

## RECOMMENDATION

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

**on enforcement of assessment of significance of the change in control and audit procedures in compliance with Regulation 402/2013**

### Date of issue

6 June 2013, version 1

### The Recommendation is addressed to

UTK officials conducting controls and audits.

### Content of the Recommendation

Inspectors and auditors who, as part of the control or audit, based on the “Checklist for the Application of Regulation 402/2013”<sup>1</sup>, reach the conclusion:

- a) that the change significance criteria have been analysed by the petitioner referred to in Regulation 402/2013<sup>2</sup> in breach with this Regulation, or
- b) that despite the analysis change significance criteria carried out by the petitioner in compliance with the Regulation which objectively shows that the change is significant, the petitioner, contrary to Regulation 402/2013, decides that the change is not significant;

must apply the following procedure:

- 1) the inspector or auditor must state the irregularity/non-compliance consisting in the controlled/audited proposer making a decision as to the significance of the change in breach of Article 4(2) of Regulation 402/2013.

In the case referred to **in letter a)**, the irregularity/non-compliance must be formulated as follows:

“Irregularity/non-compliance No. [specify the number];

Improper analysis of change significance assessment criteria:

[Specify the relevant criterion]: in connection with [specification of conclusions from application of the “Checklist for the Application of Regulation 402/2013”];

Irregularity justification: [specification of the exact nature of the irregularity with reference to the supporting documentation];

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<sup>1</sup> <https://www.utk.gov.pl/download/1/78394/Listakontrolnadotstosowaniarozporzadzenia4022013.xlsx>

<sup>2</sup> 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).

Breached regulations: [Article 5(1) in conjunction with Article 4(2) of Regulation 402/2013];

Evidence: [specify the evidence]”.

**Example:**

*“Irregularity No. 1;*

*Improper analysis of change significance assessment criteria:*

- *failure consequence: in connection with failure to indicate safety barriers outside the system under assessment;*
- *monitoring: in connection with failure to analyse the competences of people, organisational units responsible for change monitoring;*

*Irregularity justification:*

*Breach of Article 4(2) of Regulation 402/2013 by carrying out an incorrect analysis of the change significance assessment criteria presented in the Change Significance Assessment Report. The presented justification of the “failure consequence” criterion shows that the safety barriers outside the system under assessment were not analysed and taken into consideration in the assessment. In the case of the “monitoring” criterion, the controlled entity failed to analyse the competences of people, organisational units responsible for change monitoring.*

*Breached regulations:*

*[Article 5(1) in conjunction with Article 4(2) of Regulation*

*402/2013; Evidence:*

*Change Significance Assessment Report”.*

In the case referred to **in letter b)**, the irregularity/non-compliance must be formulated as follows:

*“Irregularity/non-compliance No. [specify the number];*

*Improper method of carrying out the risk management process by making the decision on change significance contrary to the analysis of criteria provided for in Article 4(2) letters (a)-(f).*

*Irregularity justification: [specification of the exact nature of the irregularity with reference to the supporting documentation];*

*Breached regulations: [Article 5(1) in conjunction with Article 4(2) of Regulation 402/2013];*

*Evidence: [specify the evidence]”.*

**Example:**

*“Irregularity No. 1.*

*Improper risk management method by making the decision on change significance contrary to the analysis of criteria provided for in Article 4(2) letters (a)-(f).*

*Irregularity justification:*

*Breach of Article 4(2) of Regulation 402/2013 by making the decision on change significance contrary to the analysis of criteria: failure consequence, novelty and reversibility*

*presented in the Change Significance Assessment Report. The description of the subject reports presented in the above-mentioned Report shows that a credible worst-case scenario may lead to an accident with fatalities, the assessed change involves use of new device types and the change is irreversible. Considering the analysis of these criteria, the team making the change drew a contradictory conclusion as regards change significance.*

*Breached regulations:*

*Article 5(1) in conjunction with Article 4(2) of Regulation 402/2013;*

*Evidence:*

*Change Significance Assessment Report”.*

- 2) in the case referred to in letter a) above, removal of the irregularity/non-compliance will consist in reanalysing the change significance assessment criteria taking into consideration the formulated irregularities/non-compliances and taking into consideration the guidelines provided for in the “Checklist for the Application of Regulation 402/2013”, and making another decision as to the significance of the change.

If the proposer conducts the change significance criteria analysis in compliance with Article 4(2) of Regulation 402/2013, the irregularity/non-compliance must be considered removed;

- 3) in the case referred to in letter b) above, removal of the irregularity/non-compliance will consist in the proposer making a decision that the change is significant and in conducting the risk management process specified in Annex I to Regulation 402/2013;
- 4) in case of failure to remove the irregularity/non-compliance in accordance with Point 2) or 3) above, procedure must be initiated against the proposer under Article 14(1) of the Act on Railway Transport<sup>3</sup> according to which “The President of the Office of Railway Transport orders, by way of decision, to remove the irregularities in the specific time limit in case of breach of regulations regarding obligations of managers, railway undertakings and users of railway sidings in the scope of railway transport safety”;
- 5) in case of failure to execute the decision issued under Article 14(1) of the Act on Railway Transport, the proposer must be fined under Article 66(2aa) of the Act on Railway Transport according to which “The President of the Office of Railway Transport, taking into consideration the scope of the breach, activity of the entity conducted so far as well as its financial capacity, can impose, by way of a decision, a fine in the amount equivalent to EUR 5000 for each day of delay in execution of the decisions referred to in Article 14(1) of the Act on Railway Transport”;

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<sup>3</sup> Act Amending the Act on Railway Transport of 23 July 2021 (Journal of Laws of 2021, item 1556)

## Related regulations

Article 14(1) of the Act on Railway Transport in conjunction with Article 4(2) of Regulation 402/2013.

## Issue description

Regulation 402/2013 does not contain provisions on the enforcement of the obligations provided for therein, including sanctions for breaching them. These provisions are included in the Act on Railway Transport. This Recommendation indicates the legal instruments with which the President of UTK intends to ensure change risk management in compliance with Regulation 402/2013.

**Team Leader**

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*/Document signed with a qualified electronic  
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