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Clarification note

Use of the one-stop shop regarding the issue management

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Document History

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1.0	21/01/2020	First 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 authorities and the applicants exchange relevant information during the assessment (i.e. after the submission of an application for a single safety certificate). Different communication channels (e.g. one-stop shop, phone, email, teleconferencing) can be used to achieve that purpose.

However, managing issues (i.e. formal comments identified during the assessment) outside the one-stop shop, which would be a breach of Article 7(1) of Regulation (EU) 2018/763, could have the following adverse effects:

- > Lack of transparency as not all authorities concerned with the assessment are informed about issues raised by others;
- > Lack of traceability of the decisions;
- > Use of different types of classification of issues by different authorities.

2. Clarification

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.

This approach should also facilitate harmonisation of the way the authorities identify issues and classify them in accordance with Articles 7 and 12 of Regulation (EU) 2018/763. Although different methods are possible, it is recommended that the authorities identify issues separately (instead of grouping them) in order to facilitate their follow-up during the assessment and also during the post-award supervision.

3. Legal background

a) Regulation (EU) 2018/763

• Article 7. Communication

"1. The safety certification body, the national safety authorities concerned with the intended area of operation and the applicant shall communicate through the one-stop shop as regards any issue referred to in Article 12.

[...]"

• <u>Article 11</u>. Coordination between the Agency and national safety authorities

"1. When acting as the certification body, the Agency shall coordinate with the national safety authorities concerned with the intended area of operation at the different stages of the safety assessment process. The Agency and the national safety authorities shall discuss any issues relating to the safety assessment process, including any deficiency, and any requests for supplementary information which have an impact on the timeframe of the assessment or have the potential to affect the work of the other national safety authorities concerned with the area of operation.

[...]″

• <u>Article 12</u>. 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:

(a) 'Type 1': issues that require a response from the applicant for the understanding of the application file;

(b) 'Type 2': issues that may lead to an amendment of the application file or minor action from the applicant; the action to be taken shall be left to the judgement of the applicant and shall not prevent the issuing of the single safety certificate;

(c) 'Type 3': issues that require specific action to be taken by the applicant, completion of which may be postponed until after the single safety certificate is granted; action to resolve an issue shall be proposed by the applicant and shall be agreed with the party that identified the issue;

(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.

[...]"