




Making the railway system
work better for society.

ACCOMPANYING REPORT

Agency proposal for the Commission Implementing Act on practical arrangements for safety certification as referred to in Article 10(10) of Directive (EU) 2016/798

	<i>Elaborated by</i>	<i>Validated by</i>	<i>Approved by</i>
<i>Name</i>	Mathieu SCHITTEKATTE	H. DELSOIR	C. CARR/T. BREYNE
<i>Position</i>	Project Manager	Head of Sector	Head of Unit/4RWP Programme manager
<i>Date</i>	20/12/2016	20/12/2016	20/12/2016
<i>Signature</i>			

Document History

<i>Version</i>	<i>Date</i>	<i>Comments</i>
0.1	13/12/2016	First draft.
1.0	20/12/2016	Final report.

Contents

1.	Executive summary	3
2.	Introduction	4
2.1.	Purpose and scope	4
2.2.	Background	4
3.	Workgroups.....	5
4.	Working method	5
5.	Content of the practical arrangements.....	7
5.1.	Objective	7
5.2.	Structure and content	7
6.	Stakeholders' opinions.....	7
6.1.	Workshops	7
6.1.1.	General opinion.....	7
6.1.2.	Minority opinions.....	8
6.2.	NSA Network consultation.....	12
6.2.1.	General opinion.....	12
6.3.	Others.....	14
6.3.1.	RISC	14
7.	Annex 1: Abbreviations	15
8.	Annex 2: Reference documents	15
9.	Annex 3: Reference legislation.....	15

1. Executive summary

Since the beginning of 2016, on request of the Commission, the Agency has worked out its proposal for the Commission Implementing Act on the practical arrangements for safety certification, as referred to in Article 10(10) of Directive (EU) 2016/798.

To that end, the Agency has arranged a series of workshops in order to provide a forum for the exchange of opinions, views and experiences among stakeholders.

During each workshop, key issues raised by stakeholders during prior consultations have been discussed and where practicable, a consensus on how to address these issues was reached.

The overall feedback from the different workshops is deemed positive as no new significant issue has been raised during these meetings and in many cases, a position gathering a large consensus among participants was reached. The remaining open issues are minority opinions identified in section 6.1.2 of the present report.

The 'Group of Experts' positively welcomed, at its first meeting in November 2016, the work accomplished so far, without raising any specific matter of residual concern.

The Agency invites DG MOVE to re-evaluate where appropriate the Agency proposals on language (recital 8 and Article 5) and transitional provisions (Article 15), respectively in the light of future discussions or decisions on the Agency's linguistic regime at the Agency Management Board and with respect to the Commission Legal Service's opinion on how to manage former Part A/Part B safety certificates, as of 16 June 2019, in particular with regard to those Member States having notified the Commission or the Agency in accordance with Article 33(2) of Directive (EU) 2016/798.

2. Introduction

2.1. Purpose and scope

The purpose of this document is to support the Agency proposal for the Commission Implementing Act on practical arrangements for safety certification as referred to in Article 10(10) of Directive (EU) 2016/798, including:

- › An outline of the objectives for carrying out this work and how these objectives have been met;
- › The working method in view of delivering the recommendation;
- › The results of the work of the relevant workgroups and in particular the different solutions and alternatives discussed and the reasons for choosing the proposed solutions;

Whenever specific issues of high importance were questioned, appealing to different solutions and alternatives, the Agency carried out light impact assessments in order to inform its technical proposal. The results of these light impact assessments are documented in separate reports.

The practical arrangements serve as an input for identifying the specifications of the one-stop shop and the necessary cooperation arrangements with the national safety authorities. Both the one-stop shop specifications and the cooperation agreements are described in a separate document and their content is discussed in specific groups.

2.2. Background

On 31 January 2013, the Commission adopted six legislative proposals for a 4RWP aiming at removing the remaining barriers to the completion to the Single European Railway Area. The package contains three groups of measures, with a view to:

- › Renewing the rules on the governance structure in relation to infrastructure management and transport operations (the “governance pillar”);
- › Ensuring further opening of the market for domestic passenger transport services by rail (the “market opening pillar”); the “governance pillar” and the “market opening pillar” forming together the “political pillar”;
- › Cutting administrative costs for rail operators and making it easier for new operators to enter the rail market by removing the remaining market obstacles and reinforcing the harmonisation of interoperability and safety requirements to ensure a higher level of harmonisation of the EU railway network and providing the new role for the European Railway Agency (the “technical pillar”).

The technical pillar covers the update of the three existing pieces of legislation:

- › The recast regulation on the European Union Agency for Railways [3];
- › The recast directive on the interoperability of the rail system in the EU;
- › The recast directive on railway safety [4].

From Mid-2015 onwards, the Agency has taken the decision to establish and manage a new programme [2], superseding the previous Agency programme for the single safety certificate, to be ready to effectively deliver its new tasks, as set out in the technical pillar of the 4RWP. As part of its new tasks, as of 16 June 2019, the Agency is empowered to issue single safety certificates for railway undertakings having an area of operation in one or more Member States. To that end, the Agency shall cooperate with the national safety authorities concerned for the intended area of operation. All applications for single safety certificates, irrespective of the area of operation, shall be submitted through the single entry point of the one-stop shop.

The technical pillar has been adopted on 11 May 2016 through the ordinary legislative procedure whereby the Council co-legislates with the European Parliament.

Article 10(10) of the recast Safety Directive specifies that the Commission shall adopt by means of an Implementing Act the practical arrangements for safety certification specifying:

- (a) how the requirements for the single safety certificates laid down in this Article shall be fulfilled by the applicant and listing the documents required;
- (b) the details of the certification process, such as procedural stages and timeframes for each stage of the process;
- (c) how the requirements laid down in this Article shall be complied with by the Agency and the national safety authority through the different stages of the application and certification process, including in the assessment of applicants' files; and
- (d) the period of validity of single safety certificates issues by the Agency or by the national safety authorities, in particular in the case of updates of any single safety certificate resulting from changes to type, extent and area of operation.

The above practical arrangements have a direct link with the Agency programme for the 4RWP and thereby becomes part of the portfolio of activities/projects necessary to achieve the 4RWP programme objectives.

The Commission has asked the Agency to prepare a proposal for the Implementing Act on practical arrangements for safety certification.

3. Workgroups

For drawing up its proposal, the Agency has arranged a series of workshops involving all the interested parties.

The representatives from the following stakeholders were invited to join the different workshops and nominate competent experts:

- › National Safety Authorities;
- › Representative Bodies (i.e. ALE, CER, EIM, EPTTOLA, ERFA, ETF, UIP, UIRR, UITP, FEDECRAIL and UNIFE).

The following table summarises in the chronological order the list of workshops chaired by the Agency in view of developing its technical proposal and future implementation guides.

Table 1: List of workshops

<i>N°</i>	<i>Type</i>	<i>Date</i>
1	OSS Workshop	26/01/2016
2	SSC Workshop #1	19-20/04/2016
3	SSC Workshop #2	14-15/09/2016
4	SSC-VA Workshop #3 (<i>joint workshop with vehicle authorisation</i>)	06-07/12/2016

The agenda items for each of above meetings are proposed in accordance with the project time plan. The agenda and the minutes of each meeting are registered on a specific workspace of the [Agency Extranet](#).

4. Working method

The working method used for drafting the Agency proposal is outlined in the project plan [1].

Workshops are planned on a regular basis at key phases of the developments in order to report on progress and to exchange views and positions among the interested parties. When practicable, these workshops are organised back-to-back with the CSM Working Party to ensure a coherency with the project developments on the revision of the Common Safety Methods on conformity assessment.

Before each workshop, the Agency proposal is published on the [Agency Extranet](#) and submitted for consultation. Considering the comments collected during the consultation phase, the Agency identifies key issues to be discussed during the workshop and also provides a preliminary answer to each comment.

Following each workshop, the Agency revises its proposal and answers to each comment accordingly.

The NSA Network and the 'Group of Experts' are regularly informed about the progress of the project developments.

5. Content of the practical arrangements

5.1. Objective

The main objective underpinning the drafting of practical arrangements for safety certification is to reduce complexity, length and cost of the certification procedure.

5.2. Structure and content

The structure and content of the Agency proposal for the Commission Implementing Act on practical arrangements for safety certification is mainly based on the provisions of Article 10(10) of the recast Safety Directive, issues (or themes) stemming from early discussions at the NSA Network subgroup on cooperation agreements and other relevant issues discussed during the different workshops.

From the very beginning, the Agency has reflected on how best to facilitate coexistence of the Common Safety Methods on conformity assessment [5][6] (under revision), as referred to in Article 6(1)(b) of the recast Safety Directive, with these new practical arrangements for safety certification, knowing the overlapping scope between them. After weighing pros and cons, it has been discussed and agreed with stakeholders that the framework principles for the certification process underpinning the requirements to be applied by national safety authorities to assess the adequacy of the safety management system would better fit into the above Common Safety Methods while other requirements enforceable by the different parties involved in that process should be managed in the new Commission Implementing Act. One of the main reason for it is that the Common Safety Methods apply both for the issuing of safety certificates and safety authorisations. Having a different approach in one of the two Common Safety Methods could create the risk of having two different processes, respectively for the issuing of safety certificates and safety authorisations, to be applied by a same authority (i.e. the national safety authority). Such result would be detrimental to an harmonised approach to safety certification/authorisation throughout the EU and in particular, to the objective of the practical arrangements for safety certification (see 5.1).

In accordance with Article 55 of the recast Agency Regulation, the Commission shall establish by means of a new Implementing Act the rules of procedure governing the establishment and the composition of the Board(s) of Appeal, as referred to in Article 10(7) and 10(12) of the recast Safety Directive. The process for managing the recommendation(s) of the Board of Appeal, e.g. in case of arbitration between the Agency and the national safety authority (or authorities) or in case of appeal against a negative decision of the Agency, and any subsequent Agency decisions, is out of scope for the present practical arrangements.

Following coordination meetings between the Agency and DG MOVE, as of 16 June 2019, any single safety certificate shall be issued according to the new certification regime as set out in Directive (EU) 2016/798, unless the Member State(s) concerned by the area of operation has (or have) notified the Agency or the Commission in accordance Article 33(2) of the same Directive. However, safety certificates (Part A and Part B) issued under Directive 2004/49/EC can still be valid at that time. Therefore, transitional provisions are proposed to describe how to handle the expiry, update or renewal of these Part A and Part B safety certificates after 16 June 2019, depending on the concerned area of operation.

6. Stakeholders' opinions

6.1. Workshops

6.1.1. General opinion

Feedback from the workshops (see Table 1) is deemed positive as no significant issues have been raised during these meetings and in many cases, a position gathering a large consensus among participants was reached.

6.1.2. *Minority opinions*

The table below summarises the minority opinions expressed by the stakeholders during the last workshop. Issues previously identified by stakeholders and solved during workshop are not listed here. Some of them have been clarified in the meantime during a coordination meeting with DG MOVE on 30 November 2016 [7].

Language issues could not be fully resolved during the discussions at the last workshop because of ongoing discussions taking place at the Agency Management Board on the content of the Agency's linguistic regime. The Agency proposal reflects the conclusions of its light impact assessment (i.e. selection of the language of the application when the area of operation involves more than one Member State) and the outcomes of discussions at the previous workshops. The Agency proposal shall be re-evaluated in accordance with the future discussions or decisions of the Agency Management Board on the Agency's linguistic regime.

Baltic states have requested to add specific requirements in the practical arrangements to ensure that the provisions contained in the future multilateral agreements between the Agency and themselves (i.e. Member States with 1520 mm track gauge), as referred to in Article 11(3) of Directive (EU) 2016/798, shall be applied by the Agency. Provided that such multilateral agreements exist in the future (as Baltic states have to demonstrate first that they share identical technical and operational requirements with neighbouring third countries), it is already clear that these multilateral agreements would be legally binding for the Agency. Having this clarification in the practical arrangements is therefore superfluous. In addition, it has been advised to the Baltic states that quoting the Directive in the practical arrangements would not bring any added value either. As a compromise solution, the Agency has proposed to refer to these specific cooperation agreements in the recital.

Table 2: Minority opinions expressed by the working party

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
NSA FI	Art. 1(2)	The scope of the PA should be limited to applications covering more than 1 MS	Art. 10(10) of the recast Safety Directive refers to any applications, irrespective of their area of operation. The current proposals, including the OSS, should allow for the same degree of flexibility. The clock can still be stopped if there are good reasons to do so. Pre-engagement is also encouraged to help the applicant understand what is expected of it.
NSA IT, CER	Art. 6	Should a minimum and maximum timeframe for requesting supplementary information be defined when the file is incomplete?	The Agency proposes not to specify a detailed timeframe for the applicant's response in the legislation. If the applicant does not provide the requested information on time, the safety certification body can still reject the application
ERFA NSA FI NSA FR CER	Art. 3 Art. 5	Agency application guide available in all languages? (ERFA) No legal base for having provisions on language use (NSA FI) In case of SSC/VA issued by the Agency, documents exchanged during coordination and results of the assessment (incl. recommendation) to be provided by the NSA in an official EU language of the MS or in any other official EU language commonly agreed? (NSA FR)	These issues are linked to the discussions at the Agency Management Board on the Agency's linguistic regime. Article 5 has to be re-evaluated by the Commission in accordance with the outcome of the discussions at the Agency Management Board.

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		In case of domestic applications, the application shall be submitted in the language permitted by the SCB/AE: <ul style="list-style-type: none"> - In at most one of the EU official languages? (CER) - Language permitted by the SCB/AE is the language of the MS? (NSA FR, ERFA) 	
NSA SE	Art. 10	The objectives, scope and timeframe for audits/inspections/visits should be <u>communicated</u> among the interested parties. To agree on something everyone involved must accept it. If a NSA want to do an audit and those other involved Agency and another NSA does not think it is necessary – you may not have a agreement'	In our view, agreement should be sought in order to be sure that there won't be duplication of activities among bodies and possible increased of costs to be borne by the applicant. Communication is an exchange of information without any obligation.
NSA FR	Art. 2	It seems necessary to include in the definitions what is covered by "pre-engagement".	The choice of the recital has been chosed following discussion with DG MOVE. I suppose a definition could also be an option but the result from a legal point of view is the same, i.e. clarify what pre-engagement means.
NSA FR	Art. 3	We consider that pre-engagement shall not be mandatory but is good practice agreed between the applicant and the SCB. We also consider that the pre engagement may be registered in the OSS, as well as the application file.	In the recital, it is explicit that pre-engagement is recognised as good practice. The nature and need of pre-engagement has been discussed many times. From our records, EPSF has also been in favour of it (at least for SSC). Applicants will be charged for it. According to the Agency, there are sufficient legal grounds (see Art. 10(10) 2 nd subparagraph)

<i>Organisation(s)/ Association(s)</i>	<i>Ref. to revised Art./Annex</i>	<i>Comment</i>	<i>Agency's response</i>
		<p>When an applicant has chosen to have pre-engagement with a SCB (Agency or NSA), it may be mandatory to keep the same SCB for the assessment of the application file</p>	<p>to introduce the concept of pre-engagement in the Practical Arrangements. The legal base is justified in the recital accordingly.</p> <p>About the choice of the SCB, it was agreed in previous workshop that the applicant could decide to change the SCB during pre-engagement (but not during the assessment). As a consequence, the applicant shall submit a new application.</p> <p>About the OSS, for SSC at least, what you call pre-engagement file is very basic and does not require additional effort as it simply consists of the recording of documents such as minutes of meeting, SMS information provided by the applicant, supervision information provided by the NSA etc.</p>
NSA FR	Art. 7(1)	<p>We do not agree in the case of SSC delivered according to Art. 10(8) of RSD that all communications are to be done through the OSS. We agreed that the results of each step of the process (Annex I of the CSM) are to be registered but not all communications.</p> <p>When the NSA does not act as SCB, we agree that the main issues and their solutions are to be registered in the OSS but not all the communications</p>	<p>This comment is linked to the use of the Issue Log in the OSS. As explained during the different workshops, not all communications are to be registered in the OSS (even if the Agency is SCB).</p> <p>Communications must be recorded whenever a traceability of the decisions is necessary.</p> <p>This principle should apply irrespective of who issues the single safety certificate.</p>

6.2. NSA Network consultation

6.2.1. *General opinion*

Since 2016, the Agency has reported back to the NSA Network the work progress on the project developments, pointing out the main issues discussed and conclusions reached during the workshops.

During the follow-up discussions, some findings have been raised by NSAs, as listed in the table below.

Table 3: Summary of findings raised during NSA Network meetings

<i>Organisation(s)</i>	<i># NSA Network</i>	<i>Comment</i>	<i>Agency's response</i>
NSA DE	42	<p>Use of audits and inspections within the assessment process - There should be ways to have unannounced inspections and more generally, to check the effective implementation of the SMS on the ground.</p> <p>What's about new entrants? An audit on the spot must be possible.</p> <p>The certification body must also have the possibility to undertake not announced inspections.</p>	<p>Following the workshop in September, it was agreed the following:</p> <ul style="list-style-type: none"> - On site audits/inspections/visits have to be announced. Relevant ISO standards can be referenced in the guide. - The proposed draft legal text already allows for audits/inspection to be carried out where appropriate (e.g. new entrants). Legal text could be clarified to better express the purpose of such audits/inspections/visits, i.e. address areas of concern not previously identified or resolved during previous supervision activities..

6.3. Others

6.3.1. RISC

The progress status on the practical arrangements for safety certification has been discussed with the 'EC RISC Working Group' in July 2016 and then, with the 'Group of Experts'.

During the first 'Group of Experts' meeting on 8 November 2016, the Agency presented the remaining open issues stemming from the previous workshop (held earlier in September). The 'Group of Experts' positively welcomed the work accomplished so far and did not raise any concern.

7. Annex 1: Abbreviations

Table 4: Table of abbreviations

<i>Abbreviation</i>	<i>Description</i>
4RWP	Fourth Railway Package (i.e. its technical pillar composed of Directive (EU) 2016/797, Directive (EU) 2016/798 and Regulation (EU) 2016/796)
CSM	Common Safety Method
EC	European Commission
EU	European Union
IM	Infrastructure Manager
NSA	National Safety Authority
OSS	One-Stop-Shop
PA	Practical Arrangements
RU	Railway Undertaking
SCB	Safety Certification Body
SMS	Safety Management System
SSC	Single Safety Certificate
VA	Vehicle Authorisation

8. Annex 2: Reference documents

Table 5: Table of reference documents

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
[1]	Project plan - Practical Arrangements for the Single Safety Certificate	ERA-REC-126/PPL	1.0
[2]	Programme Plan - Preparation and implementation of the 4th Railway Package at ERA	ERA-PRG-005/PPL	1.1

9. Annex 3: Reference legislation

Table 6: Table of reference legislation

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
[3]	Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (Agency Regulation)	OJ L 138, 26.5.2016, p. 1-43	-
[4]	Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (recast)	OJ L 138, 26.05.2016, p. 102-149	-

<i>N°</i>	<i>Title</i>	<i>Reference</i>	<i>Version</i>
[5]	Commission Regulation (EU) No 1158/2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates	<i>OJ L 326, 10.12.2010, p. 11–24</i>	-
[6]	Commission Regulation (EU) No 1169/2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation	<i>OJ L 327, 11.12.2010, p. 13–25</i>	-
[7]	Summary of legal issues relating to the development of Common Safety Methods on conformity assessment, Common Safety Method on supervision and Agency proposal of Implementing Act on the practical arrangements for safety certification		02/12/2016