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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-059	Issue 03 Date 09/11/2020

TITLE	
APPLICATION OF H MODULES FOR DESIGN EXAMINATION	
ORIGINATOR	**SUBJECT RELATED TO**
NB-RAIL SUB-GROUP STRATEGY	IOD 2016/797 H2/CH1 AND SH2/SH1 ASSESSMENT MODULES

AMENDMENT RECORD:

ISSUE 02: IOD REFERENCE UPDATE

ISSUE 03: 2008 IOD REFERENCE DELETED, ERA TO ATTACHED

DESCRIPTION AND BACKGROUND EXPLANATION

Scope

This question is related to the sampling of technical requirements in design examination according to the modules H2/CH1 and SH2/SH1 of Rolling Stock Interoperability Constituents and Subsystems. The requirements of RST + PRM + SRT + NOI TSIs are concerned too.

Note: decision 2010/713/EU introduced new modules to be applied with those TSIs entered into force after 01/01/2011, providing a "correlation table" in Annex 3 so to understand the correlation existing with the "old" modules. Some modules changed their names, some not; therefore, this RFU will refer to those modules which changed their names in the following way: "module H2/CH1" means the "old" module H2, renamed as CH1 by the Decision 2010/713/EU.

Introduction

H2/CH1 and SH2/SH1 modules plan:

- The "quality system approval" covering design and production phases, based on a Quality audit. It's issued if the quality system of the applicant is compliant with quality
- requirements listed in these modules.
- The surveillance of the quality system, based on periodical quality audits.
- **The "design examination certificate" based on the assessment of the design. This certificate is issued if the Constituent or Subsystem is compliant with the requirements of the applicable TSI(s).**

SH2/SH1 module plans in addition:

- The "EC certificate of verification". It's issued when above activities and final testing gave satisfactory results.

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After discussions among NoBos, it seems that 2 different interpretations exist:

1. The usual principle of quality assessment (= sampling) is applicable to all the chapters of the CH1/H2/SH1/SH2 module, including the chapter related to “design examination”.
This means that the “design examination” is not a detailed assessment of each individual requirement of the TSI, but an assessment of a part of the requirements, chosen by the NoBo, as the quality audit of the design phase showed that the applicant performed a satisfactory design process and that all the applicable requirements have been considered by the manufacturer.

2. The usual principle of quality assessment (= sampling) is applicable to chapters related to quality audits in module CH1/H2/SH1/SH2, but is not applicable to the chapter related to “design examination”.
This means that the “design examination” is a detailed assessment of each individual requirement of the TSI, even if the good results of quality audits showed that the applicant performed a satisfactory design process.

RFU PROPOSAL

ERA issued the TO ERA/OPI/2011-01/INT on 07/02/11 (this TO is attached to the present RFU) answering two questions raised by France; question 1 seems to reply to this RFU.

Question 1: During the procedure of EC design examination, is it authorised for a notified body to use a method based on estimations, tests or sampling ?

No, the notified body shall perform an assessment of the design by checking all the requirements of the relevant TSIs. This assessment is based on the application documents only. The notified body shall not put into question the correctness of the results because the validity of the application documents is insured by the QMS put into place by the applicant.

NB Rail takes this ERA TO in conjunction with 2010/713/ EU as the answer to this RFU and complementary give an overview the goals and tools of the NoBo in the application of module H2/CH1 and SH2/SH1.

Therefore the NoBo must check that the applicant covered all the TSI requirements and the results are compliant, but it has to trust the quality and correctness of the calculations and test methods that led to these results.

Full quality management system

The **objective** is to make sure that the quality management system applied by the applicant:

- cover the different stages of the EC conformity assessment/EC verification
- ensure compliance of the subsystem with the requirements of the relevant TSI and decision 2010/713/EU that apply to it

In order to make this, the NoBo has the following **tools**:

- progressive evaluation 'TOP-DOWN' of the technical documentation (cfr. List at§4.2 of module CH1/SH1), for example by technical domain. The technical documentation is evaluated in order to make sure that the applied processes by the applicant are producing results conform to the TSI's requirements. Once the NoBo has enough confidence in the results of the applied processes, he will trust in the correctness of the technical documentation and of the supporting evidence for the adequacy of the technical design and he will not go further in the evaluation of the technical documentation. If a problem is met during this progressive evaluation, it will be considered as a weakness of the applied QMS and this subject will be part of the quality audit.
- analysis of the principle documents (cfr. List in §3.2 of module CH1/SH1) supporting the full quality management system;
- quality audit by an audit team having at least one member experienced as an assessor in the relevant subsystem field and product technology concerned and having knowledge of the requirements of the relevant TSI and one member experienced as lead auditor for quality management system.
- surveillance audits to make sure that objectives are still fulfil until the end of the project. For example: The surveillance audit of the 'design stage' can be done during the audit of the 'production stage'.

By the full quality management system (QMS) the NoBo has to take into account the QMS of the applicant as the QMS of the main contractors. Indeed, the NoBo has to evaluate all the QMS supporting the compliance of the constituent/subsystem with the requirements of the relevant TSI's.
The progressive evaluation 'TOP-DOWN' of the technical documentation can be considered as the interface between the QMS evaluation and design examination. Any way it has to be done to have enough confidence in the application of the QMS of the applicant.

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Design examination

The **objective** is to make sure that the applicant has taken in account all the requirements of the applicable TSI during the conception of the subsystem.
In order to meet this objective, the NoBo shall perform the following tasks:

- checking that all the applicable requirements have been completely and correctly identified checking that the applicant's management system ensures that all applicable requirements are properly considered.
- checking that appropriate conformity evidence exists for each applicable requirement

THIS RFU WAS AGREED ON
PLENARY MEETING 060
THIS RFU ENTERS INTO FORCE ON
09/11/2020 (DATE OF PUBLICATION) FROM THIS DATE ON THIS RFU CAN BE APPLIED INSTEAD OF THE PREVIOUS MANDATORY VERSION.
RFU APPLICATION IS MANDATORY STARTING FROM
09/11/2020 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 060 – 04/11/2020: NO COMMENTS PROVIDED TO NB-RAIL BY WRITTEN PROCEDURE BEFORE PLE 060 AND OR DURING PLE 060.

TECHINICAL OPINION OF THE EUROPEAN RAILWAY AGENCY REGARDING: THE APPLICATION OF MODULES SH1 FOR DESIGN EXAMINATION

REFERENCE:	**ERA/OPI/2011-01/INT**	**DOCUMENT TYPE:**	**TECHNICAL OPINION**
VERSION:	FINAL	**REFERENCE TO TSI:**	
DATE:	07/02/2011		

Amendment record

Version	Date	Section number	Modification/description	Author
0.1	28/01/2011		First Draft	O. PIRON
0.2	28/01/2011		Clarification of the text	D. DIMITROVA
0.3	28/01/2011		Comments	Z. BILALIS – DG ENTR
0.4	2/02/2011		Table added	O. PIRON

1. Introduction

During 58th RISC meeting held on 19 and 20 October 2011, France presented a note regarding clarifications on the use of module SH2. This note is available in annex 1.

After this presentation, DG MOVE requested the Agency to give a technical opinion on the subject.

2. Question to the Agency

Based on the note presented by France, the questions can be summarised as follows:

1. During the procedure of EC design examination, is it authorised for a notified body to use a method based on estimations, tests or sampling ?
2. Should the assessment of the bodies carrying out conformity assessment and EC verification involve checking their competencies to assess according to particular modules?

3. Support documents

The following documents have been used to prepare this technical opinion:

- [A1] Note from France available in annex 1
- [A2] Commission Decision 2009/.../EC of ... concerning the modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the Technical Specifications for Interoperability
- [A3] Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC
- [A4] Guide to the implementation of directives based on the New Approach and the Global Approach, © European Communities, 2000
- [A5] EN ISO/IEC 17021 Conformity assessment — Requirements for bodies providing audit and certification of management systems
- [A6] EN 45011:1989 General requirements for bodies operating product specification systems (ISO/IEC Guide 65:1996)
- [A7] Directive 2008/57/EC European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community

4. Analysis

4.1. Foreword

The note [A1] involves module SH2 (Conformity based on full quality assurance plus design examination) as described in the HS RST TSI and rolling-stock subsystem.

As the procedures described in module are applicable to a large range of subsystems, the following analysis does not apply to HS RST TSI only. The analysis is also valid for all TSIs where the module describing the same procedure is envisaged, i.e. module SH2 for existing TSIs and module SH1 for the TSIs to enter in force after [A2] is enacted.

According to decision [A2], the module based on full quality management system plus design examination is called SH1 and describes the same procedure as the module SH2 of the HS RST TSI. The analysis below refers to SH1 according to decision [A2].

4.2. Full quality assurance

Module SH1 is a variant of module H defined in Decision [A3]. The particularity of the module H family is that the conformity is based on full quality assurance.

Full quality assurance is where the applicant has in place an approved quality system for design, manufacture and final testing of the subsystem with all the requirements to demonstrate a priori the ability to consistently produce a subsystem that meets the appropriate requirements of the TSIs (and other EU regulations)

Indeed, as stipulated in Annex of [A2], §3.2. of module SH1: "*The quality management system shall ensure compliance of the subsystem with the requirements of the relevant TSI(s) that apply to it.*"

In other term, the applicant operates an approved quality system for design, manufacture and final testing of the subsystems. The notified body assesses the quality system in order to determine that this system ensures compliance of the subsystems with the relevant TSIs and any other EU regulation.

4.3. Design examination

In the particular case of module SH1, the applicant operates a full quality assurance system as requested by all module H family. In addition the verification of the conformity of design and the issuance of EC design examination certificate by a notified body is necessary.

EC design examination certificate attests that the conformity of the design of the subsystem has been checked and certified by a notified body. Thus the conformity of this subsystem will be ensured by means of a full quality system operated by the applicant and approved by the notified body.

4.4. Evaluation by the notified body

The applicant shall lodge two separate applications with the same notified body:

- application for assessment of the quality management system;
- application for the subsystem design .

As indicated in the Blue Guide [A4], EN 45000 series of standards are relevant for notified bodies. In particular EN ISO/IEC 17021 [A5] specifies the general requirements that a third party operating assessment of quality systems must meet, and EN 45011 [A6] specifies the general requirements that a third party operating a product certification system must meet.

Therefore, in Modules SH1, the notified body shall work according to EN ISO/IEC 17021 [A5] for the approval of the quality system of the applicant and according the EN 45011 [A6] for issuing the EC design examination certificate[1].

§10 of EN 45011 [A6] stipulates that *"The certification body shall evaluate the products of the applicant against the standards covered by the scope defined in its application against all certification criteria specified in the rules of the scheme."*

Therefore, all the requirements of the relevant TSIs shall be assessed by the notified body before issuing an EC design examination certificate.

As the quality system of the applicant ensures compliance of the subsystem with the requirements of the relevant TSIs, the design examination aspect is based on the evaluation of the complete application (documentation) only. It does not require that a "prototype" or "representative product" is available and physically examined by the Notified Body.

In the framework of the surveillance of the quality system, i.e. after a EC design examination certificate has been issued, the notified body may pay unexpected visits to the applicant.

During such visits the notified body may, if necessary, carry out product tests, or have them carried out under its responsibility, to verify that the quality system is functioning correctly.

This is part of the overall system put in place by module SH1and should not be seen as part of the design examination.

4.5. Competencies of the notified bodies regarding modules

Annex VIII of Directive 2008/57/EC [A7] describing the minimum criteria which must be taken into account by the Member States when notifying bodies stipulates in § 4:

[1] §1 of EN45011 [A6] stipulates clearly that design appraisal is in its scope

"The staff responsible for the checks must possess:

— proper technical and vocational training,

— a satisfactory knowledge of the requirements relating to the checks that they carry out and sufficient practice in those checks,

— the ability to draw up the certificates, records and reports which constitute the formal record of the inspections conducted."

In addition, the Blue Guide in § 6.1. Principles of notification stipulates: *"Member States take the final responsibility for the competence of the notified bodies vis-à-vis the other Member States and the Community institutions. Therefore, they must verify the competence of the bodies seeking notification. This shall be based on the criteria laid down in the applicable directive in conjunction with essential requirements and the conformity assessment procedure in question."*

And § 6.4.: *"The conformity assessment procedures have been divided into a set of separate modules, which cannot be further subdivided without putting into question the coherence of the system and the responsibilities which should lie with the manufacturer and, where applicable, the notified bodies. This means that a notified body must be capable of taking the responsibility and have the competence to carry out the conformity assessment according to a complete module or for several complete modules. Consequently, the body cannot be notified for part of a module. For instance, as regards the module Hbis [read SH1 for this TO] a body may not be notified to deal with the design phase only."*

5. Technical opinion

Based on the analysis above, the Agency has the following opinions:

Question 1: During the procedure of EC design examination, is it authorised for a notified body to use a method based on estimations, tests or sampling ?

No, the notified body shall perform an assessment of the design by checking all the requirements of the relevant TSIs. This assessment is based on the application documents only. The notified body shall not put into question the correctness of the results because the validity of the application documents is insured by the QMS put into place by the applicant.

The following table summarizes the major tasks and responsibilities of the applicant and the notified body when module SH1 applies:

	Art	Tasks of applicant	Art	Tasks of notified body
Quality management system	3.2	Establish quality management system *The quality management system of the applicant insures compliance of the subsystem with the TSIs.*		
	3.1	Submit an application for the QMS assessment to the notified body		
			3.3	Assess the QMS to determine whether it satisfies 3.2 (i.e. the QMS insures that subsystem is conform the TSIs
			3.3	Issue a quality management system approval to the applicant
	3.4	Maintain the QMS		
EC verification	4.2	Submit an application for EC verification of subsystem with technical documentation and supporting evidence of the adequacy of the design		
			4.4	Examine the application for EC verification Examine where the design meets the TSIs requirements. *The design is checked regarding all the requirements of the TSIs. The checks are based on the documents given by the application.* *Confidence in the application (technical documents, tests carried out, results, supporting evidences, etc.) is insured by the QMS of the applicant .*
			4.4	Issue an EC design examination certificate
Surveillance			5.3	Carry out periodic audits *(for design, manufacture, assembly or installation)*
			5.4	Carry out unexpected visits *The notified body may carry out tests in order to check the proper functioning of the QMS*
EC declaration			6.1	Issue an EC certificate of verification
	6.2	Draw up a EC declaration of verification with reference to: • the quality management system approval • the EC design examination certificate		

Question 2: Should the assessment of the bodies carrying out conformity assessment and EC verification involve checking their competencies to assess according to particular modules?

Yes, the competencies of notified body for the application of modules shall be demonstrate prior to the notification.