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## **AUTHORIZATION PROCESSES AND PROCEDURES FOR THE RAILWAY STRUCTURAL SUBSYSTEMS**

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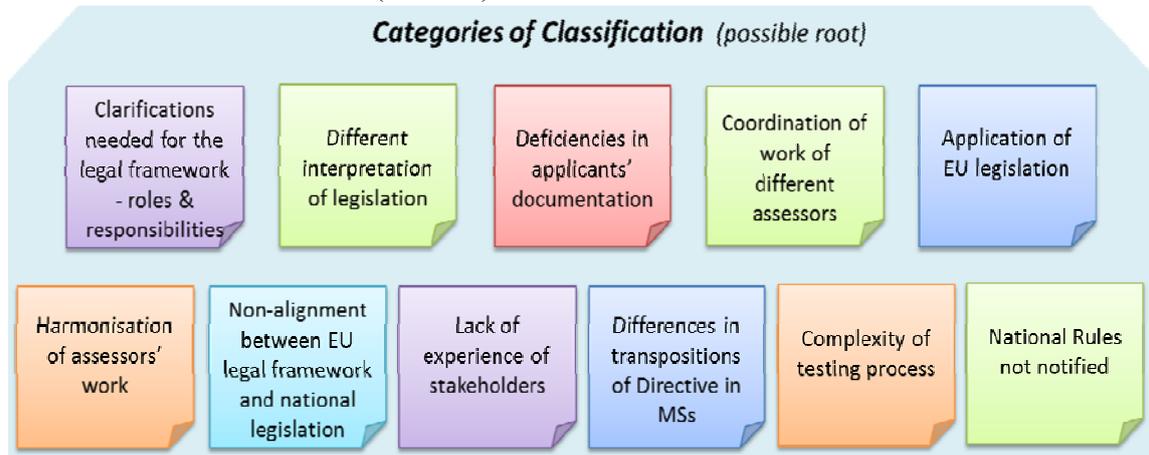
**Abstract:** *Based on the technical issues regarding the overall authorization process this article proposes an improved authorization for placing in service (APIS) process to be used as an harmonized reference at EU level. The main steps composing the proposal are defined with a general view on the overall authorization framework. A process flow was elaborated, considering the available European legislation and national specifics.*

### **INTRODUCTION**

Starting from the meaning of authorization (APIS) as stated in the EU Recommendation 2014/897 [1] it is a recognition of compliance of a railway structural subsystem to the essential requirements of the “Interoperability Directives” [2] [3]. All the considerations and proposals described in the next sections rely on the current legal background for the placing on the market and placing in service of components and subsystems for railway applications. The first important aspect to be taken into account is that such components and subsystems must respect all the laws that are applicable for them. This is recalled very clearly by the “Interoperability Directives” [2] [3], that state this obligation both for placing on the market of Interoperability Constituents (ICs) and for placing in service or on the market of subsystems and vehicles. This is an obligation for the relevant “applicant”, that must confirm the respect of all applicable regulation in the “Declarations”. Such Declarations must be supported by appropriate documentation (certificates, technical files, etc.) as required by each of the applicable regulations. The scope of [4] analysis is limited to the certificates and other documentation required by the “railway safety and interoperability Directives”, and related implementing acts; however [4] demonstrated that sometimes “interferences” from other regulations affect the authorization process requested by the railway Directives. In fact, even if other regulations should normally be harmonized at EU level (e.g. EMC Directives, “low voltage” Directive, etc.) national specific cases may still exist. Finally, the scope of work of the National Safety Authorities (NSAs) is not completely uniform in all EU countries, and some of them are charged by the national legislation with responsibilities that in other EU countries are differently allocated. All these may create a situation where an applicant is faced with different requirements (e.g. on documentation and information to provide to the NSA) according to the EU MS where the application is

submitted. [4] has noted this issue, mentioned by some stakeholder as the presence of “*shadow processes*”, i.e. national requirements appearing when interfacing with a NSA that are not expected, because not directly linked either to TSI or notified national rules.

Technical issues regarding the overall authorization process identified in the verification and authorization process in [7] are classified in some categories (Figure 1) and summarized in the table below (Table 1).



**Fig. 1** Technical issues regarding the overall authorization process

**Table 1** Categorization of issues in specific area

Area	Detailed description
Information to be exchanged at pre-engagement	Harmonize terms and definitions (national differences, changes due to amendments of legal acts); Clear definition of scope of work of all stakeholders (including Conformity Assessment Bodies); Existence and management of derogations; Possible conditions/problems for performing on-site tests; Possible use of ISVs in the process;
Information in contracts between applicant and Conformity Assessment Bodies	Object of authorization process; Clear definition of scope of work of all stakeholders; Timing for involvement of Conformity Assessment Bodies; Check list of information to be submitted by the applicant to the certification body; Specific requirements or limitations in case of application for ISV
Overview of the whole process	Understanding of the whole scope of work for each stakeholder;
Assessment/verification checklist	Harmonization of the scope of work and methodology between Conformity Assessment Bodies

Based on the reviewed issues in this section, a proposal is made to improve the APIS procedure towards better harmonization.

### **AUTHORIZATION PROCEDURE (APIS)**

In order to be authorized an Applicant establishes a procedure to be able to sign the EC declaration of verification of the railway structural subsystem concerned (i.e., the subsystem verification procedure). The “EC” declaration of verification of a subsystem is a declaration established by the “applicant” in which he/she declares on his/her sole responsibility that the subsystem concerned, which has been subject to the relevant verifications procedures, satisfies the requirements of the relevant Union legislation, including any relevant national rules.

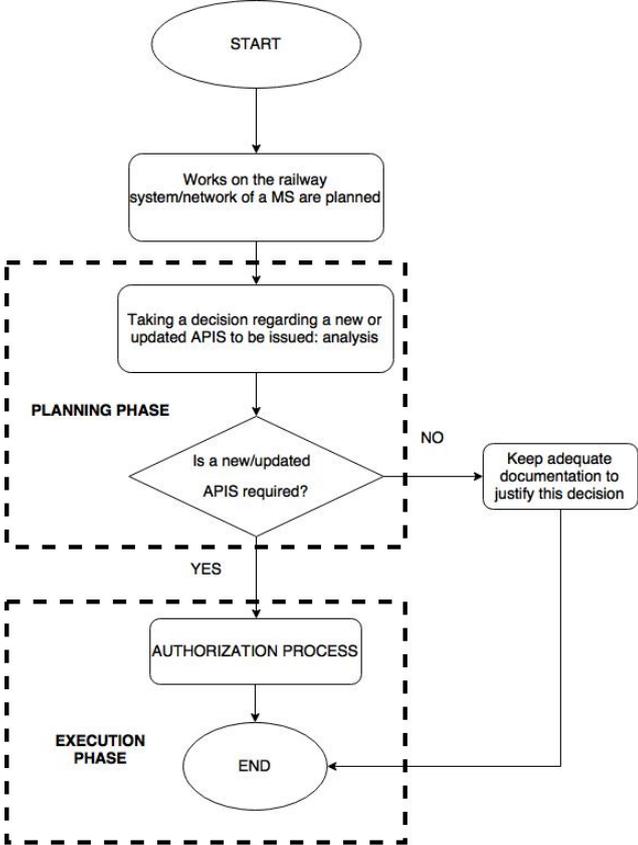
It is therefore necessary to understand if an authorization (APIS) should cover all the aspects addressed in the subsystem verification or only those relevant to railway legislation

concerned. In fact, formally a subsystem verification means a procedure carried out by the applicant within the meaning of Article 18 [2] to demonstrate that the requirements of the relevant Union legislation including any relevant national rules relating to a subsystem have been fulfilled and the subsystem may be authorized to be placed in service. From this statement seems that an authorization should cover all the aspects within a subsystem verification.

However, if the authorization covers also the aforementioned aspects it means that a NSA should be responsible to authorize the compliance to the railway subsystem concerned to a set of relevant Union legislation including any relevant national rules that potentially are extra railway domain (as for example health and safety laws, other Directives like EMC or low – voltage, etc.). This particular aspect introduces another point. Whenever within a Member State (MS) (according to national laws) a dedicated authority/entity exists that grants an authorization (or manages equivalent processes) covering specific rules like those aforementioned, a conflict might occur between the NSA concerned and the other authorities. In fact, the NSA authorizes the subsystem assessing the fulfilment of all the relevant Union legislation including any relevant national rules. On the other hand, the specific entity appointed has to authorize for such specific rules. The main issue is how a NSA may authorize a railway structural subsystem covered by a set of EU legislation or any relevant national rules that do not fall in the scope of the NSA but of other authorities (established according to national laws in agreement with EU Treaty).

**PROPOSAL OF AN OVERALL APIS PROCESS**

This section proposes an APIS process with two main stages and the following flowchart describes the proposed authorization process as a whole.



**Fig. 2** Overall flowchart describing an APIS process

The process starts considering the planning of some works within the railway system or network of a MS. The Proposer is the main actor (who is going to plan and execute such works). Furthermore, the process moves to the planning phase describing the need of an APIS or not, on the basis of the nature of the foreseen works.

The first dashed BOX contains two main steps:

- **STEP 1:** Taking a decision regarding the issue of a new or updated APIS: analysis on the foreseen works to be carried out;
- **STEP 2:** Necessity to issue a new or updated APIS on the basis on the foreseen works.

A decision (STEP 1) is usually taken considering that a set of documents (in form of a file) with a technical analysis on the impact of the works on the railway system is submitted to the relevant authority by a Proposer of the works considering what provides in the EU legislation.

If the decision (STEP 2) to issue a new/updated APIS is positive (YES branch) an execution phase starts (in practice how an APIS process has to be carried out). The execution phase is the put into practice of an authorization process.

If the decision (STEP 2) to issue a new/updated APIS is not needed (NO branch) the documentation that leads to such conclusion is kept for recording purposes.

Therefore, the APIS proposal is based on this main two phases:

- 1) A planning phase;
- 2) An execution phase (an authorization process is put into practice).

#### ◆ **Planning phase**

The planning phase concerns the following:

- The decision if the foreseen works are a new railway structural subsystem or a renewal/upgrading of an existing railway structural subsystem;
- If an APIS is required or not following the event of works to be carried out on the railway system or railway network (or part of it) of a MS.

Whenever works has to be carried out on the railway system or railway network within a MS the first activity is to identify the nature of such works and of the connected changes/modifications within the railway system/network of a MS establishing if an authorization process may be then required or not.

Works is associated to a modification or change. According to the EU Regulation 402/2013 [6] changes is intended to be applied by the Proposer to the railway system. According to the same EU Regulation the following changes or modifications are envisaged:

- Technical
- Operational
- Organizational

As regards operational/organizational changes, only those changes which could impact the operational or maintenance processes shall be subjected to consideration under the rules of Article 4 of EU Reg. 402/2013. Considering that a change of operational/organizational nature is not strictly related to a structural subsystem an APIS is not required. For this reason the focus of this analysis will be on the changes/modifications of technical nature only to be applied on a railway structural subsystem.

In the light of this, according to the Directive 2016/797/EU a technical change can be associated to the following events:

- *New* intended as a new structural subsystem that has to be designed, constructed, installed and finally tested (and further placed into service).
- *Renewal* of an existing structural subsystem:

- a) According to the Directive 2016/797 means any major substitution work on a subsystem or part subsystem which does not change the overall performance of the subsystem.
- *Upgrading* of an existing structural subsystem:
  - a) According to the old Directive 2008/57/EC means any major modification work on a subsystem or part subsystem which improves the overall performance of the subsystem.
  - b) According to the Directive 2016/797/EU means any major modification work on a subsystem or part of it which results in a change in the technical file accompanying the ‘EC’ declaration of verification, if that technical file exists, and which improves the overall performance of the subsystem.

The following table shows how the EU relevant legislation addresses the terms *new*, *renewal* and *upgrading*.

**Table 2** Association between the terms new, renewal or upgrading of a subsystem and the related action

Term	Directive 2008/57/EC	Directive 2016/797
New	No definition	No definition
Renewal	Major substitution work on a subsystem or part subsystem <u>which does not change the overall performance</u> of the subsystem	Major substitution work on a subsystem or part subsystem <u>which does not change the overall performance</u> of the subsystem
Upgrading	Major modification work on a subsystem or part subsystem <u>which improves the overall performance</u> of the subsystem	Major modification work on a subsystem or part of it which results <b>in a change in the technical file accompanying the ‘EC’ declaration of verification</b> , if that technical file exists, and <u>which improves the overall performance</u> of the subsystem

Both Directives introduce the term ‘major’. In case of renewal such term is linked with substitution while in the case of upgrading such term is linked with modification. The consequence of the term ‘major’ is associated in both case to the following:

- In case of renewal it does not change the overall performance of the subsystem.
- In case of upgrading it improves the overall performance of the subsystem.

However, firstly, the EU legislation does not explain further the meaning of the term ‘major’ and secondly the nature of ‘major substitution work’ (renewal) or ‘major modification work’.

The current practices showed that the discrimination among all terms (*new/renewal/upgrading*) and the entity of the works associated is usually managed through an internal procedure owned by who carries out the technical change (i.e. Applicant/Proposer).

In the Directive 2008/57/EC, there is no distinction of a *renewal/upgrading* of railway structural subsystems (in terms of fixed subsystem) and a vehicle. The new Directive 2016/797/EU introduces a distinction between *renewal/upgrading* of fixed subsystems and vehicles.

Finally, a further family of works may be considered and are those classified with the terms OTHERS (but not MAJOR) that are connected to works NOT classified as *renewal* or *upgrading* but as (for example):

- ‘Substitution in the framework of maintenance’ and other changes that do not introduce a deviation from the technical file accompanying the ‘EC’ declaration of verification. In this case there is no need for verification by an assessment body, the

Member State does not need to be informed, and the initial 'EC' declaration of verification remains valid and unchanged.

- Changes that introduce a deviation from the technical file accompanying the 'EC' declaration of verification which may require new checks (and therefore require verification according to the applicable conformity assessment modules) but do not have any impact on the basic design characteristics of the subsystem. In this case, the technical file accompanying the 'EC' declaration of verification needs to be updated, and the relevant information should be made available upon request by the national safety authority. This case may be ruled on the basis of national provisions where the NSA may request information to record the changes but not necessarily re-issue the in force APIS due to such changes.

#### ◆ **Execution phase**

The execution phase follows the planning phase and starts once the foreseen works requires the issue of an APIS by the relevant Entity (NSA concerned or EUAR according to the Directive 2016/797/EU).

The proposal should follow the modification/change development as carried out on the railway structural subsystem object of such modification. Such subsystem will be covered by an APIS to be issued before being brought into the project state.

The proposed APIS process is based on the following phases:

- 1) Preparation: this is a phase where APIS process is planned considering three different actors that might be involved (i.e. Applicant, Proposer, Conformity Assessment Bodies (Assessment Body, Designated Body, Notified Body whenever required) and the NSA concerned. The new Directive 2016/797 introduces a specific role for the EUAR regarding the track-side ERTMS based project as part of the control-command and signalling subsystem. The aim of this phase is to make aware all the relevant actors/stakeholders involved in an APIS process about the process development (to better know who is who and who does what and how and when). This phase should improve the overall process trying to smooth in advance any contingencies that might be expected in later stages.
- 2) Type design and testing: this is the phase where the APIS process has a connection with the design stage of the modification/change impacting on the subsystem object of an APIS. The involvement of the NSA concerned in this phase might be beneficial.
- 3) Construction, installation and final test: this is the phase where the APIS process has a connection with the construction/installation and final test stage of the modification/change impacting on the subsystem object of an APIS. It is composed of the following aspects:
  - a. Manufacture/construction;
  - b. Installation (with site installation tests);
  - c. System validation (with site acceptance tests).
- 4) Completion of the works (for fixed subsystems some works that impact on authorized configuration can only be completed after APIS is issued);
- 5) Preparation of the APIS application with the relevant evidences of the EC verification and further submission to the NSA concerned;
- 6) Assessment of the APIS application by the NSA concerned and (if positive) issue of the APIS.

## **CONCLUSION**

This paper focused on the elaboration of a tentative authorization process to be used as an harmonized reference at EU level. More in detail, this paper deals with the definition of the main steps composing the proposal aiming at the simplification and harmonization of the authorization process and procedures for placing in service/operation subsystems, with a general view on the overall authorization framework. A process flow was elaborated, considering the available legislation and some different situations/scenarios.

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