

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2019/780

of 16 May 2019

on practical arrangements for issuing safety authorisations to infrastructure managers

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) Article 12 of Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety ⁽¹⁾ requires the infrastructure managers to obtain a safety authorisation from the national safety authority in the Member State where the rail infrastructure is located in order to be allowed to manage and operate a rail infrastructure. Such a safety authorisation should confirm acceptance of the infrastructure manager's safety management system and include the procedures and provisions fulfilling the requirements necessary for the safe design, maintenance and operation of the railway infrastructure.

On 9 March 2017 the European Union Agency for Railways (the 'Agency') delivered Recommendation ERA-REC-115-REC on the revision of the common safety methods for conformity assessment and the common safety methods on supervision to the Commission. That Recommendation included provisions on practical arrangements for issuing safety authorisations to infrastructure managers.

- (2) At its meeting of 5 July 2017, the Commission Expert Group on the Technical Pillar of the 4th Railway Package suggested to the Commission to incorporate the above-mentioned provisions into a Recommendation, since there is no appropriate legal basis to include them in a Regulation. Such a Recommendation would provide a guidance laying down the practical arrangements for issuing safety authorisations to infrastructure managers. Such a common guidance should reduce the complexity of the national authorisation procedures by laying down common methodology to be used. It could also ensure that the objectives of Article 12 of Directive (EU) 2016/798 are more effectively achieved and facilitate the tasks of coordination which should be carried out by the national safety authorities under that Article. Therefore the Commission recommends to the Member States to follow those provisions.
- (3) In accordance with Article 12(1), the national safety authorities should develop an application guidance document for managing the issuing of safety authorisations, including the procedure to be followed, with a view to reducing administrative burdens and costs for the applicant coming from the administrative processing of the application.
- (4) The time-limits defined by the national safety authorities in respect of producing additional information requested of the applicant or carrying out visits, inspections or audits should be without prejudice to the timeframe allowed for the assessment of an application set out in Article 12(3) of Directive (EU) 2016/798.
- (5) Pursuant to Article 12(5) of Directive (EU) 2016/798, in the case of cross-border infrastructure, the national safety authorities concerned should coordinate their assessment to avoid, as far as possible, any duplication of assessment and to ensure consistency of decisions to be taken for the rail infrastructure located in their respective Member State.

⁽¹⁾ OJ L 138, 26.5.2016, p. 102.

- (6) Within the framework of their activities, infrastructure managers may need to use trains, infrastructure inspection vehicles, on-track machines or other special vehicles for different purposes, such as the transport of materials or staff for construction or infrastructure maintenance, the maintenance of its infrastructure assets or the management of emergency situations. In such cases, the infrastructure manager should be deemed to operate in the capacity of a railway undertaking under its safety management system and safety authorisation without the need to apply for a separate single safety certificate, irrespective of whether it owns the vehicles or not.
- (7) It is useful to harmonise for the infrastructure managers the categorisation of issues which may be identified in the course of the assessment process of the application. Such a harmonisation should ensure that the applicant understands the gravity of any issues raised by the national safety authority. That categorisation of issues is particularly relevant for the cooperation between national safety authorities in the case of cross-border infrastructure,

HAS ADOPTED THIS RECOMMENDATION:

SUBJECT MATTER AND SCOPE

1. This Recommendation lays down guidelines on the assessment of applications submitted by infrastructure managers to national safety authorities for issuing safety authorisations, or for the renewal or update of such authorisations, as provided for in Article 12 of Directive (EU) 2016/798.

DEFINITIONS

2. For the purposes of this Recommendation, the following definitions should apply:
 - (a) 'date of receipt of the application' means the first working day in the Member State concerned following the acknowledgement of receipt of the application file;
 - (b) 'pre-engagement' means a procedural stage preceding the submission of an application, in the course of which the applicant may request additional information on the following stages of the safety assessment process from the national safety authority;
 - (c) 'residual concern' means a minor issue identified during the assessment of an application for a safety authorisation which does not prevent its issuing and can be deferred for later supervision.

RESPONSIBILITIES OF THE NATIONAL SAFETY AUTHORITY

3. The national safety authority should be responsible for the planning, implementation and monitoring of the assessment work it carries out related to the issuing of a safety authorisation.
4. The national safety authority should accept pre-engagement at the request of the applicant and provide any clarifications requested by the applicant for the procedure to be followed.
5. For the purposes of issuing safety authorisations, the national safety authority should compile the following information:
 - (a) all relevant information concerning the different stages of the assessment procedure, including the reasons for any decisions taken in the course of that procedure, such as inspections, as well as any restrictions or conditions of use to be included in the safety authorisation;
 - (b) the outcome of the assessment procedure, including summary conclusions and where appropriate, an opinion concerning the issuing of the safety authorisation.
6. The national safety authority should monitor the expiry dates of all valid safety authorisations to facilitate the planning of the safety assessment activities.
7. In order to comply with the third subparagraph of Article 12(1) of Directive (EU) 2016/798, the national safety authority should publish and keep up to date an application guide, including model templates, explaining the requirements for the safety authorisation and the documents required. Those documents should include the national rules that apply to the infrastructure manager and the national procedural provisions. Such a guide should be free of charge and published on the website of the national safety authority concerned. It should also indicate the communication arrangements between the national safety authority and the applicant.

To assist the national safety authorities in this task, the Agency in cooperation with the latter should develop, publish and keep up to date a template of an application guide.

8. The national safety authority should establish internal arrangements or procedures for managing the safety assessment process. Those arrangements or procedures should take into account the need to cooperate with other competent national safety authorities in order to issue a safety authorisation in the case of cross-border infrastructure, as provided for in Article 12(5) of Directive (EU) 2016/798.
9. When assessing applications, the national safety authorities should accept other types of authorisations, certificates and any other relevant document provided by infrastructure managers or their contractors granted in accordance with relevant Union law, as proof of their capacity to fulfil the requirements laid down in Commission Delegated Regulation (EU) 2018/762 ⁽²⁾.

SUBMISSION OF AN APPLICATION

10. Without prejudice to the timeframe set out in Article 12(3) of Directive (EU) 2016/798 for the issuing of a decision by the national safety authority, the applicant should submit the application for a safety authorisation, or for the update or renewal of such an authorisation before the following dates, as appropriate:
 - (a) the planned start date of any new rail network operation;
 - (b) the planned start date of a rail network operation under conditions other than those laid down in the current safety authorisation, following a substantial change made to the infrastructure, signalling or energy subsystems or to the principles of their operation and maintenance;
 - (c) the expiry date of the current safety authorisation.
11. When submitting an application for a new safety authorisation, the applicant should provide the information listed in Annex I.
12. When submitting an application for the update or renewal of a safety authorisation, the applicant should provide the information listed in Annex I and describe changes made to its safety management system since the date the current authorisation was issued.

Where such changes may affect safety performance or create serious safety risks, or where the national safety authority identifies any other areas of concern in the framework of its supervision activities, it should decide whether the whole application file needs to be re-assessed.

13. If applicant requests pre-engagement, it should submit the information listed in points 1 to 5 of Annex I to the national safety authority.
14. Where the submitted file contains copies of documents issued by entities other than the national safety authority, the applicant should keep the originals for at least 5 years after the end of the period of validity of the safety authorisation. In the case of renewal or update, the applicant should keep the originals of documents submitted for that application and issued by entities other than the national safety authority for at least 5 years after the end of the period of validity of the renewed or updated safety authorisation. The applicant makes available those original documents at the request of the national safety authority.

PROCEDURAL STAGES AND TIMEFRAMES

15. The national safety authority should apply the process set out in Annex II.
16. The national safety authority should evaluate whether the application contains the documents listed in points 6 to 8 of Annex I. It should inform the applicant, without undue delay, and in any case no later than one month following the date of receipt of the application, whether the application is complete.

⁽²⁾ 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 (OJ L 129, 25.5.2018, p. 26).

17. Where the application is not complete, the national safety authority should promptly request the necessary supplementary information and indicate a reasonable timeframe for the applicant's response. The timeframe for providing supplementary information should be reasonable, proportionate to the difficulty of providing the information requested and agreed with the applicant as soon as it is informed that its application file is not complete. If the applicant does not provide the required information within the agreed timeframe, the national safety authority may decide to extend the timeframe for the applicant's response or to notify the applicant that its application is rejected.
18. Even if the application file is complete, the national safety authority may request from the applicant any further information at any time prior to taking its decision. It should set a reasonable deadline for the provision of such information.
19. The safety authorisation should contain the information listed in Annex III.

A unique identification number should be given to each safety authorisation.
20. In order to fulfill its obligation under Article 12(4) of Directive (EU) 2016/798, the national safety authority should transmit to the Agency the information listed in Annex III.

INFORMATION MANAGEMENT

21. The national safety authority should register, and regularly update, in an information management system, all relevant information on each stage of the safety assessment process and the outcome of that assessment.

ARRANGEMENTS FOR VISITS AND INSPECTIONS ON THE SITES OF INFRASTRUCTURE MANAGERS AND AUDITS

22. In the case of visits, inspections or audits carried out by the national safety authority, the applicant should indicate the person to represent it and the applicable site safety rules and procedures that need to be respected by the staff of the national safety authority responsible for carrying out the visit, inspection or audit. The timeframe for visits, inspections and audits should be agreed between the national safety authority and the applicant.
23. In the case of visits, inspections or audits, the national safety authority should draft a report on the issues identified in the course of the assessment and specifying whether they have been solved by evidence provided during the visit, inspection or audit and, if so, how. That report may also include additional issues to be solved by the applicant within an agreed timeframe.

COOPERATION BETWEEN THE NATIONAL SAFETY AUTHORITIES IN CASE OF CROSS-BORDER INFRASTRUCTURES

24. The applicant or applicants should submit their applications for the cross-border infrastructure with the national safety authorities in the Member States concerned. Each national safety authority concerned should deliver the safety authorisation for relevant infrastructure located in their territory.
25. The national safety authorities should discuss any issues relating to the safety assessment process, and any requests for additional information which have an impact on the timeframe of the assessment or have the potential to affect the work of the other national safety authorities concerned.
26. The national safety authority may require from the other national safety authorities concerned any relevant information related to the applicant.
27. The national safety authorities concerned should exchange among themselves all relevant information which may have an impact on the safety assessment process, including on implementation of relevant national rules, notified to the Commission by their respective Member State.
28. The objectives and scope of audits, inspections and visits, as well as the role assigned to each national safety authority, should be decided by the national safety authorities concerned. The reports of such inspections, visits and audits should be drafted by the national safety authority designed in the framework of the cooperation and be made available to the other national safety authorities concerned.

29. Before deciding on the issuing of a safety authorisation for relevant rail infrastructure located in their respective Member States, the national safety authorities concerned should take the following steps:
 - (a) discuss the outcome of their respective assessments;
 - (b) agree on any residual concerns to be deferred for consideration during later supervision;
 - (c) agree on any restrictions or conditions of use to be included in the safety authorisation, as appropriate.
30. Where the applicant has taken actions to address the identified residual concerns, the national safety authorities concerned should check and agree if those concerns have been solved. To that end, the national safety authorities should cooperate, where appropriate, in accordance with the arrangements referred to in Article 8(2) of Commission Delegated Regulation (EU) 2018/761 ⁽⁹⁾.
31. The national safety authorities should make the safety authorisation they issue for relevant rail infrastructure located in their respective Member States conditional upon the issuance of all other safety authorisations related to the concerned cross-border infrastructure.
32. The national safety authorities should keep records of their respective activities and make them available to other national safety authorities concerned.

CATEGORISATION OF ISSUES

33. The national safety authority should categorise issues identified in the course of its assessment of the application file as follows:
 - (a) 'Type 1': issues that require a response from the applicant for the understanding of the application file;
 - (b) 'Type 2': issues that may lead to an amendment of the application file or minor action from the applicant; the action to be taken is left to the judgement of the applicant and does not prevent the issuing of the safety authorisation;
 - (c) 'Type 3': issues that require specific action to be taken by the applicant, completion of which may be postponed until after the safety authorisation is granted; action to resolve an issue is proposed by the applicant and is agreed with the national safety authority that identified the issue;
 - (d) 'Type 4': issues that require an amendment of the application file or specific action to be taken by the applicant; the safety authorisation is not granted unless the issue is resolved or restrictions or conditions of use are included in the safety authorisation to address the issue; any action to resolve an issue is proposed by the applicant and agreed with the national safety authority that identified the issue.
34. Following the response or the action taken by the applicant according to the issue, the national safety authority should re-evaluate the issues it identified, re-classifies them where relevant and assigns one of the following statuses for each of the issues identified:
 - (a) 'Issue pending' if the evidence provided by the applicant is not satisfactory and additional information is still required;
 - (b) 'Residual concern for supervision' if a residual concern still exists;
 - (c) 'Issue closed out' if the applicant's response is satisfactory and no residual concern remains.

COMPETENCE OF THE STAFF INVOLVED IN ASSESSMENTS

35. The national safety authority should ensure that staff involved in assessments have the following competencies:
 - (a) knowledge of the relevant regulatory framework;
 - (b) knowledge of the functioning of the railway system;

⁽⁹⁾ 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 (OJ L 129, 25.5.2018, p. 16).

- (c) appropriate level of critical analysis;
- (d) experience in the assessment 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) problem solving, communication and team working;
- (f) any other competency required by a particular assessment.

In the case of team work, the competencies may be shared amongst the team members.

Staff carrying out inspections and audits should also demonstrate knowledge of, and experience in interviewing skills.

36. With a view to ensuring the correct application of point 35, the national safety authority should put into place a competence management system which includes:
- (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.

REVIEW

37. Any decision refusing the issuing of a safety authorisation or identifying restrictions or conditions of use other than those requested in the application should be duly justified.
38. Member States should ensure that the applicants may request, within a reasonable timeframe, the review of the decision of the national safety authorities and that the national safety authorities have sufficient time from the date of receipt of the request for review in which to confirm or reverse their decisions.
39. The review procedure should be carried out impartially.
40. The review procedure should focus on the issues which had justified the deviation of the decision of the national safety authority from the applicant's request.
41. In the case of cross-border infrastructure, the review should be carried out in coordination with the national safety authorities concerned with the cross-border infrastructure.
42. If the decision refusing the issuing of a safety authorisation or identifying restrictions or conditions of use other than those requested in the application is confirmed, the applicant may bring an appeal before the competent jurisdiction in accordance with national law.

FINAL PROVISIONS

43. Member States that have not notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798 are requested to give effect to this Recommendation from 16 June 2019. All Member States are requested to give effect from 16 June 2020.

Done at Brussels, 16 May 2019.

For the Commission
Violeta BULC
Member of the Commission

ANNEX I

Content of the application for a safety authorisation

Note: National safety authorities are encouraged to require all information listed in this Annex, including the documents to be annexed to the application, except where indicated with 'O' (optional). Where the infrastructure manager needs to establish a corrective action plan referred to in point 8, the information about it is mandatory.

1. Type of application:

- 1.1. New
- 1.2. Renewal
- 1.3. Update
- 1.4. Identification number of the previous authorisation (only in case of application for renewal or update)

2. Particulars of infrastructure(s) (*select one or more*)

- 2.1. Trans-European Transport Network (TEN-T)
 - 2.1.1. TEN-T Comprehensive Network
 - 2.1.2. TEN-T Core Freight Network
 - 2.1.3. TEN-T Core Passenger Network
 - 2.1.4. Outside TEN-T Network
- 2.2. Energy
 - 2.2.1. Overhead contact line
 - 2.2.2. Third Rail
 - 2.2.3. Fourth rail
 - 2.2.4. Not electrified
- 2.3. Control-Command and signalling
 - 2.3.1. Class A System
 - 2.3.2. Class B System
- 2.4. Other (specify)

3. Rail network operations:

- 3.1. Expected date of starting services/operations (O)
- 3.2. Member State(s) where the infrastructure is located

4. Information concerning the applicant:

- 4.1. Legal denomination
- 4.2. Acronym (O)
- 4.3. Complete postal address
- 4.4. Phone
- 4.5. Fax (O)
- 4.6. E-mail
- 4.7. Website (O)

- 4.8. National registration number
- 4.9. VAT number (O)
- 4.10. Other relevant information (O)
5. **Contact person information:**
 - 5.1. First name
 - 5.2. Surname
 - 5.3. Title or function
 - 5.4. Complete postal address
 - 5.5. Phone
 - 5.6. Fax (O)
 - 5.7. E-mail
 - 5.8. Language or languages spoken

DOCUMENTS TO BE ANNEXED TO THE APPLICATION

6. **Documents submitted for the safety management system part of the assessment:**
 - 6.1. Description of the safety management system and other documents demonstrating compliance with the requirements set out in Annex II of Delegated Regulation (EU) 2018/762.
 - 6.2. Information cross-referencing the safety management system (see point 6.1) against Annex II of Delegated Regulation (EU) 2018/762, including an indication where in the safety management system documentation the relevant requirements of the applicable technical specification for interoperability relating to the operation and traffic management subsystem are met.
 7. **Documents submitted for the national part of the assessment:**
 - 7.1. Description or other demonstration of how the safety management arrangements address the relevant national rules notified in accordance with Article 8 of Directive (EU) 2016/798.
 - 7.2. Information cross-referencing the safety management system (see point 6.1) against the requirements laid down in the relevant national rules (referred to in point 7.1).
 8. **Corrective action plan(s)**
 - 8.1. The current status of the action plan or plans established by the infrastructure manager to resolve any major non-compliance and any other area of concern identified during supervision activities since the previous assessment.
 - 8.2. The current status of the action plan or plans established by the infrastructure manager to resolve residual concerns from the previous assessment.
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ANNEX II

Safety assessment process

1. GENERAL

- 1.1. National safety authority should 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 should be iterative, as shown in the diagram below (see Figure 1 in the Appendix), that is the national safety authority is entitled to make reasonable requests for further information or re-submission in accordance with this recommendation.

2. RECEIPT OF APPLICATION

- 2.1. After receiving an application for a safety authorisation, the national safety authority should formally and promptly acknowledge receipt of the application and sets up the registered file in order to ensure information management at each stage of the assessment process.
- 2.2. The national safety authority should assign competent resources to deliver the assessment process.

3. INITIAL SCREEN

- 3.1. On receipt of the application, the national safety authority should undertake promptly 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 national safety authority conducts 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 infrastructure manager 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 infrastructure manager to resolve residual concerns from previous assessment is included.
- 3.2. Following the initial screening referred to in point 3.1, the national safety authority should decide if there are any areas in which, for their respective part, further information is necessary. Where further information is necessary, the national safety authority should promptly seek the information, to the extent that they deem reasonably necessary to support their assessment.
- 3.3. The national safety authority should read a sufficient sample of the application to check that its content is understandable. If it is clearly not, the national safety authority should decide whether it needs to be returned, with a request for an improved version.
- 3.4. When assessing the infrastructure manager's capacity to operate trains, infrastructure inspection vehicles, on-track machines or other special vehicles, including the use of contractors where relevant, the national safety authority should refer to the relevant requirements defined in Annex I of Delegated Regulation (EU) 2018/762, in particular its points 1, 5.1, 5.2 and 5.5.

4. DETAILED ASSESSMENT

- 4.1. After the completion of the initial screen stage, the national safety authority should proceed 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 national safety authority should exercise professional judgment, be impartial and proportionate, and provide documented reasons for conclusions reached.
- 4.3. The assessment determines whether the safety management system requirements and relevant notified national rules are met or whether further information is needed. During the assessment the national safety authority should 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 of the railway operations in order to ensure safe operation of the railway.
- 4.4. Any type 4 issue should be resolved to the satisfaction of the national safety authority leading to an update of the application file where appropriate before the safety authorisation 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 takes place after the issue of the safety authorisation.
- 4.6. The national safety authority should be transparent on how it judges the severity of each identified issue.
- 4.7. When identifying an issue referred to in point 33, the national safety authority should be specific and help the applicant understand the level of detail expected in the response. To that end, the national safety authority should 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;
 - (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. In application of Article 12(3) of Directive (EU) 2016/798, if the applicant significantly delays providing the requested information, the national safety authority should 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 safety authorisation may only be extended, until the requested information has been submitted, upon decision of the national safety authority and with the agreement of the applicant in one of the following cases:
 - (a) type 1 issues that, considered individually or collectively, prevent the assessment or parts of it from continuing;
 - (b) type 4 issues or multiple type 3 issues that, considered collectively, may raise the category to a type 4 issue, preventing the issuing of the safety authorisation.
- 4.10. To be satisfactory, the applicant's written responses should 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 should 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 national safety authority may consider possible contingency measures.

- 4.13. When it is concluded that either the application meets all requirements or that further progress in securing satisfactory responses to outstanding matters is unlikely, the national safety authority should 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 safety authorisation;
 - (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 safety authorisation.
- 4.14. The national safety authority should 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 the safety authorisation or to reject the application.

5. DECISION-MAKING

- 5.1. Based on the conclusions of the completed assessment, a decision should be made on whether to issue a safety authorisation or to reject the application. Where a safety authorisation is to be issued, some residual concerns may be identified. A safety authorisation is not issued where any type 4 issue is identified and not resolved during the assessment.
- 5.2. The national safety authority may decide to restrict the scope of the safety authorisation, by identifying restrictions or conditions of use, if such restrictions or conditions of use address any type 4 issue that would prevent the issue of the safety authorisation. The safety authorisation should be updated on request of the applicant after all residual concerns have been addressed in its application file.
- 5.3. The applicant should be informed about the decision of the national safety authority, including the outcome of the assessment, and a safety authorisation is issued as appropriate.
- 5.4. If the application is rejected or if the safety authorisation contains restrictions or conditions of use other than those defined in the application, the national safety authority should 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 national safety authority should complete the administrative closure by ensuring that all documents and records are reviewed, organised and archived. To continually improve its process, the national safety authority should identify historic information and lessons learned for use by future assessments.

7. SPECIFIC PROVISIONS FOR THE RENEWAL OF A SAFETY AUTHORISATION

- 7.1. A safety authorisation may be renewed upon request of the applicant before the expiry of its validity to ensure continuity of authorisation.
- 7.2. In the case of a renewal application, the national safety authority should 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.
- 7.3. The national safety authority should take a proportionate approach to re-assessment, based on the degree of changes proposed.

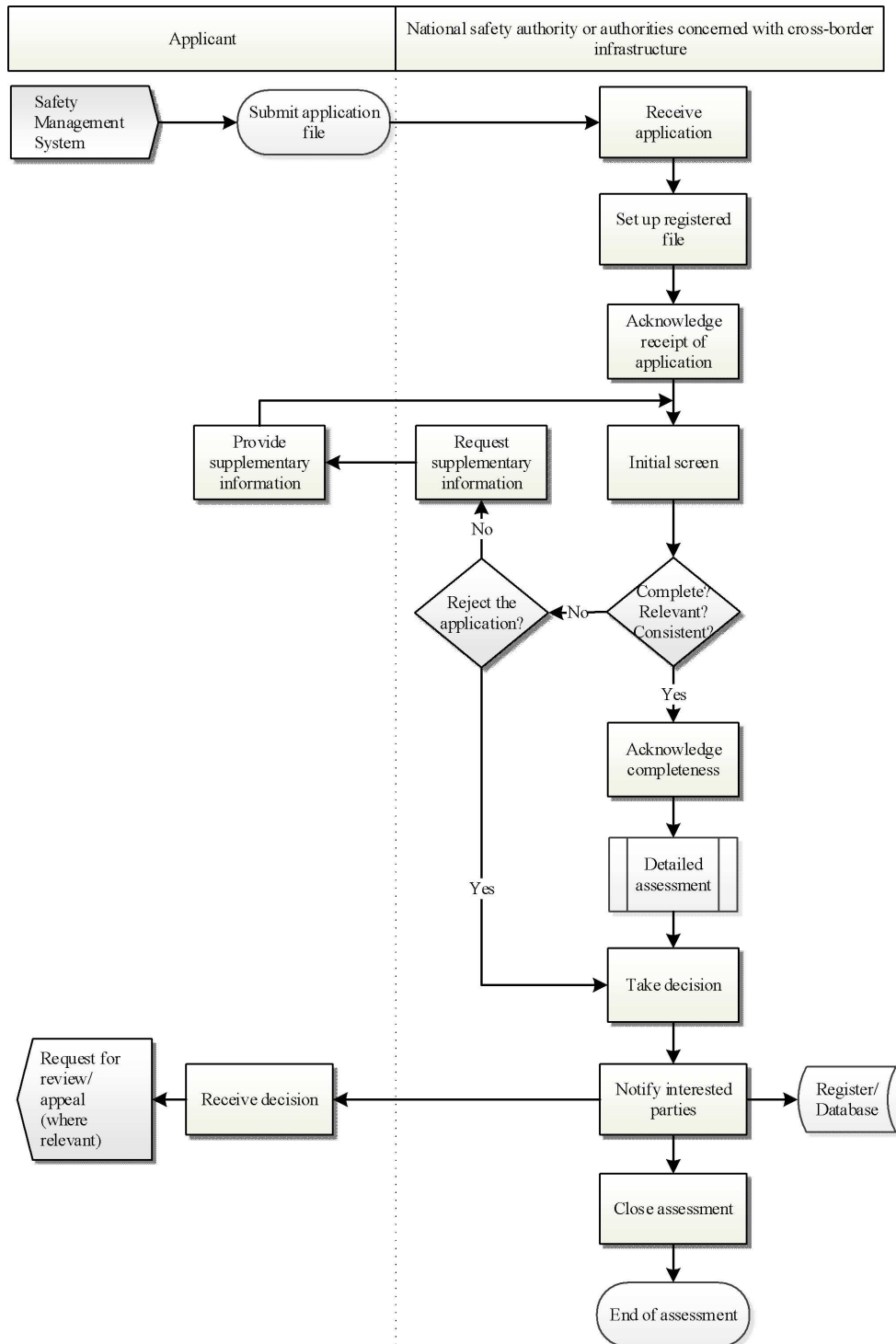
8. SPECIFIC PROVISIONS FOR THE UPDATE OF A SAFETY AUTHORISATION
- 8.1. A safety authorisation is updated whenever there is a substantial change proposed to the infrastructure, the signalling, any energy supply used in connection with the infrastructure or the principles of operation and maintenance of such infrastructure, signalling or energy supply in accordance with Article 12(2) of Directive (EU) 2016/798.
- 8.2. Where it intends to make any change referred to in point 8.1, the infrastructure manager holding the safety authorisation notifies the national safety authority without delay.
- 8.3. Following the notification by the infrastructure manager as referred to in point 8.2, the national safety authority:
- (a) checks that the change relating to any potential application is clearly described and that potential safety risks are assessed;
 - (b) discusses with the infrastructure manager the need for an update of the safety authorisation.
- 8.4. The national safety authority may make further enquiries with the applicant. Where the national safety authority agrees that the proposed change is not substantial, it informs 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 application for an update, the national safety authority should take the following steps:
- (a) check details of changes to the evidence submitted in the previous application upon which the current safety authorisation 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 national safety authority should take a proportionate approach to re-assessment, based on the degree of changes proposed.
- 8.7. An application to the national safety authority to update a safety authorisation should not lead to the extension of its validity period.
- 8.8. The national safety authority should decide at the request of the applicant whether the safety authorisation needs to be updated where the conditions under which the safety authorisation was issued are to be changed without any impact on the infrastructure, the signalling, any energy supply used in connection with the infrastructure or the principles of operation and maintenance of such infrastructure, signalling or energy supply.
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Appendix

SAFETY ASSESSMENT PROCESS

Figure 1

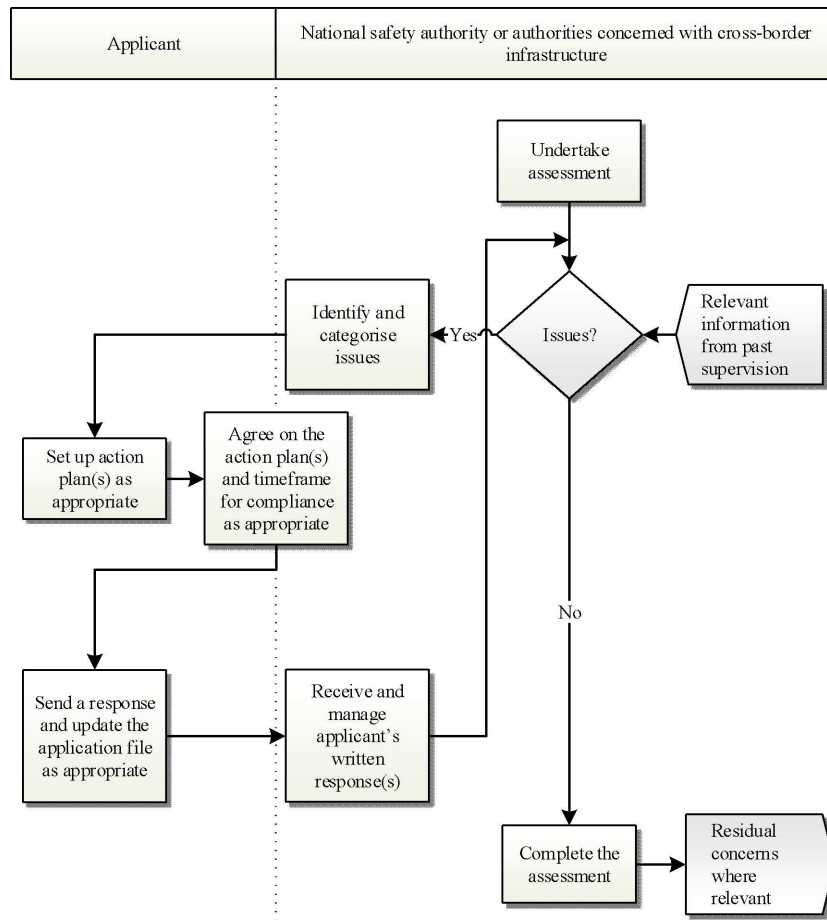
Safety assessment process



DETAILED ASSESSMENT PROCESS

Figure 2

Detailed assessment process



ANNEX III

Content of the safety authorisation

1. **Identification number of the safety authorisation**
 2. **Identification of the infrastructure manager:**
 - 2.1. Legal denomination
 - 2.2. National registration number
 - 2.3. VAT number
 3. **Identification of the national safety authority:**
 - 3.1. Organisation
 - 3.2. Member State
 4. **Authorisation information:**
 - 4.1. New
 - 4.2. Renewal
 - 4.3. Update
 - 4.4. Identification number of the previous authorisation (in case of renewal or update only)
 - 4.5. Validity start and end dates
 - 4.6. Particulars of infrastructure(s)
 5. **Applicable national legislation**
 6. **Restrictions and conditions of use**
 7. **Additional information**
 8. **Issuing date and authorised signatory/stamp of the authority**
-

Appendix

The following standard model for safety authorisation is recommended:

**SAFETY AUTHORISATION**

Safety Authorisation confirming acceptance of the safety management system within the European Union in conformity with Directive (EU) 2016/798 and applicable national legislation

IDENTIFICATION NUMBER: _____

1. AUTHORISED INFRASTRUCTURE MANAGER

Legal denomination:	
Infrastructure manager name:	Acronym:
National registration number:	VAT No:

2. AUTHORITY ISSUING AUTHORISATION

Authority:
Member State:

3. AUTHORISATION INFORMATION

This is a <ul style="list-style-type: none"> — new authorisation <input type="checkbox"/> — renewed authorisation <input type="checkbox"/> — updated authorisation <input type="checkbox"/> 	EU Identification Number of the previous authorisation: _____
Validity from:	to:
Particulars of infrastructure(s):	

4. APPLICABLE NATIONAL LEGISLATION

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5. RESTRICTIONS AND CONDITIONS OF USE

--

6. ADDITIONAL INFORMATION

--

Date issued

--

Signature

Internal reference number

--

Authority's stamp

--
