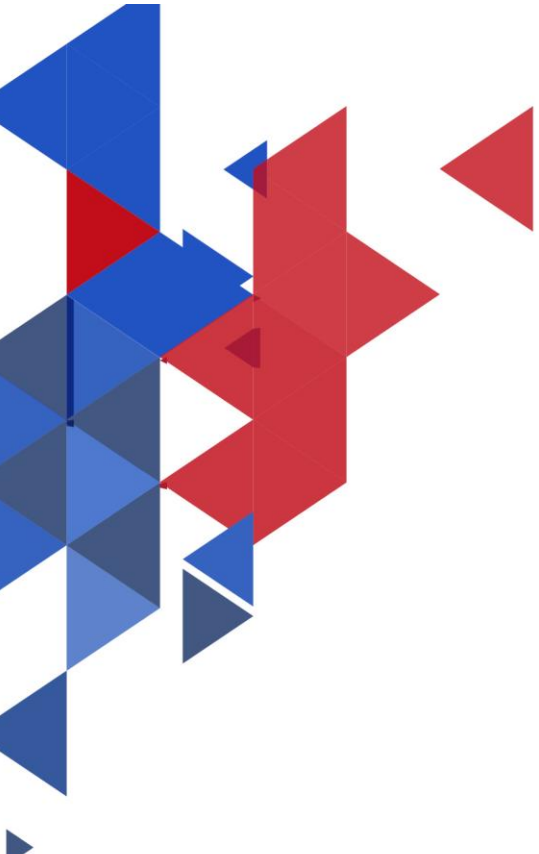




URZĄD
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Action plan for improvement of the approach to risk- based safety management





OUR MISSION

Creating safe and competitive conditions for providing railway transport services.

OUR VISION

A modern and open office that cares about high standards of service on the rail transport market

Warsaw 2021

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1. Acquisition of safety change information to verify the end-to-end application of the change assessment process

Prior to the inspection of railway undertakings and managers in the scope of risk assessment procedures and change risk management, UTK inspectors conducting the inspection will obtain information about changes that have been introduced in the inspected entity. These changes will be determined at least based on the following sources of information:

- information on the commencement of transport under changed conditions regarding: type and scope of activity, significant changes in the occupational category of employees or types of vehicles used by carriers (obtained pursuant to Article 18bd of the Act on Railway Transport);
- information on renewals and upgradings that do not require a new authorization to operate the subsystem of fixed installations (obtained on the basis of Article 25k of the Act on Railway Transport and on the basis of Railway eSafety);
- information from eSEPE regarding the commencement of operations by the carrier on the new line;
- information from the EVR about the change of the keeper/owner, which indicates the acquisition of a new type of rolling stock;
- press releases on purchases of new rolling stock, introduction of innovative solutions, changes in organization (transformations of companies, mergers and acquisitions),
- safety complaints and reports.

This information will then be confronted with a list of change assessments which the controller will be requested to submit.

2. Use of a uniform change assessment checklist

In all cases where documents from the change assessment are submitted to UTK, they will be subject to assessment according to the attached checklist. This applies to documentation obtained:

- as part of control activities,
- in cases arising from complaints that are not conducted in the course of control activities,
- as part of notifications on the commencement of transport under changed conditions regarding: type and scope of activity, significant changes in the occupational category of employees or types of vehicles used by carriers, pursuant to Article 18bd of the Act on Railway Transport;

The checklist contains open questions that facilitate the verification of the correctness of the change assessment and standardize the approach to assessment.

If, on the basis of ancillary questions, an inspector or an employee of UTK's safety department comes to the conclusion that the process has not been properly implemented (e.g. the criterion for evaluating the significance of the change has not been properly analysed), irregularities will be found consisting in:

- breach of Article 17(1ba)(1) of the Act on Railway Transport in connection with Article 5(1) and Article 3(11) of Regulation 402/2013 in relation to carriers and managers,
- breach of Article 5(1) and Article 2(11) of Regulation 402/2013 in relation to manufacturers and ECMs

and a request will be sent to the given entity to remove irregularities by re-evaluating the significance of the change.

The checklist should also be used by all entities obliged to apply Regulation 402/2013 to improve the quality of change risk management.

3. Broader acquisition of change assessment documentation

Under Article 18bd(1) and (2) of the Act on Railway Transport, the railway undertaking notifies the President of UTK of:

- commencement of transport under changed conditions regarding the type and scope of activity;
- significant changes in the occupational category of employees or types of vehicles used by carriers.

According to Article 16 of Regulation 545/2018, the entity managing the changes that do not violate the basic design characteristics introduced to the approved vehicle is not the holder of the vehicle type authorisation, e.g. notifies the authorizing entity of the changes.

As part of these obligations, the entities notifying the President of UTK will be required to provide documentation on the assessment of the change. This will enable the President of UTK to supervise more extensively the correctness of the assessment.

In the event of providing information on the commencement of operation of a new railway vehicle type, the railway undertaking should also be obliged to indicate whether it has updated its hazard record with respect to those hazards whose management has been transferred to it by the vehicle manufacturer (this concerns hazards that have been identified by the manufacturer but in relation to which safety measures can only be implemented by the user).

4. Enforcing a risk-based approach in all safety interventions undertaken by the President of UTK

Written statements of the President of UTK regarding safety will be prepared according to the same template in which the following will be indicated:

- identified hazards (whether hazards have been identified resulting from the source to which the safety report relates);
- the risk acceptance method used for these hazards;
- safety measures applied for these hazards;
- whether the effectiveness of the indicated safety measures is monitored using indicators in accordance with Regulation 1078/2012 (for hazards identified for monitoring in the monitoring plan referred to in point 2 of Annex I to Regulation 1078/2012).

- safety requirements (i.e. safety measures that will serve to supervise the risk of identified hazards).

Safety measures mean a set of actions either reducing the frequency of occurrence of a hazard or mitigating its consequences in order to achieve and/or maintain an acceptable level of risk. A safety measure may be specific provisions in national, EU or internal regulations of the manager or carrier, specific provisions in DSU, specific training activities, carrying out acceptances of construction investments, etc.

Safety requirements mean the safety characteristics (qualitative or quantitative) of a system and its operation (including operational rules) and maintenance necessary in order to meet legal or company safety targets. Safety requirements may include: obtaining environmental decisions, meeting the SILx safety integrity level by a technical component, obtaining an EC verification certificate, obtaining a marketing/operation authorisation, meeting the requirements of a specific TSI, etc.

5. Verification of safe integration in the technical dimension at the stage of issuing the authorisation of the placing in service for the subsystems of fixed installations

According to Article 25e(2) of the Act on Railway Transport in the wording applicable from 28 July 2021, the application for the authorisation of the placing in service for the subsystem should be accompanied by, inter alia, documents confirming its safe integration stated based on, e.g., CSM-RA.

In Points 1.1 and 1.4, the EUAR Clarification Note on Safe Integration (ERA 1209/063 V.1.0) stipulates that:

"(...) In practice, safe integration is an inherent part of a systematic risk assessment and risk management process, also within every structural sub-system. The concept of "safe integration" has thus a broader meaning and goes beyond the single check of the technical compatibility, or correct technical interfacing, between several sub-systems brought together. Safe integration applies also at different levels and to the entire life cycle of the design, operation, maintenance and disposal/decommissioning of the railway system and of its components.

"(...) whenever a new element is introduced into a system, or an existing element is modified, regardless of the significance of that change, the safe integration and the risk assessment and risk management must always be performed. They have to ensure that:

- (a) the new or modified element is technically compatible, and thus correctly interfaces, with the other parts of the system into which it is introduced;*
- (b) the new or modified element is safely designed and fulfils all the intended functional and technical objectives;*
- (c) where applicable, the impacts of human and organisational aspects on the operation and maintenance of that element and on the system are assessed and properly addressed;*
- (d) the introduction of that new or modified element into its physical, functional, environmental, operational, and maintenance context does not have unintended,*

adverse and unacceptable effects on the safety of the resulting system into which it is being incorporated.

In a situation where the assessment of the significance of the change, submitted together with the application for the authorization of the placing in service, is assessed on the basis of the checklist as incorrect, the proposer will be requested to submit explanations by presenting a new assessment of the significance of the change. If the assessment of the significance of the change submitted by the proposer is not assessed positively based on the checklist, the proposer will be informed that the condition for demonstrating safe integration has not been met which may result in refusal to issue the authorisation of the placing in service.

UTK will expect the proposer to demonstrate safe integration of the change introduced to the railway system, regardless of the results of its significance assessment.

- if the change has been assessed as a significant change, the proposer, in the procedure for issuing the authorisation of the placing in service for the subsystem of fixed installations (subsystem manufacturer, including the designer, contractor of construction works, etc.), will be required to submit, in addition to the documentation of the change assessment, documentation of risk assessment and safety assessment report.
- if the change has been assessed as a not significant change, the proposer, in the procedure for issuing the authorisation of the placing in service for the subsystem of fixed installations (subsystem manufacturer, including the designer, contractor of construction works, etc.), will be required to submit, in addition to the change assessment documentation, information on risk management a given change at least through presentation of the list of hazards regarding the given change, adopted safety measures for each identified hazard, adopted risk acceptability assessment methodology for each identified hazard (FMEA, as specified in the annex to RAMS, other) and its results (final risk level for each identified hazard after implementation of safety measures).

In the case of failure to submit evidence demonstrating safe integration, the proposer will be informed that the condition for demonstrating safe integration has not been met which may result in refusal to issue an authorisation for placing in service.

6. Verification of shared risk management

After receiving information from railway undertakings about the placement of a new type of railway vehicle into service and after issue of the authorisation of the placing in service for the structural subsystem of fixed installations, the railway undertaking and the manager, respectively, will be subject to verification as to whether their hazard record should be supplemented with hazards whose management has been transferred to the user by the manufacturer. This verification will take place, inter alia, as part of control activities.

7. Organization of trainings and workshops in risk management

The Office will organise permanent workshops on risk management and monitoring under Regulation 1078/2012 as part of the Railway Safety Academy. The aim of the workshop will be to exchange experiences, coordinate and draw conclusions on the application of

Regulations 402/2013 and 1078/2012. Then, each year, these conclusions will be included in the rail traffic safety report and in the safety report submitted to the European Union Agency for Railways.

8. Safety Culture competition

Proactive safety management in a risk-based approach is the foundation of the safety culture. The activities undertaken by UTK under the project "Safety culture in rail transport" should contribute to the promotion of effective risk management.

As part of the "Safety culture in rail transport competition", a module will be organised to distinguish entities that approach the risk management process most reliably.

Schedule No. 1
Change Assessment
Correctness Checklist



9. Change Assessment Correctness Checklist

9.1. Initial system definition

✓

Has it been determined what, when and how will be covered by the change, what the change consists in, what its meaning and purpose are, and what the consequences of its introduction to the railway system are?	
Has the scope of the change been taken into account: all subsystems (structural, functional), organizational changes?	

9.2. Impact on safety

✓

Does the analysis show how the change will affect safety?	
If it is indicated that the change has no impact on safety, has it been justified?	
Is the conclusion of no impact on safety valid (does the change really have no impact on safety)?	

9.3. Nature of the change

Technical changes are changes to the structural subsystem or subsystems (e.g. in the case of multi-sector upgrading or renewal of a railway line), such as upgrading of rolling stock or re-development of stations. Technical changes should also be reviewed to determine whether they introduce changes to the operation of the subsystem or subsystems under consideration.

Operational changes are changes in the operation of the railway system, including but not limited to changes in the operation of structural subsystems.

Operational changes are often the result of technical changes to the subsystem. In practice, technical changes are often made to deliver a desired operational change. In such cases, the technical change and its impact on:

- *subsystem functioning,*
- *broader railway system, or*
- *principles of railway functioning,*

must be analysed and assessed collectively.



Has it been clearly stated whether the change is of a technical, operational or organizational nature (but affecting the operational or maintenance processes)?	
Is the conclusion on the nature of the change correct?	
If the change is defined as a technical change only, does it really have no operational impact?	

9.4. Change significance assessment criteria

The proposer is responsible for determination of the weight to be assigned to each of the criteria in the context of the assessed change.

9.5. 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

A credible worst-case scenario in the event of a technical system failure may be, for example, a device failure, a defect/inoperability of the rolling stock, an incident, an accident, a serious accident, and the safety barriers existing outside the assessed technical system will be, for example, rolling stock maintenance levels, operational instructions (e.g. infrastructure managers) audits, inspections, training, periodic instructions, construction supervision, social campaigns, educational activities, operational activities of uniformed services, video monitoring, weather conditions supervision, etc.

In the case of an operational or organizational change, the effect of a system failure should also be understood as, for example, a potential inoperability of the rolling stock due to poor maintenance or a railway event resulting, for example, from lack of information flow, lack of training for new employees, lack of appropriate equipment for the changed or upgraded workplace, etc. We consider an organizational change only in the context of its impact on the operational or maintenance processes functioning in the given enterprise, the disruption of which in the worst credible scenario may lead to a collision or derailment of rolling stock, death or disability of passengers or bystanders, fires, etc.



Does the analysis of the assessment criterion clearly show the relationship between the system failure and its consequences?	
Does the analysis of the assessment criterion show what the security barriers outside the system under assessment are (the inspector should determine what security barriers outside the system under assessment have been applied by the applicant in order to determine the severity of the effect assumed by the applicant)?	
Have threats been entered incorrectly as a result of a system failure?	

9.6. 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

A novelty may be a technical, organizational or operational solution introduced for the first time to the railway system on a national scale as well as a solution already functioning in this system, but introduced for the first time by the given entity or its specific part.

✓

Does the change involve introduction of a new technology, a new, previously unused product?	
Does the change involve previously unused operational solutions?	
Has novelty been considered in relation to the environment (including users) in which the change is to be implemented?	
Has uncertainty regarding the intended purpose or operation of the system after the change been analysed?	

9.7. Complexity of the change

The assessment of the complexity of the change should take into account the number of components to be analysed (e.g. the number of structural subsystems or components and their interconnections, including the degree of complexity of these links, taking into account, for example, the complexity of maintenance processes; the number of organizational entities affected by the implemented system change; interdependencies between the entities affected by the change, including contractual arrangements that are needed for the implementation of the change, etc.) and the impact of third parties on the implementation of the introduced change.

The basic issue taken into account when assessing the complexity of the change is the number of structural and operational subsystems affected by the change, considered in the context of the uncertainty of their mutual behaviour after the change is introduced, with particular emphasis on the human factor.

✓

Has the scale of differentiation of components and the relationships between them been taken into account?	
Does the change affect more than one subsystem (both structural and functional)?	
Does the change involve a complex technical solution?	
Does the change involve technical issues?	
Can the applied technical solution cause new hazards?	
Does the change require a new staff category?	
Has the complexity resulting from the high degree of complexity of the investment process been taken into account, e.g. the assessment of the change concerned the implementation of an investment consisting in the upgrading of a railway line requiring the involvement of a large number of subcontractors and co-operators by the proposer (general contractor)?	

9.8. Monitoring: the inability to monitor the implemented change throughout the system life-cycle and intervene appropriately



Have the monitoring processes adopted in the SMS/MMS been taken into account in terms of their reference to the novelty and complexity of the introduced change (only for entities obliged to have an SMS/MMS)?	
Have the possibilities of responding to undesirable operation of the system after the change been analysed?	
Has it been analysed whether it is possible and feasible to put in place a monitoring system that gives early warnings to allow for effective intervention to prevent or mitigate any hazard arising from the change?	
Have the competencies of persons/organizational units responsible for monitoring the change been analysed?	
Are there operational procedures to monitor the system after the change?	
Have planned audits and controls, safety management plans and strategies been reviewed?	
Have technical and personnel resources with appropriate competencies necessary to monitor the introduced change and undertake interventions (e.g. repairs) been analysed?	
Does the analysis actually cover the entire system life cycle, i.e. is the proposer evaluating the monitoring criterion competent to state that monitoring the system after the change is possible "throughout the entire system life cycle", if part of this system life cycle goes beyond the proposer's control domain?	

9.9. Reversibility: the inability to revert to the system before the change



Has the scale of actions necessary to revert to the system before the change been analysed?	
Has the technical and financial rationality of possible revering to the system before the change been taken into account?	
In the event of a technical change, have the operational difficulties that reverting to the system before the change would cause been analysed?	
Can the change be reverted quickly enough to reduce the risk associated with unforeseen hazards that materialised as a result of the change?	

9.10. **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**

When assessing the analysis of this criterion, it is necessary to do some research on the basis of reports on the application of Regulation 402/2013 sent to the President of UTK, on the basis of a list of not significant changes obtained from the controlled company, press releases, information published on the company's website.

When evaluating several consecutive (not significant) changes together, there is no need to consider a combination of all types of changes since the last safety acceptance. It is only necessary to take into account safety-related changes that contribute to the creation of the same hazard in risk analyses.



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