EU processes for Authorisation

Workshop on Technical Specifications for Interoperability
Budapest, 29-30 October 2014
Sarah YOUNG, Project Officer
Antoine DEFOSSEZ, Project Officer
Background for the legal framework
EU Harmonisation
The « DV-29 bis » and the clarifications
Cross Acceptance and the Reference Document
Legal framework and processes for authorisation
  • Roles and responsibilities
  • The stages of the process
Developments
Background for the legal framework
Make rail more competitive by:

- Market opening
- International operation
- Interoperability

Gradual migration to the optimal level of harmonisation

The framework combines
- New approach to products and services
- Rules and tools for management of shared systems
Evolution of the legal frame

Simplification

Yesterday:
28 Processes
28 Sets of rules

Today:
1 Structure
28 Adaptations

Future:
1 Process
1 Set of rules
EU Harmonisation
### Developing the framework

**recent time line of EU railway regulation**

- **1996**
  - European Commission’s White paper: A strategy for revitalising the Community's railways
  - Directive 96/48: Interoperability of the trans-European (TEN) high-speed rail system

- **2001**
  - Rail infrastructure package:
    - Levying of charges for the use of railway infrastructure, licensing of railway undertakings
    - Directive 2001/16 on interoperability of the trans-European (TEN) conventional rail system

- **2004**
  - Second railway package:
    - Interoperability directives amended, Dir. 2004/49/EC on safety on the Community’s railways
    - Regulation 881 establishing European Railway Agency

- **2007**
  - Third rail package:
    - Access rights rail freight service from 1 January 2007 opening of the international passenger transport service market from 2010

- **2008**
  - Directive 2008/57/EC (merged HS and CR) covering the whole of the European Network
  - Directive 2008/110/EC amending Safety Directive giving duties to the entity in charge of maintenance (ECM)

- **2014?**
  - Fourth railway package:
    - Recast of all major railway Directives
    - Single EU wide vehicle authorization and certification
Developing the framework

**EU Framework:**
- EU Regulations, Decisions
- EU Directives
- EU Recommendations
- Reference Document
- TSIs

**MS Framework:**
- Transposition of EU Directives
- Guidance documents
- NLF
- NRD
### Developing the framework

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<th>Drafting</th>
<th>Consultation</th>
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<td>EU Recommendations / Opinions</td>
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<td>EU Framework</td>
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The «DV-29 bis» and the clarifications it brings
“The authorisation for placing in service of a subsystem is the recognition by the Member State that the applicant for this subsystem has demonstrated that it meets, in its design operating state, all the essential requirements of Directive 2008/57/EC when integrated into the rail system”

Authorisation of vehicles should not be related to any particular route, railway undertaking, keeper or ECM

The Design Operating State is: “the normal operating mode and the foreseeable degraded conditions (including wear) within the range and conditions of use specified in the technical and maintenance files. It covers all conditions under which the subsystem is intended to operate and its technical boundaries”

Limits and conditions of use related to vehicle authorisations should be specified in terms of the parameters of the characteristics of infrastructure and not in terms of geography
## The vehicle authorisation cases

<table>
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<tr>
<th>Authorisation Case</th>
<th>Vehicle Type</th>
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<th>When</th>
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<tr>
<td>First Authorisation</td>
<td>X</td>
<td>X</td>
<td>For a new basic design</td>
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<tr>
<td>New Authorisation (Upgrade/Renewal)</td>
<td>X</td>
<td>X</td>
<td>For a changed basic design</td>
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<td>Additional Authorisation</td>
<td>X</td>
<td>X</td>
<td>When already authorised in another EU MS</td>
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<tr>
<td>Renewed Authorisation</td>
<td>X</td>
<td></td>
<td>For a type authorisation that is not valid anymore</td>
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<tr>
<td>Subsequent Authorisation</td>
<td></td>
<td>X</td>
<td>For vehicles conforming to an authorised vehicle type</td>
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</table>
Authorisation compared to use

Conformity to System Specifications

Meeting the Essential Requirements
- Safety
- Technical Compatibility
- Reliability and Availability
- Health
- Environmental Protection
- Accessibility

Checks by assessment bodies

Provisions and processes of Railway Undertaking’s or Infrastructure Manager’s Safety Management System

Return of experience

System specifications = TSIs and national rules
Type authorisation allows manufacturers to offer their customers vehicle types already authorised.

By analogy a vehicle type authorisation is the recognition by the Member State that the applicant for this subsystem has demonstrated that it meets, in its design operating state, all the essential requirements of Directive 2008/57/EC when integrated into the rail system.

A vehicle type is a design described by a set of basic design characteristics. The basic design characteristics of a vehicle type are listed in ERATV. The values of the basic design characteristics of a vehicle type shall be registered in ERATV.

This

- Removes much of the authorisation risk from their customers
- Allows small orders to be placed with reduced cost of authorisation
- Allows long production runs and economies of scale by supplying the same type of vehicle to many customers
- Allows an open market in leasing and sale of authorised vehicles
- Avoids each RU having its own special vehicle designs

Is a concept applied in other transport modes
Subsystems may be authorised individually but cannot be authorised in isolation from other subsystems

Because a subsystem authorisation must always be based on a verification of its interfaces and ensure safe integration with the rest of the vehicle/network project.

This means that vehicles and the on-board subsystems must be authorised together.

DV29bis foresees that:

- A single EC Declaration of Verification may cover more than one subsystem
- A vehicle authorisation is a combination of the authorisations of the subsystem that comprise the vehicle
Vehicle composed of two subsystems – “cumulative” diagram
Vehicles and networks are managed by different actors each responsible for their part of the system.

To ensure system integrity and interoperability an (exhaustive) rule based approach is therefore necessary for the network-vehicle interface.

- Every basic parameter and interface of the target system to be explicitly checked for authorisation must be fully specified in the TSIs and national rules where not yet covered by TSIs.
- The relevant conformity assessment requirements must also be included.
(a) safe integration between the elements composing a subsystem

(b) safe integration between subsystems that compose a vehicle

(c) safe integration of a vehicle with the network characteristics

Part of the applicants EC verification for authorisation

(d) safe integration into an RUs SMS

(e) safe integration of a train with the routes over which it operates

Not part of authorisation
The TSIs and national rules may require the use of the CSM for specific parameters.

The applicant must ensure all requirements (including non-safety essential requirements) have been captured. For parameters where CSM use is not required by the TSI or national rules, the CSM approach may still be used at the choice of the applicant but is not mandatory.

It is not part of authorisation to use the CSM on RA to check or validate the correctness of TSI requirements but a discrepancy or error is perceived in TSIs or national rules then the issue must be raised as a matter of urgency, with justification, using the procedures.

An applicant is not required to assess if the change to design operating state being authorised represents a significant change to the railway system. This task is to be carried out by the RU / IM who intends to bring it into use on their part of the system.
Each NoBo and each DeBo compiles a technical file covering the verifications that they have carried out.

The applicant compiles a “technical file accompanying the EC declaration”. This contains:
- All the NoBo and DeBo files (including all certification)
- All other files required by all applicable EU legislation including drawings etc. as required by para 2.4 of Annex V I
- Everything else necessary for the authorisation, and ongoing use of the subsystem/vehicle (including the limits and conditions of use)

The MS may specify in their National Legal Framework which parts of the technical file accompanying the EC declaration they wish to see in the documentation to be submitted for authorisation.
Verifications carried out according to national rules of other Member States must be mutually recognised unless

- These are strictly necessary to check the technical compatibility of the vehicle with the relevant network and are not equivalent to the rules of the Member State of the first authorisation. (i.e. there is no evidence of technical compatibility with the network)

or

- A Member State can demonstrate to the applicant for additional authorisation a substantial safety risk

- CSM assessments carried out as part of authorisation must be mutually recognised
The SMS of RUs and IMs should cover the processes and actions necessary to maintain vehicles and subsystems in use in conformity with the essential requirements. This must take account of return of experience.

NSAs should monitor conformity with and effectiveness of the SMS in dealing with return of experience. They should not prescribe corrective action.
Cross Acceptance and the Reference Document
Based on:
- Commission Decision 2011/155/EU

Purpose:
- Transparency of rules applying to authorisation of vehicles

Composed of 3 parts:
- Part 1: Application Guide
- Part 2: 28 National Reference Documents (NRD)
- Part 3: 28 National Legal Frameworks (NLF)
Target = One European Process for Vehicle Authorisation

Now:
- One generic EU process with adaptations made for each MS = NLF
- ERA has collected 28 NLFs
- 22 NLFs are published in pdf format on ERA website
- RDD functionality for publication of NLFs is prepared
- Explanations in EU Recommendation 2011/217/EU (DV29)
- DV29bis has been drafted to give further clarifications
The current situation

National process for wagons
National process for locos
National process for CCS
National process for MUs
Cross Acceptance agreement with MS X
Cross Acceptance agreement with MS Y
Cross Acceptance agreement with MS Z

National Interpretation of EU Process x28

February 2014

A complex mix of National Processes and national interpretations

1x EU process according to Recommendation 2011/217/EU and Master flowchart

Published by ERA
The current situation
Actors and processes for authorisation for placing in service of vehicles and fixed installation
Roles and responsibilities

- Roles are linked to specific tasks
- An actor can have several roles
- There are criteria for if an actor can undertake a role
- The requirements on an actor to undertake a role is specified in the NLFs

<table>
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<th>The roles in the EU legal framework</th>
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<td>Applicant</td>
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<td>NSA</td>
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<tr>
<td>Member State</td>
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<tr>
<td>Checking Bodies (NoBo; DeBo; Risk Assessment Body)</td>
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<tr>
<td>Appeal Body</td>
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<tr>
<td>Infrastructure Manager(*)</td>
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<tr>
<td>The European Railway Agency (ERA)</td>
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(*) in cases where vehicle tests on the network are necessary
Full responsibility for subsystem design operating state meeting the essential requirements:
- The essential requirements for the railway system set out in Annex III of the Interoperability Directive
- The essential requirements of other directives
- The specific requirements contained within TSIs
- The specific requirements contained in national rules

The applicant signs an EC Declaration of verification to declare that he has discharged this responsibility.

Authorisation from NSA is not a “warranty”

Bears primary responsibility in event of accident or incident calling into question conformity with the essential requirements at the time of authorisation
The role of the NSA “should be to carry out a check of the documents accompanying the application for placing in service and providing evidence of the adequacy of the verification procedure. **This check should consist of checking the completeness, relevance and consistency of the documentation submitted for authorisation. It is limited to matters within the competence of the National (railway) safety authorities as defined in Directive 2004/49/EC**”

If the compliance at authorisation with the essential requirements is later called into question the authorising NSA should only be held accountable for the specific tasks allocated by Article 16 of the Safety Directive
Roles and responsibilities
The NSA

› The NSA Should:
› Check = Completeness, Consistency, Relevance
› Ensure the correct process is followed

› The NSA may:
› When there are justified doubts call into question the work of Checking Bodies

› The NSA Should not:
› Perform in depth verification/validation of Checking Bodies work/results
› Repeat checks
› Carry out/duplicate work of rule setters or Checking Bodies
Roles and responsibilities
The assessment bodies

- **Notified Bodies**
  - Verify conformity with TSIs and draw up the certificate(s) of verification intended for the applicant.
  - The notified body’s verification “shall also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated.”

- **Designated Bodies**
  - Carry out exactly the same tasks in respect of national rules

- **Risk Assessment Bodies**
  - Review risk assessments procedures and issue safety assessment reports when the use of the CSM is required in the authorisation process by the Interoperability Directive or by a TSI.

- The independence of the staff responsible for assessment must be guaranteed.
  - e.g. “functionally independent of the authorities issuing authorisation”
In the case of tests of the vehicles on their network, the infrastructure managers have one direct role in the context of facilitating the authorisation process.

In the case of additional tests required by a national safety authority, for an additional authorisation ‘the infrastructure manager, in consultation with the applicant, shall make every effort to ensure that any tests take place within 3 months of the applicant’s request’.

The infrastructure manager has no power to impose a sort of second authorisation to the vehicles or trains of the railway undertakings.
General Information

- General Information
- Roles & Responsibilities
- Timeframe

Master Flowchart

- 8 Stages
- + 1 extra Stage for NVR

Flowcharts

- One per Stage
- Sub-stages
The stages of the process for vehicle authorisation

- Stage 1 - Identify the rules, applicable requirements, conditions of use and assessments
- Stage 2 - Pre-engagement
- Stage 3 - Assessment
- Stage 4 - Correction of non-conformities for national rules
- Stage 5 - Establishing certificates and declarations of verification
- Stage 6 - Compiling authorisation file and submitting the application
- Stage 7 - Processing the application for authorisation
- Stage 8 - Final documentation and authorisation
- (Stage 9 - Registration of the vehicle authorisation in the NVR)
Stage 1
“Setting the scene”

› Applicant:
  › Authorisation case
  › Requirements, conditions for use and verification procedures
  › Checking bodies

› Member State:
  › Is New Authorisation required for Upgrading/Renewal
Stage 2
Common view and preparations

› Pre-engagement baseline and file
› On-track tests
› Alternative Method

› Applicant
› NSA
› Checking Bodies
› Infrastructure Manager(*)

(*) in cases where vehicle tests on the network are necessary
Stage 3
Checking

Applicant
- Verifications
- Evidences
- CSM RA (?)

Checking Bodies
- Assessments
- Documents

Applicant
- Collects documentation
- Results ok?
Remedial Action

- Applicant
- Alternative Method
- Design Modification
- Change the Conditions for use/Restrictions
Stage 5
Establishing the documents

Checking Bodies

- Documentation

Applicant

- EC/NR Declaration of verification
- Declaration of conformity to type (for vehicles of the type already authorised)
Stage 6
The application for authorisation

Applicant
Compiles Authorisation File
Submits Application

NSA
Stage 7
Processing the application

**NSA**
- Complete
  - Grant?
    - Issue Authorisation

**Applicant**
- Receipt of application
  - Timeframe respected?
    - No
      - OK = End

**Sub-process**
- Appeal
  - No
Stage 8
The authorisation of vehicle

Applicant
- Authorised vehicle type
- Authorised vehicle type + vehicle
- Deemed (type)

NSA
- Authorisation
- Confirmation Deemed (type)

ERA
- ERATV
- Register Type Authorisation
The authorisation of fixed installation

Infrastructure Manager

Authorised fixed installation

Register of Infrastructure (RINF)

NSA

Authorisation

ERA

RINF Common User Interface
In case of fixed installations, other national rules apply as well, related to e.g. environmental protection, sanitary issues, fire protection, construction law etc. The applicant (IM) needs to obtain all necessary certificates, approvals and permissions before commencing operation of the new installation.

This may be checked by the NSA before issuing the authorisation for placing in service, or it may be sole responsibility of the IM, independently from „railway authorisation” process.
Developments
ERA support and contact points?
- Via RISC
- ERA WPs
- Direct contact with ERA - [www.era.europa.eu](http://www.era.europa.eu)
- For the Reference Document - [rdd@era.europa.eu](mailto:rdd@era.europa.eu)

How to get directly involved?
- Real Vehicle Authorisation Case studies
Making the railway system work better for society.

era.europa.eu