Dear Stefano Valentino,
Please accept this email and its attachments as RSSB's response to the consultation on the Railways and Guided Transport (Miscellaneous Amendments) Regulations 2010.
Yours sincerely,
Andrew Sharpe

Andrew Sharpe
Director of Standards and Technical Services, RSSB
Block 2, Angel Square, 1 Torrens Street, London EC1V 1NY

From: Jon Taylor
Sent: 07 June 2010 16:43
To: Andrew Sharpe
Cc: Graham Arkwright
Subject: Consultation on the Railways and Guided Transport (Miscellaneous Amendments) Regulations 2010

Andrew

Industry Standards Coordination Committee (ISCC), at its meeting on 21 May 2010 supported the proposal that RSSB's response to the ORR's consultation on the Railways and Guided Transport (Miscellaneous Amendments) Regulations 2010 should take the form of the briefing papers RSSB prepared for ISCC, together with extracts from the relevant ISCC and Safety Policy Group (SPG) minutes.

As the ORR's consultation on the Railways and Guided Transport (Miscellaneous Amendments) Regulations 2010 is aligned with the DfT's consultation on the transposition of Directive 2008/57/EC on the interoperability of the rail system, the briefing papers RSSB prepared for ISCC on draft Railways (Interoperability) Regulations 2010 are also relevant, particularly as some of the issues identified within the papers relate to the interface between the two sets of regulations.

Attached are copies of the papers and extracts from the minutes.

Email consultation responses should be directed to: Stefano.valentino@orr.gsi.gov.uk.

If you are content, could you forward this e-mail to the above e-mail address as RSSB's response.

Jon T

AGENDA ITEM: 4.2

MEETING:	**Industry Standards Co-ordination Committee**
DATE:	**21 May 2010**
SUBJECT:	**Paper A4 - Draft Railways (Interoperability) Regulations 2010: Miscellaneous issues (continued)**
SPONSOR:	**Andrew Sharpe**
AUTHOR:	**Jon Taylor**

1 Purpose of the paper

1.1 The Department for Transport (DfT) initiated a consultation on a draft of the Railways (Interoperability) Regulations 2010 on 29 March 2009. These regulations transpose Directive 2008/57/EC on the interoperability of the rail system.

1.2 RSSB has produced a series of papers for ISCC discussing different aspects of the regulations.

1.3 Paper A3 in the series drew ISCC's attention to a number of miscellaneous issues relating to the draft regulations. That paper did not document every issue relating to the draft regulations – further time was needed to complete the analysis of the regulations.

1.4 This paper (Paper A4) deals with the issues identified in section 8 of Paper A3 as likely to require further analysis.

1.5 Section 2 of this paper summarises the identified miscellaneous issues. Supporting details are set out in sections 3 to 25 and recommendations are made in section 26.

2 Summary of issues

2.1 **Distinction between the rolling stock subsystem and vehicles:** In not following the Directive in distinguishing between 'rolling stock' (a structural subsystem) and 'vehicles' (a compound of subsystems or parts of subsystems), the regulations may introduce some unanticipated difficulties. See section 3.

2.2 **Determination of type:** the role of the Safety Authority, the distinction between 'rolling stock subsystem' and 'vehicle', and the determination of type when applied to the CCS, ENE and INF subsystems. See section 4.

2.3 **Implementation plans:** the scope of implementation plans, applications to the competent authority for decisions as to whether authorisation is required, and the basis for such decisions. See section 5.

2.4 **Verification assessment procedures for project subsystems:** the references to schedule 6, the meaning of 'configuration control', and the assessment of interfaces. See section 6.

2.5 **Interoperability constituents:** a potential lack of clarity as to which things are actually 'interoperability constituents', the lack of a mandatory requirement in regulation 23; the apparently mandatory use of 'European Specifications', the requirement to always use a Notified Body, the reference to 'procedures set out in Schedule 7'. See sections 7 to 9.

2.6 **Designated bodies:** the nature and use of 'designated bodies' to assess conformity with notified national technical rules. See section 10.

2.7 **The register of infrastructure:** the content of the register, structural subsystems other than rolling stock fitted to vehicles, responsibility for registers of station infrastructure, timescales for compliance. See section 11.

2.8 **The national vehicle register:** The regulations do not recognise the GB specific case exempting vehicles used in domestic traffic from carrying (that is, being marked with) the European vehicle number assigned to it. See section 12.

2.9 **Annexes from Directive 2008/57/EC:** The Annexes to the Directive are drafted in style that is significantly different from the main text of the Directive. As a result, the substantial reproduction of the Annexes as Schedules in the regulations is not always either necessary or helpful. It is suggested that the Annexes to the Directive are not simply copied into the Schedules, but are transposed (as has been done for the main body of the Directive) and subject to a proper legal review. See sections 13 to 25.

3 Distinction between the rolling stock subsystem and vehicles

3.1 One of the most significant changes introduced by Directive 2008/57/EC is that it deals with three classes of object:

- interoperability constituents (covered in Chapter III)
- subsystems (covered in Chapter IV)
- vehicles (covered in Chapter V)

3.2 The pervious Directives appear to have only dealt with two classes of object: interoperability constituents and subsystems. The introduction of 'vehicles' is probably the result of moving matters relating to the authorisation of vehicles from Article 14 of the Safety Directive (2004/49/EC) into the Interoperability Directive (2008/57/EC).

3.3 In Directive 2008/57/EC, 'rolling stock' and 'vehicles' are not the same things. Rolling stock is a structural subsystem, but a vehicle is something composed of parts of different subsystems (mainly RST, but with bits of CCS and ENE for example). This is recognised in the definitions in the Directive:

(c) 'vehicle' means a railway vehicle that runs on its own wheels on railway lines, with or without traction. A vehicle is composed of one or more structural and functional subsystems or parts of such subsystems;

(e) 'subsystems' means the result of the division of the rail system, as shown in Annex II. These subsystems, for which essential requirements must be laid down, may be structural or functional;

3.4 The Directive does not define 'rolling stock' as a term, but it does identify it in Annex II as a structural subsystem.

3.5 The draft regulations do not maintain the distinction between 'rolling stock' and 'vehicles'. They define rolling stock as:

"rolling stock" means a vehicle, or where a vehicle can only be operated as part of a fixed formation multiple unit the whole of that unit;

3.6 This definition is not what the Directive means by 'rolling stock'. In the Directive, rolling stock is only one of the subsystems from which a vehicle may be composed.

3.7 In not following the Directive in distinguishing between 'rolling stock' (a structural subsystem) and 'vehicles' (a compound of subsystems or parts of subsystems), the regulations may introduce some unanticipated difficulties.

4 Determination of type

4.1 Regulation 8(1) states:

8.—(1) If the Safety Authority has issued an authorisation under these Regulations for the placing in service of rolling stock, the Safety Authority must determine that the rolling stock is of a particular type.

(2) If the Safety Authority has issued an authorisation under these Regulations for the placing in service of a structural subsystem that is not rolling stock, the Safety Authority may determine that the structural subsystem is of a particular type.

4.2 As noted above, there is a distinction to be made between 'rolling stock' (a subsystem) and 'vehicles' (made up from different subsystems):

4.3 Directive 2008/57/EC specifically deals with vehicle types, not rolling stock types:

Article 2
Definitions

For the purposes of this Directive:

> *(w) 'type' means a vehicle type defining the basic design characteristics of the vehicle as covered by a single type examination certificate described in module B of Decision 93/465/EEC*

4.4 Regulation 8(1) should be amended to refer to the placing in service of vehicles. Regulation 8(2) should be amended by deleting the words 'that is not rolling stock'.

4.5 The extension of the concept of 'type' to structural subsystems that are not parts of a vehicle is a novelty not envisaged by Directive 2008/57/EC. Its practical application is likely to be limited.

4.6 Regulation 8 appears to place a considerable burden on the Safety Authority, as it requires the Safety Authority to determine that the rolling stock is of a particular type and, when requested by a contracting entity that the structural subsystem is of a particular type. Regulation 8(4) then requires that:

> *(4) A determination of type must describe the basic design characteristics of the structural subsystem in the same manner and to the same extent as an EC-type examination certificate issued in accordance with the procedures of Module B in Annex II to Decision 768/2008/EC of the European Parliament and of the Council of 9th July 2008 on a common framework for the marketing of products.*

4.7 This requirement is presumably derived from the definition of 'type' in Directive 2008/57/EC:

> *'type' means a vehicle type defining the basic design characteristics of the vehicle as covered by a single type examination certificate described in module B of Decision 93/465/EEC*

4.8 Decision 93/465/EEC has been superseded by Decision 768/2008/EC.

4.9 Module B in Annex II to Decision 768/2008/EC is 'EC-type examination'. It states:

> *6. Where the type meets the requirements of the specific legislative instrument that apply to the product concerned, the notified body shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.*
>
> *The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.*

4.10 It is not clear whether the regulations, when requiring a determination of type to describe the basic design characteristics of the structural subsystem 'in the

same manner and to the same extent as an EC-type examination certificate' is referring to either, or both:

- the necessary data for identification of the approved type
- all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control

4.11 In either case, the reference to 'the same manner and to the same extent as an EC-type examination certificate issued in accordance with the procedures of Module B in Annex II to Decision 768/2008/EC' does not actually set out what basic design characteristics must be described.

4.12 The modules provided in Decision 768/2008/EC are applicable only to products. They are not designed or intended for the verification of subsystems. Therefore for the purpose of EC verification of subsystems the TSIs contain 'adapted' modules, specific to that purpose.

4.13 The use of Module B is only appropriate to assessment of conformity of interoperability constituents, not subsystems. It should also be noted that TSIs allow a choice of modules for the purpose of EC verification of subsystems

4.14 Therefore the information contained in the documentation supplied to the Safety Authority for the purpose of Regulation 5(2) will not necessarily 'describe the basic design characteristics of the structural subsystem in the same manner and to the same extent as an EC-type examination certificate issued in accordance with the procedures of Module B in Annex II to Decision 768/2008/EC'.

4.15 It should be further noted that Directive 2008/57/EC states in Article 26(5):

> *5. The declaration of conformity to type shall be established in accordance with:*
>
> *(a) for TSI conform vehicles, the verification procedures of the relevant TSIs;*
>
> *(b) for non-TSI conform vehicles, the verification procedures as defined in modules D or E of Decision 93/465/EEC. Where appropriate, the Commission may adopt an ad hoc verification procedure in accordance with the regulatory procedure referred to in Article 29(3).*

4.16 Some other way of defining the manner and extent to which the basic design characteristics of the structural subsystem must be described is needed.

5 Implementation plans

5.1 The term 'implementation plan' is not defined. The purpose of the implementation plans must therefore be inferred, as it is not explicit.

Implementation plans are only referenced in Regulations 12 and 13 (although there is also a passing reference to implementation plans in Schedule 6).

5.2 Regulation 12(1) states:

> *12.—(1)The Competent Authority may publish an implementation plan for a TSI.*
>
> *(2) If such a plan is published under this regulation the Competent Authority must include in the plan a list (the "regulation 12 list") that names or describes each project or type of project that—*
>
> > *(a) deals with matters covered by the TSI to which the implementation plan relates, and*
> >
> > *(b) is, in the opinion of the Competent Authority, a project or type of project for the renewal or upgrading of an existing structural subsystem.*

5.3 Regulation 13 states:

> *13.—(1) Subject to paragraph (2), in relation to a project for the renewal or upgrading of an existing structural subsystem that deals with matters covered by a TSI, a contracting entity must apply in writing to the Competent Authority for a decision as to whether an authorisation is required for that subsystem to be placed in service.*
>
> *(2) If the Competent Authority has published an implementation plan under regulation 12 for a TSI, paragraph (1) only applies in relation to that TSI if the project is named or is of a type described in the regulation 12 list.*

5.4 The implementation plans contain a list of projects or types of project that the Competent Authority has decided in advance are 'for the renewal or upgrading of an existing structural subsystem'.

5.5 There is therefore an implication (but no more than an implication) that the implementation plan will also contain a statement as to whether particular projects or types of project require an authorisation to be placed in service.

5.6 It was understood from earlier discussions between the DfT and industry representatives that the implementation plans would also contain a statement about the 'extent TSIs must apply to the project subsystem'. This element of the implementation plans has been omitted from the draft regulations. Regulation 13(9) makes no mention of implementation plans, stating:

> *13.—(9) Where the Competent Authority determines that the subsystem requires an authorisation—*
>
> > *(a) the Competent Authority must, subject to any derogations under regulation 14, decide to what extent TSIs must apply to the project subsystem; and*

(b) the Secretary of State must notify that decision to the Commission and other Member States.

5.7 It is suggested that the term 'implementation plan' is defined in regulation 2(3).

5.8 It is suggested that the regulations should be more explicit as to the content and purpose of implementation plans. Regulation 12 should at least make it explicit that the plans must also include a statement as to whether particular projects or types of project require an authorisation to be placed in service. If the omission of a statement about the extent TSIs must apply to a particular project subsystem from the implementation plans is not intentional, then this too should be included and regulation 13(9) amended accordingly.

5.9 Regulation 12(1) states that 'The Competent Authority may publish an implementation plan for a TSI'.

5.10 There are several objections to the choice of TSIs as the target for implementation plans, particularly as Regulation 12(2) then refers to 'each project or type of project':

- Projects are not undertaken in order to implement TSIs - they are undertaken for other reasons (for example, to increase speed or capacity), but in doing so it might be necessary to implement a TSI.
- Some TSIs contain requirements relevant to vehicles, infrastructure subsystems and functional subsystems – for example, the Safety in Railway Tunnels (SRT) TSI and the People with Reduced Mobility (PRM) TSI. Generally projects will not encompass all three of the subjects (vehicles, infrastructure subsystems and functional subsystems) covered by these TSIs.
- The Regulations apply to projects for which there is not yet a TSI.
- Section 5(2) of Schedule 6 specifically refers to 'the implementation plans and technical documentation concerning the subsystem'.

5.11 It is suggested that implementation plans are targeted at subsystems rather than TSIs.

5.12 Implementation plans for functional subsystems are excluded from the regulations. However, 'implementation plans' are required for some functional subsystems. For example, the Conventional Rail Operations TSIs requires:

> *Implementation of this TSI and conformity with the relevant sections of this TSI must be determined in accordance with an implementation plan that shall be drawn up by each Member State for the lines for which they are responsible.*

5.13 [See section 7.1 of the Annex to Commission Decision 2006/920/EC of 11 August 2006 concerning the technical specification of interoperability relating

to the subsystem 'Traffic Operation and Management' of the trans-European conventional rail system.]

5.14 Consideration should therefore be given to how implementations plans required by TSIs (which are not implementation plans in the sense of the regulations) are created and given force.

5.15 Regulation 13(6)(a) refers to 'the implementation strategy provided in any applicable TSI'. To avoid confusion it is suggested that the term 'implementation strategy' is also defined in regulation 2(3).

5.16 Regulation 12(3) states:

> *(3) In deciding whether a project or type of project is a renewal or upgrade factors to be taken into account by the Competent Authority must include—*
>
> > *(c) the impact on the accessibility of the rail system to passengers of applying or not applying the TSI to the project;*

5.17 As drafted, the meaning of this requirement is not entirely clear. It is presumably intended to specifically refer to accessibility for people with reduced mobility, rather than all passengers (Regulation 48 is headed 'Accessibility for people with reduced mobility'). It is suggested the clause is redrafted to read:

> *(c) the impact on the accessibility of the rail system to people with reduced mobility of applying or not applying the TSI to the project;*

6 Verification assessment procedures for project subsystems

6.1 Most of the issues relating to verification assessment procedures for project subsystems are associated with Schedule 6, and are dealt with in the section of this paper addressing issues associated with Schedule 6. There are however a few additional issues to be considered.

6.2 Regulation 17(2) requires:

> *(2) The notified body must—*
>
> > *(a) compile a file containing:*
> >
> > > *(iv) manuals and instructions relating to the servicing, constant or routine monitoring, adjustment, maintenance and configuration controls of the project subsystem;*

6.3 This clause is based on Article 18(3) of Directive 2008/57/EC which states:

> *18(3). The notified body shall be responsible for compiling the technical file that has to accompany the 'EC' declaration of*

verification. This technical file must contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents. It should also contain all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance.

6.4 The requirement to include 'configuration controls' in the technical file is in addition to the requirements of the Directive. The term is also used in Regulation 7(3)(b)(iii) in a similar context.

6.5 The term is not defined in the regulations, and therefore may not be clear in its intent. It is presumably intended to refer to configuration management. A definition should be provided in Regulation 2(3).

6.6 Regulation 17(2) and 17(3) require:

(2) The notified body must—

(b) assess the interface between the project subsystem and the part of the rail system in which it will be placed in service to the extent that such an assessment is possible based on the available information referred to in paragraph (3).

(3) The assessment under paragraph (2)(b) must be only based on information available in the relevant TSI and in any registers kept in accordance with Article 34 (European register of authorised types of vehicles) and Article 35 (register of infrastructure) of the Directive.

6.7 It is not clear what 'assessing the interface' involves. The equivalent article in Directive 2008/57/EC refers to 'verification of the interfaces of the subsystem in question with the system into which it is incorporated'. Verification would seem to be the better word. Simple definitions of assess and verify are:

***assess**: to judge or decide the amount, value, quality or importance of something.*

***verify**: to prove that something exists or is true, or to make certain that something is correct.*

6.8 Verification is therefore the correct word, and the regulation should be amended to follow the Directive.

6.9 The regulations state the 'assessment' must be only based on information available in …'. This creates an explicit prohibition on using anything other than the documents listed. There is no equivalent prohibition in the Directive, which only states positively what must be used.

6.10 The register kept in accordance with Article 34 (European register of authorised types of vehicles) is kept by ERA.

6.11 The keeper of the register kept in accordance with Article 35 (register of infrastructure) of the Directive is not specified within the Directive. The Directive merely says 'Each Member State shall ensure that a register of infrastructure is published and updated'. Regulation 39 states that it is for an infrastructure manager to keep a register of its infrastructure, and ensure it is available on a publicly available website. It would therefore be better to refer to 'the registers kept in accordance with Regulation 39', rather than refer to Article 35 of the Directive.

6.12 To resolve the issues noted above, the regulation could be amended to read:

> (2) The notified body must—
>
> > (b) verify the interface between the project subsystem and the part of the rail system in which it will be placed in service to the extent that verification is possible based on the information available in the relevant TSI, the register kept in accordance with Article 34 of the Directive (European register of authorised types of vehicles) and the registers kept in accordance with Regulation 39.

6.13 Some guidance on what a notified body would need to do to comply with this element of the regulations is probably necessary.

7 Interoperability constituents: identifying interoperability constituents

7.1 Regulation 2(3) states:

7.2 Interpretation

> *2.—(3) In these Regulations—*
>
> *"interoperability constituent" means 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;*

7.3 The definition derives from the Directive.

7.4 In practice, TSIs specify requirements for a limited number of interoperability constituents. For example, the High Speed Infrastructure TSI lists only five: rail, rail fastening systems, track sleepers and bearers, switches and crossing, water filling connectors.

7.5 However, this is far from a complete list of constituents 'upon which the interoperability of the rail system depends directly or indirectly'. For example, the interoperability of the rail system depends on the strength of track, which in turn depends on the strength of rail joints, including insulated joints and welds. Neither are ICs.

7.6 In practice, it would never be possible for TSIs to contain a complete list of constituents 'upon which the interoperability of the rail system depends', and it would not be possible to exhaustively specify their requirements, particularly in the case of specialist items used in small numbers (consider for example a one-off design of expansion switch for an exceptionally long bridge).

7.7 There is therefore a problem in deciding what an IC is. According to the definition, there are many ICs for which there are no requirements in TSIs. But in practice, the working assumption is that only those constituents listed in the TSIs are 'interoperability constituents' requiring an EC declaration of conformity or an EC declaration of suitability for use.

7.8 The regulations should recognise the working assumption noted above. There is an opportunity to do so in Regulation 26:

> *26.—(1) No person may place any constituent identified as an interoperability constituent in a TSI on the market with a view to its use on the trans-European rail system or, if there is an applicable TSI, on any other part of the rail system, unless—*

7.9 This will a allow constituents that meet the strict definition of an interoperability constituent, but for which there are no requirements in TSI, to be placed on the market without an EC declaration of conformity or suitability for use.

7.10 If necessary, a new definition could be added for 'constituent':

> *"constituent" means an elementary component, group of components, sub-assembly or complete assembly of equipment that is incorporated or intended to be incorporated into a subsystem; and the concept of a "constituent" covers both tangible objects and intangible objects such as software;*

7.11 Longer term, there is a case to be made for rethinking the concept of an IC from scratch.

8 Interoperability constituents: use of notified bodies to assess conformity or suitability for use

8.1 Regulation 25(1) states:

> *25.—(1) The appropriate procedures for assessing the conformity or suitability for use of an interoperability constituent must be carried out by a notified body in accordance with—*
>
> > *(a) subject to paragraph (2), the procedures (if any) specified in any TSIs with which the interoperability constituent must comply;*

(b) the procedures (if any) specified in any European specifications with which the interoperability constituent must comply;

(c) any relevant procedures set out in Schedule 7.

8.2 If an interoperability constituent is identified as such in a TSI there should always be a procedure for assessing the conformity or suitability for use specified in Chapter 6 of the TSI.

8.3 However, not all the procedures specified in TSIs require the involvement of a notified body. For example, in the High Speed Infrastructure TSI, application of Module A, Internal Production Control, does not require the involvement of a notified body. This module may be used in certain circumstances for all interoperability constituents except rail.

8.4 The requirement in Regulation 25(1) to always employ a notified body for assessing the conformity or suitability for use of an interoperability constituent is contrary to Article 13(2) of Directive 2008/57/EC, which states:

2. Where the corresponding TSI so requires, assessment of the conformity or suitability for use of an interoperability constituent shall be carried out by the notified body with which the manufacturer or his authorised representative established in the Community has lodged the application.

8.5 In passing, it should be noted that the 'European specifications' referred to in 25(1)(b) includes, by definition, a common technical specification, and a common technical specification includes, by definition, a TSI. Formally, 25(1)(a) is probably redundant.

8.6 There are no relevant procedures for 'assessing the conformity or suitability for use of an interoperability constituent' in Schedule 7.

9 Interoperability constituents: EC declaration of conformity or of suitability for use

EC declaration of conformity or of suitability for use

23.—(1) An EC declaration of conformity or an EC declaration of suitability for use is a declaration drawn up by the relevant person in accordance with the requirements of ***Schedule 4*** *that indicates that the interoperability constituent satisfies the requirements—*

(a) of such European specifications as have been published in the Official Journal that are relevant to the interoperability constituent;

(b) of such TSIs that are relevant to the interoperability constituent;

(c) where a TSI relevant to the interoperability constituent requires compliance with a European specification that has not been published in the Official Journal, of the latest version of that draft European specification if so required by the TSI.

9.1 It should be noted that Regulation 23, as drafted, is not actually a regulation, but a definition that ought perhaps to be part of Regulation 2(3). It does not require anybody to do (or not do) anything.

9.2 The statement that a declaration 'indicates …that the interoperability constituent satisfies the requirements … of such European specifications as have been published in the Official Journal that are relevant to the interoperability constituent' may be misleading.

9.3 The interpretation of this regulation hinges on the meaning of the term 'published in the Official Journal'. If 'published' means that the full text of the European specification is set out in the Official Journal, the regulation is probably correct. However, if 'published' encompasses listing*, the regulation is misleading.

9.4 [* For example, the Official Journal publishes a list of 'titles and references of harmonised standards under the directive' for the high-speed rail system.]

9.5 An interoperability constituent does not necessarily have to satisfy the requirements of a European standard, even though the Official Journal may list it as harmonised against a TSI (and it is therefore 'relevant to the interoperability constituent'). Under the new approach, a manufacturer may choose to demonstrate that the essential requirements have been met by either conformity with the harmonised standard, or by some other way.

9.6 Again, note that 'European specifications' includes, by definition, a common technical specification, and a common technical specification includes, by definition, a TSI. Formally, 23(1)(b) is probably redundant.

10 Designated bodies and assessment of conformity with notified national technical rules

10.1 The role of the designated body is to assess conformity with notified national technical rules if any are applicable. Note that notified national technical rules apply only to subsystems, and not interoperability constituents.

10.2 The regulations expect the output from the conformity assessment to be a 'certificate of conformity with notified national technical rules'. This is a certificate issued by the designated body containing a statement from the body 'that in its opinion a subsystem conforms with the applicable notified national technical rules'.

10.3 The regulations recognise that the EC verification procedure produces more than a simple certificate, and that these outputs are to be included in the technical file.

10.4 However, there is no recognition that the output from the assessment of conformity with notified national technical rules is also likely to be far more than a certificate. For example, regulation 49 permits dispensations from notified national technical rules in accordance with Regulation 49, and that these may be conditional.

10.5 Regulation 19(2) requires:

> *(2) A contracting entity must ensure that—*
>
> > *(a) any alterations made to the project subsystem are documented;*
> >
> > *(b) the documentation recording any alterations and any maintenance manuals in relation to the project subsystem are added to and kept as part of the technical file; and*
> >
> > *(c) the safety assessment report and any certificate of conformity with notified national technical rules are added to and kept as part of the technical file.*

10.6 A Notified Body is not required to include the certificate of conformity with notified national technical rules in the technical file that they compile in accordance with Regulation 17(2)(a).

10.7 As Regulation 19(1) applies 'From the time a project subsystem is authorised' and points (a) and (b) of Regulation 19(2) refer to 'alterations', it can be supposed that the certificate of conformity with notified national technical rules is only included within the technical file after authorisation, and not before.

10.8 Article 18(3) of Directive 2008/57/EC requires:

> *18(3). The notified body shall be responsible for compiling the technical file that has to accompany the 'EC' declaration of verification. This technical file must contain all the necessary documents relating to the characteristics of the subsystem and, where appropriate, all the documents certifying conformity of the interoperability constituents.*

10.9 The outputs from the assessment of conformity with notified national technical rules are 'necessary documents relating to the characteristics of the subsystem' and should therefore be included in the technical file by the notified body.

10.10 Section 1 of Schedule 6 states that EC verification is the procedure whereby a notified body checks and certifies that the subsystem complies with the Directive. To do this, the notified body must check that conformity with notified national technical rules has been assessed, even though the assessment itself is undertaken by a separate body. To do this, the notified body will need copies of the outputs from the assessment of conformity with notified national technical rules.

10.11 The process for assessment of conformity with notified national technical rules set out in the regulations therefore does not appear to be fully integrated into the authorisation process.

10.12 One possible approach is to require the designated body to pass the certificate of conformity with notified national technical rules, together with the equivalent of a technical file relating to the assessment of conformity, to the notified body for inclusion in the technical file before authorisation. The notified body is already required to collate other conformity assessment certificates, notably for the interoperability constituents incorporated into the subsystem, but also, where necessary, the certificates produced in response to other Directives (See Schedule 6, section 1, last point).

10.13 Regulation 32(3) states that 'For the purposes of this regulation Schedule 7 applies to a designated body as it applies to a notified body'. The section of this paper addressing issues associated with Schedule 7 therefore applies as much to designated bodies as to notified bodies.

11 The register of infrastructure

11.1 Regulation 39(1) states:

39.—(1) An infrastructure manager must keep a register of its infrastructure.

11.2 The term 'infrastructure manager' is not defined in the regulations. ROGS 2006 states:

> *"infrastructure manager" means the person who—*
>
> *(a) in relation to infrastructure other than a station, is responsible for developing and maintaining that infrastructure or, in relation to a station, the person who is responsible for managing and operating that station, except that it shall not include any person solely on the basis that he carries out the construction of that infrastructure or station or its maintenance, repair or alteration; and*
>
> *(b) manages and uses that infrastructure or station, or permits it to be used, for the operation of a vehicle;*

11.3 There are therefore many infrastructure managers in UK, and there will be many infrastructure registers. It is likely that 'in relation to a station, the person who is responsible for managing and operating that station' will need to have the responsibilities imposed by the regulations specifically drawn to their attention.

11.4 Regulation 39(6) states:

(6) In this regulation—

(a) "infrastructure" means a structural subsystem, other than rolling stock;

11.5 Parts of the CCS and ENE subsystems are incorporated into vehicles (see the definition of vehicle in regulation 2(3)). Vehicles are not the responsibility of infrastructure managers, so therefore in accordance with regulation 39(1) such subsystems do not need to be recorded in an infrastructure register. However, to be clear, it would be better to revise the regulation to read:

(a) "infrastructure" means a structural subsystem, other than a structural subsystem or part of a structural subsystem composing a vehicle.

11.6 The regulations come into force on 19th July 2010, but in its application to infrastructure that is not authorised infrastructure, Regulation 39 comes into force on 19th July 2011.

11.7 Achieving compliance with Regulation 39 by these dates is likely to be challenging.

12 The national vehicle register

12.1 Regulation 40(6) requires

> *Any person who places in service a unit of rolling stock must ensure it is marked with the European vehicle number assigned to it.*

12.2 The Conventional Rail Operations TSI* contains a specific case exempting vehicles used in domestic traffic from carrying (that is, being marked with) the European vehicle number assigned to it. Note though that the vehicle will be assigned such a number.

12.3 [* Commission Decision 2006/920/EC of 11 August 2006 concerning the technical specification of interoperability relating to the subsystem 'Traffic Operation and Management' of the trans-European conventional rail system.]

> *7.3.2. LIST OF SPECIFIC CASES*
>
> *Temporary Specific Case (T2) UK*
>
> *For the implementation of Annex P of this TSI in the United Kingdom, passenger coaches and locomotives which are used solely in domestic traffic may be exempted from carrying the standard 12-digit number. This may apply also for crossborder traffic between Northern Ireland and the Republic of Ireland.*

12.4 It is suggested that the regulation be amended to read:

> Any person who places in service a unit of rolling stock must ensure it is marked with either the European vehicle number assigned to it or a number using a coding system specified in notified national technical rules, where permitted by TSIs relating to the 'Traffic Operation and Management' subsystem.

12.5 The use of domestic vehicle numbers is necessary to provide compatibility with current operating systems.

13 Annexes from Directive 2008/57/EC

13.1 All bar one of the nine Annexes from Directive 2008/57/EC are reproduced as Schedules within the regulations.

13.2 The omitted Annex is Annex VII, 'Parameters to be checked in conjunction with the placing in service of non-TSI conform vehicles and the classification of the national rules'.

13.3 All the Schedules refer back to Regulation 2(2). Regulation 2(2) contains no requirements, but merely says:

> *(2) Annexes I to VI, VIII and IX of the Directive are substantially reproduced in Schedules 1 to 8.*

13.4 The word 'substantially' implies some editing, but this is not made evident.

13.5 The Annexes to the Directive are drafted in style that is significantly different from the main text of the Directive. They have the feel of being drafted by disparate persons and without being subject to the same level of legal review that has been applied to the main body of the Directive. As a result, the substantial reproduction of the Annexes as Schedules in the regulations is not always either necessary or helpful. A detailed argument relating to each Schedule is given in the following sections.

13.6 It is suggested that the Annexes to the Directive are not simply copied into the Schedules, but are transposed (as has been done for the main body of the Directive) and subject to a proper legal review.

14 References to Schedule 1

> ***Interpretation***
>
> *2.—(3) In these Regulations—*
>
> *"trans-European rail system" means the trans-European conventional and high-speed rail systems as set out in paragraphs 1 and 2 of* ***Schedule 1*** *and includes any extensions to the networks referred to in those paragraphs;*

14.1 Only paragraphs 1 and 2 of Annex I of the Directive (and therefore Schedule 1 are required). There appears to be no reason to include paragraphs 3 and 4 in the regulations.

14.2 Further, paragraphs 1 and 2 contain extraneous matter which should be edited out, for example the statement that:

> *For the purposes of the Directive, this network may be subdivided into the following categories—*
>
> *lines intended for passenger services;*
>
> *lines intended for mixed traffic (passengers and freight);*

lines specially designed or upgraded for freight services;

passenger hubs;

freight hubs, including intermodal terminals;

lines connecting the abovementioned elements.

This network includes traffic management, tracking and navigation systems, technical installations for data processing and telecommunications intended for long-distance passenger services and freight services on the network in order to guarantee the safe and harmonious operation of the network and efficient traffic management.

14.3 Much of the text in Annex I of the Directive should perhaps be regarded as an argument or explanation. It is neither suitable nor necessary as part of a legal definition. For example, based on the text it could be argued that items intended for short-distance passenger services are excluded from scope.

14.4 It is also questionable if reference to 'Decision No 1692/96/EC as amended by Decision No 1346/2001/EC, Decision 884/2004/EC and Council Regulation (EC) No 1791/2006' would actually allow, for example, a contracting entity to know whether or not the slow lines between Watford and Rugby were part of the trans-European rail system.

14.5 A more focused Schedule, that unambiguously defines the trans-European rail system within UK, is needed.

15 References to Schedule 2

Interpretation

2.—(3) In these Regulations—

"functional subsystem" means a functional subsystem as specified in paragraph 1(b) of ***Schedule 2****;*

"structural subsystem" means a structural subsystem as specified in paragraph 1(a) of ***Schedule 2****;*

"subsystem" means the whole, or, as the context requires, part of a subdivision of the rail system as specified in paragraphs 1(a) and 1(b) of ***Schedule 2****, namely structural subsystems and functional subsystems;*

15.1 Only paragraphs 1(a) and 1(b) are referenced in the regulations. They do not actually 'specify' anything. They simply list sub-systems without defining them.

15.2 The bulk of Schedule 2 is a 'Description of the subsystems'. In some sense these actually specify the subsystems, as for example:

Control-command and signalling

All the equipment necessary to ensure safety and to command and control movements of trains authorised to travel on the network.

Rolling stock

Structure, command and control system for all train equipment, current-collection devices, traction and energy conversion units, braking, coupling and running gear (bogies, axles, etc.) and suspension, doors, man/machine interfaces (driver, on-board staff and passengers, including the needs of persons with reduced mobility), passive or active safety devices and requisites for the health of passengers and on-board staff.

15.3 As can be seen for these examples, the drafting may lead to difficulties of interpretation. Control-command and signalling could be read as encompassing any equipment 'necessary to ensure safety'. The dividing line between Rolling Stock and Control-command and signalling is not clear.

15.4 For the purpose of the regulation, a simple list of subsystems is probably sufficient. Adapting the 'Descriptions of the subsystems' is probably too difficult and they should simply be omitted.

16 References to Schedule 3

Interpretation

2.—(3) In these Regulations—

*"essential requirements" means all the conditions set out in **Schedule 3** that must be met by the rail system, subsystems and interoperability constituents, including interfaces;*

List of projects for the renewal or upgrading of subsystems

12.—(3) In deciding whether a project or type of project is a renewal or upgrade factors to be taken into account by the Competent Authority must include—

> *(b) the impact of the project on the rail system having regard to its effect on safety, reliability and availability, health, environmental protection and technical compatibility**(a)**;*

***(a)** See the general requirements listed in **Schedule 3**.*

16.1 The problems with Schedule 3 have been discussed in section 5 of Paper A3.

17 References to Schedule 4

EC declaration of conformity or of suitability for use

*23.—(1) An EC declaration of conformity or an EC declaration of suitability for use is a declaration drawn up by the relevant person in accordance with the requirements of **Schedule 4** that indicates that the interoperability constituent satisfies the requirements—*

17.1 No particular issues have been identified with Schedule 4 itself.

17.2 It has been noted elsewhere that Regulation 23, as drafted, is not actually a regulation, but a definition. It does not require anybody to do (or not do) anything.

18 References to Schedule 5

Authorisation decision

6.—(1) The Safety Authority must issue an authorisation under these Regulations for the placing in service of a structural subsystem on or as part of the rail system, where it is satisfied that—

*(a) the verification declaration has been drawn up in accordance with **Schedule 5** or, in the case of an application under regulation 5(1)(d), in accordance with regulation 7(7);*

18.1 No particular issues have been identified with Schedule 5 itself.

18.2 Schedule 5 simply requires the EC declaration of verification and the accompanying documents to be dated and signed; to be written in the same language as the technical file; and to contain certain information. It is not a procedure setting out how the declaration should be drawn up, as might be expected by the words 'drawn up in accordance with Schedule 5'.

18.3 The reference to drawing up the verification declaration 'or … in accordance with regulation 7(7)', as an alternative in the case of an application under regulation 5(1)(d), would lead one to expect that regulation 7(7) would similarly require the declaration of verification and the accompanying documents to be dated and signed; to be written in a particular language; and to contain certain items.

18.4 However, Regulation 7(7) is quite different. It actually requires:

7.—(7) The contracting entity must draw up a declaration in relation to the project subsystem where—

(a) the contracting entity is satisfied the essential requirements are met in accordance with regulation 15 (including interfaces with the part of the rail system on which it will be placed in service);

(b) if there are applicable notified national technical rules, the body appointed under paragraph (5) has—

(i) assessed the subsystem as conforming with those rules in accordance with such procedures as are reasonably appropriate to make that assessment; and

(ii) issued a certificate of conformity with notified national technical rules.

18.5 This suggests some confusion has arisen in the drafting of the regulations as to the nature of Schedule 5.

18.6 The regulations should be amended to align the differing requirements relating to what must be satisfied in respect of how verification declarations are drawn up.

19 References to Schedule 6 in Regulation 2, Interpretation

Interpretation

2.—(3) In these Regulations—

"ISV" means an intermediate statement of verification issued by a notified body in relation to the design stage or the production stage of a subsystem in accord with paragraph 2 of ***Schedule 6****;*

"verification assessment procedure" means—

(a) the procedures specified in regulation 17(1) and the reference in ***Schedule 6*** *to "verification procedure" shall be construed as a reference to the verification assessment procedure, or*

(b) in the case of an application for an authorisation under regulation 5(1)(d), the procedure undertaken by a notified body in relation to the authorisation referred to in regulation 4(1)(c);

19.1 Article 18(4) of Directive 2008/57/EC states:

18(4). The notified body may issue intermediate statement verifications to cover certain stages of the verification procedure or certain parts of the subsystem. In such a case, the procedure set out in Annex VI shall apply.

19.2 The definition of 'ISV' in the regulations is not aligned with Directive 2008/57/EC in that it omits reference to coverage of 'certain parts of the subsystem'. The reference to paragraph 2 of Schedule 6 is not needed for the purposes of the definition.

19.3 An alternative definition could be:

"ISV" means an intermediate statement of verification issued by a notified body to cover certain stages of the verification procedure or certain parts of the subsystem;

19.4 An 'intermediate statement of verification' is actually an 'intermediate certificate of verification', and the Directive would have been clearer if the latter term had been used.

19.5 Section 2 of Schedule 6 refers to an (undefined) 'EC Declaration of intermediate subsystem conformity':

> *For the design stage (including the type tests) and for the production stage the applicant may apply for an assessment as a first step. In this case , this assessment or assessments lead to one or more intermediate statement verifications (ISV) issued by the notified body chosen by the applicant. The notified body in turn draws up an EC declaration of intermediate subsystem conformity for the relevant stages.*

19.6 It is almost certain that this is the result of a drafting error within Annex VI of Directive 2008/57/EC, and that what the Annex intended to say was:

> The applicant in turn draws up an EC declaration of intermediate subsystem verification for the relevant stages.

19.7 This would then align with Regulation 16(3) which requires the contracting entity (that is, the applicant) to draw up a verification declaration. Notified Bodies do not draw up declarations; and conformity is a term used in connection with interoperability constituents, not subsystems.

20 References to Schedule 6 in Regulation 7, Authorisation for rolling stock already authorised for another Member State

> ***Authorisation for rolling stock already authorised for another Member State***
>
> *7.—(1) This regulation applies when an application is made pursuant to regulation 5(1)(d).*
>
> *(2) When this regulation applies paragraph (3) applies instead of regulation 5(2) and paragraph (4) applies instead of regulation 5(4).*
>
> *(3) The application must be made in writing to the Safety Authority and accompanied by—*
>
> > *(a) a copy of the authorisation referred to in regulation 4(1)(c) ("the first authorisation");*
> >
> > *(b) a file containing——*
> >
> > > *(i) the items referred to in paragraph 4 of* ***Schedule 6,*** *including the certificate of verification;*

20.1 See comments on ‘References to Schedule 6 in Regulation 17(2), technical file’, below.

21 References to Schedule 6 in Regulation 16, Duties on a contracting entity

> ***Duties on a contracting entity***
>
> *16.—(3) The contracting entity must draw up a verification declaration in relation to that project subsystem where—*
>
> > *(c) a certificate of verification has been drawn up by a notified body in accordance with the procedures required by **Schedule 6**;*

21.1 See comments on ‘References to Schedule 6 in Regulation 17(1), verification assessment procedure’, below.

22 References to Schedule 6 in Regulation 17(1), verification assessment procedure

> *17.—(1) The appropriate verification assessment procedure in relation to a project subsystem is—*
>
> > *(a) in so far as that subsystem is required to conform with all or part of a TSI, the procedures specified in the TSI or part of the TSI with which that subsystem is required to conform; and*
> >
> > *(b) the procedures set out in **Schedule 6**.*

22.1 Section 1 of Schedule 6 states that:

> *1. EC verification is the procedure whereby a notified body checks and certifies that the subsystem:*
>
> > *complies with the Directive;*
> >
> > *complies with the other regulations deriving from the Treaty, and may be put into operation.*

22.2 This appears to contradict Regulation 15(1), which effectively only requires compliance to be demonstrated with TSIs, applicable national notified technical rules and ‘any necessary measures’ deriving form application of the CSM on risk evaluation and assessment.

22.3 Section 1 of Schedule 6 also gives rise to two questions:

- What does the notified body have to check <u>in addition</u> to conformity with the TSIs in order to be satisfied that the subsystem complies with the Directive?

- How does the notified body know what 'other regulations deriving from the Treaty' are relevant and how do they check conformity against these regulations?

22.4 It could be argued that Section 1 of Schedule 6 is not actually a verification assessment procedure, as it states what has to be verified (which is dealt with elsewhere in the regulations), not how it is to be verified.

22.5 It should be noted that Section 4 of Schedule 6 requires the technical file to contain 'certificate from the notified body responsible for EC verification, accompanied by corresponding calculation notes and countersigned by itself, stating that the project complies with the Directive', but makes no mention of a certificate that the subsystem 'complies with the other regulations deriving from the Treaty'.

22.6 Schedule 6 contains requirements that are not verification assessment procedures – for example, in section 7, which requires:

> *7. Each notified body must periodically publish relevant information concerning:*
>
> > *requests for EC verification received;*
> >
> > *ISVs issued or refused*
> >
> > *certificates of verification issued or refused;*
> >
> > *certificates of conformity refused.*

22.7 It would therefore be better to extract the actual verification assessment procedure (the 'how') from Annex VI of Directive 2008/57/EC and publish only that as Schedule 6.

23 References to Schedule 6 in Regulation 17(2), technical file

> *17.—(2) The notified body must—*
>
> > *(a) compile a file containing:*
> >
> > > *(i) the items required by paragraph 4 of **Schedule 6**, including the certificate of verification;*

23.1 An example of what the file must contain is:

> ***Technical file***
>
> *4. The technical file accompanying the declaration of verification must be made up as follows:*
>
> > *for infrastructure: engineering-structure plans, approval records for excavations and reinforcement, testing and inspection reports on concrete, etc;*

23.2 The list for infrastructure excludes all the specific features of a railway – track, for example. It is difficult to see how compliance with 'etc' can be assessed.

23.3 Paragraph 4 of Schedule 6 is insufficient as a regulation. An alternative should therefore be drafted that translates Paragraph 4 of Annex IV of the Directive into a set of reasonably precise (but not overly specific) requirements.

24 References to Schedule 7

Assessment procedure for interoperability constituents

25.—(1) The appropriate procedures for assessing the conformity or suitability for use of an interoperability constituent must be carried out by a notified body in accordance with—

*(c) any relevant procedures set out in **Schedule 7**.*

24.1 There are no relevant procedures for 'assessing the conformity or suitability for use of an interoperability constituent' in Schedule 7.

24.2 Schedule 7 sets 'criteria which must be taken into account by the Member States when Notifying Bodies'. However, as noted below, is drafted in the form of requirements from which criteria could be derived, rather than giving the criteria themselves. The requirements define the expected standards of behaviour of notified bodies.

24.3 If the reference to Schedule 7 is to be retained in Regulation 25(1), point (c) should be revised to read something like 'the requirements for independence, integrity and competence set out in Schedule 7'.

Appointment of notified bodies and designated bodies

*32.—(2) The Secretary of State must not appoint any person as a notified body or a designated body in accordance with paragraph (1) unless the Secretary of State is satisfied that the person is capable of meeting the criteria specified in **Schedule 7**.*

*(3) For the purposes of this regulation **Schedule 7** applies to a designated body as it applies to a notified body.*

(7) If at any time it appears to the Secretary of State in relation to a notified body appointed by the Secretary of State or the Strategic Rail Authority or in relation to a designated body that—

(a) any of the conditions of the appointment of that body are not being complied with; or

*(b) the body is not meeting the criteria specified in **Schedule 7**,*

the Secretary of State may, by notice in writing to that body, specify a date on which the appointment of that person as a body shall terminate.

*(13) Where it appears to the Secretary of State that a notified body appointed by another Member State fails to meet the criteria set out in **Schedule 7**, the Secretary of State must notify the Article 21 Committee of that fact forthwith.*

24.4 Schedule 7 is titled 'Minimum criteria which must be taken into account by the Member States when Notifying Bodies'. It is drafted in the form of requirements from which criteria could be derived, rather than giving the criteria themselves (criterion: a standard by which you judge, decide about or deal with something)

24.5 For example, section 6 of Schedule 7 says 'The body must take out civil liability insurance', rather than 'The body must be able to provide evidence of civil liability insurance'.

24.6 Section 2 of Schedule 7 requires 'The body and the staff responsible for the checks must carry out the checks with the greatest possible professional integrity and the greatest possible technical competence'. The term 'the greatest possible' does not sit easily with UK law, where reasonableness is usually seen as the key test.

24.7 Consideration should be given to redrafting Schedule 7 as a set of criteria, rather than requirements from which criteria could be derived. Section 2 of Schedule 7 should be redrafted to align with the principle of reasonableness.

25 References to Schedule 8

Exemption from need to conform with TSIs (derogations)

*14.—(3) The Competent Authority shall not make a derogation from the application of a TSI or part of a TSI unless the Secretary of State has first forwarded a file to the Commission containing the information set out in **Schedule 8**.*

25.1 In Great Britain, the Competent Authority is the Secretary of State. Schedule 8 appears to be included as a way of advising contracting entities who may be seeking a derogation for their projects of the information they will need to supply to the Secretary of State.

26 Recommendations

26.1 ISCC is asked to:

- **NOTE** the issues identified in this paper.
- **DISCUSS** the case for raising these issues formally in the industry's responses to the DfT's consultation on the draft regulations.