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# OPINION

2021-8

OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for

THE EUROPEAN COMMISSION

regarding

AMOC - TSI OPE - RSD

## Disclaimer:

The present document is a non-legally binding opinion of the European Union Agency for Railways. It does not represent the view of other EU institutions and bodies, and 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. General Context

Railway Undertakings (RUs) and Infrastructure Managers (IMs) shall manage their operations and the traffic among others in accordance with the Technical Specifications for Interoperability for the Operation and Traffic Management, hereinafter “TSI OPE” (annex to Commission Implementing Regulation (EU) 2019/773<sup>1</sup>).

According to Article 2(33) of the Directive on the interoperability of the rail system within the European Union (Directive (EU) 2016/797<sup>2</sup>), Acceptable Means of Compliance (AMOCs) are “*non-binding opinions issued by the Agency to define ways of establishing compliance with the essential requirements*”. Therefore, AMOCs define good practices also by referring to available standards, which the actors of the railway sector can use in their safety management system as evidence that their operational procedures comply with high-level requirements set out in EU legislation (in this case the TSI OPE and the Common Safety Method on requirements for safety management systems – CSM on SMS (Regulation (EU) 2018/762<sup>3</sup>).

AMOCs cover areas that are for the RU’s SMS to manage, no national rules on the topics covered by AMOCs are allowed.

## 2. Legal Background

According to the provisions of Article 10(2) of Regulation (EU) 2016/796<sup>4</sup>, the Agency shall issue opinions at the request of the Commission on amendments to any act adopted on the basis of Directive (EU) 2016/797.

According to Article 19(1)(d) of Regulation (EU) 2016/796, the Agency shall issue opinions which constitute acceptable means of compliance concerning deficiencies in TSIs in accordance with Article 6(4) of Directive (EU) 2016/797 and provide those opinions to the Commission.

According to section 4.4.3 of the TSI OPE the Agency may by means of technical opinions define acceptable means of compliance, which shall be presumed to ensure compliance with specific requirements and ensure safety in accordance with Directive (EU) 2016/798<sup>5</sup>.

Section 4.4.3 of the TSI OPE requires the Agency to develop AMOCs on a number of topics. These are:

1. Safety of load,
2. Safety of passengers,
3. Checks and tests before departure, including brakes and checks during operation,
4. Train departure,
5. Degraded operation.

This opinion covers the development of the first three. The justification for not developing AMOCs on the last two is set out in paragraph 3.2.4 of this opinion. The AMOC itself constitutes a non-legally binding opinion and its use is strictly voluntary.

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<sup>1</sup> Commission Implementing Regulation (EU) 2019/773 of 16 May 2019 on the technical specification for interoperability relating to the operation and traffic management subsystem of the rail system within the European Union and repealing Decision 2012/757/EU, OJ L 139, 27.5.2019, p. 5.

<sup>2</sup> Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union, OJ L 138, 26.5.2016, p. 44.

<sup>3</sup> Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010, OJ L 129, 25.5.2018, p. 26.

<sup>4</sup> 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, OJ L 138, 26.5.2016, p. 1.

<sup>5</sup> Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety, OJ L 138, 26.5.2016, p. 102.

In order to develop AMOCs the Agency returned to the Working Party (WP) that was set up for the revision of Regulation (EU) 2015/995<sup>6</sup>.

### 3. Analysis

#### 3.1. Concept

As a general concept, the RUs/IMs are responsible to manage their specific operational and traffic management requirements in their SMS.

Article 4(1) (d) of the Railway Safety Directive (Directive (EU) 2016/798) states as follows:

*“With the aim of developing and improving railway safety, Member States, within the limits of their competences shall:*

*d) ensure that the responsibility for the safe operation of the Union rail system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings, each for its part of the system, obliging them to:*

- (i) implement necessary risk control measures as referred to in point (a) of Article 6(1), where appropriate in cooperation with each other;*
- (ii) apply Union and national rules;*
- (iii) establish safety management systems in accordance with this Directive”.*

Article 4(3) (a) and (b) of the Railway Safety Directive states as follows:

*“Railway undertakings and infrastructure managers shall:*

- a) implement the necessary risk control measures referred to in point (a) of Article 6(1), where appropriate in cooperation with each other and with other actors;*
- b) take account in their safety management systems of the risks associated with the activities of other actors and third parties.”*

The same concept has been detailed in the CSM on SMS, ANNEX I Point 3.1.1.1 (for RUs) and ANNEX II point 3.1.1.1 (for IMs):

According to these provisions, the organisation shall:

- a) identify and analyse all operational, organisational and technical risks relevant to the type, extent and area of operations carried out by the organisation. Such risks shall include those arising from human and organisational factors such as workload, job design, fatigue or suitability of procedures, and the activities of other interested parties (see Annex I, Section 1. Context of the organisation);
- b) evaluate the risks referred to in point (a) by applying appropriate risk assessment methods;
- c) develop and put in place safety measures, with identification of associated responsibilities (see Annex I, Section 2.3. Organisational roles, responsibilities, accountabilities and authorities);
- d) develop a system to monitor the effectiveness of safety measures (see Annex I, Section 6.1. Monitoring);
- e) recognise the need to collaborate with other interested parties (such as railway undertakings, infrastructure managers, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on shared risks and the putting in place of adequate safety measures;

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<sup>6</sup> Commission Regulation (EU) 2015/995 of 8 June 2015 amending Decision 2012/757/EU concerning the technical specification for interoperability relating to the ‘operation and traffic management’ subsystem of the rail system in the European Union, OJ L 165, 30.6.2015, p. 1–69.

- f) communicate risks to staff and involved external parties (see Annex I, Section 4.4. Information and communication).

Therefore, it is the responsibility of RUs and the IMs to identify, assess, mitigate when needed, monitor and review continually their own operational risks.

Based on that, the AMOC is a proposed way to demonstrate compliance with TSI OPE as a mean to manage operational risks, taking into account that the provisions of the TSI OPE cover the entire operational and traffic management subsystem, whilst every single RU or IM has specific, different responsibilities managing the subsystem.

The RUs should in compliance with the EU and national legal requirements define their operational context and consequently they should identify the risks occurring in their operational activities. Then, on a voluntary basis, they are free to assess and decide for themselves whether an AMOC is applicable for their specific responsibilities to manage the particular part of their operation. An AMOC could be entirely or partially applicable to the RUs operational context, for example an RU could be involved in the freight transport but not in the transport of dangerous goods, whilst an AMOC could deal with both.

If an RU evaluates this AMOC as applicable to the operational context and decides to use this AMOC, the RU should assess the risks the AMOC could cover within the operational activities to be performed. For example, loading risks should be identified and the relevant part of the good practice in the AMOCs should then be cross referenced with the risk in the RUs risk assessment process. This should regularly be kept up to date as part of the monitoring activities for their operation.

As AMOCs are non-binding opinions issued by the Agency to define ways of establishing compliance with the essential requirements, the RUs are free to decide whether to apply the AMOC/part of the AMOC, or not. Nevertheless, the RUs are responsible for managing their operational risks.

AMOCs should be accepted throughout the EU by Member States and National Safety Authorities (NSAs) as examples of good practice usually developed by the sector. National rules on the same AMOC topics are generally not permitted under Appendix I of the TSI OPE. If a RU decides not to apply the AMOC and develop its own processes, it may do this and does not have to prove that its processes are as good or better than the good practice set out in the AMOC and it should ensure that its processes are adequate in controlling/mitigating the risks that it has identified.

As a result, the substantiated use of this AMOC can be accepted by the Agency or the NSAs when a RU applies for a safety certificate or authorisation, when the certification body assesses compliance of the applicant with the requirements of the CSM on SMS and the TSI OPE. The certification body will check how the AMOC is used by reviewing the risk assessment process of the RUs' to ensure that the AMOC best practice has been identified as a relevant control measure for the identified risk. If the AMOC is not used, the certification body will check the sufficiency of the RUs processes in controlling the risks.

## 3.2. Analysis of requirements and their evolution

### 3.2.1. Safety of load

The TSI OPE paragraph 4.2.2.4.1 Safety of load states that the RU shall make sure that freight vehicles are safely and securely loaded and remain so throughout the journey.

A number of Member States had notified in NOTIF-IT the *Code of Practice for Loading and Securing of goods on railway wagons - Volume 1 - Principles and Volume 2 - Goods*. The WP agreed that these Guidelines were good examples of good practice that were developed and updated by the sector members of UIC (International Union of Railways) and used successfully across the EU and beyond. UIC has made these Guidelines available for free to non members. The WP also suggested a reference to the EN standard 16860 on *Railway applications – Requirements and general principles for securing payload in rail freight transport* which sets out the general principals on loading.

### 3.2.2. *Safety of passengers*

The TSI OPE paragraph 4.2.2.4.2 Safety of passengers states that the RU shall ensure that passenger transport is undertaken safely at the departure and during the journey.

France provided an Acceptable means of compliance to support the Order of 19 March 2012. The WP reviewed the content of the AMOC and took the relevant parts into an Annex to the AMOC. This now covers (1) Boarding and leaving a train (2) Train departure (3) Train journey (4) Arrival of a train (5) End of service and (6) Coupling and decoupling.

### 3.2.3. *Checks and tests before departure, including brakes and checks during operation*

The TSI OPE paragraph 4.2.3.3.1 Checks and tests before departure, including brakes and checks during operation states that the RU shall define the checks and tests to ensure that any departure is undertaken safely (e.g. doors, load, brakes).

A number of Member States notified the Agency under TSI OPE requirement 4.4.3 the UIC Agreement on freight Train Transfer Inspection (ATTI). The WP agreed that these Guidelines (and indeed a number of others) were good examples of good practice that were developed and updated by the sector members of UIC and used successfully across the EU and beyond. UIC has made these Guidelines available for free to non members.

The WP also agreed to include a reference to the Verband Deutscher Verkehrsunternehmen (VDV) Recommendation 758 but also that it should include a statement stressing that the VDV recommendations are developed and produced by the German rail sector for their use. However, many of the principles may be of use to RUs who operate throughout Europe. The recommendations are voluntary and it is up to the RU to decide if they are relevant to them. If they are used, any reference to German law is not applicable unless the RU operates in Germany.

It has been agreed to make reference to other available good practice such as the UIC IRS 40471-3 identifying specific tests and checks to be performed on dangerous goods consignments, the UIC IRS 40453 on the way to perform brake tests, the UIC leaflet 541-4 on the use of composite brake blocks.

The WP defines in the AMOC good practices on checking the efficiency and effectiveness of the brake system based on several national experiences.

The last point on which the WP decided to provide the sector with was good practice on the train “braking sheet & wagon list” and brake position rules for freight trains.

### 3.2.4. *Other topics*

ERA was asked to develop two additional AMOCs on train departure and degraded mode. However, after research by the Agency and detailed discussions with the WP, it was agreed with the Commission that it would not be possible or beneficial to develop AMOCs on these topics. The justification is set out below.

#### 3.2.4.1. *Train departure*

There is already a Common Operational Rule (no. 2) in TSI OPE Appendix B which sets out the key conditions for train departure. The WP considered what extra would be needed to help the RU as well as the main requirements in paragraph 4.2.3.3 of the TSI OPE:

##### 4.2.3.3.1. *Checks and tests before departure*

The railway undertaking shall define the checks and tests to ensure that any departure is undertaken safely (e.g. doors, load, brakes).

#### 4.2.3.3.2. *Informing the infrastructure manager of the train's operational status*

The railway undertaking shall inform the infrastructure manager when a train is ready for access to the network. The railway undertaking shall inform the infrastructure manager of any anomaly affecting the train or its operation having possible repercussions on the train's running prior to departure and during the journey.

For the checks and tests elements this will be covered by the AMOCs on checks and tests before departure and safety of passengers. The part on degraded operation is linked to the AMOC on that topic and therefore the same issues are relevant (see 6.2.5).

Therefore it was agreed by the WP that it was not appropriate to develop this topic into an AMOC.

#### 3.2.4.2. *Degraded operation*

The WP discussed this issue in depth using the inventory of degraded operations that contained the list of topics already included in TSI OPE Appendixes B and C as well as other topics that were considered. It was agreed that the issue was so wide ranging and encompassed a number of national issues and permitted national rules in Appendix I of the TSI OPE (national signaling systems/speed etc), it was difficult to understand what the scope was. In addition, in relation to Commission's Issue Log Book and the priorities, this issue was not even mentioned. For the sector it can be seen that this is not a priority to delivering improvements in cross border operation. Therefore the Agency is focusing on the areas that will give the biggest return in improvements to interoperability, effective cross border operation and the long term development of the Single European Railway Area (SERA) (checks and test, train braking, train composition).

In addition when the Agency was reviewing some of the national rules as part of the transition to Single Rules Database (SRD), a lot of those that covered degraded operation often resulted in the driver having extra responsibilities to cover such situations, not all being the same and with some contradicting each other. From a Human and organisational factors perspective, the Agency needs to be careful about putting generic responsibilities in EU legislation or guidance. This is something that the RU and IM should agree as part of their co-ordination arrangements in their SMS as clearly set out in 4.2.3.6.1 of the TSI OPE.

Finally, in Appendix A there are already rules that relate to this topic, these include:

- 6.38 "Managing route unsuitability"
- 6.40.2 "A train is rejected"
- 6.42 "Managing a trackside malfunction"
- 6.43 "Managing incompatibility between trackside and ETCS onboard"
- 6.44 "Managing a level crossing not-protected"
- 6.45 "Managing a balise read error"
- 6.47 "Managing absence of RBC information"
- 6.48 "Managing a radio communication failure"
- 6.49 "Managing a failure of self-test"
- 6.50 "Managing a failure affecting the onboard radio equipment" (etc.)

More specific rules for Appendix A are hard to define in a harmonized manner (some of the afore mentioned ones are equally non-harmonized), mainly due to the diversity of fallback systems which may be used in degraded situations, most of them Class-B. The ERA Operational Harmonisation group is currently working on the harmonization of as many as possible out of the currently non-harmonised rules in Appendix A.

Therefore it was agreed by the WP that it was not appropriate to develop this topic into an AMOC.

### 3.3. Impact assessment

The Agency performed the Light Impact Assessment for the developed AMOCs. The influence the introduction of the AMOCs would have on the sector stakeholders was analysed. The current framework containing a vast number of national rules in force in Member States was also considered in the analysis. The assessment compared two options:

- Option 0 being the baseline scenario where AMOCs are not adopted and stakeholders have to continue to comply with non harmonised and unstable national rules.
- Option 1 being the adoption of the AMOCs as an Agency's opinion in accordance with Article 19(1)(d) of Regulation (EU) 2016/796.

The results show clearly that the overall impact for option 0 was very negative for most stakeholders while option 1 proved to provide very positive impact for stakeholders involved, that is RUs, NSA, passengers, railway staff, shippers and the Agency itself. The only stakeholder being impacted in a neutral way in both options were the Member States.

According to the results of the assessment option 1 was preferred and it was recommended to adopt the AMOCs as they have high value considering that they were developed together with the rail sector. The AMOCs can increase interoperability and therefore competitiveness of rail transport and their adoption does not require an amendment of TSI OPE. In addition they can be applied as a control measure to the RUs risk assessment. Considering the voluntary character of the AMOCs. The benefits largely outperform the costs of implementing the AMOCs which are mostly related to an adaptation of the skills of NSA/ the Agency's staff to this new scheme.

### 4. The opinion

In accordance with Directive (EU) 2016/797 the Agency may by means of non-binding opinions define acceptable means of compliance, which shall be presumed to ensure compliance with specific requirements and ensure safety in accordance with Directive (EU) 2016/798.

The annexes provide the final AMOC's on following topics:

- Safety of load,
- Safety of passengers,
- Checks and tests before departure, including brakes and checks during operation.

The opinion is addressed to the European Commission.

Valenciennes, 20/12/2021

  
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## Annexes

**Annex I** – AMOC on safety of load

**Annex II** – AMOC on safety of passengers

**Annex III** – AMOC on checks and tests before departure, including brakes and checks during operation