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## RECOMMENDATION FOR USE

### NB-RAIL COORDINATION GROUP

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



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**RFU-STR-092**

Issue 03  
Date 23/06/2020

#### TITLE

USE AND COMPARISON OF THE DIFFERENT ASSESSMENT MODULES FOR SUBSYSTEMS

#### ORIGINATOR

SUBGROUP STRATEGY (ARSENAL RACE)

#### SUBJECT RELATED TO

IOD 2008/57 and IOD 2016/797  
Decision 2010/713/EU and all 'old'  
TSIs with module descriptions

AMENDMENT RECORD: ISSUE 03, IOD REFERENCES UPDATE

#### DESCRIPTION AND BACKGROUND EXPLANATION

##### Explanatory statement:

Due to the ongoing misunderstanding of the modules by clients and some NoBos this RFU has been drafted. The main reasons are therefore the following:

- To provide clients a useful guideline when choosing a module (see also table 19 in Application Guide ERA/GUI/07-2011/INT Version 1.02 of 30 November 2012)
- To explain and highlight the differences and ad- or disadvantages of the different modules
- To explain the correct use of the different modules
- To explain the responsibilities of the parties involved in EC-verification (especially responsibility for testing – link to RFU-STR-022)

##### Description and background explanation:

Within the scope of the Interoperability Directive 2008/57/EC specific assessment modules have been defined, that have been derived from the generic assessment module that are defined in 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, which are used in a wide range of industries.

Initially these modules were defined in the Annexes of the Technical Specifications for Interoperability (TSIs). For TSIs published after 2010, these modules are defined in the separate Decision 2010/713/EU and are no longer in the Annexes of the TSIs. The abbreviations of the modules changed slightly with the Decision 2010/713/EU. For modules for subsystems the 'old' module SH2 was renamed to SH1. In this RFU the abbreviation SH1/SH2 is used to account for both.

The following modules can be applied for EC verification of subsystems:

- Module SG - EC verification based on unit verification
- Module SB – EC-type examination
- Module SF – EC verification based on product verification
- Module SD – EC verification based on quality management system of the production process
- Module SH1/SH2 – EC verification based on full quality management system plus design examination

It has to be kept in mind that module SB cannot be used alone – it needs another module



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(SD or SF) to finish the EC-verification and to be able to issue an EC Certificate of Verification. Therefore the following combinations of modules are possible:

- SG
- SB + SF
- SB + SD
- SH1/SH2

In chapter 6 of each TSI it is stated which module and which module combination is allowed for the procedure of the EC-verification. Some modules are not possible in some TSIs or subsystems (e.g. module SB+SD is not possible for TSI Infrastructure).

For simplicity reasons interoperability constituents are not regarded in this RFU.

### RFU PROPOSAL

Each module has advantages and disadvantages depending on the design, complexity and amount of similar parts in a project. The following figures help to understand the different modules and to define the scope of work for the notified body as well as the applicant according to each module. The examples displayed in each figure are chosen to be well suited for that specific module.

Legend of symbols used in the figures:



Subsystem or  
Part of Subsystem



EC-Certificate



Assessment by NoBo

Jigsaws that have the same pattern are identical parts of a subsystem. This means, that they are based on the same drawing, specification or calculation in the design phase. In the production phase the parts with the same pattern are produced then according to the same design. The interfaces between different parts are displayed through the connections of the jigsaw pieces. These interfaces are part of the verification by a NoBo.

The phases of EC-verification are shown on the horizontal axis whereas the project characteristics are displayed on the vertical axis. The phases are simplified to "DesignPhase" and to "Production-Phase" to limit the complexity of the figures. These two phases shall account for the different phases that are defined in the different TSIs. The "Design-Phase" also includes type examination where this is applicable. Type examination includes production and assessment of a representative prototype. The "Production-Phase" in this RFU also includes the phase "final testing" (see stages in Annex VI of Directive 2008/57/EC point 2.2.3).



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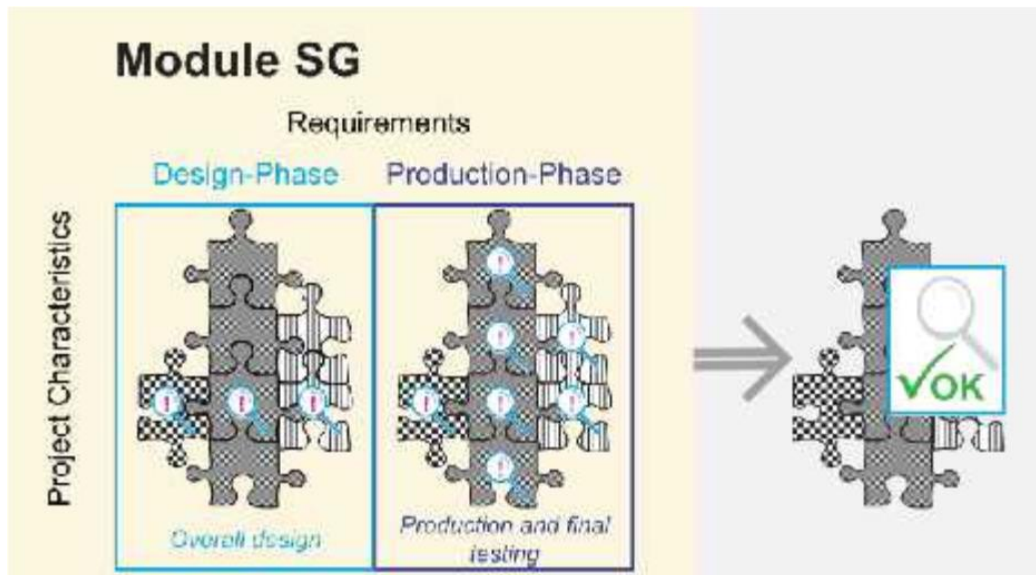
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#### Module SG - Unit verification



The task of the notified body in module SG is to assess all different subsystems in a project according against all applicable TSI requirements. Parts with identical design (= same pattern of jigsaw in figure above) do not have to be checked twice in the design phase. In the production phase each subsystem has to be checked regardless of identical design, because there is no quality management system to rely on (jigsaws with same pattern have to be checked individually). For the assessment, the notified body can take into account evidence of examinations, checking, or tests by other bodies under certain conditions as defined in the module description (accreditation, witnessing, etc.), but the notified body still has to verify all the results of these checks or tests by himself (see point 5.2 of module SG in 2010/713/EU). Especially for the production phase it is not allowed for the notified body to assess only one part (sampling) according to all TSI requirements and to rely on the results of other bodies for all other parts without verifying the results of the examinations or tests for all the other parts. The RFU-STR-022 applies for all tests and gives criteria for acceptance of tests performed by other testing bodies.



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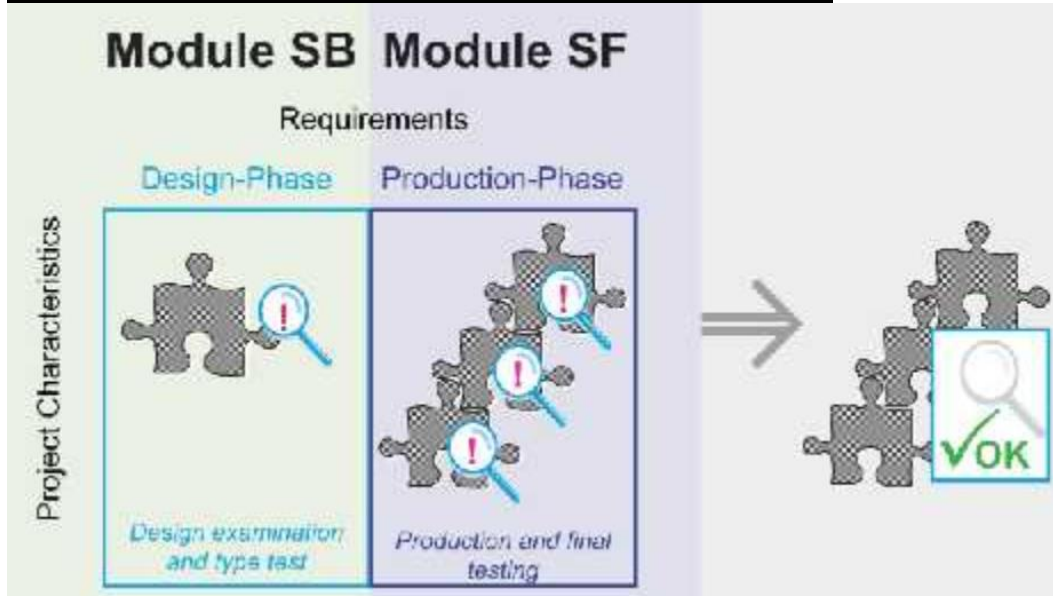
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#### Modules SB+SF – Type examination + product verification



EC-type examination (module SB) is a first part of an EC verification procedure that covers the design phase. It is always followed by another module demonstrating the conformity of the products with the approved type. The examination has to be carried out for the 'design type' (= design examination) and the 'production type' (equal to specimen) (=type test) as stated in point 2 of module SB in Decision 2010/713/EU. For the design type the notified body has to examine the technical documentation and supporting evidence to assess whether the technical design of the subsystem is adequate to fulfil the requirements of the TSI. For the production type the notified body has to verify that the specimen(s) have been manufactured in conformity with the TSI requirements and carry out appropriate examinations and tests, or have them carried out according to RFU-STR-022. Where the type meets the requirements of the relevant TSI(s) that apply to the subsystem concerned, the notified body shall issue an EC-type examination certificate with the necessary data for the identification of the approved type. It is important that the specific type is clearly identified and described. EC verification based on product verification (module SF) follows module SB. The notified body shall carry out appropriate examinations and tests in order to check the conformity of the subsystem with the approved type as described in the EC-type examination certificate. This then implies conformity with the requirements of the relevant TSI(s). All subsystems shall be individually examined and appropriate tests set out in the relevant TSI(s), harmonised standard(s) and/or technical specifications, or equivalent tests shall be carried out in order to verify conformity with the approved type (for use of tests results see RFU-STR-022).

The application of this module combination will be limited to a certain amount of subsystems due to costs of assessment work by notified bodies, because every characteristic of every single subsystem has to be examined individually by the notified body.





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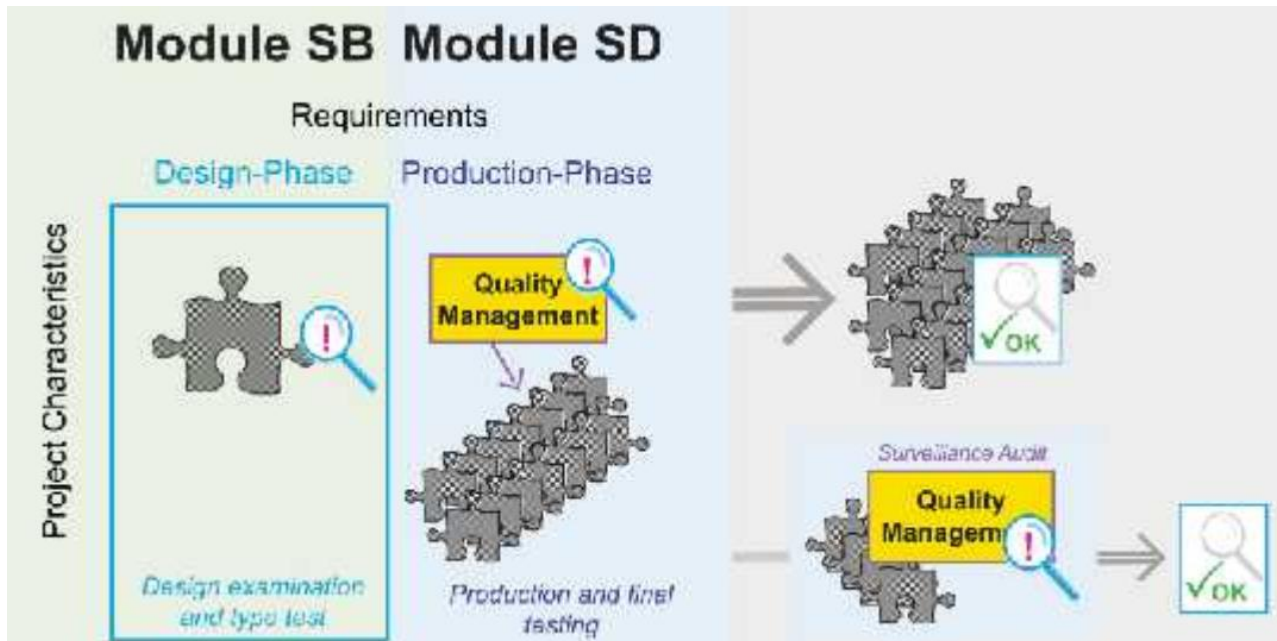


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#### Modules SB+SD – Type examination + quality management system for production



EC-type examination (module SB) is already described above. EC verification based on the quality management system of the production process (module SD) follows on module SB. The quality management system shall ensure by means of QMS documentation that the subsystem is in conformity with the type described in the EC-type examination certificate and therefore complies with the requirements of the relevant TSI(s). The notified body shall assess the quality management system for production to determine whether it assures conformity with the type and issue a QMS approval certificate.

The notified body does not have to take part in any tests performed in the production phase, because he can rely on the approved quality management system. Once the quality management system approval has been issued by the notified body, then the manufacturer can reproduce the subsystems according to the approved type during the validity period of the certificate. To prolong the validity of a certificate one or more surveillance audit(s) must be carried out by a notified body. This may be ongoing surveillance and may include unexpected visits.

Application of this module combination fits well for subsystems that are reproduced identically in large numbers, but it is limited to the specific type that has been approved. If there are changes or variations of the type then a new type examination has to be performed. Moreover, only the exact type as approved can be reproduced. The recommendation 2011/217/EU gives guidance on modifications of already approved types (Note: The document "DV29bis" has been published as 2014/897/EU and contains more detailed guidance about modifications).

If the manufacturer of a part of the subsystem or the whole subsystem is changed



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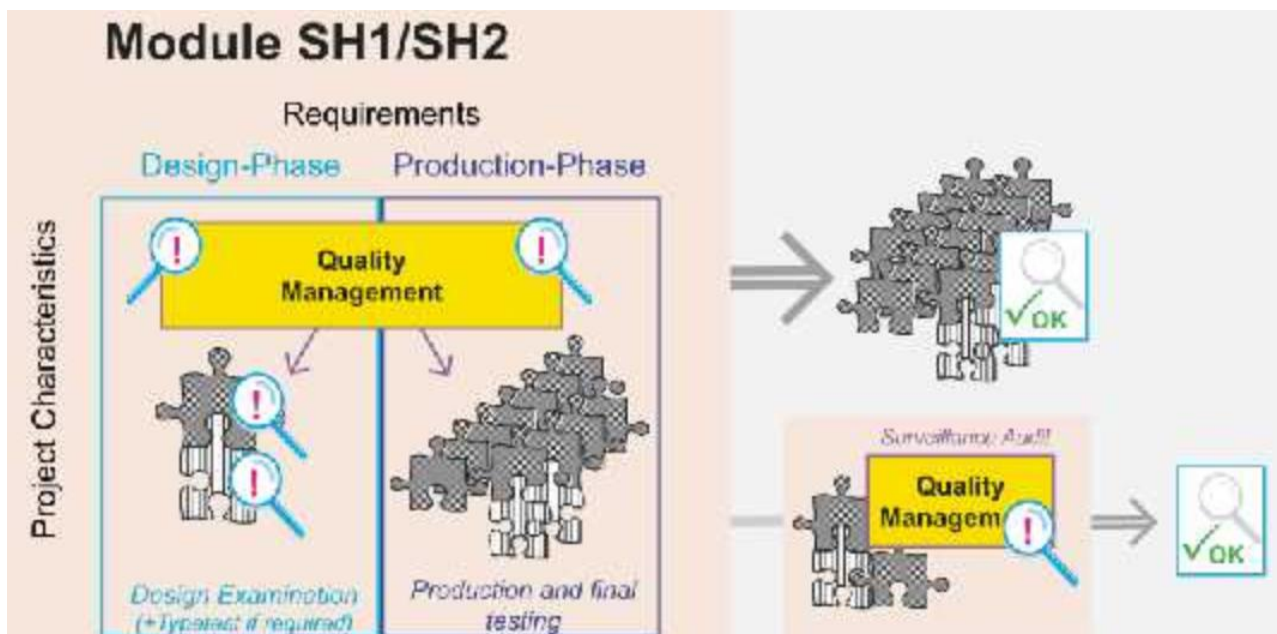
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during the project than a new assessment of the quality management system for production of this manufacturer has to be carried out.

If projects have a short time schedule and if experiences from assessment with similar types are available, then the activities for modules SB and SD or SB and SF can take place in parallel. However, the modules SB must be finished before or on the same date as module SD or SF.

Note: In these cases, a negative SB assessment can lead to delays in the project.

#### Module SH1/SH2 – Full quality management system plus design examination



The applicant can apply for EC verification of the subsystem(s) through full quality management system and examination of the design with a notified body. The design, manufacture and final inspection and testing of the subsystem concerned shall be covered by an approved quality management system that is checked against all the requirements of the relevant TSI(s) by a notified body. The notified body has to examine the design of the subsystem and, where the design meets the requirements of the relevant TSI(s) that apply to the subsystem, it shall issue an EC-design examination certificate.

The “RFU-STR-059 on the application of H modules for design examination”, that takes the Technical Opinion “ERA/OPI/2011-01/INT” of 07/02/11 into account, states clearly that in this phase all requirements have to be checked by the NoBo and sampling is not allowed (for more detail see text of RFU-STR-059). Where this is required by a TSI, also a type test has to be performed by the applicant according to RFU-STR-022. For tests in the production phase RFU-STR-022 does not apply, because all the tests are carried out under the already approved quality management



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system of the applicant (however, NB Rail is recommending to use it anyhow). The EC-design examination certificate must not be confused with the EC-type examination certificate of module SB that attests the conformity of a specimen “representative of the production envisaged”, so that the conformity of the products may be checked against this specimen. Under the EC-design examination certificate there is no such specimen. The EC-design examination certificate attests that the conformity of the design of the product with the applicable TSI requirements has been checked and certified by a notified body.

The module SH1/SH2 is suitable for projects with a complex architecture, where certain parts are reproduced in a different amount within the project (one part appears in a large number and other parts with different characteristics appear only once or twice). The module is also quite flexible for changes to an already approved subsystem.

#### Note:

It should be noted that the same work needs to be done whichever module or combination of modules is selected. The point is about where the work is done – i.e. either by the applicant under their QMS or else by the NoBo being contracted to do the work. In the first case, the work is under the responsibility of the applicant (In the case of QMS based modules SD or SH) and in the second, under the responsibility of the Notified Body (in the case of ‘inspection’ based modules SF or SG).

#### **THIS RFU WAS AGREED ON**

PLENARY MEETING 059

#### **THIS RFU ENTERS INTO FORCE ON**

23/06/2020 (DATE OF PUBLICATION)

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

#### **RFU APPLICATION IS MANDATORY STARTING FROM**

23/06/2020

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 059 – 17/06/2020: NO COMMENTS