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Application guide for the ERTMS trackside approval

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1.   Introduction

Directive 2016/797 lays down the objective and the general rules regarding the approval of the European Union Agency for Railways (the Agency) in relation to the Article 19 of Directive (EU) 2016/797. In order to support the applicant and to ensure an efficient and smooth procedure, it is necessary to provide some guidance. The decision on approval is a part of the application file for an authorization for placing in service of fixed installations that include ETCS or GSM-R, according to Art. 18 (4) of Directive 2016/797.

The Commission published a Recommendation in June 2018 that provides further elaboration on the legal text to facilitate the approval process. In this Recommendation, a stage called 'initial engagement' is introduced, in which the applicant engages in a dialogue with the Agency to prepare for the approval process, before submission of an application. Also, the documentation to be requested in the application file is listed. The recommendation, however, does not provide further detail to the process but it introduces the main concepts and pillars to ease the approval process , as for example the issue list and a positive approval with conditions. This Agency application guide follows the Directives, includes all this recommended concepts, and provides further details for the ERTMS trackside approval process. This document aims to clarify what is included in the Commission recommendation and to further define the process and the documentary evidences that are requested in order to obtain the positive decision of the Agency on the envisaged technical solutions.

This application guide establishes the guidelines for the approval of ERTMS trackside envisaged technical solutions.

The guidelines set out details aiming an effective and efficient approval process that will enable the Agency to take a decision on the ERTMS trackside envisaged technical solutions.

2.   Background information

The so-called 'technical pillar' of the 4th railway package introduced important changes to the interoperability regulatory framework and revises the Agency Regulation, Interoperability and Safety Directives. Under this new framework, which was published in June 2016, the Agency will be responsible for issuing safety certificates, authorisations for railway vehicles and approval of the ERTMS trackside solutions, from the application of the new Interoperability Directive.

As stated in the Directive (EU) 2016/797, the ERTMS trackside approval is a new task, additional to the process for authorization for the placing in service which is carried out under the responsibility of the national safety authorities. The aim of the new approval task is to ensure interoperability of the envisaged ERTMS trackside technical solutions.

The Agency approval process introduces an opportunity to identify issues related to interoperability on trackside projects and to share those issues with the sector. The Agency, through the approval process, will check that those issues are not being repeated in new projects. From a very early stage, before the tender is launched, those issues are to be considered in any type of new ERTMS trackside projects. The approval process will facilitate the sharing of knowledge and will avoid solving issues too late that are common to ERTMS trackside projects. With an early identification of the issues, the relevant entities that contribute to achieving an interoperable and effective ERTMS trackside systems can still react and solve the issues. The applicants and national safety authorities will benefit from the checks and information related to the design phases of the ERTMS. These checks can enhance the interoperability of the projects and facilitate the authorisation processes by adding the approval decision on the application file of the authorisaion, and by making visible to the NSA all the approval process.

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The Figure 1 provides an overview of the different documents that support the ERTMS trackside approval

4 RP legislation

Published June 2016

Directive (EU) 2016/797, Art 19
Regulation (EU) 2016/79, Art 22

Practical arrangements

*Workshops Nov 2016 & Feb 2017
New versions with comments received*

Draft description of process and application file

Commision Recommendation

Application Guide

Internal procedures

Published in June 2018

January 2019, update with Learning cases

2019

Approval process description
Stable principles and concepts to facilitate approval, e.g: Initial Engagement, Issue Log

More details on decision process
More details on application file
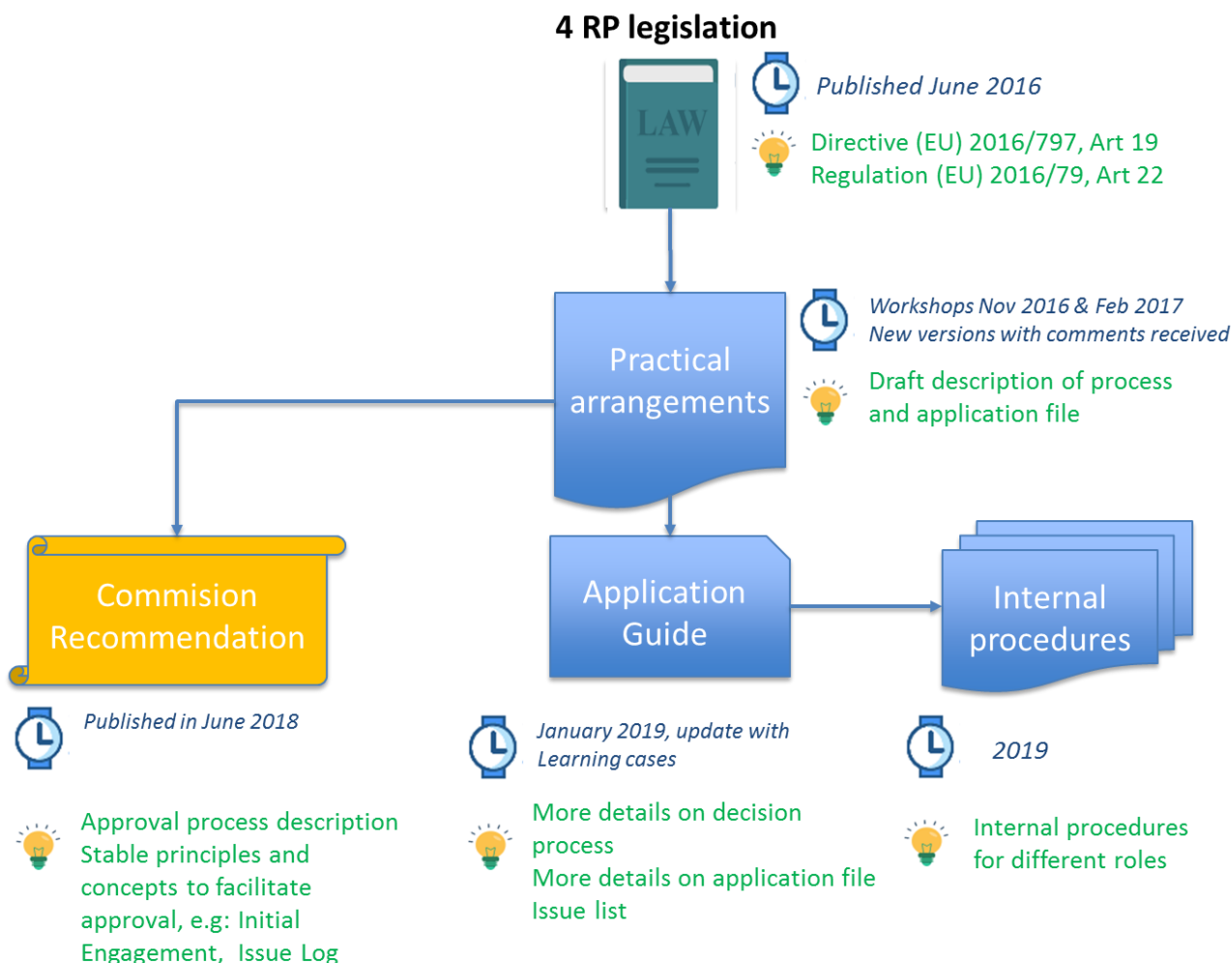Issue list

Internal procedures for different roles

Figure 1: Main documents related to the ERTMS trackside approval.

The European legal framework relevant for the ERTMS trackside approval is composed by:

Directive (EU) 2016/797 on the interoperability of the rail system within the EU (Interoperability Directive) is one of the three legislative acts that form the technical pillar of the 4th Railway Package and establishing the conditions to be met to achieve interoperability within the Union rail system. According to Article 19 (*Harmonised implementation of ERTMS in the Union*), in order to ensure the harmonised implementation of ERTMS and interoperability at Union level, before any call for tenders relating to ERTMS trackside equipment, the Agency shall check that the technical solutions envisaged are fully compliant with the relevant TSIs and are therefore fully interoperable. The other main related articles are Article 18 (*Harmonised implementation of ERTMS in the Union*) and Article 55 (*Other transitional provisions*).

Regulation (EU) 2016/796 on the European Railway Agency for Railways (Agency Regulation), is one of the other two legislative acts of the technical pillar of the 4th Railway Package. It describes, among other things, the role and responsibilities of the Agency in relation to the granting of decision on approvals to the ERTMS trackside envisaged technical solutions. The main related articles are Article 22 (*Placing in service of trackside*

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control-command and signalling subsystem) and Article 30 (*Compatibility between ERTMS on-board and trackside subsystems*).

Commission Implementing Regulation (EU) 2018/867 laying down the rules of procedure of the Board(s) of Appeal of the European Railway Agency for Railways describes the procedure applied during an appeal against an Agency decision. It provides details on the notification of an appeal, the Board(s) of Appeal's workings and voting rules, the conditions for reimbursement of expenses of their members, etc.

Commission Implementing Regulation (EU) 2018/764 on the fees and charges payable to the European Union Agency for Railways and their conditions of payment provides the rules related to the fees and charges payable to the Agency for processing, among other things, the ERTMS trackside approval application. It provides details about the calculation of the fees, the conditions of payment, etc.

The Commission Recommendation 2018/C 253/01 on guidance for the harmonised implementation of the ERTMS. The Commission Recommendation provides further elaboration on the legal text to facilitate the approval process. It provides details about the different stages of the approval process, the content of the application file, the classification of the issues, etc.

The Agency drafted a first version of practical arrangements for the trackside approval. These were discussed with the railway sector during two workshops, held on November 22nd, 2016 and February 22nd, 2017. Comments from the stakeholders were discussed during these two meetings, and the practical arrangements were adapted in line with the discussions.

The practical arrangements were the basis for the draft EC Recommendation. The draft EC Recommendation was discussed during the workshop of February 22nd, 2017 and improved with the comments from the stakeholders. The improved version of the Commission Recommendation contains those parts that were considered as stable after the discussions: it introduces the concept of the initial engagement phase, the issue log, conditional approval, and a description of the application file.

The Agency held learning cases during 2017 and 2018 to test and validate the approval process as defined in the practical arrangements and EC recommendation. Learning cases were carried out with an identical methodology. It was concluded that the issue log was a very useful tool, and the learning cases enabled the Agency to further improve the function list and issue list by clarifying and adding issues (the function and issue lists can be found in Appendix 1 as a separate file to this document).

No further updates to the practical arrangements are foreseen. The Agency will continue detailing the process in this application guide. The Agency will also prepare internal procedures on how the approval activity will be managed by its staff.

If agreed, cooperation agreements between the Agency and the NSA can complement the above levels process set out in the documents mentioned in Figure 1.

The details on the Boards of Appeal and fees and charges are included in the relevant implementing acts.

3.   General provisions

3.1.   Actors: roles and responsibilities

This section describes the actors involved in the approval process. The only actors directly involved in the ERTMS trackside approval processes are the applicants, the NSAs and Agency. These actors will make use of a single and coherent tool throughout the entire approval process, called the one-stop shop (OSS).

Applicant:

Following Directive (EU) 2016/797 for the purpose of Article 19, the 'applicant' means a natural or legal person requesting the Agency's decision for the approval of the technical solutions envisaged for the ERTMS track-side equipment implementation;

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The decision to act as the applicant should consider the roles and responsibilities and the necessary information that has to be provided. The applicant could be the same as for the request of authorisation of the fixed installations, an IM, or any natural or legal person that bests fits with the role and responsibilities, and considering the necessary information that has to be provided for decision on approval.

The applicant is responsible for:

- Contacting the Agency for initial engagement (if chosen to do so – this is recommended);

- Submitting an application through the one stop shop

- Providing the required documentation listed in the application file description

- Providing the required information and clarifications upon request of the Agency to explain the information or documentation shared with the Agency, through the OSS or , if agreed, during conferences calls or meetings;

- Paying the fees related to the application as defined in the Commission Implementing Regulation (EU) 2018/764.

NSAs:

The approval process does not modify or add new responsibilities to the NSAs responsibilities stated in other articles of the EU legislation in those processes that are not related to the approval. The NSA can provide opinions and propose issues to the envisaged technical solutions before and during the approval process, and the Agency shall consider them for the decision on approval. The NSA will have visibility of the approval process.

The NSA must verify the compliance with the positive decision of the Agency before issuing the authorization for placing in service of fixed installations with ERTMS equipment.

NSAs have the possibility to;

- Provide opinions on envisaged technical solutions;

- Propose interoperability issues to be considered by the Agency;

- In case of a conditional approval issued by the Agency, the NSA can considers the conditions and remarks;

- In case the conditions are not fulfilled, or the technical envisaged solutions have changed, the NSA can request the applicant to apply for a new approval or to apply Article 30 (2) of Regulation (EU) 2016/796.

Agency:

The Agency checks the compliance of the technical solutions envisaged with the ERTMS requirements of the control-command and signalling TSI and related to the ERTMS equipment, and gives its approval by means of a decision.

The Agency checks do not cover the details on the envisaged technical solution that are not required in the ETCS and/or GSM-R technical documents in the CCS TSI. Other trackside equipment such as interlocking, trackside detection elements, external detectors to ERTMS (hot axle detectors, wind detectors, fallen objects), level crossing, etc., are not in the scope of the decision on approval. The safe integration and other safety or operational aspects of the technical solution envisaged are not covered by the approval process. The approval process is added to the global process to achieve safe and interoperable trackside projects and does not change the responsibilities of NoBos, AsBos, and NSAs derived from the EU legislation.

The Agency checks will be based on a list of functions implemented trackside and a related list of

interoperable issues ("issue list"). The issues are risks to the interoperability that might generate a deviation on the trackside subsystem or that might impose a behavior of the train that generates a deviation on the on-board subsystem. Experiences from other projects that required a modification on the design in a very late stage should also be included as issues to avoid unnecessary re-engineering. The Agency will maintain the list of issues and add further issues to this list when these issues have appeared in several ERTMS trackside projects or when issues are relevant for any ERTMS trackside project. The issues from the issue list that are applicable to an especific request for approval application will be included in an issue log, specific to the application.

The possible statuses are of issues in the issue log are:

Query: a status "Query" indicates that it is not clear how the issues is controlled and will be resolved and the applicant is expected to provide evidences of addressing the issue.

Every issue will have a default status of "Query" in the issue log.

Closed: an issue will have the status "Closed" if the applicant has provided satisfactory evidence that demonstrates the issue is controlled.

Closed but unacceptable: the issue is closed but there is a major non-conformity that requires an amendment of the application file. If there is an issue that is closed but unacceptable, the Agency will issue a negative decision.

Closed with conditions: the issue is closed under conditions to be fulfilled at a later stage.

The Agency decision on approval can be negative, positive or positive with conditions.

The Agency is responsible for:

- Updating the issue list
- Ensuring that the approval process is followed according to the provisions laid down in Article 19 of the Interoperability Directive and as stipulated in the Application Guide;
- Updating the issue log;
- Considering NSA opinions;
- Providing the decision on approval.

3.2. Application file

This chapter enumerates and describes the required information that enables the Agency decision on approval in compliance with the article 19 of Directive (EU) 2016/797. The objective of the application file is that the technical solutions envisaged should be clearly described and that sufficient documentary evidences are made available to ensure its compliance with the relevant CCS TSI.

The Agency needs the applicant to provide this documentation through the one-stop shop that describes the technical solutions envisaged and allows the Agency to check compliance of the technical solutions envisaged with the CCS TSI.

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These are the elements required for the application file:

1- Application scope description (*Project description*)

The application may encompass a network, a section of a line, a set of sections, a line or a set of lines and may concern one or more projects. It is up to the applicant to decide what is more suitable for the submission of request of decision on approval. The initial engagement phase can help to establish an efficient submission strategy. Applications that only include GSM-R also fall in the scope of the trackside approval

Application description, including the details of the line, group of lines, or network that are covered by a project or combination of projects that are part of the application, including the related geographical location, number of kilometers in single and double track, ERTMS level, baseline and version, interoperability constituents and stations, and interfaces with other lines and/or signalling or radio systems.

The details of the application scope description should be sufficient to identify in a unique way the complete application itself. It should be made clear by the applicant and should include:

- The geograhipcal scope of the line or group of lines, the number of stations within the project;

   The information provided should indicate clearly the geographical extension and boundaries of the application. It should include any information about the sections or lines that defines clearly their geographical extension and boundaries, as for example kilometer points in the line, signals (located in the line or in a station), stations, GPS data, etc. The extension may be different for each track in the case of multiple tracks; when known, this data should also be included. The information should state clearly if the application includes the terminal stations (at both ends of the sections or lines) or not (e.g. if, with lateral signalling, the application starts at the exit signals of the station A and finishes at the entry signals of station B). and interfaces with other lines and/or signalling or radio systems.

   The decision on approval should be added later to the proper application file for request on authorisation of the fixed installations. A similar geographical description on the approval application request and on the authorisation application request will enable the NSAs to check the coverage of the scope of both processes. For network description, a more simple description og the geographical scope could be delivered.

- If the line includes parts located at country border, identification of all these parts;

- The description of elements that concern ERTMS and related to its operation (such as lateral signalling, Class B systems, other infrastructure elements affected by the project);

- If the application includes ETCS, the ETCS level (s), the baseline and the version of the different sections;

- If the application includes GSM-R, the baseline and for which uses it is intended (voice only, ETCS Level 2 in Circuit Switched mode or also in Packet Switched mode);

   Applications that only include GSM-R also fall in the scope of the trackside approval.

- If the line is expected to have level crossings, side tracks, links with other lines equipped or not with ERTMS, identification of the links with others lines and all possible ERTMS level transitions;

- The Interoperability Constituents envisaged to be implemented;

- If parts of the application were authorised with ERTMS before, identification of those parts and their authorisations;

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2- Evidence that the draft tender or contract or both include the relevant control-command and signaling TSI, and the necessary details on the baseline, releases or versions

This information should include all references on the application scope documents of draft tender, tender or contract evidencing the inclusion of the relevant CCS TSI and the applicable sets of specifications on the Annex A (set #1, set #2, set #3), baselines, releases or versions.

3- Projects plan indicating deliverables, milestones and deadlines of the application

The planning information should cover the lines, groups of lines or networks in the application description. Several plans could be delivered separately to cover all the application scope. The planning information should include the contract award decision estimate date, and should also include the main relevant milestones of any ERTMS deployment, as for example: the scheduled start of the installation, the scheduled start of the testing in the laboratory, the scheduled finalization of the works, the scheduled start of the testing in the field, the schedule of the authorisation process, etc. The provided information should include possible deviations on the different tasks. The planning information provided needs to help on identifying the plan for delivering the necessary information related to the design of the technical solutions envisaged before it is implemented and tested. If needed, depending on the completeness check, the planning information is considered to set the reasonable deadline for the decision on approval. The planning information should allow as well to schedule application deliveries and their possible updates.

4- List of ERTMS functions to implement

The applicant should identify the intended functions to be part of the technical solutions envisaged that are to be implemented. The list of functions, identified by the applicant, defines the scope of the approval checks and serves to identify the applicable issues from the issues list of the approval process. The identification of functions should be done by using the approval functions list template included in this application guide annex.

Depending on the complexity of the application, and considering the diversity of sections with different functions to be implemented or functions to be implemented with different ERTMS design requirements, it might be necessary to build several functions lists.

5- Demonstration that the risks impacting interoperability have been addressed

The applicant should provide specific and clear references to the design requirements of the technical solutions envisaged that are relevant to assess the identified applicable issues. These requirements should demonstrate that the issues are addressed and controlled.

The information should be provided using the issues log. For each issue of the issues log there is a need to demonstrate that the issues are addressed. For that purpose, and for each issue, clear references of the design requirements of the technical solutions envisaged, in the documentation provided, are needed to be included in the issues log.

As there is one issues log for each functions list, depending on the complexity of the application there might be several issues logs for the complete application scope. Each issues log should clearly identify the geographical scope that is covering.

6- Engineering rules and operational test scenarios:

This item of the application file should cover all the documentation of the ERTMS design requirements that describe the ERTMS technical solution and all the documentation used for demonstration of controlling issues. This documentation should include the engineering rules and operational tests scenarios, but should also include requirements used for the design of technical solutions envisaged to be implemented. The ERTMS requirements delivered should be the ones used for the implementation and considered for the EC verification process of the trackside subsystem. The ERTMS design requirements should be sufficient to

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describe all intended system operations relevant for the subsystem both in normal and in identified degraded situations and should:

- be consistent with the specifications referenced in the CCS TSI;

- assume that functions, interfaces and performance of the CCS On-board Subsystems interacting with the Trackside Subsystem are compliant with the requirements of the CCS TSI;

- be used in the EC Verification of the Trackside CCS Subsystem, to check that the implemented functions, interfaces and its performances are able to ensure that the intended system operation in combination with the relevant modes, and transitions between levels and modes, of the CCS On-board Subsystems are respected.

There is no template for the submission of these documentation and requirements of other non ERTMS equipment can be in the same documentation, but clear identification of each document, the version, author, and the description of its use and the precise parts related to the ERTMS issues should be identified. The description of the use of each document provided related to the implementation or verifications of the technical solutions envisaged should also be provided.

7- Test strategy and test plan

The test strategy and test plan information should cover the intended relevant testing phases (in laboratory, in the field and the different iterations) identifying the responsible entities, the testing environment, testing objectives and stage of the testing (before installation of the equipment, part of the verification of subsystem, integration of subsystems, before authorisation, after authorisation, etc.). For the testing in the field with vehicles, it should be stated if the vehicles are certified and on which TSI and baseline.

The test strategy relevant to the application and the corresponding test plan should be provided. There is no template for the submission of the testing strategy and test plan. The same those intended to be used for the infrastructure under the scope of the application should be provided.

Information of the schedule of all tests identified should also be delivered.

8- Conditions necessary for the technical and operational compatibility of the subsystem with the vehicles intended to operate in the trackside

This information should include any conditions that the vehicles intended to operate on the trackside will be required to fulfill, if any. These conditions may be related to the use of Class B systems, to limitations for some vehicle characteristics, to the maximum speed of the vehicles, etc. Also the applicable ETCS System Compatibility and the voice and data Radio System Compatibility checks should be provided, if available.

In case there is a list of vehicles intended to operate in the trackside, this may also be provided.

9- A previous ERTMS trackside authorisation or opinions by an NSA, relevant for the technical solutions envisaged

The applicant should inform if parts of the application were authorised before with the ERTMS subsystem. If applicable and available, a previous ERTMS trackside authorisation from an NSA, which is relevant to any part of the scope of the application should be delivered.

The applicant should provide also the NSA opinion(s) on the request for approval, if any, that may have been provided to the applicant before the submission of the application.

10- EC Certificates and EC Declarations of conformity of the interoperability constituents:

The applicant should submit, if available, the EC Certificates and EC Declarations of conformity of the interoperability constituents planned to be included in the technical solutions envisaged.

The Agency template for deviations in the certificates should be used.

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11- <u>EC Certificates and EC Declarations of verification of the trackside subsystem</u>

The applicant should submit, if available, the EC Certificates and EC Declarations of verification of compliancy to the TSI of the subsystem planned to be included in the technical solutions envisaged.

The Agency template for deviations in the certificates should be used.

12- <u>National rules related to ERTMS that must be considered in the application scope</u>

The applicant should submit, if any, the National rules related to ERTMS and applicable to the technical solutions envisaged under the application scope.

13- <u>Exemption from the application of one or more TSIs or parts of them</u>

The applicant should inform concerning the documents provided by the Member State or by the European Commission, granting the derogation to apply one or more CCS TSIs or parts of them (according to Article 7 of Directive (EU) 2016/797), that are relevant for the trackside under the scope of the application.

The applicant should provide any derogation request, already submitted but for which no decision has been provided yet by the Member State or by the European Commission.

14- <u>Previous approval(s) identification</u>

The approval process promotes the standardization of types of lines and the use of the same technical successful solutions. When making a request for approval, the applicant therefore can re-use parts of the application file(s) from previous approval(s) which resulted in a positive decision by the Agency.

The applicant should inform if there were previous approvals using the same functions and ERTMS design requirements or if the changes can be easily identified. The applicant should provide the information of the precise references of the previous approval(s) and should clearly identify the common applicable documentation. The applicant should indicate which ERTMS functions are the same in both requests for approval, which ones are added and which ones are modified. Also, the applicant should indicate which of the documentation items from the application file are identical in both applications, or what documentation items are different and what these differences are. The Agency will avoid to recheck this common part of the application file.

In case the an new approval following a negative decision and the corresponding correnctions, a new approval request with the corrections could allow the re-use of the parts of the previous assessments not impacted by the corrections.

3.3.   Approval process stages

The approval consists of the following stages: initial engagement (non-mandatory but recommended), submission and verification of completeness, assessment and decision, and if needed, Boards of Appeal. See Figure 2 for an overview of the stages and Figure 3 for a flowchart explaining these stages and the activities within them.

Technical meetings could be held to clarify complex issues with queries or non-conformities. They are carried out where it is expected that meetings are a more efficient way to clarify questions.The Agency will respect its agreed language policy, but the applicant is encouraged to provide all documentation in English to reduce the approval duration and therefore its costs.
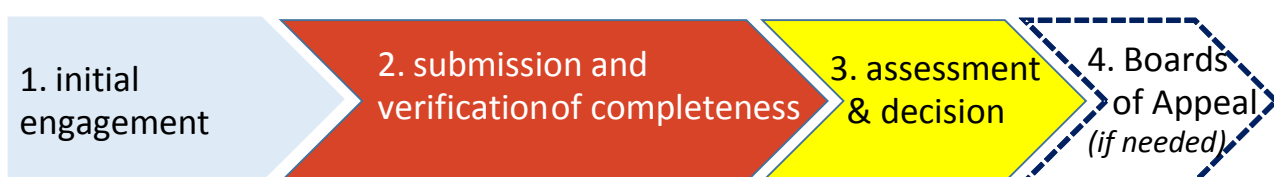

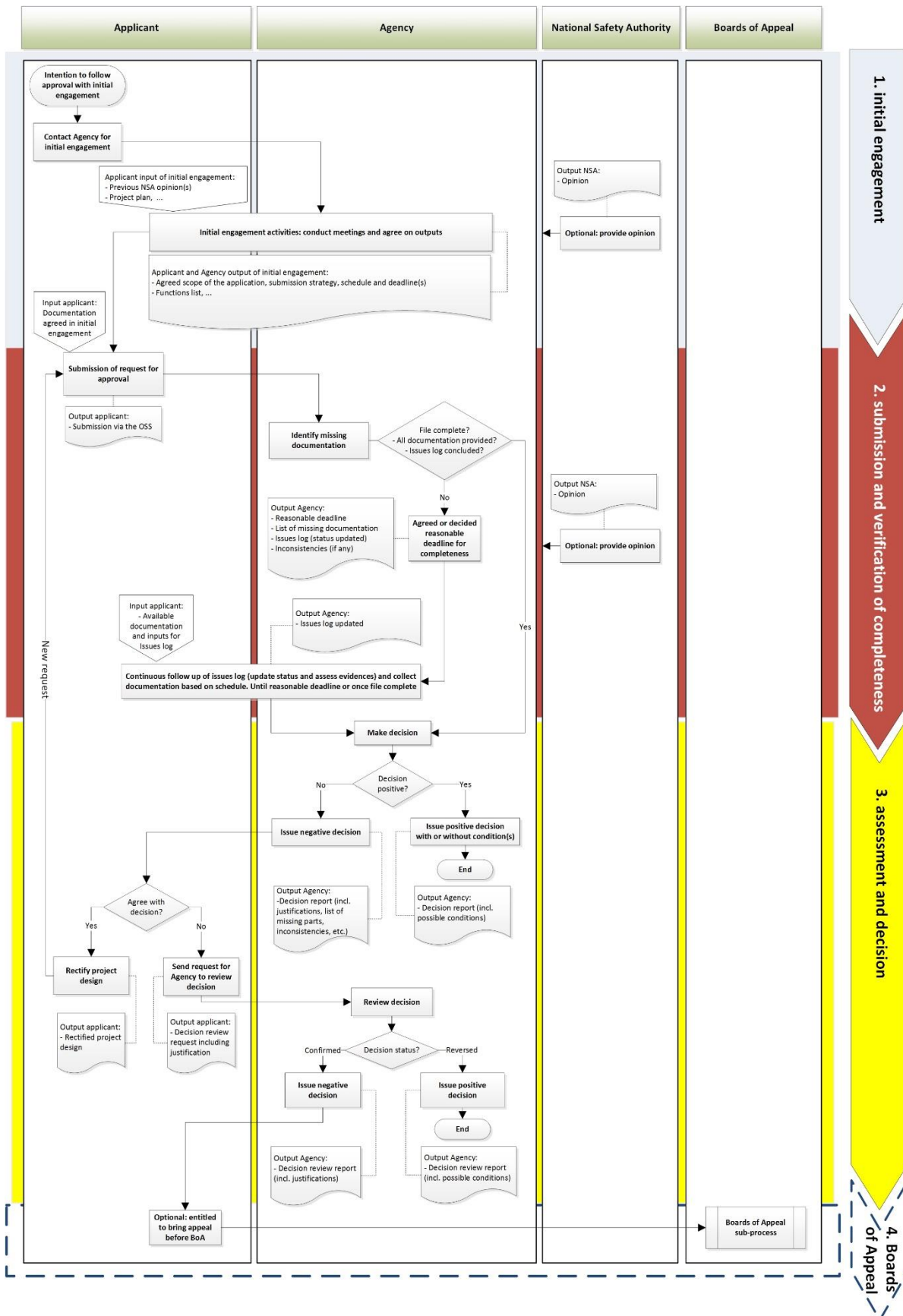Figure 2 : Overview of the stages of the approval process.

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Figure 3 : Flowchart containing stages and activities of the approval process.

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3.4.   Stage 1 Initial engagement

As set out in the Recommendation 2018/C 253/01[1], the applicant, prior to formal submission of an application, should initiate a dialogue with the Agency to facilitate the approval process. This initial engagement stage is a non-mandatory but highly recommended stage, which intends to prepare as much as possible the approval(s) to perform it in the best conditions. For this purpose, the Agency also highly recommends the participation and the collaboration of the NSAs that can provide an opinion to be considered on the outcomes of this stage.

The submission strategy should consider different timelines or different authorisation strategies for parts of the line, group of lines or network concerned. The first proposal of submission could be slipt in several request for decision of approval.

The initial engagement is performed at applicant's request, informing the Agency of its intention to submit an ERTMS trackside approval(s). The initial engagement stage can start as soon as the applicant has sufficient information about a future call for ERTMS trackside tenders and ends before the first request for approval submission. If needed, additional initial engagement stage(s) can be performed for the remaining application(s). However, each request for approval shall be submitted through the One-Stop Shop before any call for tender.

Nevertheless, exceptions could occur according to the transitional provisions[2] and therefore some projects subject to approval can have already launched calls for tenders or even already contracted supplier(s) before submitting a request for approval.

The initial engagement serves to facilitate the approval process and does not include any assessment of the approval process. The Agency will not charge, during this stage, the applicant for the time spent by its employees or related costs incurred (e.g. travelling costs). Nevertheless this stage should be confined to a limited number of discussions, agreed at the beginning of the stage.

The initial engagement is performed through face-to-face meeting(s) with relevant parties or through alternatives such as telephone or video conference(s), to reduce travel time and associated costs. Before each meeting, an agenda shall be proposed and agreed by all participants. To keep records of the agreements achieved during these meeting(s), the Agency will draft minutes and send them for review and approval to all participants.

This initial engagement facilitates the approval process and it is aimed at:

›   Agreeing on the submission strategy (number of approval requests and the scope of each one) according to the related scope characteristics (planning, number of line(s), authorisation requests, etc.);
›   Identifying previous approval(s) from which some parts could be re-used;
›   Ensuring a good understanding by the applicant of the approval process needs;
›   Defining a preliminary approval schedule including links with all project milestones concerned by the approval request(s) to plan the necessary checks in an efficient way and to reflect possible delays on the approval milestones and approval deadline(s);
›   Agreeing on a deadline for the decisions on approvals considering the availability and completeness of the application file for each submission;

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[1] Commisson Recommandation of 18 July 2018 on guidance for the harmonised implementation of the ERTMS in the Union (2018/C 253/01), whereas (9).
[2] Directive (EU) 2016/797, Article 55 (3): "Projects which have completed the tendering or contracting phase prior to 16 June 2019 are not subject to the pre-authorisation by the Agency referred to in Article 19."

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> › Issuing the function lists to be implemented and thus stablishing the applicable issues log(s) for submission. The issue log for submission is established automatically with the function list by filtering the generic issues list according to the applicable functions identified by the applicant.

At the beginning of the initial engagement, the applicant presents the application proposal, its planning (including relevant design, implementation, testing and authorisation milestones) and the already available parts of the envisaged technical solution. Based on this information, the applicant proposes the number of application requests he intends to submit and the scope of each one (line, group of lines or network). This submission strategy proposal will be discussed with all participants, considering also the possible opinions of the NSA. The final submission strategy shall be agreed and recorded in the minutes of the associated meeting.

For each request of approval, the applicant is encouraged to provide also as many of the requested documents as possible (listed in the application file chapter) and to identify, if any, common part(s) – i.e. same applicable documentation and evidences - with previous successful approval(s).

The applicant should also provide the functions list, needed to issue the so called "issues log" that identifies the applicable issues from the generic issues list (i.e. some functions will not be implemented and therefore, the related issues are not applicable). A clear and clean issues log, available before approval submission, is needed to have an efficient approval process. It is, therefore, very important to identify exhaustively the applicable functions in the functions list. For this, the functions list should be filled in considering all necessary experts (ETCS, GSM-R, etc.). Several functions lists, and therefore several issues logs, could be needed, depending on the scope of the related application that can include several sections or lines with different functionalities.

As part of the application file, the applicant should demonstrate that each issue of the issues log(s) is controlled and will be resolved. In the initial engagement stage, the Agency will provide explanations related to the required level of details needed to cover the issues. For that aim the Agency and the applicant experts can discuss together some examples of issues and/or evidences, even if no formal assessment will be performed during this stage. The applicant experts involved in the discussions, shall have a deep technical knowledge of the application related project, of the ETCS/GSM-R specifications and of the documentation describing the envisaged ERTMS technical solution. The applicant and the Agency should also discuss how and when updates to the issues log(s) will be made during the approval.

Based on the documents and information provided by the applicant, the Agency and the applicant should agree on a schedule of the requested documents deliveries and the final deadline for each approval decision, including the mechanisms to handle any possible delays. The schedule should be established considering also the authorisation planning and possible opinions of the NSA. This schedules will avoid innecesary checks that should be repeated with new imputs based on the schedule milestones for completeness and to achive an efficient approval process.

To perform the initial engagement stage, the applicant submits the following inputs documents:

> › Submission strategy proposal including the number of approval requests and description of the associated scope (the line, group of lines, sections, group of sections or network);
> › Project planning including all parts of the application (line, group of lines, etc.) subject to approval(s) with deliverables milestones (including relevant design, implementation, testing, and authorisation milestones);
> › Test strategy and test plan(s);
> › Functions list(s), completed as much as possible to build the applicable issues log(s) before submission;
> › Evidences that the draft tender (or tender or contract if applying the transitional provisions or other specific cases) includes the relevant control-command and signaling TSI, the baseline and the system version;
> › When applicable, any relevant derogation(s) (already granted or only requested);

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> › When applicable, identification of previous approval(s) from which some parts could be re-used in the approval.

The main outputs of the initial engagement stage should be:

> › An agreed submission strategy: According to the application description and plannings, the applicant can decide with help of the Agency, and considering the possible opinions of the NSA and the authorisation strategy, to submit one or several applications from the same tendering process. The scope of each application is also clearly defined;
> › A clear understanding of the approval process: the Agency can verify that the applicant has been provided with sufficient information so that the applicant knows what is needed to be provided to the Agency to allow the decision on approval.
> › An agreed deadline for each complete application file: according to the planning and the documentations availability, the applicant and the Agency agree, for each application, on a reasonable deadline to have the complete associated application file available in the One-Stop Shop, allowing the Agency to provide a decision on approval.
> › Planning alignment: the initial engagement should help in identifying the planning of the approval(s) activities considering the project planning including all parts of the application and the planning of the possible stages on the authorisation process. The initial engagement allows the Agency to understand the application related project life cycle and how the design and necessary details of the envisaged technical solution will be achieved. Approval deadline(s) and other approvals milestones (submission of each requested document listed in the application file chapter, updates of the issues log(s), etc.) should be linked to relevant associated project milestones.
> › Optimization of the total workload: the initial engagement stage will enable the applicant to build proper functions list(s) and issues log(s) that will only include applicable issues. Also the identification of previous approval(s) could avoid unnecessary re-assessments.

All the agreements between the parties involved achieved during the initial engagement stage are recorded in the approved minutes of meeting(s) and, if requested, specific agreements can be signed between the parties.

The initial engagement stage can be close when agreed by relevant parties and must be closed before the first approval request submission.

At each submission of approval request, the applicant should use the One-Stop Shop to register the agreed documentation in the initial engagement stage.

3.5. Stage 2 Submission and verification of completeness

This stage starts when the Agency receives a formal request for approval. The aim of this stage is to verify whether the application submitted by the applicant is complete. Each request for approval shall be submitted by the applicant through the One-Stop Shop, and should start before any call for tenders relating to ERTMS trackside equipment. As already stated in the previous chapter, exceptions could occur according to the transitional provisions and therefore some projects subject to approval can have already launched calls for tenders or even already contracted supplier(s) before submitting a request for approval.

The submission of the request covers all the activities related to the collection of the documentation required for a formal request for the Agency's approval. In order to optimize the application, the applicant is encouraged to identify, if any, common part(s) – i.e. same applicable documentation and evidences - with previous successful approval(s). The applicant should do in the same way for the case of new approval request for the same scope, in case of previous negative decision or requested by the NSA.

Within one month of receipt of the submission, the Agency will inform the applicant of its decision on the completeness through the One-Stop Shop. The National Safety Authority can issue an opinion at any moment during the submission and verification of completeness stage, using the One-Stop Shop.

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An application is considered as complete if information described in the application file has been submitted through the One-Stop Shop and is complete, relevant consistent and no discrepancy has been identified.

The applicant can also provide certificates from a NoBo with a clear scope of the assessments as evidence(s) that parts of the documentation have been checked by other entities in order to avoid duplicity of work.

Up to the reasonable deadline, the Agency may add additional issue(s) in the issues log based on:

- Issue(s) suggested by the applicant;
- Issue(s) suggested by the NSA;
- New issue(s) integrated in the issues list and applicable for the scope of the application.

If the application is considered as complete, the Agency will proceed to the assessment and decision stage.

If the application is not complete, the Agency will specify to the applicant the missing information to be submitted at a reasonable deadline together with the relevant justification. The applicant should then continue providing the requested documentation and evidences until this deadline. The Agency may decide to carry out technical meetings if the missing information is not provided according to the schedule. If relevant and in order to optimize the application file verification of completeness, the delivery of intermediate mature documents updates can be agreed (if not already done during the initial engagement stage). In particular, the Agency can follow-up the issues log(s) updates by making accordingly updates of their status. The delivery schedule of such updates should also have been agreed between the applicant and the Agency.

If inconsistencies are identified in the documentation provided, the Agency will inform the applicant, which should provide clarifications and the related corrected documentation if needed.

Once the deadline is reached, the Agency will proceed to the assessment and decision phase.

When initial engagement stage has been performed:

The applicant should follow the agreed schedule and upload, upon submission, the documentation, documentary evidence and evidences to the issues agreed to be provided during the initial engagement stage.

When the applicant is forced to postpone the delivery of documentations or updates of the issues log(s), it should make use of the mechanisms for handling updates to the schedule as discussed in the initial engagement stage.

The reasonable deadline will be the one agreed during the initial engagement stage.

When initial engagement stage has not been performed:

If the application is not considered complete, the Agency will decide on a reasonable deadline for completeness based on the documentation provided by the applicant. The Agency can set a schedule for the provision of pending documentation and for updating the issues log considering the decided deadline, the information provided and the opinion of the national safety authority, if any.

As indicated in the initial engagement stage, if requested, specific agreements can be signed between the parties.

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3.6. Stage 3 Assessment and decision

The assessment and decision stage follows the conclusion of the submission and verification of completeness stage. It starts once the Agency informs the applicant that the application is considered as complete or at the decided deadline. Then, the Agency shall provide its decision within two months. The decision shall be based on the application file and on possible opinions of the NSA.

The Agency decision can be either a positive, with or without condition(s), or a negative decision. The Agency will inform the relevant parties of its decision together with a decision report including a summary of the final issues statuses as recorded in the issues log(s).

This stage ends once a positive decision is issued or a negative decision has been issued and the applicant has not requested a review of this decision within one month from its receipt, according to the conditions defined in art. 19(5) of Directive (EU) 2016/797. If a decision review has been requested by the applicant, this stage will end once the reviewed decision is issued by the Agency. The decision is provided together with a report, available on the One-Stop Shop, containing relevant information as the decision argumentation and justification, a summary of the issues status and information depending on the decision granted (conditions to be respected, missing information, non-acceptable part(s), incoherencies, etc.). As a decision is applicable for a specific application file, it shall be clearly and unambiguously identified. The report will therefore list each references and versions of the documentation provided. The report will also refer to the potential NSA opinions.

Positive decision:

The Agency will issue a positive decision when all of the following conditions are met:

› All requested documentation or documentary evidences have been provided by the applicant in the One-Stop Shop;
› The issues log(s) has been concluded and all issues have the status "Issue closed", or "Issue closed with conditions".

The positive decision may include conditions to be fulfilled at a later stage if one or more issues have the status "Issue closed with conditions". The Agency will provide explanations related to these conditions, aiming to highlight potential areas of concern that should be considered by the NSA during the authorisation process.

Negative decision:

The Agency will issue a negative decision if at least one of the following conditions is met:

› The application file is concluded as "not complete" at the decided deadline, according to the verification of completeness step, as described in the previous chapter;
› One or more issues of the issues log(s) have the status "Query", meaning that no evidence has been provided to demonstrate that the issue is controlled. There is therefore a risk of interoperability.
› One or more issues of the issues log(s) have the status "Issue closed but unacceptable", meaning that an interoperability issue has been identify and no solution to solve it exists in the envisaged technical solution.

The Agency will inform the applicant of its decision and provide, in the decision report, the justifications about the negative decision.

If the applicant agrees with the negative decision it may rectify non-conformities and submit a new approval request including the corrections. The applicant can submit documentation already provided in the previous request for approval and identify the parts and the evidences for closing issues that are still valid and not impacted by the correction measures. The Agency will avoid assessing again these common parts (similar to what is described earlier when the applicant makes use of the similarities in the technical solutions envisaged with earlier successful requests for approvals).

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If the applicant doesn't agree with the Agency negative decision, the applicant may request the review of the decision within one month from its receipt.

Decision review:

The decision review request should also be submitted by the applicant through the One-Stop Shop. The applicant must provide an argumentation for this review request together with justifications related to the issues that he considers having not been properly assessed by the Agency.

The review process should then focus on these issues highlighted in the justifications. The Agency shall confirm or reverse its first decision within two months of receipt of the decision review request. The reviewed decision and possible findings should be communicated to the relevant parties through the One-Stop Shop.

If the Agency reverses its decision and issues a positive decision, this decision may also include conditions.

If the Agency confirms its initial negative decision, it will provide the applicant with appropriate justifications. The applicant is then entitled to bring an appeal before the Boards of Appeal established under Article 55 of Regulation (EU) 2016/796.

3.7. Stage 4 Boards of Appeal

The procedural rules applicable to an appeal against the Agency decision are detailed in the Commission Implementing Regulation (EU) 2018/867 laying down the rules of procedure of the Board(s) of Appeal of the European Union Agency for Railways.

3.8. Fees and charges

The fees and charges levied by the Agency for the processing of approval application, handling appeals and other services provided by the Agency shall be in accordance with Commission Implementing Regulation (EU) 2018/764 on the fees and charges payable to the Agency and their conditions of payment.

3.9. Transitional provisions

Due to the transitional provisions, there might be requests for authorisation of the placing in service of fixed installations including ERTMS that do not need any approval decision, but that require specific provisions, as stated in Article 55 (5) of Directive (EU) 2016/797 (Interoperability Directive). This, for example, concerns all tendering processes that were not officially awarded to a bidder before 16th June 2019.
In such cases, following Article 55 (5) of Directive (EU) 2016/797 (Interoperability Directive) and then Article 30 (3) of Regulation (EU) 2016/796 (Agency Regulation), if the NSA has identified a risk on interoperability or a lack of technical compatibility between the relevant network(s) and vehicles fitted with ERTMS, the NSA shall inform the Agency. Then the Agency shall cooperate with the NSA, according to these identified risk(s), to ensure that the technical solution is fully interoperable.

3.10. Renewal or upgrading of existing ERTMS trackside subsystems

According to the Article 18 of Directive (EU) 2016/797 (Interoperability Directive), in the event of renewal or upgrading of an already authorised trackside subsystem impacting the ERTMS part, the NSA, in close cooperation with the Agency, shall decide whether a new authorisation for placing in service of the related fixed installations is needed. Some decision criteria can be agreed in advance between the NSA and the Agency to define when such a collaboration is needed.

When a new authorisation is decided, if an approval is also needed, two cases should be distinguished:

- Initial project was subject to a trackside approval process:
  In this case, in order to optimize the new approval, the applicant should submit the documentation already provided in the previous approval and identify the parts of it and the evidences for closing issues that are still valid. The Agency will based the checks on the parts affected by the modifications.

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- Initial project was not subject to a trackside approval process:
  In this situation, in order to optimize the approval, the applicant should identify the ERTMS functions of the trackside subsystems impacted by the renewal(s) or upgrade(s). Based on this, the Agency will assess the parts linked to these modifications.

3.11.   Article 30

The trackside approval decision issued by the Agency may be amended or changed in case new or additional information justifies or requires it (e.g. article 33, 35 of the 2018/C 253/01) by re-submitting a request for the Agency's approval only (This does not apply for error corrections of the Agency).

Issues/findings leading to new trackside approval procedure require that the applicant provides an amendment/update of the existing application file with the new or additional information and/or an additional assessment by the agency according to the relevant parts of the ERTMS trackside approval process.

The accounting of the agencies activities related to article 30 (or more general for all activities described in the guideline) of the 2016/796/EU regulation is made according to the Agencies regulation on fees and charges.

Article 30 (2) of the 2016/796/EU regulates cases which may have a relation or impact on trackside approval issued by the agency. Where, before an authorization is issued by the national safety authority, the Agency becomes aware or is informed by the applicant through the one-stop shop in accordance with Article 19(6) of Directive (EU) 2016/797 that a project design or specification was changed after the Agency had issued an approval in accordance with Article 19 of Directive (EU) 2016/797 and that there is a risk of a lack of technical and operational compatibility between the ERTMS trackside subsystem and vehicles fitted with ERTMS, it shall cooperate with the parties involved, including the applicant and the relevant national safety authority, in order to find a mutually acceptable solution. If no mutually acceptable solution can be found within 1 month of the beginning of the coordination process, the matter shall be referred to the Board of Appeal for arbitration.

Article 30 (3) of the 2016/796/EU regulates cases which may have a relation or impact on trackside approval issued by the agency. Where the Agency finds after an authorization is issued by the national safety authority that there is a risk of a lack of technical or operational compatibility between the relevant networks and vehicles fitted with ERTMS equipment, the national safety authority and the Agency shall cooperate with all parties involved in order to find, without delay, a mutually acceptable solution. The Agency shall inform the Commission about such cases.

Article 55 (5) of the 2016/797/EU regulates cases (mainly in the transition period) which has a relation on trackside approval activities by the agency referring to Article 30 (3) of 2016/796/EU to be applied before an authorization is issued by the national safety authority. In case that before authorising the placing in service of any ERTMS track-side equipment which was not subject to the preauthorisation by the Agency referred to in Article 19, national safety authorities shall cooperate with the Agency in order to ensure that the technical solutions are fully interoperable, in accordance with Articles 30(3) and 31(2) of Regulation (EU) 2016/796.

The cooperation for the subsystem concerned is initiated by the authority that issues the authorization decision. In case of trackside authorization this is the relevant NSA. In case the risk of a lack of technical or operational compatibility between the relevant networks and vehicles fitted with ERTMS is identified by another party involved (e.g. applicant, agency) it shall be addressed to the relevant NSA.

In case that the commonly agreed solution according to article 30 (2) or (3) requires an additional assessment by the Agency, the NSA recommend the applicant to re-submit a request for the Agency's approval.

The additional assessment of the changes or issues will focus on the risk of a lack of technical and operational compatibility identified. In order to be as efficient as possible and to avoid double work the agency will closely cooperate with the relevant NSA. The applicant shall provide a sufficiently detailed description of the changes

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and/or an impact assessment justifying the risk of a lack of technical and operational compatibility identified. Within this documentation it is highly recommended, that the relevant parts of the ERTMS trackside approval decision are identified at least indicating:

- the ERTMS functions concerned (including an proper justification that the other functions are not concerned) and
- the issues from the issue log, the evidences in the issue log concerned (if applicable).

In order to apply the supporting activities regulated in art 30 of the 2016/796/EU and other sources referring to it in a coherent way it is recommended that the close cooperation with the NSA after issuing the decision on approval by the agency continues. It is recommended to exchange e.g. information from the authorisation and supervision activities related to the fulfilment of conditions set in the decision on approval issued by the Agency.

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Appendix A: Issue list

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