

## RECOMMENDATION

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

**on responsibility of assessment bodies in the risk management process**

### Date of issue

22 August 2022, version 1

### The Recommendation is addressed to

Office of Rail Transport (UTK)

### Content of the Recommendation

Safety assessment reports not prepared in compliance with Recommendation for Use No. 1 ASBO Cooperation 001NET1108 Version 1.1., presented as part of the activities and procedures conducted by the Office of Rail Transport (UTK) shall be rejected as non-compliant with Article 6(1) and (2) of Regulation 402/2013<sup>1</sup>.

### Related regulations

Article 3(14), Article 6(1) and (2) of Regulation 402/2013.

### Issue description

The European Union Agency for Railways issued the Recommendation for Use No. 1 ASBO Cooperation 001NET1108 Version 1.1 as part of the Workforce of Assessment Bodies [hereinafter: "AsBo"].

The Recommendation issued by the Agency shows that many stakeholders and assessment bodies have incorrect understanding of the responsibility of assessment bodies in the risk process management under Regulation 402/2013. In this understanding, the role of the assessment body is to come down only to determination if the consecutive stages and actions provided for in Annex I to Regulation 402/2013 have been fulfilled.

The Recommendation presents the proper interpretation of Articles 3(14) and Article 6(1) and (2) of Regulation 402/2013 which describe the responsibility of the assessment body as follows:

*assessment body means the independent and competent external or internal individual, organisation or entity which undertakes investigation to provide a judgement, based on*

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<sup>1</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).

evidence, of the suitability of a system to fulfil its safety requirements.

1. An assessment body shall carry out an independent assessment of the suitability of both the application of the risk management process as set out in Annex I [to Regulation 402/2013] and of its results. [...]

2. To perform the independent assessment, the assessment body shall:

- a) ensure it has a thorough understanding [i.e. thorough understanding by AsBo, author's note] of the significant change based on the documentation provided by the proposer;
- b) conduct an assessment of the processes used for managing safety and quality during the design and implementation of the significant change, if those processes are not already certified by a relevant conformity assessment body;
- c) conduct an assessment of the application of those safety and quality processes during the design and implementation of the significant change.

Having completed its assessment in accordance with points (a), (b) and (c), the assessment body shall deliver the safety assessment report provided for in Article 15 and Annex III [to Regulation 402/2013]."

Recommendation for Use No. 1 indicates that the task of the assessment body is *to arrive at the expert judgement on the correctness of the application of the risk management process of the CSM RA and of the suitability or appropriateness of the results from the risk management to permit the system under assessment to fulfil safely the intended objectives.*

In order to perform this task reliably, the assessment body shall, in compliance with Recommendation for Use, in particular:

1. conduct a thorough vertical slice assessment<sup>2</sup> at least on the areas the AsBo considers to be of highest or most critical risks, independently on the proposer's risk classification, as well as on the areas of medium and low risks the AsBo considers necessary in its assessment strategy, in order to:
  - check whether the proposer applies correctly the requirements for every step of the risk management process in Annex I of Regulation 402/2013;

The AsBo has to pay particular attention to:

- the methods the proposer applies for the hazard identification phase and whether the used methods ensure that all reasonably foreseeable hazards are systematically identified for the whole system under assessment, its functions and its interfaces;
- the correct implementation by the proposer of the safety requirements (risk control measures) defined by the risk management,

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<sup>2</sup> The term "vertical slice assessment" refers to a review of the application of the risk management process contained in the Appendix to Annex I to Regulation 402/2013, at least for the areas of highest or most critical risk(s) of the change under assessment. The purpose is to check a representative cross-sectional slice of the results from the risk management and to cover all the steps of the risk management process of Regulation 402/2013.

- including thus when codes of practice are used the independent safety assessment of their correct application;
- check whether the proposer actually applies the safety and quality processes for the design and the implementation of the change;
  - check whether the application of the safety and quality processes is effective and permits the proposer’s risk assessment to identify appropriate risk control measures
  - check the absence of non-compliances, including for the sub-contractors, with:
    - the provisions of the risk management process in Regulation 402/2013;
    - the company (and project) organisation as described in the documentation;
    - the safety or quality processes;
  - detect any other potential problems such as:
    - any issues with respect to the project management and risk management (e.g. insufficient or not enough qualified resources allocated to the risk assessment and risk management activities);
    - weaknesses in the processes and insufficient documentation of the activities actually done;
  - achieve required certainty as to the conclusions of the independent safety assessment.
2. assess that all hazards identified and registered by the proposer in the hazard record are properly managed. This implies to assess that every hazard in the hazard record is:
- assigned to an actor who is in charge of controlling the identified hazard;
  - is controlled to an acceptable level, or;
  - is transferred to another actor with its written agreement (however, under Point 1.1.5 of Annex I to Regulation 402/2013, the proposer must not assign to an actor safety requirements and hazards that go beyond the scope of responsibility and the domain of control of that actor).
3. ensure that the independent safety assessment report and the interpretation of the results from the proposer’s risk management process are correct and cover all steps, and all results, of the risk management process (if the sampling method is applied).
4. gather the evidence and follow up the proposer’s action plan(s). This includes the following:

- the gathering of any relevant evidence of the actual deployment of the strategy set out in the assessment plan;
- the management of any outcomes from the independent safety assessment, including:
  - a proactive and early identification of (potential) issues;
  - a regular reporting of the identified issues to the proposer to enable the proposer to take timely remedial actions;
  - keeping the history of the identified non-compliances or raised issues and tracking them either until they are managed and closed by the proposer to a satisfactory solution or they are documented as open issues in the final safety report;
  - the gathering of evidence from independent safety assessment is likely to be a combination of audits and inspections including document reviews, observations, interviews, organisational and personnel competency checks, safety culture and organisation assessment, sampling and vertical slice analyses, use of checklists, etc. The precise scope and level of detail or size of the selected samples or of the vertical slices for the independent safety assessment depend on the complexity of the risk management activities, complexity or novelty of the technology, safety culture of the proposer, safety criticality and level of risk introduced by the change;
  - It is important that the AsBo promptly reports (e.g. verbally, via telephone, using e-mails, etc.) the identified issues and non-compliances, especially on major concerns, to enable the proposer to take timely any necessary remedial actions. However, in order to foster the mutual recognition, it is important that all issues and non-compliances are formally confirmed afterwards in a written form. The history of all identified issues and non-compliances needs also to be systematically and formally recorded in a history log. Every issue and non-compliance should have a priority assigned and should be tracked down until a proper resolution by the proposer. This provides traceable evidence (i.e. documentary proofs) of a proactive involvement of the AsBo in the identification and the assessment of resolution of problems based on the level of risk associated with the change or on the priority associated with the raised finding. The final independent safety assessment report of the AsBo has to clearly document all issues and non-compliances on which according to Article 15(1) of Regulation 402/2013 the proposer disagrees at the end of the independent safety assessment.

Independent safety assessment conclusions and report:

1. the independent safety assessment report has to comply with Annex III of Regulation 402/2013. It will, thus, include:
  - the definition of the scope;
  - a summary of the independent safety assessment plan and a reference to the complete independent safety assessment plan;
  - all issues and non-compliances on which according to Article 15(1) of Regulation 402/2013 the proposer disagrees at the end of the independent safety assessment, and;
  - the limitations of the independent safety assessment;
2. it must also give a clear statement and the expert judgement on:
  - the correct application or not of the risk management process in Annex I of Regulation 402/2013;
  - the suitability of the results from the risk management for the change under assessment to fulfil its safety requirements;
  - a reference to any safety related application conditions, or exported constraints (if applicable), for the safe use of the system (change).

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