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## Clarification note

*Temporary measures adopted by the European Union Agency for Railways for delivering single safety certificates in the framework of the restrictions related to the COVID-19 pandemic*

	<i>Drafted by</i>	<i>Validated by</i>	<i>Approved by</i>
<i>Name</i>	S. D'ALBERTANSON	T. BREYNE	J. DOPPELBAUER
<i>Position</i>	Technical coordinator	Head of Unit	Executive Director
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<i>Signature</i>			

### *Document History*

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1.0	21/04/2020	Initial version

*The purpose of this document is to foster an harmonised EU approach to the safety certification process. Those concerned with this clarification note are encouraged to voluntarily apply it.*

*The present document is a non-legally binding guidance of the European Union Agency for Railways. It is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.*

## 1. Description of the issue

The emergency measures adopted in different countries to fight the COVID-19 outbreak, which often include severe travel restrictions, shutdowns of offices and teleworking of the concerned staff, are creating difficulties for some actors involved in the safety certification process to fulfil their legal duties and obligations. In particular, it may be not possible to issue a single safety certificate within the appropriate timeframe either because of temporary constraints on the safety certification body side (including an inability to carry out visits, inspections or audits) or because of the limited capacity of an applicant to develop, internally agree and submit the relevant evidence.

Since an application for a new updated or renewed safety certificate should be submitted before the planned start date or the expiry date of the current certificate (see Article 4 of Regulation (EU) 2018/763), and preferably 6 months before in order to give some additional time in the process (see section 3.1 of the [“ERA application guide for the granting of single safety certificates: A guide for applicants”](#)), it is likely that applications will be in progress when the extraordinary circumstances described above come into being and that some applications would be required to be submitted while it is being.

For applications received during the exceptional or extraordinary circumstances the applications should as far as possible be prepared and assessed in the normal way.

In both cases it is possible that due to the exceptional or extraordinary circumstances a full assessment of any particular file becomes difficult because the applicant is unable to fulfil his obligations to supply relevant information to allow the assessment to proceed or the safety certification body has difficulties in undertaking the necessary assessment tasks.

As Directive (EU) 2016/798 requires that a railway undertaking must have a valid safety certificate in order to be able to run trains this creates a potential problem. If the assessment was unable to be completed before the existing certificate expires it would mean that the railway undertaking would have to stop their train service until a safety certificate could be issued. This Clarification note explains the process the Agency would adopt to manage this situation.

It is important for the safety certification body to be able:

- › To demonstrate reasonable due diligence, mutual understanding and trust with the applicant; and
- › To establish an appropriate course of action in response to exceptional or extraordinary circumstances.

## 2. Clarification

To enable the safety certification body to assess risk for continuing certification and to understand the certified railway undertaking's current and expected future situation and where it becomes apparent that the assessment cannot be completed before the safety certificate expires, the certified organisation should provide the safety certification body as soon as possible with the necessary information from the moment when an assessment is imminent and which would in the present circumstances, due to the COVID-19 pandemic, make it difficult or impossible to complete the assessment in the legal timeframe, before deciding on an appropriate course of action. The information provided to the safety certification body should include the following as appropriate:

- › When will the organisation be able to follow the normal assessment process?
- › When will the organisation be able to perform the service defined within the current scope of certification?
- › To what extent has operation of the safety management system been affected and will this affect the assessment process?

Based on the collected information the safety certification body may need to consider alternative short-term methods of assessment or supervision to verify continuing system effectiveness for the organisation. If the safety certification body has planned on site audits or visits this may have to be dealt with by alternative means. This may include requesting relevant documentation (e.g. management review meeting minutes, corrective action records, results of internal audits, test/inspection reports, etc.) to be reviewed off site by the safety certification body to determine the continuing suitability of the certification (on a short-term basis only). At a minimum, the process should address the following items:

- › Proactive communication between the affected organisation and the safety certification body and any other authorities concerned;
- › Steps the safety certification body and any other authorities concerned will take to assess the affected organisation and how the plan to move forward will be communicated;
- › Ensuring that any reasonable and proportionate deviation from legal requirements and certification procedures is justified and documented.

If contact with the organisation cannot be made, the safety certification body should follow normal processes and procedures.

When developing alternate short-term methods of assessment and where it becomes apparent that the assessment cannot be completed before the safety certificate expires, the safety certification body shall consider, in consultation with the relevant authorities, issuing a single safety certificate restricted by time to allow the assessment to be completed. Taking into account the legal timeframe for the assessment, such a certificate with a time restriction and possibly other restrictions should not be valid for more than 6 months. An assessment of a new application should then take place according to the arrangements agreed between the relevant parties. The safety certification body shall transfer any open issues from the existing application to the new one.

The criteria to be considered when deciding whether it is possible to proceed with issuing a single safety certificate for a restricted period should be that:

1. The applicant has provided information as to their existing safety management system in the one-stop shop (OSS) as part of their existing application;
2. The applicant should have completed the mapping table in the OSS and supplied relevant supporting evidence;
3. The national safety authorities for the area of operation supply the Agency with information on the performance of the safety management system of the applicant from relevant supervision in accordance with Articles 5(1) and (2) of Regulation (EU) 2018/761, or if no supervision has been carried out a view on whether the applicants request for a single safety certificate under extraordinary circumstances is a reasonable one and that issuing a safety certificate with a restricted time period is the most suitable option.

If the safety certification body agrees after consultation with the relevant authorities that issuing a single safety certificate for a restricted period, possibly with other restrictions identified during the assessment, is the most suitable option, the safety certification body should then promptly contact the applicant, agree on the restricted period based on the application information previously supplied, and justify the reasons for the issuing of a safety certificate in these extraordinary circumstances in its decision. A "Type 4" issue would then be raised in the OSS in accordance with Article 12 of Regulation (EU) 2018/763.

If on the resumption of supervision activities by a national safety authority after an extraordinary circumstance it becomes apparent that the applicant's safety management system does not meet the safety management system requirements then any relevant enforcement action shall be taken as normal to return the situation to a safe state. If this enforcement action fails to redress the situation then the national safety authority shall either revoke the safety certificate or refer the matter to the relevant safety certification body along with the appropriate evidence and ask that the safety certificate be restricted or revoked in accordance

with the requirements set out in Article 17(5) of Directive (EU) 2016/798. The safety certification body will consider each case on its merits.

If the exceptional or extraordinary circumstances continue beyond the agreed timeframe for the assessment and it has still not been possible to complete it the same process could be followed again.

### 3. Legal background

#### a) Railway Safety Directive (EU) 2016/798

- Article 10. Single Safety Certificate

*“1. Without prejudice to paragraph 9, access to the railway infrastructure shall be granted only to railway undertakings which hold the single safety certificate issued by the Agency in accordance with paragraphs 5 to 7 or by a national safety authority in accordance with paragraph 8.*

*The purpose of the single safety certificate is to provide evidence that the railway undertaking concerned has established its safety management system and that it is able to operate safely in the intended area of operation.”*

- Article 17. Supervision

*“1. National safety authorities shall oversee continued compliance with the legal obligation incumbent on railway undertakings and infrastructure managers to use a safety management system as referred to in Article 9.*

*For that purpose, the national safety authorities shall apply the principles set out in the relevant CSMs for supervision*

*referred to in point (c) of Article 6(1), ensuring that supervision activities include, in particular, checking the application by railway undertakings and infrastructure managers of:*

*(a) the safety management system to monitor its effectiveness;*

*(b) the individual or partial elements of the safety management system, including operational activities, the supply of maintenance and material and the use of contractors to monitor their effectiveness; and*

*(c) the relevant CSMs referred to in Article 6. The supervision activities relating to this point shall also apply to entities in charge of maintenance, where appropriate.”*

*[...]*

*“5. If a national safety authority finds that a holder of a single safety certificate no longer satisfies the conditions for certification, it shall ask the Agency to restrict or revoke that certificate. The Agency shall immediately inform all the competent national safety authorities. If the Agency decides to restrict or revoke the single safety certificate, it shall give reasons for its decision.”*

#### b) Commission Implementing Regulation (EU) 2018/763

- Article 12. Categorisation of issues

*“1. The safety certification body and the national safety authorities concerned with the intended area of operation shall categorise issues identified in the course of their assessment of the application file as follows:*

*[...]*

*(d) ‘Type 4’: issues that require an amendment of the application file or specific action to be taken by the applicant; the single safety certificate shall not be granted unless the issue is resolved or restrictions or conditions of use are included in the certificate to address the issue; any action to resolve an issue shall be proposed by the applicant and shall be agreed with the party that identified the issue.”*

- Annex II. Safety assessment process

*[...]*

*“5.2. The safety certification body may decide to restrict the scope of the single safety certificate, by identifying restrictions or conditions of use, if it is concluded in coordination with the national safety authorities concerned with the intended area of operation that such restrictions or conditions of use address any type 4 issue that would prevent the issue of the single safety certificate. The single safety certificate shall be updated on request of the applicant after all residual concerns have been addressed in its application file.”*

*[...]*