National procedure for the assessment and certification of components which relate to Interoperability Constituents and UK/GB Specific Cases

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1 Background

For some projects seeking an authorisation for the placing in service of vehicles and infrastructure, potential difficulties have been encountered in the conformity assessment process regarding “Interoperability Constituents”. In some cases, TSIs contain a specific case for the requirements of the Interoperability Constituent (either described in the TSI itself or in a national rule). Notified bodies have identified issues in certifying rail components as an Interoperability Constituent where they are built according to the specific case. The two main issues/questions that were identified are:

1. Whether the constituent if built to the requirements of a specific case and not necessarily fully compliant with the main part of the TSI (chapter 4 and 5), may be considered as an “Interoperability constituent”, as the latter is meant to have an EU wide application, and not only in one member state.

2. How the assessment and authorisation might be carried out in the case where the specific case requirements are fully described in the TSI, or where the specific case in the TSI refers to the notified national technical rules.

[In the TSIs the specific cases are referred to as ‘Particular Requirements’.]

The UK requested the European Railway Agency (ERA) to issue a technical opinion on how interoperability constituents should be certified when they need to meet the requirements resulting from a specific case. The process described in this paper is a voluntary process that has been developed in order to address the problem and gives projects a way of dealing with this issue.
2 ERA’s technical opinion and the need for a national procedure

In response to the UK’s request, on 17 April 2015 ERA published the technical opinion ERA/OPI/2015-2 of the European Railway Agency for European Commission regarding the issue of Interoperability Constituents and Specific Cases raised by UK. The technical opinion states the following:

It seems reasonable that the component, identified as an IC in the TSI, impacted by the specific case requirements, should not need to be considered as an ‘IC’ according to art. 10 to 14 of the Interoperability Directive and in particular it should not require full conformity assessment according to art. 13 and annex VI of the Interoperability Directive. Such component could be assessed at the level of the subsystem into which it is being integrated. The assessment procedures should be agreed between the applicant (manufacturer or entity placing the subsystem in service) and the Member State concerned. The Member State may define a procedure that allows not repeating all the tests each time when the same component is used in the subsequent projects. The component assessed in such a way can only be used within the Member State where the specific case applies.

This technical opinion clearly allows a Member State to develop a procedure such that the component is assessed once and avoids unnecessary repetition of testing.
3 A workshop to identify the national procedure

On the 23 April 2015, RSSB, at the request of the Department for Transport (DfT), facilitated an urgent workshop with involvement from experts and representatives from:

- Department for Transport (DfT)
- Office of Rail and Road (ORR)
- RSSB
- Notified Body for the subsystem
- Notified Body for the IC/component
- Project entity

The objective of the workshop was to develop a generic national framework/procedures aligning with the recommendations set out in ERA’s technical opinion. A sub-objective was that such a framework rely upon existing procedures and certification, and avoid the introduction of new types of certificates or assessment procedures.

RSSB, based on the discussions and decisions at the workshop, has developed the outcomes into a procedure which is set out in Annex A of this document. This procedure can be adopted as the Member State’s procedure associated with the certification of ICs/Components affected by any specific cases in the TSIs.
4 Key elements of the procedure

ERA’s technical opinion under section 3(1) states that:

1. The components of a subsystem which are identified as ICs are listed in chapter 5 of each TSI. If they bear the ‘EC’ Declaration of conformity, ICs may be placed on the market in the conditions set forth in article 10 of the Interoperability Directive.

ERA’s technical opinion under section 3(1) goes on to state the following text which sets out the conditions when a component can be deemed to not be an IC even if it identified as such under Chapter 5 of the relevant TSI:

It seems reasonable that the component, identified as an IC in the TSI, impacted by the specific case requirements, should not need to be considered as an ‘IC’ according to art. 10 to 14 of the Interoperability Directive and in particular it should not require full conformity assessment according to art. 13 and annex VI of the Interoperability Directive... The Member State may define a procedure that allows not repeating all the tests each time when the same component is used in the subsequent projects. The component assessed in such a way can only be used within the Member State where the specific case applies.

The technical opinion also highlights in section 3(2) the scenario where a component can be both an IC and comply with a member state’s specific case(s):

If the component meets also (in addition to specific case) all the requirements as specified for an IC in chapter 4 and 5 of the relevant TSI, the component may be assessed as an IC by NoBo. A NoBo may issue an EC certificate of conformity, and an applicant may issue an EC declaration. Such a component being an IC may be used in the entire EU rail system.

The procedure set out in Annex A of this document, puts this opinion and the associated three scenarios highlighted into effect by setting out how it would apply in the UK.

2.2.1 Principles
At the request of the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18), the verifications may be done for parts of a subsystem or may be limited to certain stages of the verification procedure. In these cases, the results of verification may be documented in an "intermediate statement of verification" (ISV) issued by the notified body chosen by the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18). The ISV must provide reference to the TSIs with which the conformity has been assessed.

It goes on to state:

2.2.1 Parts of the subsystem
The applicant within the meaning of Article 18 may apply for an ISV for any part into which he decides to split the subsystem. Each part shall be checked at each stage as set out in point 2.2.3.

2.2.3 Stages of the verification procedure
The subsystem, or certain parts of the subsystem, shall be checked at each of the following stages:

(a) overall design,
(b) production: construction, including, in particular, civil-engineering activities, manufacturing, constituent assembly and overall adjustment,
(c) final testing.

The applicant (within the meaning of Article 18) may apply for an ISV for the design stage (including the type tests) and for the production stage for the whole subsystem or for any part into which the applicant decided to split it (see paragraph 2.2.2).

The national procedure set out in Annex A of this document uses the ISV process to allow components which cannot be designated as ICs (due to the
need to comply with specific cases which will cause the component to become non-compliant with requirements in Chapter 4 and 5 of the TSI) to be assessed and certified independently from the subsystem into which they may be integrated. It allows for the documentation/evidence developed as part of the first assessment of the component to then be re-used for other projects in the member state.

The ISV would cover any tests associated with the component which can be performed depending on the scope of the ISV and the stage of the project associated with the subsystem.

The procedure in Annex A of this document also clearly sets out the different activities performed by the following actors to get to the point where the component under consideration gains the appropriate assessment documentation/evidence in different scenarios:

- A person(s) who wishes to place a component defined as an IC on the market
- The Nobo assessing the component
- The DeBo assessing conformity with the national rules and supporting the ISV issued by the Nobo for the component

Annex B sets out some additional guidance on the responsibilities of the following actors who would use the assessment documentation/evidence supplied with the component to be integrated into the subsystem:

- The project entity seeking authorisation to place into service for the subsystem into which the component will be integrated
- The Nobo assessing the subsystem

The guidance in Annex B highlights how the documentation related to the component is gathered together and used.
5 The benefits of the proposed procedure

The proposed procedure:

- Gives flexibility to component manufacturers to assess their component independently from the subsystem and then reuse the documentation and evidence in other projects in the member state.
- Gives adequate confidence to the project entity, the NSA and the subsystem NoBo because the evidence produced is based on existing and familiar processes (ISVs).
- Allows for the manufacturers to define the scope of their product/component that they wish to certify and associated tests, without being restricted by what is defined as an IC in the TSI.

6 Next steps

In order to give adequate confidence to the industry projects, the procedure needs to be validated and formally communicated and made available by the NSA and/or the Member State. RSSB recommends that the procedure set out in Annex A is adopted for this purpose.
## 7 References

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<td>Issue of Interoperability Constituents and Specific Cases raised by UK</td>
<td>ERA</td>
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Annex A: National procedure for the assessment and certification of components which relate to Interoperability Constituents and UK/GB Specific Cases

Start
Component is designated as an Interoperability Constituent (IC) (usually in Chapter 5 of the relevant TSI)

1
Is there at least one Specific Case for the UK/GB associated with the IC?

Yes
In complying with all applicable UK/GB Specific Case(s), is it possible for the component to comply with Chapter 4 & 5 of the TSI?

No
Component cannot be considered an IC

3A
Component cannot be considered an IC

3B
Component can be an IC while also complying with the specific cases

4A
An intermediate statement of verification (ISV) issued by a Notified Body (NoBo) can be obtained. The scope of assessment (which requirements in the TSI and National Rules have to be assessed) as well as conditions/limits of use must be clearly set out as part of the ISV.

A Designated Body will carry out the assessment and submit evidence certifying conformity of the component against the National Rules to the component NoBo.

The Notified Body will assess conformity with the TSI requirements as part of issuing the ISV.

5A
An ISV for use in UK/GB.

4B
The component is assessed by a NoBo to obtain an “EC” certificate of conformity and the manufacturer issues an “EC” declaration of conformity or suitability for use as an IC.

The assessment will cover all applicable requirements set out in the TSIs.

For UK/GB use, the EC certificate to be supplemented by an ISV issued by the NoBo, covering National Rules referred to by the Specific Case(s).

A Designated Body will carry out the assessment and submit evidence to the NoBo, certifying conformity of the component against these National Rules.

5B
EC declaration of conformity plus an ISV for use in UK/GB.

4C
The component is assessed by a NoBo to obtain an “EC” certificate of conformity and the manufacturer issues an “EC” declaration of conformity or suitability for use as an IC.

5C
EC declaration of conformity for use in the entire EU rail system.

Annex B sets out the consequences on the subsystem if a component not following this procedure is integrated into it.
Annex B: Additional guidance on how component assessment documentation is used at the subsystem level and what may be expected

Relevant assessment documentation identified in Annex A, will accompany the component which is to be integrated into the subsystem which the applicant is seeking to have authorised to place into service in the member state. In the scenarios, where the component relies on the ISV, it is important to note that Annex VI of COMMISSION DIRECTIVE 2014/106/EU, section 2.3 states the following:

2.3.1 The notified bodies responsible for the verification assesses the design, production and final testing of the subsystem and draw up the certificate of verification intended for the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18), who in turn draws up the “EC” declaration of verification. The certificate of verification must provide reference to the TSIs with which the conformity has been assessed.

2.3.2 Where ISV have been issued, the notified body responsible for the verification of the subsystem takes these ISV into account, and, before issuing its certificate of verification:

(a) verifies that the ISV cover correctly the relevant requirements of the TSI(s),

(b) checks all aspects that are not covered by the ISV, and

(c) checks the final testing of the subsystem as a whole.

It is clear that in order for the subsystem NoBo to carry out the checks and verification efficiently and effectively, it requires a clear and explicit statement of the scope of assessment carried out by the NoBo and/or the DeBo as part of any ISV produced when following the procedure set out in Annex A.

In scenarios 3a. and 3b set out in Annex A, if ISVs are not used/provided as evidence for the component then all TSI requirements and NTRs not covered
will need to be verified and checked at the subsystem level (in line with the NoBo obligation set out in Annex VI, 2.3.2 b) of the Directive 2014/106/EU) and the project entity trying to gain authorisation to place into service.

A component not conforming to NTRs addressing a UK/GB specific case(s) or any applicable TSI requirements will negatively impact the ability of subsystem to meet the essential requirements (safety, reliability and availability, health, environmental protection and technical compatibility), and the subsystem’s ability to gain an authorisation for placing in service from the relevant National Safety Authority (ORR for Great Britain and the Department for Regional Development for Northern Ireland), and to be put into use on the mainline network.

It is recommended that the project entity seeks the advice of the relevant National Safety Authority to validate component assessment scope assumptions and associated testing requirements to ensure that all legal obligations associated with the component are being met.