

Moving Europe towards a sustainable and
safe railway system without frontiers.

OPINION

ERA/OPI/2025-6

OF THE EUROPEAN UNION AGENCY FOR RAILWAYS

for THE EUROPEAN COMMISSION regarding

the combination of modules for assessment of conformity and
suitability for use of interoperability constituents and EC
verification of subsystems.

Disclaimer:

The present document is a non-legally binding opinion of the European Union Agency for Railways. It does not represent the view of other EU institutions and bodies and is without prejudice to the decision-making processes foreseen by the applicable EU legislation. Furthermore, a binding interpretation of EU law is the sole competence of the Court of Justice of the European Union.

1. General Context

Request for a technical opinion.

On 27 November 2025, the European Commission (EC) requested a technical opinion from the European Union Agency for Railways (the Agency) (see annex I) pursuant to Article 10 (2) Regulation (EU) 2016/796.

This request follows the Question / Clarification QC-STR-11 from NB-Rail¹ (See annex II)

2. Legal Background

According to Article 10 (2) Regulation (EU) 2016/796, *"The Agency shall issue opinions at the request of the Commission on amendments to any act adopted on the basis of Directive (EU) 2016/797 or Directive (EU) 2016/798, especially where any alleged deficiency is signalled."*

2.1. Scope and background

This opinion is issued in accordance with Article 10 (2) (d) Regulation (EU) 2016/796.

This opinion details some principles implemented by the Commission Decision 2010/713/EU² (hereinafter referred as module decision).

The module decision describes the procedures used for conformity assessment in railway and in particular the procedures for assessment of conformity and suitability for use of the interoperability constituents and for EC verification of subsystems. The modules are referred in all Technical Specification for Interoperability applicable to structural subsystems. This opinion addresses in particular:

For interoperability constituents

Module CB: EC type examination

Module CD: Conformity to type based on quality management system of the production process

Module CF: Conformity to type based on product verification

For subsystems:

Module SB: EC type examination

Module SD: EC verification based on quality management system of the production process.

Module SF: EC verification based on product verification.

The other modules described in the module decision are not in the scope of this technical opinion.

xB modules (CB and SB) are dedicated to EC type examination. EC type examination is the part of conformity assessment procedure/EC verification procedure in which a notified body examines the design and verifies

¹ NB-Rail's Coordination Group's main purpose is to discuss matters relating to the application of the relevant TSIs, of the procedures for assessing conformity or suitability for the use of interoperability constituents, and of the procedures for the verification of subsystems. <https://nb-rail.eu/>

² Commission decision of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council

Decision No 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/EEC3

and attests that the design meets the requirements of the technical specification for interoperability (TSI) that apply to it. These modules are generally called “type examination modules”.

xD modules (CD and SD) are dedicated to the manufacturing of the assessed object (Interoperability constituents or subsystem). The quality management system of the production, final subsystem inspection and testing of the object concerned shall be covered by a quality management system(s) assessed by a Notified Body. These modules are generally called “QMS modules”.

xF modules (CF and SF) are dedicated to product verification where all objects subject to assessment (subsystem or interoperability constituent) shall be individually examined and appropriate tests) shall be carried out in order to verify conformity with the approved type described in the EC-type examination certificate and with the requirements of the relevant TSI(s). These modules are generally called “product verification modules”.

2.2. Problem statement

The Technical Specifications for Interoperability specify the application of modules, some modules can be used only in combination with others.

To what concerns the use of modules: xB, xD, xF, to draw up either the EC declarations of verification for the subsystems, and/or the EC declaration of conformity or suitability for use for the interoperable constituents, the applicant can use in the context of rolling stock TSIs, a combination of either xB+xD or xB+ xF.

The current wording of Decision 2010/713/EU may result into a too strict roll-out of the conformity assessment procedures when a combination of modules is requested to perform the EC verification of a subsystem or the EC conformity assessment of an Interoperability Constituent.

In particular, the rail specific module decision contains the following requirement for module SD and SF:

“The notified body chosen by the applicant shall first examine the application concerning the validity of the EC type examination certificate and its annexes.”

It happens that Notified Bodies are facing nonconformity from the National accreditation bodies applying this strict approach i.e. the need of a full validated SB module before starting any activity of the SD or SF modules.

The development of a new railway product is often a long-lasting activity (often several years). To ensure the time to market, the production activities are generally starting before the end of the design phase. For example, the manufacturing of the bodyshell of the railway vehicles starts just after the validation of the design of the bodyshell but way before the design of the interior of the train is completed.

One other aspect is that, to ensure that all the testing activities fit into the planning, the manufacturer produces several prototypes to run the tests in parallel. In most cases, once the type is approved, the prototypes manufactured for tests are upgraded to the Type approved configuration and placed on the market.

Applying the module decision in the strictest way may lead to delays in the production and an extension of the time to market that is not compatible with the demand for railway products on the European market as well as the financial health of the railway sector.

2.3. Analysis

The module decision defines the content of the application for a Type examination certificate.

The application shall contain documents related to design and testing of the object of assessment (subsystem or interoperable constituent).

As an example, the application for module SB shall contain (among others) the technical documentation. This technical documentation shall make it possible to assess the subsystem's conformity with the requirements of the relevant TSI(s). It shall specify the requirements of the relevant TSI(s) and cover, as far as relevant for the EC-type examination procedure, the design, the manufacture and the operation of the subsystem. The technical documentation shall contain the following elements:

- results of design calculations made, examinations carried out, etc.,
- test programme and reports,

The TSIs define in chapter 7 the implementation strategy and includes provisions on the design phase. The design phase is the period starting once a Notified Body, which is responsible for EC verification, is contracted by the applicant of conformity assessment and ending when the EC type or design examination certificate is issued. (see TSI Loc&Pas³ point 7.1.3.1.1 (3) or TSI CCS⁴ clause 7.2.4.1.1(3)).

Therefore, it is clear that the documentation that shall be assessed by the notified body and what is listed in the module decision is not to be delivered at the date of application for a Type examination certificate, but all along the design phase that ends with the deliverance of the EC type examination certificate.

For the modules covering production and final testing D and F, the application shall contain (among others) the technical documentation of the approved type and the associated EC Type examination certificates.

Similarly to the deliverance of the documentation for the EC Type examination certificate, the Agency considers the assessment of the quality management system, or the product verification can be gradually performed during the project.

In such case, the notified body in charge of assessment related to modules covering production and final testing should assess:

- if the maturity of the design allows to perform the inspections and/or audits,
- the changes brought to the design and/or the manufacturing process between the inspection/audit and the delivery of the EC Type examination certificate. These checks shall cover the changes themselves and their implementation on the object of assessment.

The documentary evidence of these activities shall be part of documentation (so called 'NoBo file') accompanying the certificate.

In any case, the certificates related to modules covering production and final testing issued by the Notified Body(ies) shall be posterior to the delivery of the EC Type examination certificate.

When the EC Type examination and the product/QMS assessment is ensured by different Notified Bodies, the documentary evidence on design maturity and changes may be based on ISVs released by the Notified Body in charge of the EC Type examination.

³ COMMISSION REGULATION (EU) No 1302/2014 of 18 November 2014 concerning a technical specification for interoperability relating to the 'rolling stock —locomotives and passenger rolling stock' subsystem of the rail system in the European Union

⁴ COMMISSION IMPLEMENTING REGULATION (EU) 2023/1695 of 10 August 2023 on the technical specification for interoperability relating to the control-command and signalling subsystems of the rail system in the European Union and repealing Regulation (EU) 2016/919

2.4. Impact assessment

See Annex 3.

3. The opinion

3.1 The Agency is of the opinion that activities performed by the Notified Body in the context of the modules xD/xF can be done in parallel to those related to modules xB.

The Notified Body responsible for the modules xD/xF shall ensure that:

- At the time the inspections/audits are made, the design is mature enough to allow the verification/QMS assessment. Documentary evidence of these activities shall be part of documentation accompanying the certificate.
- The changes brought to the design and/or the manufacturing process between the inspection/audit and the delivery of the EC Type examination certificate are assessed as well as their implementation on the object of assessment. Documentary evidence of these activities shall be part of documentation accompanying the certificate.
- The EC Type examination certificate (module xB) is released before of the certificates related to production and final testing (module xD or xF).

It should be noted that xH1 modules (full quality management system with design examination) might be preferred by applicants in case of parallel activities.

3.2 The Agency is of the opinion that the statements described in 3.1 shall not be limited to the case where a single Notified Body is selected by the applicant for both modules as far as the conditions are fulfilled and documented.

3.3 The Agency is of the opinion that the wording in the module decision for module SD point 5.2 and for module SF point 4.2 "*The notified body chosen by the applicant shall first examine the application concerning the validity of the EC type examination certificate and its annexes.*" should be rephrased in a future revision to better reflect the gradual delivery of the required documentation all along the project.

Valenciennes,
Oana GHERGHINESCU
Executive Director

Annex 1: European Commission's request



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR MOBILITY AND TRANSPORT
Directorate C – Land
The Director

Ref. Ares(2025)10520874 - 01/12/2025

Brussels, 27 November 2025
MOVE.DDG2.C.4/FS

NOTE FOR THE ATTENTION OF Ms GHERHINESCU - EXECUTIVE DIRECTOR (EUROPEAN UNION AGENCY FOR RAILWAYS)

Subject: Request for technical opinion to the Commission pursuant to Article 10(2) of the EU Agency for Railways regulation (EU) 2016/796

Article 10(2) of Regulation (EU) 2016/796 sets out that the Commission may request an opinion from the Agency on amendments to any act adopted on the basis of Directive (EU) 2016/797 or Directive (EU) 2016/798. NB-Rail has reported to the Commission (*QC-STR-011*) an issue regarding the combination of modules for EC verification (SB + SD or SB + SF) or EC conformity assessment of interoperability constituents (CB+CD or CB + CF). They claim that the current wording of 2010/713/EU results into a too strict ordering of the conformity assessment procedures when a combination of modules is requested.

The Commission wish to obtain an opinion on:

- (1) The materiality of the issue described.
- (2) Its impact on the conformity assessment practices in the European rail sector.
- (3) Possible solutions to this matter both in the long term, by modifying the *Modules decision*, and in the short term by any means the Agency may consider.

Please, acknowledge the reception of this note and confirm the deadline for this opinion.

c.c.:

From ERA

From the Commission:

Annex 2: QC-STR-011 Version 1 Date 15/10/2025

 Supported by NB-Rail Association	QUESTION / CLARIFICATION NB-RAIL COORDINATION GROUP INTEROPERABILITY DIRECTIVE OF THE RAIL SYSTEM WITHIN THE EUROPEAN UNION	 Co-funded by the European Union
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TITLE	
COMBINATION OF MODULES	
ORIGINATOR	SUBJECT RELATED TO
NB-RAIL _ STR	EC verification EC conformity assessment Combination of modules

AMENDMENT RECORD:

VERSION 1: 1ST VERSION BASED ON PRESENTATION TO RISC 106 (01/06/2025) AND NRB 53 (18/09/2025)

DESCRIPTION AND BACKGROUND EXPLANATION	
<u>Introduction note :</u> The scope of the present question and clarification relates to the same issue that arises when applying a combination of modules for EC verification (SB + SD or SB + SF) or EC conformity assessment of Interoperability Constituents (CB+CD or CB + CF).	
To improve understanding, the current Q&C will focus on an example of an EC verification of a Freight Wagon as being a subsystem by its own applying assessment methods SB + SD according to WAG TSI, based on the assumption that it applies mutatis mutandis to any EC verification process based on the combination of modules and EC conformity assessment based on the combination of modules according to module decision 2010/713/EU .	

Description

Since almost 20 years ([2006/861/EC](#)), a NoBo selected by an applicant to perform the EC verification of a Freight Wagon according to the combination of SB + SD is starting the module SD (EC verification based on the quality management system of the production process) before the end of the module SB (EC-type examination SB).

It appears today that this methodology of starting module SD before the end of module SB is putted into question by some National Accreditation Bodies (NAB) members of European Accreditation (EA).

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INTEROPERABILITY DIRECTIVE OF THE RAIL SYSTEM WITHIN THE EUROPEAN UNION		

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More and more NoBos are reporting on NABs raising concerns on this process and putting non-conformities by referring that the Module Decision 2010/713/EU is requesting to provide the type certificate as part of the application to the NoBo.

Background explanation based on the 'Five Whys' principle.

1st why :

According to [IOD \(EU\) 2016/797](#) art. 15.3: The task of the notified body responsible for the 'EC' verification of a subsystem shall begin at the design stage and cover the entire manufacturing period through to the acceptance stage before the subsystem is placed on the market or in service. It shall, in accordance with the relevant TSI, also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated.

From [Blue Guide 2022](#) clause 5.1.5 related to One- and two modules procedures, In cases conformity assessment procedures are composed of two modules; the first module is always module B.

The conformity assessment body involved under module B is not necessarily the same as the one involved in the module that is used together with module B. The date of issue of the certificate of the module issued together with module B must always be later as the date of the module B certificate. Both certificates must be available before the first placing of the product on the market.

In practice, when the NoBo for EC verification according to Module SD is the same as the one for Module SB, the two modules work together, enabling the notified body responsible for SD to be aware of the product's design from the outset, enhancing him to have enough knowledge of the product to be certified before starting module SD.

Certificate decisions from module SD are always taken after the one from module SB as reference of the certificate issued according to module SB is part of the certificate issued according to module SD. This sequence is traceable via the date and time of the corresponding certificates.

2nd why :

When TSI requires type tests to be performed, a possible cost-effective way to ensure that the samples used for the tests are representative of the type to be certified is to control the production process and assess the related quality management system.

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In practice, when the NoBo for EC verification according to Module SD is the same as the one for Module SB, the two modules work together, enabling the notified body responsible for SD to be aware of the product's design from the outset, enhancing him to have enough knowledge of the product to be certified before starting module SD and to provide confidence for the purpose of module SB on the suitability of the production process to provide samples representative of the type to be certified.

3rd why :

The entire content of an application file, as described within module decision 2010/713/EU, is never submitted as a single package at the time of application for any module.

In practice, the applicant is providing the set of documents/evidences throughout the project and before its end. This takes into account the specificities of the related product and management system applied, if any.

4th why :

Railway modules (2010/713/EU art. 4 & art.6) are provided as conformity assessment procedures to be chosen in respect of a particular product in accordance with the following criteria:

- (a) whether the module concerned is appropriate to the type of product;
- (b) **the nature of the risks entailed by the product and the extent to which conformity assessment corresponds to the type and degree of risk;**
- (c) where third party involvement is mandatory, the need for the manufacturer to have a choice between quality assurance (SB+SD or SH1) and product certification modules (SB+SF).

All EC verification certificate have the same value independently of the assessment procedures applied. The EC verification certificate based on the combination of modules SB and SD and a certificate based on module SH1 (EC verification based on a full quality management system and design examination) could be used to cover the same type of product and same degree of risk.

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QC-STR-011

Version 1
Date 15/10/2025**5th why :**

Railway modules (2010/713/EU art. 4 & art.6) are provided as conformity assessment procedures to be chosen in respect of a particular product in accordance with the following criteria:

- (d) the need to avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned.

In practice and when contracted for both of them, a NoBo can start the SD module before the SB module ends, if they have the necessary knowledge of the product type under assessment. This significantly reduces the time (and consequently the cost) required by the sector.

Conclusion :

The current wording of 2010/713/EU may result into a too strict roll-out of the conformity assessment procedures when a combination of modules is requested to perform the EC verification of a subsystem of the EC conformity assessment of an Interoperability Constituent.

Imposing to a NoBo, when a combination of modules is requested, not to start the conformity assessment of the production before the issuance of the type certificate, is obliging :

- the NoBo to request additional check to get confidence that the samples used for type test are representative of the type to be certified.
- the applicant to produce a limited number of samples for type test and then to suspend the production as long as the type certificate is not issued.

SUGGESTED RESOLUTION / INTERPRETATION

Prior to starting the revision of Decision 2010/713/EU, action should be taken as soon as possible to avoid a major impact on the viability of NoBos with a high percentage of activities in the railway vehicle domain, as well as on the supply- and the operating railway communities, by avoiding tremendous certification delays.

By action, the Q&C is looking to EC and ERA clarifying :

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- When conformity assessment is based on a combination of modules, the module SD or SF /CD or CF may be started before the end of the module SB/CB, under the conditions that :
 - o One single NoBo has been contracted to perform the assessment of both modules SB + SD / SB + SF or CB + CD / CB + CF.
- As consequence of this clarification, it should be understood , for all the modules listed in the decision 2010/713/EU that the set
- of the documents to be submitted with the application is the set of the documents to be provided to the NoBo by the manufacturer / applicant during assessment activities, in respect of the type of product and the assessment procedure(s) to be performed, and not a the date of application.

ORGANISATION(S) REQUESTED TO RESPOND (E.G. TSI GROUP, RISC, ERA ETC.)
EC / ERA
DATE OF AGREEMENT AT NB RAIL PLENARY STRATEGY MEETING
RESPONSE FROM ORGANISATION ABOVE
Disclaimer: ERA TO always supersedes NB-Rail suggested solution in case of difference.

Annex 3: Impact Assessment

1. Context and assessment of impacts									
1.1. Scope									
<p>The Technical Opinion concerns the application of modules for interoperability constituents (ICs) and subsystems, specifically the combination of CB+CD or CB+ CF for ICs or SB+SD or SB+ SF for subsystems.</p> <p>Historically, and is still the practice in most countries across the EU, it is possible to start with vehicle production processes prior to the issuance of the EC-type certificate. This practice enables faster production processes and reduces costs.</p> <p>Yet, in the last few years some national accreditation bodies (NAB) have applied a more stringent interpretation of the Module Decision (2010/713/EC). The consequence is that production activities are not allowed to start prior to the delivery of the EC-type examination certificate. Such actions by NABs can be imposed by national law, based upon the Module Decision text that <i>'the notified body chosen by the applicant shall first examine the application concerning the validity of the EC type examination certificate'</i>.</p>									
1.2. Assessment of impacts									
<p>The situation described above creates divergences in application of the module decision across the EU.</p> <p>The Agency deems that the impacts on production of applying the strict interpretation of the module decision is disproportionate and should not be applied if the Notified Body responsible for the modules xD/xF ensures that:</p> <ul style="list-style-type: none"> At the time the inspections/audits are made, the design is mature enough to allow the verification/QMS assessment. Documentary evidence of these activities shall be part of documentation accompanying the certificate. The changes brought to the design and/or the manufacturing process between the inspection/audit and the delivery of the EC Type examination certificate are assessed, as well as their implementation on the object of assessment. Documentary evidence of these activities shall be part of documentation accompanying the certificate. The EC Type examination certificate is released before of the certificates related to production and final testing (e.g for xD module: QMS approval , for xF module: EC verification based on product verification) <p>Under those conditions the Agency deems that the module decision can be applied uniformly across the EU, while maintaining the speed in production and certification processes.</p>									
1.3. Stakeholders affected									
<table border="1"> <tr> <td>Railway undertakings (RU)</td> <td><input type="checkbox"/></td> <td>Member States (MS)</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Infrastructure managers (IM)</td> <td><input type="checkbox"/></td> <td>Third Countries</td> <td><input type="checkbox"/></td> </tr> </table>		Railway undertakings (RU)	<input type="checkbox"/>	Member States (MS)	<input checked="" type="checkbox"/>	Infrastructure managers (IM)	<input type="checkbox"/>	Third Countries	<input type="checkbox"/>
Railway undertakings (RU)	<input type="checkbox"/>	Member States (MS)	<input checked="" type="checkbox"/>						
Infrastructure managers (IM)	<input type="checkbox"/>	Third Countries	<input type="checkbox"/>						

Manufacturers	<input checked="" type="checkbox"/>	National safety authorities (NSA)	<input checked="" type="checkbox"/>
Keepers	<input type="checkbox"/>	European Commission (EC)	<input type="checkbox"/>
Entity Managing the Change (EMC)	<input type="checkbox"/>	European Union Agency for Railways (ERA)	<input checked="" type="checkbox"/>
Notified Bodies (NoBo)	<input checked="" type="checkbox"/>	Shippers	<input type="checkbox"/>
Associations	<input type="checkbox"/>	Other (Please specify) ...	<input type="checkbox"/>

2. Preferred option

2.1. Conclusion

The Agency is of the opinion that activities performed by the Notified Body in the context of the modules xD/xF can be done in parallel to those related to modules xB as per the Opinion text above.