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CER strongly supports the idea to provide a common understanding amongst the Member States and the stakeholders. The second draft of DV29 already provides a good basis for a common understanding. Nevertheless further points still need to be clarified. CER would be glad to discuss the comments raised below further with you at your earliest convenience.

Additionally CER would like to draw your attention to a number of further points which we think will help to reach a common understanding about authorisation processes. In considering our comments on DV29, it should be remembered that the purpose of the document is to assist all parties in understanding the requirements, roles and responsibilities in the processes of placing into service (PIS), especially to inform the Member States in forming their implementing legislation for the 2008 revisions of the Interoperability and Safety Directives. Therefore time spent now addressing misunderstanding and inconsistencies will be well spent.

CER supports to separate the authorisation of the structural subsystems/vehicles and the regulation of their operation, but it is difficult to understand the process as a whole. CER therefore asks ERA to provide an **unambiguous flowchart of the process** for placing into service of a subsystem or vehicle, indicating the relevant parties, their activities and the sequence of activities and milestones. This will help to create coherent understanding and interpretation of the directive. It would also be helpful if the relevant references to the Directives and Regulations could be shown on the flowchart.

Some aspects contained within this document are not well understood, so in order to be clear about what does and does not apply to placing into service, the DV 29 should address both 2008/57/EC and 2004/49/EC directives and the relationship between them and the CSM regulation 2009/352/EC.

We would hope that there is no duplication between the requirements of any of these documents, particularly in respect to (notified) national safety rules and (notified) national technical rules (especially considering art 4§1 and 8 of the SD). In order to keep the introduction

of new specific national rules to a minimum and thus prevent further barriers from being created, and with a view to the gradual harmonisation of safety rules, the Commission shall monitor the introduction of new national rules by Member States

We would highlight an apparent contradiction between DV29 3.1.4 and 5.3.2 in that 3.1.4 states that MS cannot adopt any new national rules from the moment a TSI is adopted, but 5.3.2 states that any identified missing requirements will need to be notified as rules. This contradiction should be explained.

We would recommend that the responsibilities of the NSAs in respect of all these regulations be described in more detail. Furthermore the difference between the NSA's authorisation for placing in service of a rail vehicle on a network and the point at which a vehicle can be used by a RU in revenue service needs to be better clarified as it will govern the tasks of each of the actors.

This is a subject that could be covered in more depth in a specific workshop on the subject of authorisation for PIS.

We would like to draw attention to a concern with the use of the word authorisation. It has a totally different meaning in the context of the Interoperability Directive and in the context of the Safety Directive, both of which are referenced in this document.

We note that whilst the document introduction speaks about this only applying to vehicles, it also refers throughout the document to infrastructure-related subsystems. Either the 5th paragraph in the introduction needs amending or we would appreciate to find a similarly specific document for infrastructure related subsystems.

The provisions set in §9.4 confirm the need of updating the NVR in a time frame compatible with operational purposes. It shall be completed, in accordance with art 33 §2e of the ID, with restrictions linked to a specific vehicle other than the ones lasting only some hours or days (which are treated by applying a label on the vehicle).

2. DETAILED COMMENTS

2.1 General remarks

There are numerous examples throughout the document where the wording makes the text either incorrect or unclear. Among others:

1. 4th § *" Secondly, the procedures for authorising vehicles are harmonised and include few clear steps with fixed response time by the competent authorities".*

We suggest to replace "few" by "some" to improve clarity of the English

2.1 The last § must be more precise in order to describe how the NSA shall check that these structural subsystems comply, where applicable, with the relevant TSI provisions on operation and maintenance related to placing in service [ID article 15 §2]. Our question raised in the workshop of 16th April has not yet been answered.

3.1.1 Box: Please replace the final wording to read as follows "...in order to ensure (instead of prevent) that radio and other telecommunications equipment can operate (instead of cannot) as intended"

3.1.3 Last § Replace *"inexistence"* by "non-existence"

5. The title should read "*authorisation for placing into service*" in order to be consistent with the directive.

5.2.1 Header *"Breaking through"* makes no sense in the context of the document. We suggest either to delete or to replace with something more meaningful
"After the placing in service, as provided for in ?" a reference is missing or incomplete sentence!

We would point out that in 5.2.1 Paragraph 2 Manufacturers and Contracting Entities can seek an authorisation to place into service, but cannot actually place into use.

When a reference is made to "national rules" please specify that only "notified national rules" have to be considered and thus add "notified" each time "national rules" is used. Please provide a notification transition target timetable, starting from today where the list of notified national rules is rather incomplete and in some Member States not written so as to be easily assessable by a DeBo.

2.2 Detailed remarks

The remarks refer to the appropriate numbered paragraph of DV29.

2.1 3rd § group of components is repeated twice, please remove one.

3.1.4 National rules

In understanding of DV29 we are of the view that some MS still have requirements for authorisation for PIS in their National Safety Rules. It may be that not all National Technical Rules are notified. We request EC and ERA to enforce the MS to fulfil their responsibilities.

3.1.5 Harmonised standards (ENs)

Suitable and sufficient application of a harmonised standard shall be sufficient for successful demonstration of conformity in front of a NoBo.

4.1

We have here an incoherency between DV29 and recent TSIs and ask for clarification. DV29 mentions "*EC declaration of conformity or suitability for use*", whereas the new TSI LOC & PAS and the draft of the revised TSI CCS (chapter 6.2.1) do not require suitability for use for their products.

4.2.1 2nd paragraph. Use of the term "*real world*" is not helpful. Suggest delete as the meaning of the sentence is still clear.

4.2.1: Use of ICs in the current process of EC verification creates problems which must be addressed in DV29:

- For the same spare parts certified and non-certified ICs with the same technical characteristics exist, and it should be possible to equally use it in certified subsystems
- Re-certification of an IC after 5 years may cause design changes due to changed standards. This may result in incompatibility with the original vehicle/subsystem and therefore obsolescence problems for spare parts.

4.2.1 3rd § CSM 2009/352/EC regulation has to be taken into account and thus we suggest adding the following sentence: "The NoBos could act as CSM assessment bodies (AB) for risk

assessments where required by the TSIs or take into account such CSM safety assessment report [articles 2.2a, 5 §1b and 7 §3 of the regulation 2009/352/EC] (but if the Contracting Entity contracted with such an organisation to do so, then it would not be acting as a NoBo)".

4.2.3 after 2nd § CSM 2009/352/EC regulation has to be taken into account and thus we suggest adding the following sentence: "Where relevant, the applicant shall include the CSM Safety Assessor's report as part of the evidence in the technical file"

Furthermore, at least in the process flowchart requested, it should be clarified which are the European conditions and times for this process; wording like "at that moment" would be better written as something like "only once all of the preceding evidence and declarations have been compiled is the applicant in a position to be able to apply for an authorisation ...".

5.1.3 Authorisation of placing in service for vehicles

The route compatibility dealt by the RU according to its SMS shall be based on the clear description, in the authorisation of the vehicle, of its conditions of use and other restrictions. Thus in the 4th § we suggest modifying the 2nd sentence as follows: "For example, an authorisation shall specify the voltage of lines on which the vehicle is allowed to run in the case of electric traction vehicles." and also the last sentence: "of the Railway Undertaking (RU) using the conditions of use and restrictions written down in the authorisation and the information on the nature of the infrastructure supplied by the Infrastructure Manager (IM) in the RINF"

5.2 The border between the Authorisation for placing in service and the operation and maintenance of subsystems and vehicles

We would like to ask for further clarification on some areas in § 5.2 and would like to discuss it in the aforementioned workshops

As there is no clear definition of "the design operating state" and of the "authorisation for placing in service" and the link with the safety directive is not well specified, it is necessary to make a clear difference between 2 major things:

- 1) the operating and maintenance rules specific to the design that have to be taken into account at the level of the authorisation for placing in service before the subsystem or the vehicle could be used by an operator. ID art 15 §2 requires check by the MS and the NSA shall check these rules before the granting of the authorisation
- 2) The operational and maintenance rules covered by the safety certificate or authorisation of the RU/IM or, for maintenance, by the ECM certificate (mandatory for wagons, voluntary for other vehicles) that are necessary for ensuring the ability of these actors (RU/IM and ECM) to operate or to maintain the subsystem or the vehicle.

5.2.1 7th §

"All specifications relating to operational requirements that should be defined at the design operating state (e.g. braking characteristics, horns on driving vehicles) are covered by the structural TSIs" We look forward to seeing the changes to the structural TSIs so as to ensure that the context of this statement is correct. See also our comment on 5.2.2

5.2.1 8th §

"All the requirements relevant to maintenance are included in the structural TSIs." This could be misinterpreted, as TSI will never specify maintenance completely. It shall be reworded: "All the requirements needed for authorisation..."

5.2.1 9th §

"Thus the rules and authorisation process under Directive 2008/57/EC regulate the design operating state of a vehicle and Directive 2004/49/EC regulates the entities that use, operate and maintain it, as shown in the following picture"

We would appreciate clarity about some terms in the picture

- after "Design, Construction and Installation", whether this also includes "maintenance and operating rules specific to the design"
- "Operation and maintenance" we would recommend to replace by "Ability to operate or maintain the subsystem"
- for "provision and processes of SMS", please include **some clarification about** the ECM responsibilities related to maintenance
- for "Open points in TSI check by DeBo" can we be certain that for the casual reader this includes also "specific cases, derogations, integration of vehicles or fixed installations on not fully TSI compliant lines". We would request clarification to whom it is the DeBo will report.
- In the box where it is mentioned "Current TSI" we would point out that it may not in every case be the current version in force that the NoBo is using (see chapter 7 of some TSIs, with phases A and B or other kinds of transitional periods).

5.2.2 last §

Again this statement is not true as there are currently still functional requirements in structural TSIs (generally §4.4 operating rules and 4.5 maintenance rules) and a NoBo has nothing to do with them, except compiling the technical file. Another example in the other direction is the TAP TSI drafted by the ERA (look at §4.2.12 and 4.2.13), which concern the structural subsystems RST and infrastructure (stations), when the major part of this TSI is functional. ERA is urgently requested to "clean up" the TSI accordingly!

5.2.3 Safety Management Systems (SMSs)

There is insufficient clarity as to the role that the ECM plays.

5.3.1 Technical compatibility

We support the conclusion in the box, but we are not sure that all MS have implemented it in that way. We welcome the opportunity to explore in considerably more detail at the aforementioned workshop.

5.3.2 Safe integration

CSM on RA should be applied as an action for systematic and structured identification of missing or incomprehensive requirements. It will result in creating or improving technical rules and setting up possible mitigation measures. This action should be performed independent from a product under assessment, as it loads cost only on the first applicant for the benefit of any further applicant. IPR issues related to the publication of the identified requirements must be addressed. Hence the statement of the 4th § 2nd dash that requests to make public results of the risk analysis done by the first applicant must be amended accordingly.

Proposal:

Modify the 2nd bullet point in the box as follows: "For interfaces not covered by TSI or NNSR/NNTR: The hazards for which requirements are currently missing in TSI or NNSR/ NNTR shall be identified by comparison with reference systems or **an explicit risk estimation** (RA-principle 2 or 3 of CSM-RA) thus enabling full coverage of the interoperable interfaces by the TSIs. Otherwise the first applicant will suffer from discrimination by one-time costs. These "missing

requirements" will have to be considered in future revisions of TSIs in order to progressively arrive at a full coverage of the interoperable interfaces by TSIs."

The 2nd § must take into account all the integration cases and thus suggest change as follows: "To this end, the applicant needs to demonstrate the safe integration between different subsystems inside the vehicle, the safe integration between vehicles or the safe..."

5.6 Authorisations for vehicles running on TEN and off TEN

This § is a copy of the ID but it is not clear: what is the difference between *"at least partially"* and *"occasionally"*? What is the definition of occasionally? (Once a day, once a year?)

CER strongly recommends that MSs transpose the Directive in their national act that only one authorisation is needed covering TEN and off TEN!

Regarding authorisation for PIS on TEN and off-TEN lines, even before the technical work on TSI scope extension is done by ERA, consideration should be given to whether it is feasible to authorise any vehicle that already has authorisation for PIS on the TEN network (based on TSIs and Notified National Rules) also on the off-TEN network. However, it is critical to take into account the identification of specific cases and types of infrastructure (e.g. line categories) not yet defined in current TSIs.

6.1 Role of the RU

Do you agree that the technical compatibility between vehicles themselves must also been taken into account, If yes, this comment applies to § 5.3.1 as well

4th § The statement *"IMs must maintain their infrastructure to the limits declared in the Infrastructure Register"* is not sufficient. The IM has also to inform RUs about temporary restrictions to its infrastructure, which are not to be described in the RINF, but in the Infrastructure restrictions data base regulated by the TAF TSI (and also useful for passenger trains).

5th § The statement referring to the "route book" is unclear. The RU has not to *"to refer to the route book described in the OPE TSI to establish if there are any train related restrictions"*, but it has to write the route book and to deliver it to its drivers! (§ 4.2.1.2.2 of the OPE TSI). The IM is required to advise the RU of any changes that will affect the content of the "Route Book" including in "real-time".

6.2 Role of the IM

Last § RINF *"needs to be available in advance"* please make a reference to the appropriate Directive or TSI.

7.2 Link between specific cases, derogations and partial application of TSIs in the case of renewal/upgrading

Here the case of derogation could be a little bit more taken into consideration as below:

For new or upgraded/renewed subsystems and vehicles:

- "When chapter 7 allows for flexibility, it is not necessary to ask for derogation.
- When derogation is asked for:
 - o Either it is because the project is at an advanced stage: this stage is to be evaluated vis-à-vis the date of entry into force of the TSI. It is not linked to a national specific date.
 - o Or it is because to comply with the TSI would be a cause of economic failure of the project. In a lot of cases, this is independent from national specificities."

It is the reason why, in order to limit bureaucracy, an “EC” decision about derogation related to a vehicle or to a subsystem should not be limited to a MS and should be valid EU widely. Of course, this does not mean that such vehicle or subsystem would be automatically accepted in any country as being technically compatible.

8 ROLES AND RESPONSIBILITIES

The statement relating to the sub-contracting is unclear and even false as contradictory to article 4 §4 of the SD. We suggest deletion of *“but they may not create new requirements, roles or responsibilities.”* But DV29 must be equally clear that an IM/RU/ECM etc. cannot absolve themselves of responsibility because they sub-contract it.

8.1 *“The applicant may be the contracting entity or the manufacturer, or...”*: This and following quotes from Article 18(1) are related to the EC verification procedure, not to authorisation for placing in service. It should be checked if similar rules are valid for the latter and the role of the CSM assessment body has also to be taken into account.

8.3 The cases of the vehicles of the IMs (infrastructure inspection and maintenance vehicles) and also the technical compatibility between different trackside subsystems (INF/ENE/trackside CCS on one hand, adjacent or parallel line sections in the other hand) must be dealt with.

3rd §: *“Where the network does not conform to TSIs or national rules, the IM must to maintain it to a declared and published set of limits.”* It is not clear to us what this means and we would seek clarification, please clarify!

5th §: IM's may also act manufacturers (ÖBB is the manufacturer of four interoperable overhead contact lines).

9.3 European register of authorised type of vehicles (ERATV)

Last § The statement about the route book is not right. (See CER remark about 6.1). We suggest deletion of the sentence *“Train-route compatibility is covered by the “route book” envisaged by the OPE TSI”*

We would further point out that the “Route Book” is designed as a route guide for drivers and whilst it may show restrictions, it cannot be considered as sufficient to cover all aspects of train/route compatibility.

3. CHANGES PROPOSED TO THE FUTURE LEGAL FRAMEWORK

- Type authorisation shall be worked on at ERATV working party, as opposed to what is suggested in ERATV intermediate report,
- Some concepts should be defined: “substantial”, “significant” and “important” modifications, “type” (which modification in design would cause a type change?). We would reiterate that there is a lack of definitions in this paper and we would strongly recommend inclusion of a glossary of terms/definitions.
- Besides the RINF, there is a need for the infrastructure restriction database and last minute measures in order to allow the RU to be confident on D-day line characteristics for checking route compatibility for its trains. The role given to the route book is not the right one
- Role of standards in the authorisation process needs clarification (Which parts are mandatory, which ones remain voluntary? What happens after changes in standards?)

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