

Warsaw, 20 July 2023

RECOMMENDATION

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

on the content and methodology of preparation of the safety assessment report

Date of issue

20 July 2023, version 1

The Recommendation is addressed to

Assessment bodies

Content of the Recommendation

1. The safety assessment reports must contain the following elements:

- 1.1 In the scope of “ensuring thorough understanding of the significant change based on the documentation provided by the proposer”, the body should include its own (not mechanically copied from the Proposer) description of the change. If the documentation provided by the Proposer needed to be supplemented in order to understand the change, in the safety assessment report the body should indicate what doubts it had and how they were resolved on the basis of the supplemented documentation.
- 1.2 In the scope of “assessment of the processes used for managing safety and quality during the design and implementation of the significant change”:
 - 1.2.1 Regardless of whether the processes used for managing safety and quality during the design and implementation of the significant change were assessed by the assessment body, or if these processes were already certified by the relevant conformity assessment body, the safety assessment report must clearly indicate:
 - the procedures used for implementation of the safety and quality and management processes during the design and implementation of the significant change the Proposer has in place;
 - what these procedures mean for the change risk management process.
 - 1.2.2 If the processes used for managing safety and quality during the design and implementation of the significant change were subject to assessment by the assessment body, the safety assessment report must contain a comprehensive, substantive and detailed assessment of the Proposer’s approach to:
 - identification of hazards,
 - risk analysis and evaluation,
 - determination of safety measures and requirements,
 - demonstration of compliance with safety requirements,
 - transferring and agreeing upon transferred hazards.
- 1.3 In the scope of “assessment of the application of those safety and quality processes during the design and implementation of the significant change”:

1.3.1 The safety assessment report must contain a comprehensive, substantive and detailed assessment of the method of implementation of safety and quality processes during the design and implementation of the significant change (procedures, assessed in compliance with Point 1.2 of this Recommendation), especially in relation to:

- identification of hazards,
- risk analysis and evaluation,
- determination of safety measures and requirements,
- demonstration of compliance with safety requirements,
- transferring and agreeing upon transferred hazards.

1.3.2 The safety assessment report must contain a list of evidence from implementation of safety and quality processes during the design and implementation of the significant change the body obtained from the Proposer and on which it relied in its independent assessment. The report must contain a substantive assessment of the said evidence (in connection with the conclusions of the independent assessment (Point 1.3 of this Recommendation)).

1.3.3 If the assessment body identifies non-compliances in the Proposer's safety and quality management processes, previously certified by the competent conformity assessment body, it should indicate these non-compliances in the safety assessment report as observations and communicate them to the conformity assessment body that certified these processes.

1.4 In the scope of the “conclusions of the independent assessment”:

1.4.1 Detailed assessment of competences of the team members implementing the change risk management process.

1.4.2 All observations and objections of the assessment body that remain to be addressed by the Proposer - in accordance with the Recommendation for Use No. 11 AsBo Cooperation 001NET1108.

1.4.3 All observations and objections of the assessment body that arose in the course of the assessment and were addressed by the Proposer, together with a description of how the Proposer addressed them - in accordance with Recommendation for Use No. 11 AsBo Cooperation 001NET1108.

1.4.4 Substantive assessment of the adequacy of each specific safety measure and requirement for risk control, with justification.

1.4.5 Clear indication and justification of whether, in the body's opinion, the system is capable of meeting the safety requirements.

1.4.6 Clear indication whether the Proposer has demonstrated compliance with all safety requirements necessary to accept the change, for example regarding infrastructure investments: those requirements that must be implemented before obtaining the authorisation for placing in service.

1.4.7 Clear indication at which stage of the change implementation the assessment takes place (acceptance of the change, e.g. at the design stage, at the change implementation stage [before subsystem commissioning], at the commissioning stage).

1.4.8 Indication of assessment methods/techniques used by the body as part of the

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process of independent assessment of adequacy of the risk management process: document review, observations, interviews, checks competences of the proposer's personnel, assessment of the proposer's organisational culture, sampling, checklists, etc. The safety assessment report should describe how these assessment methods have been applied to the process.

2. Methodology of preparation of the safety assessment report

- 2.1 The assessment body should conduct an independent assessment immediately after engagement by the Proposer. It must establish a project schedule with the Proposer and require the Proposer to provide evidence of implementation of the risk management process on a current basis.
 - 2.2 Regardless of the stage of the process at which the body is engaged, the safety assessment report must include information on the date of contracting cooperation in the field of conducting the independent assessment.
 - 2.3 The report must be created on a current basis, in the course of subsequent stages of implementing the change (conducting an independent assessment), and not at the end of the process. The stages after which subsequent versions of the report must be prepared should result from the independent assessment plan, prepared taking into account information received from the Proposer in this regard. If the change is so uncomplicated or not spread over time that its division into stages would be unreasonable, the assessment body may depart from this rule.
 - 2.4 In the course of the assessment and along with the progress of the change implementation process, subsequent versions of the report must be created until a version is prepared that confirms compliance with all safety requirements that should be implemented at the change acceptance stage (including but not limited to obtaining the authorisation).
 - 2.5 Assessment bodies must prepare safety assessment reports iteratively - subsequent versions of safety assessment reports should be presented to the Proposer during the assessment. These versions must contain all the necessary elements required by the PN-EN 17020 standard Conformity assessment – Requirements for the operation of various types of bodies performing inspection, Regulation 402/2013, relevant AsBo Cooperation RFUs (e.g. AsBo Recommendation For Use No. 02), DAK-08 document.
 - 2.6 The safety assessment report, concluding the independent assessment process, should be submitted to the Proposer after assessing the evidence of compliance with all safety requirements, compliance with which must be demonstrated before acceptance of the change (in accordance with the stage at which the acceptance takes place).
 - 2.7 Failure to demonstrate compliance with the requirements referred to in Point 2.6 of this Recommendation should be clearly indicated in the report as non-compliance.
 - 2.8 The fact of engagement of the assessment body to assess the process after the change has been implemented should be clearly indicated in the report as a non-compliance. Removal of this type of non-compliance should consist in taking measures by the Proposer to mitigate the risk of its occurrence in the future. The assessment body must be informed about the method of removing non-compliances.
- 3.** All actions taken by the Proposer as a result of requests from UTK after the safety assessment report ending the independent assessment process is issued must be assessed by the assessment body and the conclusions of this assessment must be

included in the next version of the report. It is recommended that assessment bodies, as far as possible, use the template of the safety assessment report provided for in the Clarification note Requirements capture ERA1209/146 V1.2, also in assessment processes that do not relate to the determination of applicable requirements, in accordance with Article 13 of Regulation 545/20181.

Related regulations

Article 6(1) and (2); Article 15(1); Point 1.1.7, Point 3.3, Point 5 of Annex I; Annex III to Regulation 402/2013².

Issue description

The independent safety assessment is a key element of the change risk management process under Regulation 402/2013. Feedback from a professional, competent body allows for more effective hazard management and provides a better basis for taking responsibility for safety. This may contribute to the improvement of quality management in the Proposer's organisation. It also allows addressing non-compliances in change risk management before the documentation of this process is submitted for assessment by the President of UTK.

These benefits will only materialize if assessment bodies perform their tasks to a high, uniform level of quality. The requirements for conducting an independent safety assessment are specified primarily in Recommendation for Use No. 1 ASBO Cooperation 001NET1108 Version 1.1.

This Recommendation supplements Recommendation for Use No. 1 ASBO Cooperation 001NET1108 Version 1.1, indicating how the entity should document the course of the independent assessment in the safety assessment report. This way, all stakeholders (e.g. the proposer, \Polish Center for Accreditation, President of UTK) will be convinced that the body has performed its work in a way that ensures achievement of added value from an independent assessment.

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¹ Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council (O.J. EU L 90, 06.04.2018, pp. 66-104).

² <https://www.utk.gov.pl/download/1/78394/Listakontrolnadotstosowaniarozporzadzenia4022013.xlsx>
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