
5. Manage coordination:
  - (a) share existing supervision strategies and plans;
  - (b) establish common points of interest and/or common issues;
  - (c) plan efficiently individual, coordinated or joint initiatives without causing unnecessary inconvenience to the railway undertakings and infrastructure managers and by avoiding overlaps in the scope of these initiatives.
6. Agree on which national safety authority (or authorities) should follow up actions aimed to address residual concerns which have been deferred for supervision where appropriate.
7. Agree what areas to target in a coordinated or joint manner:
  - (a) identify key risks for the relevant railway undertakings and infrastructure managers to be addressed in a coordinated or joint manner by national safety authorities;
  - (b) agree which national safety authority will lead activities on what issues, where relevant, on the basis of well-established criteria;

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- (c) agree what types of joint supervision activities to undertake, where relevant;
  - (d) agree how railway undertakings and infrastructure managers should be made aware of the arrangements and agreements national safety authorities are reaching.
8. Share good practice:
- (a) develop arrangements to review and coordinate on a regular basis the supervision activities for the relevant railway undertakings and infrastructure managers;
  - (b) develop arrangements to evaluate the effectiveness of the coordination and cooperation between national safety authorities, including the Agency as appropriate.

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