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## **THE MOVE FROM A RULE BASED TO RISK ORIENTED SYSTEM – CHALLENGES FOR THE COMPETENT AUTHORITY**

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### **SUMMARY**

Besides technical advancement and detailed regulation, the transition from a traditionally rule based to a risk based system contributed in a significant way to the positive development of railway safety records, leading to a generally high safety level over the last decades. A consequent implementation of a risk based system is necessary to address future developments, i.e. proactively identify and mitigate new or increasing risks due to the introduction of new technologies and the involved operational changes. However, a risk based approach has drawbacks and its establishment by regulation is not a sufficient condition to assure a benefit from the implementation.

On the one hand, the transition will largely depend on the human and technical capital of the competent authorities and the regulated entities, requiring a fundamental change in the mind-set. Approaches of overseeing / supervision should move from simple compliance checking to triggering discussions on the basis of performance indicators and targets. Such discussions will require a certain maturity of the management and exemplary acting in terms of a just culture. For the competent authority, the ability to measure safety performance should become part of the competence.

On the other hand, decision making must be based on solid evidence as a result of thorough data and risk assessment, not only in the context of the Safety Management System of the regulated entities. The competent authorities also need a comprehensive and robust risk management, which systematically collects and assesses all relevant safety information to use resources efficiently.

However, a purely risk based system would i.a. lead to inefficient approval processes. Technical standards should guarantee interoperability and lean project solutions but also project specific solutions and innovation. Operational rules should allow case specific action (especially in critical situations) without the threat of non-compliance.

In the case of the railway sector a combination of risk based approaches and prescriptive rules is needed for the sake of clarity, harmonisation, interoperability, a level playing field or reference systems for risk assessments.



## INTRODUCTION

For some sectors, e.g. coal mining [1] or health system [2], evidence has been given, that the move from a rule based to a risk based system had a positive influence on safety records. With respect to railways, technical advancements and development of detailed regulation have helped to reduce significantly the yearly numbers of occurrences and consequences, caused by railway accidents, over the last decades [3,4,5], thereby establishing a safe railway system despite increased transport volume and growing network complexity. Simultaneously, many national railway regulation and overseeing systems moved from the traditional rule based system to a more risk based system. Based on the evidence from other sectors, it is assumed, that this move also contributed in a significant way to the positive development of the safety records.

Many railway systems are actually confronted with aging infrastructure and rolling material and the concurrent application of new technologies on the same network. Networks which are furthermore growing in complexity due to increasing train frequencies to meet increasing transport demands. Additionally, regular processes are more and more performed by technical systems, reducing active intervention of collaborators to infrequent exceptional situations. These developments lead to new or enhanced risks, which have to be considered by the competent authorities and the railway sector.

To cope with such changes, i.e. proactively identify and mitigate new or increasing risks, a consequent implementation of risk based systems is needed, should actual safety records be maintained or improved. However, the implementation of a risk based system comprises many challenges, for the competent authorities as well as for the industry or railway companies which are targeted by the respective regulation.

## CHARACTERISTICS OF RULE BASED AND RISK BASED SYSTEMS

In both, the rule based and the risk based system, the competent authorities set a regulative framework, which should ensure that public values, e.g. an effective, safe and environmental-friendly transport system, are achieved, if the regulated entities comply. However, regulation in a rule based system differs significantly from the one in a risk based system, especially with respect to roles and duties of the competent authorities and the regulated entities.

Not only in the railway sector, regulation was traditionally based on prescriptive rules which were developed with growing knowledge of the systems' technology, activities and with experience of accidents or other unwanted occurrences. Enforcement of compliance to the prescriptions was thought to be sufficient, regardless specific or unusual situations or system changes. This made the system rather non-transparent and inflexible, by being to a large extend only reactive. Critical emerging risks were often not addressed in time by rules and prescriptions, because regulators as well as regulated entities were slow in their responses. Since for the railway transport mode, accidents with high consequences have low probabilities, learning can be slow and at a high cost. Moreover, it is impossible to develop prescriptions for every possible situation, and such an inflexible system cannot cope with the fast development of complex technical systems in dynamic market places [6].



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A risk based system sets objectives, i.e. performance oriented goals, coupled with functional requirements. It requires individual responsibility on each level of the regulated entities and a partnering of regulator and regulated entities to prevent unwanted negative effects on the achievement of targeted public values. Within a risk based system, regulation will focus on those risks that hamper the delivery of public value, rather than expending resources on ensuring compliance to rules, where no real hazard exist or hazards only lead to very low potential risks. The risk-based approach calls for a regulator that is not solely focussed on technical compliance and enforcement, but rather a more purpose-driven and agile approach in which the regulator exercises choices about the issues to focus on and employs a range of instruments to address risks that impede the achievement of outcomes, and thus influence or ensure the delivery of public value [6].

However, a risk based approach also has drawbacks and the establishment of a risk based regulation is not a sufficient condition to assure benefit from the implementation of such a system.

### CHALLENGES OF A RISK BASED SYSTEM

The challenges of a move from a rule based to a risk based system concerns all parties of the railway sector, the competent authorities as well as the regulated entities like infrastructure managers, railway undertakings (train operators), entities in charge of maintenance, wagon keepers, notified bodies etc.

A risk based approach comprises systematised decision making frameworks and procedures to prioritise activities and deploy resources - in the case of the competent authorities for normative (regulatory) and approval (approvals, authorizations, issuing of certificates etc.) activities and the relating overseeing / supervision of the operational phase - based on an assessment of the risks that regulated entities pose to the regulator's objectives [8]. A risk based approach therefore needs the definition of a clear set of objectives against which indicators are used to measure the effectiveness of the regulatory system. Performance indicators allow for an assessment of the observed situation by measuring trends, providing feedback and helping to identify the means to achieve these objectives [7]. Both, the set of objectives and the performance indicators have to be defined for each level, regulations and regulated entities, separately.

Instead of establishing prescriptive rules telling individuals and businesses what they can and cannot do, Safety Management Systems (SMS) are introduced to support the development of solutions based on solid evidence as a result of data-driven decision making. Safety management recognises the interactions, interdependencies and interconnections of an entity [7]. While existing regulations and guidelines specify the risk management system within an SMS and e.g. ISO standards treat integration of risk management into overall enterprise management systems, there is no such common basis for the competent authorities. Scope and methodology of a regulator's risk management has to be determined carefully as a function of its tasks (normative, approval, overseeing/supervision) and the interfaces to the SMS of the regulated entities in view of a sharing of safety relevant data. A successful risk management, and therefore risk based system, depends on the ability of the competent authorities and the regulated entities to specify, measure, and monitor performance, to collect reliable and appropriate data that can provide decision makers with the detail they need to make the right choices.

Furthermore, the introduction of a risk based system requires a fundamental change in the safety regulatory mind-set. A shift in responsibilities has to take place, since the regulated entities will be in principle able to choose the means that will fulfil performance goals. This will lead to a different and more advanced



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approach of overseeing / supervision as it will trigger discussions on the basis of performance indicators and targets whether the applied method is suited to meet the performance goal. Such discussions will require a certain maturity of the management of the regulated entities and exemplary acting in terms of a just culture. Successful transitioning from a rule based to a risk based system will thus largely depend on the human and technical capital of the regulator and the regulated entities. If transition is made too fast, insufficient resources and competence will lead inter alia to formalistic risk assessments due to convenience, loss of internal knowledge of operation and their hazards due to externalisation of assessments combined with inappropriate expert estimation and poor comprehensibility as well as a general tendency to hide problems.

Not each and every decision can be made solely based on a risk assessment. Such a system would be very cumbersome. For the sake of clarity, harmonisation, interoperability, a level playing field or reference systems for risk assessments, prescriptive rules will remain the only option. In this context, the role of standards (international and national norms, best practice rules) and (national) operational rules in a risk based system have to be carefully evaluated and a balance between risk based and prescriptive rules will have to be determined.

### **TRANSITION TO A RISK BASED SYSTEM**

The above statements show that a transition from a rule based to a risk based system is not a matter of simply adapting the respective regulation but comprises stringent processes for both, introduction and application of risk management systems as well as adoption of the required mind sets and competences in the case of the competent authorities and the regulated entities.

With respect to normative activities of the competent authorities, risk management should be consequently applied while revising existing or elaborating new regulations, by prioritizing activities based on risk assessments, setting comprehensible objectives and targets and defining indicators enabling the measurement of performance. The latter needs a thorough development of risk assessment methodology and definition of acceptance criteria having regard to the methodologies and criteria used in the context of the SMS of the regulated entities. Existing rules and prescriptions should be carefully evaluated in view (1) of their further requirement to allow for efficient and harmonised standard solutions and (2) the level of regulation, i.e. legal rule, guideline of the competent authority, norm, accepted best practices of national or international railway associations. In many cases, the evaluation may result in the need of transitional measures. E.g. simple replacement of the existing Swiss National Operational Rules by general objectives and targets in the regulation would lead to a situation where every railway undertaking (train operator) and infrastructure manager would optimise its own sector, irrespective of the consequences for the other players, thereby introducing safety gaps (as long as SMS interfaces between the different player do not work correctly) and jeopardise interoperability on the national and the international level.

Without standard solutions, the approval phase (approval of infrastructure projects, vehicle authorisations, issues of safety certificates etc.) will become laborious and inefficient due to uncertainties of the applicant and endless discussions about different opinions between the competent authorities and the applicants with respect to risk assessment results based on inevitable expert judgements, since risk information is neither generated nor used against a neutral background. Approvals, based exclusively on risk assessments would furthermore lead in many cases to very heterogeneous solutions on the railway network, jeopardising interoperability. Technical standards and operational rules can help to prevent these disadvantages. However,



operational rules should allow case specific action (especially in critical situations) without the threat of non-compliance. Technical standards should guarantee interoperability and lean project solutions but also project specific solutions and innovation. To assure these qualities of technical standards and operational rules, the competent authorities have to contribute in a significant way to the elaboration of such documents.

Oversight / supervision approaches will need to change too. A closer collaboration between the competent authority and the supervised companies, engaging in a dialogue on safety assurance and safety objectives rather than just checking compliance with prescriptive regulatory is required. The focus should be more on how risks are mitigated and on assessing the effectiveness of the mitigation process, based on the implementation of the respective safety management system and the results of the underlying risk management process. Since supervision will mainly be based on performance, the ability to measure safety performance should become part of the competence of the competent authority's inspectors. This means a basic understanding of safety analysis techniques and an understanding on how to work with safety performance indicators.

Supervision based on the results of risk management processes provides a better identification of hazards and evaluation of risk mitigation. It would allow the competent authority to focus its attention on organisations that require additional or higher attention. However, the key issue of dealing with bulge, low risk companies still has to be determined.

Regulative, approval and supervision activities of the competent authorities in a risk based system ultimately need a robust risk management system, which systematically collects and assesses the relevant safety information, thereby identifying historical, current and emerging risks, defining mitigation measures for the normative or the supervision phase and measuring the performance with respect to regulative objectives and mitigation measures.

## CONCLUSIONS

Besides technical advancement and detailed regulation, the transition from a traditionally rule based to a risk based system contributed in a significant way to the positive development of railway safety records, leading to a generally high safety level over the last decades. A consequent implementation of a risk based system is necessary to address future developments, i.e. proactively identify and mitigate new or enhanced risks due to the introduction of new technologies and the involved operational changes.

However, the move from a rule based to a risk based system implies many challenges for the competent authorities and regulated entities of the railway sector. On the one hand, the transition will largely depend on the human and technical capital of the competent authorities and the regulated entities. A fundamental change in the safety regulatory mind-set is required. Approaches of overseeing / supervision should move from simple compliance checking (tick-a-box) to triggering discussions on the basis of performance indicators and targets. Such discussions will require a certain maturity of the management of the regulated entities and exemplary acting in terms of a just culture. The ability to measure safety performance should become part of the competence of the competent authority's inspectors.

On the other hand, decision making must be based on solid evidence as a result of thorough data and risk assessment, not only in the context of the SMS of the regulated entities. The competent authorities need also



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a comprehensive and robust risk management, which systematically collects and assesses all relevant safety information to use resources effectively by setting priorities for normative and supervision activities and to be capable to monitor the achievement of objectives and targets, defined in the regulation.

The competent authorities would also need to contribute actively in the development of standards, creating preconditions for standard solutions to avoid inefficient and expensive approval processes. Technical standards should guarantee interoperability and lean project solutions but also project specific solutions and innovation. Operational rules should allow case specific action (especially in critical situations) without the threat of non-compliance. In the case of the railway sector a combination of risk based approaches and prescriptive rules is needed for the sake of clarity, harmonisation, interoperability, a level playing field or reference systems for risk assessments.

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