

Moving Europe towards a sustainable
and safe railway system without
frontiers.

OPINION

ERA/OPI/2022-9

OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for

Italy

regarding

existing national rules on the safety critical function ‘SMS
Manager’- ANSF Decree 04/2011

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

In line with Article 8 of Directive (EU) 2016/798 (the Railway Safety Directive) and in conjunction with article 26 of Regulation (EU) 2016/796 (the Agency Regulation), this opinion covers the examination by the European Union Agency for Railways (the Agency) of the national rules defined in the ANSF Decree 04/2011 adopted by Italy regulating the essential requirements for qualification of the Safety Management System Manager (RSGS) leading to a negative assessment.

On the 12th of July 2022, the Agency sent a letter (JD/Is/D(2022)7805) to the Italian NSA (National Safety Authority or ANSFISA) on this subject, sharing its preliminary opinion that the Italian NSA Decree 04/2011 is not in line with the EU legal framework.

The Italian NSA answered on the 27th of September 2022 to the Agency that it cannot be left to each operator's SMS to identify the role and competencies of the staff responsible for establishing and maintaining the SMS: these requirements must be identified outside the SMS, even by analogy with other contexts such as the health&safety at workplaces (Head of the Prevention and Protection Service) and the transport of dangerous goods (Dangerous Goods Safety Advisor). ANSFISA believes that a person possessing the skills provided for the RSGS in the ANSF Decree 4/2011 is of fundamental importance for the management of safety in the current set-up of the European railway system and it is proposed that it be provided for in the Union legislation. Pending this, ANSFISA considers it necessary to keep in force the national decree.

This opinion is addressed to Italy with a copy to the European Commission.

2. Legal Background

Article 26 (3) of the Agency Regulation sets out the following:

Where the examination referred to in paragraph 1 leads to a negative assessment, the Agency shall inform the Member State concerned and ask it to state its position regarding that assessment. If, following that exchange of views with the Member State concerned, the Agency maintains its negative assessment, the Agency shall within a maximum period of 1 month:

(a) issue an opinion addressed to the Member State concerned, stating that the national rule or rules in question has or have been the subject of a negative assessment and the reasons why the rule or rules in question should be modified or repealed; and

(b) inform the Commission of its negative assessment, stating the reasons why the national rule or rules in question should be modified or repealed.

The conclusion of the assessment in this opinion is that the adopted national rules of Italy contradict already harmonised EU legislation and more precisely:

- Directive (EU) 2016/798 of 11 May 2016 on railway safety
- 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;
- 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;
- Commission Delegated Regulation (EU) 2018/761 of 16 February 2018 establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012;
- Commission Implementing Regulation (EU) 2015/1136 of 13 July 2015 amending Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment.

3. Analysis of the Agency's assessment

As part of its assessment, the Agency received from ANSFISA an excel file (latest version sent in April 2022). This file contained references, among others, to the national rules adopted by Italy regulating the assessment of the elements set out in point (b) of paragraph 3 of Article 10 of Directive (EU) 2016/798. Pending completion of its analysis, the Agency identified that specific rules in the excel file refer to the ANSF Decree 04/2011 on the qualification of the Safety Management System Manager (RSGS).

This decree defines the mandatory requirements for the qualification of the RSGS and the procedure for obtaining and maintaining such a qualification. For each of the indicated requirements (8 requirements), the decree defines the purpose, the competences that are deemed necessary to acquire the requirement, the documentation necessary to prove possession of the competence, and the minimum set of professional experience. It also defines the procedure for obtaining the qualification, which provides for an examination to be taken at the NSA, concluding with the identification of the minimum requirements for maintaining and possible revocation of the qualification.

Although Directive (EU) 2016/798 permits in principle type 5 rules, the specific requirements in the Italian Decree need to undergo an additional compatibility check against Regulations (EU) 2018/762 and (EU) 2019/773.

The competence requirements for staff carrying out safety-related tasks shall be managed under the Safety Management System (SMS) of the Railway Undertaking (RU) and the Infrastructure manager (IM) in accordance with Annex I point 4.2 and with Annex II point 4.2 to the Commission Delegated Regulation (EU) 2018/762 which stipulate (underlining done by the Agency) that:

*"4.2.1" The **organisation's competence management system shall ensure** that staff having a role that affects safety competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:*

- (a) identification of the competencies (including knowledge, skills, non-technical behaviours and attitudes) required for safety-related tasks;*
- (b) selection principles (basic educational level, psychological and physical fitness required);*
- (c) initial training, experience and qualification;*
- (d) ongoing training and periodic update of existing competencies;*
- (e) periodic assessment of competence and checks of psychological and physical fitness to ensure that qualifications and skills are maintained over time;*
- (f) specific training in relevant parts of the safety management system in order to deliver their safety-related tasks.*

*"4.2.2" The **organisation shall provide** a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:*

- (a) the training programme is delivered according to the identified competency requirements and individual needs of the staff;*
- (b) where applicable, the training ensures that staff can operate under all operating conditions (normal, degraded and emergency);*
- (c) the duration of the training and the frequency of the refresher training are appropriate for the training objectives;*
- (d) records are kept for all staff (see 4.5.3. Control of documented information);*
- (e) the training programme is regularly reviewed and audited (see 6.2. Internal auditing) and changes made when necessary (see 5.4. Management of change).*

"4.2.3" Back to work arrangements shall be in place for staff following accidents/incidents or long absences from work, including providing additional training where such a need is identified.

Therefore, according to the aforementioned EU Regulation, it is up to the RUs and IMs exclusively to define, as part of their SMS, the roles and responsibilities of those carrying out safety-related tasks, identify the relevant competencies and establish training programmes to develop and maintain their competencies.

In addition, the Technical Specifications for Interoperability for the Operation and Traffic Management (TSI OPE), in section 4.6 of its Annex, also defines that the initial and ongoing assessment of staff and the analysis and update of training needs is part of the requirements in the safety management system in line with Regulation (EU) 2018/762. This is because risk assessment and the operational context need to be fully considered by an RU or IM to identify and to manage the competency requirements for staff carrying out safety-related tasks.

It is therefore an exclusive task of the RU and the IM to decide on the deeper content of safety-related tasks, as this is highly dependent on each RU/IM's operational context and each RU/IM's specific and tailored-made risk evaluation and assessment.

Besides, the matter of staff competencies is a crucial responsibility of each RU and IM operating in the Single European Railway Area. It should be well included in the Safety Management System of each RU and IM as the proper identification of risks and their mitigation is of great importance for safe operations. To this end, the NSAs shall use all available legal instruments, such as Commission Delegated Regulation (EU) 2018/761 establishing common safety methods for supervision by national safety authorities, to verify through their supervision activities the ability of the RU/IMs' Safety Management Systems to function properly and address all relevant risks, including those arising from the human and organisational factors and impacting the competence management system.

Assuming that risks can be generated within hazardous situations related to the activities carried out by the organization, it should be noted that the main scope of an SMS (Safety Management System) is to manage and control risks with the aim of making rail transport as safest as possible.

In accordance with the aforementioned rules, the following articles from the Railway Safety Directive shall be respected:

ART 3

(9) 'safety management system' means the organisation, arrangements and procedures established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations;

ART 4

3. 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; (c) where appropriate, contractually oblige the other actors referred to in paragraph 4 having a potential impact on the safe operation of the Union rail system to implement risk control measures; and (d) ensure that their contractors implement risk control measures through the application of the CSMs for monitoring processes set out in the CSMs on monitoring referred to in point (c) of Article 6(1), and that this is stipulated in contractual arrangements to be disclosed on request of the Agency or of the national safety authority.

ART 9

4. The safety management system shall be adapted to the type, extent, area of operations and other conditions of the activity pursued. It shall ensure the control of all risks associated with the activity of the infrastructure manager or railway undertaking, including the supply of maintenance, without prejudice to Article 14, and material, and the use of contractors. Without prejudice to existing national and international liability rules, the safety management system shall also take into account,

where appropriate and reasonable, the risks arising as a result of activities by other actors referred to in Article 4.

Finally, the purpose of the SMS is to ensure that the railway undertakings and infrastructure managers achieve their business objectives in a safe manner. How objectives are met with the relevant safety level, is a responsibility of the organization. The organisation sets the business objectives and manages the operational risks and therefore they should collectively hold the responsibility of ensuring that everything is in place to manage and monitor the safe operation.

Therefore, insofar that the Italian national Decree reserves the responsibility for the SMS and for risk evaluation and risk management to one single person/role rather to the organisation itself, it is not in line with Directive (EU) 2016/798 and Commission Delegated Regulation (EU) 2018/762.

4. The opinion

In accordance with article 26 (3) of Regulation 2016/796, the opinion covers the examination of adopted national rules of Italy by the Agency leading to a negative assessment of the provisions of the NSA Decree 04/2011 regulating the essential requirements for qualification of the Safety Management System Manager (RSGS).

The Agency considers that the adopted national safety rules belonging to the NSA Decree 04/2011 are not compliant with the relevant EU legal requirements as described in the analysis. The Agency's opinion is that such RSGS requirements should be part of a wider risk-based approach attributed to the organisation and not only to one role.

This opinion is addressed to Italy, with a copy to the European Commission (DG MOVE).

Valenciennes, 21/11/2022

SIGNED

Josef DOPPELBAUER
Executive Director

Annex 1

Impact Assessment Note

existing national rules on the safety critical function ‘SMS Manager’ – ANSF Decree 04/2011

Issued as per Art. 8(1) of Regulation (EU) 2016/796 and the Impact Assessment procedure adopted by the ERA Management Board (Decision n.290, 16/03/2022)

<p>1. Context and assessment of impacts</p>
<p>1.1. The national rule in object</p> <p>As part of the assessment of the national safety rules under Article 8 of Directive (EU) 2016/798 in conjunction with article 26 of Regulation (EU) 2016/796, the Agency received the from Italian National Safety Authority (ANSFISA) an excel file (latest version sent in April 2022). ANSF Decree 04/2011 contained therein defines the mandatory requirements on the qualification of the Safety Management System Manager (RSGS) for RUs and IMs. The decree mandates also procedures for obtaining and maintaining such a qualification. For each of the indicated 8 requirements to become RSGS, the decree defines the purpose, the competences that are deemed necessary to acquire each requirement, the documentation necessary to prove the relevant competence, the minimum set of professional experience, diplomas, training as well as fluency in Italian language at level C2. The decree goes on to define the procedure for obtaining the qualification, which also provides for an examination to be taken at the NSA.</p>
<p>1.2. Analysis performed</p> <p>In its first assessment and exchange of letters with ANSFISA, the Agency provided substantial evidence that the national rule in object is in contradiction with existing EU legal acts which state that the competence requirements, roles and responsibilities, training, qualifications for staff carrying out safety-related tasks should be managed under the Safety Management System (SMS) of each individual company. It is in fact an exclusive task of the company to decide on the specificities of safety-related tasks, as this is highly dependent on each company's operational context as well as specific and tailored-made risk evaluation and assessment. Instead of checking legal compliance of each RSGS' individual, the NSAs shall use all available legal instruments, such as Commission Delegated Regulation (EU) 2018/761 establishing common safety methods for supervision by national safety authorities, to verify through their supervision activities the ability of the Safety Management Systems to function properly and address all relevant risks, including those arising from the human and organisational factors and impacting the competence management system. The Agency believes that responsibilities for risk management are well covered by EU legal acts and that it should be the company and not necessarily a single person who bears the relevant responsibilities unless the SMS provides such a concentration of responsibilities.</p>
<p>1.3. Assessment of impacts</p> <p>The national rule in object by Italy falls within the scope of the Light Impact Assessment 'Revision of the Common Safety Methods on Conformity Assessment and the Common Safety Methods on Supervision' performed by the Agency in February 2017 and of the Full Impact Assessment on the TSI OPE Revision carried out in 2018. The impacts were therefore already adequately assessed and it is confirmed that the rule would compromise uniformity of application of well-established EU requirements on SMS, increase the risk of low transparency of the national rules framework that stakeholders have to comply within Italy as well as interoperability of RUs. In particular, the rule in object imposes very far reaching administrative, training, educational and language requirements on individuals working as RSGS in any RU or IM. These requirements are applicable to all companies operating on the Italian rail network regardless of the scope and type of their operations. Furthermore, the rule imposes a specific placement and reporting lines of the RSGS within the company structure. All these requirements have a negative impact on interoperability given that they are Italy-specific. For example, a RU holding a valid SSC and with a perfectly compliant SMS which wishes to extend its area of operations to Italy would need to transform its internal organisation, potentially recruit a RSGS certified, trained and fluent in Italian and amend its SMS according to the national rule in object. Compliance with the rule may also backfire on the validity of the SMS in other Member States or force RUs to develop a parallel safety framework specific for operations in Italy but separated from the SMS of the rest of the company. The rule generates important compliance costs on RUs.</p>

Regarding safety, the national rule in object forces ANSFISA to perform legal and administrative checks as well as examinations of individuals which are resource-intensive for the NSA staff. Therefore the staff available to perform supervision activities of the Safety Management Systems risks to be reduced. It is concluded that the national rule in subject generates important negative impacts on interoperability, undue compliance costs for RUs, costs for the NSA as well as it risks to discourage RUs entering the Italian market.

1.4. Stakeholders affected

The most affected stakeholder are the railway undertakings.

Railway undertakings (RU)	<input checked="" type="checkbox"/>	Member States (MS)	<input type="checkbox"/>
Infrastructure managers (IM)	<input checked="" type="checkbox"/>	Third Countries	<input type="checkbox"/>
Manufacturers	<input type="checkbox"/>	National safety authorities (NSA)	<input checked="" type="checkbox"/>
Keepers	<input type="checkbox"/>	European Commission (EC)	<input type="checkbox"/>
Entity Managing the Change (EMC)	<input type="checkbox"/>	European Union Agency for Railways (ERA)	<input type="checkbox"/>
Notified Bodies (NoBo)	<input type="checkbox"/>	Shippers	<input type="checkbox"/>
Associations	<input type="checkbox"/>	Other (Please specify) ...	<input type="checkbox"/>

2. Preferred option

2.1. Recommendation

It is confirmed a negative assessment of the national rule in object by Italy.