

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

# OPINION

*ERA/OPI/2022-11*

## OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for

LITHUANIA

regarding

two adopted rules setting requirements for staff executing safety-critical tasks

### 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 (Railway Safety Directive) and in conjunction with Article 26 of Regulation (EU) 2016/796, this opinion covers the examination by the European Union Agency for Railways (hereinafter the Agency) of the Lithuanian adopted national rules establishing requirements for staff executing safety-critical tasks leading to a negative assessment.

Lithuania notified two adopted safety rules in the Single Rules Database (SRD)<sup>1</sup> on the 23<sup>th</sup> of August 2022. The Agency assessed them and reached to the conclusion (also recorded in the SRD) that the following Lithuanian notified legal requirements contained in the following documents and references are not in line with the EU legal framework:

- Lietuvos respublikos geležinkelių transport eismo saugos įstatymas (version 16.06.2022): Art. 20, Art. 21.
- Fizinių asmenų, pageidaujančių vykdyti krovinių krovimo ir tvirtinimo vagonuose darbų vadovų funkcijas, žinių tikrinimo tvarkos aprašas (version 24.06.2022): the entire document.
- Krovinių krovimo ir tvirtinimo vagonuose darbų vadovų mokymų trukmės ir turinio reikalavimai (version 14.07.2022): the entire document.
- Fizinių asmenų, pageidaujančių dirbti darba, tiesiogiai ar netiesiogiai susijusį su geležinkelių transporto eismu, žinių tikrinimo tvarkos aprašas (version 22/12/2020): entire document
- Fizinių asmenų, kurių darbas tiesiogiai arba netiesiogiai susijęs su geležinkelių transporto eismu, mokymų trukmės ir turinio reikalavimai (version 22.01.2021): the entire document.

The Agency notified Lithuania on its negative assessment of the above notified adopted safety rules on the 21<sup>st</sup> of October 2022.

On the 26<sup>th</sup> of October 2022, Lithuania notified the Agency in SRD its rejection of the Agency's negative assessment on both adopted safety rules.

This opinion is addressed to Lithuania with a copy to the European Commission and is uploaded on the Single Rules Database (SRD).

## 2. Legal Background

Article 26 (3) of 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<sup>2</sup> (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.*

This opinion is issued pursuant to Article 26 (3) of the Regulation (EU) 2016/796.

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<sup>1</sup> Rule ID LT-SA-332-1-A and Rule ID LT-SA-333-1-A (reference in SRD)

<sup>2</sup> OJ L 138, 26.5.2016, p. 1.

This opinion points out the fact that the adopted national rules of Lithuania contradict already harmonised European legislation according to the analysis and the Annex to this opinion.

The applicable EU legislation which is relevant for this opinion is:

- 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

The Lithuanian legal requirements on safety-critical staff laid down in the notified legal acts set out:

- The mandatory certification process and validity period.
- The ongoing training needs and the mandatory periodic update.
- The duration and content of the training.

The Agency acknowledges that the Railway Safety Directive permits in principle type 5 rules. However, all national rules shall not contradict EU law.

Under this light, the specific requirements in the Lithuanian rules underwent an additional compatibility check against Regulations (EU) 2018/762 and (EU) 2019/773.

More precisely, Annex I point 4.2 of Regulation (EU) 2018/762 stipulates:

“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.

Requirements on leadership and commitment to the safety management system are even so laid down in Annex I point 2.1 of the Regulation (EU) 2018/762.

In other words Annex I point 4.2 to Regulation (EU) 2018/762 requires that the competence requirements for staff carrying out safety-related tasks is managed only under the Safety Management System (SMS) of the Railway Undertaking (RU) and the Infrastructure Manager (IM) and not at the Member State level through a national rule.

Therefore, RUs and the IM are the only ones according to the applicable EU law 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 a railway undertaking 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 of the IM to decide on the deeper content of safety-related tasks, as this is highly dependent on each undertaking's operational context and each undertaking's specific and tailored-made risk evaluation and assessment. The Member State has no right to substitute the company's obligation and right to define the requirements.

The matter of staff competencies is a crucial responsibility of each railway undertaking and infrastructure manager operating in the Single European Railway Area. It shall be well included in the Safety Management System of each undertaking as the proper identification of risks and their mitigation is of great importance for safe operations.

Under this light, the National safety Authorities of the Member States shall apply the relevant EU law on supervision and in particular the 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 undertaking's 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. Moreover, the following Articles from the Railway Safety Directive shall be complied with

**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 organisation. 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.

As a conclusion, the Agency's opinion is that such requirements on safety critical staff should be part of a risk-based approach that is company-specific.

#### 4. The opinion

The adopted national safety rules laid down in the following legal documents with references are not compliant with the relevant EU legal requirements as described above under Section 3 of this opinion:

- Lietuvos respublikos geležinkelių transport eismo saugos Įstatymas (version 16.06.2022): Art. 21, Art. 22.
- Fizinių asmenų, pageidaujančių vykdyti krovinių krovimo ir tvirtinimo vagonuose darbų vadovų funkcijas, žinių tikrinimo tvarkos aprašas (version 24.06.2022): the entire document.
- Krovinių krovimo ir tvirtinimo vagonuose darbų vadovų mokymų trukmės ir turinio reikalavimai (version 14.07.2022): the entire document.
- Fizinių asmenų, kurių darbas tiesiogiai arba netiesiogiai susijęs su geležinkelių transporto eismu, mokymų trukmės ir turinio reikalavimai (version 22.01.2021): the entire document.

For this reason, in accordance with article 26 (3) of Regulation 2016/796, the Agency with this opinion confirms its negative assessment. This opinion is addressed to Lithuania, with a copy of it shared with the European Commission (DG MOVE).

Valenciennes, 22/11/2022

Signed

Josef DOPPELBAUER  
Executive Director

# Annex 1

## Impact Assessment Note

*Two adopted rules setting requirements for staff executing safety-critical tasks*

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)

<b>1. Context and assessment of impacts</b>
<b>1.1. The national rule in object</b>
<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 from Lithuania the notification of national rules in subject. The relevant national legal acts set out requirements on staff performing loading of cargo and works related to rail safety including: mandatory certification process and validity of staff certificates, mandatory training needs and periodic updates that staff need to undertake, duration and content of training.</p>
<b>1.2. Analysis performed</b>
<p>In its first assessment, 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, 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 certified staff and relevant training, 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 of each company 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 a national rule to set out requirements and training programmes.</p>
<b>1.3. Assessment of impacts</b>
<p>The national rule in object by Lithuania 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. The impacts were therefore already adequately assessed and it is confirmed that the rules 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 Lithuania as well as interoperability of RUs. In particular, the rules in object impose certification and training requirements on individuals working on safety-critical tasks. These requirements are applicable to all companies operating on the Lithuanian rail network regardless of the scope and type of their operations. This has a negative impact on interoperability given that the rules are Lithuania-specific. For example, a RU holding a valid SSC and with a perfectly compliant SMS which wishes to extend its area of operations to Lithuania would need to certify its staff, train them according to local requirements and amend its SMS according to the national rule in object. The rule generates important compliance costs on RUs.</p> <p>Regarding safety, the national rule in object forces the Lithuanian NSA to perform legal and administrative checks of certificates and training programmes 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 rules in subject generate important negative impacts on interoperability, undue compliance costs for RUs, costs for the NSA as well as they risk to discourage RUs entering the Lithuanian market.</p>



**1.4. Stakeholders affected**

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**

No alternative options are to be assessed and it is confirmed a negative assessment of the national rules in object by Lithuania.