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safe railway system without frontiers.

Application guide for the ERTMS trackside approval

Document History

<i>Version</i>	<i>Date</i>	<i>Comments</i>
1.0	14/01/2019	First distributed version
2.0	01/09/2026	Version updated to reflect: - Experience gained from the processing of trackside approval applications and feedback received from applicants. - Comments provided by the Trackside Approval Working Group members. - The outcome of the ERA internal review.

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1. Introduction

The trackside approval process is in place since 2019¹. This document is intended to assist applicants in applying for ERTMS trackside approval and does not create any legal obligations beyond those established by the applicable EU legislation.

New projects within the territory of EU Member States that involve ERTMS equipment (ETCS, GSM-R, FRMCS and/or ATO) shall submit a request for ERTMS trackside approval to the Agency before launching the call for tenders. The Agency's positive decision is required to request an authorisation for the placing in service to the NSA.

The Interoperability Directive (EU) 2016/797 lays down the objectives and general rules for the Agency's approval process under Article 19. The Agency's positive decision is part of the application file for authorisation to place fixed installations including ERTMS in service, according to Article 18(4) of Directive (EU) 2016/797.

The Article 55 of the Interoperability Directive introduces exceptions to the ERTMS trackside approval process due to possible transitional provisions. Given that the process has been in place since June 2019, such exceptions are limited and primarily concern specific contractual options signed before 2016.

In the absence of calls for tenders, trackside approval is not mandatory. For further details on the application of the provisions in Articles 19 and 55 of Directive (EU) 2016/797 in relation to tendering procedures, please refer to the *"Clarification note on application of Article 19 and Article 55 of Directive (EU) 2016/797 in relation to tendering procedures"*, available on the Agency's Trackside Approval webpage.

In June 2018, the European Commission published a Recommendation (2018/C 253/01) clarifying the legal framework to facilitate the approval process. This Recommendation specifies the information to be included in the application file and introduces the main concepts such as the issues list and positive decision with conditions. However, it does not provide detailed procedural guidance.

To support the applicants and to ensure an efficient process, this application guide follows the Directive and the Commission Recommendation. It sets out practical guidelines for an effective approval process, enabling the Agency to take a decision on the ERTMS trackside technical solutions envisaged.

¹ Some Member States extended the transposition period for Directive (EU) 2016/797 on railway interoperability until 31 October 2020, in accordance with Directive (EU) 2020/700.

2. Background information

The so-called “technical pillar” of the Fourth Railway Package introduced relevant and significant changes to the interoperability regulatory framework and revised the Agency Regulation, as well as the Interoperability and Safety Directives. The proposals were presented by the European Commission in January 2013, negotiated by the European Parliament and the Council of the European Union, and adopted with entry into force in April 2016. Member States started transposition in June 2019, with a mandatory deadline set for late October 2020.

Under this legal framework, the Agency is responsible for issuing safety certificates, authorisations for railway vehicles and approvals of ERTMS trackside solutions.

Between 2016 and the submission of the first trackside approval applications, the Agency organised several workshops and meetings with the railway stakeholders to discuss the details of the approval process. In addition, the Agency proposed and conducted learning cases with voluntary Infrastructure Managers and National Safety Authorities. The learning cases aimed to assess the trackside approval process and facilitate understanding prior to the first applications. Many Member States participated and contributed to the issues list and to the overall process definition. The learning cases were closed in June 2019 with the entry into force of the trackside approval process. It was concluded that the functions and issues list is a particularly valuable tool, and the learning cases enabled the Agency to enhance it further by improving existing issues and adding new ones. The functions and issues list can be found in Appendix A as a separate file to this document. The functions and issues list version in force² is published on the Agency’s Trackside Approval webpage.

² The handling of functions and issues list updates during an ongoing application is described in Section 5 of Chapter 4.4.

3. The European legal framework relevant for the ERTMS trackside approval

Directive (EU) 2016/797 on the interoperability of the rail system within the EU (Interoperability Directive) is one of the three legislative acts forming the technical pillar of the 4th Railway Package. It establishes the conditions required to achieve interoperability within the Union rail system. Article 19 (*Harmonised implementation of ERTMS in the Union*) defines the ERTMS trackside approval. According to Article 19, 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 (*Authorisation for the placing in service of fixed installations*) and Article 55 (*Other transitional provisions*).

Regulation (EU) 2016/796 on the European Railway Agency for Railways (Agency Regulation), is also one of the three legislative acts of the technical pillar of the 4th Railway Package. It outlines the Agency's role and responsibilities, including decisions on approvals for the ERTMS trackside technical solutions envisaged. Main relevant articles include Article 22 (*Placing in service of trackside 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 details the notification of an appeal, the Boards 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 establishes the fees and charges payable to the Agency for processing, among other things, the ERTMS trackside approval applications. It specifies 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 provides detailed guidance to facilitate the approval process. It clarifies the legal framework and outlines key elements such as the approval stages, the content of the application file, and the classification of issues.

These documents and, where applicable, their consolidated versions can be accessed from the Agency's Trackside Approval webpage.

4. Trackside approval process

4.1. General provisions

As stated in the Directive (EU) 2016/797, the ERTMS trackside approval is a new task introduced in addition to the authorisation process for the placing in service of fixed installations, the latter remaining under the responsibility of the National Safety Authorities (NSAs). The approval process complements the global process to achieve interoperability in ERTMS trackside projects without changing the roles and responsibilities of NoBos, AsBos, and NSAs defined by the EU legislation.

All verifications performed by the Agency are based solely on documentation submitted in a single and coherent platform, called the One-Stop Shop (OSS).³ No audits or technical visits are performed as part of the trackside approval process.

The scope and planning of the approval process differ significantly from those of NoBo and NSA, avoiding duplication. It applies regardless of the ERTMS maturity level of the projects or applicants. The approval process starts before the call for tenders is launched, as required by Article 19 of the Directive (EU) 2016/797, at a stage when NoBos are generally not yet involved. In practice, the Agency encourages applicants to submit their applications sufficiently in advance, enabling applicants to consider the Agency's feedback on the available information before launching the call for tenders. The control of interoperability must start at the earliest stage of a project as design changes become increasingly costly and cause greater delays as the project progresses. The approval process is successfully completed on time when the applicant demonstrates the interoperability of the ERTMS technical solutions envisaged through documentary evidence submitted at least three months before requesting authorisation to the NSA, ensuring that the Agency's decision is available at the time of the authorisation request.

The approval process can only be positively concluded when all the required documentary evidence is available. Consequently, the duration of the process depends on the timely provision of the relevant detailed information on the ERTMS technical solutions envisaged to be verified by the Agency. Accordingly, initial approvals may take longer, but subsequent ones should be faster by reusing previously approved technical solutions, which should already be available at the tender stage to ensure a harmonised ERTMS deployment.

Applicants are encouraged to avoid, as much as possible, submitting new or different documentation for each project. There is a clear incentive to identify and reuse common parts to prevent unnecessary reassessments. This would ultimately contribute to the deployment of harmonised ERTMS trackside solutions across Europe.

The Agency's checks focus on details of the ERTMS technical solutions envisaged that relate to the CCS TSI. The Agency verifies that the technical solutions include compatible deployment of the ERTMS functions to achieve interoperability by controlling identified interoperability issues.

The approval process provides an opportunity to identify interoperability issues early in trackside projects and to share them with the sector. This ensures that those issues are not repeated in new projects. From the earliest stage, before the call for tenders is launched, such issues must be considered in ERTMS trackside projects. The approval process promotes knowledge sharing and prevents late-stage resolution of common issues in ERTMS trackside projects. Early identification allows stakeholders to react and resolve issues effectively, contributing to an interoperable and efficient ERTMS trackside subsystem.

The ERTMS trackside approval concerns the ERTMS (European Rail Traffic Management System) trackside subsystems, which include⁴:

- › ETCS (European Train Control System) – Class A train protection system;
- › RMR (Railway Mobile Radio system) – Class A radio system, comprising:
 - GSM-R (Global System for Mobile Communications – Railway),

³ Detailed guidance on the use of OSS is provided in the OSS User Guide, which is available on the Agency's Trackside Approval webpage.

⁴ As defined in the §2.2 of Annex 1 of the CCS TSI 2023/1695

- FRMCS (Future Railway Mobile Communication System);
- › ATO (Automated Train Operation) – Class A automation train operation.

When referring to both Class A radio systems, the term RMR system is used. When referring to specific one of these Class A radio systems, the terms GSM-R or FRMCS are used.

Other trackside equipment and their functions such as Class B systems, interlocking, train detection, detectors (e.g., hot axle detectors, wind, fallen objects detectors), marker boards, level crossing, are outside the trackside approval scope. However, their interaction with, and potential impact on, the ERTMS trackside subsystem must be considered, if applicable. Operational and safety considerations, as well as essential requirements not directly covered by the CCS TSI, are also excluded.

4.2. Entities: roles and responsibilities

This section describes the entities involved in the approval process. The only entities directly involved in the ERTMS trackside approval process are applicants, NSAs and the Agency. These entities will make use of OSS throughout the approval process.

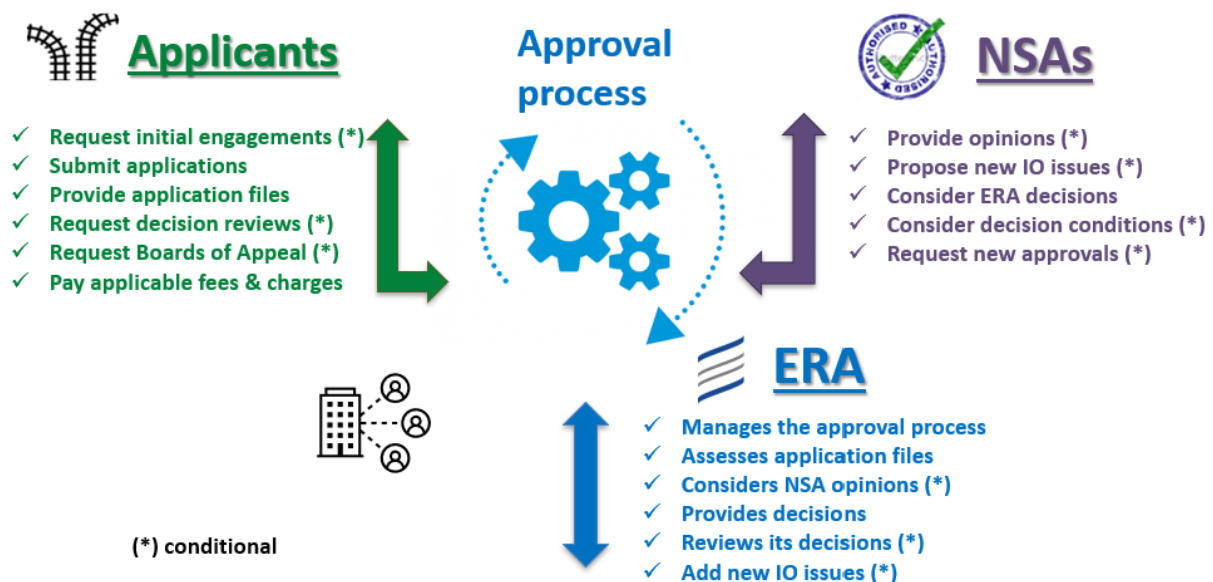


Figure 1: Entities of the approval process

4.2.1. Applicants

There must be only one single legal entity as applicant in each application, even when the application covers several EU Member States.

Following Directive (EU) 2016/797 for the purpose of Article 19, the ‘applicant’ refers to a natural or legal person requesting the Agency’s decision on the approval of the technical solutions envisaged for the ERTMS trackside equipment implementation.

The applicant could be the same as the one requesting the authorisation to the NSA, an Infrastructure Manager, or any natural or legal person best suited to the role, responsibilities, and considering the required information that must be provided and when.

The applicant is responsible for:

- › Submitting initial engagement requests in OSS (optional, but recommended);
- › Submitting applications in OSS, before the call for tenders is launched;
- › Providing complete, accurate and applicable documentation as described in the Application file chapter;

- › Providing in OSS the additional information and clarifications requested by the Agency;
- › Updating the information in OSS when impacting modifications occur or previously provided answers are no more accurate or valid, and informing the Agency accordingly;
- › Paying applicable fees and charges related to the application as defined in the Commission Implementing Regulation (EU) 2018/764.

It is strongly recommended to assign at least one additional applicant user with read-and-write access rights for each application in OSS to ensure adequate backup and continuity in the management of the application. The applicant may also assign additional users, such as observers, with read-only access rights to the OSS application.

The applicant remains solely responsible for the accuracy, completeness, consistency and timely submission of all information provided in OSS.

4.2.2. [NSAs](#)

The NSA can provide opinions and propose interoperability issues before and during the approval process, that the Agency must consider in its decision. The NSA has visibility to the trackside approval applications related to its Member State.

The NSA TA Programme Managers are NSA staff members who have automatic access to all TA applications related to their Member State. They may grant access to NSA observers on an application-by-application basis. It is strongly recommended that each NSA designates at least two Program Managers for trackside approval in OSS to ensure backup coverage.

Before issuing an authorisation for placing in service of fixed installations with ERTMS equipment, the NSA must verify compliance with the Agency's positive decision.

NSAs:

- › May provide opinions on the ERTMS technical solutions envisaged;
- › May propose interoperability issues to be considered by the Agency;
- › Should consider any conditions or remarks in the Agency's decision;
- › Should request the applicant to either request a new approval or apply Article 30(2) of Regulation (EU) 2016/796 if the conditions are not fulfilled, or if the ERTMS trackside technical solutions envisaged have changed.

4.2.3. [Agency](#)

The Agency's verification process primarily relies on the list of functions implemented on the trackside subsystem and the corresponding filtered list of applicable interoperability issues, referred to as the "Issues log". The Agency maintains the list of interoperability issues and updates it whenever new issues arise in ERTMS trackside projects or when issues are deemed relevant to any such projects.

The expected publication date of the next version of the Functions and Issues list will be indicated on the Agency's website once it is known.

In addition to updates to the Functions and Issues List, the Agency may add a specific issue to the application's ongoing issues log whenever an interoperability risk is identified during the assessment of the application file. In such cases the applicant will be duly notified.

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

The Agency is responsible for:

- › Maintaining the issues list;
- › Ensuring that the approval process follows the provisions of Article 19 of the Interoperability Directive and those of this Application guide;
- › Verifying the completeness of the application files;

- › Updating the application issues log when necessary (e.g. as soon as a risk of deviation from CCS TSI specifications is identified);
- › Considering any NSA opinions;
- › Providing trackside approval decisions.

4.3. 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.

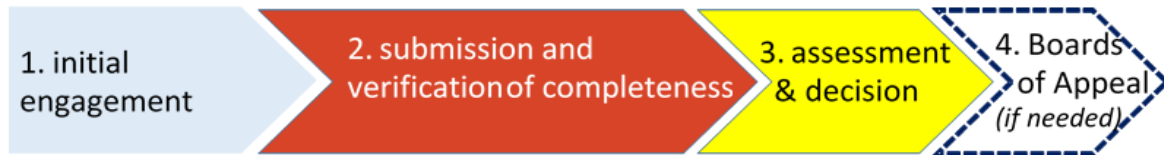


Figure 2 : Overview of the stages of the approval process.

4.3.1. Stage 1 Initial engagement

As set out in the Recommendation 2018/C 253/01, applicants are encouraged to initiate a dialogue with the Agency prior to formal submission of an application. The initial engagement is a non-mandatory but highly recommended stage, which aims to support the preparation of the future applications. For this purpose, the Agency also recommends the participation and the collaboration of the NSAs.

The initial engagement is initiated at the applicant's request, submitted in OSS, to inform the Agency of an upcoming call for ERTMS trackside tenders.

The initial engagement facilitates the preparation of the application and, where necessary, clarifies the approval process. However, it does not involve any assessment activities. It also provides the Agency with advance notice of forthcoming TA applications. The Agency will not charge the applicant for the time or the related costs incurred during this stage. Nevertheless, this stage should normally be limited to one or two meetings.

The initial engagement is usually performed through video conference meetings. The Agency prepares and shares the meeting minutes. The meeting minutes are recorded in the related initial engagement request in OSS.

At the beginning of the initial engagement, the applicant presents the project, its planning, including relevant design, implementation, testing and authorisation milestones, as well as available information on the ERTMS technical solutions envisaged.

Based on this information, the submission strategy, covering the number of approval requests and the scope of each, will be discussed with all participants, taking into account any opinions from the NSA. This submission strategy, which may be adapted during the approval process, should be agreed upon and included in the minutes of meeting.

A preliminary approval schedule will also be discussed to define the approval milestones, especially the deadline that should be linked to a project milestone. This will enable efficient planning of the necessary checks and allow for adjustments in case of potential project delays.

The Agency may also present the Functions and Issues List and provide preliminary information on any planned updates. This initial engagement aims to:

- › Ensure a good understanding by the applicant of the approval process;
- › Agree on the submission strategy;
- › Identify previous approvals from which some parts may be reused;
- › Agree on a preliminary approval schedule.

The initial engagement stage concludes upon submission of the related request for approval.

4.3.2. Stage 2 Submission and verification of completeness

The aim of this stage is to verify whether the application is complete. Each request for approval shall be submitted by the applicant through OSS before any call for tenders relating to ERTMS trackside equipment. As already stated in a previous chapter, exceptions may apply under transitional provisions (refer to Chapter 5) and therefore some projects subject to approval may have already launched calls for tenders or even already contracted suppliers before submitting a request for approval.

This stage starts when the request for approval is submitted in OSS. Prior to submission, the applicant prepares the application by uploading new documents or retrieving documents from other applications in OSS and adding comments. Once the draft application is ready, the applicant can submit it, allowing the Agency to start the verification process. Before submission, the Agency does not have access to the application.

Once the application has been submitted, the applicant may share it with additional users, granting either read-only or read-write access rights. There is no technical limitation on whether these users belong to the same organisation or not. However, access rights are granted under the applicant's responsibility. It is strongly recommended to assign at least one additional user with read-write access rights as a backup.

At submission, all application file items should be completed with the information available at that time. If some information is missing or expected to change, it should be indicated in the relevant comments section of the OSS mapping table so that some assessments can be postponed to a more appropriate date.

Within one month of the application's submission, the Agency will notify the applicant in OSS regarding its completeness.

If the application file is not complete at submission, the approval process continues beyond the tender phase until a reasonable deadline. The applicant can then provide the missing information by that deadline. However, any missing information should be submitted as soon as it is available in order to ensure that any necessary modifications can be considered at the earliest stage of the project and to minimise the risk of reaching the deadline with an incomplete application.

The deadline will be the one agreed during the initial engagement stage and should be aligned with the information provided in the application file item 3 (planning). If no initial engagement was performed, the Agency will determine a reasonable deadline based only on the planning information provided in the application file item 3. The deadline should be set at the latest 3 months before the authorisation request to the NSA, ensuring that the Agency's decision is available at the time of the authorisation request. The deadline should be linked to project milestones, so if there are project delays, the deadline is delayed accordingly.

When the application is incomplete, the Agency provides intermediate feedback, specifying the missing information, to help applicants achieve completeness before the deadline and avoid late corrections that could delay project implementation. The Agency's feedback can be considered in the next relevant change to the project's ERTMS technical solutions. Applicants are therefore encouraged to communicate planned updates to the application file.

The Agency's feedback, including clarifications, requests for additional information, or actions, will be provided through "application issues" in OSS. These application issues may allow applicants to update the relevant items in the mapping table, which are otherwise locked after submission.

The information considered by the Agency will also be identified in application issue reports. Where necessary, the applicant may be requested to respond to clarification requests identified in these reports by issuing a revised version to be uploaded in OSS. Additional guidance on updating the application file using application issues in OSS is available in a tutorial published on the Agency's Trackside Approval webpage.

To optimize the application, the applicant is encouraged to identify any common parts (i.e. same applicable documentation and/or same applicable requirements) with previously submitted approvals. The OSS platform allows to reuse documents from other applications and automatically identifies the source application.

If necessary, an application may be split during this stage to adjust the scope and planning to the project evolution. This may be achieved by submitting one or more new applications covering part of the scope of the initial application, while reducing the scope of the latter. In such cases, a delta approach can be applied between the resulting applications. Conversely, if relevant considering the plannings and similar technical solutions, several applications may be merged into a single application. This may be achieved by terminating the relevant applications and updating the scope of the remaining application to incorporate them.

Dedicated meetings may be organized at the request of ERA or the Applicant to address any questions related to trackside approval process, including the Functions and Issues list. No assessments will be conducted during these meetings.

An application is considered complete when all information in the application file is accurate, relevant and consistent, with no discrepancies, no pending clarifications, and all issues in the issues log are closed.

The Assessment and decision stage starts either at the deadline or when the application file is complete. The Agency will then proceed to deliver the decision.

The following figure illustrates the application timeline for both scenarios: when the application reaches completeness before the deadline and when the deadline is reached before the application is deemed complete.

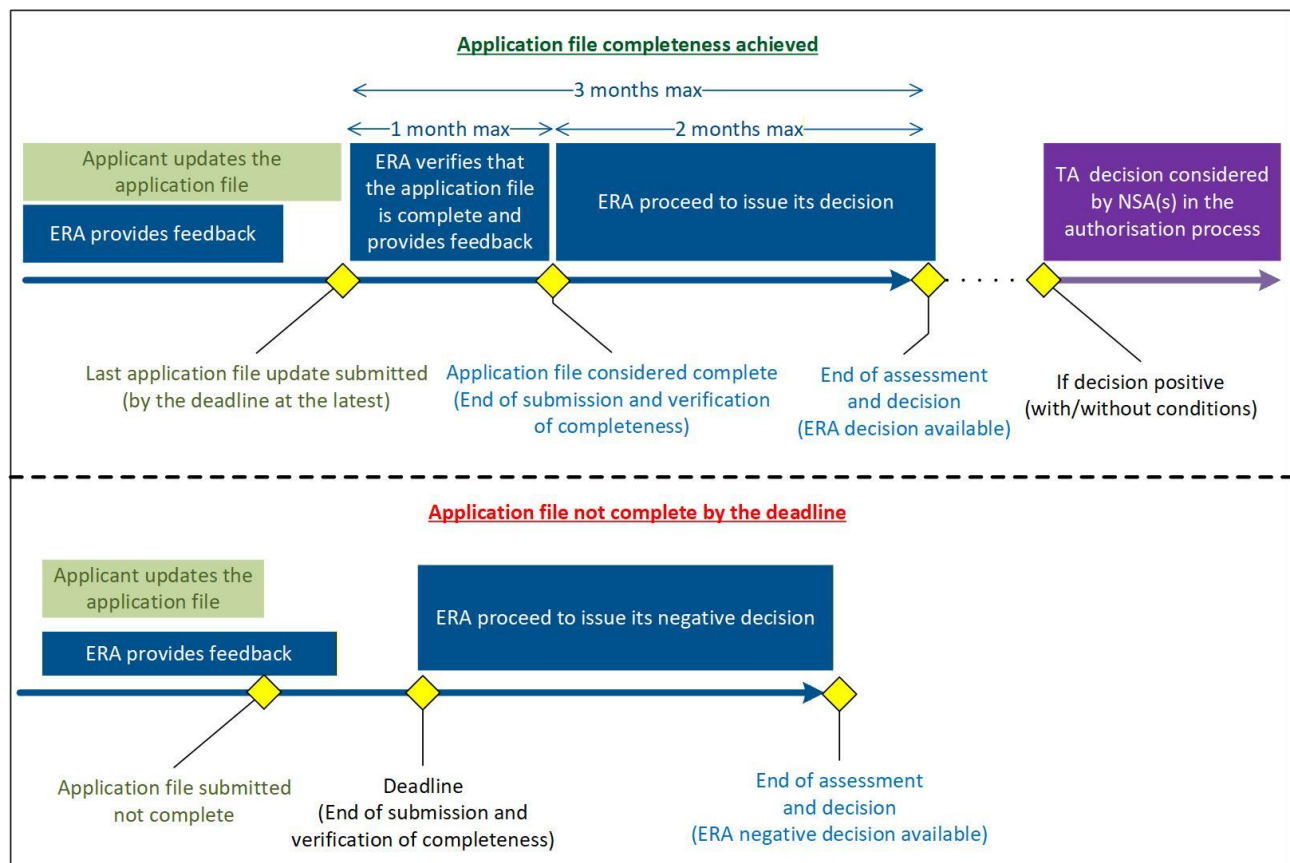


Figure 3 : Application timeline

The applicant may terminate the application in OSS at any time during the submission and verification of completeness stage (e.g. if the project is cancelled).

The NSA can issue an opinion at any moment during the submission and verification of completeness stage, by contacting the Agency.

4.3.3. Stage 3 Assessment and decision

The assessment and decision stage follows the conclusion of the submission and verification of completeness stage. It starts either when the Agency notifies the applicant that the application is considered complete or at the deadline, whichever occurs first. The Agency will deliver its decision within two months, based on the application file and any NSA opinions.

The Agency's decision may be either positive, with or without conditions, or negative. The decision, available in OSS, contains relevant information such as the application scope, a summary of the interoperability issues status, and any conditions to be considered. Since the decision is based on the submitted documents, these are listed in the decision. The decision will also reference NSA opinions, if any.

Positive decision

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

- › All documentary evidence has been provided in OSS by the deadline at the latest (the application file is considered "complete");
- › The issues log(s) has been concluded with all issues "Closed" or "Closed with conditions".

The positive decision may include conditions 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 considered "not complete" at the deadline;
- › One or more issues of the issues log(s) have the status "Issue closed but unacceptable".

If the applicant agrees with the negative decision, they may submit a new approval request including the necessary corrections. The applicant may resubmit documentation already provided in the previous application, clearly identifying the parts that remain valid and not impacted by corrections.

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

Decision review

The decision review request must be submitted by the applicant in OSS. The request must include justifications related to the parts that the applicant considers having not been properly assessed.

The Agency shall then confirm or reverse its initial decision within two months of reception of the decision review request. The reviewed decision, that may be positive with conditions, will be available in OSS.

If the Agency confirms its 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.

4.3.4. 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 Boards of Appeal of the European Union Agency for Railways.

4.4. **Application file**

This chapter lists and describes the information required in the application file that enables the Agency to issue an approval decision in compliance with the Article 19 of Directive (EU) 2016/797.

The applicant must upload in the OSS all the documents describing the envisaged ERTMS technical solutions and covering the application file items outlined in this chapter. Hyperlinks to documents stored elsewhere should be avoided.

The applicant shall provide, in the “Documentary evidence” section of the OSS mapping table, documents applicable to the project (such as tender, contractual or project technical specifications) rather than documents created solely for trackside approval, except for application file items 4 & 5. All documents may be submitted in English or in any official language of an EU Member State.

To ensure an efficient trackside approval process, documentary evidence must be clearly and accurately identified using the documents reference, version, filename, and any relevant sections, as applicable. Comments may be provided to facilitate understanding of the status of the documents provided and to include any additional useful information. However, the verification of the information provided is based on documentary evidence, not on comments.

The documents referenced in the OSS mapping table are considered documents applicable to the project, with which the ERTMS technical solution envisaged must comply. The approval decision is based on these documents that are listed within the decision and visible to the NSA.

It is the responsibility of the applicant to ensure that the information provided is applicable to the application scope and up to date. In case the documentary evidence provided is modified or not valid anymore, the applicant must inform the Agency thereof and perform the relevant updates in OSS.

The application file comprises the following 14 items:

1- Application scope description (Project description)

The application may cover a network, individual lines, sections of lines and may relate to one or more projects. It is the applicant’s responsibility to define the most appropriate application scope. The initial engagement phase is intended to establish an efficient submission strategy.

The information provided should be sufficient to clearly define the complete application scope and should include:

- › The application scope: ETCS, GSM-R, FRMCS, and/or ATO;
- › The application geographical scope: the information provided should indicate clearly the geographical boundaries. Identification of all geographical limits can be done through kilometre points on the relevant lines, signals (located on lines or at stations), stations (with reference to entry/exit points or signals), GPS data, etc. This information should enable the NSA to verify that the application geographical scope covers the scope of the authorisation request;
- › Identification of any parts located at country borders;
- › The description of the planned actions (main interventions) together with the components and systems to be installed;
- › When the application scope includes ETCS, the authorised ETCS levels and their priority order for all level transitions (i.e. details of packets 41/46), for all directions, inside the geographical scope and at its boundaries. Any temporary ETCS level transitions ordered by the trackside must be also detailed;
- › When the application includes RMR (GSM-R or FRMCS):
 - the intended use: voice or data (for ETCS or ATO, in Circuit or Packet Switched mode);
 - any planned additional functionalities than the mandatory ones from the EU legislation;
 - in case of tunnels of more than 1 km: if repeaters are already installed or planned to be installed to ensure sufficient coverage.
- › Description of any specific infrastructure elements that impact or directly interface to the ERTMS technical solutions, such as level crossings or detectors (e.g., failing object, wind, hot axle box, fire detection);
- › The applicable Interoperability Constituents;

- › Any parts of the application scope that include Class B subsystems and whether they will remain in operation during the ERTMS implementation, testing or after the placing in service;
- › Any temporary migration phases planned during the project execution and the number of authorisations requests planned;
- › In case a delta approach with ERTMS parts already authorised is requested to be applied: a clear identification of the parts concerned, the related authorisations (delivered in item 9) and the detailed description of the planned ERTMS modifications.

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

The information provided for item 2 must include:

- › The CCS TSI version, including any amendments, planned to be applied for the 'EC' verification of the ERTMS parts of the trackside CCS subsystem;
- › Any planned exemption from the application of the CCS TSI or parts of it. The available evidence must be provided under the item 13;
- › The applicable set of specifications;
- › When the application includes ETCS, the highest ETCS system version;
- › The RMR baseline, if applicable;
- › The Agency opinion on Error correction to the CCS TSI considered;
- › The Baseline Compatibility Assessments considered;
- › Any provisions during the project execution and maintenance phase to consider updates of the ERTMS specifications, detected interoperability issues, new Agency opinions on error correction to the CCS TSI or Baseline Compatibility Assessments and mitigation measures.

Note that all parts of the documents applicable to the project that refer to the CCS TSI or parts of it and any other EU legislation related to ERTMS should be referenced in the item 2.

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

The planning information, that should cover the entire application scope, is needed to ensure efficiency and coherence with approval planning, to prevent impacts on solution deployment and authorisation.

The planning information does not need to include extensive details, but only relevant milestones related to call for tenders, contract award, design stages, installation, verification and validation phases, EC certification and authorisation requests to the NSA. The planning information should help identify the main application file deliveries and updates related to the design of the ERTMS technical solutions envisaged before it is implemented and tested.

The Agency will either consider the reasonable deadline agreed upon during the initial engagement or, if no initial engagement took place, establish a reasonable deadline based on the information provided in this item.

It is the responsibility of the applicant to update the planning when the relevant milestones dates are modified. The Agency may request planning updates if the information provided is considered incoherent or insufficient.

4- List of ERTMS functions to implement

The item 4 refers to the list of functions planned to be implemented. The applicant must identify the functions included in the ERTMS technical solutions envisaged, using the version in force of the functions and issues list template, published on the Agency's Trackside Approval webpage. The list of functions implemented, defines the approval technical scope and determines the applicable interoperability issues, "the issues log", from the issues list (item 5).

Depending on the complexity and diversity of the ERTMS technical solutions envisaged, or when different project phases involve different sets of functions or functions subject to different requirements, it may be necessary to use multiple functions lists. Each list must clearly specify the geographical scope or phases it covers.

The answers provided in the functions list are considered as an applicant declaration. It is the applicant's responsibility to ensure that the answers are accurate and kept up to date. The Agency does not carry out any formal verification of these answers. However, any inconsistencies identified in the functions list may lead to requests for clarification.

In case the implementation of functions is not yet decided, these functions should be left unanswered with a comment indicating that the answer will be provided in a future version of the functions list.

Although not mandatory, it is recommended to establish traceability, as far as possible, between the answers provided and the project's technical documentation. This should ensure the correct configuration of the functions list and facilitate efficient updates in case of modifications.

Only the functions list and issues log file, including the latest applicable answers to the functions, must be referenced in the item 4 of the OSS mapping table.

5- Demonstration that the risks impacting interoperability have been addressed

The applicant must demonstrate that interoperability issues are properly addressed and effectively controlled using the functions and issues list template version in force, published on the Agency's Trackside Approval webpage.

Based on the answers provided in the functions list (item 4), the issues list is filtered to include only the interoperability issues relevant to the functions planned for implementation. This filtered issues list is referred to as the "issues log".

For each issue in the issues log, the applicant must provide documentary evidence demonstrating that the issue is controlled. The documentary evidence must be based on the design requirements of the ERTMS technical solutions envisaged and must be clearly and accurately identified using the documents reference, version, filename, and any relevant sections, as applicable. When reusing a demonstration from another application, the same response and supporting documentation must be provided, along with the OSS identification of the original application.

If some documentary evidence is not yet available, the related part of the concerned issues should be left empty, and a comment should indicate that these issues will be addressed in a future version of the issues log.

If the documentary evidence provided for an issue does not demonstrate that it is properly controlled, the issue will remain in "Query" status, and the Agency will explicitly request the necessary additional information. In such cases, the applicant must update the issues log with the missing information in a new version, while preserving the history of previous answers.

The possible issues statuses are:

- › Query: indicates that it is not clear how the issue is controlled and will be resolved, and the applicant is expected to provide evidence addressing the issue. Every issue will have by default the "Query" status in the issues log.
- › Closed: if the applicant has provided satisfactory evidence demonstrating that the issue is under control.
- › Closed but unacceptable: the issue is closed, but a non-conformity with the CCS TSI has been identified that requires an amendment of the application file and is not covered by an exemption from the application of the relevant CCS TSI provisions. The Agency will notify the applicant of the non-conformity. If it is not addressed, the Agency will issue a negative decision.
- › Closed with conditions: the issue is closed under conditions. These conditions will be explicitly included in the decision and should be considered by the NSA.

As there is one issues log for each functions list, an application may have several issues logs (refer to the previous section 4). Only the issues log(s) containing the latest applicable answers must be referenced in Item 5 of the OSS mapping table.

If a new version of the Functions and Issues list is published during the approval process, the Agency will perform an impact analysis on the ongoing issues log(s) and will then apply or propose the most efficient migration strategy.

Up to the application deadline, the Agency may include additional issues in the issues log based on:

- › Any issues suggested by the applicant or by the NSA;
- › Any new version of the functions and issues list;
- › Any possible deviations from the CCS TSI detected.

To prevent recurrence of known interoperability issues, applicants should inform the Agency of any interoperability problems encountered during the implementation or operation of ERTMS projects.

6- Engineering rules and operational test scenarios

The item 6 must include all documents referenced in the issues log to demonstrate control of the applicable issues. These documents should include the engineering rules and requirements applied in the design of the ERTMS technical solutions envisaged. The requirements provided should correspond to those implemented during the project and be considered for the EC verification process of the trackside ERTMS subsystem.

7- Test strategy and test plan

The global test strategy and test plan information should identify the relevant ERTMS test phases (in laboratory and on-site), responsible entities, test environment, test objectives and stages (before installation, subsystems integration, subsystems verification, before authorisation, after authorisation, etc.). Test cases and test results should not be provided.

Evidence must be provided that the operational tests scenarios are planned to be performed with at least two certified CCS on-board subsystems from different suppliers.

If the application scope includes RMR, evidence must be also provided that on-site measurements of the RMR coverage are planned.

There is no specific template for the test strategy and test plan, documents applicable to the project should be provided.

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

This item refers to any conditions or constraints beyond those required for CCS TSI conformity.

The following information must be provided for item 8:

- › any specific constraints, restrictions or conditions of use related to the ERTMS part that the vehicles must consider for operation on the approval scope;
- › any specific constraints, restrictions or conditions of use on the trackside ERTMS technical solutions exported or imposed by the vehicles intended to operate on it;
- › any new envisaged national technical rules (as defined in Article 2(30) and Article 13 of Directive (EU) 2016/797) related to ERTMS that must be considered on the approval scope.

The examination of national rules is not part of the trackside approval scope, it is addressed under Article 26 of the Agency Regulation.

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

When an applicant requests a trackside approval including envisaged modifications of an already authorised ERTMS trackside subsystem (i.e. a delta approach is requested), item 9 must include the previous related ERTMS trackside authorisations delivered by the NSA.

Any NSA opinions on the approval request issued prior to the submission of the application must be also included in this item.

An NSA intending to issue opinions during the trackside approval process must contact the Agency.

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

As required in Article 19 of the Directive (EU) 2016/797, the applicant should submit, if available during the approval process, the EC Certificates and EC Declarations of conformity for the interoperability constituents planned to be included in the ERTMS technical solutions envisaged. The absence or incompleteness of documentary evidence for this item does not prevent the application from proceeding to the decision stage.

The EC Certificates and EC Declarations of conformity of the interoperability constituents shall be included in the application for authorisation to the NSA.

11- EC Certificates and EC Declarations of verification of the trackside subsystem

As required in Article 19 of the Directive (EU) 2016/797, the applicant should submit, if available during the approval process, the EC Certificates and EC Declarations of verification of compliance to the TSI of the subsystem planned to be included in the ERTMS technical solutions envisaged. The absence or incompleteness of documentary evidence for this item does not prevent the application from proceeding to the decision stage.

The EC Certificates and EC Declaration of verification of the trackside CCS subsystem shall be included in the application for authorisation to the NSA.

12- National rules related to ERTMS that must be considered in the application scope

The applicant should submit any new envisaged national technical rules (as defined in Article 2(30) and Article 13 of Directive (EU) 2016/797), related to ERTMS that must be considered in the application scope.

The examination of national rules is not part of the trackside approval scope, it is addressed under Article 26 of the Agency regulation.

13- Exemption from the application of one or more TSIs or parts of them

The evidence related to the CCS TSI version (including amendments, if any) planned to be applied for the ERTMS subsystem verification must be provided in item 2.

In item 13, the applicant should submit any documents issued by the Member State or the European Commission, granting a derogation from applying a CCS TSI or parts of it, in accordance with Article 7 of Directive (EU) 2016/797, where relevant to the scope of the application.

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

14- Previous ERTMS trackside approval(s) identification

The comments section of the item 14 in the OSS mapping table may be used to indicate the OSS ID of other applications from which documentary evidence is reused.

The approval process encourages the standardisation of proven ERTMS technical solutions. Therefore, the applicant may reuse parts of the application file from previously submitted trackside approval requests, provided they are also applicable to the scope of the new application.

The applicant must indicate the previous trackside approvals and clearly identify within the relevant items, which parts of the reused documentation apply. These common parts will not be re-verified by the Agency.

New approval requests following a negative decision, including subsequent corrections, should re-use unchanged parts that were previously assessed positively.

4.5. Fees and charges

The fees and charges levied by the Agency for the processing of trackside approval applications, handling appeals, and other services (including delivery of Vehicle Authorisations and Single Safety Certificates) shall comply with the Commission Implementing Regulation (EU) 2018/764, as amended, which sets out the fees and charges payable to the Agency and their conditions of payment.

The applicable fixed fees and hourly rate are those in effect at the time the application was submitted.

The applicant may request an estimate of the fees and charges related to the application. This estimate, provided by the Agency, is non-binding and based on experience with similar applications. The final amount may vary significantly, as it depends on the time required to process the application, which is directly linked to the quality and completeness of the submitted information. At the applicant's request, if the actual costs risk exceeding the estimate by more than 15%, the Agency will inform the applicant accordingly.

The Agency may invoice interim amounts every 6 months, provided the accumulated amount is considered sufficient.

5. 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. This may concern, for example, tendering phases that had been officially completed prior to the applicable transposition date in the relevant Member State (16 June 2019, 16 June 2020 or 31 October 2020, as applicable, pursuant to Directive (EU) 2016/797 and Directive (EU) 2020/700). In such cases, following Article 55(5) of Directive (EU) 2016/797 and then Article 30(3) of Regulation (EU) 2016/796, if a lack of technical compatibility between the relevant networks and vehicles fitted with ERTMS has been identified, the NSA should inform the Agency with the related details. Then the Agency shall cooperate with the NSA, considering these identified risks, to ensure that the technical solution is fully interoperable.

6. Renewal or upgrading of existing ERTMS trackside subsystems

According to the Article 18 of Directive (EU) 2016/797, 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 the placing in service of the related fixed installations is needed. Some decision criteria may be agreed in advance between the NSA and the Agency to define when such a collaboration is needed.

Where the NSA decides no new authorisation is needed, such projects do not require ERTMS trackside approval. For further details, refer to the *“ERA1210-001 Clarification on approval only with authorisation after renewal or upgrade of ERTMS”* available on the Agency’s Trackside Approval webpage.

7. Article 30 of the Agency regulation

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. Articles 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.

Agency's activities related to Article 30 of the Regulation (EU) 2016/796/EU (or more general for all activities described in the guideline) are carried out in accordance with the applicable 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 authorisation is issued by the NSA, the Agency becomes aware or is informed by the applicant through OSS 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 NSA, 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 authorisation is issued by the NSA that there is a risk of a lack of technical or operational compatibility between the relevant networks and vehicles fitted with ERTMS equipment, the NSA and the Agency shall cooperate with all parties involved 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 authorisation is issued by the NSA. In case that before authorising the placing in service of any ERTMS trackside equipment which was not subject to the preauthorisation by the Agency referred to in Article 19, NSAs shall cooperate with the Agency 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 authorisation decision. In case of trackside authorisation 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 or Agency) it shall be addressed to the relevant NSA.

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

The additional assessment will focus on the risk of a lack of technical and operational compatibility identified. For the sake of efficiency, the Agency will closely cooperate with the relevant NSA. The applicant shall provide a sufficiently detailed description of the changes and/or an impact assessment justifying the identified risk of a lack of technical and operational compatibility. Within this documentation, at least the following parts of the ERTMS trackside approval decision should be identified:

- the ERTMS functions concerned (including a proper justification that the other functions are not concerned) and
- the related interoperability issues from the issues log and their mitigation evidence (if applicable).

To apply the supporting activities regulated in Article 30 of the 2016/796/EU and other sources referring to it in a coherent way it is recommended that 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.

Appendix A: Functions and issues list

The version of the Functions and issues list in force is published on the Agency's Trackside Approval webpage.