



AN APPROACH TO THE LEGAL REQUIREMENTS REGARDING RAILWAY TRANSPORT SAFETY MONITORING IN THE EUROPEAN UNION

Marek SITARZ[#], Katarzyna CHRUZIK^{*}

Dept of Transport and Computer Science, WSB University, Poland

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Abstract. The targeted liberalisation of the European Union railway market in 1998 could have led to a decrease in the safety of rail transport. To prevent this, the European Commission developed and implemented new requirements in this area without explicitly deciding on the methods and tools to be used for their implementation. Entities operating in the market faced a new challenge, the development of a systems model approach to safety management. Only a correctly designed process model, along with the appropriate tools for monitoring and managing risk, allows the level of safety to be maintained at current levels or improved. As part of the research, solutions were developed for a systems approach to safety management in railway transport and the risk management and maintenance monitoring of railway vehicles. Safety is an essential criterion for assessing the functioning of a railway system, it determines its efficiency as well as – in a widely understood sense – the quality of its transport services. This paper describes the legal requirements and practical methods of implementation arising from the issue of Directive 2004/49/EC as it concerns the monitoring of railway safety (Chruzik *et al.* 2014). The directive enforces the gradual introduction of Common Safety Targets (CST) and Common Safety Methods (CSM) to maintain (or increase) the existing high safety levels after the opening up (liberalisation) of the rail market. The introduction of CST and CSM necessitates the development of methods for the evaluation of the level of safety and activity of operators, both at the level of the Member States and also at the level of the European Union. The paper describes the practical solutions developed for railway operators as part of the implementation of maintenance management systems (Sitarz *et al.* 2013; Chruzik *et al.* 2014).

Keywords: railway transport, reliability, analysis, vehicle, transport management.

1. Common safety assessment methods in railway transport

The European Railway Agency was established in order to develop the tools required for further harmonisation and (without indicating specific solutions) for Common Safety Targets (CST), Common Safety Methods (CSM) and Common Safety Indicators (CSI), as well as to monitor the development of railway safety in the Community (directly by the National Safety Authorities – NSAs).

The common safety requirements condition the ways of assessing safety levels and the achievement of safety requirements, as well as compliance with other safety requirements. This is accomplished by developing and defining CSM with respect to:

- quantification methods and risk assessment;
- methods for assessing conformity with the requirements included in safety certificates and in documents confirming safety authorisations;

– verification method, as long as they are not covered by Technical Specifications for Interoperability (TSI), whether the structural subsystems of the Trans-European Network of high-speed and conventional railways are operated and maintained in accordance with the relevant essential requirements.

In practice, railway operators and national safety authorities create solutions based on legal requirements regarding the issue of the safety certificates/authorisations (NSA), ongoing safety monitoring (operators), and the ongoing supervision of the functioning of operators (NSA) – Figure 1.

During the research work described in the article, a common method of risk management was developed for rail operators, infrastructure managers and entities in charge of maintenance. In addition, optimal indicators

*Corresponding author. E-mail: katarzyna.chruzik@gmail.com

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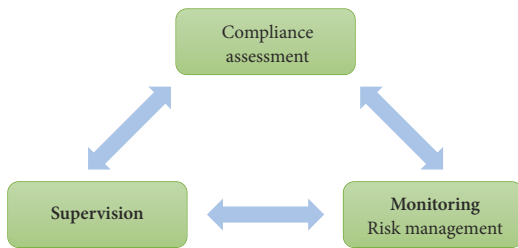


Figure 1. Model of the utilisation of common safety assessment methods in railway transport according to the Commission Regulation (EU) No 1078/2012 (EU 2012b)

for monitoring the maintenance of railway vehicles were determined using the principles of good practice under standard PN-EN 50126:2002.

The first CSM package, covering methods of risk valuation and the assessment of significant changes to a railway system was adopted by the Commission in 2009 (EU 2009). This package had already been replaced by a Commission Implementing Regulation (EU) No 402/2013 published in 2013 (EU 2013). The second CSM package including the remaining methods described in paragraph 3 of the Directive 2004/49/EC (EU 2004) was adopted in 2010 for methods of assessing compliance with the requirements of safety certificates and documents confirming the safety authorisation (EU 2010a, 2010b), and in 2012 for methods of checking whether the structural subsystems of the Trans-European Network of high speed and conventional railways are operated and maintained in accordance with the relevant basic requirements – supervision and monitoring (EU 2012a, 2012b).

2. A process model for monitoring safety

Commission Regulation (EU) No 1078/2012 (EU 2012b) on the common safety assessment method related to monitoring is the current regulation regarding CSM. It stipulates techniques to enable railway operators to obtain verification during the assessment of the implementation of safety management systems. It is to be applied by railway undertakings and infrastructure managers after receiving a safety certificate or safety authorisation as well as by entities responsible for maintenance (EU 2011). Its implementation ensures the effective safety management of a railway system during its operation, maintenance, and its improvement where necessary and possible. It should also ensure the early identification of cases of non-compliance in the application of a management system, which could result in accidents, incidents, accident precursors or other dangerous events. It requires both railway undertakings and infrastructure managers to monitor the correctness of their application, and the results obtained from, solutions developed within the framework of their own safety management system in order to ensure the safe operation of specific networks (Sitarz *et al.* 2013; Chruzik *et al.* 2014; Kinney, Wiruth 1976; Kontovas, Psaraffis 2009; Li *et al.* 2008; PMI 2013; Luxhøj 2003).

Monitoring is to be understood as solutions introduced by railway undertakings, infrastructure managers, or entities responsible for maintenance in order to control the correct application and effectiveness of their own management system.

The regulation is to be applied in the following areas:

- a) controlling the correct application and the effectiveness of all management system processes and procedures, including technical, operational and organisational risk control measures;
- b) controlling the correct application of the management system as a whole and the achievement by this system of the expected results;
- c) determining and implementing the correct preventive or corrective measures, or both kinds of measures, in the event of detecting appropriate cases of non-compliance with the requirements specified in points (a) and (b).

The monitoring process incorporates the following activities:

- defining the strategy, priorities and monitoring plan (plans);
- collecting and analysing information;
- developing an action plan in the event of detecting an unacceptable level of non-compliance with the requirements specified in the management system;
- implementing an action plan, if such a plan has been developed;
- assessing the effectiveness of the measures specified in the action plan, if such a plan was developed.

Moreover, the regulation enforces the implementation of comprehensive safety related information flows. Railway undertakings, infrastructure managers and entities responsible for maintenance, together with their contractors, are to ensure a mutual exchange of all relevant safety related information, resulting from the implementation of the monitoring process determined in the Annex, by means of contractual arrangements to enable other entities to take on any necessary corrective measures to ensure the continuous safe state of a railway system. The regulation also introduces a reporting requirement.

In practice it specifies more tightly criteria already included in previous legislation by placing emphasis on the timeliness of monitoring, verification of the validity of any agreed actions, and the continuity of the process – Figure 2.

The evaluation of the effectiveness of an action plan should include the following tasks:

- verification of the correctness of the implementation of the action plan and its completion according to a project plan;
- verification as to whether the expected result has been achieved;
- ensuring that the initial conditions have not changed in the meantime, and whether the risk control measures specified in the action plan are still appropriate in the current circumstances;
- examining whether it may be necessary to implement other risk control measures.

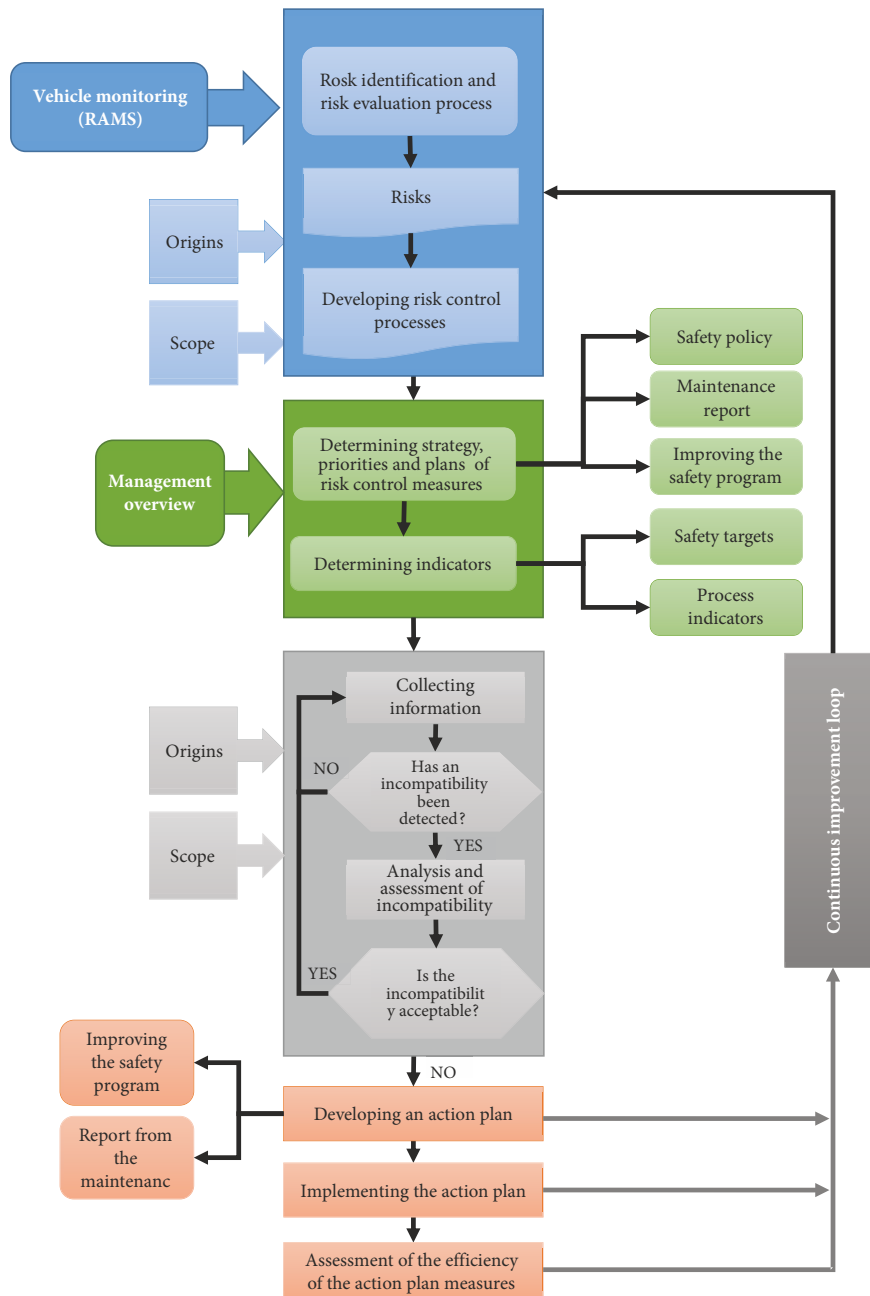


Figure 2. A practical model of monitoring in a railway transport management system according to the Commission Regulation (EU) No 1078/2012 (EU 2012b)

As can be seen in Figure 2 the proposed safety monitoring model is based on two implemented tools – risk management and the monitoring of railway vehicles.

3. Monitoring of railway vehicles

In an attempt to improve the supervision of railway vehicles, railway operators have searched for off-the-shelf solutions. Unfortunately, in this respect, there is a dearth of relevant material. In order to fill this gap we have devised a complete set of tools for rolling stock monitoring based on the standard PN-EN 50126:2002. The standard PN-EN 50126:2002 covers the definition of Reliability, Availability,

Maintainability and Safety (RAMS) with respect to a railway vehicle’s RAMS (as well as the mutual interaction of these characteristics), which enables its effective supervision. A methodology has also been specified for the effective management and control all objectives and requirements of the standard by applying the RAMS procedure based on the life cycle of the system (PN-EN 50126:2002).

Safety and availability are linked with each other in such a way, that the weakening of one may lead to a conflict between the safety and availability requirements, which may prevent a reliable system from being achieved. The safety targets regarding operation and availability can only be reached by meeting all the requirements. Safety is

the element that characterises the resistance of a railway system to intentional actions such as vandalism and irrational human behaviour (PN-EN 50126:2002). The technical concepts of availability are based on knowledge of:

- regarding reliability:
 - all the possible causes of system failure;
 - the probability of every failure or the frequency with which a particular failure occurs;
 - the impact on other system functions.
- with respect to maintenance:
 - the time for planned maintenance activities to be completed;
 - the time taken to detect, identify and locate faults;
 - the time needed to restore a damaged system to use (emergency repair – unscheduled).
- operation and maintenance in the following:
 - all possible modes of operation and required maintenance through the life cycle of the system;
 - human factors (PN-EN 50126:2002).

RAMS analysis is usually understood as a set of activities, which encompass various disciplines, ultimately related to: the investigation of failures, maintenance activities and system availability. Its main application is to predict – at each stage of the system’s life cycle – the expected failure rate, or other criteria such as: mean time between failures, mean time to restore to use, availability, probability of failure, etc. These parameters are then used to predict the life cycle costs of a given element (as these costs are associated with downtime at work and maintenance activities) (PN-EN 50126:2002).

The standard PN-EN 50126:2002 can be applied to a complete railway system or its subsystems, while the scope of safety analysis will depend on the scope of the given subsystem that is being analysed. It is also necessary to consider the level of detail in the risk analysis that is being carried out, which should be directly proportional to the risk (Aven 1992; Greenberg, Cramer 1991). The risk assessment process should reference both quantitative and qualitative methods (Ale 2002). Qualitative risk assessment can be applied to the majority of dangers, while quantitative evaluation is related to high potential dangers, which may lead to serious or catastrophic consequences (Greenberg, Cramer 1991; HSE 1998; Haight 1986).

A quantitative test could also be justified for new systems, where there is insufficient operational experience.

The standard PN-EN 50126:2002 describes the method and possibility of calculating all the indicators, unfortunately in the majority of cases it does = specific examples, but only possible data for further use.

One of the stages of the study was to identify the necessary indicators based on the annexes included in the standard PN-EN 50126:2002 for which data collection is realistic. The next step is to select the necessary parameters required by a given undertaking. A reduction of the number of necessary indicators takes place during the identification of the area of the product life cycle, which forms the current scope of the exercise, during the definition of the product itself, and in consequence of the availability of data.

In order to perform a RAMS analysis and calculate each of the indicators, which in the case below relate only to operation/usage, and not the entire life cycle – it is necessary to possess data on the vehicle and its operation.

These include: wagon type, type of activity along with its description, damage code, the damaged system, whether the system was a critical one, the estimated effect of the damage, the maintenance workshop performing the repair, withdrawal from service date, start of repair date, completion of repair date, return to service date, mileage. The information is selected as required depending on the variables in the formula for a given indicator.

Below are the forms developed in the Railway Transport Team (Tables 1–4). These forms have been developed in line with the standard for specific domains of indicators.

Factor analysis of the sample variables identified the most significant RAMS indicators, which accounted for nearly 90% of the total variance of the sample. If such a method is adopted, only five indicators need to be used for monitoring to be considered effective. They are:

- $MTTR_{Common}$ – mean time to repair;
- $MTTR_{NP}$ – mean time to planned maintenance;
- $FPMK$ – number of faults per million kilometres;
- $MTBSF$ – mean time between systemic failures;
- A_O – operational availability.

Table 1. RAMS indicators – reliability

Indicators		Data required	Calculation method
FPMK	Number of failures per million kilometres	n – number of failures; D_T – number of kilometres covered in the analysed period	$FPMK = \frac{n \cdot 1000000}{D_T} [-]$
MTBF	Mean time between the failure (mean time without a failure) (for renewable/serviceable systems)	n – number of failures; D_{A_i} – date of the damage occurring, $i = 1, 2, \dots$	$MTBF = \frac{\sum_{i=1}^{n-1} (D_{A_{i+1}} - D_{A_i})}{n-1} [\text{days}]$
MDBF	Mean distance between the failure (the number of kilometres without a failure) (for renewable/serviceable systems)	n – number of failures; P_{A_i} – mileage at subsequent failures, $i = 1, 2, \dots$	$MDBF = \frac{\sum_{i=1}^{n-1} (P_{A_{i+1}} - P_{A_i})}{n-1} [\text{km}]$

Table 2. RAMS indicators – availability

Indicators		Calculation method
A_O	Operational availability	$A_O = 1 - ((1 - A_p) + (1 - A_N))$
A_p	Availability due to scheduled maintenance	$A_p = \frac{MTBM}{MTBM + MTTR} [\%]$
A_N	Availability due to non-scheduled maintenance	$A_N = \frac{MTBF}{MTBF + MTTR} [\%]$
F_A	Rolling stock availability	$F_A = \frac{\text{available rolling stock}}{\text{total rolling stock}}$

Table 3. RAMS indicators – maintainability

Indicators		Data required	Calculation method
MTTR	Mean time to return to service	n – total number of maintenance activities; N_{P_i} – date of withdrawal from service, $i = 1, 2, \dots$; N_{Z_i} – date of returning to service, $i = 1, 2, \dots$	$MTTR = \frac{\sum_{i=1}^n (N_{Z_i} - N_{P_i})}{n}$ [days]
MTBM	Mean time between scheduled maintenance activities	n – number of scheduled maintenance activities; U_{P_i} – begin date of activity, $i = 1, 2, \dots$; $U_{Z_{i-1}}$ – completion date of activity, $i = 1, 2, \dots$	$MTBM = \frac{\sum_{i=1}^{n-1} (U_{P_i} - U_{Z_{i-1}})}{n-1}$ [days]
MDBM	Mean distance between scheduled maintenance activities	n – number of scheduled maintenance activities; P_{U_i} – current mileage at the respective activities, $i = 1, 2, \dots$	$MDBM = \frac{\sum_{i=1}^{n-1} (P_{U_{i+1}} - P_{U_i})}{n-1}$ [km]
MTTM	Mean duration of maintenance related activities	n – number of all maintenance activities; U_{P_i} – begin date of activity, $i = 1, 2, \dots$; U_{Z_i} – completion date of activity, $i = 1, 2, \dots$	$MTTM = \frac{\sum_{i=1}^n (U_{Z_i} - U_{P_i})}{n}$ [days]

Table 4. RAMS indicators – safety

Indicators		Data required	Calculation method
MTBSF	Mean time between systemic failures	n – number of systemic failures; D_{Asys_i} – date of consequent systemic failures, $i = 1, 2, \dots$; Systemic failures relate to: brake systems, wheelsets, coupling devices, tanks and valves of freight wagons for the carriage of dangerous goods	$MTBSF = \frac{\sum_{i=1}^{n-1} (D_{Asys_{i+1}} - D_{Asys_i})}{n-1}$ [days]
MTBHF	Mean time between hazardous failures	n – number of hazardous failures; D_{AF_i} – dates of consequent hazardous failures (that is those the effect of which in the FMEA table exceeds the assumed value), $i = 1, 2, \dots$	$MTBHF = \frac{\sum_{i=1}^{n-1} (D_{AF_{i+1}} - D_{AF_i})}{n-1}$ [days]
H	Degree of risk	T_{AF} – number of hazardous failures (as above); T – analysed period of time/number of years; t – total number of failures	$H_{(t)} = \frac{L_{AF}}{T} [-]$

Since the value of A_O parameters is calculated directly from the values of A_N and A_p , for the purpose of factor analysis the intermediate availability values were replaced by operational availability. In addition, the value of the MTBHF index was also ignored because the sample values of this index were equal to the values of the MTBSF index. Particular attention should be paid to the fact that the above indices represent average values. Values significantly deviating from the calculated average may occur

in a given study population. Unfortunately, the standard method of calculating these indices is not immune to such cases. The use of appropriate data filtering or statistical tests in order to eliminate extreme values may allow for such values to be excluded before they are included in the analysis. However, it is worth considering the root cause of such extreme values and to implement appropriate corrective measures.

4. Methods of risk assessment and evaluation

The first step in the implementation of the requirements with respect to common safety assessment methods was the publication and introduction of Commission Regulation (EC) No 352/2009 on the adoption of the common safety assessment method with respect to risk assessment and valuation (EU 2009).

This regulation established the common safety assessment method with respect to the valuation and assessment of risk (CSM) within the scope of:

- safety management processes applied to the assessment of safety levels and their compliance with safety requirements;
- exchange of safety relevant information between different entities in the railway industry in order to facilitate safety management within the framework of different connections existing in this industry;
- proofs acquired through the application of the safety management process (EU 2013).

CSM with respect to risk valuation and assessment is applicable to all changes to a railway system in a member state; that are considered to be significant. A system refers to every element of a railway system, which is being changed. Such changes can have a technical, operational or organisational character. In the case of organisational changes, only those changes, which may influence operational conditions should be taken into account (EU 2013). The regulation describes also the approach that is to be applied should significant changes be related to structural subsystems, to which Directive 2008/57/EC shall be applicable (EU 2008).

If no suitable national legislation has been reported on the basis of which it can be determined in a given member state whether a given change is significant or not, the railway entity is to assess the potential influence of the change on the safety of a railway system. Should the proposed change not be safety critical there is no need to apply the risk management process.

Should the proposed change have an impact on safety, the applicant is to decide, based on expert judgement, about the significance of the following criteria (Figure 3):

- the effects of system failure: a reliable worst option scenario in the case of a failure of the system being investigated, acknowledging the existence of safety barriers beyond this system;
- the degree of innovation applied when introducing change: this criterion includes innovation concerning both the railway industry as a whole, as well as exclusive to the entities introducing a change;
- the complexity of the change;
- extent of monitoring: difficulties in monitoring the introduced change during the complete life cycle of a system as well as in implementing appropriate interventions;
- the reversibility of the change: any difficulties in returning the system to the state it was in before the before the change has been introduced;
- additionality: assessment of the importance of change taking into account all recent safety related changes to the system under assessment, which were not at the time of their introduction assessed as significant. The applicant shall keep adequate documentation to justify their decision (EU 2013).

The criteria for the assessment and quantification of particular domains depend on the applicant; however, they must be clearly defined at the beginning of a process. In addition, the system being assessed should be clearly defined (its scope, functions and interfaces).

If a change is considered to be significant, the relevant entities are obliged to carry out a risk management process. Risk management refers to the systematic application of policies, procedures and management practises within the framework of tasks related to the analysis, quantification and supervision of risk (EU 2013).

The decision-making process is to be the responsibility of applicants, if any of the following factors apply:

- it is impossible to come up with harmonised thresholds or rules, on the basis of which a decision could be made as to whether a particular change was significant;
- it is impossible to prepare a detailed list of significant changes;

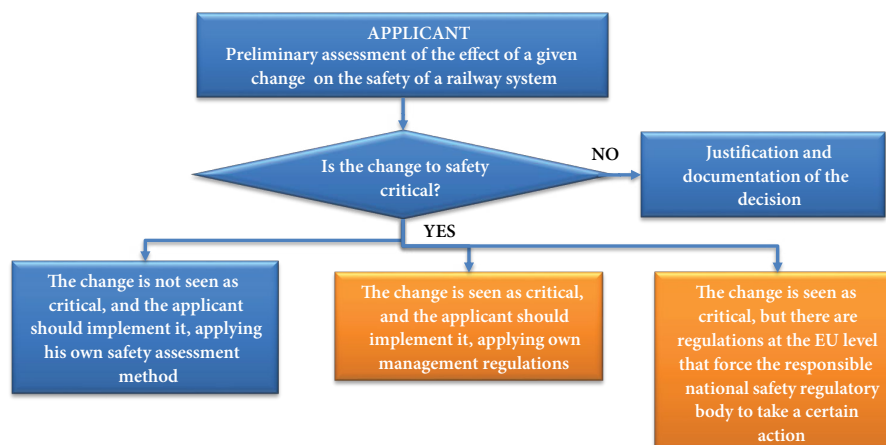


Figure 3. Assessment of the significance of a change according to CSM (EU 2013)

- a decision may not be valid for all the applicants and for all technical, operational, organisational and environmental conditions.

The independent assessment of the correctness of an application of the risk management process (as described in Annex I of the Commission Regulation (EC) No 352/2009 (EU 2009)) and its results is to be performed by an assessment body. In cases where such a body has not already been identified in Community or national legislation, the applicant shall appoint their own assessment body, which may be another organisation or an internal department. An assessment body is to be understood as an independent competent person, organisation, or entity, which undertakes a study in order to assess, based on the available evidence, the ability of a system to meet the safety requirements applicable to it. The assessment body shall provide the applicant with a safety assessment report. The responsibility associated with the work of such a body entails a reassessment of the risk register and risk assessment, and also the risk acceptance principles (EU 2013). Therefore, it has to be performed by entities or persons with the appropriate industry experience.

The principle of risk acceptance refers to the principles, which are applied in order to draw a conclusion as to whether or not the risk associated with the specific threat, or specific threats, can be deemed to be acceptable.

The acceptability of a risk belonging to a system under assessment is evaluated by the application of one or more of the following risk acceptance methods:

- applying codes of practice;
- performing a comparison with similar systems;
- undertaking an explicit risk estimation (EU 2013).

Codes of practice in risk assessment. The applicant is determines, with the assistance of any other involved entities, and based on the requirements listed in the Commission Regulation (EC) No 352/2009 (EU 2009), whether the hazard or hazards are covered by the relevant codes of practice. The codes of practice should at the minimum meet the following requirements:

- be widely recognised in the railway industry – otherwise the code of practice must be justified and should be acceptable to the assessment body;
- be appropriate from the point of view of the supervision over the considered risks in the evaluated system;
- be publicly available to all the entities that want to use them (EU 2013).

If one or more hazards are controlled by the codes of practice that meet the requirements, the risk related to those hazards may be considered to be acceptable. This means that:

- there is no need for a deeper analysis of this risk;
- the application of the codes of practice shall be registered in the hazard record, as a safety requirement for the relevant hazards (EU 2013).

Using a reference system during risk assessment. The applicant determines, with the assistance of any other

involved entities, whether the hazard or hazards have already been taken into account in a similar system, which may be used as a reference system. The reference system must meet the following minimum requirements:

- to have already proven itself in practise as a system displaying an acceptable level of safety and still meet the conditions required for its approval in the member state in which the change is being introduced;
- to have similar functions and interfaces as the system under assessment;
- to be used under similar operational conditions as the system under assessment;
- to be used under similar environmental conditions as the system under assessment.

If the system meets these requirements, it means that in the case of the evaluated system:

- the risk associated with the hazards taken into account by the reference system may be considered to be acceptable;
- the safety requirements for the hazards taken into account by the reference system can be derived from the safety analyses of the main process or the evaluation of the safety records of reference system;
- the safety requirement defined in this way are to be recorded in the register of risks as the safety requirements for the relevant hazards (EU 2013).

If there are differences between the evaluated system and the reference system, the risk assessment should demonstrate that the evaluated system has at least the same level of safety as the reference system. In this case, the risk associated with the hazards covered by the reference system may be considered to be acceptable. If it is impossible to demonstrate the same level of safety as the reference system, additional safety measures with regard to the differences between the systems should be specified, using one of the two other risk acceptance principles (EU 2013).

Estimation and evaluation of explicit risk. In cases where risks are not covered by one of the two risk acceptance methods described above (and this situation will apply to most changes to be analysed) the acceptability of a risk may be proved using estimation and explicit risk assessment. The risks arising from these hazards should be assessed qualitatively or quantitatively, taking into account any existing safety measures. The acceptability of an estimated risk is evaluated using risk acceptance criteria, resulting from the legal requirements laid down in Community legislation, or in notified national rules, or based upon the previously mentioned requirements. Depending on the risk acceptance criteria, the acceptability of a risk may be evaluated individually for each associated hazard, or collectively in relation to the combination of all hazards considered in the assessment of an explicit risk. If the estimated risk is deemed not to be acceptable, it will be necessary to identify and implement additional safety measures to reduce the risk to an acceptable level. If the risk associated with one, or a combination of several hazards, is deemed to be acceptable then the identified safety

measures should be recorded in the register of risks. In cases where hazards arise from failures of technical systems are not covered by codes of practice or the use of a reference system, then the following risk acceptance criterion applies with respect to the design of the technical system. The risk associated with technical systems, where there is credible probability of catastrophic failure as a direct result of a failure of the system to act properly, does not have to be further reduced if the frequency of such incidents is equal to or less than 10^{-9} per hour of operation of the system.

The estimation and evaluation of explicit risk must satisfy the following minimum requirements:

- the methods used for explicit risk estimation are correctly matched to the system under evaluation and its parameters (including all working modes);
- the results are sufficiently accurate to serve as a credible justification for decision making, i.e. slight changes in the initial assumptions or initial conditions shall not cause significantly different results regarding requirements (EU 2013).

Another aspect of risk management is the current risk analysis in railway undertakings resulting from the safety requirements contained in Directive 2004/49/EC (EU 2004) (Figure 4).

The risk management process refers to all processes that affect the main safety management system process (rail transport, railway infrastructure management) or the maintenance management system process (maintenance management) directly or indirectly. It is based on the registers of threats that are created, and updated on an ongoing basis, in an entity. These are verified, expanded or modified with fresh risk estimation and quantification data at certain intervals. This method enables the direct management of threats and precise allocation of resources to deal with unacceptable areas, while at the same time monitoring and communicating risks.

In practice, estimation and explicit risk assessment methods are applied across the whole of the European Union. A proposed risk management model example is shown in Figure 5.

Presented below is a comparison of several methods of explicit risk assessment currently used in the railway industry: checklists; Failure Mode and Effects Analysis (FMEA); Hazard and Operability Study (HAZOP); Committee of Sponsoring Organisations of the Treadway Commission (COSO II); Fault Tree Analysis (FTA). They show that the choice of a method depends on several factors. The first is the size of the process being undertaken (transport, infrastructure management, maintenance). This is coincident with the number of events recorded by the operators. In the absence of adequate data from incidents, accidents, and serious accidents, data methods based on historical data, such as FTA, cannot be used.

Another factor relevant to determining the choice of method is the experience gained in carrying out the process, on which the method (FTA, FMEA, HAZOP or

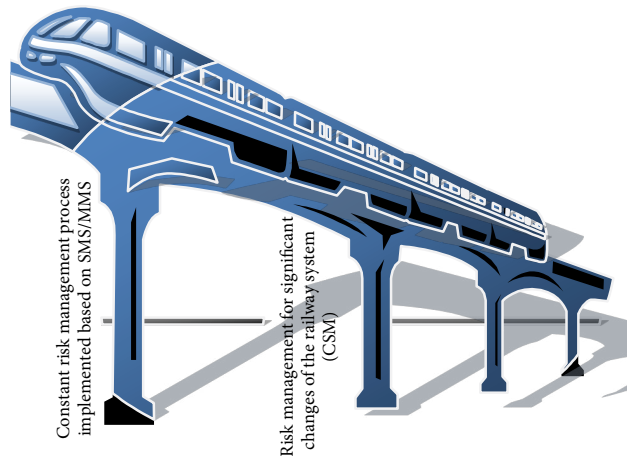


Figure 4. Risk management in a safety/maintenance management system



Figure 5. Risk management model

COSO II) is based. This applies, for example, to new entities entering the railway market, who are also required to submit a risk analysis. Summing up, the recommendations on the methods applied can be presented in Table 5 form.

Analysing the development of risk assessment in the field of transport, safety may be defined as the absence of threats of unacceptable risk (a threat is the actual origin of a railway incident). The origins of threats are created entities in the specified area of the analysis (e.g. physical, chemical, biological, psychophysical, organisational, and personal) whose presence, status, and properties may be the cause (origin) of the formulation of a threat. Risk is the combination (origin) of the probability of activation of the threat in a railway incident leading to consequent damages.

A combination of threat origins can create real threats, which may (but need not) lead to a railway incident. Therefore, the basis for risk management in railway transport is an awareness of threat sources (based on historical data or experience), and thus an awareness of actual threats.

Table 5. Recommendations of methods of analysis used

Analysis method	Kind of entity
FTA	Entity well experienced in the process, possessing a large amount of data on events – the biggest freight and passenger operators, main infrastructure managers
FMEA, HAZOP, COSO II	Entity well experienced in the process – experienced railway operators
Checklist	Entity starting to perform a process in the railway market

This allows the estimation of the identified threats and the referencing of these values to the ranges established at the beginning (acceptable, tolerable, unacceptable). In cases where the risk posed by threats is excessive, it also allows corrective and preventive actions to be introduced to processes, the continuous monitoring of the whole process, as well as communication of the threats to those directly involved in the process (employees) and those receiving its outputs (passengers and bystanders).

As a result of the risk management domains that are present in train operating companies, FMEA is the most commonly used methodology. The FMEA risk assessment methodology comprises the following steps.

Analysis of all the processes involved in the operations of an entity. The objective of this stage is to review all the processes performed by the entity. It is necessary to review the possible risk areas in relation to the processes/activities described in the safety management/maintenance system flow chart (defining areas of possible threats) e.g. the transport process, personnel management, maintenance of rolling stock and technical resources, communication processes, the process of document management, load control processes related to the activities of suppliers, and coordination activities. Details of the review are the basis for the management of risk.

Threat identification. The objective of this stage is to draw up a list of possible threats in an organisation, taking into account mutual threats and also threats arising from the activities of third parties (including social risk) and a preliminary designation of consequences. All identified types of threats are recorded in a threat register.

Risk estimation. The objective of this stage is the quantification of identified risks for the all threats according to a scale of 1...10 for factors that affect risk where:

- *W* – the probability of a hazard occurring (potential hazard) determined in a range from 1 to 10. The probability of an occurrence is more a relative measure than an absolute value. The only way to reduce the ranking value, is to prevent or control the cause of the fault causing the risk by changing the process;
- *Z* – the probability of detecting a threat, determined in a range from 1 to 10, is an assessment (ranking position) associated with the best control tool. De-

tection is a relative assessment of in the context of a specific FMEA. In order to achieve a low score in the ranking table in most cases the planning of the control toolset should be improved;

- *S* – the possible consequences of a railway incident as a result of the propagation of a threat, a value in the range from 1 to 10, is the ranking level assigned to the most serious effect for a specific type of error causing a threat in the railway industry.

The estimated risk associated with a threat is calculated on the basis of the product:

$$R = W \cdot Z \cdot S,$$

where: *W* is the probability of the formulation of a hazard; *Z* is the probability of identifying a hazard; *S* is the consequences of a hazard.

Commission Regulation (EC) No 352/2009 (EU 2009) also describes the supervision process for risk assessments (audits), and the process of transmitting information regarding the implementation of its stipulations. The regulation as a whole entered into force on 1 July 2012.

As early as 2013, Commission Regulation (EC) No 352/2009 (EU 2009) received its first update – Commission Implementing Regulation (EU) No 402/2013 (EU 2013). The reasons for introducing these changes were:

- an analysis carried out by an agency of the general effectiveness of CSM in risk evaluation and assessments, and experience gained so far concerning its use;
- further development of the roles and responsibilities of assessment bodies;
- emerging qualification requirements (from the development of recognition/accreditation programmes) for assessment bodies with respect to their role in CSM, in order to improve transparency and to avoid inconsistencies in its application in Member States, taking into account interfaces with existing EU authorisation or certification procedures in the railway industry;
- modification of risk acceptance criteria, which can be used to assess the acceptability of risk during the estimation and valuation of explicit risk.

The first of these changes amended (to remove any ambiguity) the definition of an applicant as one of the following:

- a railway undertaking or infrastructure manager, that implements risk control measures in accordance with Art. 4 of Directive 2004/49/EC (EU 2004);
- an entity responsible for maintenance, who undertakes activities in accordance with Art. 14a, para. 3 of Directive 2004/49/EC (EU 2004);
- a principal or sub-contractor who requests a notified body to implement the European Commission verification procedure in accordance with Art. 18 paragraph 1 of Directive 2008/57/EC or an entity designated pursuant to Art. 17 paragraph 3 of this Directive (EU 2008);

- an applicant applying for authorisation to commission in service structural subsystems.

The change with respect to the unambiguity of the definition will assist national safety authorities to carry out assessments of the significance of any change being planned by any operators in the railway market.

The revised regulation emphasises the obligation to document decisions regarding changes that do not affect safety as well as insignificant changes. The possibility of carrying out an internal evaluation was also taken into account by clarifying the definition of assessment bodies, at the same time widening the criteria that have to be satisfied by such bodies. An independent and competent internal or external person, organisation or entity, National Safety Authority (NSA), a notified body, or an authority designated in accordance with Art. 17 Directive 2008/57/EC (EU 2008) may act as a assessment body provided that they meet the criteria set out in Annexe II of the Regulation (EU 2013). The assessment body must meet all the requirements of the standard ISO/IEC 17020:2012 with its subsequent amendments. When performing audit work as specified in this standard, the assessment unit uses professional judgement and must meet both the general criteria for competence and independence contained in this standard, as well as the following detailed criteria for competence:

- competence in the field of risk management: knowledge and experience in the field of standard techniques of safety analysis and the relevant standards;
- all the necessary expertise to assess the elements of a railway system that is being affected by the change;
- competence in the proper use of safety and quality management systems or in management systems auditing.

Similarly, as in the case with Art. 28 of Directive 2008/57/EC concerning the notification of notified bodies, the assessing body needs to be accredited or recognised for the particular competence domains related to the railway system, or parts thereof, for which there are substantial safety requirements, including the competence domain related to the operation and maintenance of the railway system (EU 2008). The assessment body must be accredited or recognised for the purposes of assessing the overall consistency of risk management and the safe integration of the system under assessment with the entire railway system. This includes the assessment body's competence with regard to the control of its:

- organisation, i.e. mechanisms necessary to ensure a co-ordinated approach to securing the safety of a system through a uniform understanding and application of risk control measures to subsystems;
- methodology, i.e. evaluation methods and resources used by different interested parties to support safety at both the subsystem and system level; and any
- technical aspects required to assess the relevance and completeness of risk assessment measures and the safety level in relation to the system as a whole.

In connection with the accreditation and recognition of assessment bodies, Commission Implementing Regulation (EU) No 402/2013 (EU 2013) introduced new definitions: certifying body, conformity assessment unit, accreditation, national accreditation body, recognition, and described all these entities and processes.

At the same time, the possibility was introduced of using less restrictive criteria to those included in Annex II of the Commission Implementing Regulation (EU) No 402/2013 (EU 2013) in those cases where the mutual recognition of a significant change is not anticipated, and provisions have been extended with respect to supplying information from the implementation of CSM to the European Railway Agency.

The character interaction with respect to risk management was changed from optional to mandatory. The applicant – in compliance with this regulation – guarantees the management of risk caused by his suppliers and service providers, including subcontractors. For this purpose, by way of contractual agreements, the applicant may require the participation of their suppliers and service providers, including subcontractors, in the risk management process set out in Annex I (EU 2013).

Attention was drawn to the starting point of the process of the assessment of the significance of a change, which should be – at the earliest possible stage of the risk assessment process.

A set of basic elements was defined that must be included in a safety assessment report submitted to the applicant by the assessment body. The applicant is also additionally responsible for determining whether and how the conclusions contained in the safety assessment report should be taken into consideration during the acceptance of a change with safety implications. The applicant should also document and justify his views with respect to that part of the safety assessment report with which they ultimately does not agree.

In accordance with the Commission Implementing Regulation (EU) No 402/2013, a report of the assessment body regarding a safety assessment is to include the following information (EU 2013):

- identification of the assessment body;
- a plan of the independent assessment;
- a definition of the scope of the independent assessment and its limitations;
- results of the independent assessment in particular:
 - detailed information on the activities related to the independent assessment in order to verify compliance with the provisions of this Regulation;
 - any identified non-compliance with the provisions of this Regulation and recommendations of the assessment body.

In practice, the report should include:

- a plan, and the scope, of the evaluation;
- assumptions for the independent assessment;
- a description of the railway system;

- evaluation results (assessment process methodology, evaluation of the significance of change);
- a risk assessment;
- conclusions from the evaluation;
- attachments.

The Commission Implementing Regulation (EU) No 402/2013 also introduces Applicants' Declarations – based on the results of the application of the said regulation and on the report about the safety assessment presented by the assessment body, the applicant submits a written declaration to the effect that all identified hazards and their associated risks are being kept at an acceptable level (EU 2013).

Summing up the validations of the safety assessment methods within the scope of risk quantification and assessment described in the Commission Implementing Regulation (EU) No 402/2013 (EU 2013):

- it is the result of the gradual improvement of CSM in order to ensure the preservation of a high level of safety and its further improvement where it is necessary and possible;
- an independent and competent internal or external person, organisation or entity, NSA, a notified body, or an authority designated in accordance with Art. 17 Directive 2008/57/EC may act as a assessment body (EU 2008), provided that they meet the criteria set out in Annexe II of the Commission Implementing Regulation (EU) No 402/2013 (EU 2013);
- the regulation clarifies the definitions of an applicant;
- introduces accreditations/recognition of the assessment body;
- forces suppliers to take part in the risk management process;
- extends the area of supervision of the NSA with respect to risk valuation and assessment to maintenance systems;
- slightly modifies the risk management and independent assessment processes;
- introduces requirements for the contents of a report by the assessment body regarding safety assessment;
- its entering into force is related with completion time of the project – the scope of assessment of the significance of change must be coordinated with the introduction time of the project.

The Commission Implementing Regulation (EU) No 402/2013 was enter into force on 21 May 2015 (EU 2013).

Conclusions

The tools and criteria related to safety monitoring described in this article allow the entities involved in the supervision and functioning of the railway industry to easily implement the requirements posed by the safety Directive 2004/49/EC (EU 2004). Unfortunately, their development and entry into force as mandatory legal requirements took the European Commission as long as eight years (from the date of publication of the Directive 2004/49/EC to the

publication of the last executive act). Those years were a period of random interpretation, misinterpretation or total negation of certain system requirements stipulated in the legal requirements. The present legal situation fully allows the further development of policies and procedures that are currently mandatory in railway industry management systems. It gives clear guidance on the implementation and supervision of the tools described in this article.

The article presents research work on the development of a methodology to implement the requirements of Commission Regulation (EU) No 445/2011 with respect to the monitoring of the condition of railway vehicles and the use of the results of such monitoring for continuous improvement (EU 2011). The chosen methodology allows the most relevant indicators to be easily identified, thereby reducing the number of indicators that have to be tracked. The methods described herein enable persons involved in the management of safety in individual enterprises to broaden their knowledge and awareness of safety states. This is facilitated through the use of a uniform risk assessment tool that improves the identification and assessment of common threats between individual elements and allows their effects to be mitigated, or avoided altogether, when incidents occur. Another aspect of safety improvement is the analysis of historical operational data for rolling stock. This not only provides a basis for enhancing the operational process of a specific vehicle, but also – after the development of appropriate solutions with manufacturers – for improving new construction.

Currently, the largest development process of risk assessment is to be expected to be in the area of joint risk. At the moment, in the EU, the majority of entities independently identify such threats.

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