NATIONAL TECHNICAL SPECIFICATION NOTICE

concerning the assessment of interoperability constituents against UK specific cases, including the further assessment of interoperability constituents which hold an EC declaration of conformity or suitability for use

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Railway Interoperability – The Railways (Interoperability) Regulations 2011

Notice to all:
- Manufacturers and distributors of railway equipment
- Infrastructure managers and railway undertakings
- Railway infrastructure and train: builders, designers, operators, owners and managers
- Certifying authorities, approved bodies, designated bodies, notified bodies, recognised organisations and railway consultants

This Notice should be read with the Railways (Interoperability) Regulations 2011 and other relevant National Technical Specifications Notices (NTSNs). Unless otherwise defined, expressions used in this NTSN have the same meaning as in the Railways (Interoperability) Regulations 2011.

Summary

This Notice has been published by the Secretary of State for Transport pursuant to regulation 3B of the Railways (Interoperability) Regulations 2011 and has effect from exit day.

The objective of the Railways (Interoperability) Regulations 2011 (RIR 2011) is to enhance the interoperability of the rail system through the uniform application of technical standards relating to railway equipment to be placed into service in the UK.

This Notice sets out the procedure that must be followed for the assessment of interoperability constituents against UK specific cases in accordance with regulation 24 (1) and (2) of RIR 2011, including the further assessment of interoperability constituents which hold an EC declaration of conformity or suitability for use in accordance with regulation 24(4) of RIR 2011. The regulation 24(4) further assessment procedure applies in cases where there is an applicable UK specific case for the constituent and the exception at regulation 23(2)(b) of RIR 2011 does not apply.

These constituents are components or groups of components used in railway subsystems and are identified within the NTSNs as products which may be placed on the market providing the necessary assessments have been carried out.
Introduction

1. This NTSN sets out the procedure for designated bodies to undertake the assessment of interoperability constituents (ICs) against UK specific cases, including the further assessment of interoperability constituents which hold an EC declaration of conformity or suitability for use. These requirements for assessment are set out in regulation 24 of RIR 2011 as amended by the Railways (Interoperability) (Amendment) (EU Exit) Regulations 2019. The relevant procedure must be applied for the IC to be placed on the UK market and is necessary in cases where an assessment against an applicable UK specific case is required, and, in the case of a further assessment, where an EC declaration of conformity or suitability for use has already been drawn up and the relevant exceptions do not apply.

UK specific cases and ICs

2. A “UK specific case” is defined under Regulation 2 of RIR 2011 as: “a special provision in relation to the technical specifications for a subsystem or an interoperability constituent to allow for its compatibility with the rail system, which is set out in an NTSN or an NTR and described in that NTSN or that NTR as a “UK specific case.””

3. Under RIR 2011 an “interoperability constituent” is defined as: “any elementary component, group of components, sub-assembly or complete assembly of equipment that is incorporated or intended to be incorporated into a subsystem upon which the interoperability of the rail system depends directly or indirectly; and the concept of a “constituent” covers both tangible objects and intangible objects such as software;”

Determining the appropriate procedure for the assessment of conformity of an IC

4. Under Regulation 24(1), the procedures for assessing the conformity or suitability for use of an interoperability constituent must be carried out by an approved body or, where assessment against an applicable UK specific case is required, by a designated body. The applicable NTSN for the relevant subsystem sets out the appropriate procedures for assessing the conformity or suitability for use of an interoperability constituent by reference to the NTSN concerning modules for the procedures for assessment of conformity or suitability for use and UK verification. If there is an applicable UK specific case relevant to the interoperability constituent identified in the applicable NTSN, the appropriate assessment procedure is described below.

5. Unless an IC was placed on the market in the EU prior to exit day (see reference to the transitional arrangement in regulation 47A(8) below), where no previous assessment of the IC has been undertaken in the UK or the EU and the applicable NTSN contains an assessment requirement (excluding a self-assessment) in respect of that IC, the manufacturer must engage an approved body to assess the IC. Where appropriate, the manufacturer must also engage a designated body to assess the IC’s compliance against any applicable UK specific cases.
6. Under Regulation 24(4), where a person wishes to rely upon an EC declaration of conformity or suitability for use in order to place an interoperability constituent on the UK market they must engage a designated body to carry out a further assessment against any applicable UK specific cases.

7. Under Regulation 23(2) of RIR 2011, a person may place an IC on the market in reliance on an EC declaration of conformity or suitability for use in certain circumstances. One of these is where an EC declaration has been drawn up (either before or after exit day), and there is no UK specific case applicable to the IC (regulation 23(2)(a)). Another is where the EC declaration was drawn up before exit day, there is an applicable UK specific case (or cases), but there is no “material difference” between any of the pre-exit specific case or cases against which the IC was assessed prior to exit and the current applicable UK specific case or cases (regulation 23(2)(b)). The Regulations provide that material difference in this context does not include the replacement of a standard in a TSI or NNTR as it had effect immediately before exit day by an NTSN or National Technical Rule published by the Secretary of State.

**Determining if there is an applicable UK specific case for the IC**

8. There are a number of ICs identified in the NTSNs which may have UK specific cases that are applicable to that constituent. For example, wheels, wheelsets and pantographs are identified as ICs in the relevant NTSNs and there are UK specific cases that are relevant to these ICs. These specific cases cover issues such as the compatibility of pantographs with UK wire heights and wheelsets with UK gauges.

9. The manufacturer will need to determine if there is a UK specific case that is applicable to the IC. Section 5 of each NTSN lists the ICs and section 7 lists the UK specific cases (this mirrors the approach taken in the TSIs). Each NTSN will identify those ICs where there is an applicable UK specific case.

10. The question of whether there is an applicable UK specific case for an IC should also be considered in the context of the railway environment where the IC is intended to be used. For example, it is possible that certain parts of the UK rail system have not been constructed to the requirements set out in the specific case and are constructed as TSI compliant networks instead. This means that ICs that are intended for use on these networks do not need to meet the requirements of the UK specific case because it is not an applicable specific case in that context.

11. When the manufacturer places the IC on the market and makes the declaration required under Schedule 7 of RIR 2011, they will need to refer to its conditions of use (Schedule 7, paragraph 3(e)). Such conditions will include reference to the suitability of the IC for a TSI-compliant railway environment or an environment constructed according to a UK specific case, as appropriate.

12. If a designated body is asked to carry out the assessment procedure against a UK specific case by a manufacturer (including a further assessment), but the designated body considers there is not an applicable specific case for the IC in the context of the railway environment where the manufacturer proposes the IC
to be used, it should inform the manufacturer in writing of its reasons for believing this to be the case and may decline to apply the process.

**Procedure for the assessment of an interoperability constituent where no previous assessment has been carried out**

13. The procedure for the assessment of an IC requires the person proposing to place the IC on the UK market to refer to the applicable NTSN. In practice, this will be the NTSN that replaces or substantially reproduces the TSI which was applicable to the IC prior to exit. That NTSN (e.g. LOC and PAS, WAGON, ENERGY) will list the ICs it covers. The NTSN will also refer to any UK specific case requirements that are relevant to those ICs. The NTSN for the subsystem will also determine the assessment module to be used to assess conformity of the IC. If there are no applicable UK specific cases, the approved body will issue one of the following “examination certificates” depending upon the relevant modules for the IC:

    - UK certificate of conformity,
    - UK certificate of suitability for use,
    - UK type examination certificate,
    - UK design examination certificate
    - Quality management system approval.

14. If there is an applicable UK specific case for the IC, unless the NTSN provides for self-assessment, the person proposing to place the IC on the market must first engage an approved body to assess the conformity against any NTSN requirements which must be met irrespective of the specific case. If the environment where the IC is intended to be used (as described above) is one where the UK specific case does not apply, the person proposing to place the IC on the market need not engage a designated body to check compliance against the applicable UK specific case. However, if this is not the case they shall engage a designated body to check compliance against the applicable UK specific case, and (assuming the IC is compliant) that body will issue the relevant examination certificate as listed above according to the applicable NTSN.

**Flowchart: Procedure for an assessment or a further assessment of ICs**

15. The flowchart at Annex A illustrates a number of scenarios for manufacturers wishing to place ICs on the UK market and how the requirements under RIR 2011 could apply depending upon the circumstances. The boxes at the bottom of the flowchart illustrate some possible outcomes in terms of making or relying upon UK and EC declarations of conformity or suitability for use in order to place ICs on the market.

16. The scenario which involves the procedure for further assessment of an IC by a designated body is illustrated in the flowchart on the left-hand side and the procedure ends at Box A. This illustrates how this procedure will be applied if there is a UK specific case applicable to an IC, that IC already holds an EC
declaration and neither of the exceptions at regulation 23(2)(b) or regulation 47A(8) of RIR 2011 (described at paragraph 10 of this notice) applies.

17. The further assessment procedure is not required in the following cases:

- Cases which fall within regulation 23(2) of RIR 2011, as set out at paragraph 4 (above). Manufacturers of ICs falling within this category do not need to engage a designated body appointed in the UK to undertake a further assessment.

- Cases falling within regulation 47A(8) of RIR 2011, which states that where an IC was placed on the market anywhere in the European Union (including the UK) prior to exit, it should be treated on or after exit day as an IC placed on the UK market in accordance with Part 3 of RIR 2011. The further assessment procedure set out in this notice is not required for such ICs. However, regulation 41 (notices relating to interoperability constituents not meeting the essential requirements) and regulation 42 (notice of improper drawing up of the EC or UK declaration of conformity or suitability for use for an interoperability constituent) of RIR 2011 will continue to apply to such ICs. Regulation 2 sets out a definition of “place on the market”.

18. The flowchart illustrates the different scenarios. These end in the outcomes shown in Boxes A, B, C and D. A description of all of the scenarios is provided below. The provisions for interoperability constituents under Part 3 of RIR 2011 (excluding the further assessment procedure) are still applicable to C and D. Note the explanation below about the previous guidance issued by the RSSB about the national procedure for assessing ICs against specific cases.

19. The outcome of the further assessment procedure set out in Box A at the bottom of the flowchart is based on the assumption that the designated body’s assessment of the IC is positive, i.e. that it considers the IC meets the requirements of the applicable UK specific case.

20. Following a positive assessment by a designated body, they must issue a UK certificate of conformity to confirm that the requirements of the UK specific case have been met. The certificate should include a statement to this effect. The UK declaration of conformity or suitability for use can then be made by the manufacturer for the purposes of placing on the market.

21. It is possible that the designated body applies the further assessment procedure and the outcome is negative. If this is the case the designated body should inform the manufacturer that in its opinion the IC in question does not meet the requirements of the applicable UK specific case. If this is the outcome then a declaration cannot be made by the manufacturer and the IC cannot be placed on the UK market.

22. When carrying out the further assessment procedure, the designated body will refer to the relevant NTSN that replaces or substantially reproduces the TSI which was applicable to the IC prior to exit. That NTSN (e.g. LOC and PAS, WAGON, ENERGY) will list the ICs it covers. The NTSN will also refer to the UK specific case requirements that are relevant to the IC. The designated body will
need to consider the following EC certificate or certificates issued by notified bodies.

- EC certificates of conformity,
- EC certificates of suitability for use,
- EC type examination certificates,
- EC design examination certificates
- Quality management system approvals.

23. They should ask the manufacturer for any supporting evidence they may have as a result of these notified body checks. The designated body may consider that this provides sufficient evidence that the requirements set out in the applicable UK specific case have been met and issue a UK certificate of conformity to reflect this.

24. It is not possible to describe in this NTSN the extent to which such EC certificates and supporting evidence may be relied upon as sufficient evidence to satisfy the designated body that the UK specific case requirements are met. That will be a matter for them to determine on a case by case basis. Depending upon the facts of the individual case, it is possible that the designated body considers that testing of the IC is necessary to determine if the applicable UK specific case requirements are met. If the results from these tests are positive then a UK certificate of conformity may be issued by the designated body which should state the result of these tests.

25. Manufacturers making a declaration for an IC following a positive assessment described above should refer to Schedule 7 of RIR 2011, which lists the contents of the declaration. Paragraph 3(d) refers to a description of the procedure followed in order to declare conformity or suitability for use. It is appropriate to refer to the further assessment procedure when making the declaration. Paragraph 3(f) refers to the date of the examination certificate. In the context of the further assessment procedure this means the date of the UK certificate of conformity issued by the designated body for the IC.

26. Box B - describes a possible outcome where there is an applicable UK specific case and the IC in question does not have an EC declaration. It will require assessment by an approved body (against relevant NTSN requirements additional to those in the UK specific case) and a designated body unless the relevant NTSN allows for self-assessment. The requirements relating to the IC that are separate from the specific case requirements are within the remit of the approved body. These checks are carried out by reference to the relevant NTSN for that subsystem and the Modules NTSN. If the necessary assessments are positive then a UK declaration can be made.

27. Box C - describes a possible outcome where there is not an applicable UK specific case for the IC and an EC declaration has not been made. Unless the relevant NTSN provides for self-assessment, the IC must be assessed by an approved body and the necessary certificates issued as set out in the relevant
NTSN. If the necessary assessments are positive then a UK declaration can be made.

28. **Box D** - describes a possible outcome if there is not an applicable UK specific case for the IC and an EC declaration has been made. The EC declaration will have validity for the purposes of placing the IC on the UK market.

**RSSB procedure for assessing if ICs meet the requirements of UK specific cases**

29. In June 2015 the RSSB published a national procedure for the assessment and certification of components which relate to interoperability constituents and UK/GB specific cases. This procedure was produced in response to concerns about the lack of a framework and methodology for the assessment of ICs in these circumstances. The procedure set out in this notice replaces that RSSB procedure.

**Declarations required and transitional arrangements in NTSNs**

30. Manufacturers should be aware that NTSNs may refer in some cases to the possible issue of certificates of verification for subsystems that may contain ICs without declarations of conformity or suitability for use. These certificates of verification can be issued during periods set out in transitional arrangements within the NTSN. However, such arrangements do not remove obligations under Part 3 of RIR 2011 for a UK declaration of conformity or an EC declaration of conformity or suitability for use falling within the exceptions at regulation 23(2) of RIR 2011 to have been drawn up in respect of an IC in order to place it on the market in the UK.
ANNEX A FLOWCHART

PLACING AN IC ON THE MARKET IN THE UK AFTER EXIT

START

1. Component is identified as an Interoperability Constituent (IC) in the relevant NTSN.

2. Is there an applicable UK Specific Case for the IC?

   NO

   4. The IC must be assessed by an Approved Body for conformity against relevant NTSN requirements in accordance with the relevant subsystem NTSN and the Modules NTSN, unless the relevant NTSN allows for self-assessment. Approved body issues relevant examination certificates.

   YES

   3. Do you have an EC declaration for the IC?

      NO,
      there is no technical documentation associated with conformity assessment

      YES,
      there is technical documentation associated with conformity assessment against relevant requirements except the UK Specific Case

      4. The IC must be assessed by a Designated Body (DeBo) for conformity against relevant NTSN requirements which are additional to the UK Specific Case(s) in accordance with the relevant subsystem NTSN and the Modules NTSN, unless the relevant NTSN allows for self-assessment. The DeBo issues relevant examination certificates.

      A. If assessment is positive, the manufacturer must issue a ‘UK’ declaration of conformity for the purpose of placing the IC on the market in the UK.

      B. If assessments are positive, the manufacturer must issue a ‘UK’ declaration of conformity for the purpose of placing the IC on the market in the UK.

      C. If assessment is positive, the manufacturer must issue a ‘UK’ declaration of conformity for the purpose of placing the IC on the market in the UK.

      D. ‘EC’ declaration of conformity is recognised in the UK for the purpose of placing the IC on the market in the UK.

   NO,
   there is no technical documentation associated with conformity assessment

   3. Do you have an EC declaration for the IC?

      NO,
      there is no technical documentation associated with conformity assessment

      YES,
      there is technical documentation associated with conformity assessment against relevant requirements

      4. The IC must be assessed by an Approved Body for conformity against relevant NTSN requirements in accordance with the relevant subsystem NTSN and the Modules NTSN, unless the relevant NTSN allows for self-assessment. Approved body issues relevant examination certificates.

      A. If assessment is positive, the manufacturer must issue a ‘UK’ declaration of conformity for the purpose of placing the IC on the market in the UK.

      B. If assessments are positive, the manufacturer must issue a ‘UK’ declaration of conformity for the purpose of placing the IC on the market in the UK.

      C. If assessment is positive, the manufacturer must issue a ‘UK’ declaration of conformity for the purpose of placing the IC on the market in the UK.

      D. ‘EC’ declaration of conformity is recognised in the UK for the purpose of placing the IC on the market in the UK.