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# RECOMMENDATION FOR USE

**NB-RAIL COORDINATION GROUP**

Administrative Decision according to Interoperability Directive (EU) 2016/797 art. 30.6

Co-funded by the European Union

| RFU-STR-700 | Issue 03<br>Date 18/11/2021 |
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## TITLE

GUIDANCE FOR APPLICATION OF CB AND CD BY TWO DIFFERENT APPLICANTS

| ORIGINATOR | SUBJECT RELATED TO |
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| VÝZKUMNÝ ÚSTAV ŽELEZNIČNÍ, A.S. (VUZ)<br>ARSENAL RACE<br>STRATEGY SUBGROUP | IOD 2008/57 and IOD 2016/797<br>ALL APPLICABLE TSIS<br>COMMISSION DECISION 2010/713/EU |

AMENDMENT RECORD:

ISSUE 02: IOD REFERENCES UPDATE

ISSUE 03: POINT 2 MODIFIED FOR SENSITIVE DATA ISSUE

## DESCRIPTION AND BACKGROUND EXPLANATION

According to Commission Decision 2010/713/EU, chapter „Module CD. Conformity to type based on quality management system of the production process“, article 3.1, it is stated that manufacturer's application for certification of ICs according to module CD shall include also:

- the technical documentation of the approved type and a copy of the EC-type examination certificate (to module CB).

Question:
Can a module CD make a reference to a module CB from different applicant?

## RFU PROPOSAL

In this RFU the “applicant 1” is related to applicant of design phase module CB and “applicant 2” of module CD.

**Yes, it is possible that the applicant 2 for module CD is different from the applicant 1 of the module CB.**

The following related topics have been subject of uncertainties in the past and are therefore explained in this RFU:

1) Interfacing between Applicant 1 and Applicant 2:
   It is obvious, that the interface between applicant 1 and applicant 2 must be managed in a formal and controlled manner, to ensure that relevant requirements/ information on the production process and possible (small) modifications (which do not interfere with the characteristics of the type) to the product during production are evaluated/ known by the design team as well as the production team as necessary.
   Also feedback from the production and serial testing may be of relevance for the

design team, which in turn may necessitate small adjustments to the production process.
This need for professional interfacing is not different from the case where design and production are performed by the same applicant in different production sites. The robustness of interfacing process must be demonstrated as part of the CD module assessment activities.

2) Availability of "the technical documentation of the approved type" (2010/713/EU CD Article 3.1) at the CD Applicant 2:
The NoBo has to assess if all the necessary elements contained in the technical documentation is available for applicant 2.

   The necessary elements to be checked by the NoBo, in this context, do not compulsory include the whole set of technical documentation defined in module CB. It shall include at least the documentation necessary for the correct manufacturing (including related validation and testing).

3) Specimen for Type tests / Specimen for Tests to demonstrate the capabilities of the Production Line:
In some cases applicant 1 and 2 cooperate also for module CB. When applicant 1 is not capable of producing prototype by himself, then the type test (if required) must be performed with a product which was produced by the production line of applicant 2. In this case it will be necessary for Applicant 1 and Applicant 2 to cooperate in order to complete the module CB activities of applicant 1 first and secondly to complete the module CD at Applicant 2.

   The series production of the specimen, or of the ICs, and the specimen for type tests shall be manufactured according to an equivalent set of specifications, including drawings, procedures and quality plan. Any differences that could influence the outcome of the type tests shall be shown to be acceptable.
In other cases it may be required by TSIs or standards, that the capability of each production line must be demonstrated by a test of a specimen taken from that production line. This activity must be performed as part of module CD by Applicant 2.

4) Product -examinations by manufacturer during and at end of production:

   2010/713/EU CD Article 3.3: "The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point CD 3.1, second paragraph, fifth indent, to verify the manufacturer's ability to identify the requirements of the TSI and to carry out the necessary examinations with a view to ensuring compliance of the interoperability constituent with those requirements."
The NoBo as part of module CD shall evaluate if applicant 2 has the necessary competence and know-how in the product technology necessary for manufacturing the IC. This includes the applicant's ability to derive from "the technical documentation of the approved type" the necessary definition of product

requirements and product-examinations (in each case adjusted to the product technology) to assure that manufacturer (applicant 2) is capable of producing the IC in accordance with the EC Type Examination Certificate. From experience it is known, that in most cases – depending on the technology of the IC – this will require additional documentation for manufacturing of the IC to that documentation which was prepared under module CB by applicant 1.

5) Modifications/ Change Management:

   The notified body has as part of module CD to evaluate that the resulting products are conform to the approved type and also to the TSI and standards as defined by the designer (applicant 1) during module CB. If (small) modifications are present (e.g. tolerated geometric differences to the approved type, which are still in conformity with the TSI and defined standards and do not invalidate the assumption, that type tests performed on a prototype are still representative for the series products), then the Applicant 2 has to demonstrate conclusively to the NoBo that these do not create an unacceptable deviation from the approved type or to the TSI and standards as defined by the designer. In many cases applicant 2 may need/ wish to cooperate with applicant 1 to establish this argument.

   It is further important that the additionality of multiple small modifications is evaluated.

   Based on continuous improvement activities the manufacturer may decide to define (small) changes to the production/ examination requirements. In this case the same applies as stated for (small) modifications.

   As part of module CD the applicant 2 needs to demonstrate the change management process they use to control the effects of modifications and changes.

6) It is not required to conduct certification of the same IC according to CB module for applicant 1 and CD module for applicant 2 by the same NoBo.

7) Note: It has to be respected that the manufacturer (applicant 2) declares on his sole responsibility that the IC concerned are in conformity with the type described in the EC-type examination certificate and that they satisfy the requirements of the technical specification for interoperability (TSI) that apply to it. Applicant 1 is not required or involved in this declaration.

| THIS RFU WAS AGREED ON |
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| PLENARY MEETING 063 |
| **THIS RFU ENTERS INTO FORCE ON** |
| 18/11/2021<br>FROM THIS DATE ON THIS RFU CAN BE APPLIED INSTEAD OF THE PREVIOUS MANDATORY VERSION. |

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| **RFU APPLICATION IS MANDATORY STARTING FROM** |
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| 18/11/2021<br>AT THIS DATE ANY PREVIOUS VERSIONS OF THIS RFU WILL BE WITHDRAWN.<br>RFUS SHALL BE APPLIED BY ALL NOBOS. PLEASE REFER TO RFU-STR-702, CHAPTER 3 OF THE SECTION "DESCRIPTION AND BACKGROUND EXPLANATION", FOR THE LEGAL BASIS SUPPORTING THIS OBLIGATION. |
| **ERA COMMENTS** |
| PLE 063 – 10/11/2021: NO COMMENTS |