

**Guidance for safety  
certification and  
supervision**



# **Application guide for the granting of single safety certificates**

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**Guidance for safety certification and supervision**

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# 1. Introduction

Railway undertakings and infrastructure managers bear the full responsibility for the safe operation of the railway system and the control of risks associated with it, each in relation to its own part of the system. The establishment of a safety management system is identified as the appropriate way to fulfil this responsibility.

The single safety certificate gives evidence that the railway undertaking has established its safety management system and is able to comply with the legal obligations as referred to in Article 10(3) of [Directive \(EU\) 2016/798](#).

Access to the railway infrastructure should be granted only to railway undertakings that hold a valid single safety certificate.

The single safety certificate is valid for a given area of operation, i.e. a network or networks within one or more Member States where the railway undertaking intends to operate.

Depending on the area of operation, the issuing authority (also named hereafter 'the safety certification body') can be either the European Union Agency for Railways (also named hereafter 'the Agency') or the competent national safety authority. For ease of reading and unless stated otherwise, the case where the Agency is responsible for issuing the single safety certificates is used as a basis for the guidance in this document. This includes collaboration with one or more national safety authorities, dependent on the area of operation. However, the same guidelines apply in the case where the application for a single safety certificate is addressed to a national safety authority.

This guidance document is a living document that has been developed in collaboration with national safety authorities and sector representatives. It is intended to be continually improved based on the feedback of users and taking into account the experience gained during the implementation of [Directive \(EU\) 2016/798](#) and relevant Union law.

## 1.1. Purpose of the guide

This Guidance provides information for both National Safety Authorities and Applicants on the process and matters to be aware of. It is to be read in conjunction with the Guidance on the Agency website on the use of the One Stop Shop. Templates and forms referred to in the present document are available in the one-stop shop.

It describes in particular:

- ▶ The conditions of application for a single safety certificate;
- ▶ The process for the application for a single safety certificate;
- ▶ The structure and content of the application file to be submitted by the railway undertaking;
- ▶ The details of the safety assessment;
- ▶ The conditions for updating or renewing a single safety certificate;

- ▶ The conditions for reviewing and appealing decisions; and
- ▶ The conditions for restricting or revoking a single safety certificate.

### 1.2. Who is this guide for?

This document is addressed to the railway undertakings (also named hereinafter the 'applicant') who want to submit an application for a single safety certificate as well as to the Agency and the national safety authorities when undertaking the safety assessment of safety certificate applications.

### 1.3. Scope

This document provides detailed practical information that is primarily intended to support applicants and authorities in understanding the requirements regarding single safety certificates, as stipulated in the European legal framework. This guide is supplemented by:

The application guides of the national safety authorities.

The national safety authority guide should describe and explain the national procedural rules, including the documents to be submitted by the applicant to demonstrate compliance with the national rules, the applicable language policy of the national safety authority (or the Member State) and further information about appeals against national safety authority decisions.

The Guide and the Tutorials on the use of the One Stop Shop available on the Agency Website.

Clarification Notes on the Safety Assessment Process for Single Safety Certificates published on the Agency website.

Applicants are advised to read the relevant National Guides carefully and to contact the relevant National Safety Authorities for advice on the evidence required to meet the national requirements.

For cross border stations information can be found on the Agency website, in addition, a consultation on the current position regarding this subject with appropriate NSA's is also strongly advised.

In all cases an applicant who contacts the NSA and who is considering making an application to the Agency should be advised to Contact the Agency via the Contact form on the Website to discuss the potential plans and the timescale for the application. The purpose of this discussion is to aid both the Agency and the applicant in planning the application and to avoid the applicant making errors in the application which require the application to be closed and resubmitted.

For more detailed information on how to comply with specific safety management system requirements applicants and authorities should consult the SMS Requirements Guide available on the ERA website.

#### 1.4. Guidance structure

This document covers the granting of single safety certificate. It is also part of the Agency compendium of guidance supporting railway undertakings, infrastructure managers, national safety authorities and the Agency, in fulfilling their roles and undertaking their tasks in accordance with [Directive \(EU\) 2016/798](#). The information published in this guide is supplemented by other guidance to be developed by the national safety authorities, as mentioned above.

Figure 1: Compendium of Agency guidance





### 1.5. European legal framework

[Directive \(EU\) 2016/798 on railway safety \(Railway Safety Directive\)](#) is one of the three legislative acts that form the technical pillar of the 4th Railway Package. Among its aims is the simplification and harmonisation of the safety assessment process to benefit the applicants who apply for a single safety certificate. This will help to reduce the burden and costs being borne by the applicants, irrespective of the intended area of operation and of the authority responsible for issuing the single safety certificate.

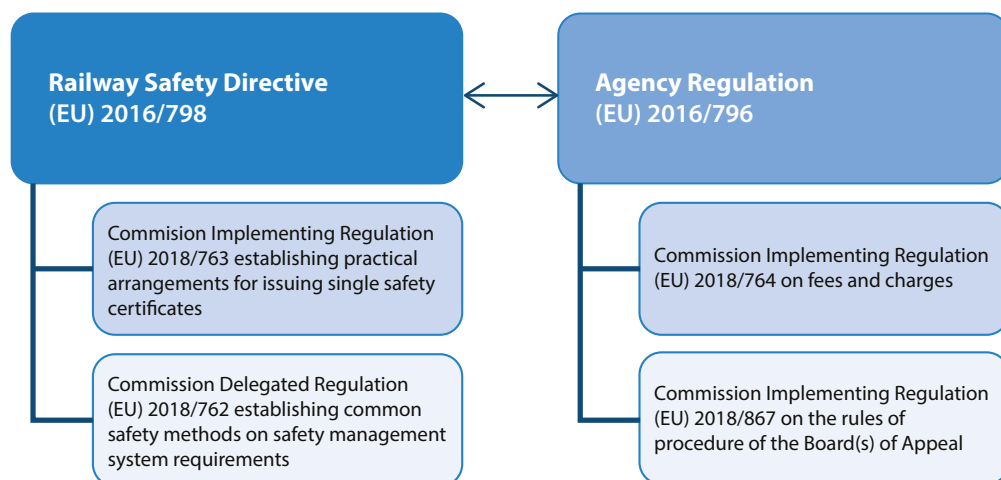
In accordance with [Directive \(EU\) 2016/798](#), the purpose of the single safety certificate is to provide evidence that the railway undertaking:

Has established its safety management system as stipulated in Article 9 of [Directive \(EU\) 2016/798](#);

- Meets the requirements laid down in the relevant notified national rules; and
- Is able to operate safely.

The European legal framework relevant for the granting of single safety certificates is summarised in Figure 2 below.

Figure 2: Overview of the European legal framework



[Regulation \(EU\) 2016/796 on the European Railway Agency for Railways \(Agency Regulation\)](#), being one of the other two legislative acts of the technical pillar of the 4th Railway Package, describes, among other things, the role and responsibilities of the Agency in relation to the granting of single safety certificates.

[Commission Implementing Regulation \(EU\) 2018/763](#) establishing practical arrangements for issuing single safety certificates further increases harmonisation of the approach to safety certification at Union level and fosters collaboration among all the parties involved in the safety assessment process. It therefore clarifies the responsibilities of the Agency, the national safety authorities and the applicant and sets out the provisions necessary for smooth cooperation between them. Annex II of this Regulation provides a structured and auditable

process that ensures that the competent authorities (i.e. the Agency and the national safety authorities) take similar decisions in similar circumstances and that there is a degree of assurance that the assessment process is undertaken in a similar way by all authorities.

[Commission Delegated Regulation \(EU\) 2018/762](#) establishing common safety methods on safety management system requirements (also named hereafter 'the CSMs on SMS') provides in its Annex I the requirements to be evaluated by the competent authorities to assess the relevance, consistency and adequacy of the railway undertaking's SMS. In addition, the applicant for the single safety certificate has to provide evidence in its application file that it complies with these requirements.

[Commission Implementing Regulation \(EU\) 2018/764](#) as amended by Commission Implementing Regulation (EU) 2021/1903 lays down the fees and charges payable to the Agency and their conditions of payment, in particular:

- ▶ Fees and charges levied by the Agency for applications addressed to the Agency, including the costs for tasks assigned to the national safety authority; and
- ▶ Charges for services offered by the Agency.
- ▶ The possibility of a discount for Small and Medium Sized Enterprises
- ▶ Fees and charges levied by the national safety authority for domestic applications addressed to it are outside the scope of the above Regulation and therefore, are regulated at national level.

[Commission Implementing Regulation \(EU\) 2018/867](#) lays down the rules of procedure of the Board(s) of Appeal of the Agency. These Rules describe namely the procedure applied during an appeal or arbitration case relating to the Agency issuing the single safety certificate. They provide details on the lodging of an appeal, the Board(s) of Appeal's workings and voting rules, the conditions for reimbursement of expenses of their members, etc.

## 2. Conditions of application for a single safety certificate

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Directive (EU) 2016/798 applies to the rail system in the Member States and requires a railway undertaking to hold a single safety certificate in order to obtain access to the railway infrastructure of one or more Member States, according to its declared area of operation.

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The railway undertakings whose principal business is to transport goods and/or passengers, whether or not their activities are limited to providing traction only, shall have a licence according to [Directive 2012/34/EU](#). For these railway undertakings, possession of a valid licence and a single safety certificate are the conditions to be met before being granted access to the railway infrastructure. An applicant must in some cases have both the licence and the single safety certificate to start operation, however, it is not required that the applicant already has a licence **before** they apply for a single safety certificate or vice versa **both** processes can be conducted in parallel. However, both processes must be completed before services can start.

The provisions of [Directive \(EU\) 2016/798](#) are valid only for those railway companies that fall within its scope. Whether a particular operation falls within the scope of the Directive depends on how this Directive has been transposed in the Member States. Member States may identify exclusions from the scope of [Directive \(EU\) 2016/798](#) and therefore a single safety certificate may not be needed in the following cases:

- (a) *privately owned railway infrastructure, including sidings, used by the owner or by an operator for the purpose of their respective freight activities or for the transport of persons for non-commercial purposes, and vehicles used exclusively on such infrastructure;*
- (b) *infrastructure and vehicles reserved for strictly local, historical or tourist use;*
- (c) *light rail infrastructure occasionally used by heavy rail vehicles under the operational conditions of the light rail system, where it is necessary for the purposes of connectivity of those vehicles only; and*
- (d) *vehicles primarily used on light rail infrastructure but equipped with some heavy rail components necessary to enable transit to be effected on a confined and limited section of heavy rail infrastructure for connectivity purposes only.*

National safety authorities are asked to state and explain in their respective application guides whether any of the above exclusions are applicable in their Member States. Railway Undertakings are advised to consult with national safety authorities in order to understand what applies to their particular circumstances. Shunting services may or may not require a single safety certificate depending on whether they fall into (a) above or not (a question of the transposition in each member state). If they do it is important that in the one stop shop the applicant is clear as to whether they intend to operate freight services and shunting services in which case, they must select freight services or 'shunting only' in which case they select this tab in the one stop shop.

It may happen that, for the intended area of operation covering more than one member state, the exclusions established by the relevant Member State(s) are not the same. For example, operations in sidings on privately owned railway infrastructure may be excluded from the scope of [Directive \(EU\) 2016/798](#) in one Member State but not in another Member State. In such cases it is important that the railway undertaking describes and explains in its application the type(s) of operation in each Member State and where it intends to operate, detailing also any specific national requirements related to the type(s) of operation where relevant (see also point 2.6 in Annex I).

In any case, the application for a single safety certificate must always cover the type(s) of operation for the relevant area of operation. For example, a railway undertaking that provides only traction for the haulage of freight wagons must hold a single safety certificate for freight services (including or excluding the transport of dangerous goods). If the same undertaking wants to provide traction for the haulage of passenger coaches as a public service as well then it must hold both a single safety certificate for freight and also for passenger transport (including or excluding the transport of dangerous goods and including or excluding high-speed services). If the transport is of empty passenger coaches only then the company operates as a freight company only. Companies operating track maintenance vehicles on the railway network that falls in the territorial scope of the [Directive \(EU\) 2016/798](#) in a particular member state must either have their own single safety certificate as a freight railway undertaking or if this is allowed in the member state concerned by providing their services as subcontractors in which case, they would operate under the safety authorisation of that infrastructure manager. In this second case, the infrastructure manager is fully responsible for the products delivered or the services supplied, and its subcontractor is not required to have a single safety certificate.



Infrastructure managers may need to use - within the limit of their activities - trains, infrastructure inspection vehicles, on-track machines or other special vehicles for different purposes, such as the transport of materials and/or staff for construction or infrastructure maintenance, the maintenance of its infrastructure assets or the management of emergency situations. In such cases, **the infrastructure manager is deemed to operate in the capacity of a railway undertaking under its safety management system and safety authorisation without the need to apply for a separate single safety certificate**, irrespective of whether it owns the vehicles or not.



Activities performed in sidings, such as the loading of wagons, are industrial activities that interface with specific railway activities such as the composition, preparation and movement of rakes of vehicles that can be trains or will be used in trains. This includes the coupling of different vehicles to form rakes of vehicles or trains and moving them. No movement of trains or rakes of vehicles can be made on the rail network under the responsibility of an infrastructure manager if they are not covered by a single safety certificate (or a safety authorisation). It means that such movements can only be carried out by railway undertakings (or infrastructure managers) having valid safety certificates (or safety authorisations) or by any other organisation acting as a subcontractor for those railway undertakings (or infrastructure managers) and operating under their SMS

## 2. Conditions of application for a single safety certificate

Activities such as the transport of military vehicles with associated carriages for military personnel is not considered a passenger operation as the main activity is the freight transport of vehicles. The same logic applies to train services where lorries are loaded onto wagons as a freight load and the lorry drivers are transported in the same train in a separate passenger coach.



Newcomers to railway operations should be aware that they will need to show their business plans for their proposed operation along with any pre contract or other agreements to demonstrate that they have the elements in place to allow an assessment against the requirements set out in [Regulation \(EU\) 2018/762](#). They should also think carefully about when to apply since plans several years ahead will make the assessment of parts of the safety management system problematic.



### 3. How to apply for a single safety certificate?

#### 3.1. Submission of the application <sup>(1)</sup>

The railway undertaking is requested to submit any application for a single safety certificate through the single entry point of the one-stop shop, available from the [Agency website](#).



It is recommended that an application for a single safety certificate is submitted **at least 6 months** before:

- (a) *the planned start date of any new rail transport operation which requires a **new** single safety certificate;*
- (b) *the planned start date of a rail transport operation following one or more substantial changes made to the type, extent or area of operation which requires an **update** of the single safety certificate; or*
- (c) *the end of the period of validity of the current single safety certificate which requires a **renewal** of the single safety certificate for the continuity of the rail operations.*

This timeframe aims at mitigating potential risks associated with prolonging the time taken for the assessment, for example if the application file is not satisfactory and additional time is needed by the applicant to provide supplementary information. This could prevent the operation starting on a planned date or could impair the business continuity of an already-certified railway undertaking (see also **section 7**). Applicants should be aware that in normal circumstances the Decision date (the date on which the Single Safety Certificate is issued) will be the date that the Certificate starts from. Applicants should note that the legal time frame is the same for new, update and renewal applications. However, in the latter two cases the Safety Certification Body is expected to take a proportionate approach concentrating on changes or outstanding matters since the previous assessment and the outcomes of any Supervision activities which have taken place between the granting of the original certificate and the current application.

An application for a single safety certificate may be rejected for formal reasons such as in situations below (note there may be other situations when a rejection is appropriate):

- (a) *If the applicant submits an application (new, update or renewal) while another application is already ongoing, irrespective of the type, extent and area of operation;*
- (b) *If the applicant already holds a valid single safety certificate issued by a safety certification body and wishes to extend its area of operation in other Member State(s) by applying for a new single safety certificate in the Member State(s) affected by the extended area of operation;*

<sup>(1)</sup> Before the submission of the application it is recommended for the applicant to contact all the safety certification bodies involved and to consider requesting pre-engagement.

### 3. How to apply for a single safety certificate?

- (c) *If the applicant already holds a valid single safety certificate and submits an application for a “new” certificate irrespective of the type, extent and area of operation;*
- (d) *If a valid single safety certificate does not already exist for an applicant who is submitting a renewal or update application.*
- (e) *An application may also be rejected for a failure to submit valid evidence of compliance with the requirements set out in [Regulation \(EU\) 2018/762](#).*

It should be noted that all **first** applications for a single safety certificate whether the applicant has held a previous safety certificate or not, should be entered in the one-stop shop as ‘new’ applications. If the applicant has held a previous safety certificate under the previous regime this may be taken into account by the safety certification body in carrying out its assessment of the file.

In general, once an application is submitted in the one-stop shop it cannot be amended unless the applicant requests it and the safety certification body reopens parts of the application via an issue. In the course of the assessment the applicant may also request termination of its application, e.g. to reduce the cost if it concludes that the application is not sufficient to get a positive assessment. These requests have to be formally addressed to the safety certification body and submitted through the issue log of the one-stop shop.

The applicant can start a new application from a previous pre-engagement request or application. This may be particularly useful to avoid inconsistencies between different applications and to speed up the submission process.

In all cases an applicant who is considering making an application to the Agency is strongly advised to Contact the Agency via the Contact form on the Website to discuss the potential plans and the timescale for the application. The purpose of this discussion is to aid both the Agency and the applicant in planning the application and to avoid the applicant making errors in the application which require the application to be closed and resubmitted.

## 3.2. The one-stop shop

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The one-stop shop is an IT platform managed by the Agency, available in all the official languages of the Union, through which all applications for a single safety certificate are to be submitted.

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In order to submit an application for a single safety certificate, the applicant needs to have a registered user in the one-stop shop. By definition, a user is a natural person appointed by the applicant to manage the application process in the one-stop shop. It is highly recommended that this registered user is someone from within the applicant’s organisation, and the organisation puts in place measures to make sure that there is always a registered user. At the same time, the user submitting an application in the one-stop shop becomes the contact person to whom all the communication relevant for the application is addressed. The applicant’s contact person may however give rights to other persons within (or external to) its organisation to access the application. Instructions on how to do this can be found in

the OSS User Guide on the Agency website. The management of users within the applicant's organisation and related access rights to applications is the sole responsibility of the applicant.

For the Authorities the relevant staff must be registered users of the one stop shop assigned to the application by the programme manager of their respective authorities after being notified of a new application involving them. By definition, a user is a natural person appointed by the authority to manage the safety assessment in the one-stop shop. The management of users within the authority's organisation (e.g. in case of sick leave) and related access rights to applications is the sole responsibility of the relevant authority and its programme manager.

The one-stop shop is designed with the aim of recording the results and outcome of the assessment process, including the reasons for it. Both Applicant and Assessors should take into account that all relevant communication should be recorded in OSS. It also provides the applicant with the status of all stages of the safety assessment process, the outcome of the assessment and the decision whether or not to issue a single safety certificate. The applicant can scrutinise the results and outcome of the assessment once the latter is approved by the relevant authority. When several authorities are involved in the safety assessment the results and outcome of the assessment of the different authorities are compiled by the Agency. The decision whether or not to issue the single safety certificate and the reasons for it are then notified to the applicant through the one-stop shop. Similarly, when the Agency is the safety certification body, the notification of invoicing is managed through the one-stop shop.

The one-stop shop also ensures configuration management of all uploaded documents. The staff of the authorities involved in the safety assessment have the necessary credentials to access all documents and information relating to an application to which they are assigned (i.e. the application file as well as other documents or information pertaining to the assessment). The staff of an authority have read-only access to the results and outcome of the assessment of another authority. Similarly, to the applicant, the authority's staff can also submit new or revised documents during the assessment to support its decision. Documents recorded in the system cannot be deleted but can only be replaced by a newer version.

Any applicant has the right to prepare and submit at any time valid applications in the one-stop shop in line with the applicable EU railway legislation, the specifications and the Terms of Use of the one-stop shop. When the Agency acts as safety certification body, the application for a single safety certificate is submitted to the Agency as well as the national safety authority or authorities concerned with the area of operation to address the national rules part.

In such cases, the compliance with any formal and substantial rules, requirements, prerequisites or conditions linked with administrative issues, such as:

- ▶ finalisation and formal submission of an application in the one-stop shop;
- ▶ content of formal acknowledgement of receipt of an application by the Agency;
- ▶ requirement of signature of applications in the one-stop shop and Agency's reports, including final decisions/acts; and
- ▶ any other relevant EU law governed issue.



### 3. How to apply for a single safety certificate?

falls under the exclusive responsibility of the Agency which defines the relevant specifications. Consequently, in relation to the aforementioned administrative issues, all national safety authorities involved in the assessment of an application (when the Agency acts as safety certification body) should consider any application submitted in the one-stop shop as valid, given also that when the Agency acts as safety certification body it is subject to EU law and not to any national requirements set out in the national administrative law of the EU Member States.

The key features of the one-stop shop are summarised in the following table:

Table 1: One-stop shop key features

Applicant	Authorities involved in the safety assessment
▶ Submission of an electronic application file;	▶ Acknowledgement of receipt of an application;
▶ Configuration management of the application file (library);	▶ Configuration management of the assessment file (library);
▶ Viewing of milestones and progress status of the different stages of the safety assessment process (dashboard);	▶ Setting of milestones and reporting on progress against the different stages of the safety assessment process (dashboard);
▶ Recording of communications with the authorities (issue log), ensuring a traceability of decisions;	▶ Recording of communications with the applicant (issue log), ensuring traceability of decisions;
▶ Viewing the assessment results and outcome (once approved);	▶ Reporting the assessment results and outcome;
▶ Notification of the decision relating to the issue of the single safety certificate;	▶ Communicating the decision relating to the issue of the single safety certificate;
▶ Management of requests for the review of the decisions of the safety certification body;	▶ Authentication and management of users;
▶ Authentication and management of users;	▶ Assignment of users to the application (roles and rights management);
▶ Assignment of users to the application;	▶ Management of all applications for a single safety certificate assigned to the authority;
▶ Management of all applications for a single safety certificate submitted by the applicant;	▶ Recording of events (event log);
▶ Recording of events (event log).	▶ Update of ERADIS database.

The national safety authority is free to establish its own information management system on the condition that any issues addressed to the applicant are communicated, or at least recorded, through the one-stop shop. This includes any documents necessary to ensure that the traceability of decisions is transferred to the one-stop shop before the decision-making process takes place.

More information regarding the one-stop shop functionalities can be found in the one-stop shop user manual on the [Agency website](#).

### 3.3. Selection of the safety certification body

Where its area of operation is limited to one Member State, the applicant can choose in the one-stop shop which authority, either the Agency or the national safety authority of the Member State concerned, will be responsible for issuing the single safety certificate.

Railway undertakings may operate services as far as border stations in neighbouring Member States if such stations are recognised as such by those Member States. Such cases do not require an extension of the area of operation when the network characteristics and the operating rules are similar and therefore, following consultation and agreement with the relevant national safety authorities, can be assimilated into an operation otherwise limited to one Member State. The applicant is requested to identify the country in the OSS where the area of operation will be a Border Station and to indicate in the Description of the Area of Operation what the extent of this operation will be, for example, state border to... (name of the station or track section).

Applicants are advised to consult the Application Guides produced by each member state in which they intend to operate for availability and detailed requirements concerning Border Stations.

Where the area of operation is not limited to one Member State the Agency is the safety certification body by default, and therefore in this case the applicant is not able to change the certification body identified in the one-stop shop.

Applicants should be aware that if they are operating in a single member state and choose the Agency as the Safety Certification Body then the relevant NSA will still be involved in the process for the National Rules part.

The choice of the safety certification body is binding until the safety assessment process is completed or terminated, which means that the applicant is not able to change it once its application for a single safety certificate is submitted in the one-stop shop.

During pre-engagement (see **section 5.1**), in the case where the area of operation is limited to one Member State, the applicant may decide to address its request to another authority. In such a case, a new request for pre-engagement must be submitted in the one-stop shop after the first request is terminated.

### 3.4. Language policy

**Where a national safety authority acts as safety certification body**, the language to be used for the application file must be an official language of the Member State for the intended area of operation, as indicated in the application guide of the competent national safety authority.

**Where the Agency acts as safety certification body**, the language to be used for the application is as follows:

- For the part of the application file relating to the establishment of the safety management system: one of the official languages of the Union;
- For the part of the application file relating to the demonstration of compliance with the notified national rules: the language determined by the Member State for the intended area of operation and indicated in the application guide of the competent national safety authority.

### 3. How to apply for a single safety certificate?

A national safety authority for the intended area of operation may require the applicant to provide translation of the parts of documents relevant for checking the compliance with applicable national rules into a language accepted by the national safety authority. This requirement is, however, limited to a description or any other demonstration of how the safety management arrangements address the requirements of the notified national rules and does not allow the national safety authority to request a translation of the whole safety management system.

The applicant is advised to anticipate the needs for translation while planning its application for a single safety certificate.

#### 3.5. Fees and charges

**In the case where the national safety authority acts as safety certification body**, the fees and charges are levied by the national safety authority in accordance with its national legislation. Further information can be found in the application guide of the competent national safety authority.

**In the case where the Agency acts as safety certification body**, the fees and charges levied by the Agency for the purposes of issuing new, updated or renewed single safety certificates are in accordance with Commission Implementing [Regulation \(EU\) 2018/764](#) as amended by Commission Implementing Regulation (EU) 2021/1903 *on the fees and charges payable to the European Union Agency for railways and their conditions of payment*. A discount may be available on the submission of appropriate evidence for a small and medium sized enterprise. Further details may be found on the Agency website.



Fees and charges are defined as follows:

- ▶ **Fees:** Amounts levied to obtain, maintain, update or revoke single safety certificates;
- ▶ **Charges:** Amounts levied for other services such as pre-engagement, audits, inspections or visits.

The calculation of fees and charges is the total of:

- ▶ the number of hours spent by the Agency on the processing of the application multiplied by the hourly rate of the Agency; and ,
- ▶ the relevant costs of the NSAs resulting from the processing of the national part of the application.

The Agency's hourly rate is set to balance both its direct costs (e.g. staff salary, travel expenses) and indirect costs (e.g. management/support services such as secretariat, finance and overhead costs). The costs for audits are not included in the formula and are charged separately.

Any pre-engagement activities (see [section 5.1](#)) are charged in accordance with the above formula.

In the case of rejection or termination of the application upon request of the applicant, the fees and charges incurred for the services already delivered are to be borne by the applicant.

Where the Agency is the safety certification body, the notification of invoicing is managed through the one-stop shop. The invoice is uploaded to the file and the notification, together with information on the deadline for the payment is sent to the registered user as appointed by the applicant to manage the application file. The notification process follows the same principles as notification of issues. The deadline for the payment is set, in accordance with the IA on fees and charges, to 60 calendar days from the date on which the invoice is notified to the applicant.

## 4. Structure and content of the application file

The application file consists of:

- ▶ the application form;
- ▶ When the applicant has a dedicated address for invoicing, it is advised to include this information in a separate file and upload it in the one-stop shop;
- ▶ documentary evidence that the applicant has established its safety management system in accordance with Article 10(3)(a) of [Directive \(EU\) 2016/798](#);
- ▶ documentary evidence that the applicant meets the requirements laid down in the relevant national rules notified in accordance with Article 8 of [Directive \(EU\) 2016/798](#);
- ▶ cross referencing within the safety management system documentation to identify the location of the evidence that the relevant requirements of the CSMs on SMS, the applicable Technical Specification for Interoperability relating to the operation and traffic management subsystem, and the applicable national rules are met; and
- ▶ the current status of the corrective action plan (or plans) to resolve any major non-compliances or other areas of concern identified during supervision activities that have taken place since the previous assessment. In the case of an application for the renewal or update of an existing single safety certificate this should include residual concerns from previous assessments, where relevant.

The application file must be submitted electronically through the one-stop shop, using the web forms provided by the system. Instructions for use with regard to the content of the application for a single safety certificate are provided in the Annex 1 to this guide.

The application must be concise and self-contained with all relevant information provided within it.

Using the mapping table available in the one-stop shop, the applicant is required to map separately its documentary evidence against:

- ▶ the requirements set out in Annex I of the CSMs on SMS (more information on these requirements may be found in the Agency's guide on SMS requirement);
- ▶ the requirements of the applicable Technical Specification for Interoperability relating to the operation and traffic management subsystem (TSI OPE); and
- ▶ the requirements laid down in the applicable national rules for each Member State affected by the area of operation.

The mapping table allows for the indexing of information so that the assessor can easily find it, including links to supporting documents. In this respect the applicant should use the comments column of the mapping table in the OSS to identify where in any given document the required evidence can be found. Doing this will speed up the assessment and reduce the costs as assessors will not be looking through multiple pages of documents to find the appropriate evidence of compliance with the requirements. Documents provided in support of the application should be concise and referenced in the mapping table appropriately.

Careful use of the mapping table can help to demonstrate how the Safety Management System works and the applicant's mastery of it. Other documents can be referenced so that:

- ▶ the assessor can have confidence that they exist and can check them if necessary; and
- ▶ they can be requested for examination after the issue of the single safety certificate during subsequent supervision.

Each national safety authority is requested to describe and explain in its application guide the requirements laid down in the national rules notified by its Member State. The National Safety Authority may require that applicants complete a mapping table of their processes against national requirements and upload this in the relevant national part of the application.

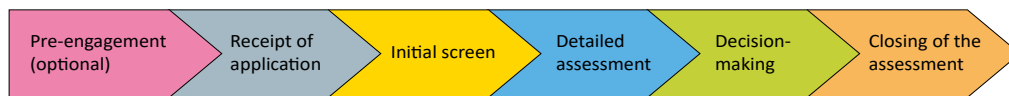
In general, for each of the legal requirements to be met the applicant will need to show both that a process exists and also provide evidence that it is applied.



As a general rule, an application for a renewal or an update of the single safety certificate still includes all the constituent elements of an application file. However, the applicant is asked to identify and describe the changes to the documentary evidence sent since the previous application (for which a single safety certificate was granted). To help identify the changes made to the documentary evidence, the applicant is advised to both mark the changes in the updated documents and provide an explanation of the changes. A simplified process is envisaged for specific changes of an administrative nature

## 5. Safety assessment process

The safety assessment process contains the following stages:

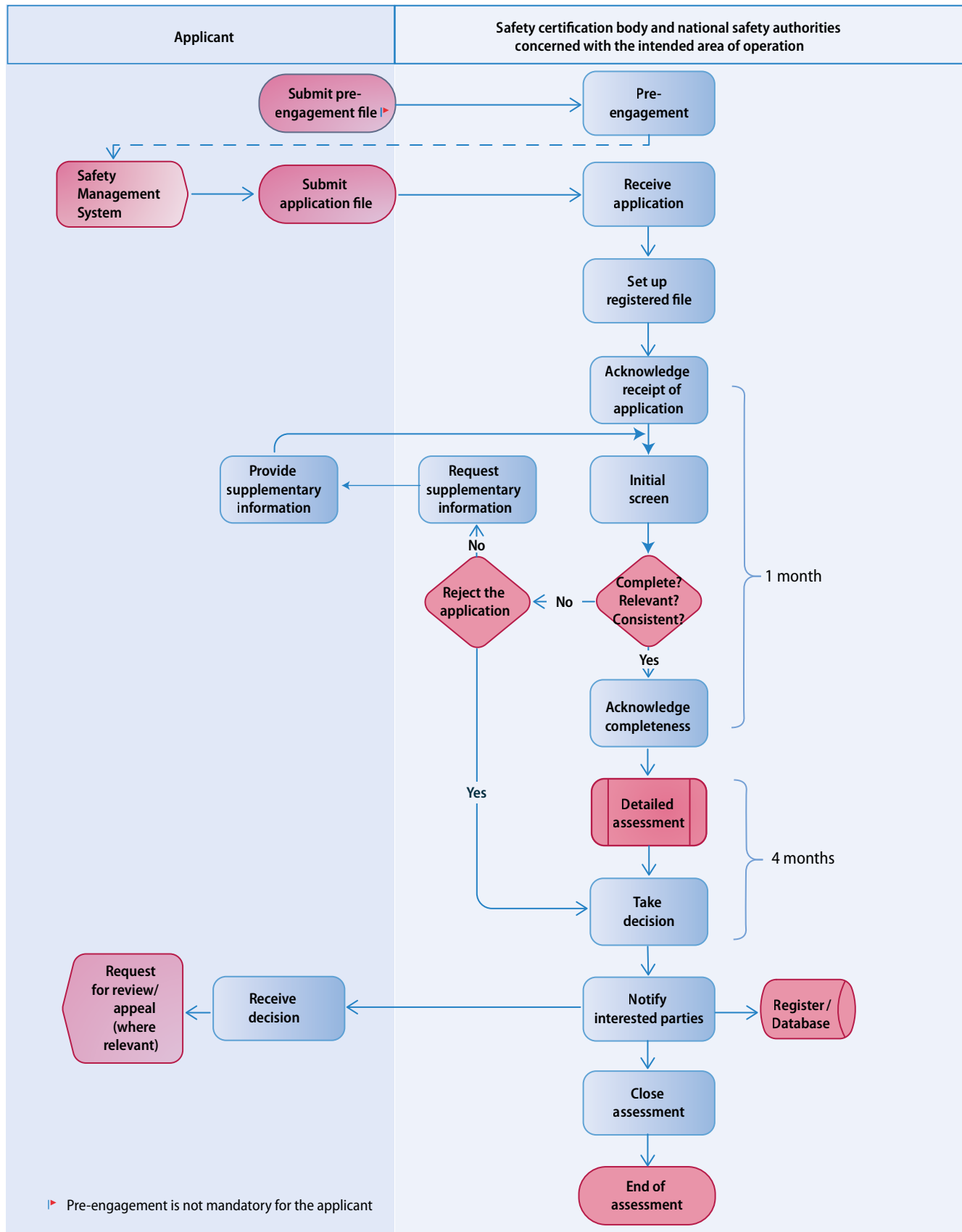


In the following sections, the safety assessment process is detailed from the applicant's perspective.

The safety assessment process is iterative, as shown in **Figure 3**. This means that the authorities for the intended area of operation are entitled to make reasonable requests for further information or re-submission of elements of the application during the course of the assessment.

Applicants are advised to make sure that there is always someone the Agency can contact during the application that will ensure that the best available use of the assessment period is made, and time is not lost because the contact person is unwell on holiday or otherwise unavailable.

Figure 3: The safety assessment process





### 5.1. Pre-engagement

It is highly recommended that the applicant requests pre-engagement through the one-stop shop before submitting its application for a single safety certificate (new, update and renewal) in order to help understand what is expected and to mitigate at the earliest possible stage the risks of delays in issuing the single safety certificate which could impair business continuity.

The pre-engagement is aimed at:

- ▶ Facilitating early contact;
- ▶ Developing the relationship between assessor(s) and applicant;
- ▶ Gaining familiarity with applicant's safety management system; and
- ▶ Verifying that the applicant has been provided with sufficient information to know what is expected, the way the assessment process will be conducted and how decisions will be made.

To make pre-engagement effective in achieving its full benefits, the following approach is advocated:

- ▶ The applicant prepares a file which includes at least an overview of its SMS and submits it through the one-stop shop. The file must include the information listed in items 1 -6 of Annex 1 of [Commission Implementing Regulation 2018/763 \(EU\)](#) but the amount of information provided is not limited to this list. The actual subject matter of the pre-engagement need not be the whole of the SMS nor need it involve all the authorities who will assess the formal application. The choice of what is to be assessed and by whom is the applicant's, however, a clear focus on what is important for the applicant will simplify the process and save time and money.
- ▶ The safety certification body sets the date(s) of the meeting(s) and is responsible for the organisational arrangements (e.g. meeting venue or use of other communication means, invitation of experts);
- ▶ The applicant sets the agenda of the meeting(s).
- ▶ The national safety authority for the area of operation provides overall results/trends from their previous supervision as applicable, on the request of the safety certification body.
- ▶ The safety certification body coordinates with the applicant and other national safety authorities as appropriate, with the aim of discussing the content of the pre-engagement file and, if considered to be relevant for the application, the feedback from supervision activities performed by the relevant national safety authority (or authorities);
- ▶ For the sake of transparency and the clarity of exchanges between the Agency (when acting as safety certification body), relevant national safety authority (or authorities) and the applicant, issues identified at the pre-engagement stage are recorded and tracked following the same principles used for the assessment itself (see [sections 5.3](#) and [section 5.4](#)). The same approach is also strongly recommended if the safety certification body is a national safety authority.

- The applicant keeps records of the meeting(s) by drafting and circulating the minutes for review and approval by all participants. The records of the meeting(s) can be archived in the one-stop shop to facilitate the future safety assessment.

It should be noted that pre-engagement is not the same thing as initial contact to explain the scope of a project. The Agency advises applicants to contact both it and the relevant NSAs before submitting an application to discuss what is intended. Doing this will prevent unnecessary errors in applications and therefore reduce the workload on the authorities involved.



The pre-engagement stage is not mandatory for the applicant, but it is recommended as it mitigates potential risks at the assessment stage and facilitates the assessment process itself. If it wishes, the applicant can still submit its application for a single safety certificate without pre-engagement. However, if the applicant requests a pre-engagement, the different authorities for the area of operation are required to participate. It is advised that applicants contact the Agency via the Contact us point on the website for a preliminary discussion on what pre-engagement involves before submitting an application.



Any pre-engagement is subject to charges (see **section 3.5**) and follows the standard communication rules (see **section 8**). The documents provided by the applicant and those developed during the pre-engagement stage are archived in the one-stop shop including, where relevant, the records of coordination activities.

Once the applicant requests pre-engagement the choice of the safety certification body becomes binding until:

- The application for a single safety certificate has been submitted by the applicant; or
- The applicant has requested to terminate the pre-engagement. In such a case the applicant can request new pre-engagement, selecting another safety certification body.
- The pre-engagement stage must be closed, at the request of the applicant or when agreed by relevant parties before the application for a single safety certificate is submitted.

In the Guides of National Safety Authorities there should be information on the arrangements that apply for pre-engagement including the process of application for pre-engagement and an explanation of the reasons for it.

## 5.2. Receipt of the application

Following the submission of an application for a single safety certificate (new, update or renewal), the one-stop-shop automatically acknowledges the receipt of the application on behalf of the safety certification body. It should be noted that all **first** applications for a single safety certificate whether the applicant has held a previous safety certificate or not, should be entered in the one-stop shop as 'new' applications. If the applicant has held a previous safety certificate under the previous regime this may be taken into account by the safety certification body in carrying out its assessment of the file. To make this process more efficient applicants should indicate in their application any changes made to their safety management system since the last assessment. The notification sent to the applicant also includes information about the start date of the assessment against which milestones

and deadlines will be monitored. The start date of the assessment corresponds to the date of acknowledgement of receipt of the application as defined in Article 2(2) of [Commission Implementing Regulation \(EU\) 2018/763](#) [practical arrangements for issuing single safety certificates to railway undertakings].

The receipt of an application is not acknowledged by the individual authorities for the intended area of operation, but only by the safety certification body who is managing the application. As all communication on new applications will be addressed to appointed programme managers, to avoid problems such as the individual's absence when a new application is submitted, the authorities are encouraged to set up an additional functional mailbox to which all notifications are forwarded.



To support the notification process, the Agency and the national safety authorities are invited to use the one-stop shop to record information about public holidays applicable to their organisation. This information is used by the one-stop-shop to process the start date of the assessment which is set in the acknowledgement of receipt of the application. The information on public holidays for a given year is recorded in the system by each of the authorities not later than the end of the preceding year and is updated, if necessary, when there are changes in public holidays within the year.



For each application, the competent resources are assigned within the one-stop shop by the programme manager of each authority concerned with the area of operation. To avoid shortening the time available for the safety assessment, the authorities concerned are invited to assign their resources promptly (see [section 6](#)).

The following table describes the various roles and responsibilities available in the one-stop shop for the different authorities (i.e. the Agency and national safety authorities). According to the complexity of the application and its internal procedure, each authority allocates one or more resources to conclude the safety assessment process within the legal timeframe. The same resource can be assigned one or more roles. Each application is managed as a project with a specific start and end date corresponding respectively to the acknowledgement of receipt of the application and the decision taken by the safety certification body. It is recommended that the project management methodology is proportionate to the size and complexity of the application.

**Table 2: Roles and responsibilities**

Roles	Responsibilities
Programme Manager	<p>Responsible for the set-up, management and delivery of the programme, which entails:</p> <ul style="list-style-type: none"> <li>▶ Receiving notifications of new applications;</li> <li>▶ Forward planning resources to address new, update and renewal applications;</li> <li>▶ Assigning competent resources to each project;</li> <li>▶ Ensuring consistency of the decisions made for the different projects;</li> <li>▶ Managing the evaluation of the effectiveness of the programme and its continual improvement.</li> </ul>

Roles	Responsibilities
Project Manager	<p>Responsible for the set-up, management and delivery of the safety certification project assigned to him/her, which entails:</p> <ul style="list-style-type: none"> <li>▶ Providing leadership and coordinating the assessment process, including pre- engagement as applicable;</li> <li>▶ Fulfilling the project objectives, in particular the timely delivery of the assessment work in accordance with quality standards;</li> <li>▶ Identifying any issues that could prevent the completion of the assessment;</li> <li>▶ Liaising with the programme manager to share issues that may affect the completion of the assessment and the final decision-making over whether or not to issue the single safety certificate;</li> <li>▶ Escalating any diverging opinions between assessors that could not be resolved by the decision-maker(s);</li> <li>▶ Suspending the assessment whenever a significant issue is identified, pending the receipt of supplementary information from the applicant;</li> <li>▶ Managing the recommendation whether to issue the single safety certificate;</li> <li>▶ Submitting any rejection decision at an early stage of the process (i.e. before the completion of the assessment) to the decision-maker(s);</li> <li>▶ Reporting on the progress of the assessment to the decision-maker(s);</li> <li>▶ Preparing the single safety certificate (if the decision is to issue the single safety certificate).</li> <li>▶ Ensuring the correct application of the relevant processes and procedures.</li> </ul>
Lead Assessor (if more than one assessor)	<p>Responsible for the set-up, management and delivery of the technical assessment of a safety certification project assigned to him/her, which entails:</p> <ul style="list-style-type: none"> <li>▶ Coordinating the technical work between assessors as appropriate at different stages of the assessment process and during pre- engagement as applicable.</li> <li>▶ Liaising with the project manager to share issues that may impede the completion of the assessment.</li> <li>▶ Escalating any diverging opinions between assessors that cannot be resolved to the project manager.</li> <li>▶ Ensuring consistency of the decisions among the different assessors.</li> <li>▶ Managing the overall results of the assessment.</li> </ul> <p>In addition, the responsibilities set out below for the assessor apply.</p>
Assessor	<p>Responsible for the specific part(s) of the assessment assigned to him/her, which entails:</p> <ul style="list-style-type: none"> <li>▶ Contributing to fulfil the project objectives, in particular the timely delivery of the assessment work in accordance with quality standards.</li> <li>▶ Coordinating with the applicant as appropriate, e.g. to request supplementary information or clarification or to agree on action plan(s) set by the applicant.</li> <li>▶ Identifying any issues that could prevent the completion of the assessment.</li> <li>▶ Liaising with the lead assessor to share issues that may impede its part(s) of the assessment or that of another assessor(s);</li> <li>▶ Managing the results of its part(s) of the assessment.</li> <li>▶ Reporting on the progress of its part(s) of the assessment to the lead assessor and project manager (if different from the lead assessor).</li> <li>▶ Applying the relevant processes and procedures.</li> </ul>
Assuror	<p>Responsible for checking that the safety assessment process has been correctly applied before making any decision over whether to issue the single safety certificate, which entails:</p> <ul style="list-style-type: none"> <li>▶ Checking the correct application of the relevant processes and procedures.</li> <li>▶ Providing a recommendation whether to issue the single safety certificate, including any rejection decision at an early stage of the process (i.e. before the completion of the assessment), based on the results of its checks.</li> <li>▶ Submitting its recommendation to the decision-maker(s).</li> </ul>
Decision-maker	<p>Responsible for approving the opinion and/or taking the decision over whether to issue the single safety certificate.</p>

### 5.3. Initial screen

The initial screen ensures that the documentary evidence submitted by the applicant is sufficient, relevant and consistent for the detailed assessment to begin. The authorities for the area of operation each consult the application file as appropriate to:

- ▶ Determine whether the application is structured and internally cross-referenced so as to permit assessment to be effective and properly recorded;
- ▶ Identify whether evidence is provided against the applicable requirements; and
- ▶ Ascertain the current status of the corrective action plan (or plans) put in place by the applicant to resolve any major non-compliance and any other area of concern identified during supervision activities since the previous assessment. For an application for the renewal or update of an existing single safety certificate this should include any residual concerns from the previous assessment, as appropriate.

Within the first month following the receipt of the application, the authorities involved in the safety assessment each check as appropriate that:

- ▶ The applicant has provided the information which is required by the legislation;
- ▶ The application contains sufficient evidence, is structured and internally cross-referenced (e.g. the SMS manual contains signposts to other procedures and rules) to permit assessment to be effective and properly recorded; and
- ▶ The language of the application is of sufficient quality to permit the application file to be assessed.

Where the Agency acts as safety certification body, coordination is sought between authorities involved in the safety assessment in order to discuss:

- ▶ The internal and external communication (see [section 8](#)).
- ▶ The organisational arrangements.
- ▶ The task assignment.
- ▶ The detailed schedule
- ▶ The appointment of members of the pool of experts.
- ▶ Relevant Information collected on the applicant's safety performance from past supervision activities as applicable (see also [section 12](#)). This information is provided by the national safety authority.
- ▶ Feedback from pre-engagement as applicable.

Preferably, a first coordination meeting is held shortly after the various resources are assigned to the application. Other coordination meetings can be arranged at the request of the safety certification body to discuss intermediate and final results of the initial screen.

Where the applicant indicates in its application that it intends to operate to stations in neighbouring Member States with similar network characteristics and similar operating rules when those stations are close to the border, the applicant will indicate this by selecting the area of operation for that member state and then border station providing an appropriate

description of the area of operation. This is usually in the form of state border of x to x.. The NSA where the border station is located is then responsible for assessing the evidence the applicant has provided to access this section of railway and giving a positive or negative conclusion.

The above-mentioned consultation does not have to take place if specific cross-border agreements exist between Member States or national safety authorities that cater for operations between stations close to the border where there are similar network characteristics and similar operating rules. In such cases, the national safety authorities for the intended area of operation are considered to be competent to check that the relevant notified national rules and the obligations arising from the relevant cross-border agreements are met. If there are any consultation arrangements in the cross-border agreement these should be followed. The national safety authorities are invited to identify these cooperation arrangements and the border stations covered by them in their national application guide (see [Annex 2](#)) to facilitate the assessment process.

The requirements that apply will differ according to whether it is a first, renewal or update application. For a **first application**, all the requirements set out in Annex I of the CSMs on SMS (including the relevant requirements in the TSI OPE) and the requirements laid down in the relevant national rules will apply. For **renewal and update applications**, the applicable requirements may vary from one case to another and, while the authorities involved in the safety assessment may make an initial judgement as to whether evidence for the correct requirements has been provided, this may not be fully evident until the detailed assessment is under way.

The national safety authority also checks that the documentary evidence provided by the applicant for the concerned area of operation is clearly identified and it takes into account any exclusions that would mean a single safety certificate is not required in accordance with Article 2.3 of [Directive \(EU\) 2016/798](#).

If any of the necessary information is not provided or if the application contains insufficient evidence or if the evidence is not presented clearly enough, including the quality of the language used, the applicant will be asked for the missing details or for clarifications through the issue log. If the quality of the language is so poor that it is not possible to understand the application at a level that allows the safety assessment, any necessary translation may be undertaken if this is possible within the timeframe. If the translation cannot be undertaken during the 1-month timeframe either the timeframe for the initial screen assessment can be extended or the application can be rejected.

Under Article 10 (1), (2) and (3) of the [Railway Safety Directive \(EU\) 2016/798](#) it is clear that a new applicant for a single safety certificate must have a reasonable plan for conducting railway operations within a relatively short period after the granting of that single safety certificate. This is because they must have a safety management system which controls risks and be compliant with TSI's and other legislation in force. Since there are requirements which cover for example competence and asset management the applicant should be able to supply information to the assessment body for example on the rolling stock that will be used the area and type of operation and the competence of staff. The safety assessment

process is not simply a paper exercise it must have a basis in reality. A safety certification body receiving an application for a single safety certificate which does not contain enough information to properly assess whether the SMS of the applicant is capable of controlling its risks because it is incomplete or it does not relate to real activities, should be prepared to reject the application, and advise the applicant to reapply when they have a realistic prospect of starting operations. It is recommended that where an applicant is a new applicant that they supply a copy of their on going business plan as part of the assessment. Such a plan should include the dates of starting operation and the dates when assets eg locomotives and staff will be available along with the plans for reviewing the operations once they have begun. Applicants should not submit an application until they are in a position to demonstrate that their planning is advanced enough to allow them to provide evidence of compliance with the Safety Management System requirements. Failure to do so will likely result in a rejection or restriction of the proposed operation.

The safety certification body takes the final decision over the completeness, relevance and consistency of the application file and notifies the applicant of its decision through the one-stop shop.

The authorities and the applicants may use different communication channels at their discretion to make the assessment more efficient. However, the identification and recording of issues (in the meaning of Article 12 of [Regulation \(EU\) 2018/763](#)) should be managed through the issue log of the one-stop shop in order to ensure transparency and traceability of the decisions taken by the authorities concerned with the area of operation.



As part of their request for more information, each authority can seek as much detailed information as it deems reasonably necessary to help its assessment of the application and to that end can make direct contact with the applicant. When doing so each authority is requested to be precise and accurate, and to provide clear and understandable information to the applicant together with a timeframe for the expected response. In turn, the applicant provides the requested information within the agreed timeframe through the issue log.



If the applicant does not provide the requested information or if the supplementary information provided in the application is not satisfactory, the timeframe of the assessment may be extended or a Decision reached with restrictions on the type or area of operation or the length of the Single Safety Certificate, or finally an application can be rejected. Rejecting an application is used as the last resort and when the safety certification body decides to do so the decision and the reasons for it are recorded in the assessment report and notified to the applicant. Any rejection decision requires a resubmission of the application.

As the authorities involved in the safety assessment can be consulted on the content of the application before its submission (i.e. during a pre-engagement stage), they may already know that the application contains adequate evidence, in which case it will be possible to reduce this stage to a minimum as appropriate and move faster on to the main assessment. It may also be that the results from previous supervision activities provide sufficient knowledge of aspects of the applicants Safety Management System so that a decision on a part or parts of the application can be made. In such cases, a justification needs to be recorded in the assessment report.

Before sending any request for further information that may affect the work of other authorities, the relevant authorities involved in the safety assessment should coordinate via the appointed Project Manager to discuss the draft issues logged in the issues log before submitting them to the applicant. Likewise, before rejecting the application or even taking the decision to proceed to the next stage, the authorities involved in the safety assessment should coordinate to discuss any pending issues relating to the initial screen stage and agree on the way forward. In any case, the decision over the completeness, relevance and consistency of the application is recorded by each authority involved in the safety assessment in their respective assessment reports. If there is disagreement between these reports and no agreement can be reached between the different parties, the safety certification body takes a final decision on the completeness, relevance and consistency of the application. Each authority is however free to take its own decision and may request arbitration, as appropriate.

The status of the initial screen stage is visible to all relevant parties, including the applicant, in the dashboard of the one-stop shop. The progress status of the stage, as reported individually by each authority is visible to all authorities in the dashboard, but not to the applicant to the same level of granularity. The summary of the initial screen and conclusions in relation to completeness of the file are recorded in the dedicated part of the assessment report by each of the authorities before starting the detailed assessment.

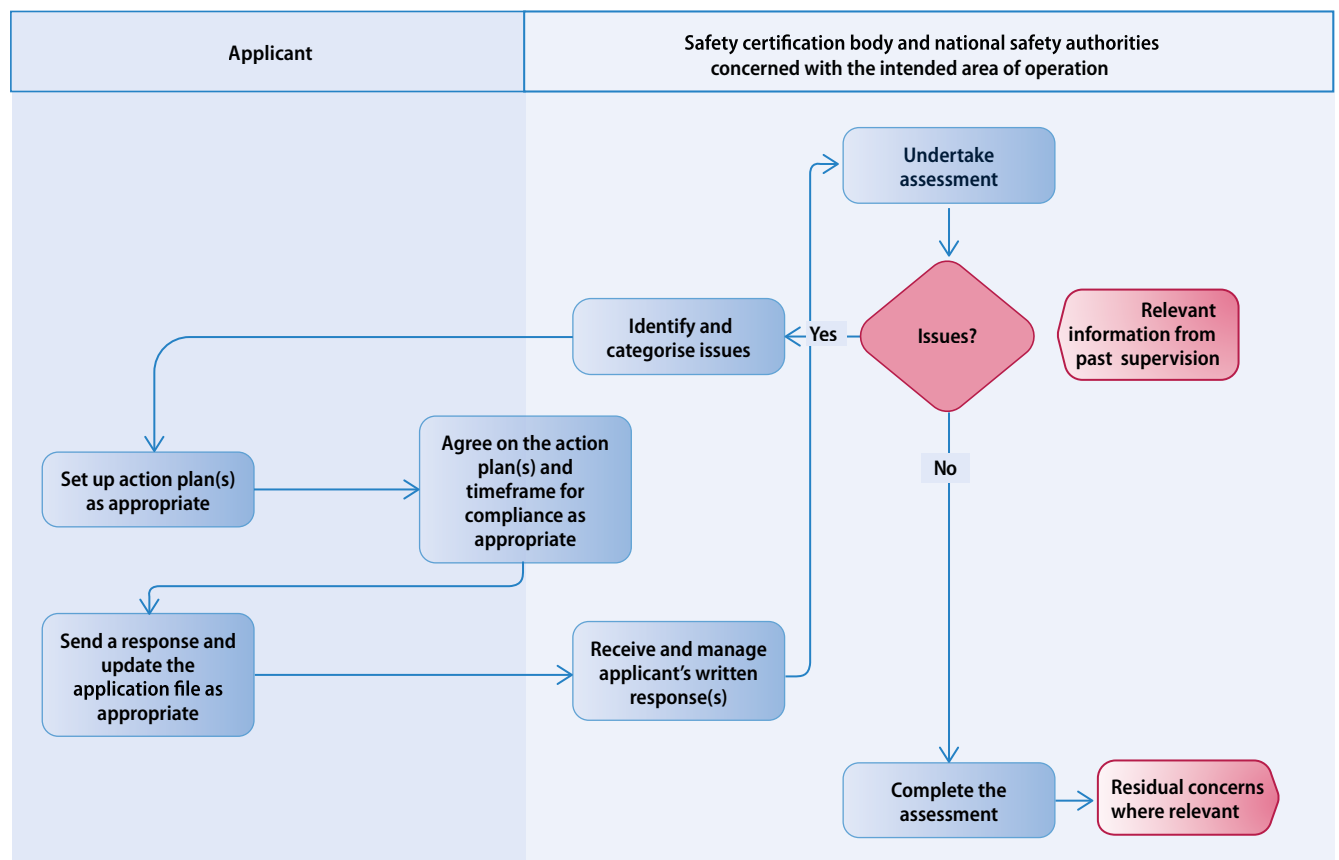
#### **5.4. Detailed assessment**

The detailed assessment starts after a positive decision on the completeness, relevance and consistency of the application. Each authority proceeds for its own part to the detailed assessment of the application file. In the course of this stage, each authority:

- ▶ Analyses the results of past supervision collected during the initial screen (when applicable);
- ▶ Carries out the assessment of the evidence submitted by the applicant.
- ▶ Issues its opinion over the issuing of the single safety certificate.



Figure 4: The detailed assessment



The detailed assessment covers the assessment of compliance with both the SMS requirements including the relevant TSIs and the national rules.

The assessment of compliance with the SMS requirements falls within the competence of the safety certification body. The assessors may find useful guidance on how to perform this assessment in the *Agency guide on safety management system requirements*.

The assessment of compliance with the notified national rules falls within the competence of the national safety authority for the intended area of operation. To help the applicant understand what is expected of it, the national safety authority is requested to publish and keep up to date an application guide, free of charge, describing and explaining the rules that are valid for the intended area of operation (including the scope of transposition of the safety directive and the arrangements for accessing any Border Stations) and the documents that the applicant has to submit.

Based on the information collected during the previous stages, the authorities involved in the safety assessment define the scope of the assessment and decide whether issues have to be further investigated during on-site audits or inspections (see also [section 11](#)).

In the case of an update or renewal application (see also [section 15](#)), the authorities are required to have a targeted and proportionate approach to re-assessment.

During the course of the detailed assessment, similarly to the initial screen stage, authorities involved in the safety assessment should promptly coordinate discussion of:

- ▶ Any issues (e.g. instance of non-compliance) and the need to request for further information;
- ▶ The outstanding issues identified during previous supervision;
- ▶ The contingency measures in case it will take a longer time to reach a final decision than the expected period.

When concluding such activities, the authorities involved in the safety assessment decide who will address each individual issue with the applicant.



Whenever the application is for a renewal or update of a single safety certificate, the conditions or restrictions of use or outstanding issues from the previous assessment are to be considered during this stage to verify whether they are still valid or if they should be lifted.

Similarly, this stage should be used to clarify:

- ▶ possible issues deferred to supervision within the previous assessment, and
- ▶ the implementation of corresponding action plans by the applicant.

If there are outstanding issues raised from previous supervision, the authorities involved in the safety assessment should coordinate to decide whether they need to be recorded in the issue log.

Any differences of opinion among experts (including those experts belonging to the same authority) can also be recorded in the issue log.

When raising an issue, the authorities involved in the safety assessment are encouraged to be as specific as possible, in order to assist the applicant in understanding the level of detail expected in the response without imposing particular actions to resolve it. Editorial or presentational concerns, or typographical errors, are not to be taken as evidence that the applicant has not demonstrated compliance unless they affect the clarity of the evidence provided by the applicant.

If all or parts of the application are deficient, the authorities involved in the safety assessment can request supplementary information from the applicant, using the issue log and specifying a timeframe for the expected response which is reasonable and proportionate to the difficulty of providing the information requested. In turn, the applicant provides the requested information through the issue log. If the applicant does not agree with the proposed timescale, it can still discuss it with the concerned authority, which in turn can decide to modify it using the issue log.

To be satisfactory, the applicant's written responses must be sufficient to allay the concerns expressed and to show that its proposed arrangements will meet the relevant requirements. When creating an issue the assessor should open the relevant part of the application form (eg the specific part of the Mapping Table) to allow the applicant to update relevant documents. It can submit new documents and/or rephrase parts of the originally submitted documents replacing what was unsatisfactory in the original application and including an explanation of

how the revision deals with the identified deficiencies. The applicant may in addition supply relevant supporting information (e.g. SMS procedures). New and/or updated documents are submitted through the issue log as attachments to the respective issues. The applicant is responsible for identifying changes made to documents previously submitted (e.g. using track changes) and uploading the new versions in the OSS. This allows the assessors to check that the relevant parts of the documents have been modified accordingly and that other parts have not been changed.

Likewise, the applicant may propose measures to resolve issues and define timescales for their implementation. If the relevant authority does not agree with the proposed measures and/or timescales, it is invited to contact the applicant promptly to resolve the issue and record the decision in the issue log.

Where a response is largely satisfactory, but there is a residual concern, the authorities involved in the safety assessment should decide, each for its own part, whether to raise this matter with the applicant as an issue for the applicant to resolve over the lifetime of the certificate (a Type 2 Issue) or to agree to defer complete resolution to supervision after the issuing of the single safety certificate (a Type 3 issue). Whichever route is taken, the authorities involved in the assessment should record, each for its own part, the decision with reasons in their respective assessment report.

If there are significant matters to be raised, an authority or several authorities in coordination with each other can request to meet the applicant to resolve outstanding matters and avoid multiple exchanges of correspondence. To that end, they confirm any pre-arranged date for this with the applicant or, otherwise arrange a date. In either case, confirmation has to be sent and an acknowledgement requested. This confirmation is sent with details of the matters of concern.

When such a meeting is deemed necessary, the objectives are set as follows:

- ▶ Ensure that the applicant has clearly understood the identified areas of non compliance'
- ▶ Discuss what is required to remedy them;
- ▶ Agree the nature of the further information and any supporting evidence to be provided (action plan).

The authorities may also decide to undertake audits, inspections or visits (see also **section 11**) in order to collect additional evidence that cannot be retrieved from the documentary review of the application file and to get assurance that areas of concern not previously addressed by previous supervision as applicable have been adequately addressed by the applicant. For example, the authorities may decide to audit an applicant when there are doubts about how accurately the SMS reflects the company's operations, i.e. that the company does what is said in the SMS. In such a case an on-site audit, by interviewing staff, may help to collect evidence relevant to the safety certification body's knowledge about the submitted SMS. However, the main purpose of those audits, inspections, or visits should be to collect evidence to close out issues recorded within the assessment process. Reports of the findings should be uploaded in the OSS.

Where the Agency acts as safety certification body, before a decision is taken about issuing of the single safety certificate, the authorities involved in the assessment should coordinate to discuss the content of their respective assessment reports. This should also include agreement on any restrictions and/or conditions of use, any residual concerns to be deferred for later supervision, and set out which national safety authority will follow up the related actions. Following this coordination, the Agency must produce a final assessment report reflecting the outcome of the assessment. Any diverging opinions between assessors will need to be managed by the project manager and they can be recorded in the assessment report if they remain unresolved.

Coordination between the relevant authorities involved in the safety assessment is also necessary if the identified non-compliances cannot be resolved, either because the applicant is unable to resolve the matter to the satisfaction of the authority or a timescale cannot be agreed. If the safety certification body confirms this conclusion, the application may be rejected or restrictions or conditions of use imposed.

## 5.5. Decision-making and closing of the assessment

The safety certification body prepares its decision in the one-stop shop, which is composed of a cover letter, the final assessment report and the single safety certificate when one is to be issued. When doing so, the safety certification body checks that the documents are consistent with each other and with the application (unless it has been proposed to set restrictions and conditions of use) as the information provided in the application form is reused in the single safety certificate. The Decision is notified electronically to the applicant it can also be downloaded from the one-stop shop, using the library functions. Following the notification, the electronic version of the single safety certificate is automatically transferred by the one-stop shop to the ERADIS database. No specific action is required from the safety certification body.

If the decision is a refusal the applicant will only receive a cover letter and the final assessment report, the applicant may request that the safety certification body review its decision (see also [section 14.2](#)). If still not satisfied, the applicant may appeal (see [section 14.3](#)) to the competent authority, either a national appeal body (if the national safety authority is the safety certification body) or the Board of Appeal (if the Agency is the safety certification body). The applicant is obliged to request a review before it can appeal against the decision of the safety certification body.

The applicant may also decide to request a judicial review (see [section 14.4](#)).

The safety certification body completes the administrative closure of the assessment by ensuring that all documentation and records are reviewed, organised and archived in the one-stop shop.

The safety certification body is invited to review this information and update it with the outcome of the assessment with specific attention to changes in the area of operation and restrictions and/or conditions of use identified during the assessment.



## 5. Safety assessment process

The authorities involved in the safety assessment should coordinate to identify lessons learned for use by future assessments and to improve their respective internal procedures. This can include results from internal/external audits and information on issues and risks as well as techniques that worked well that can be applied to future assessments and possibly shared with (or even learned from) other bodies for continual improvement.

## 6. Timeframe for the safety assessment

In accordance with Article 6 of [Commission Implementing Regulation \(EU\) 2018/763](#), the timeframe for completing the safety assessment is managed as follows:

- ▶ A **1-month period** for checking the completeness of the application file (see also [section 5.3](#)). This period starts on the date of receipt of the application file. Where the national safety authority acts as the safety certification body, this date corresponds to the first working day in the Member State concerned following the acknowledgement of receipt of the application file. Where the Agency acts as the safety certification body, this date corresponds to the first working day common to the safety certification body and the national safety authorities for the area of operation following the acknowledgement of receipt of the application file. By the end of this period the safety certification body has to either inform the applicant that the file is complete or ask for relevant supplementary information, setting a reasonable deadline for the provision thereof;
- ▶ A **4-month period** to complete the detailed assessment of the application file (see also [section 5.4](#)), which begins with the notification of completeness of the application file and ends with the notification of the decision for issuing the single safety certificate to the applicant.

With a view to reducing the complexity, length and cost of the certification procedure whenever possible, the safety certification body is encouraged to complete the assessment process before these deadlines.

Although not prescribed in law, where the Agency acts as safety certification body, the following intermediate milestones are proposed:

- ▶ Each authority assigns the competent resource no later than 1 week following the receipt of the application for a single safety certificate;
- ▶ Relevant information that has been collected in respect of the applicant's safety performance from past supervision activities is provided by the national safety authorities to the Agency at the latest when taking its decision regarding the completeness of the application;
- ▶ Each authority involved in the safety assessment concludes its own part of the detailed assessment no later than 5 working days before the agreed timeframe for taking the decision regarding the issuing of the single safety certificate, in order to give the Agency sufficient time to compile the different results and outcomes of the assessment.



During the safety assessment different authorities may ask for additional information and clarification, each for its respective part of the assessment, always specifying the content of the request and a timeframe for the response. If the request for information or clarification has the potential to affect the work of other authorities, the different authorities are invited to coordinate in order to avoid duplicating the same request to the applicant. This does not, in general, extend the timeframe for the assessment unless major deficiencies/non-conformities or multiple minor deficiencies/ non-conformities are identified that prevent all or part of the assessment from continuing.

## 6. Timeframe for the safety assessment

Any decision to extend the timeframe of the assessment is taken by the safety certification body in coordination with the different national safety authorities concerned with the area of operation and agreed with the applicant. The extended timeframe includes both the period necessary for the applicant to provide the requested information and the period necessary for the relevant authorities to check if the newly provided information satisfies the request. If the response is not satisfactory, the safety certification body may further extend the timeframe of the assessment or propose the rejection of the application.

In the case where the Agency disagrees with the national safety authority(ies) concerned with the area of operation with regard to the results and outcome of their assessment (see also **section 14.1**), the timeframe of the assessment can also be extended for the following periods:

- ▶ the period of cooperation with a view to agreeing on a mutually acceptable assessment (i.e. up to 1 month);
- ▶ the period when the matter is referred to the Agency's Board of Appeal for arbitration (i.e. up to 1 month).

If the matter has been referred by the national safety authority(ies) to the Agency's Board of Appeal for arbitration, the time allotted to the Agency to take its final decision, based on the conclusions of the Board of Appeal, is part of the timeframe for the safety assessment.

If the end date of the assessment is such that a decision cannot be taken before the expiry date of the current single safety certificate or the planned start date of any new rail transport operation (e.g. due to delayed submission of an application file by an applicant or agreed extension of the timeframe of the assessment), the authorities involved in the safety assessment together with the applicant may apply contingency measures (see **section 7**).

## 7. Contingency measures

The different authorities may consider adopting contingency measures to address possible concerns regarding the prescribed timeframe for the assessment, in particular if it is felt that the single safety certificate cannot be granted on time (e.g. before the planned start date of a new rail transport operation). In such cases, a way to resolve the problem may be sought by the authority or authorities through mitigating measures, e.g. increasing the number of staff assigned to the application or issuing a single safety certificate with restrictions or conditions of use.

If a single safety certificate cannot be issued on time because the applicant has not submitted all requested information, the authorities should discuss the different options together with the applicant, for example to reject the application or to issue a single safety certificate with restrictions or conditions of use. The latter may relate to:

The validity period of the certificate, under the condition that a shorter period is necessary to ensure the effective control of risks affecting the safety of railway operations;

The type of operation – for example a single safety certificate excluding the transport of dangerous goods;

The area of operation – for example a single safety certificate excluding a part of the intended area of operation.

Moreover, contingency measures might be necessary when a safety certificate is likely to expire before a renewal process can be completed due to the late submission of the application file. The authorities concerned, following partial assessment and information collected from past supervision may issue a certificate with a limited validity period and other restrictions or conditions of use (if applicable). This should allow an appropriate timeframe for the detailed assessment and, upon completion of this process, should allow the issuing of a single safety certificate for five years assuming that all the requirements have been met.



## 8. Communication arrangements

The safety certification body should manage the coordination of the different authorities and with the applicant throughout the safety assessment process. When meetings (face to face or tele/video conferences) or other coordination activities have to be organised, records are made by the safety certification body, with copies sent to all participants, and uploaded to the one-stop shop. When such a meeting is to be organised, the party requesting the meeting communicates all relevant details to the others, e.g. the meeting venue, date, agenda, contributions needed from each party etc. Records of meetings or any other coordination activities are made by the requester, with copies sent to all participants and uploaded in the one-stop shop.

Coordination between parties involved in the safety assessment process is normally done in a mutually agreed language which does not have to be the language of the application. This also includes the exchange of views between the Agency and national safety authorities with regard to the results and outcome of assessment as well as any other communication.

Upon request of the national safety authority (or authorities) for the area of operation, the Agency acting as safety certification body can translate its decision and the reasons for it in the language of the national safety authority (or authorities). The translation request is managed outside the safety assessment process, without any cost for the applicant.

The decision of the safety certification body and the reasons for it are always made available in the language of the applicant (i.e. an official language of the Union chosen for the application file).

The above principles apply to all types of oral and written communication including all reports relevant for the safety assessment and other reports produced following a visit, inspection or audit (see also **section 11**).

## 9. Management of issues

### 9.1. Use of the issue log

The authorities involved in the safety assessment have to determine whether the applicable requirements (see **section 6**) are met. During the course of the safety assessment process, the assessors may raise issues during both the initial screen stage and the detailed assessment stage. All issues categorised as one of the four types specified below are recorded in the **issue log** of the one-stop shop to facilitate the communication and exchange of information between the different parties.

If all or part of the application is deficient, the authorities involved in the safety assessment can request supplementary information from the applicant, using the issue log and specifying a timeframe for the expected response. This should be reasonable and proportionate to the difficulty of providing the information requested. In turn, the applicant provides the requested information through the issue log. If the applicant does not agree with the proposed timeframe, it can discuss it with the concerned authority, which in turn can decide to adapt the timeframe for the expected response in the issue log.

To be satisfactory the written responses of the applicant must be sufficient to allay the concerns expressed and to show that its proposed arrangements will meet the relevant requirements. It can submit new documents and/or rephrase parts of the originally submitted documents, replacing what was unsatisfactory in the original application with an explanation of how this deals with the identified deficiencies. The applicant may in addition supply relevant supporting information (e.g. SMS procedures). The applicant should note that all new documents should be added in the relevant part of the library and linked to the relevant issue and not uploaded in the issue folder in the library and all new versions of documents should be updated using the relevant button. The applicant is recommended to look at the relevant tutorial in the OSS Guide available on the ERA website. The applicant is responsible for identifying changes made to documents previously submitted (e.g. using track changes). This allows the assessors to check that the relevant parts of the documents have been modified accordingly and that other parts have not been changed.

Similarly, the applicant may propose measures to resolve issues and timescales for their implementation. If the concerned authority does not agree with the proposed measures and/or timescales it is invited to contact the applicant promptly to resolve the issue. The agreed resolution of the issue should be recorded in the issue log.

## 9.2. Categorisation of issues

Article 12 of [Commission Implementing Regulation \(EU\) 2018/763](#) identifies four types of issues:

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**Type 1** corresponds to a query. In this case, the applicant is requested to provide additional information to clarify some aspects of the application file.

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*In this case the applicant may be required to supply information to clarify a particular matter of concern. For example, the organogram submitted by the applicant appears to show responsibilities for safety related matters to align in a certain way. However, the supporting explanatory text appears to show a different alignment, demonstrating a lack of clarity of safety responsibilities.*

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**Type 2** corresponds to an observation or remark that is left to the judgement of the applicant during the lifetime of the single safety certificate.

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*For example, the assessor has noticed in the application file that there are some inconsistencies between referenced standards of the company. These discrepancies relate to different standards applied by different departments of the company. They do not have safety implications but do need to be resolved by the applicant. The applicant should be aware that Type 2 issues will be checked at the renewal or update of a single safety certificate. Failure to resolve these at that time may result in the Safety Certification Body raising a different Type of issue going forward to resolve the matter.*

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**Type 3** corresponds to a minor non-compliance or residual concern. The assessor raising the issue decides whether the resolution of the issue can be postponed until after the issue of the single safety certificate. In this case, the applicant is expected to resolve the matter by the date specified in the accompanying Action Plan or before the next application for renewal or update. Before issuing the single safety certificate, it should be agreed among the authorities involved in the safety assessment which of them will follow-up these issues during its supervision activities. Type 3 issues that are not closed before the issuing of the single safety certificate will be transferred into the issue log for re-evaluation during the next renewal/update application.

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*A 'type 3' categorisation means that the issue identified will be noted with an expectation that it will be followed up by the relevant national safety authority during the supervision activities after the granting of the single safety certificate. Residual concerns may be closed by the safety certification body at the next renewal/update application by taking into account the information provided by the national safety authority or where no supervision has yet taken place (eg in the case of an update) by the safety certification body following a response by the applicant.*

*For example, the assessor observes that an applicant states that it has set up a monitoring process in accordance with [Regulation \(EU\) 1078/2012](#) but s/he finds evidence that the process has been accepted by only four out of five contractors. The applicant confirms that it still awaits final confirmation from the fifth, which will be responsible for non-safety-related tasks such as cleaning*

*trains. In that case the assessor can accept the assurance of the applicant that the information will be provided and reclassify the issue as a residual concern to be confirmed later by supervision of the national safety authority.*

*The applicant will normally be expected to provide an Action Plan to address the concerns laid out in the Type 3 issues raised. This Action Plan should cover the points set out in the [Annex to regulation \(EU\) 1078/2012](#) on Monitoring by Railway Undertakings and Infrastructure managers. A template of such an Action Plan is given in Annex 3. Note there is no requirement that Type 2 issues are covered by an Action Plan, however, for an applicant to keep track of such matters during the lifetime of a Single Safety Certificate they may include them. The National Safety Authority has no obligation to check and resolve these Type 2 issues in ongoing supervision but they may choose to ask questions as to progress.*

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**Type 4** corresponds to a major non-compliance where the point raised by the absence of information or the lack of clarity of such information is so important that the application cannot be accepted as it stands and a single safety certificate cannot be issued or will need to have a restriction or condition of use applied unless the issue is closed.

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*For example, an applicant submits an application where it has provided some evidence that a process for planning changes is in place. The analysis of the submitted information shows that there is no mention of [Regulation \(EU\) 402/2013](#) as part of its risk management process. As there is a legal requirement to use this Regulation where appropriate, this is a major deficiency in the application file that must be corrected before the issue of the single safety certificate.*

*In general, 'Type 4' issues will be those where the applicant has not demonstrated in its application file that it is complying with EU or national law, or there is evidence from the supporting documentation that it may not be. One possible solution for the resolution of such issues might be to impose restrictions or conditions of use in the single safety certificate. This option is appropriate if the restrictions or conditions of use can be clearly defined and do not affect other parts of the SMS. For example, an organisation may specify that it intends to operate both passenger and freight operations but provides no evidence that is able to control the risks related to its freight operations. In that case the applicant could have its single safety certificate restricted only to passenger operations. In such a case the restriction is tied to the Type 4 issued that has been raised and which will be referred to in the final assessment report along with an appropriate justification for the decision.*

Based on the information provided by the applicant, the authority adapts the status of the issue as follows:

- (a) 'Issue pending' if the evidence provided by the applicant is not satisfactory and additional information is still required during the assessment process;
- (b) 'Issue closed out' if a suitable response has been provided by the applicant and no residual matter of concern remains.

At the end of the process an issue resolution must be reached for all issues. There are four possibilities:

- (a) *For all types of issue an issue resolution of 'closed out; because the applicant has resolved the matter. The accompanying text to the resolution should explain the assessors reasoning.*
- (b) *For Type 2 issues, the issue will be closed with a resolution status 'pending'. This is to reflect the fact that the applicant has the lifetime of the SSC to resolve the matter. The accompanying text to the resolution should explain the assessors reasoning.*
- (c) *For Type 3 issues 'Residual concern(s) for supervision' The resolution status of residual concerns for supervision meaning the issue will be followed up by the relevant NSA during their supervision activities over the lifetime of the SSC and the status of the issue will be set to closed. The accompanying text to the resolution should explain the assessors reasoning and which NSA will take responsibility for the follow up during supervision unless this is obvious because the application is only for one member state.*
- (d) *For Type 4 issues where a restriction or condition of use will be applied. The issue will be closed, and the resolution issue set to restrictions or conditions of use. The accompanying text to the resolution should explain the assessors reasoning.*

Where a response to a pending issue is received, the assessor will see that the issue status has been changed to responded and being the issue owner, will scrutinise the response and reclassify as necessary the issue to reflect that the matter has been either satisfactorily dealt with or not. In the latter case the assessor provides its decision and the reasons for it in the issue log and requests additional information as appropriate.

The assessor indicates why compliance is not achieved but it is then for the applicant to identify how it will achieve compliance and to agree with the assessor a timescale for doing so. If the timescale extends beyond the expected date of certification, then further judgement is needed about whether the issue pending is a blocking point for issuing the single safety certificate.

If the applicant does not provide the requested information, or if the supplementary information provided by the applicant is not satisfactory, the timeframe of the assessment may be extended, or an application can be rejected. Rejecting an application is the last resort, and when the safety certification body decides to do so the decision and the reasons for it are recorded in the assessment report and notified to the applicant. Any rejection decision requires a re-submission of the application. The applicant will have to pay the costs involved in the assessment of any rejected application as well as the costs of re-assessment.



## 10. Quality assurance

The safety certification body is responsible for ensuring that:

- ▶ The different stages of the process have been correctly applied;
- ▶ There is sufficient evidence to show that all relevant aspects of the application have been assessed;
- ▶ The applicant has responded to all matters of non-compliance (i.e. 'type 3' and 'type 4' issues) and any other requests for further information have been received from the applicant;
- ▶ Type 3 and type 4 issues were all resolved or, where not resolved, the reasons for this were clearly documented;
- ▶ Residual concern for supervision are assigned to and agreed with the competent national safety authority;
- ▶ The decisions made are documented, fair and consistent;
- ▶ The opinion over the issue of the single safety certificate, given in the assessment report, reflect the assessment as a whole.

If the conclusion is that the process has been properly followed it will be sufficient to confirm that the above steps have been followed, accompanied by any qualifying comments. If the conclusion is that it has not, then the reasons for reaching this conclusion should be stated clearly.

## 11. Audits, inspections or visits

The authority or authorities involved in the safety assessment are empowered to conduct audits, inspections or visits at the site(s) of the applicant.

For the purposes of this guide:

- ▶ **Audit** means the structured intervention where the railway undertaking is examined against a particular safety management standard or against a particular audit protocol. Audits can be performed either off-site or on-site, using various techniques such as document review, interviews or sampling;
- ▶ **Inspection** means the use of an authorised and competent staff member of the safety certification body or relevant national safety authority, as appropriate, to examine a particular and limited aspect of the activity of a railway undertaking. Inspection should be for the purpose of establishing compliance with the SMS requirements and the notified national rules, or for verifying that what has been said or recorded in documents supporting the safety management system actually happens in practice. An inspection in the sense intended here both verifies that the process is in place and examines how well it works. It does not mean the 'tick-box' verification of the presence of certain documents or equipment, because this can only tell the Inspector that something is present not that it is being used in practice.
- ▶ **Visits** to the site of the applicant, other than those performed for the purpose of an inspection or an audit, are short notice interventions to specific parts of the site of the railway undertaking with the aim of observing the correct implementation of an SMS procedure.

**Where the Agency acts as a safety certification body**, the objectives and scope of, inspections or visits and the role assigned to each authority involved has to be coordinated in order to avoid duplication of effort and to reduce the possibility of requiring the applicant to accommodate multiple audits, inspections or visits. When the Agency conducts an inspection or visit, the relevant national safety authority (or authorities) provides the necessary support and assistance to the Agency in order to meet any applicable safety rules in force on the site(s) of the applicant.

The authority undertaking an audit, inspection or visit is expected to have internal arrangements or procedures setting out the framework for delivering it. For that purpose, it may decide on a voluntary basis to apply the principles and requirements established by relevant standards such as ISO 19011 and ISO 17021 for the conduct of management system audits and ISO 17020 for the inspections.

Findings from audits, inspections or visits are evidence that may support the closing of issues recorded in the issue log. However, in some cases, they may cover issues (e.g. instances of non-compliance) not previously identified and in that case they are to be recorded in the issue log as new issues.

More detailed information regarding the audit and inspection techniques can be found in the *Agency guide on supervision*.

## 12. Interface between assessment and supervision

Assessment and subsequent supervision have a close relationship where the results of the assessment inform the national safety authority supervision and, in turn, the outcomes of the national safety authority supervision inform the re-assessment before the renewal or the update of the single safety certificate.

Issues identified during the assessment can be deferred for later supervision unless they concern major non-compliances that would prevent the issue of the single safety certificate (i.e. 'type 4' issues) and on condition that their follow-up is agreed by the competent national safety authority.

Supervision helps determine how effectively the SMS works, which can serve as input for the re-assessment of the application before the renewal or update of the single safety certificate. More detailed information can be found in the *Agency guide on supervision*.



## 13. Training centres, entities in charge of maintenance and transport of dangerous goods

In accordance with Article 5 of Commission Decision 2011/765/EU and Article 13(2) of [Directive \(EU\) 2016/798](#), the recognition of a training center which belongs to a railway undertaking can be stated on its single safety certificate in the case where the following preconditions are fulfilled:

- ▶ The railway undertaking is not the only training provider on the market;
- ▶ The railway undertaking provides training only to its own staff.

The applicant should select the option Recognition of a Training Centre on page 1 of the application form when making their application. It is recommended that the relevant national safety authority confirms the recognition of the railway undertaking's training centre in its assessment report and that the statement of recognition is displayed on the single safety certificate even if that national safety authority is not the safety certification body.

Railway undertakings acting as entities in charge of maintenance (ECMs) and maintaining vehicles exclusively for their own operations do not have an obligation to hold an 'ECM certificate' in accordance with Article 3(2)(b) of [Commission Implementation Regulation \(EU\) 779/2019](#). However, their maintenance system must still comply with Annex II to this Regulation. Evidence of compliance with this Annex must be provided by these railway undertakings when applying for a single safety certificate. The applicant should indicate in the appropriate part of page 1 of the application form in the OSS if it wishes to be assessed in this way. Appropriate wording will be displayed in the Single Safety Certificate to reflect such an application.

The fact that this has been assessed as part of the application may be added to the issued SSC under the Additional Information section.

Where the applicant has indicated dangerous goods as part of the scope of operations the SCB should be aware that it must consult with the competent authority for the carriage of dangerous goods by rail as to compliance with the relevant legislation. Where ERA is the SCB this consultation will be carried out via the relevant NSA(s) for the area of operation.

## 14. Arbitration, review and appeal

### 14.1. Arbitration

Arbitration only applies in cases where the Agency acts as safety certification body, as referred to in Article 10(7) of [Directive \(EU\) 2016/798](#).

During the course of the safety assessment, before taking its decision over the issue of the single safety certificate, the Agency may disagree with the assessment undertaken by one or more national safety authorities.

When the Agency disagrees with the negative assessment of one or more national safety authorities and no mutually acceptable assessment can be agreed on, the relevant national safety authority (or authorities) may refer the matter to the Agency's Board of Appeal. In such a case the Agency suspends its decision until the arbitration procedure is completed. Therefore, the time elapsed between the request for arbitration and the decision of the Board of Appeal is not considered part of the safety assessment timescale.

The applicant is informed through the one-stop shop about the extension of the timeframe of the assessment due to the arbitration procedure.

Where the Board of Appeal agrees with the Agency, the latter will take a decision and grant a single safety certificate without delay. Where the Board of Appeal agrees with the national safety authority the Agency will grant a single safety certificate without delay, with an area of operation excluding the parts of the network that received a negative assessment.

Requests for arbitration are addressed to the Board(s) of Appeal. The proceedings are registered by the Registrar of the Board(s) of Appeal in the one-stop shop.

The Board of Appeal dealing with the arbitration case has access to the complete application file available in the one-stop shop. The Board of Appeal decides whether to confirm the Agency's draft decision within 1 month of the request for arbitration of the national safety authority or authorities.

The decision of the Board of Appeal is notified to all parties involved in the safety assessment, including the applicant, through the one-stop shop.

The same arbitration procedure also applies in the event of a disagreement between the Agency and the national safety authority when the latter finds during its supervision that the holder of a single safety certificate issued by the Agency no longer satisfies the conditions for certification and asks the Agency, as safety certification body, to restrict or revoke the certificate.

Considering that the arbitration procedure would lead to an extension of the timeframe of the assessment, the Agency specifies the different milestones relating to the arbitration in the dashboard of the one-stop shop (see also **section 3.2**).

### 14.2 Review

The review process applies both to the Agency and to the national safety authority acting as safety certification body, as referred to in Article 10(12) of [Directive \(EU\) 2016/798](#).

In cases where the safety certification body refuses the issue of a single safety certificate or issues a single safety certificate with restrictions or conditions of use other than the ones identified by the applicant in its application form, the applicant may request the review of the decision within one month of the date of its notification. This request is submitted by the applicant through the one-stop shop.

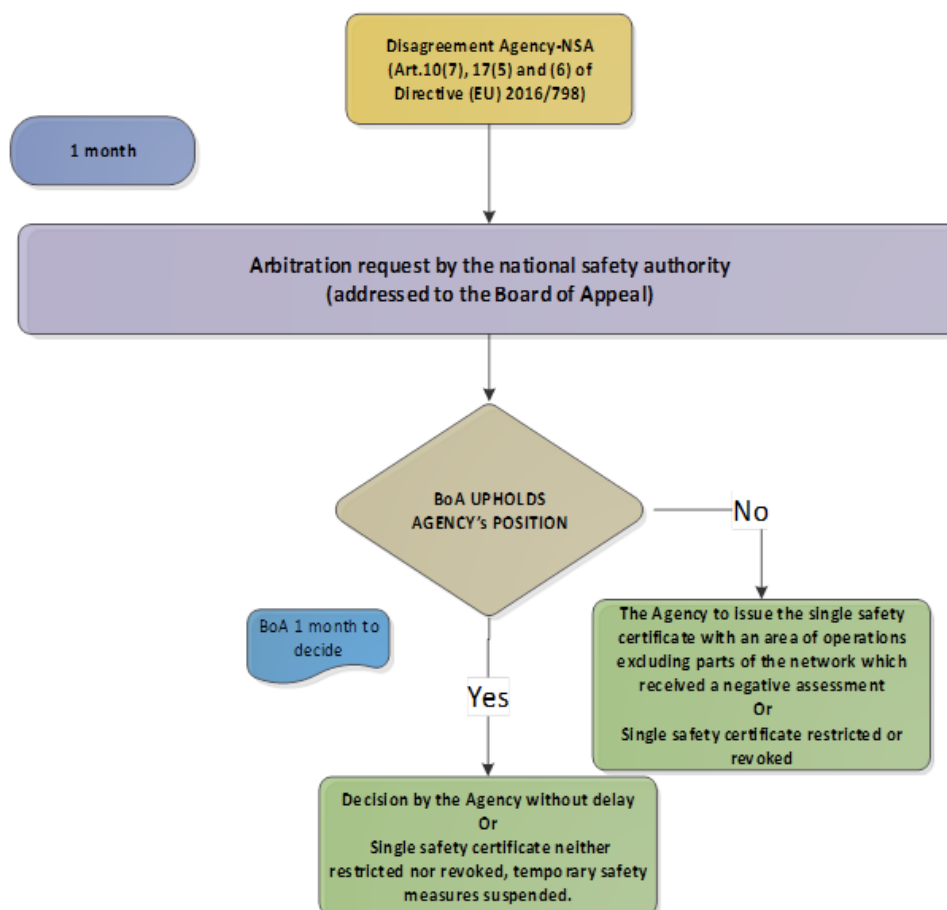
The applicant justifies its request for review and includes a list of issues that, in its view, have not been properly considered during the safety assessment. In doing this the applicant should note that new supplementary evidence that has been developed after the notification of the decision will be disregarded by the safety certification body. If the applicant wants new evidence to be considered and assessed, this can be done only in the context of a new application.

When reviewing the case the safety certification body acts within the framework of its internal rules of procedure to ensure the impartiality of the process including, as far as reasonably practicable, the use of assessors that have not been involved in the first assessment. The review process follows the structure of the safety assessment process but is, however, limited to those issues that were the basis for the negative decision at the first assessment. In addition, the authorities involved will not perform any audit, inspection or visit to the site(s) of the applicant in relation to the list of issues included in the request for review.

The decision of the safety certification body to confirm or reverse its first decision is communicated to all parties involved in the safety assessment, including the applicant, through the one-stop shop within two months from the date of receipt of the request for review. Where the negative decision is reversed within the review process, the safety certification body issues a new single safety certificate without delay. The reviewed certificate is the same type of certificate (new/amended/renewed) as the original one subject to the review process. The original certificate is invalidated in the ERADIS database. If the negative decision of the safety certification body is confirmed, the applicant may bring an appeal before either:

- ▶ the Board of Appeal, for applications for which the Agency has been selected as a safety certification body – see also **section 14.3**; or
- ▶ the national appeal body in accordance with the relevant national procedure, for applications for which the national safety authority acts as safety certification body.

Figure 5: Flowchart of the arbitration procedure



### 14.3 Appeal



**After a request for review** and in cases where the negative decision is confirmed, the applicant may still appeal against the decision of the safety certification body, as referred to in Article 10(12) of [Directive \(EU\) 2016/798](#).

According to Article 59 of the [Agency Regulation \(EU\) 2016/796](#), natural or legal persons may also appeal against a decision that is of direct and individual concern to them, even though the decision is addressed to another person (i.e. the applicant in the present case).

In the case where the national safety authority is the safety certification body, the appeal process is described in the application guide of the national safety authority.

**In the case where the Agency is the safety certification body**, the following appeal process applies.

The applicant files its appeal to the Board of Appeal. The Registrar of the Board of appeal notifies the relevant Project Manager and the Project Manager will set the dates of the appeal

in the Dashboard and upload as necessary any documentation. The Board of Appeal decides within 3 months after the appeal has been filed whether to grant or refuse that appeal. The decision of the Board on Appeal on the appeal is also recorded in the one-stop shop.

Where the Board of Appeal finds that the grounds for appeal are well founded, it remits the case to the Agency. The Agency, in coordination with the national safety authority (or authorities) concerned by the area of operation, reviews its decision following the recommendation(s) of the Board of Appeal. This process follows the internal rules of procedure of the Agency and ensures impartiality including, as far as possible, the use of assessor(s) that have not been involved in the first assessment. The decisions of the Board of Appeal are recorded in the one-stop shop.

Where the decision, subject to the appeal process either of the Board of Appeal or the national appeal body, is reversed the safety certification body issues the single safety certificate without delay and in any case not later than one month following the notification of findings by the Board of Appeal.

The procedural rules applicable to the appeal are further detailed in Commission Implementing Regulation (EU) 2018/867 [*rules of procedure of the Board(s) of Appeal of the Agency*]. The fee for an appeal is determined in accordance with [Commission Implementing Regulation \(EU\) 2018/764](#) on fees and charges.

### 14.4 Judicial Review

Decisions taken by the safety certification body are subject to judicial review.

**In the case where the Agency is the safety certification body**, its decisions are subject to judicial review under Article 263 of the TFEU. An action for the annulment of an Agency decision or for failure to act within the applicable time limits may be brought before the Court of Justice of the EU only after the appeal procedure (see also **section 14.3**) has been exhausted, as stipulated in Article 63 of [Regulation \(EU\) 2016/796](#).

**In the case where the national safety authority is the safety certification body**, its decisions are subject to judicial review under provisions of the national legislation. The procedure to request a judicial review is described in the application guide of the competent national safety authority.

## 15. Update and renewal of a single safety certificate

According to Article 10(13) and Article 10(14) of [Directive \(EU\) 2016/798](#), the single safety certificate needs to be updated when the railway undertaking makes **substantial changes to the type or extent of the operation, or in case of extension of the area of operation**. The holder of a single safety certificate has to notify the safety certification body without delay whenever it proposes to make such changes. The changes can be of technical, operational or organisational nature.

An updated single safety certificate may also be required when there are substantial changes in the safety regulatory framework in accordance with Article 10(15) of [Directive \(EU\) 2016/798](#).



A single safety certificate might also need to be updated when the conditions under which it was issued have changed without any impact on the type, extent or area of operation. For example, if the complete Safety Management System has been revised and all the procedures altered as a result. If the applicant is unsure whether an update is required they should contact the relevant Safety Certification Body for advice.

A renewal of a single safety certificate is necessary for those railway undertakings who already have a valid single safety certificate and wish to continue their railway operations after the expiration of their current single safety certificate.

The safety certification body may bring to the attention of the applicant that its single safety certificate needs to be updated or renewed. It is good practice that this is done at least six months before the expiry of any existing safety certificate. The actual application for an update or renewal of a single safety certificate should not be on the initiative of the safety certification body but an action by the railway undertaking.

When applying for an update or renewal, the railway undertaking must hold a valid single safety certificate for the area of operation to be covered by the single safety certificate.

### 15.1 Assessment of the need to update a single safety certificate

An update of a single safety certificate is only required when there is a 'substantial' change to the conditions under which it was issued ie to the Type, area or extent of operation. When considering whether to make an 'update' application the applicant should consider that the legal timeframe for assessment of this is 5 months (1 month for the Initial Screen and 4 months for the Detailed Assessment). The applicant therefore needs to consider both the expiry date of their existing certificate and the date that they need the update for. If these dates are close

together then it may be a better option to wait for or anticipate the time left until the expiry of the current SSC. This will avoid applicants incurring unnecessary costs.

It can be summarised that:

- (a) *the railway undertaking establishes and uses an SMS to ensure the control of all risks associated with its activities, including the safe management of changes. As part of the SMS, the railway undertaking also monitors the correct application and the effectiveness of the SMS arrangements, including the risk control measures;*
- (b) *the safety certification body is responsible for granting the safety certificate. After the granting of the single safety certificate, the national safety authority undertakes supervision to oversee the continued compliance of the railway undertaking's SMS with its legal obligations;*
- (c) *Article 10 (13), Article 10 (14) and Article 10(15) of [Directive \(EU\) 2016/798](#) set out the conditions for the update of the safety certificate;*
- (d) *Annex II of [Implementing Regulation \(EU\) 2018/763](#) requires the holder of the single safety certificate to inform the safety certification body of all substantial changes in the type, extent or area of operation.*

The railway undertaking submits an application through the one-stop shop for the update of its valid single safety certificate.

The applicant describes the proposed changes, including as necessary a risk assessment, (this may require the use of the measures required by CSM for Risk Assessment and Evaluation (EU) 402/2013 where the change is considered to be significant.) It should be noted that the term significant as defined in [Regulation \(EU\) 402/2013](#) is not the same as the term 'substantial' referred to in the [Regulation \(EU\) 2018/763](#). The latter only refers to the cases mentioned above whilst the former could apply to a larger set of possible changes.

The changes made to the documentation may be indicated in a number of ways, using a table or highlighted text for example, but need to be clearly identified in the tables cross-referencing the documentary evidence with the legal requirements, that are annexed to the application file.

In the case of an update of the single safety certificate, the scope of the SMS re-assessment should in any case be proportionate to the level of risk introduced by the change(s) and should focus on the relevant areas.

In order to identify the relevant requirements upon which to assess the application for the update the authorities involved in the safety assessment consider the changes made to the documentary evidence that was submitted in the previous application and take into account the results of past supervision activities.

The applicant should also include as part of any update application information on the actions taken to address any outstanding issues (Type 4, Type 3 and Type 2) from the previous

assessment as well as a table of any other changes made to their Safety Management System beyond that for which the update is being made.

Then applicant should also be aware that the Safety Certification Body will contact the relevant National Safety Authorities for information about any supervision activities they may have conducted in the period from the issue of the single safety certificate to the point where the update application is made.



All of the above does not preclude the authorities involved in the safety assessment from making, in certain cases, a complete re-assessment of the application file. For example, a complete re-assessment might be performed if the applicant does not provide sufficient information about the changes made to its SMS, or the application is made during a transition phase between one regulatory regime and another, or if there are significant matters of concern raised during previous supervision activities.

## 15.2 Type and extent of operation

The terms “type” and “extent” of operation are defined in Article 3 of [Directive \(EU\) 2016/798](#) as follows:

(a) **Type of operation** *is characterised by:*

1. passenger transport, including and excluding high-speed services;
2. freight transport, including and excluding dangerous goods services, and;
3. shunting services only;

(b) **Extent of operation** *is characterised by:*

1. the number of passenger and/or volume of goods, and;
2. the estimated size of the railway undertaking in terms of employees working in the railway sector (micro, small, medium sized, large enterprise).

Furthermore, regarding the type of operation, it has been acknowledged that other types of services may exist, such as operations in privately owned sidings, testing of vehicles etc. These additional types of services should be identified in the application form.

## 15.3 Extension of the area of operation

In the case of an extension of the area of operation, the railway undertaking makes the necessary changes to the evidence submitted in the previous application. This should cover the relevant requirements laid down in the notified national rules for the new area of operation. The applicant will also be required to show that they have considered the additional risks posed by the new operation and that it has been integrated into its safety management arrangements.

When such an application for an update is submitted, even if the change affects only one authority, all authorities involved in the previous safety assessment will be notified accordingly.



## 15.4 Change of safety regulatory framework

Any substantial change in the safety regulatory framework (e.g. a new EU Regulation, a national regulation including new or revised notified national safety rules) has to be identified and managed by the railway undertaking through its SMS processes (e.g. compliance with legal and other safety requirements, change management process). The railway undertaking is then responsible for complying with the new or revised legal requirements. As part of its duties the national safety authority has to promote the safety regulatory framework. Therefore, the national safety authority is expected to give support as appropriate to the railway undertaking for it to understand the content of the changes made to the safety regulatory framework.

## 15.5 Change to the conditions under which the single safety certificate was issued.

As a general rule, the railway undertaking is responsible for engaging with the safety certification body when it plans a change to the conditions under which the single safety certificate was issued. This covers a variety of changes that the railway undertaking might plan. These may range from simple administrative ones to substantial operational ones (e.g. a change to the SMS procedures that has been identified as significant according to [Regulation \(EU\) 402/2013](#)).

The administrative changes are limited to changes in basic information in the single safety certificate (e.g. legal denomination, registration number and VAT number) without any impact on the type, extent or area of operation. For such administrative changes a simplified process for updating the single safety certificate may be applicable and the safety certification body decides, at the request of the railway undertaking, whether the single safety certificate needs to be updated.

Before taking the decision to apply such a simplified process, the safety certification body is encouraged to check that the notified change does not hide organisational changes which may affect the operation of the train (e.g. change of the name or registration data due to restructuring of the company or merging of two different companies with reallocation of safety related tasks and responsibilities).

## 15.6 Examples of changes that could require the update of a safety certificate

Any substantial change made to the type or extent of the operation requires the update of the single safety certificate. In addition, any extension of the area of operation requires the update of the single safety certificate. The provisions in the SMS of the railway undertaking should be arranged in such a way that they are valid for the intended area of operation (e.g. infrastructures of different Member States).

In most of the cases any change made to the type of operation as specified in the certificate requires an update.

Changes made to the extent of operation require more reflection as this information is not directly reflected in the certificate and is more dependent on changes in company resources and its business performance.

All changes recognised as “substantial” lead to a re-assessment and an update of the certificate. This applies whether the change concerned arises from business developments within a company or from the taking over of another company’s operation.

For example, if a railway undertaking delivering passenger transport intends also to operate freight transport, after either merging with or acquiring another company, this should be considered as a “substantial change” in the “type and extent” of the service delivered by the railway undertaking and the single safety certificate should then be updated.

If the change does not affect the type or extent of the operation, or if the need for update of the single safety certificate is not obvious, the question of new or increased risk for the railway company’s operation may need to be considered as a parameter. In addition, it should be questioned whether the change can be managed safely through the safety management system of the railway undertaking. As already mentioned, the scope of the SMS re-assessment must in any case be proportionate to the level of risk introduced by the change(s) and to the nature and significance of the change(s). The applicant should always carry out a risk assessment and where necessary apply the provision of the [CSM Risk Evaluation and Assessment \(EU\) 402/2013](#). This would entail the analysis of whether the change is significant or not:

- (a) **Example 1:** a change of legal denomination of the railway company requires the Administrative update of the certificate. However, the change of legal denomination of the railway company should not require the re-assessment of the railway undertaking’s SMS as it is an act of an administrative nature and there is no change to their operation, in this case if this is the only change a simplified process can be adopted with an updated Decision with no formal assessment and a note to the file describing the reason for the change. The applicant will be expected to confirm in writing that there are no other changes taking place which would require a more formal update of the SSC;
- (b) **Example 2:** changes to a lower risk (e.g. change from passenger transport including high-speed services to passenger transport excluding high-speed services) is generally an administrative exercise with only minimal checks on the implications for the railway company SMS in this case a simplified process can be adopted with an updated Decision with no formal assessment and a note to the file describing the reason for the change;
- (c) **Example 3:** changes to a higher risk (e.g. from freight transport excluding dangerous good services to freight transport including dangerous good services) would likely be regarded as a significant change under the [CSM Risk Evaluation and Assessment \(EU\) 402/2013](#) but it would also make this a substantial change from the point of view of the update of the SSC since it alters the type of the operation. This will require the assessment of the change under the SMS provisions and the update of the single safety certificate. As a significant change it will also require the submission of a report from an Assessment Body as required by the regulation;

- (d) **Example 4:** Changes that potentially create higher risks for the operation could be regarded as substantial ones requiring the update of the SSC and would therefore require the assessment of the change under the SMS provisions and the consideration of whether the change was significant under the [CSM Risk Evaluation and Assessment \(EU\) 402/2013](#): A freight operator which went into the passenger market, either running charters or ancillary services as a passenger train operator with a number of services, should normally be regarded as a substantial change as it is changing the type of operation. A risk assessment and the consideration of whether the change was significant under the CSM Risk Evaluation and Assessment (EU) 402/2013 applied would be required;
- (e) **Example 5:** taking into account that the internal restructuring of a railway company could have adverse effects on its SMS arrangements and that the existing processes and procedures of the SMS need to be redesigned or new ones to be developed, such a change could be considered as a significant change under the [CSM Risk Evaluation and Assessment \(EU\) 402/2013](#). It might also then require consideration of whether changes were so great (substantial), that an update of the SSC was required.
- (f) **Example 6:** A change of route could be a substantial change if an operation is proposed for a line or a part of the network on which there was previously no operation by that railway undertaking (except for temporary diversions) and this new route would increase the risk (e.g. exposure to a new risk for that railway undertaking). If the existing SSC contains a list of lines and the new line is not on it, then an update of the SSC would be required. A risk assessment would also be needed and a consideration of whether the change was significant under the [CSM Risk Evaluation and Assessment \(EU\) 402/2013](#);
- (g) **Example 7:** an increase in the frequency of service could increase the risk for the railway undertaking, e.g. potential risks arising from congestion. Such changes should not be considered as substantial ones however, they may be considered significant; they can be managed safely through the SMS of the railway undertaking through risk assessment and compliance with the [CSM Risk Evaluation and Assessment \(EU\) 402/2013](#) :
  1. The SMS has processes and procedures in place to keep risks under control and to take appropriate preventive or corrective actions in case of detection of non-compliances during the monitoring of the operation by the railway undertaking;
  2. The railway undertaking notifies changes to the national safety authorities, so that the national safety authority is able to identify the additional supervisory tasks to be included in its strategy and plan for the supervision of the railway undertaking;
- (h) **Example 8:** similarly, an increase in “route passenger-km per year” or “freight tonne-km per year” might increase the risk as the scale of the operation is affected. However, such changes and the associated risks can also be managed safely through the railway undertaking’s SMS (see example 7 above). The national safety authority can verify how this is done during the supervision activities of the railway undertaking, taking into account the change management information notified by the railway undertaking.

## 16. Renewal of a single safety

A single safety certificate is renewed upon the request of the applicant before the expiry of its validity, to ensure continuity of certification. The legal timeframe for a renewal is 5 months (1 month for the Initial Screen and 4 months for the Detailed Assessment). The applicant applies for the renewal of its valid single safety certificate through the one-stop shop (see also **section 3.2.**).

In the case of a renewal the authorities concerned with the area of operation follow a targeted and proportionate approach to re-assessment, checking the changes to the evidence submitted in the previous application and also considering the results of past supervision activities to identify the relevant requirements against which to assess the application for the renewal.



However, this does not preclude the authorities involved in the safety assessment from making, in certain cases, a complete re-assessment of the application file. For example, a complete re-assessment might be performed if the applicant does not provide sufficient information for the changes made to its SMS or if there are significant matters of concern raised during previous supervision activities.



An application for renewal of a single safety certificate may be merged with an application for an update of the same single safety certificate. For example, an applicant having a single safety certificate that covers an area of operation in two Member States.



Applicants need to consider carefully when to make a renewal and whether to combine this with an update of their application.

## 17. Restricting or revoking a single safety certificate

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A single safety certificate may be restricted or revoked by the safety certification body that has issued it. Such a restriction or revocation happens when the safety certification body is notified by a national safety authority that, following its supervision activities, the holder of the single safety certificate no longer satisfies the conditions under which it has been certified.

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If the national safety authority identifies a serious safety risk, it may decide to take proportionate enforcement action. For instance, the national safety authority may decide to suspend the rail operations of the railway undertaking. Based on this decision the safety certification body evaluates the need to update the single safety certificate with restrictions or, in the last resort, to revoke it. Where the Agency acts as safety certification body the National Safety Authority will provide its justification for a restriction or revocation and coordination takes place between the authorities for the area of operation before a decision is taken.

The railway undertaking whose single safety certificate has been restricted or revoked has the right to appeal against the decision of the safety certification body (see **section 14.3**).

Any request from the national safety authority to restrict a single safety certificate is managed in the one-stop shop. If the decision is to restrict the single safety certificate, the safety certification body issues a new single safety certificate including the restrictions or conditions of use.

Any request from the national safety authority to revoke a valid single safety certificate that has been issued by that national safety authority is managed directly in the ERADIS database in accordance with existing procedures. No separate entry is needed in the OSS.

An applicant can apply for an update of its Single Safety Certificate to remove a restriction or condition of use. In making such an application the applicant will need to provide evidence that the matters which gave rise to the restriction no longer apply and provide any necessary evidence. The Safety Certification Body will process such an application as an update and if the required evidence is provided will issue a new Single Safety Certificate with the previous restriction removed.

An applicant who wishes to operate in both an EU member state and another state or Border Station in another state which is not in the EU should contact the Agency in the first instance for advice on how to proceed.

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## ANNEX 1

## Instructions with regard to the content of the application for a single safety certificate

When submitting an application for a single safety certificate or requesting pre-engagement, the applicant is requested to complete an application form in the OSS.

The following table provides commentary on the application for a single safety certificate, as drawn up in Annex I of [Implementing Regulation \(EU\) 2018/763](#). For easy reference and guidance, this table uses the same numbering as Annex I of the Implementing Regulation.

Table 3: Commentary on the application for a single safety certificate

<a href="#">Annex I of Implementing Regulation (EU) 2018/763</a>	Commentary
1.1-1.3	<p>The applicant selects the relevant type of application as follow:</p> <ul style="list-style-type: none"> <li>▶ 'New': if applying for the first time for a single safety certificate or if the previous single safety certificate has been revoked;</li> <li>▶ 'Renewal': if the previous valid (single) safety certificate is about to expire and its period of validity needs to be extended to ensure continuity of its rail operations;</li> <li>▶ 'Update': if the type or extent of the operation is substantially altered, or substantial changes have been made to the safety regulatory framework, or if the conditions have changed under which the (single) safety certificate was issued.</li> </ul>
1.2	A single safety certificate shall be renewed upon application by the railway undertaking at intervals not exceeding five years, in accordance with Article 10(13) of <a href="#">Directive (EU) 2016/798</a> .
1.4	<p>When applying for a renewal or an update, specify or select the EIN(s) of the previous (single) safety certificate (e.g. a single safety certificate or a Part A safety certificate) in relation to which the application is being submitted to the safety certification body.</p> <p>The EIN(s) of the previous safety certificate are used to invalidate the corresponding certificate(s) in the ERADIS database. In case of doubt, it is advised that the applicant contacts the safety certification body before submitting its application</p>
2.1-2.2	When applying for passenger services (as a part of or as the whole of an application), it has to be specified, by ticking the appropriate box, whether the operations include or exclude high-speed services: only one option may be selected. However the services referred to by selecting option 2.1 or 2.2 include any other type of passenger operation (i.e. regional, short, medium, long distance etc.) as well as of any other service necessary to carry out the passenger services applied for (shunting operations etc.). For the definition of high-speed services, refer to Annex I of <a href="#">Directive (EU) 2016/797</a> .
2.3-2.4	When applying for freight services (as a part of or as the whole of an application), it has to be specified, by ticking the appropriate box, whether the operations include or exclude transport of dangerous goods: only one option may be selected. However the services referred to by selecting option 2.3 or 2.4 include any other type of freight transport not explicitly mentioned as well as of any other service necessary to carry out the freight services applied for (shunting operations etc.). The applicant should also be aware that if they select 'dangerous goods' they will need to provide evidence of compliance with the Transport of Dangerous Goods by Rail Regulations as part of their application.

<a href="#">Annex I of Implementing Regulation (EU) 2018/763.</a>	Commentary
OSS form	Whether the applicant intends to apply for an assessment of its Entity in Charge of Maintenance (ECM) functions as part of its application (only where it intends to be the ECM for its own vehicles). Whether the applicant intends to apply for assessment of its Training Centres by the relevant National Safety Authority as part of its application. (Only where it runs a training centre for its own staff)
2.5	This box shall be selected if the applicant intends to carry out only shunting services without performing passenger or freight transport. The applicant has to specify whether the intended services include or exclude shunting wagons of dangerous goods. This box may also be selected in conjunction with box 2.6 if the applicant intends to carry out other types of operations.
2.6	If the applicant intends to carry out other types of operations it has to specify what these services are, for example: <ul style="list-style-type: none"> <li>▶ Operation of vehicles on privately owned sidings, when not excluded from the scope of its safety management system in accordance with Article 2(3) of <a href="#">Directive (EU) 2016/798</a>;</li> <li>▶ Tests of running behaviour of vehicles and/or stationary tests of vehicles;</li> <li>▶ Operation of vehicles for infrastructure maintenance activities.</li> <li>▶ Any training centres to be recognised in accordance with Article 5 of Commission Decision 2011/765/EU (see <b>section 13</b>).</li> </ul> Any particular national requirements relating to the type(s) of operations can also be added in this field.
3.1	When referring to the services applied for, it is necessary to specify the date on which operational service is intended to begin or, in case of a renewed or updated certificate, the date on which the certificate is intended to become effective and replace the previous one.
3.2	The applicant has to select the Member State for the intended area of operation, including any Member States where they intend to only operate to a Border Station
3.3	The applicant defines its intended area of operation, which may cover the whole railway network of one or more Member States or only a defined part thereof. In the case where the applicant intends to operate only on a defined part of an network it has to either: describe the area of operation it intends to operate as “from point A to point B” (e.g. Paris – Brussels), or list the networks on which it intends to operate, or specify clearly all the lines, including all relevant diversionary lines, where services are intended to be operated. Applicants must refer to lines using the denomination/names given in the ‘Network Statement’ (refer to Article 3 and Annex IV of Directive 2012/34/EU). It is also advised to include the type of signalling systems intended to be used and their geographical extent Please note that when an applicant decides to apply for a detailed area of operation, any change to this area will require an update of the single safety certificate. The way the area of operation is defined is a business decision for the applicant. For Border Stations the applicant must define the area of operation typically, state Border to Border Station X
4.1-4.2	The applicant may select the Agency or the national safety authority as safety certification body (or issuing authority) if the area of operation is limited to one Member State. The applicant shall select the Agency if the area of operation is more than one Member State.
5.1	Only Legal Denomination is to be included.
5.2	The acronym of the railway undertaking can be indicated here (optional).



<a href="#">Annex I of Implementing Regulation (EU) 2018/763.</a>	Commentary
5.3-5.7	<p>Each applicant shall provide the necessary information to allow the safety certification body to contact the railway undertaking.</p> <ul style="list-style-type: none"> <li>▶ A telephone number should be for the railway undertaking's switchboard, where applicable, and not for the person in charge of the assessment process.</li> <li>▶ Telephone numbers, and fax numbers where applicable, should include the country code.</li> <li>▶ The e-mail address should be for the general mail box of the railway undertaking.</li> <li>▶ The railway undertaking contact information should indicate the general address, and avoid references to a specific person as this information may be entered in points 6.1 to 6.6. Specification of the website (5.7) is not compulsory.</li> </ul>
5.8-5.9	If several registration numbers are attributed under national law to the applicant railway undertaking, the one-stop shop form permits the entry of both the VAT number (5.9) and a second registration number (5.8) (e.g. trade register).
5.10	Information in addition to that clearly requested in the other fields can be added if necessary.
6.1-6.8	Throughout the assessment process the contact person is the interface between the railway undertaking submitting its application for a single safety certificate and the safety certification body and relevant national safety authority (or authorities) as appropriate. The contact person provides support, assistance, information and clarifications where necessary, and is the reference point for the safety certification body and relevant national safety authority (or authorities) as appropriate. The contact person is authorised and empowered to represent the applicant organisation. Telephone numbers, and fax numbers where applicable, should include the country code.
7.1	This documented information shall be submitted when applying for a single safety certificate. If the application is for a renewal or an update of the single safety certificate then the changes made to the information submitted in the previous application shall be clearly identified in the different documents as applicable. The 'Summary of the Safety Management System (SMS)' is intended to be a document reviewing and underlining the main elements of the railway undertaking's SMS. It must detail and give supporting information to demonstrate the compliance of the SMS with the assessment criteria set out in Annex II of <a href="#">Commission Delegated Regulation (EU) 2018/763</a> , cross-referencing more detailed documents where relevant. Clear reference should be made to the processes and documents where the Technical Specifications for Interoperability (TSIs) are applicable and implemented. To avoid duplication of work and to reduce the amount of information submitted, summary documentation should be provided in respect of elements that comply with TSIs and other EU applicable legislation.
7.2	A table mapping the main elements of the railway undertaking's SMS to the assessment criteria set out in Annex II of <a href="#">Commission Delegated Regulation (EU) 2018/763</a> , providing evidence of compliance of the general SMS provisions with requirements from Article 9 of <a href="#">Directive (EU) 2016/798</a> . Also an indication of where in the safety management system documentation the requirements of the applicable functional Technical Specification for Interoperability relating to the operation and traffic management subsystem are met.
8.1	The applicant shall submit documentation relating to the notified national rules applicable to the services intended to be operated with the requested certificate. The specific documentation relating to the rail transport operation on the network (or part of it) of each Member State in which the applicant intends to operate shall be part of separate attachments to the application form, as appropriate, in accordance with the language policy set by the national safety authority of the relevant Member State(s).
8.2	A table mapping the specific elements of the railway undertaking's SMS to the requirements laid down in the relevant notified national rules, providing evidence of compliance of the specific SMS provisions with the applicable requirements set out in the notified national rules.



<a href="#">Annex I of Implementing Regulation (EU) 2018/763.</a>	Commentary
9.1	The current status of the action plan (or plans) established by the railway undertaking to resolve any major non-compliance and any other area of concern identified during supervision activities since the previous assessment;
9.2	The current status of the action plan (or plans) established by the railway undertaking to resolve residual concerns from previous assessments.

## ANNEX 2

## List of issues to be covered in the national safety authority application guide

The national safety authorities are invited to cover the following issues in their application guides in respect of their national requirements, in accordance with Article 10(3)(b) of [Directive \(EU\) 2016/798](#):

1. *The scope of the national measures implementing [Directive \(EU\) 2016/798](#) – The national safety authority identifies any possible exclusions applicable in their Member State, according to Article 2.3 of the Directive. It clarifies specific national requirements in relation to the type(s) of operation that require(s) holding a single safety certificate;*
2. *Language policy – Describe the applicable language for the application file where the national safety authority is selected as safety certification body and for the national part of the application file where the Agency is selected as safety certification body;*
3. *Communication arrangements – Describe what and how the national safety authority intends to communicate with the applicant in the case where the national safety authority is selected as safety certification body;*
4. *Fees and Charges – Describe the model for fees and charges in the case where the national safety authority is selected as safety certification body and the hourly rate applied by the national safety authority for the assessment of the national part in the cases where the Agency is selected as safety certification body;*
5. *Description of cross-border agreements or any other kind of applicable arrangements and identification of border stations covered by these. It is also sensible to provide contact details or website for neighbouring member states so that potential applicants can find appropriate information, (where applicable).;*
6. *Description and explanation of requirements laid down in the notified national rules, and applicable national administrative procedures. Any applicable national procedural rules should also be clarified, as this may, for example, relate to specific arrangements or may explain how national certification schemes could serve as proof of the ability of the applicant to meet requirements of the notified national rules. Additionally, the national safety authority will instruct the applicant on how to map its evidence with the national requirements. This mapping can be done through:*
  - *a web-form having the requirements pre-registered by the NSA in the one-stop shop. This is the preferred option,*
  - *an available web-form in the one-stop-shop, where the applicant registers by himself the relevant national requirements, as described by the NSA in its national application guide, or*

- *a template provided by the NSA in its national application guide. The applicant in this case uploads this document to the one-stop shop;*
7. *Minimum insurance requirements (where applicable) such as the need to send evidence of insurance or financial cover for liability;*
  8. *National appeal procedure for the cases where the national safety authority is selected as safety certification body;*
  9. *National provisions regarding judicial review for the cases where the national safety authority is selected as safety certification body.*
  10. *Border station arrangements for the member state that the guide is for and contact details and advice for neighbouring member states.*

ANNEX 3

Template of an Action Plan

Monitoring to Action plan related to issues with need for supervision in line with [Regulation \(EU\) 1078/2012](#).

No.	Issue(s)	Description of the action(s)	Link with the risk assessment	Responsible for implementation	Involved	Monitoring: Execution	Monitoring: Efficiency	If any... ERA suggested milestones	Status of the supervision
0	Make the link or copy-paste the number, the title and the content of the residual concern from the issue in OSS.	Description of the Why, the What, and the How the action(s) will be done, incl. with the corresponding deliverables (can be separated lines)	When relevant, the risk control measures or corrective actions should be explained or linked to this action	Name of the person in charge of the implementation	Link the staff or stakeholders involved before, during or after the execution of the action	Dates (dd/mm/yy) (or steps with dates) of the realisation of the action	How it will be seen, estimated, or measured that the action is achieving the goal for which it was created (linked with CSM on Regulation (EU) 2018/762, 6.1.1d)		To be completed when a renewal or update application is to made. Has an NSA carried out supervision on the action - if so which and with what result. If no supervision on this topic indicate no supervision.
1									
...									

## ANNEX 4

## Instructions on how the safety certification body fills in the fields of the one-stop shop to produce a single safety certificate

When a single safety certificate is to be issued, the safety certification body has to fill in the relevant fields in the one-stop shop (OSS). The following table provides instructions on how to do this, using the same numbering as the one-stop shop.

**Table 4:** Instructions on how the safety certification body reviews and when necessary, updates the fields of the one-stop shop to produce a single safety certificate

Field name	Commentary
<b>1. Certificate information:</b>	
European Identification Number	The EIN is automatically generated.
Type of certificate	New, renewal or update: it is automatically filled in by the OSS, based on the information available in the relevant application form, and may be edited by the safety certification body.
Previous certificate	This is not automatically filled in by the OSS based on the information available in the relevant application form, and may be edited by the safety certification body. The safety certification body is invited to check that this information is accurate. Note this information is not filled in unless the person completing the SSC double clicks on the field.
Validity period:	The safety certification body specifies the validity period. The start validity date does not necessarily correspond with the date of the decision about issuing the SSC, but aligned with the start of operation, as requested by the applicant or the expiry dates of the previous certificate. The OSS automatically calculates 5 years using the start validity date that has been entered. The safety certification body may update it.
<b>2. Railway undertaking:</b>	
2.1 Legal denomination	The railway undertaking will be identified by its legal denomination. This field is automatically filled in by the OSS based on the information available in the relevant application form and may be edited by the safety certification body
2.2 National registration number	This is automatically filled in by the OSS based on the information available in the relevant application form and may be edited by the safety certification body
2.3 VAT number	This is automatically filled in by the OSS based on the information available in the relevant application form and may be edited by the safety certification body.
<b>3. Safety certification body:</b>	
3.1 Organisation	This is automatically filled in by the OSS and may be edited by the safety certification body. For applications issued by the Agency this will read European Union Agency for Railways
3.2 Member State	This is automatically filled in by the OSS and may be edited by the safety certification body
<b>4. Content of the certificate:</b>	

Field name	Commentary
4.1 Type of operation	This is automatically filled in by the OSS and may be edited by the safety certification body
4.2 Area of operation	This is automatically filled in by the OSS and may be edited by the safety certification body.
4.3 Restrictions and conditions of use	Here the one-stop shop allows the safety certification body to identify possible restrictions or conditions of use that have been agreed during the assessment.
4.4 Applicable national legislation	When specifying the applicable national legislation the authorities involved in the safety assessment are encouraged to identify specific exclusions from Directive (EU) 2016/798 applicable to their respective Member States which are relevant for the type and extent of operations. If more details are needed, they may still be provided in the field 4.6 "Additional information" of the single safety certificate.
4.5 Additional information	The authorities may use this field to add other information relevant to the authorities, such as additional types of operation as required by the national legislation (see point 4.5), the entity in charge of maintenance role, or the role of an accredited or recognised training center undertaken by the railway undertaking
<b>5. Issuing date and signature:</b>	The date is automatically generated by the OSS when the document is signed.

## Appendix

## Model template of mapping table against the requirements laid down in the national rules

To be completed by the national safety authority		To be completed by the applicant for the single safety certificate	
Reference (Reference to the applicable notified national safety rule)	Requirements (Headline of the requirement laid down in the applicable notified national safety rule)	Documentary evidence (Document reference / version / date / chapter / section etc.)	Description (Brief description of the document)





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**Guidance for Safety certification:**

- ▶ Application Guide for the Granting of Single Safety Certificates
- ▶ Supervision guide
- ▶ Management maturity model
- ▶ Enforcement management model
- ▶ Coordination between national safety authorities – A common approach to supervision
- ▶ Competence management framework for authorities