

## ANNEX II

### Safety assessment process

#### 4. DETAILED ASSESSMENT

- 4.1. After the completion of the initial screen stage, the safety certification body and the national safety authorities concerned with the intended area of operation shall proceed, each for their own part, to the detailed assessment of the application file (see Figure 2 in the Appendix), using the safety management system requirements and relevant notified national rules.
- 4.2. In undertaking the detailed assessment referred to in point 4.1, in accordance with Article 18(1) of Directive (EU) 2016/798, the safety certification body and the national safety authorities concerned with the intended area of operation shall exercise professional judgment, be impartial and proportionate, and provide documented reasons for conclusions reached.
- 4.3. The assessment shall determine whether the safety management system requirements and relevant notified national rules are met or whether further information shall be requested. During the assessment, the safety certification body and the national safety authorities concerned with the intended area of operation shall also seek evidence that the safety management system requirements and relevant notified national rules have been met 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 in order to ensure safe operation of the railway.
- 4.4. Any type 4 issue shall be resolved to the satisfaction of the safety certification body and lead to an update of the application file where appropriate before the single safety certificate can be issued.
- 4.5. Residual concerns may be deferred for consideration to supervision, or actions may be agreed upon with the applicant, based on its proposal for updating the application file, or both. In such a case formal resolution of the issue shall take place after the issue of the single safety certificate.
- 4.6. The safety certification body and the national safety authorities concerned with the intended area of operation shall be transparent on how they judge the severity of each identified issue referred to in Article 12(1).
- 4.7. When identifying an issue referred to in Article 12(1), the safety certification body and the national safety authorities concerned with the intended area of operation shall be specific and help the applicant understand the level of detail expected in the response. To that end, the safety certification body and the national safety authorities concerned with the intended area of operation shall take the following steps:
  - (a) refer accurately to the relevant safety management system requirements and notified national rules and help the applicant to understand the identified issues;
  - (b) identify the relevant part of related regulations and rules;
  - (c) state why the individual safety management system requirement or notified national rule, including any related legislation, is not met;

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**Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/763, Division 4.. (See end of Document for details)

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- (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 safety management system requirement or the notified national rule;
  - (e) specify and agree with the applicant on a timeframe for compliance, reasonable and proportionate to the difficulty of providing the information requested.
- 4.8. If the applicant significantly delays providing the requested information, the safety certification body may decide to extend the timeframe for the applicant's response or to reject the application after notice.
- 4.9. The timeframe for taking the decision on the issuing of the single safety certificate may only be extended, until the requested information has been submitted, upon decision of the safety certification body in coordination with the national safety authorities concerned with the intended area of operation and with the agreement of the applicant in one of the following cases:
- (a) type 1 issues referred to in Article 12(1) that, considered individually or collectively, prevent the assessment or parts of it from continuing;
  - (b) type 4 issues or multiple type 3 issues referred to in Article 12(1) that, considered collectively, may raise the category to a type 4 issue, preventing 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.
- 4.12. If concerns emerge that the application could be rejected, 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 measures.
- 4.13. When it is concluded that either the application meets all requirements or that further progress is unlikely in securing satisfactory responses to outstanding matters, the safety certification body and the national safety authorities concerned with the intended area of operation shall, each for their own part, complete the assessment by the following steps:
- (a) stating whether all criteria have been met or whether there are still matters outstanding;
  - (b) identifying any residual concern;
  - (c) identifying any restriction or condition of use to be included in the single safety certificate;
  - (d) reporting on the follow-up of major non-compliances identified during supervision activities, as referred to in Article 5 of Delegated Regulation (EU) 2018/761, where appropriate;
  - (e) ensuring that the safety assessment process has been correctly applied;
  - (f) compiling the outcome of the assessment, including summary conclusions and where appropriate, an opinion concerning the issuing of the single safety certificate.

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- 4.14. The safety certification body and the national safety authorities concerned with the intended area of operation shall record and justify in writing all findings and judgments in order to facilitate both the assurance process and the decision-making process, as well as to assist with any appeal against the decision to issue or not the single safety certificate.

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