

Commission Implementing Regulation (EU) 2018/763 of 9 April 2018 establishing practical arrangements for issuing single safety certificates to railway undertakings pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council, and repealing Commission Regulation (EC) No 653/2007 (Text with EEA relevance)

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

ANNEX II

Safety assessment process

1. GENERAL

- 1.1. The safety certification body and the national safety authorities concerned with the intended area of operation shall develop a structured and auditable process for the complete activity which takes into account the elements set out in this Annex. The safety assessment process shall be iterative, as shown in the diagram below (see Figure 1 in the Appendix), that is the safety certification body and the national safety authorities concerned with the intended area of operation shall be entitled to make reasonable requests for further information or re-submission in accordance with this Regulation.

2. RECEIPT OF APPLICATION

- 2.1. After receiving the application for a single safety certificate, the safety certification body shall formally and promptly acknowledge receipt of the application.
- 2.2. The safety certification body and the national safety authorities concerned with the intended area of operation shall assign competent resources to deliver the assessment process.

3. INITIAL SCREEN

- 3.1. The safety certification body in coordination with the national safety authorities concerned with the intended area of operation shall undertake promptly on receipt of the application an initial screen to check the following elements:

- (a) the applicant has provided the basic information which is either required by the legislation or needed for it to be processed effectively;
- (b) the application file contains sufficient evidence and is structured and internally cross-referenced so that it can be properly assessed against the safety management system requirements and relevant notified national rules. The safety certification body in coordination with the national safety authorities concerned with the intended area of operation shall conduct an initial review of the actual content of the evidence contained in the application to make an initial judgement on the quality, sufficiency and appropriateness of the safety management system;
- (c) if applicable, the current status of the action plan (or plans) established by the railway undertaking to resolve any major non-compliance and any other area of concern identified during supervision activities since the previous assessment is included;
- (d) if applicable, the current status of the action plan (or plans) established by the railway undertaking to resolve residual concerns from previous assessment is included.

- 3.2. The national safety authorities concerned with the intended area of operation shall also check that the evidence for the type, extent and intended area of operation is clearly identified.

- 3.3. Following the checks referred to in points 3.1 and 3.2, the safety certification body and the national safety authorities concerned with the intended area of operation shall decide if there are any areas in which, for their respective part, further information is necessary. Where further information is necessary, the safety certification body and the national safety authorities concerned with the intended area of operation may promptly

seek the information, to the extent that they deem reasonably necessary to support their assessment.

- 3.4. The safety certification body and the national safety authorities concerned with the intended area of operation shall read a sufficient sample of the application, each for their own part, to check that its content is understandable. If it is clearly not, the safety certification body and the national safety authorities concerned with the intended area of operation shall decide, each for their own part, whether it needs to be returned, with a request for an improved version.

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;

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

- (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;
 - (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.
- 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.
5. DECISION-MAKING
- 5.1. Based on the conclusions of the completed assessment, a decision shall be made on whether to issue a single safety certificate or to reject the application. Where a single safety certificate is to be issued, some residual concerns may be identified. A single safety certificate shall not be issued where any type 4 issue referred to in Article 12(1) is identified and not resolved during the assessment.
- 5.2. The safety certification body may decide to restrict the scope of the single safety certificate, by identifying restrictions or conditions of use, if it is concluded in coordination with the national safety authorities concerned with the intended area of operation that such restrictions or conditions of use address any type 4 issue that would prevent the issue of the single safety certificate. The single safety certificate shall be updated on request of the applicant after all residual concerns have been addressed in its application file.
- 5.3. The applicant shall be informed about the decision of the safety certification body, including the outcome of the assessment, and a single safety certificate shall be issued as appropriate.
- 5.4. If the issuing of the single safety certificate is refused or if the single safety certificate contains restrictions or conditions of use other than those defined in the application, the safety certification body shall inform the applicant, giving the reasons for the decision, and notify it of the procedure to request a review of or to appeal against the decision.
6. CLOSING ASSESSMENT
- 6.1. The safety certification body shall complete the administrative closure by ensuring that all documents and records are reviewed, organised and archived. To continually improve its process, the safety certification body shall identify historic information and lessons learned for use by future assessments.
7. SPECIFIC PROVISIONS FOR THE RENEWAL OF A SINGLE SAFETY CERTIFICATE
- 7.1. A single safety certificate may be renewed upon request of the applicant before the expiry of its validity to ensure continuity of certification.
- 7.2. In the case of a renewal application, the safety certification body and the national safety authorities concerned with the intended area of operation shall check details of changes to the evidence submitted in the previous application and consider the results of past supervision activities as referred to in Article 5 of Delegated Regulation (EU) 2018/761 to prioritise or target the relevant safety management system requirements and notified national rules upon which to assess the renewal application.

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

- 7.3. The safety certification body and the national safety authorities concerned with the intended area of operation shall take a proportionate approach to re-assessment, based on the degree of changes proposed.
8. SPECIFIC PROVISIONS FOR THE UPDATE OF A SINGLE SAFETY CERTIFICATE
- 8.1. A single safety certificate shall be updated whenever there is a substantial change proposed to the type or extent of operation in accordance with Article 10(13) of Directive (EU) 2016/798, or in case of extension of the area of operation in accordance with Article 10(14) of that Directive.
- 8.2. Where it intends to make any change referred to in point 8.1, the railway undertaking holding the single safety certificate shall notify the safety certification body without delay.
- 8.3. Following the notification by the railway undertaking as referred to in point 8.2, the safety certification body shall:
- (a) check that the change relating to any potential application is clearly described and that potential safety risks are assessed;
 - (b) discuss with the railway undertaking and the national safety authorities concerned with the intended area of operation the need for an update of the single safety certificate.
- 8.4. The safety certification body in coordination with the national safety authorities concerned with the intended area of operation may make further enquiries with the applicant. Where the safety certification body agrees that the proposed change is not substantial, it shall inform the applicant in writing that an update is not required, keeping a record of the decision for the registered file.
- 8.5. In the case of an update application, the safety certification body and the national safety authorities concerned with the intended area of operation shall:
- (a) check details of changes to the evidence submitted in the previous application upon which the current certificate was issued;
 - (b) consider the results of past supervision activities as referred to in Article 5 of Delegated Regulation (EU) 2018/761, and in particular, issues relating to the ability of the applicant to effectively implement and monitor its change management process;
 - (c) prioritise or target the relevant safety management system requirements and notified national rules in order to assess the update application.
- 8.6. The safety certification body and the national safety authorities concerned with the intended area of operation shall take a proportionate approach to re-assessment, based on the degree of changes proposed.
- 8.7. An application to the safety certification body to update a single safety certificate shall not lead to the extension of its validity period.
- 8.8. The safety certification body shall decide at the request of the applicant whether the single safety certificate needs to be updated where the conditions under which the single safety certificate was issued are to be changed without any impact on the type, extent or area of operation.

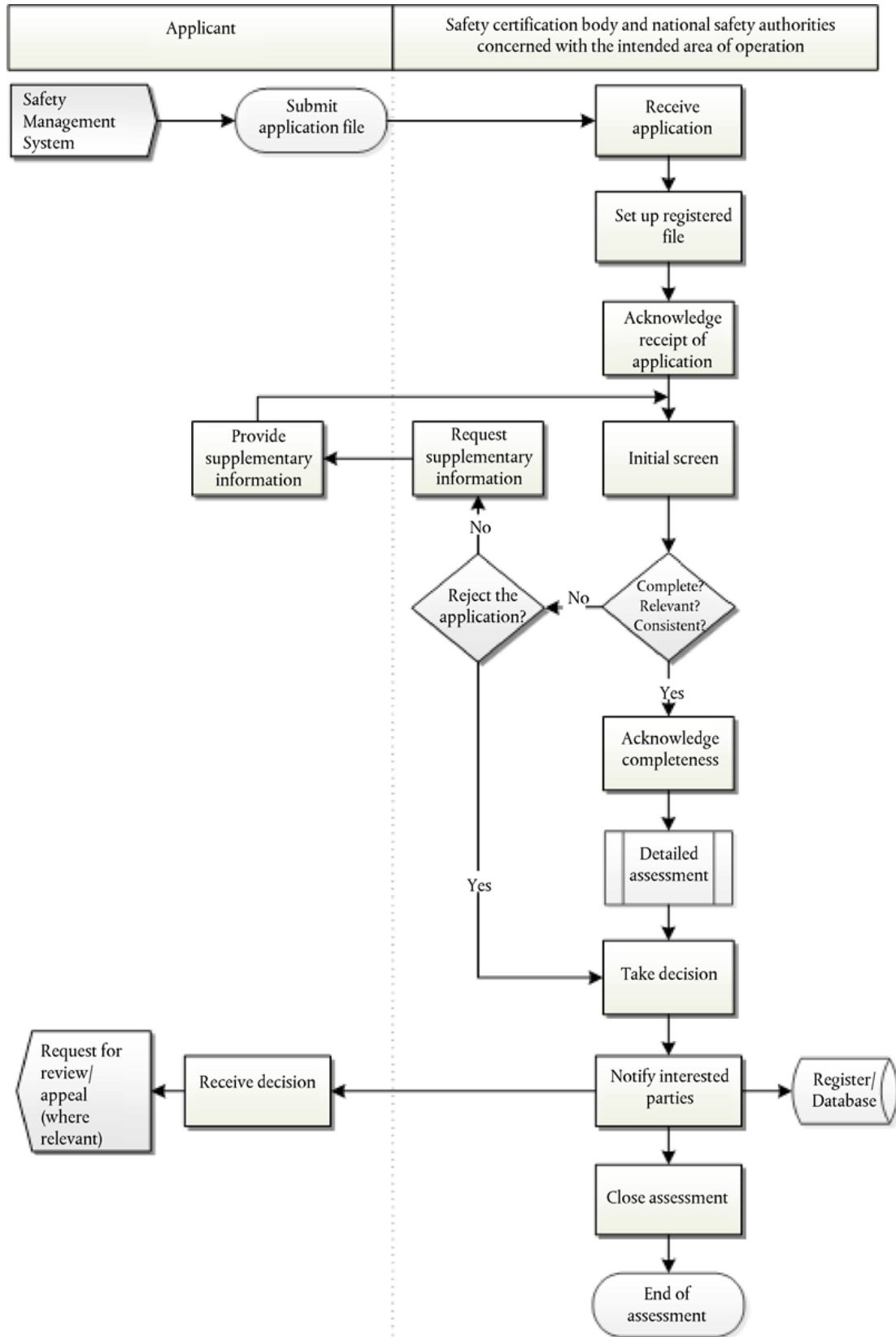
Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/763, ANNEX II. (See end of Document for details)

Appendix

Safety assessment process

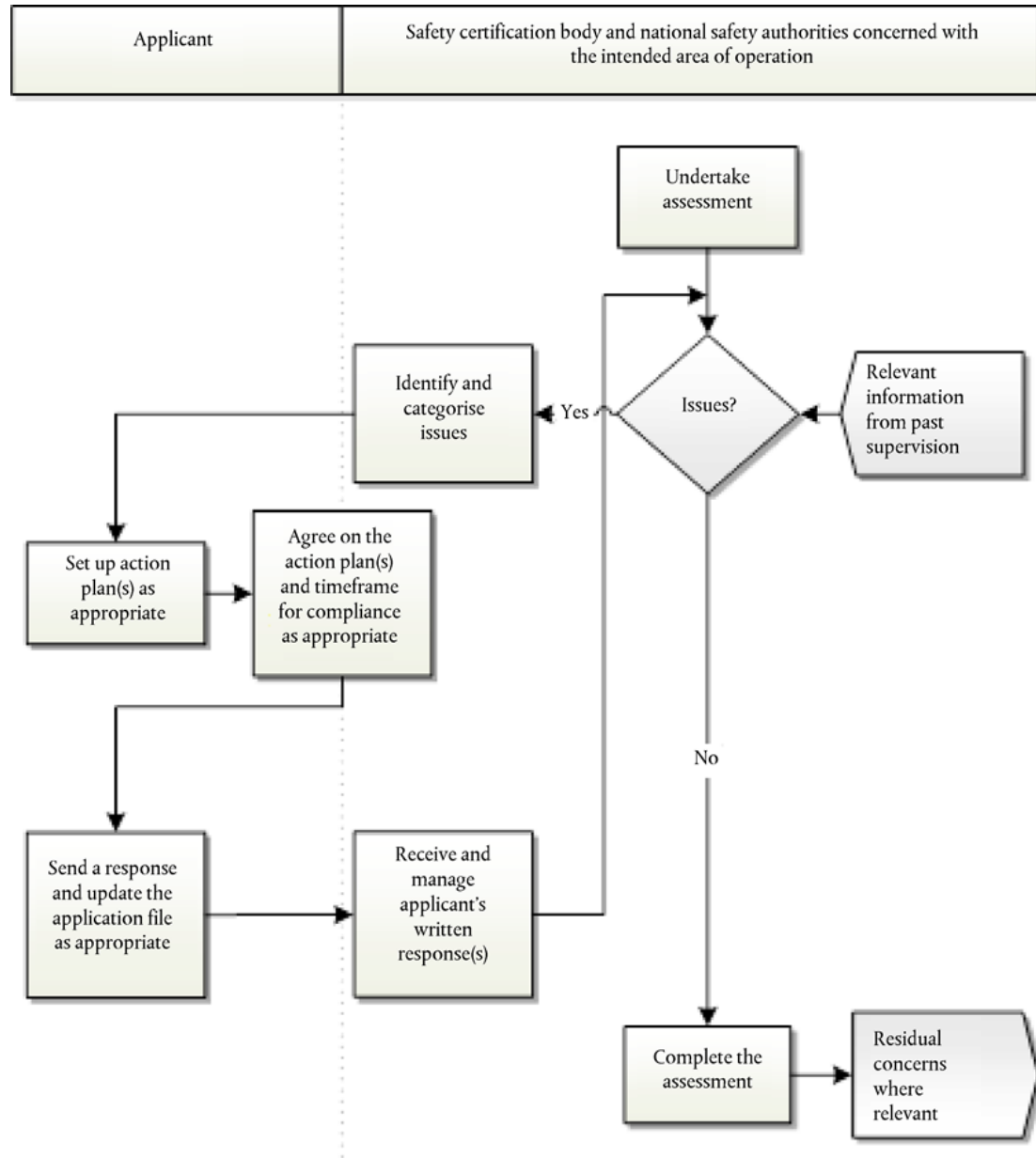
Figure 1: Safety assessment process.

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



Detailed assessment process

Figure 2: Detailed assessment process.



Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/763, ANNEX II.