EUROPEAN UNION AGENCY FOR RAILWAYS

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Supporting guidance for AMOCs management

In accordance with Article 19(3) of Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016

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Document History

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1. Scope of this guide

This supporting guidance is for use by railway undertakings applying an Acceptable Means of Compliance (AMOC) to specific clauses that are allowed for in TSI OPE. This guidance is produced and managed by ERA.

1.1. Reference documents

DOCUMENT REFERENCE	*OFFICIAL JOURNAL*
[1] 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	L 138, 26.5.2016, p. 1-43
[2] 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	L 138, 26.5.2016, p. 44-101
[3] Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety	L 138, 26.5.2016, p. 102-149
[4] Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area	L 343, 14.12.2012, p. 32-77
[5] Directive 2007/59/EC of the European Parliament and of the Council on the certification of train drivers operating locomotives and trains on the railway system in the Community – as amended and supplemented	L 315 03.12.2007 p.51
[6] Regulation (EC) 402/2013 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council - as amended and supplemented	L 121 03.05.2013 p. 8-25
[7] Regulation (EU) 2018/762 on the common safety method on Safety Management System	L 129 25.05.2018 p.26-48
[8] Regulation (EU) 2012/1078 on the common safety method on monitoring	L320 17.11.2012 p.8-13
[9] Regulation (EU) 2016/773 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	L139 27.05.19 p. 5-88

1.2. Abbreviations

ABBREVIATION	*FULL TEXT*
AMOC	Acceptable Means of Compliance
ATTI	Agreement on freight Train Transfer Inspection
COR	Common Operational Rule
CSM	Common safety method
EC	European Commission
ECM	Entity in Charge of Maintenance
EI	European Instructions
EOA	End of Authority (ERTMS)
ERA	European Union Agency for Railways also called “the Agency”
ERTMS	European Rail Traffic Management System
ETCS	European Train Control System
EU	European Union
EVN	European Vehicle Number
FOP	Fundamental Operational Principle
FS	Full supervision (ERTMS mode)
GCU	General Contract of Use for Wagons
GSM-R	Global System for Mobile communications- Railway
IM	Infrastructure Manager
INF	Infrastructure
DMI	Driver–Machine Interface
MS	EU or EEA Member State
NIB	National Investigation Body
NSA	National Safety Authority
NR	National Rules
OJ	Official Journal of the European Union
OPE	Operations
OS	On-sight
PRM	Persons with reduced mobility
RINF	Register of Infrastructure
RS	Rolling Stock

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ABBREVIATION	*FULL TEXT*
RSD	Rail Safety Directive
RU	Railway Undertaking
SMS	Safety management system
SR	Staff responsible
TSI	Technical Specification for Interoperability
TSI OPE	Technical specification for interoperability relating to the operation and traffic management subsystem
UIC	Union Internationale des Chemins de fer
VDV	Verband Deutscher Verkehrsunternehmen
WAG	Wagon
WG	Working Group
WP	Working Party

1.4 List of the latest version of the AMOCs

Document	Issuing body	Version in force
Safety of Load	ERA	V1 2022
Safety of passengers	ERA	V1 2022
Checks and tests before departure, including brakes and checks during operation	ERA	V1 2022

2. Guidance on the AMOC implementation and management

2.1. Introduction and content

2.1.1 This application guide has been developed with the contribution of the Working Party specifically defined for developing AMOC.2.1.2

This guidance provide explanation on:

- the implementation of an AMOC within the RU SMS processes involving IMs or suppliers if necessary;
- how ERA may update an AMOC and the return of experience;
- the use of external documents based on good practice
- acceptance throughout the EU
- assessment of the AMOC as part of the single safety certificate process
- supervision of the AMOC by NSAs.

2.1.3 This guide is presented so that the reader can understand how the AMOC and the good practices in general can be implemented in the SMS. The guide provides the RU with more details on “Part 1” of the AMOCs and their applicationThis will be important when developing the operational element of the SMS and the move away from national rules mandated at Member State level to risk based company rules.

2.2. AMOC implementation

2.2.1 AMOCs are defined in Directive (EU) 2016/797 as *non-binding opinions issued by the Agency to define ways of establishing compliance with the essential requirements.* In relation to AMOCs, they include non binding examples of good practice for compliance with the safety requirements. In the case of the TSI OPE this covers the control of certain operational risks. Therefore the RU does not have to provide any justification for the use of the AMOC which confirms that the sector are responsible for managing and controlling the risk and developing appropriate risk control measures which are relevant for their own areas of operation.

2.2.2 It is not just about compliance with an AMOC. The whole purpose of the AMOCs is that they are risk based, therefore an RU must, using the information from their risk assessment, be able to demonstrate that the AMOC controls the identified risks. In return the NSA as part of their supervision strategy and plan can review the RUs risk assessment and ask the RU to demonstrate how they apply the AMOC as a control measure for the risk and the TSI OPE requirement.

2.2.3 The use of the AMOC is voluntary and it is for the RU to decide whether the good practice fits in with their operational context and risk assessment.

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2.2.4 An AMOC defines good practices to be used to cover operational risks when these are applicable, in doing so, an AMOC can define the good practice or contain reference to external document that are to be considered as good practice. In the case of the AMOCs to support the TSI OPE this is good practice provided by a number of sector organisations and NSAs. Some of which have been adapted to reflect the European legal framework and others that are directy linked to good practice developed bysector organisations within the EU and internationally.

2.2.5. The SMS and its functioning is described in a series of documents. This series of documents is necessary in order to meet the safety requirements described in EU Regulation 2018/762 for the RU. This includes:

- Processes that explain what the organisation does, with the inputs and outputs from the risk assessment etc.
- Procedures / instructions or both that explain the how, where, when, who, why,… in more detail of how the RU will undertake operational tasks in a safe way that ensures the safety of their part of the rail system.

Diagram below explains the hierarchy.

2.2.6 An AMOC, if used, will be part of the supporting operational procedures for the SMS process. . It is important to note that the AMOC is not the procedure but the information to contribute to the procedure. For example, in the SMS the RU cannot just say that the AMOC is applied but they need to explain how it is applied in a supporting operational procedure for the relevant operational requirement.. EU Regulation 2018/762 Requirement 5.1.3 (b) it states that:

> *To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:*
> *(c)* ***preparation of trains or vehicles before movement****, including pre-departure checks and train composition;*
> *(d) running trains or movement of vehicles in the different operating conditions (normal, degraded and emergency);*

Therefore, information from the output of the risk assessment should set out how, when preparing the train, the safety of the load is ensured before it commences its operation and secondly, that all the necessary checks and tests have been undertaken before departure and during operation so that it will continue to be safe throughout the journey. It should include information for staff involved in train preparation or other staff including the driver. This information should form the basis of SMS processes, procedures and instructions for staff.

2.2.7 The RU has to decide what part of the AMOC is relevant and then include that part in the supporting operational procedures. The RU should be aware that they may have to to provide the evidence in the SMS of how the AMOC controls the risks. This will be important when applying for a safety certificate or if requested during supervision by a NSA.

2.2.8 All applicable legislation must be taken into account by operators. This document is a guide and is therefore not legally binding. However, it clarifies certain concepts and procedures as stated above and will therefore support the common understanding and application of the TSI OPE.

2.2.9 This Guide should also be read alongside the ERA Guide on SMS requirements and the Application Guide on the TSI OPE.

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3. External document to be considered good practices

3.1. Concept

3.1.1 As a general concept, in order to manage specific operational topic within the SMS process under the RU/IM responsibility, it should be considered that the Railway Safety Directive (Directive (EU) 2016/798) art 4(3) point a) and b) 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.

3.1.2 The same concept has been detailed in the CSM on SMS requirements Regulation (EU) 2018/762 Annex I and Annex II point 3.1.1.1:

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 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 2.3. Organisational roles, responsibilities, accountabilities and authorities);
d) develop a system to monitor the effectiveness of safety measures (see 6.1. Monitoring).

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

3.1.4 Based on that, the AMOC is a proposed way to demonstrate compliance with TSI OPE as a mean to manage operational risks. The TSI OPE provisions are high level and try to cover the entire operational and traffic management subsystem whilst every single RU or IM could manage only part of the subsystem that is relevant to their operation.

3.1.5 An ERA Acceptable Means of Compliance is a series of good practice guidance and information that has been developed by the sector. They are based on actual experience on the development of risk based and relevant operational practice.

3.1.6 AMOCs are flexible and can be used by a variety of RUs and are particularly useful for cross border operation because they allow the same practice to be used in any Member State providing they are effective

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at controlling the operational risk and ensuring the safe operation of the train. They are also useful in ensuring the interoperability of the rail system because they do not put up different operational barriers at the border. This has been a key issue for many RU's who operate in a number of Member States.

3.1.7 The development of the AMOCs, whilst setting out some harmonised elements, also needs to ensure that they are not so prescriptive and at a level of detail which could result in a potential contradiction with the results of a risk assessment undertaken as per requirement 5.1 in the EU Regulation 2018/762. An RU cannot a priori apply an AMOC as it will be (or it is) defined. An RU must include the AMOC in its SMS, which means that it must apply a risk management process to identify the best way of implementation and to control the related risks. AMOCs are therefore a potential input to the risk analysis in RUs operations.

3.2. Link between the Agency and the entities issuing referenced external document

3.2.1 Periodical coordination with entities issuing referenced external document will take place. For those referenced external documents developed by the EU Rail Sector, regular discussions will take place under the auspices of the Working Party on the TSI OPE and traffic management. This is because many of the organisations responsible for the development of their sector practices are also members of the Working Party. The updating of the sector documents will be a standing item on the agenda of the TSI OPE WP meetings.

3.2.2 The sector organisations responsible for the development of the good practice, will inform ERA as and when the referenced external documents are updated. The updating process of the external good practice is for the sector organisations.

3.2.3 For those referenced external documents that are issued by UIC, this is covered by the arrangements in the ERA/UIC Co-ordination framework [to be signed]. When any changes are made to the referenced UIC documents, the WP will be consulted.

3.3. Acceptance throughout the EU

AMOCs should be accepted throughout the EU by Member States and 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 Member State and/or NSA requires an RU to comply **with national requirements**, then that MS or NSA will have to provide evidence to the RU as to why their **national requirements** provide a higher degree of risk control than that set out in the AMOC. However, AMOCs are not national rules and if an RU decides not to apply the AMOC and develop their own processes, they can do this and do not have to prove that their processes are as good or better than the good practice set out in the AMOC. But they do need to ensure that their processes can demonstrate a means of controlling the operational risk.

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4. AMOC implementation by Railway undertakings within their SMS processes

4.1. AMOC concept

4.1.1 Defining the context of the organization

The key part of the development of the SMS is the risk assessment and an understanding of how the SMS processes control this risk. The SMS is a series of procedures, good practice and rules that should be linked back to the risk assessment and crucially how the individual elements contribute to the management and control of risk. Purely stating that the RU applies a rule or a procecedure is not sufficient, there needs to be a supporting process that uses information from the operational context of the organisation to define how the AMOC will help to manage and control the risks.

The operational context in Regulation (EU) 2018/762 (requirement 1) sets the scene for the whole SMS and how it will be applied. For example, one of the requirements is to describe the type, extent and areas of operation. This will include a definition of the routes, whether passenger or freight, whether dangerous goods are applied, the staff used (i.e. contractors or employed staff), the vehicles used (whether owned or rented). From this information, the RU needs to highlight the specific serious risks that they are likely to encounter from their operation or from their contractors operation or tasks. This information should determine the type of risks that need to be addressed and the procedures that should be developed in the SMS. The operational context should also include the management of the interfaces between the IM and RUs or sector good practice that may need to be considered when conducting the risk assessments and developing the RU SMS.

4.1.2 Identifying operational risks and operational needs

The RU should consider all the technical, operational, organisational and human* risks that will occur for their operation, starting from before the operation starts (e.g. all the checks and tests necessary) to the train journey itself and when the journey ends. The basis for understanding what is necessary is the TSI OPE (Regulation (EU) 2019/773). This sets out the operational interfaces and key issues that need to be considered by both the RU and IM during train operation. However, the TSI OPE does not set out how these operational elements need to be considered. This should be covered by the RUs SMS which should detail all the operational processes, good practice and rules that will help to manage the risks and ensure the safe operation of the train. It is up to the RU to decide how this principle should be achieved using their procedures in their respective SMS's,based on the results from risk assessment for the operation and then linking them to their own procedures, good practice and National Rules and other requirements.

The operational risk assessment should be broken down into specific areas that are covered by the 6 Fundamental Operational Principles (FOPs) in the TSI OPE. These FOPs cover all areas of train operation and give the overarching principles for a safe railway system. These need to be considered when developing procedures for identifying operational risks and deciding what is needed to control them. These FOPS are mandatory and they are the initial starting point for developing and applying operational rules/manuals etc. inside the SMS.

* https://www.era.europa.eu/activities/safety-management-system/human-and-organisational-factors-hof_en

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4.1.3 Managing operational risks

4.1.3.1 The AMOC is designed as an input into the outcomes of the risk assessment process. For example, if risks from loading have been identified, then the AMOC on Safety of loading can be applied. However, the SMS process should specifiy how the key operational risks will be controlled by the application of the AMOC and which part of the AMOC that is applied. Staff should be informed and trained in the use of the guidance that is applied from the AMOC. Just applying the AMOC is not sufficient because the RU needs to ensure that the process and content of the AMOC can be regularly reviewed and revised against the risk assessment and SMS processes. To help with the identification of the risks, each AMOC sets out the relevant safety requirements that have to be met. In addition, the application of the AMOCs should also be part of the monitoring process and performance evaluation process which should identify issues and or problems that need to be rectified either with the application of the AMOC or changing the supporting process.

4.1.3.2 The benefits of using the AMOC cross border means that RU's can use the same SMS procedure and good practice for operation across a number of Member States. This means that they should not be constrained by individual national rules that require the RU to change their procedure without any links to the operational context and risk. This makes it easier and more targeted for the RU to manage, control and monitor operational risks.

4.2. General examples of an AMOC implementation

4.2.1 Each AMOC contains references to good practice developed by the sector. The RU should identify the parts that are the most relevant to their operational context and risk assessment. The whole AMOC does not need to be applied if it is not relevant. The key is being able to identify the specific risk and linking it to a part of the good practice in the AMOC. This evidence is important for obtaining a single safety certificate and providing information to the NSA during supervision.

4.3. Return of experience

4.3.1 The Agency will take into account any experience in relation to the application of the AMOC from the sector, NSAs or other organisations in the review of the good practice to make sure it remains relevant and useful in controlling operational risks. It is therefore important that the sector provides feedback to their relevant organisations such CER, UIP etc. so that this information can be given to ERA and the process for updating the AMOC can be put into effect.

4.3.2 The review and update of the AMOCs and the good practice they take into account will be taken forward with the organisations outlined in 3.2.

5. Assessment of the AMOCs as part of the single safety certificate

5.1 In the development of AMOCs, an important point is that they may be seen as a way of ensuring safety as per Directive (EU) 2016/798 on railway safety. In addition, compliance with the TSI OPE is assessed by the appropriate Safety Certification body (ERA or NSAs) through the safety management system requirements. It is up to the RU to monitor their processes, procedures and risk mitigation measures, and then for the NSA to follow up the monitoring activities, through a (risk based) strategy and plan(s) for supervision.

5.2 The assessment of the SMS by the appropriate Safety Certification body (ERA or NSAs) will consider the use of the AMOCs as evidence for compliance with the requirements in Regulation (EU) 2018/762. This assessment will consider how the RU has identified its operational risks, developed suitable procedures and mapped exactly how the AMOC will control them. If this is clearly set out, this should make the assessment process easier and quicker and thereby reduce costs for the RU.

5.3 It should also be noted that the AMOC should be seen as a presumption of conformity and the RU through the risk assessment undertaken, can also demonstrate alternative controls (processes and company rules) which must be accepted by the the appropriate Safety Certification body (ERA or NSAs). The key being that they can demonstrate that the approach, whilst different to the AMOC, demonstrates a means of controlling the operational risk

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6. Supervision of the AMOCs by National Safety Authorities

6.1. The NSA during their supervision activities will consider the need to look at the RU's SMS and risk assessment and how the AMOC is being applied against the risk assessment. This should not just be checking that the AMOC is used but questioning and reviewing how the SMS procedures such as the AMOCs are applied, how the risks for which it is used against are monitored and reviewed by the RU and any necessary changes made to the application.

6.2 The operational context of the organisation is fundamental for this topic. AMOCs are a form of a good practice. The approach to them is not the same as with national rules. It is crucial that a risk based approach is understood. RUs need to understand their role in applying the AMOC against their risk assessment and NSAs need to understand that they have to focus on the SMS and risk assessment when performing supervision. This was already introduced in CSM on Supervision (EU Regulation 2018/0761).

6.3 The AMOCs can therefore be used by the NSA to review the application of the RUs risk assessment, by seeking further information during their supervision activities, on how the risk assessment process controls the risks. This will include a variery of tools available to the NSA such as interviews, analysing documents and data, investigating safety performances, etc.).

6.4 The NSAs should target how RUs use the the common safety method on monitoring (EU Regulation 1078/2012) on monitoring their SMS to ensure it remains effective in controlling operational risks at all levels and through all processes, operational requirements and good practice such as the AMOCs. This regulation requires the development of a monitoring strategy and plan to ensure continuous improvement, and can be used by the NSAs to check that the RU is applying the correct and relevant procedures and if not what have they done to make the necessary changes. RU's documentation on monitoring activities should provide evidence for NSA's of RUs checking the correct application and the effectiveness of their processes and procedures in the safety management system, including their technical, operational and organisational risk control measures (including the use of AMOCs)