

Team for implementation of the action plan for improvement of the approach to risk-based safety management

Warsaw, 13 October 2022

## RECOMMENDATION

of the Team for implementation of the action plan for improvement of the approach to risk-based safety management

on the powers of the President of the Office of Rail Transport (UTK) to verify the Proposer's decision on the significance of the change

## Date of issue

13 October 2022, version 2

#### The Recommendation is addressed to

Office of Rail Transport (UTK)

#### Content of the Recommendation

Documentation on the assessment of the of change significance, prepared by the Proposer in accordance with Article 4(2) of Regulation 402/2013<sup>1</sup>, presented as part of activities and procedures conducted by the Office of Rail Transport (UTK), shall be rejected if the conclusion as to the significance of the change has not been supported by an analysis in accordance with the requirements of Regulation 402/2013 (criteria specified in Article 4(2) of Regulation 402/2013).

# Related regulations

Article 4(2) of Regulation 402/2013

## Issue description

Decisions regarding the assessment of a change as not significant are often not the result of a thorough analysis, but rather of the intention to avoid the process described in Annex I to Regulation 402/2013, in particular the involvement of the assessment body. This practice jeopardizes the safety of the railway system as it leads to unjustified abandonment of proactive safety management for organizational or financial reasons. According to data for 2021, the percentage of significant changes in the total number of changes introduced to the railway system is 1%.

Under Article 4(2) of Regulation 402/2013, if the proposed change has an impact on safety, the proposer shall decide, by expert judgement, on the significance of the change based on the following criteria:

a) failure consequence: credible worst-case scenario in the event of failure of the system under assessment, taking into account the existence of safety barriers outside the system under assessment:

 $_{1}$  Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 (O.J. EU L 121 of 03.05.2013, p. 8, as amended).

- b) novelty used in implementing the change: this concerns both what is innovative in the railway sector, and what is new for the organisation implementing the change;
- c) complexity of the change;
- d) monitoring: the inability to monitor the implemented change throughout the system lifecycle and intervene appropriately;
- e)reversibility: the inability to revert to the system before the change;
- f) additionality: assessment of the significance of the change taking into account all recent safety-related changes to the system under assessment and which were not judged to be significant.

The President of the Office of Rail Transport (UTK) is the national safety authority authorized to control the implementation of railway regulations.

The President of UTK is competent to control the implementation of the provision of Article 4(2) of Regulation 402/2013 by the Proposers specified in Article 3(11) of Regulation 402/2013. If the decision as to change significance has not been made on the basis of a reliable, comprehensive and all-round analysis of the criteria provided for in Article 4(2) of Regulation 402/2013, it is a violation of this provision.

An incorrectly conducted process of evaluating the change significance may be the basis for finding a violation of the regulation as part of inspections carried out by the President of UTK. It may also be the basis for rejecting applications for authorization to place a railway vehicle (or type of railway vehicle) on the market, imposing an obligation to obtain a new authorization for the vehicle after introducing changes or rejecting applications for authorization to operate subsystems of fixed installations due to the failure to demonstrate safe integration. A non-compliant manner of fulfilling the obligations related to the assessment of change significance may also lead to refusal to renew the single safety certificate or safety authorization (Article 18bc(4) and Article 18a(3c) of the Act on Railway Transport<sup>2</sup>).

Team Leader

KAMIL WILDE VICE-PRESIDENT OF THE OFFICE OF RAIL TRANSPORT FOR SAFETY

/Document signed with a qualified electronic signature./

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The President of the Office of Rail Transport processes the provided personal data in compliance with the law. For detailed information, visit www.utk.gov.pl/pl/rodo

<sup>2</sup> Act on Railway Transport of 28 March 2003 (consolidated text: Journal of Laws of 2021, item 1984, as amended).

Page 2 of 2