Quality assurance in the framework of a risk-based approach regulation

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Aim: Explain how assurance on the quality of a system can be provided by the legislation when this system is risk based.

Case of the European Railway System

1) Aspects of the European Railway System
2) Safety = quality requirement
3) How to control safety?
4) Conclusions
Aspects of the European railway system (1)
Setup of the EU rail transport policy and railway legislation

1°) Objective: new dynamism in provision of rail transport services

2°) How: **Open railway market** to competition for rail transport services and railway supply industry!

3°) Need: Prevent sector from using safety as a barrier to market access or an excuse to resist change!

Need: remove the historical barriers to free circulation of trains and make railways business oriented and competitive!

4°) Solutions: Technical Harmonisation & Common European approach for safety
Aspects of the European railway system (2)
Main stakeholders resulting from railway market opening

- Keepers
- Manufacturers & Suppliers
- NoBos
- DeBos
- Customers (Passengers & Freight)
- CSM risk assessment Assessment Body
- ECM Certification Body

National Railway Companies

NSA + RU & IM + ECM

NIB
Aspects of the European railway system (3)
Cornerstones in EU legislation for regulating railway market

- Technical harmonisation (interoperability)  
  - TSIs – NOBOs – DEBOs
- Separation of former vertically integrated railway companies
  - RUs – IMs
- Change from self-regulated railways to regulation by public authorities
  - Regulatory Body + NSA (safety regulator)
- Introduction of a framework for entry into market for railway undertakings
  - Licensing & Safety Certification

- Maintain at least, and increase when reasonably practicable, existing safety level and create a basis for mutual trust
  - Development of common approach to safety [SMS, ECM certification & CSMs]
- Transparency of safety data
  - CSI, CST & CSMs
Safety is key quality requirement expected by the railway transport customers, passengers and freight companies and ... the society

Two aspects to ensure safety:

1. **At least maintain the existing level of safety** in the EU railways, *and increase it when reasonably practicable*

2. Create a basis for mutual trust between railway actors (RUs, IMs, keepers, ECMs, suppliers,...)
How to control safety? (1)

Common instruments for opening railway market

When opening the railway market, in order to:

1) Maintain at least the existing level of safety in the EU railways, and increase it when reasonably practicable

2) Create a basis for mutual trust with many new railway actors and interfaces

It is necessary to set up a common approach for:

- safety regulation
- safety management
- safety control

in line with the "new approach" for the creation of a single European railway market
Definition by EU legislation of “Roles and Responsibilities” of railway stakeholders:

RUs, IMs, Vehicle Keepers, ECMs, NSAs, Notified Bodies, Designated Bodies, Manufacturers and others

WHO shall do WHAT?

Responsibility for safety of railway system put on those who OPERATE and MAINTAIN parts of the railway system:

- RUs, IMs must manage and monitor safely their activities through a Safety Management System (SMS)
- ECMs must manage and monitor maintenance activities through a “System of Maintenance”

NSAs & other assessment bodies (e.g. ECM Certification Body, NoBo, DeBo, etc.) guarantee RUs, IMs and ECMs comply with their obligations
Two classifications are proposed

1st classification of controls

- **Internal controls** = safety management
  
  e.g. 1) RUs and IMs set up SMS. They manage their railway operational risks in conformity with the CSM on risk assessment and CSM on monitoring.
  
  2) RUs controls risks associated with the provision of wagons by Keepers by means of a contract of use.

- **External controls**
  
  • by accredited or recognised or notified bodies
    
    NoBos, ECM Certification Bodies, Risk Assessment Bodies
  
  • by public authorities
    
    National Safety Authorities
How to control safety? (4)

Control of the railway system: Classifications 2

2\textsuperscript{nd} classification

- **Ex-ante**: controls of competence of individuals or capability of organisations by means of a certification scheme.
  - e.g. 1) license and certificate of train drivers
  - 2) Safety certifications/authorisations of RUs/IMs
  - 3) Certification of Entities in charge of maintenance

- **Design and manufacturing/implementation**: Check of the conformity of a product or service with specifications.
  - e.g. 1) freight wagons: verification of conformity to TSI by NoBos, authorisation of placing in service by NSAs.
  - 2) Assessment made by a risk assessment body of a change in a maintenance plan.

- **Ex-post**: control of the performance of an organisation or an individual
  - e.g. 1) 1\textsuperscript{st} party: monitoring by RUs of their SMS, annual review of the SMS
  - 2) 3\textsuperscript{rd} party: Supervision of the SMS of RUs/IMs by NSAs
How to control safety? (5)

Safety Management System

- Safety Regulation
  - Safety Control
    - External
      - Ex-ante
    - Internal control
  - Safety Control
    - External
      - Design/implementation
    - Ex-post

- NSA
  - Directive 2004/49
    - Art. 9 & Annex III
  - CSM for Conformity Assessment (Reg. 1158 & 1169/2011)
  - SMS Certification
  - IM
  - RU
    - Design, Implement, Use, monitor their SMS
      - CSM for Risk Assessment (Reg. 352/2009 & 402/2013)
      - CSM for Monitoring (Reg. 1078/2012)
  - CSM for Supervision applied by NSAs (Reg. 1077/2012)
How to control safety?

System of maintenance

Design, Implement, Use their “System of Maintenance”

Surveillance by certification body according to Regulation 445/2011

ECM Certification

ECM Certification Body

ECM

Directive 2004/49
Art. 14a

Regulation 445/2011

Safety Regulation

Safety Control
External
Ex-ante

Safety Management
Internal control

Safety control
External
Design/implementation

Safety control
External
Ex-post
To ensure safety is under control, necessity to get assurance that the ECM certification is **effective** and **efficient**.

- **Accreditation of certification bodies (external, ex-ante & ex-post)**
  - Control capability of certification bodies
  - Accreditation scheme issued by ERA with European Co-Operation for Accreditation (EA), representative bodies and NSAs.

- **Cooperation of certification bodies (external, ex-post):**
  - Clarify open questions
  - Working group led by ERA, participation of representative bodies

- **Freight Focus Group (external, ex-post):**
  - Monitoring of implementation and development of improvement,
  - PDCA approach
**Different** types of controls

- Addressed to the different parts of the system and to the system as a whole
- Internal and external
- Ex-ante, design and manufacturing/implementation, Ex-post

**No unique** way to make control

Apportionment between the controls to meet quality on an effective and efficient way (acceptable cost)
Many thanks for your attention!