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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 04 Date 19/06/2024

TITLE

GUIDANCE FOR APPLICATION OF TYPE EXAMINATION (CB / SB) AND CONFORMITY TO TYPE BASED ON QUALITY MANAGEMENT SYSTEM OF THE PRODUCTION PROCESS (CD/SD) BY TWO DIFFERENT APPLICANTS

ORIGINATOR	SUBJECT RELATED TO
VÝZKUMNÝ ÚSTAV ŽELEZNIČNÍ, A.S. (VUZ) ARSENAL RACE STRATEGY SUBGROUP	IOD 2016/797 ALL APPLICABLE TSIS FOR RST AND CCO COMMISSION DECISION 2010/713/EU

AMENDMENT RECORD:

ISSUE 02: IOD REFERENCES UPDATE

ISSUE 03: POINT 2 MODIFIED FOR SENSITIVE DATA ISSUE

ISSUE 04: REVIEW BY **CLARIFYING (THE PRODUCTION SITE FOR THE RST AND CCO SOFTWARE UPDATE IN CASE OF CONFORMITY TO TYPE) AND EXTENSION TO SUBSYSTEMS MODULE SB+SD;**

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).

According to Commission Decision 2010/713/EU, chapter “Module SD. EC verification based on quality management system of the production process”, article 3.1, it is stated that the applicant’s application for assessment of subsystem’s according to module SD shall include also :

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

Question:

Can a module CD make a reference to a module CB from different applicant/manufacturer?
Can a module SD make a reference to a module SB from different applicant?

RFU PROPOSAL

In this RFU the “applicant 1” is related to applicant for assessment of design phase (CB or SB) and “applicant 2” to the applicant for assessment of production QMS (CD or SD).

Yes, it is possible that the applicant 2 for production QMS assessment is different from the applicant 1 of the type examination.

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 production QMS assessment activities.

2) Availability of "the technical documentation of the approved type" (2010/713/EU CD or SD Article 3.1) at the 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 type examination module CB or SB. It shall include at least the documentation necessary for the correct manufacturing (including related validation and testing).

3) 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*."

   2010/713/EU SD Article 3.3: "*The audit shall include an assessment visit to the premises of the relevant entities concerned. The auditing team shall review the technical documentation referred to in point SD 3.1, second paragraph, seventh indent, to verify the ability of the relevant entities concerned to identify the requirements of the relevant TSI(s) and to carry out the necessary examinations*

with a view to ensuring compliance of the subsystem with those requirements."

The NoBo as part of module CD or SD shall evaluate if applicant 2 has the necessary competence and know-how in the product technology necessary for manufacturing the object under assessment. 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) seeking to provide assurance on capability to produce the object under assessment in accordance with the EC Type Examination Certificate. From experience it is known, that in most cases – depending on the technology of the object under assessment – this will require additional documentation for manufacturing of the object to that documentation which was prepared under module CB or SB by applicant 1.

4) Modifications/ Change Management:

   a. Of the design

The notified body has as part of module CD or SD to evaluate that the resulting products are conform to the approved type and to the TSI and standards as defined by the applicant 1 during module CB or SB. 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 NoBo has to check that these do not create an unacceptable deviation from the approved type or to the TSI and standards as defined by applicant 1.

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

   b. Of the production

Based on continuous improvement activities the applicant 2 may decide to define (small) changes to the production QMS requirements. In this case the same applies as stated for (small) modifications.

As part of module CD or SD the NoBo has to check the change management process of applicant 2 they use to control the effects of modifications and changes.

When deploying upgrade of software solutions impacting the TSI compliance of a vehicle, the deployment process of the software solution is performed on flexible way allowing a reduced standstill time of the vehicle. Such a deployment process part of the production QMS of the upgraded software solution may involve fixed and or mobile teams, and may be aligned with maintenance activities or not. In such a case, the approach is similar to a multi-site organisation as defined by "IAF

Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization" (IAF MD 1).

The NoBo has to check the description covered by the single production QMS comprising an identified central function at which certain processes/activities are planned and controlled, and a number of sites at which such processes /Activities are fully or partially carried out. Mobile teams, if any, shall be linked to one to a permanent or a temporary site (depending the organisation, central function could be one of those sites).

5) It is not required to conduct certification of the same object under assessment according to CB or SB module for applicant 1 and CD or SD module for applicant 2 by the same NoBo.

6) Note: The NoBo has to respect that the applicant 2 declares on his sole responsibility that the object under assessment concerned is in conformity with the type described in the EC-type examination certificate and that it satisfies 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

PLENARY MEETING 071

THIS RFU ENTERS INTO FORCE ON

03/07/2024 (DATE OF PUBLICATION)

FROM THIS DATE ON THIS RFU CAN BE APPLIED INSTEAD OF THE PREVIOUS MANDATORY VERSION.

RFU APPLICATION IS MANDATORY STARTING FROM

03/07/2024 AT THIS DATE ANY PREVIOUS VERSIONS OF THIS RFU WILL BE WITHDRAWN.

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 071 – 19/06/2024: NO COMMENTS