European Railway Agency

Guide for the application of Technical Specifications for Interoperability (TSIs)

Annex 2 – Conformity assessment and 'EC' verification

According to Framework Mandate C(2007)3371 final of 13/07/2007

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Document prepared by	European Railway Agency Rue Marc Lefrancq, 120 BP 20392 F-59307 Valenciennes Cedex France
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European Railway Agency ● Rue Marc LEFRANCQ, 120 ● BP 20392 ● F-59307 Valenciennes Cedex ● France ● Tel. +33 (0)3 27 09 65 00 ● Fax +33 (0)3 27 33 40 65 ● http://www.era.europa.eu

0. DOCUMENT INFORMATION

0.1. Amendment record

Table 1: Status of the document

Version date	Author(s)	Section number	Modification description
Guide Version 1.0 30 November 2012	ERA IU	All	First publication
Guide Version 1.01 26 Aug 2011	ERA IU	2.2 Table 2, 3.2 Table 13,	Update following the adoption of TSIs CR INF, CR ENE, CR LOC&PAS, TAP.
Guide Version 1.02 30 Nov 2012	ERA IU	Tables n°4, 5, 8 ,9, 15 and 16	Correction for the role of NoBo in modules CA1 and CA2. Additional information on the applicant for the modules for conformity to type. Minor editorial corrections.

European Railway Agency ● Rue Marc LEFRANCQ, 120 ● BP 20392 ● F-59307 Valenciennes Cedex ● France ● Tel. +33 (0)3 27 09 65 00 ● Fax +33 (0)3 27 33 40 65 ● http://www.era.europa.eu

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1. INTRODUCTION

1.1. The TSIs applicable to structural subsystems adopted before 2010 include an annex with the description of modules for the conformity assessment of interoperability constituents and the 'EC' verification of subsystems ('old modules').

1.2. These 'old' modules were prepared using as a basis the modules defined in Decision 93/465/EEC, but adapting them to the particularities of the railway system, especially making a distinction between modules for the conformity assessment of interoperability constituents and subsystems.

1.3. From a formal point of view, each of these TSIs includes its own modules. The modules defined in different TSIs are basically the same, but there may be slight differences.

1.4. In 2010 the Commission adopted a separate decision (Decision 2010/713/EU) on modules for conformity assessment in railways ('new modules'). The TSIs adopted after entry into force of this decision will not include a description of modules, but make reference to this separate decision. Thus the definition of the modules will be exactly the same for all these TSIs.

1.5. These 'new' modules were prepared using as a basis the modules defined in Decision 768/2008/EC (which replaced Decision 93/465/EEC), but adapting them to the particularities of the railway system.

1.6. Decision 2010/713/EU does not amend the TSIs that had been adopted before its entry into force. When conformity to the requirements of these TSI is assessed, the 'old' modules must be used as they are defined in these TSIs.

1.7. The differences between the 'new' and 'old' modules also reflect the changes introduced by Directive 2008/57/EC.

1.8. The following section provides a summary of the differences, as well as a summary of the tasks of the parties involved for each of the 'new' modules.

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2. CONFORMITY ASSESSMENT OF INTEROPERABILITY CONSTITUENTS

2.1. 'Old' and 'new' modules for interoperability constituents

2.1.1. For interoperability constituents, the letter 'C' has been added to the title of each 'new' module (CA, CA1, CA2, CB, CC, etc.). The main changes introduced in the 'new' modules are:

- the 'old' module A1 has been split into two new modules: CA1 for individual product examination and CA2 for product examination at random intervals;
- modules CA1 and CA2 let the manufacturer choose between a NoBo or an accredited in-house body; however, in both cases the certificate of conformity is issued by a NoBo;
- it has been clarified that module CV is to be used as a module complementary to modules (or combinations of modules) CB+CC, CB+CD, CB+CE or CH1

2.1.2. Both the 'old' and 'new' modules are intended for assessment of conformity to the requirements of the TSIs. Where an IC is subject to other directives, conformity to them has to be assessed by bodies notified for and modules defined in these other directives.

2.1.3. The following figures show the structure of the 'old' and 'new' modules. For the 'new' modules, the differences with the 'old' modules are highlighted in red.

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Figure 1: Structure of the 'old' modules for ICs

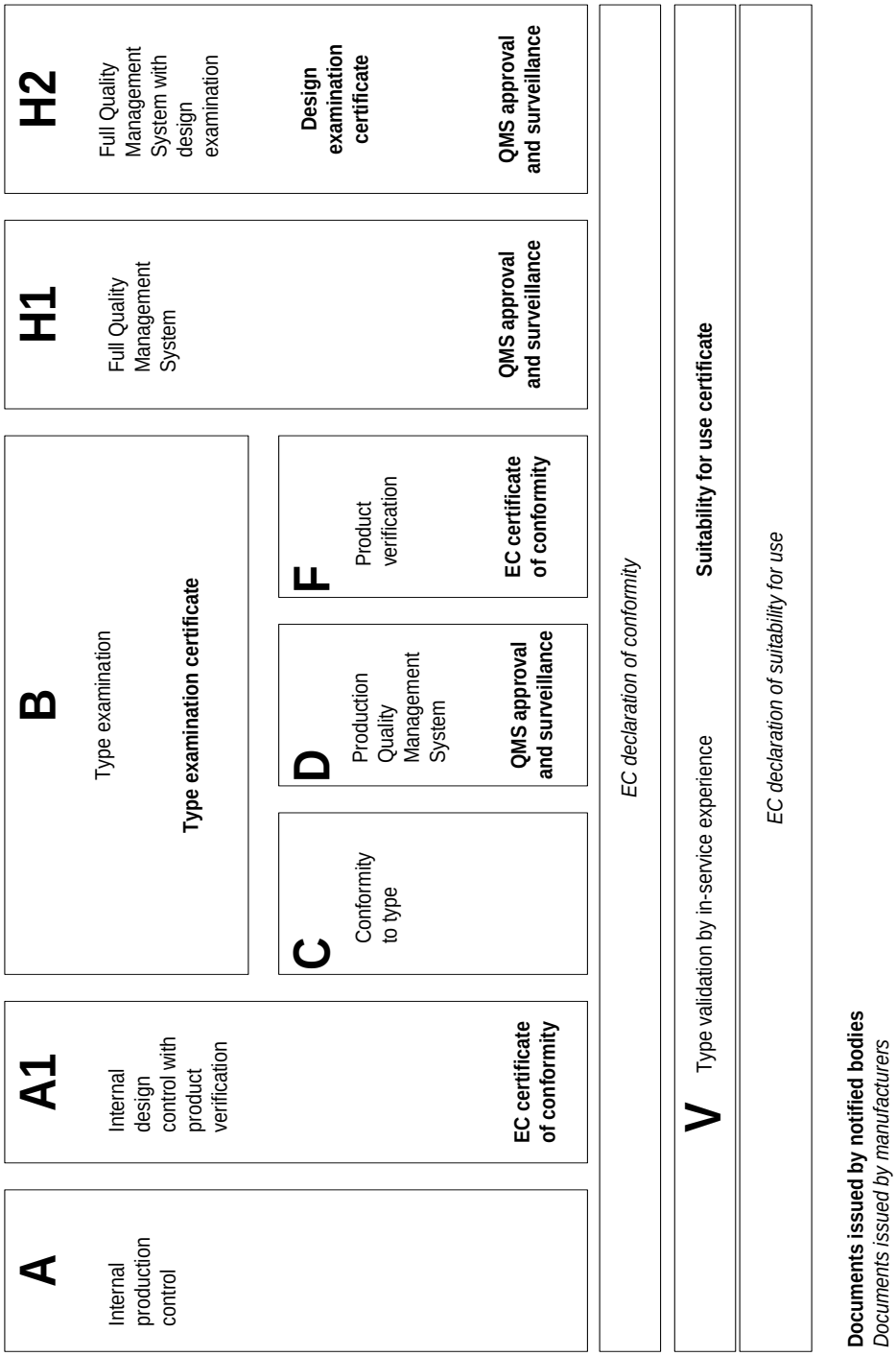

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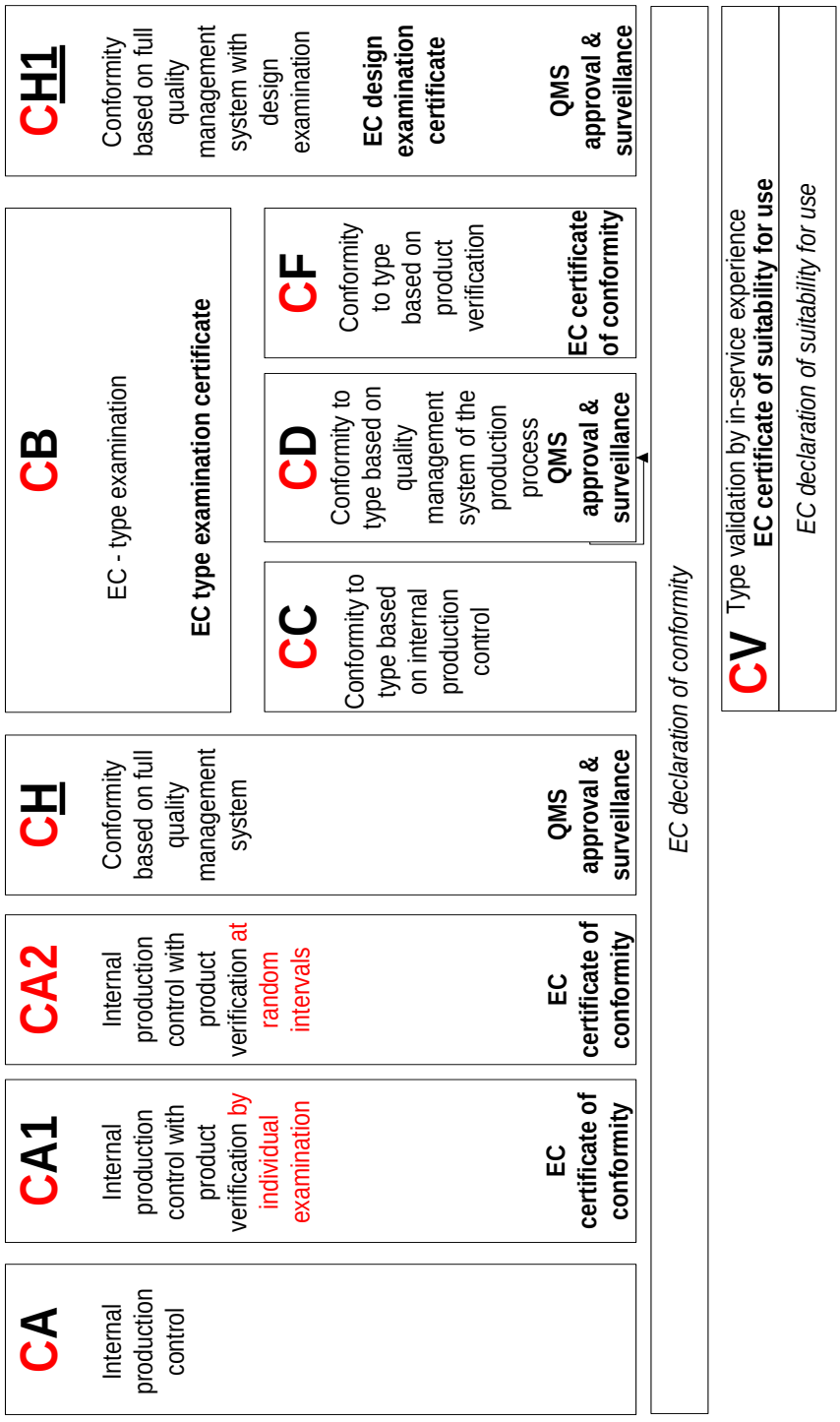
Figure 2: Structure of the 'new' modules for ICs



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2.2. Modules applicable to different TSIs

Table 2: Modules for 'EC' conformity assessment of interoperability constituents applicable to different TSIs

HS and CR TSI	Applicable modules								
HS Infrastructure (Decision 2008/217/EC)	A	A1			B/D	B/F	H1	H2	V
CR Infrastructure (Decision 2011/275/EU)	CA				CB/ CD	CB/ CF	CH		
HS Energy (Decision 2008/284/EC)		A1		B/C			H1	H2	
CR Energy (Decision 2011/274/EU)	CA			CB/ CC			CH	CH1	
HS&CR Control-Command and Signalling (Decision 2012/88/EU)	CA				CB/ CD	CB/ CF	CH1		
HS Rolling stock (Decision 2008/232/EC)	A	A1		B/C	B/D	B/F	H1	H2	V
CR Locomotives and Passenger Rolling Stock (Decision 2011/291/EU)	CA	CA1	CA2	CB/ CC	CB/ CD	CB/ CF	CH	CH1	CV
Freight Wagons (Decision 2006/861/EC)	A	A1			B/D	B/F	H1	H2	V
Rolling Stock – Noise (Decision 2011/229/EU)	No ICs								
Safety in Railway Tunnels (Decision 2008/163/EC)	No ICs								
Accessibility for PRM (Decision 2008/164/EC)	A	A1		B/C	B/D	B/F	H1	H2	V

Note: TSIs that contain no requirements for structural subsystems are not included in the table.

2.2.1. As graphically represented in the previous sections:

- modules CA, CA1, CA2, CH and CH1 may be used for the conformity assessment of an IC on their own;
- modules CC, CD and CF may only be used following the application of module CB;
- module CV is always complementary to application of modules CB+CC, CB+CD, CB+CF or CH1.

2.2.2. The same principle applies for the 'old' modules.

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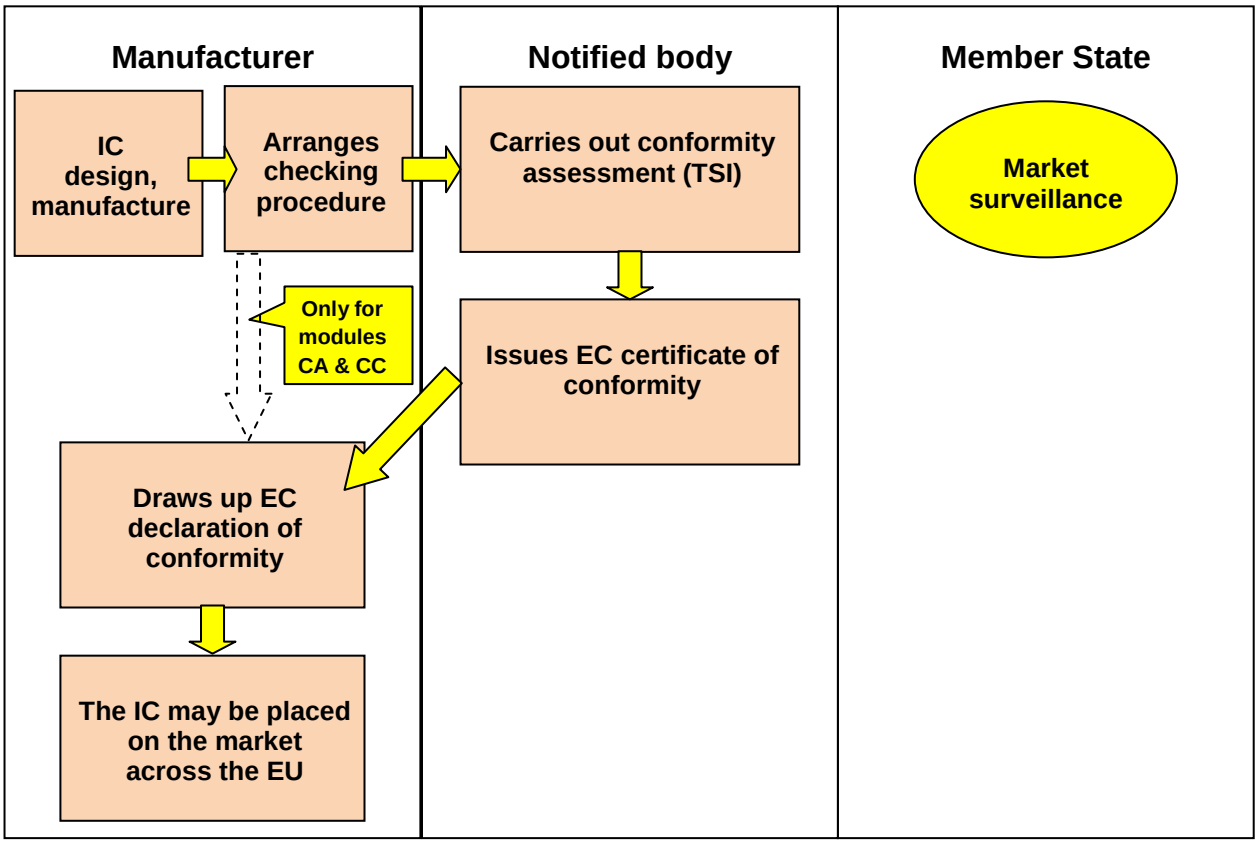
2.3. Tasks of manufacturer and notified body for conformity assessment of ICs

2.3.1. Regarding the conformity assessment of ICs, the process and general principle of allocation of tasks to the manufacturer (or its authorised representative established in the EU) and the notified body may be represented as follows:

Figure 3: Tasks of manufacturer and notified body for conformity assessment of ICs



2.3.2. The lists in the tables below are intended to summarise the main tasks (where relevant, subdivided into different phases) of the manufacturer and the notified body; these lists may not be exhaustive. These lists and the quotations in italics correspond to the 'new' modules. The title of the corresponding 'old' module is indicated in brackets. This indication is for reference only; the exact text of the 'old' modules may be different.

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Table 3: Module CA 'Internal production control' ('old' module A 'Internal production control')

Tasks of the manufacturer or his authorised representative	Tasks of the notified body
Design, production and final product inspection and testing 1. *'[Establishes] the technical documentation (...) [which must cover], as far as relevant for the assessment, the design, manufacture, maintenance and operation of the IC'.* 2. *'[Takes] all measures necessary so that the manufacturing process (...) [ensures] compliance of the ICs with the technical documentation (...) and with the requirements of the TSI that apply to them'.* 3. *'[Draws] up a (...) EC declaration of conformity (...)'* **After placing on the market** 4. *'[Keeps] [the EC declaration of conformity] together with the technical documentation (...) for the [defined] period (...)'*	No tasks

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Table 4: Module CA1 'Internal production control plus product verification by individual examination'
('old' module A1 'Internal design control with production verification')

Tasks of the manufacturer or his authorised representative	Tasks of the notified body/accredited in-house body
1. Chooses the NoBo.	
Design	**Design**
2. *'[Establishes] the technical documentation [which must cover], as far as relevant for the assessment, the design, manufacture, maintenance and operation of the IC [and] where applicable [give] evidence that the design of the IC, already accepted before the implementation of the applicable TSI is in accordance with the TSI and that the IC has been used in service in the same area of use'*.	No tasks
Production and final product inspection and testing	**Production and final product inspection and testing**
3. *'[Takes] all the measures necessary so that the manufacturing process (...) [ensures] compliance of the ICs with the technical documentation (...) and with the requirements of the TSI that apply to them'*.	1. Carries out tests *'in order to verify the conformity [of each ICs manufactured] with the type described in the technical documentation and with the requirements of the TSI'*. (This may be done by accredited in-house body).
4. Chooses whether the product *'tests are carried out (...) by an accredited in-house body or under the responsibility of a NoBo'*.	2. *'[Issues] an EC certificate of conformity in respect of the examinations and tests carried out'*. (i.e. for each successfully assessed IC.)
5. *'[Draws] up a (...) EC declaration of conformity (...)'*	
After placing on the market	
6. *'[Keeps] the EC certificate of conformity for the [defined] period (...)'*	
7. *'[Keeps] [the EC declaration of conformity] together with the technical documentation (...) for the [defined] period (...)*'	

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Table 5: Module CA2 'Internal production control plus product verification at random intervals'

Tasks of the manufacturer or his authorised representative	Tasks of the notified body/accredited in-house body
1. Chooses the NoBo.	
Design	**Design**
2. *'[Establishes] the technical documentation [which must cover], as far as relevant for the assessment, the design, manufacture, maintenance and operation of the IC [and] where applicable [give] evidence that the design of the IC, already accepted before the implementation of the applicable TSI is in accordance with the TSI and that the IC has been used in service in the same area of use'*.	No tasks
Production and final product inspection and testing	**Production and final product inspection and testing**
3. *'[Takes] all the measures necessary so that the manufacturing process (...) [ensures] compliance of ICs with the technical documentation (...) and with the requirements of the TSI that apply to them'*.	1. Draws from each lot a random sample.
4. Chooses whether the product *'tests are carried out (...) by an accredited in-house body or under the responsibility of a NoBo'*.	2. Individually examines all ICs in a sample and carries out appropriate tests *'to ensure the product conformity with the type described in the technical documentation and the requirements of the TSI that apply to it and to determine whether the lot is accepted or rejected'*.
5. *'[Presents] his products in the form of homogeneous lots and [takes] all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced'*.	Steps 1 and 2 above may be done by accredited in-house body.
6. *'[Draws] up a (...) EC declaration of conformity (...)'*	3. *'[Issues] an EC certificate of conformity in respect of the examinations and tests carried out'*. (i.e. for each successfully assessed lot.)
After placing on the market	
8. *'[Keeps] the EC certificate of conformity for the [defined] period (...)'*	
7. *'[Keeps] [the EC declaration of conformity] together with the technical documentation (...) for the [defined] period (...)*'	

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Table 6: Module CB 'EC-type examination' ('old' module B 'Type examination')

Tasks of the manufacturer or his authorised representative	Tasks of the notified body
Design 1. *'[Lodges] an application for EC-type examination with a NoBo of his choice'.* Design type 2. *'[Establishes] the technical documentation (...) [which must cover], as far as relevant for the assessment, the design, manufacture, maintenance and operation of the IC'.* Production type(s) 3. Places at the disposal of the NoBo: - the technical documentation - *'the specimens representative of the production envisaged'* - *'supporting evidence for the adequacy of the technical design solution'* 4. Agrees with the NoBo *'on a location where the examinations and tests will be carried out'*.	**Design** Design type 1. For the interoperability constituent: - *'[examines] the technical documentation and supporting evidence to assess the adequacy of the technical design of the IC with the requirements of the relevant TSI'.* Production type(s) 2. For the specimen(s): - *'may request further specimens if needed for carrying out the test programme'* - *'[verifies] that the specimen(s) have been manufactured in conformity with the requirements of the TSI and the technical documentation, and [identifies] the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards'* - *'[agrees] with the manufacturer on a location where the examinations and tests will be carried out'.* - *'[carries] out appropriate examination and test, or [has] them carried out, to check whether'* o *'requirements of the TSI have been applied correctly'* o *'where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly'* o *'where the solutions in the relevant*

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Table 6: Module CB 'EC-type examination' ('old' module B 'Type examination')

Tasks of the manufacturer or his authorised representative	Tasks of the notified body
	harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding requirements of the TSI'.
Type 5. *'[Informs] the NoBo that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the interoperability constituent with the requirements of the TSI or the conditions for validity of the certificate'*. 6. *'[Keeps] a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation (...) for the [defined] period (...)'*	Type 3. *'[Draws] up an evaluation report that records the activities undertaken and their outcomes. releasing its content, in full or in part, only with the agreement of the manufacturer'*. 4. *'[Issues] an EC-type examination certificate.'* 5. For the modifications that require additional approval issues *'[additions] to the original EC-type examination certificate'*. 6. Informs its notifying authorities and the other NoBos of EC-type examination certificates and additions issued, withdrawn, refused, suspended or restricted. 7. '*[Keeps] a copy of the EC-type examination certificate, its annexes and additions, including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.*'

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Table 7: Module CC 'Conformity to type based on internal production control' ('old' module C 'Conformity to type')

Tasks of the manufacturer or his authorised representative	Tasks of the notified body
Production and final product inspection and testing 1. *'[Takes] all measures necessary so that the manufacturing process and its monitoring ensure conformity of the IC with the approved type described in the EC-type examination certificate and with the requirements of the TSI that apply to them'.* 2. *'[Draws] up a (...) EC declaration of conformity (...)'* **After placing on the market** 3. *'[Keeps] [the EC declaration of conformity] together with the technical documentation (...) for the [defined] period (...)*'	No tasks

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Table 8: CD 'Conformity to type based on quality management system of the production process' ('old' module D 'Production quality management system')

Tasks of the manufacturer or his authorised representative	Tasks of the notified body
Production and final product inspection and testing 1. *'[Lodges] an application for assessment of his QMS with a NoBo of his choice'*. 2. *'[Operates] an approved QMS for production, final product inspection and testing of the ICs concerned'* which must ensure their *'conformity with the type as described in the EC-type examination certificate and with the requirements of the TSI that apply to them'.'[Undertakes] to fulfil the obligations arising out of the QMS as approved and to maintain it so that it remains adequate and efficient'*. 4. *'[Keeps] the NoBo that has approved the QMS informed of any intended change to the [QMS] having impact on the IC, including changes of [QMS] certificate'*. 5. *'For periodic audits purposes, [allows] the NoBo access to the manufacture, inspection, testing and storage sites and [provides] it with all necessary information'*. 6. *'[Draws] up a (...) EC declaration of conformity (...)' (it must be the signed by the same manufacturer as the one who got the EC type examination certificate).* **After placing on the market** 7. Keeps the QMS documentation, the updates, and the decisions and reports of the NoBo, for the defined period. 8. *'[Keeps] [the EC declaration of conformity] (...) for the [defined] period (...)'*	**Production and final product inspection and testing** *1. '[Assesses] the QMS to determine whether it satisfies the requirements (...)'* 2. *'[Issues] a QMS approval'.* 3. *'[Evaluates] any proposed changes and [decides] whether the modified QMS will continue to satisfy the requirements (...) or whether a reassessment is necessary'*. *4.* Carries out surveillance *'to make sure that the manufacturer duly fulfils the obligations arising out of the approved QMS'.* - *'[Carries] out periodic audits', 'at least once every two years'.* - *'May pay unexpected visits [and] (...) if necessary, carry out IC tests, or have them carried out, in order to verify that QMS is functioning correctly (...)'* 5. Informs its notifying authorities and the other NoBos of QMS approvals issued, withdrawn, refused, suspended or restricted.

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Table 9: CF 'Conformity to type based on product verification' ('old' module F 'Product verification')

Tasks of the manufacturer or his authorised representative	Tasks of the notified body
Production and final product inspection and testing 1. Chooses the NoBo. 2. *'[Takes] all measures necessary so that the manufacturing process ensures conformity of the ICs with the approved type described in the EC-type examination certificate and with* the requirements of the TSI'. 3. Chooses whether *'the examinations and tests to check the conformity of the interoperability constituents with the requirements of the TSI shall be carried out (...) by examination and testing of every interoperability constituent (...) or by examination and testing of the interoperability constituents on a statistical basis'*. 4. *'When a test is not set out in the TSI, harmonised standard(s) and technical specification(s)'* decides with the NoBo *'the appropriate tests to be carried out'*. 5. In the case of *'Statistical verification of conformity'*, - *'[takes] all the measures necessary so that the manufacturing process (...) [ensures] homogeneity of each lot produced, and* - *[presents] his ICs for verification in the form of homogeneous lots'* 6. *'[Draws] up a (...) EC declaration of conformity (...)' (it must be signed by the same manufacturer as the one who got the EC type examination certificate).* **After placing on the market** 7. *'[Keeps] the EC certificates of conformity (...) for the [defined] period (...)*' 8. *'[Keeps] [the EC declaration of conformity] (...) for the [defined] period (...)'*	**Production and final product inspection and testing** 1. *'[Carries out] appropriate examinations and tests in order to check the conformity of the ICs with the type described in the EC-type examination certificate and with the requirements of the TSI'*. 2. *'When a test is not set out in the TSI, harmonised standard(s) and technical specification(s)' decides with the manufacturer 'the appropriate tests to be carried out'.* 3. *In the case of 'Verification of conformity by examination and testing of every interoperability constituent'*, individually examines all interoperability constituents and carries out appropriate tests. 4. In the case of *'Statistical verification of conformity'*, - Takes from each lot a random sample, - Individually examines all interoperability constituents in a sample and carries out appropriate tests. 5. *'[Issues] an EC certificate of conformity in respect of the examinations and tests carried out'*. (i.e. for each successfully assessed IC.)

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Table 10: CH 'Conformity based on full quality management system' ('old' module H1 'Full quality management system')

Tasks of the manufacturer or his authorised representative	Tasks of the notified body
1. *'[Lodges] an application for assessment of his QMS with the NoBo of his choice'* including *'technical documentation for one model of each category of interoperability constituents intended to be manufactured'.*	
Design, production and final product inspection and testing	**Design, production and final product inspection and testing**
2. *'[Operates] an approved QMS for design, manufacture and final product inspection and testing of the ICs concerned'*. 3. *'[Undertakes] to fulfil the obligations arising out of the QMS as approved and to uphold it so that it remains adequate and efficient'*. 4. *'[Keeps] the NoBo that has approved the QMS informed of any intended change of the QMS, having impact on IC, including changes of QMS certificate'*. 5. *'For periodic audits purposes, [allows] the NoBo, access to the design, manufacture, inspection, testing and storage sites, and [provides] it with all necessary information(...)'* 6. *'[Draws] up a (...) EC declaration of conformity (...)'*	1. Evaluates whether the design review and type examination were performed for previous applications under comparable conditions, and are in conformity with the requirements of the applicable TSI. 2. *'[Assesses] the QMS to determine whether it satisfies the requirements (...)'* *3. '[Issues] a QMS approval to the applicant'.* 4. *'[Evaluates] any proposed changes and [decides] whether the modified QMS will continue to satisfy the requirements (...) or whether a reassessment is necessary'*. *5.* Carries out surveillance *'to make sure that the manufacturer duly fulfils the obligations arising out of the approved QMS'.* - *'[Carries] out periodic audits', 'at least once every two years'.* - *'May pay unexpected visits to the manufacturer [and] (...) if necessary, carry out IC tests, or have them carried out, in order to verify that QMS is functioning correctly (...)'*
After placing on the market 7. Keeps the technical documentation, QMS documentation, the updates, and the decisions and reports of the NoBo, for the defined period. 8. *'[Keeps] [the EC declaration of conformity] for the [defined] period (...)'*	*6.* Informs its notifying authorities and the other NoBos of QMS approvals issued, withdrawn, refused, suspended or restricted.

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Table 11: CH1 'Conformity based on full quality management system plus design examination' ('old' module H2 'Full quality management system with design examination')

Tasks of the manufacturer or his authorised representative	Tasks of the notified body
Design, production and final product inspection and testing	**Design, production and final product inspection and testing**
Regarding the QMS approval:	Regarding the QMS approval:
1. *'[Operates] an approved QMS for design, manufacture and final product inspection and testing of the ICs concerned'.*	1. *'[Assesses] the QMS to determine whether it satisfies the requirements'*.
2. *'[Lodges] an application for assessment of his QMS with the NoBo of his choice'*.	2. *'[Issues] a QMS approval (...)'*
3. *'[Undertakes] to fulfil the obligations arising out of the QMS as approved and to uphold it so that it remains adequate and efficient'.*	3. *'[Evaluates] any proposed changes and decide whether the modified QMS will continue to satisfy the requirements (...) or whether a reassessment is necessary'.*
4. *'[Keeps] the NoBo that has approved the QMS informed of any intended change of the QMS, having impact on IC, including changes of QMS certificate'.*	4. Carries out surveillance *'to make sure that the manufacturer duly fulfils the obligations arising out of the approved QMS'*. - *'[Carries] out periodic audits', 'at least once every two years'.* - *'May pay unexpected visits to the manufacturer [and] (...) if necessary, carry out IC tests, or have them carried out, in order to verify that QMS is functioning correctly (...)'*
5. *'For periodic audits purposes, [allows] the NoBo, access to the design, manufacture, inspection, testing and storage sites, and [provides] it with all necessary information (...)'*	5. Informs its notifying authorities and the other NoBos of QMS approvals issued, withdrawn, refused, suspended or restricted.
Regarding the design examination:	Regarding the design examination:
6. *'[Lodges] an application for examination of the design with the NoBo [that have approved his QMS]'*.	6. Examines the application for design examination, including technical documentation and supporting evidence.
7. *'[Establishes] the technical documentation (...) [which must] make it possible to assess the interoperability constituent's conformity with the requirements of the relevant TSI'.*	7. *'[Issues] an EC design examination certificate'*.
8. Places at the disposal of the NoBo: - the technical documentation - *'supporting evidence for the adequacy of the technical design'*	8. For the modifications that require additional approval issues *'[additions] to the original EC design examination certificate'*.
9. *'[Keeps] the NoBo that has issued the EC*	9. Informs its notifying authorities and the other NoBos of the design examination certificates issued, withdrawn, or refused, suspended or restricted.
	10. *'[Keeps] a copy of the EC design examination certificate, its annexes and additions, as well*

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Table 11: CH1 'Conformity based on full quality management system plus design examination' ('old' module H2 'Full quality management system with design examination')

design examination certificate informed of any modification to the approved design that may affect the conformity with the requirements of the TSI or the conditions for validity of the certificate(...)' General: 10. *'[Draws] up a (...) EC declaration of conformity (...)'* **After placing on the market** 11. *'[Keeps] [the EC declaration of conformity] (...) for the [defined] period (...)'* 12. *'[Keeps] a copy of the EC design examination certificate, its annexes and additions, together with the technical documentation for the [defined] period.* 13. Keeps the QMS documentation, the updates, and the decisions and reports of the NoBo, for the defined period.	*as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.'*

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Table 12: CV Type validation by in service experience (Suitability for use) ('old' module V 'Type-validation by in-service experience')

Tasks of the manufacturer or his authorised representative	Tasks of the notified body
1. *'[Obtains] an agreement to contribute to a suitability for use assessment by in-service experience'* with an infrastructure manager and/or railway undertaking 2. *'[Lodges] an application for type validation by in service experience with a NoBo of his choice'*. 3. Establishes the technical documentation, which must *'make it possible to assess the interoperability constituent's conformity with the requirements of the relevant TSI'* and programme for the validation by in-service experience. 4. *'[Places] at the disposal of the company(ies), undertaking the operation of the IC in service, a specimen or a sufficient number of specimens, representative of the production envisaged'*. 5. *'[Agrees] with the [NoBo] and the company(ies) undertaking the operation of the IC (...) the programme and the location where the inspections will be carried out and, if necessary, the test(s) and the body performing the test(s)'.* 6. *'[Informs] the NoBo that holds the technical documentation relating to the EC certificate of suitability for use of all modifications to the approved type that may affect the suitability for use of the IC or the conditions for validity of the certificate'*. 7. *'[Draws] up a (...) EC declaration of suitability for use (...)'* **After placing on the market** 8. *'[Keeps] [the EC declaration of suitability for use] for the [defined] period'.*	1. *'May request further specimens if needed (...)'* 2. *'[Agrees] with the applicant and the company(ies) undertaking the operation of the IC (...) the programme and the location where the inspections will be carried out and, if necessary, the test(s) and the body performing the test(s)'*. 3. Performs *'type validation by in-service experience'*: - *'[examines] the technical documentation and the programme for validation by in service experience'.* - *'[verifies] that the type is representative and has been manufactured in conformity with the technical documentation'.* - *'[verifies] that the programme for validation by in service experience is well adapted to assess the required performance and in service behaviour of the IC concerned'.* - *'[monitors] and [inspects] the progress of in service running, operation and maintenance of the IC'* - *'[assesses] the report, to be issued by the company(ies) operating the IC (...), and all other documentation and information, collected during the procedure (...)'.* - *'[evaluates], whether the in-service behaviour meets the requirements of the TSI'.* *4. '[Issues] an EC certificate of suitability for use (...)'* 5. For the modifications that require additional approval issues *'[additions] to the original EC certificate of suitability for use'*. 6. Informs its notifying authorities and the other NoBos of the EC certificates of suitability for use issued, withdrawn, or refused, suspended or restricted.

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3. 'EC' VERIFICATION OF SUBSYSTEMS

3.1. 'Old' and 'new' modules for subsystems

3.1.1. Concerning the conformity assessment of subsystems, the main changes introduced in the 'new' modules are:

- *'applicant may be the contracting entity or the manufacturer, or their authorised representative within the [EU]'* (according to Article 18(1) of the Interoperability Directive) (In the 'old' modules, the applicant could only be the contracting entity; the manufacturer could not apply on its own, only as a representative of the contracting entity);

- the applicant has to provide documents for the technical file (Article 18(3) and section 2.4 of Annex VI of the Interoperability Directive) and the registers referred to in Articles 34 and 35 of the Interoperability Directive (European register of authorised types of vehicle and Register of infrastructure, respectively);

- an intermediate statement of verification (ISV) may be issued '(...) *to cover certain stages of the verification procedure or certain parts of the subsystem'* (Article 18(4));

- in the cases where the TSIs have not been applied in full (e.g. derogations, upgrade or renewal) or application of specific cases, the 'EC' certificate and 'EC' declaration must have a reference to the TSI(s) or its/their parts not assessed in the EC verification by the NoBo;

- reference to Annex V of the Interoperability Directive, which lists the minimum requirements for the 'EC' declaration of verification.

3.1.2. The following figures show the structure of the 'old' and 'new' modules. For the 'new' modules, the differences with the 'old' modules are highlighted in red.

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Figure 4: Structure of the 'old' modules for subsystems

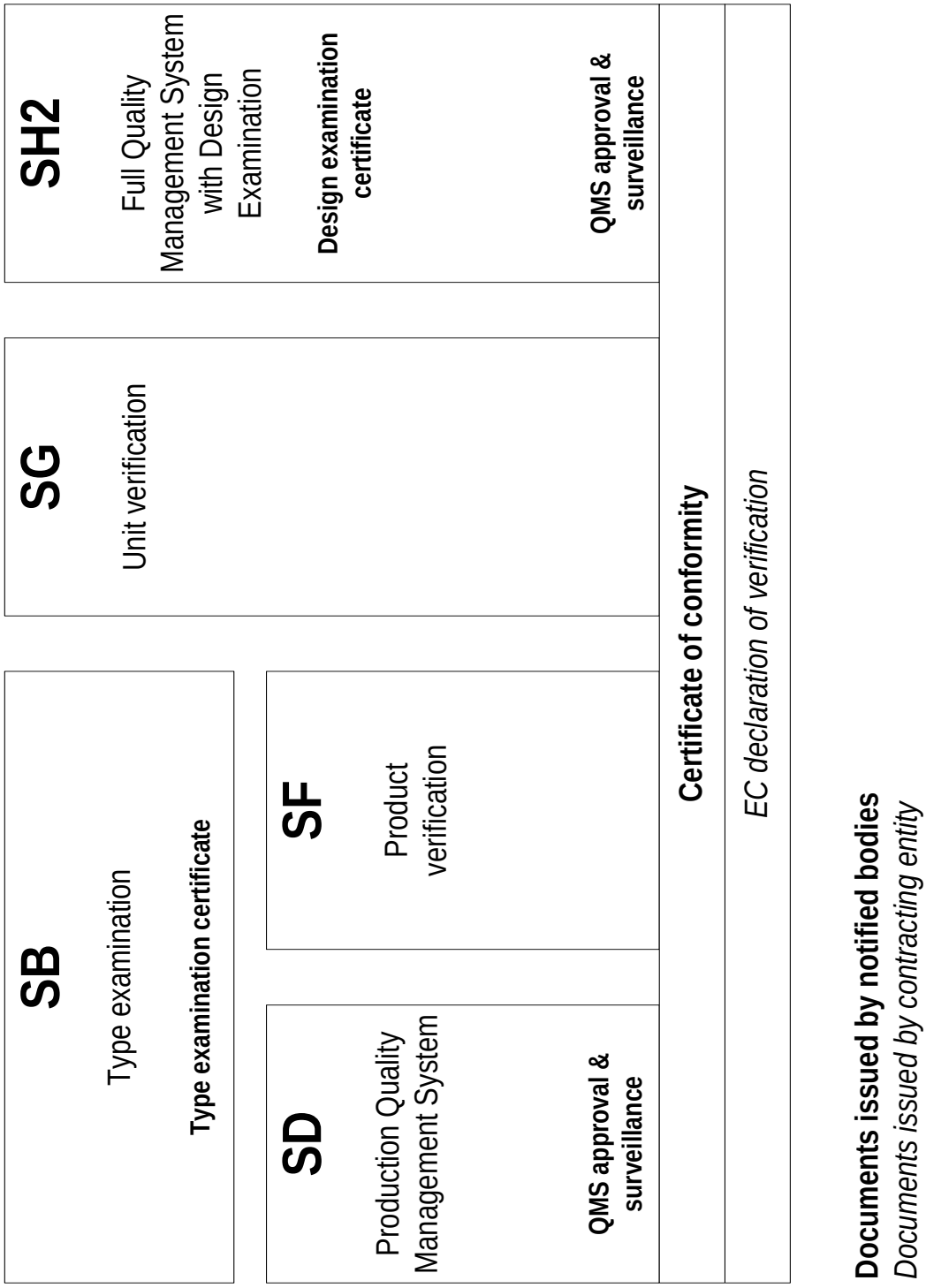

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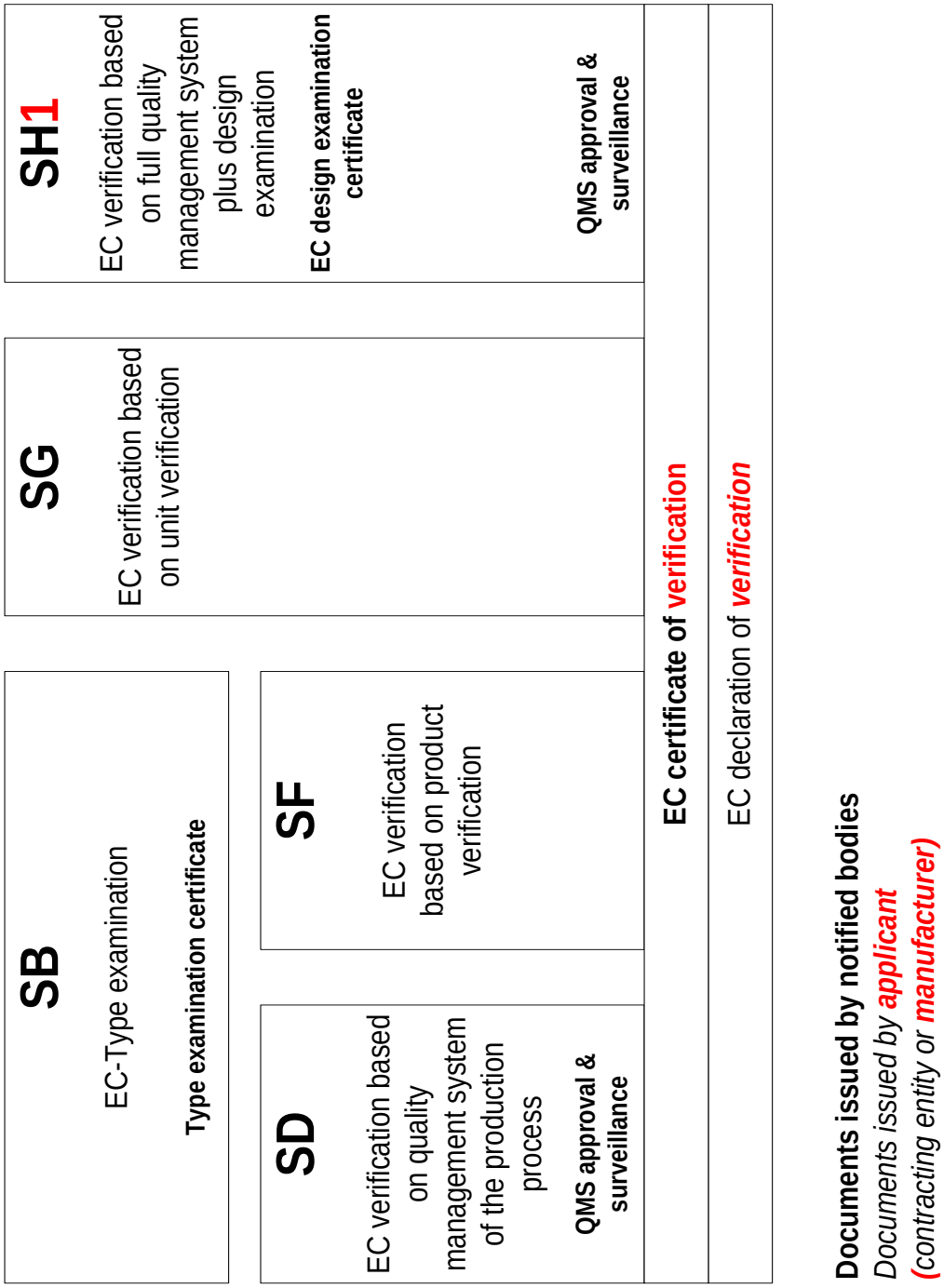
Figure 5: Structure of the 'new' modules for subsystems



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3.2. Modules applicable to different TSIs

Table 13: Module for 'EC' verification of subsystems applicable to different TSIs

HS and CR TSI	Applicable modules			
HS Infrastructure (Decision 2008/217/EC)			'Old' SG	'Old' SH2
CR Infrastructure (Decision 2011/275/EU)			'New' SG	'New' SH1
HS Energy (Decision 2008/284/EC)			'Old' SG	'Old' SH2
CR Energy (Decision 2011/274/EU)			'New' SG	'New' SH1
HS&CR Control-Command and Signalling (Decision 2012/88/EU)	'New' SB/SD	'New' SB/SF	'New' SG	'New' SH1
HS Rolling Stock (Decision 2008/232/EC)	'Old' SB/SD	'Old' SB/SF		'Old' SH2
CR Locomotives and Passenger Rolling Stock (Decision 2011/291/EU)	'New' SB/SD	'New' SB/SF		'New' SH1
Freight Wagons (Decision 2006/861/EC)	'Old' SB/SD	'Old' SB/SF		'Old' SH2
Rolling Stock – Noise (Decision 2011/229/EU)	'Old' SB/SD	'Old' SB/SF		'Old' SH2
Safety in Railway Tunnels (Decision 2008/163/EC)		'Old' SB/SF	'Old' SG	'Old' SH2
Accessibility for PRM (Decision 2008/164/EC)	'Old' SB/SD	'Old' SB/SF	'Old' SG	'Old' SH2

Note: TSIs that contain no requirements for structural subsystems are not included in the table.

3.2.1. As graphically represented in the previous sections:

- the 'new' modules SG and SH1 may be used for the verification of a subsystem on their own,
- the 'new' modules SD and SF may only be used following the application of the 'new' module SB.

3.2.2. The same principle applies for the 'old' modules.

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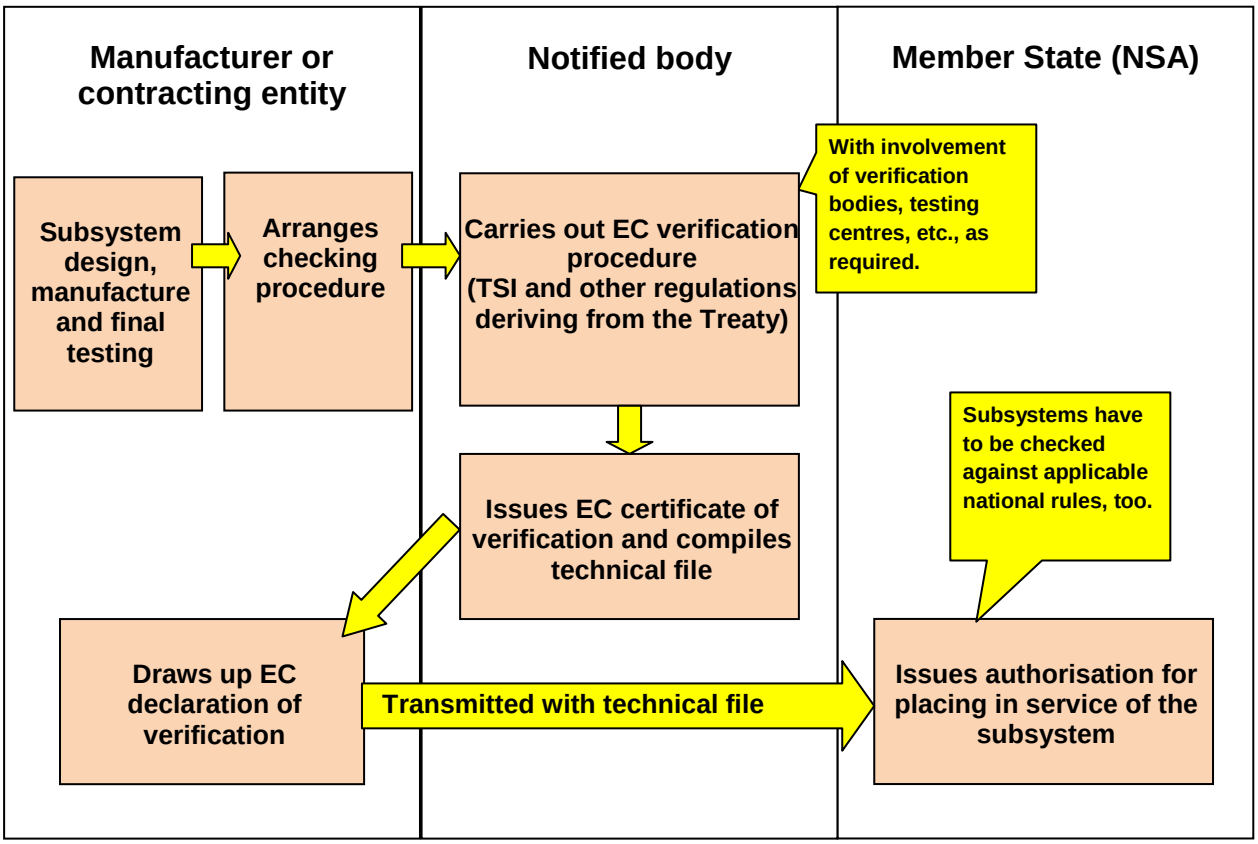
3.3. Tasks of applicant and notified body for 'EC' verification of subsystems

3.3.1. Regarding the conformity assessment of subsystems, the process and general principle of allocation of tasks to the applicant for the EC verification (which 'may be the contracting entity or the manufacturer, or their authorised representative within the [EU]') and the notified body may be represented as follows:

Figure 6: Tasks of applicant and notified body for EC verification of subsystems



3.3.2. The lists in the tables below are intended to summarise the main tasks of the applicant for EC verification and the notified body; these lists may not be exhaustive. These lists and the quotations in italics correspond to the 'new' modules. The title of the correspondent 'old' module is indicated in brackets. This indication is for reference only; the exact text of the 'old' modules may be different.

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Table 14: Module SB 'Type examination'
('old' module SB 'Type examination')

Tasks of the applicant	Tasks of the notified body
Design 1. *'[Lodges] an application for EC-type examination with a NoBo of his choice'*. 2. *'When the subsystem (...) is subject to derogation(s) (...) [informs] the NoBo thereof'.* 3. *'[Establishes] the technical documentation (...) [which must] make it possible to assess the subsystem's conformity with the requirements of the relevant TSI(s)'*. 4. Places at the disposal of the NoBo: - the technical documentation - *'the specimens representative of the production envisaged'* - *'supporting evidence for the adequacy of the technical design solution'* 5. *'[Agrees] with the [NoBo] on a location where the examinations and tests will be carried out'*. 6. *'[Draws] up a (...) EC declaration of intermediate subsystem conformity'*. 7. *'[Informs] the NoBo that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the subsystem with the requirements of the relevant TSI(s) or the conditions for validity of the certificate'*.	**Design** 1. For the design type: - *'[Examines] the technical documentation and supporting evidence to assess whether the technical design of the subsystem is adequate (...)'* - *'Where a design review is requested in the relevant TSI(s), [examines] design methods, the design tools and the design results (...)'.* 2. For the production type: - *'[Verifies] that the specimen(s) have been manufactured in conformity with the requirements of the relevant TSI(s) and with the technical documentation'* - *[Identifies] the elements which have been designed in accordance with the applicable provisions of the relevant TSI(s), harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards'.* - *'[Agrees] with the applicant on a location where the examinations and tests will be carried out'.* - *'[Carries] out appropriate examinations and tests, or have them carried out, to check whether',* o *'where the applicant has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly',* o *'where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding requirements of the relevant TSI(s).'* 3. *'[Draws] up an evaluation report'*.

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Table 14: Module SB 'Type examination'
('old' module SB 'Type examination')

Tasks of the applicant	Tasks of the notified body
After placing in service 8. *'[Keeps] a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation (...) throughout the service life of the subsystem'*.	4. *'[Issues] an EC-type examination certificate (...) [or], if only certain parts of the subsystem are covered (...), an Intermediate Statement of Verification (ISV) (...)'* 5. For the modifications that require additional approval issues *'[additions] to the original EC-type examination certificate'.* 6. Informs its notifying authorities and the other NoBos of the EC-type examination certificates and/or any additions issued, withdrawn, refused, suspended or restricted. 7. *'[Keeps] a copy of the EC-type examination certificate, its annexes and additions, including the documentation intended for the technical file submitted by the applicant, until the expiry of the validity of the certificate'*.

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Table 15: Module SD 'EC verification based on quality management system of the production process' ('old' module SD 'Production quality management system')

Tasks of the applicant	Tasks of the notified body
Production and final subsystem inspection, final testing 1. Ensures that *'the production, final subsystem inspection and testing of the subsystem concerned [is] covered by approved QMS(s)'*. 2. *'[Lodges] an application for assessment of the QMS with the NoBo of his choice'*. 3. *'[Undertakes] to fulfil the obligations arising out of the QMS as approved and to maintain it so that it remains adequate and efficient'*. 4. *'[Keeps] the NoBo that has approved the QMS informed of any intended change having impact on the subsystem design, manufacture and final inspection, testing and operation, as well as of any changes of QMS certificate'*. 5. *'[Lodges] an application for the EC verification of the subsystem with a NoBo of his choice'*. 6. *'When the subsystem (...) is subject to derogation(s) (...) [informs] the NoBo thereof'*. 7. *'For periodic audits purposes, [allows] the NoBo access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information (...)*' 8. *'[Draws] up a (...) EC declaration of verification'* or *'in case of intermediate statement of verification (ISV) procedure (...) [an] EC declaration of intermediate subsystem conformity' (it must be signed by the same applicant as the one who got the EC type examination certificate).*	**Production and final subsystem inspection, final testing** NoBo in charge of the assessment of QMS: 1. '[Assesses] the QMS to determine whether it satisfies the requirements (...)' 2. '[Issues] a QMS approval'. 3. Carries out surveillance *'to make sure that the manufacturer duly fulfils the obligations arising out of the approved QMS'*. - *'[Carries] out periodic audits', 'at least once every two years'.* - *'May pay unexpected visits (...) [and] if necessary, carry out subsystem tests, or have them carried out, in order to verify that QMS is functioning correctly'* 4. *'[Evaluates] any proposed changes and decide whether the modified QMS will continue to satisfy the requirements (...) or whether a reassessment is necessary'*. 5. Informs its notifying authorities and the other NoBos of the QMS approvals issued, withdrawn, or refused, suspended or otherwise restricted. NoBo in charge of the EC verification: 6. *'[Examines] (...) the validity of the EC-type examination certificate and its annexes'*. 7. *'If not [carries] out the surveillance of all the QMS concerned [coordinates] the surveillance activities of any other NoBos responsible for that task (...)'* 8. *'[Issues] an EC certificate of verification'* or *'if only certain parts or certain stages of the subsystem are covered (...) an intermediate statement of verification (ISV)'*. 9. Compiles *'the technical file that has to accompany the EC declaration of verification and the EC declaration of intermediate subsystem conformity'*. 10. Informs its notifying authorities and the other

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Table 15: Module SD 'EC verification based on quality management system of the production process' ('old' module SD 'Production quality management system')

Tasks of the applicant	Tasks of the notified body
	NoBos of the EC certificates of verification issued, withdrawn, or refused, suspended or otherwise restricted. Notes: • The NoBo in charge of the EC verification may be different from the one in charge of the assessment of QMS. • If several partners are involved in the process (e.g. in the case of a consortium of different manufacturers), each of these partner may have his own QMS. These QMS may be assessed by different NoBos.
After placing in service 9. *'[Keeps] [the EC declaration of verification] throughout the service life of the subsystem'*. 10. *'Throughout the service life of the subsystem, [keeps]'* the QMS documentation, any updates of it, audit, decisions and reports of the NoBo and the technical file.	

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Table 16: Module SF 'EC verification based on product verification' ('old' module SF 'Product verification')

Tasks of the applicant	Tasks of the notified body
Production and final subsystem inspection, final testing 1. *'[Lodges] an application for the EC verification of the subsystem with a NoBo of his choice'*. 2. *'When the subsystem (...) is subject to derogation(s) (...) [informs] the NoBo thereof'.* 3. Agrees with the NoBo *'the locations where the tests and the final testing of the subsystem will be carried out'*. 4. *'Whenever required in the relevant TSI(s)'*, carries out *'tests or validation under full operating conditions (...) under direct supervision and attendance of the NoBo'*. 5. *'[Draws] up a (...) EC declaration of verification (...)'* or *'in case of intermediate statement of verification (ISV) procedure [draws] up (...) [ac] EC declaration of intermediate subsystem conformity' (it must be signed by the same applicant as the one who got the EC type examination certificate).* **After placing in service** 6. *'[Keeps] a copy of the EC certificate of verification (...) throughout the service life of the subsystem'*. 7. *'[Keeps] [the EC declaration of verification] (...) throughout the service life of the subsystem'*.	**Production and final subsystem inspection, final testing** 1. *'[Examines] (...) the validity of the EC-type examination certificate'.* 2. *'[Agrees] with the applicant the locations where the tests and the final testing of the subsystem will be carried out'*. 3. *'[Carries] out appropriate examinations and tests in order to check the conformity of the subsystem with the approved type described in the EC-type examination certificate and with the requirements of the relevant TSI(s)'*. 4. *'Whenever required in the relevant TSI(s)'* directly supervises and attends *'tests or validation under full operating conditions (...) carried out by the applicant'*. 5. *'[Issues] an EC certificate of verification'* or *'if only certain parts or certain stages of the subsystem are covered (...) an intermediate statement of verification (ISV)'*. 6. Compiles *'the technical file that has to accompany the EC declaration of verification and the EC declaration of intermediate subsystem conformity'*. 7. Informs its notifying authorities and the other NoBos of the EC certificates of verification issued, withdrawn, or refused, suspended or otherwise restricted.

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Table 17: Module SG 'EC verification based on unit verification' ('old' module SG 'Unit verification')

Tasks of the applicant	Tasks of the notified body
Production and final subsystem inspection, final testing 1. *'[Lodges] an application for the EC verification of the subsystem with a NoBo of his choice'*. 2. *'When the subsystem (...) is subject to derogation(s) (...) [informs] the NoBo thereof'*. 3. *'[Establishes] the technical documentation (...) [which must] make it possible to assess the subsystem's conformity with the requirements of the relevant TSI(s)'*. 4. *'[Takes] all measures necessary so that the manufacturing and/or installation/construction process (...) [ensures] conformity of the subsystem with the requirements of the relevant TSI(s)'.* 5. *'In the absence of [relevant] harmonised standard and/or technical specification'* decides with the NoBo *'the appropriate tests to be carried'*. 6. Agrees with the NoBo *'the locations where the tests and the final testing of the subsystem will be carried out'*. 7. *'Whenever required in the relevant TSI(s)'*, carries out *'tests or validation under full operating conditions (...) under direct supervision and attendance of the NoBo'*. 8. *'[Draws] up a (...) EC declaration of verification'* or *'in case of intermediate statement of verification (ISV) procedure [draws] up (...) [an] EC declaration of intermediate subsystem conformity'*. **After placing in service** 9. *'[Keeps] the technical documentation (...) throughout the service life of the subsystem'*. 10. *'[Keeps] [the EC declaration of verification] (...) throughout the service life of the subsystem'*.	**Production and final subsystem inspection, final testing** 1. *'In the absence of (...) a harmonised standard and/or technical specification'* decides with the applicant *'the appropriate tests to be carried'*. 2. *'[Agrees] with the applicant the locations where the tests and the final testing of the subsystem will be carried out'*. 3. *'[Carries] out appropriate examinations and tests, set out in the relevant TSI(s), harmonised standards and/or technical specifications, or equivalent tests, to check the conformity of the subsystem with the requirements of the relevant TSI(s), or have them carried out'*. 4. *'May take into account evidence of examinations, checking or tests that have been successfully performed, under comparable conditions by other bodies or, when this is specified by the relevant TSI(s), by (or on the behalf of) the applicant'*. 5. *'[Issues] an EC certificate of verification'* or *'if only certain parts or certain stages of the subsystem are covered (...) an intermediate statement of verification (ISV)'*. 6. Compiles *'the technical file that has to accompany the EC declaration of verification and the EC declaration of intermediate subsystem conformity'*. 7. Informs its notifying authorities and the other NoBos of the EC certificates of verification issued, withdrawn, or refused, suspended or otherwise restricted.

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Table 18: Module SH1 'EC verification based on full quality management system plus design examination'
('old' module SH2 'Full quality management system with design examination')

Tasks of the applicant	Tasks of the notified body
Design, production and final subsystem inspection, final testing 1. Operates an approved QMS for *'design, manufacture and final subsystem inspection and testing of the subsystem'*. 2. *'[Lodges] an application for assessment of QMS for the subsystem concerned (...) with a NoBo of its choice'*. 3. *'[Undertakes] to fulfil the obligations arising out of the QMS as approved and to maintain it so that it remains adequate and efficient'*. 4. *'For periodic audits purposes, [allows] the NoBo access to the design, manufacture, inspection, testing and storage sites and [provides] it with all necessary information'*. 5. *'[Keeps] the NoBo that has approved the QMS informed of any intended change having impact on the subsystem design, manufacture and final inspection, testing and operation, as well as of any changes of QMS certificate'*. 6. '[Lodges] an application for the EC verification of the subsystem'. 7. Establishes technical documentation that must *'make it possible to understand the design, manufacture, maintenance and operation of the subsystem, and to assess the conformity with the requirements of the TSI(s), that apply to it'*. 8. *'When the subsystem (...) is subject to derogation(s) (...) [informs] the NoBo thereof'*. 9. *'[Keeps] the NoBo that has issued the EC design examination certificate informed of any modification to the approved design that may affect the conformity with the requirements of the relevant TSI(s) or the conditions for validity of the certificate until its expiry date'*. 10. *'[Draws] up a (...) EC declaration of verification (...)'* or *'in case of intermediate statement of verification (ISV) procedure [draws] up (...) [an] EC declaration of intermediate subsystem*	Regarding the QMS approval 1. *'[Assesses] QMS to determine whether it satisfies the requirements (...)*' 2. *'[Issues] a QMS approval'*. 3. Carries out surveillance 'to make sure that the manufacturer duly fulfils the obligations arising out of the approved QMS'. - *'[Carries] out periodic audits', 'at least once every two years'.* - *'May pay unexpected visits (...) [and] if necessary, carry out subsystem tests, or have them carried out, in order to verify that QMS is functioning correctly'* 4. *'[Evaluates] any proposed changes and decide whether the modified QMS will continue to satisfy the requirements'*. 5. Informs its notifying authorities and the other NoBos of the QMS approvals issued, withdrawn, or refused, suspended or otherwise restricted. **Design** Regarding the design examination 6. *'[Examines] the application'* including technical documentation and supporting evidence. 7. *'[Issues] an EC design examination certificate'* or *'if only certain parts or certain stages of the subsystem are covered (...) an intermediate statement of verification (ISV)'.* 8. For the modifications that require additional approval issues '[additions] to the original EC design examination certificate'. 9. *'[Keeps] copy of the EC design examination certificate, its annexes and additions as well as the technical file including the documentation submitted by the applicant until the expiry of the validity of the certificate'*. 10. Informs its notifying authorities and the other NoBos of the EC design examination

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Table 18: Module SH1 'EC verification based on full quality management system plus design examination'
('old' module SH2 'Full quality management system with design examination')

Tasks of the applicant	Tasks of the notified body
conformity'.	certificates issued, withdrawn, refused, suspended or restricted. **Production and final subsystem inspection, final testing** Regarding the EC verification 11. *'If not [carries] out the surveillance of all the QMS concerned [coordinates] the surveillance activities of any other NoBos responsible for that task (...)'* 12. *'[Issues] an EC certificate of verification'* or *'if only certain parts or certain stages of the subsystem are covered (...) an intermediate statement of verification (ISV)'*. 13. Compiles *'the technical file that has to accompany the EC declaration of verification and the EC declaration of intermediate subsystem conformity'*. 14. Informs its notifying authorities and the other NoBos of the EC certificates of verification issued, withdrawn, refused, suspended or restricted.
After placing in service 11. *'[Keeps] copy of the EC design examination certificate, its annexes and additions together with the technical documentation (...) throughout the service life of the subsystem'*. 12. *'[Keeps] [the EC declaration of verification] throughout the service life of the subsystem'*. 13. Throughout the service life of the subsystem, shall, keeps the QMS documentation and any related updating, the technical file and decisions and reports from the NoBo.	

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4. CERTIFICATES

4.1. In the context of the 'EC' conformity assessment of interoperability constituents and the 'EC' verification of subsystems defined in the Interoperability Directive, a certificate is a document issued by a notified body.

4.2. Notified bodies may issue certificates of the following types:

- For interoperability constituents:
  - EC-type examination certificate (module CB),
  - EC design examination certificate (module CH1),
  - Quality management system approval (module CD, CH or CH1),
  - EC certificate of conformity (module CA1, CA2 or CF),
  - EC certificate of suitability for use (module CV),
- For subsystems:
  - EC-type examination certificate (module SB),
  - EC design examination certificate (module SH1),
  - Quality management system approval (module SD or SH1),
  - EC certificate of verification (module SD, SF, SG or SH1),
  - ISV certificate[1], which may be regarding
    - Type examination (module SB),
    - Design examination (module SH1),
    - EC verification (module SD, SF, SG or SH1)

4.3. As indicated in Annex VI of the Interoperability Directive *'[w]here a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case), the "EC" certificate shall give the precise reference to the TSI(s) or their parts whose conformity has not been examined by the notified body during the "EC" verification procedure'*.

[1]The term 'ISV certificate' is used in Annex VI of the Interoperability Directive. In the 'new' modules, this document is referred to as an 'Intermediate statement of verification'.

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5. DECLARATIONS

5.1. Types of declaration

5.1.1. In the context of the 'EC' conformity assessment of the interoperability constituents and the 'EC' verification of subsystems defined in the Interoperability Directive, a declaration is a document issued *'on his sole responsibility'* by a manufacturer (or its authorised representative) or applicant for the EC verification procedure.

5.1.2. There are the following types of declaration:

- For interoperability constituents:
  - 'EC' declaration of conformity
  - 'EC' declaration of suitability for use
- For subsystems:
  - 'EC' declaration of verification of subsystem
  - 'EC' ISV declaration[2]

5.2. Content and format of declarations

5.2.1. Information to be provided on the declarations is indicated in Annexes IV and V of the Interoperability Directive.

5.2.2. As stated in Article 13(3) of the Interoperability Directive, *'[w]here interoperability constituents are the subject of other Community directives covering other aspects, the 'EC' declaration of conformity or suitability for use shall, in such cases, state that the interoperability constituents also meet the requirements of those other directives'*.

5.2.3. ERA keeps templates for declarations on its website:

http://www.era.europa.eu/Document-Register/Documents/IU-ERADIS-20090827-Practical%20arrangements%20for%20transmitting%20interoperability%20documents%20to%20ERA%20-%20published%20in%20CIRCA.pdf

[2]The term 'EC ISV declaration' is used in Annex VI of the Interoperability Directive. In the 'new' modules, this document is referred to as an 'EC declaration of intermediate subsystem conformity'.

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5.3. Registration of declarations

5.3.1. ERA keeps EC declarations of verification of subsystems and EC declarations of conformity of constituents in the public database:

http://pdb.era.europa.eu/

5.3.2. For further information, see the ERADIS Application Guide on:

http://www.era.europa.eu/Document-Register/Pages/ERADIS-application-guide.aspx

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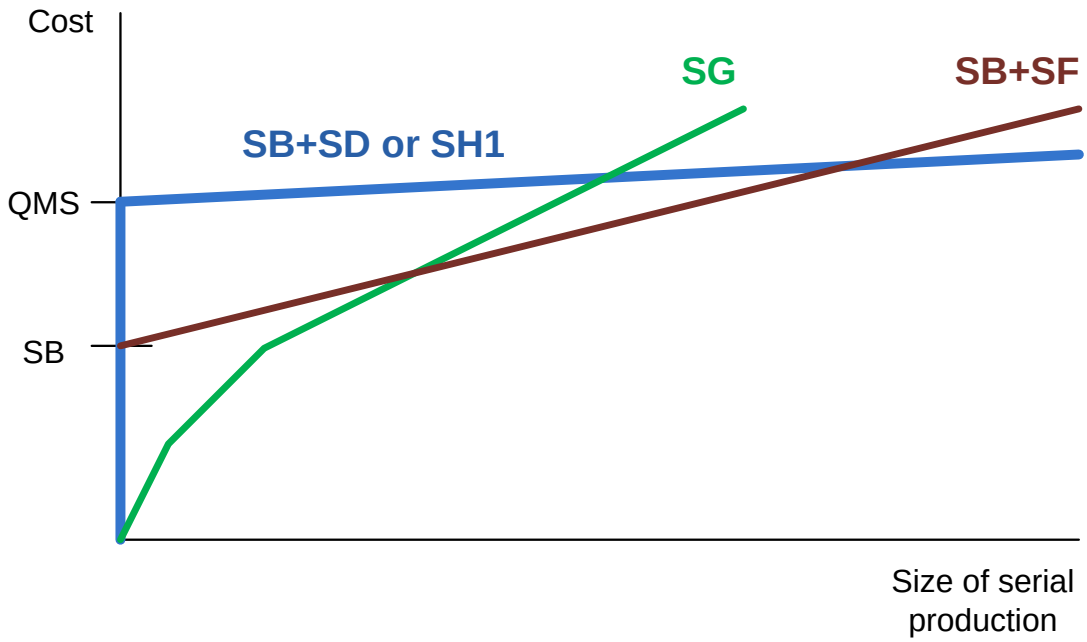
6. CHOICE OF MODULES

6.1. Each TSI indicates which modules may be used for the conformity assessment of an interoperability constituent or verification of a subsystem. It is up to the manufacturer of the IC or applicant for the verification of the subsystem to choose, from those indicated in the TSIs, the module or combination of modules.

6.2. Some of the modules have higher fixed costs (e.g. application of SB+SD or SH1 implies costs before the first unit is produced) and smaller marginal costs for each new unit. The bigger the size of serial production, the more suitable these modules are.

6.3. Some other modules have small fixed costs, but higher marginal costs (e.g. application of SG implies individual verification for every unit). These modules are more appropriate for one-off products.

Figure 7: Cost of application of different conformity assessment modules depending on the size of serial production



6.4. The choice of the module may have an important impact from the cost and time points of view. It is not possible to give a general straightforward rule on which module to select. The choice depends on the particular situation of each company and specific characteristics of the products. However, the following table includes some points that should be taken into account when choosing the conformity assessment modules.

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Table 19: Guidance for selection of conformity assessment modules

Question	Where to find the answer / Comments
1. Is my product • an interoperability constituent or • a subsystem or • a vehicle or • none of the above?	Interoperability constituents are listed in Chapter 5 of each TSI. If the product is not in any of these lists, it is not an interoperability constituent. Subsystems are listed in Annex II of the Interoperability Directive. Further on, the TSIs elaborate on what is the subject of the EC verification. For ICs, the modules CA to CV apply. For subsystems, the modules SB to SH1 apply. Products that are neither ICs nor subsystems are not subject to an independent conformity assessment. They are assessed as part of an IC or a subsystem when integrated into it. They may however be covered by an ISV as a part of a subsystem. Vehicle may be composed of one or more subsystems. Each of these subsystems is subject to EC verification.
2. Interoperability constituents	
2.1. Which TSIs are applicable for my IC?	Chapter 5 of different TSIs, taking into account if the IC intended to be used in several types of subsystem (e.g. in two different types of locomotive, one for high-speed and one conventional) (see section 7 below) For covering several TSIs by one certificate, the NoBo in charge of the conformity assessment must be competent for all the applicable TSIs.
2.2. Is my IC an innovative solution?	Applicable TSIs. If the product does not meet the requirements of the TSI or may not be assessed by the methods specified in the TSI, but is considered to meet the essential requirements of the Interoperability Directive, it is an innovative solution.

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Table 19: Guidance for selection of conformity assessment modules

Question	Where to find the answer / Comments
2.3. Is there any IC of the same type already on the market (i.e. placed on the market before the entry into force of the applicable TSI) or is my IC a new design? • Are these ICs already on the EU market? • Are these ICs already on the EU rail market? • Are these ICs used in similar conditions?	Some TSIs have special provisions for the IC of a type that has been in service at the moment of the TSI's entry into force.
2.4. If my IC is a new design, is it subject to an assessment of suitability for use?	Applicable TSI (normally Chapter 6) indicates whether the use of module CV is required.
2.5. What is the size of my serial production?	Internally, taking into account the potential market in the future. The bigger the size of serial production, the more suitable are modules with lower marginal costs (such as QMS-based modules).
2.6. Will the production be distributed among different design & production sites?	Internally. The NoBo will need to visit these different sites. The associated costs will depend on whether these visits are for QMS approval and audits or for product tests.
2.7. Do I manufacture different ICs or different types of ICs?	Internally, bearing in mind the definition of an IC and their lists in the TSIs. For example, a manufacturer may produce wheelsets and wheels (different ICs) or two types of wheelset (different types of ICs). The same QMS may be used for several products.
2.8. Do I have a Quality Management System in my organisation?	Internally (it may be a non-certified QMS). If yes, QMS-based modules may be used.

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Table 19: Guidance for selection of conformity assessment modules

Question	Where to find the answer / Comments
2.9. What stages does my QMS cover?	Internally. The stages as defined in the modules are: 1. design, 2. production, final product inspection and testing. If both stages are covered, modules CH or CH1 or the combination CB+CD may be used. If the design stage is not covered, CH and CH1 cannot be used, but the combination CB+CD may be used.
2.10. Does my QMS cover different design & production sites?	Internally. For applying QMS-based modules, these sites must be covered by the QMS.
2.11. Do I have in-house resources to demonstrate the conformity of my IC?	Internally. This may be own staff and resources or subcontracting arrangements.
3. Structural subsystems	
3.1. Which TSIs are applicable for my subsystem?	Chapter 1 of different TSIs (see also table in section 2.13 of the guide). A subsystem intended to be used for high-speed and conventional rail is normally covered by both HS and CR TSIs (e.g. rolling stock and onboard CCS). A subsystem is usually covered by a TSI specific to this subsystem (e.g. CR Loc&Pas TSI) plus transversal TSIs (Noise, PRM, SRT)
3.2. Are there any open points applicable to my subsystem?	For the open points, national rules notified by the Member States apply. Conformity with them is assessed by a designated body (DeBo) (Article 17 and Annex VI of the Interoperability Directive). The same organisation may act as NoBo and DeBo.
3.3. Are there any specific cases applicable to my subsystem?	Chapter 7 of the applicable TSIs. Distinction should be made between temporary and permanent specific cases. Conformity with the specific cases is assessed by a designated body (DeBo) (Article 17 and Annex VI of the Interoperability Directive). The scope of work of the NoBo is therefore reduced. The same organisation may act as NoBo and DeBo.

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Table 19: Guidance for selection of conformity assessment modules

Question	Where to find the answer / Comments
3.4. Is my subsystem • new, • the subject of renewal or • the subject of upgrading?	Internally (see definitions of 'renewal' and 'upgrading' in Articles 2(m) and (n) of the Interoperability Directive).
3.5. In the case of renewal or upgrading, to which extent need the TSIs be applied?	According to Article 20(1) of the Interoperability Directive, the Member State in which the subsystem is located *"shall decide to what extent the TSIs need to be applied"*.
3.6. Is there a derogation applicable to my subsystem?	Derogation has to be requested by the Member State and granted by the Commission (Article 9 of the Interoperability Directive). Conformity with the rules that apply instead of the TSI is assessed by a designated body (Article 17 and Annex VI of the Interoperability Directive). The scope of work of the NoBo is therefore reduced. The same organisation may act as NoBo and DeBo.
3.7. What is the size of my serial production?	Internally, taking into account the potential market in the future. The bigger the size of serial production, the more suitable are modules with lower marginal costs (such as QMS-based modules).
3.8. Will the production be distributed among different design & production sites?	Internally. The NoBo will need to visit these different sites. The associated costs will depend on whether these visits are for QMS approval and audits or for product tests.
3.9. Should I apply for several subsystems?	Internally. For example, an infrastructure manager may apply for EC verification of INF, ENE and trackside CCS subsystems. In this case, fixed costs (e.g. QMS approval) may be partially shared.
3.10. Should I apply for different types of the same subsystem?	Internally. For example, a rolling stock manufacturer may apply for different types of locomotives. In this case, fixed costs (e.g. QMS approval) may be partially shared.
3.11. Do I have a Quality Management System in my organisation?	Internally (it may be a non-certified QMS).

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Table 19: Guidance for selection of conformity assessment modules

Question	Where to find the answer / Comments
3.12. What stages does my QMS cover?	Internally. The stages as defined in the modules are[3]: 1. design, 2. production and final subsystem inspection, 3. final testing If all three stages are covered, module SH1 or combination SB+SD may be used. If the design stage is not covered, SH1 cannot be used, but the combination SB+SD may be used.
3.13. Does my QMS cover different design & production sites?	Internally. For applying QMS-based modules, these sites must be covered by the QMS.
3.14. Does my subsystem have an ISV certificate for one or more of its parts?	Internally (ISVs may be provided by suppliers of parts of the subsystem).
3.15. Does my subsystem have an ISV certificate for one or more stages of EC verification (design, production)?	Internally (ISVs may be provided by suppliers of the design).
3.16. Should I apply for an ISV?	In the module SB, an ISV may be especially useful in the case where parts of the design are intended to be reused. An ISV may be used as a tool for ensuring that for each new type only the changes are assessed. For example, in a case of a locomotive 'platform' with different types of vehicle for different energy supply systems, an ISV may cover the mechanical part.
3.17. Do I have in-house resources to demonstrate the conformity of my subsystem?	Internally. This may be own staff and resources or subcontracting arrangements.

[3]Even though the wording defining the stages 1 and 2 for subsystems is slightly different from that defining stages 1 and 2 for ICs, in both cases these two stages should be understood as (1) 'design' and (2) 'production, final product inspection and testing', where 'product' (in the meaning of ISO 17000:2004) is a subsystem or an IC, respectively. The third stage for the subsystem is in accordance with Annex VI of the Interoperability Directive.

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Table 19: Guidance for selection of conformity assessment modules

Question	Where to find the answer / Comments
4. Do I already have EC certificates for the same products for other directives or do I intend/need to apply for them?	Internally.

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7. INTEROPERABILITY CONSTITUENTS SPECIFIED IN DIFFERENT TSIs

7.1. Some ICs may be used for subsystems falling under the scope of different or several TSIs. The following tables show examples of ICs that may be certified under different TSIs. In some cases, the name of the constituent differs slightly from one TSI to another. The manufacturer may have an interest in carrying out a conformity assessment and certifying its ICs simultaneously under these different TSIs. Obviously, the IC must be in conformity with all of these TSIs, and the NoBo must be competent for them.

7.2. Many high-speed trains are also operated on conventional lines. In this case, the CR LOC&PAS TSI also applies to them. Some ICs may be valid for freight and passenger rolling stock.

Table 20: ICs relevant to different TSIs (rolling stock)

WAG TSI	CR LOC&PAS TSI	HS RST TSI
		Automatic centre buffer couplers
Buffers Draw gear		Buffing and draw gear components
Decals for markings		
	Rescue couplers	Towing couplers for recovery and rescue
		Driver's cab windscreens
Bogie and running gear		
Wheelsets		
Wheels	Wheels	Wheels
Axles		
	WSP (wheel slide protection system)	
	Headlights*	Headlamps
	Marker lights*	Marker lamps
	Tail lights*	Tail lamps
	Horns*	Horns

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Table 20: ICs relevant to different TSIs (rolling stock)

WAG TSI	CR LOC&PAS TSI	HS RST TSI
	Pantograph**	Pantographs
	Contact strips*	Contact strips
	Main circuit breaker	
	Toilet discharge connection*	Connections for toilet discharge systems
		Mobile discharge trolleys
	Inlet connection for water tanks*	Water filling adapters
Distributor		
Relay valve for variable load/Automatic empty-load change-over brake		
Wheel slide protection device		
Slack adjuster		
Brake cylinder/actuator		
Pneumatic half coupling		
End cock		
Isolating device for distributor		
	* EC certificates issued for these ICs under the HS RST TSI are valid for the CR LOC&PAS TSI. **EC certificates issued for these ICs under the HS RST TSI is valid for the CR LOC&PAS TSI under certain conditions.	

7.3. ICs defined in the PRM TSI are also relevant for the 'Rolling Stock' subsystem, but do not correspond to any IC defined in either the CR LOC&PAS or HS RST TSIs, and are therefore not included in the table above.

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7.4. Certain types of rail, fastenings and sleepers may be used on both high-speed and conventional lines.

Table 21: ICs relevant to different TSI (infrastructure subsystem)

CR INF TSI	HS INF TSI
Rail	Rail
Rail fastening systems	Rail fastening systems
Track sleepers	Track sleepers and bearers
	Switches and crossings
	Water filling connector

7.5. Normally, due its cost, the overhead contact line for high-speed lines is not used for conventional lines. However, in view of the future merging of the two TSIs, making the conformity assessment for both TSIs simultaneously may be considered.

Table 22: ICs relevant to different TSI (infrastructure subsystem)

CR ENE TSI	HS ENE TSI
Overhead contact line	Overhead contact line

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TERMINOLOGY RELATING TO CONFORMITY ASSESSMENT

The following table provides list of terms used in this guide and their definitions. These terms have mostly already been already defined in the relevant legal documents; in these cases, they are given in italics and in quotation marks, and the source of the definition is indicated. Some of the terms are not defined in the legal documents; in these cases, the definitions have been worked out by the team that drafted this guide, and are not binding.

Table 23: Terminology relating to conformity assessment

Term	Definition (reference)
conformity assessment *)	demonstration that specified requirements (3.1) relating to a product (3.3), process, system, person or body are fulfilled (ISO/IEC 17000:2004, clause 2.1) (clause referred to in the definition is a clause of ISO/IEC 17000:2004)
inspection *)	examination of a product design, product (3.3), process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements NOTE Inspection of a process may include inspection of persons, facilities, technology and methodology. (ISO/IEC 17000:2004, clause 4.3) (clause referred to in the definition is a clause of ISO/IEC 17000:2004)
surveillance *)	systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity (ISO/IEC 17000:2004, clause 6.1)
verification *)	*'confirmation, through the provision of objective evidence (3.8.1), that specified requirements (3.1.2) have been fulfilled* *NOTE 1 The term 'verified' is used to designate the corresponding status.* *NOTE 2 Confirmation can comprise activities such as* *— performing alternative calculations,* *— comparing a new design specification (3.7.3) with a similar proven design specification,* *— undertaking tests (3.8.3) and demonstrations, and* *— reviewing documents prior to issue.'* (EN ISO 9000:2005, clause 8.4) (clauses referred to in the definition are clauses of EN ISO 9000:2005)
validation *)	*'confirmation, through the provision of objective evidence (3.8.1), that the requirements (3.1.2) for a specific intended use or application have been fulfilled* *NOTE 1 The term 'validated' is used to designate the corresponding status.* *NOTE 2 The use conditions for validation can be real or simulated'.* (EN ISO 9000:2005, clause 3.8.5) (clause referred to in the definition are clause of EN ISO 9000:2005)

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Table 23: Terminology relating to conformity assessment

Term	Definition (reference)
certification *)	third-party attestation (5.2) related to products processes, systems or persons (ISO/IEC 17000:2004, clause 5.5) (clause referred to in the definition is a clause of ISO/IEC 17000:2004)
attestation *)	issue of statement, based on a decision following review (5.1), that fulfilment of specified requirements (3.1) has been demonstrated (ISO/IEC 17000:2004, clause 5.2) (clauses referred to in the definition are clauses of ISO/IEC 17000:2004)
good behaviour in service	the fulfilment of the requirements set for the product while in service (-)
in-service experience	validation of product requirements of suitability for use by operation or use of the product in service, integrated representatively into the railway system, over a specified operation time or running distance (-)
validation under full operating conditions *)	validation of a subsystem's conformity to special requirements after installation and placing in service under full operating conditions for a specified period of time (-)
in-service tests	tests, undertaken in service under real operation conditions, to measure and/or to record specified characteristics of the product (-)
monitoring of manufacturing process *)	documented, comprehensive and systematic examination of the manufacturing process devised for manufacturing a product, to evaluate its contribution to product conformity, carried out at the completion of the design process (-)
sampling or drawing of sample *)	selection of one or more specimens out of a whole lot (e.g. on a statistical base) to ensure that the specimens represent the whole (-)
evaluation report	a report on the results of conformity assessment of the extent to which a product fulfils specified requirements (-)

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Table 23: Terminology relating to conformity assessment

Term	Definition (reference)
validation under full operating conditions	validation of a subsystem's conformity to special requirements after completion of the production stage and under the operating conditions the subsystem is intended to be used under after its placing in service (-)

*) Actions within the assessment of conformity procedure.

(-) No reference available to a standard or equivalent document; definition by AEIF or ERA.

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