Department for Transport

29 March 2010

Consultation on the transposition of Directive 2008/57/EC on the interoperability of the rail system within the Community

Contents

Annexes to the Consultation Document

Executive Summary

Why are we consulting?

i. This document sets out the Government's policy proposals for implementing Directive 2008/57/EC ("the new Directive") on the interoperability of the rail system within the European Community (published on 18 July 2008), and available in this Document at Annex F.

ii. The Government is required to transpose the new Directive's provisions into UK implementing measures by 19 July 2010. This is a UK-wide public consultation covering England, Scotland, Wales, Northern Ireland and the British half of the Channel Tunnel system.

What are we consulting on?

iii. Although the European regulatory framework is fixed by the requirements of the new Directive, we have some flexibility in how we implement it into domestic provisions, including legislation.

iv. This document seeks your views on our proposals for transposition of the new Directive's requirements, in particular on:

- how we implement the new requirements of the new Directive, including proposed draft Regulations ("the draft Regulations");
- when the authorisation process, including verification of the application of European Technical Specifications for Interoperability (TSIs), should be used;
- how we have optimised the existing provisions that have already been transposed in the current UK Regulations (RIR 2006, as amended);
- whether the proposed revised Guidance is sufficiently practical for use by railway stakeholders; and,
- whether the Department's draft Impact Assessment has adequately addressed the impacts of the proposed draft Regulations (including positive benefits and costs).

v. This document is the second of two public written consultations related to the transposition of Directive 2008/57/EC. In the first consultation (held between March and May 2009) we sought your views on our initial policy proposals for transposition including how to optimise our current implementation of the existing interoperability Directives ("the existing

Directives"), which the new Directive replaces. This second Consultation Document includes the proposed draft Regulations intended to implement the provisions of the new Directive into UK law, a partial Impact Assessment and revised Guidance. The Guidance is provided in the form of new "Help Notes" that address the areas where we propose significant changes.

vi. As part of the UK's implementation, the new Directive will need to be transposed for the Channel Tunnel ("the Tunnel"). The current provisions of the interoperability regime were applied to the Tunnel via the Railways (Interoperability) Regulations 2006 (RIR 2006). Since then, the Railway Safety Directive (RSD) has been transposed by a bi-national (UK/France) Regulation introducing the same safety requirements in UK and French law, implemented in UK law by the Channel Tunnel (Safety) Order 2007. Our preferred option for interoperability is to continue to reflect transposition for the UK half of the Tunnel in the new draft Regulations.

Legal Disclaimer

vii. Although this document aims to be helpful by summarising legal provisions governing the current interoperability regime and the provisions of the new Directive, it is not a legal document and should not be relied on as a primary source of rights or obligations, nor as an interpretive tool. Consultees must always refer to the source legislation and take their own legal advice on how to interpret these, if in doubt.

What does the new Directive do?

viii. Directive 2008/57/EC was produced to contribute to the further development of the interoperability of the European rail system and the progressive creation of the internal market in equipment and services for the construction, renewal, upgrading and operation of the rail system within the European Union.

ix. The new Directive merges the existing Directives under which the European railway interoperability regime was introduced and provides for the use of harmonised technical standards and a common European assessment and authorisation process for placing new rail developments or major upgrades and renewals of the existing railway into service.

x. It also establishes the procedures for the placing in service of interoperability constituents and subsystems, the conditions for vehicles to enter the market and the requirement for vehicle and infrastructure registers.

Who should read this consultation document?

xi. This consultation will be of particular interest to you if you are a:

- railway infrastructure manager or infrastructure maintenance contractor;
- railway undertaking, train operator or rolling stock leasing company;
- freight operator or wagon owner;
- notified body;
- safety authority, competent authority or economic regulator;
- manufacturer or supplier to the railway industry; or,
- representative of railway passengers or a trades union in the railway industry.

xii. This consultation may be of interest to other parties and all are welcome to comment on our proposals.

Section 1: How to respond

1.1 We are consulting on these proposals from Monday 29 March 2010 until Monday 7 June 2010. If you would like further copies of this consultation document, it can be found at:

www.dft.gov.uk/consultations/open/2010-14

or, if you would like an alternative format (e.g. Braille or audio) please contact us. Please send consultation responses to:

by post: EU Rail Safety & Interoperability Team
(Interoperability Consultation)
Department for Transport
Zone 4/32
Great Minster House
76 Marsham Street
London SW1P 4DR

by fax: 020 7944 2160

by e-mail: interoperability@dft.gsi.gov.uk
(please include "Interoperability Consultation" in the subject heading)

1.2 When responding, please state whether you are responding as an individual or representing the views of an organisation. If responding on behalf of a larger organisation please make it clear who the organisation represents, and where applicable, how the views of members were assembled.

1.3 The Department for Transport would like to thank you in advance for taking the time to reply. We do not intend to acknowledge individual responses unless by request.

1.4 A list of those consulted is attached at Annex I. If you have any suggestions of others who may wish to be involved in this consultation process please contact us.

Freedom of Information

1.5 Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the

Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

1.6 If you want information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

1.7 In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

1.8 The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

1.9 A summary of responses received to this consultation will be published on the Department for Transport's website.

Help with queries

1.10 Questions about policy issues raised in the document can be addressed to:

Gabriel Hammond
Rail Standards & Safety Division
Department for Transport
Zone 4/32, Great Minster House
76 Marsham Street, London SW1P 4DR

Tel: 020 7944 6286
Email: interoperability@dft.gsi.gov.uk

Comments or complaints

1.11 This consultation is being carried out in accordance with the Government's Code of Practice on Consultations and more information is available at Annex H.

1.12 Whilst the key criteria include a requirement for the consultation period to be a minimum of twelve weeks, the Code recognises that this may not always be possible, particularly where deadlines are driven by our Treaty commitments with the European Union. Since we have a deadline to bring the provisions of Directive 2008/57/EC into force in the UK by 19 July 2010, regrettably it has been necessary to specify a reduced consultation period of ten weeks to allow for the required Parliamentary process before the draft Regulations can come into force. Chris Mole, Parliamentary Under Secretary of State for Transport, has agreed that a shortened consultation period is acceptable in this case.

1.13 If you consider that this consultation does not comply with the criteria or have comments about the consultation process please contact:

Giada Covallero
Department for Transport
Zone 2/25,
Great Minster House
76 Marsham Street
London SW1P 4DR

Email: consultation@dft.gsi.gov.uk

Section 2: Introduction to European railway interoperability

2.1 Background to European railway interoperability

2.1.1 Interoperability of the rail system is a European initiative aimed at improving the competitive position of the rail sector so that it can compete effectively with other transport modes, and in particular with road transport.

2.1.2 The European Commission (EC) introduced its first Directive (the "High Speed Directive") on railway interoperability in 1996 (Directive 96/48/EC), requiring European Member States to use harmonised Technical Specifications for Interoperability (TSIs) as the set of standards to build and renew the Trans European Network (TEN) for 'High Speed' railways. This was followed by a further Directive (the "Conventional Directive") in 2001 (Directive 2001/16/EC), applying the same principle to key 'Conventional' railway networks that form part of the TEN, including those used for freight operations. These Directives (including amendments) have been transposed into UK law under the extant Railways (Interoperability) Regulations 2006 (RIR 2006), as amended.

2.1.3 The objective of interoperability is to create a harmonised European railway system that allows for safe and uninterrupted movement of trains, i.e. to:

- ensure compatibility between European railways to allow for through running of trains between Member States;
- harmonise Member State design assessment, acceptance and approval processes to prevent barriers to trade and to promote a single European market for railway products and services; and,
- deliver benefits of standardisation through economies of scale for railway components, improving the economic performance of European railways and the environmental performance of the whole European transport system.

2.1.4 The TSI specifications are developed and revised by the European Railway Agency (ERA) and introduced by the EC as Decisions or Regulations. The TSIs specify the design of 'subsystems' of the railway system, i.e. infrastructure and tunnels, rolling stock, signalling systems, power systems and provisions for access for Persons with Reduced Mobility (PRM). Operational rules, passenger information and ticketing systems and electronic logistics systems for freight are also specified through TSIs.

2.1.5 Whenever any new subsystem is to be authorised to be placed into service on the TEN railway network, the design has to comply with the relevant TSIs in order to meet the mutually acceptable Essential Requirements (ERs)

for the whole European railway (i.e. 'essential requirements' for health, safety, environment, technical compatibility and reliability). The authorisation is given by the National Safety Authority (NSA), which confirms the application of the TSIs and the application of the European harmonised verification process, which provides for presumption of conformity with the ERs.

2.1.6 Similarly, whenever any existing subsystem is to be renewed or upgraded, the parts of the subsystem being changed should be considered for compliance with TSIs, as part of a gradual transition to a standardised European railway. In Great Britain the NSA is the Office of Rail Regulation (ORR), for Northern Ireland it is the Department for Regional Development Northern Ireland (DRDNI) and for the Channel Tunnel it is the Inter-Governmental Commission (IGC).

2.2 Progress with European railway interoperability

2.2.1 There has been significant progress in the implementation of interoperability since the current Regulations were made in 2006.

2.2.2 The Department, UK industry and wider European players have gained real experience of implementing the interoperability process for a wide range of projects, and the requirement to transpose the new Directive has now provided the opportunity to make improvements to the existing regulatory framework, in consideration of the practical application of RIR 2006 so far.

2.2.3 However, the European processes have not yet been perfected for practical application in all circumstances and some industry stakeholders have found the application of some of the TSIs to be difficult and consider that the application of the current interoperability process for authorisation could introduce risk or complexity to railway projects. The proposed draft Regulations address these issues by:

- making some aspects of the interoperability process voluntary in the UK and fully providing for any stakeholder that wants to take advantage of the mutual acceptability of the European process and specifications;
- subjecting the development of infrastructure to a transparent and inclusive planning process (i.e. "Implementation Plans" for TSIs);
- introducing flexibility in the provisions to encourage the practical and realistic application of the TSIs (allowing for "Type Authorisations" and for authorisations with restrictions and limitations to be applied to infrastructure subsystems); and,
- introducing the role of "Designated Body" (DeBo) for the assessment of Notified National Technical Rules (NNTRs), making it clearer that the

market for verification services is fully open to non-UK conformity assessment bodies.

2.3 Progress with TSI development

2.3.1 The suite of TSIs developed by ERA is now nearly complete, with only the conventional railway TSIs for rolling stock, infrastructure, energy and passenger telematics to be finalised and formally adopted. Other TSIs, including the Freight Wagon TSI and the Conventional Rolling Stock Noise TSI are undergoing revision this year.

2.3.2 However, the TSIs do not yet provide a complete European specification, as they contain technical parameters that have been identified for harmonisation, but the specifications have not yet been agreed at a European level. Such gaps are known as “open points”, and the verification of such technical parameters (and associated Essential Requirements) is completed using Notified National Technical Rules (NNTRs) - for the GB mainline railway these are generally Railway Group Standards (RGS).

2.3.3 As the TSIs are revised over time, it is anticipated that the open points will be addressed in the TSI specifications by the harmonisation of the remaining national rules, leading to a complete European specification for railway systems.

2.4 Extension of scope of application of TSIs

2.4.1 Under the existing Directives, the scope of application of TSIs, through the interoperability process, is limited to the Trans European Networks (TENs) for High Speed and Conventional railways. The scope of the current TEN is illustrated on a map drawn up by the European Commission (and is contained in EC Decision 1692/96/EC), and is referred to in the current TSIs.

2.4.2 The new Directive provides powers to ERA to extend the scope of application of TSIs beyond the established TEN, by creating new TSIs or by revising current TSIs, to cover the whole railway network of the European Union, subject to a positive Cost Benefit Analysis (CBA). The proposed Regulations address the potential for extension of scope of TSIs (and therefore the interoperability process), in the event that the TSIs are extended.

2.5 Policy development since the first consultation

2.5.1 The Department carried out an initial consultation on transposing the Directive last year (March-May 2009), including 28 questions on the development of policy. A summary of responses, including the Government's response, was published in August 2009 and is available for download from the Department's website at:

http://www.dft.gov.uk/consultations/closed/interoperability/response.pdf

2.5.2 As a result of subsequent discussions with stakeholders, the Department has changed its proposed policy position in a number of areas (for example, on dealing with appeals) and has developed and strengthened other policy options (making flexible authorisation processes available to infrastructure projects as well as to rolling stock projects).

2.6 Further development of the Department's proposals for transposition

2.6.1 After three years of operating under the framework governed by RIR 2006, feedback from stakeholders, in particular from those in the freight sector, has indicated that in the short term the cost of complying with, or applying for derogations from, TSIs can in many instances compromise the business case for vehicle projects, or in the worst case, make vehicle projects totally unviable. The Department recognises that the full long term benefits of a TSI compliant railway can only be realised for the capability of vehicles when sufficient infrastructure is either built, renewed or upgraded to TSI compliant standards (and is "TSI conform").

2.6.2 Following the positive feedback received from stakeholders to the first consultation exercise, notably with regards to the use of Implementation Plans to support the managed roll out in the UK of interoperability, the Department has considered how best to apply TSIs through the development in the first instance of interoperable infrastructure so that the advantage of interoperable vehicle design can be achieved in the longer term.

2.6.3 We have explored in some detail whether the provisions in the new Directive to positively exclude certain rail systems from the application of the Regulations could be used to create a blanket exemption for 'national' vehicles from the requirements to apply the full suite of relevant TSIs and the authorisation process. In theory a strong economic argument can be made to support this policy. A vehicle designed to conform with all relevant TSIs cannot be fully optimised for economic use on the existing UK's non TSI

conforming infrastructure. We have therefore sought to exclude from scope 'national' vehicles that are not intended to operate on the wider European railway network. However, in testing the theory the Department has been advised that an interpretation of Article 1(3)(d) of the new Directive ("vehicles reserved for a strictly local use") to mean 'national' or 'domestic only' vehicles would not be a correct transposition of the new Directive. The risk of infringement proceedings being taken against the UK is therefore high. Significantly, the risk of having to revise (i.e. reverse) the regulatory framework as a result of such proceedings places what we believe is an unacceptable risk to rolling stock projects which would only increase the economic burden on such projects.

2.6.4 Our preferred approach is to review the processes in place in the UK which govern both our engagement with the European institutions and the application of derogations provided for under the new Directive. On the former, the Department will be looking to build on recent successes whereby we, with the ORR and industry stakeholders, have sought to influence developments at the European level. This has included increased input into influencing the drafting of TSIs and their economic assessment and contributing to a common understanding of the application of interoperability across Europe. We believe there is scope to better manage our engagement on the development of TSIs, to develop more effective horizon scanning, to anticipate change, influence it and plan for it, and mitigate the risks to our railways. On the latter, we are seeking to put in place better and more responsive processes for derogations as well as greater and more timely influencing of the European decision making process for derogations.

2.7 Summary of key proposals in this consultation document

2.7.1 The key proposals included in the enclosed draft Regulations have been provided in order to enable:

- the development of UK railway infrastructure through the use of Implementation Plans (see section 3.12);
- certain railway systems, such as trams and metros, to be excluded according to an Approved List of exclusions (see section 3.3);
- voluntary application of the authorisation process for rail systems that are excluded from scope, or for rail systems that are out of geographical scope (see section 3.5);
- the authorisation of rolling stock stipulating restrictions and limitations, with these provisions applying to *all* subsystems, including infrastructure subsystems (see section 3.6);

- the Type Authorisation of new vehicles, with these provisions applying to *all* new subsystems, including infrastructure subsystems; and to all upgraded/renewed subsystems (see section 3.8);
- the scope of verification by NoBos to be limited to verification of TSIs (and assessment of compatibility only where the infrastructure has been defined in an infrastructure register) and for Notified National Technical Rules to be verified by a Designated Body (see section 3.16); and,
- a process of appeals against Safety Authority decisions to be aligned to the process already available in the ROGS Regulations, i.e. an appeal to the Secretary of State (in Great Britain) (see section 3.41).

2.8 Alignment with the railway safety regulations

2.8.1 The new Directive is part of a package of revisions to existing European legislation, tabled by the European Commission in December 2006, including revisions to the Railway Safety Directive (RSD), implemented by Directive 2008/110/EC.

2.8.2 The revised RSD introduced provisions for a system of certification for entities in charge of maintenance of freight vehicles, which is referred to in the new Directive on interoperability with respect to new provisions for a National Vehicle Register. Another key change in the overall package is that provisions related to 'reauthorisation' of vehicles, in Article 14 of the original RSD (2004/49/EC), have now been transferred to the provisions on authorisation in the new Directive on interoperability.

2.8.3 Directive 2008/110/EC was adopted in December 2008 and will be transposed into UK legislation through three distinct geographical Statutory Instruments. The Office of Rail Regulation (ORR) is consulting on proposals to transpose the Directive for Great Britain by amendment to the Railways and Other Guided Transport (Safety) Regulations 2006 (ROGS). ORR has launched its consultation in tandem to this consultation on interoperability. ORR's Consultation webpage can be found at:

http://www.rail-reg.gov.uk/server/show/nav.67

2.8.4 Given the substantial existing links between the two Directives on railway interoperability and railway safety (for example, with respect to initial

integrity and engineering change), and with a view to better regulation that promotes consistency and clarity, the Government believes there are benefits in working to a common commencement date of July 2010 for implementing the two Directives. This is despite the later date (December 2010) permitted for the transposition in Directive 2008/110/EC.

Please Note: A new draft Help Note describing the relationship between interoperability and safety has been included in Annex D of this Consultation Document.

2.8.5 The Department for Regional Development (Northern Ireland) will prepare separate Regulations for Northern Ireland to amend the railway safety Regulations in Northern Ireland. Similarly, a separate bi-national Regulation on railway safety to cover the Channel Tunnel will be prepared by the Intergovernmental Commission (IGC) using its powers under the Treaty of Canterbury.

2.8.6 As is the case with the current Regulations on interoperability, the proposed Regulations enclosed with this consultation document will cover the whole of the UK, and will therefore need to interface with all three sets of railway safety Regulations in the UK.

Section 3: Proposals

Introduction to proposals for new Regulations

3.0.1 Please read through the whole of this proposals section before considering your responses to the individual questions regarding the Department's policy approach.

3.0.2 This section details the proposed approach in the draft Regulations to transpose the new requirements of the new Directive, including changes to the continuing provisions that were brought into force through the existing Regulations on interoperability.

3.0.3 In this section of the Consultation Document each Regulation is addressed in turn, providing:

- background information on the Regulation, including cross-references to other Regulations, the Directive and Guidance;
- details of what has changed compared to the current Regulations (RIR 2006), including cross-references to the current Regulations;
- brief discussion of the expected impacts of any proposed changes, including cross-references to the Impact Assessment; and,
- a question (where appropriate) seeking your views on the proposed approach in the draft Regulations.

3.0.4 A consolidated list of questions is provided at Annex A and a consultation response form is provided at Annex J.

RIR 2010 PART 1: INTERPRETATION AND APPLICATION

3.1 Regulation 1: Citation and commencement

3.1.1 Draft Regulation 1 provides a title for the draft Regulations, i.e. "The Railways (Interoperability) Regulations 2010" (RIR 2010), and states the date for the Coming Into Force (CIF) of its general provisions as 19 July 2010. Where transitional arrangements apply, the date that those transitional provisions apply is specified and can differ from the date of CIF of the general provisions.

3.1.2 The key point to note about this Regulation is that the draft Regulations are not presented as "amendment Regulations", but rather as a new set of Regulations that revokes at draft Regulation 50 the Railways (Interoperability) Regulations 2006 ("RIR 2006" and its subsequent amendments) and replaces them with a new set of Regulations that implements the new provisions in the new Interoperability Directive (2008/57/EC).

3.1.3 The Railways (Interoperability) Regulations 2006 (SI 2006/397) have, since their introduction, been amended twice, i.e.:

- the Railways (Interoperability) (Amendment) Regulations 2007 (SI No.2007/3386), which introduced the (then) new Annex VI to the current Interoperability Directives, to allow for Intermediate Statements of Verification to be issued by a Notified Body; and,
- the Rail Vehicle Accessibility (Interoperable Rail System) Regulations 2008 (SI No. 2008/1746), which scoped out the Rail Vehicle Accessibility Regulations 1998 (RVAR) for heavy rail vehicles from RIR 2006, substituting the national provision with requirements to comply with the Technical Specification for Interoperability on Persons with Reduced Mobility (PRM TSI), and to have its application verified by a Notified Body (NoBo) and the passenger vehicles authorised under the interoperability process by the Safety Authority.

3.1.4 Given that some of the new changes at Directive level are fairly substantial (e.g. TSI scope extension and inclusion of Type Authorisation), producing a third set of amendment Regulations was considered by the Department to not be a suitable way to present the changes to the regulatory framework.

3.1.5 The Department, in response to feedback from stakeholders, decided that the requirement to transpose the new Directive presented an ideal opportunity to refresh the national regulatory framework for interoperability.

This includes those parts of the new Directive that have already been implemented in the current Regulations but, in light of experience, could be improved. This approach was regarded as preferable to a "minimum transposition" of just the new provisions. The Department is confident that the proposed draft Regulations, as described in this Consultation Document, provide for a more effective and flexible regime than the current RIR 2006 (as amended).

Please Note: This issue is also described in the partial Impact Assessment which is attached to this Consultation Document at Annex E.

Question 1: Do you agree that revisiting the current regulatory framework, repealing the existing Regulations (as amended), and introducing a single new set of Regulations is the right approach? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.2 Regulation 2: Interpretation

3.2.1 Draft Regulation 2 provides a description of the key terms that are used throughout the draft Regulations.

Key changes to definitions

3.2.2 The new Interoperability Directive consolidates the provisions in the existing "High Speed" and "Conventional" Directives on interoperability, so many references to "conventional" and "high speed" have consequently been consolidated in the draft Regulations. Although definitions for these Directives have been added to the new draft Regulations, references to the "high-speed rail system", the "conventional rail system", "high-speed rolling stock" and "conventional rolling stock" in the current Regulations have all been removed. Additionally the reference to "basic parameters" has been removed.

3.2.3 The following terms have been **added** to the draft Regulations:

"**certificate of conformity with notified national technical rules**" - to refer to a certificate provided by the designated body that verifies NNTRs;

"**CSM Regulation**" - to refer to the Commission Regulation on the adoption of a Common Safety Method (CSM) on risk evaluation and

assessment (EC Regulation No. 352/2009), which comes into force on 19 July 2010 and applies to significant changes to the rail system (see section 3.15);

"**designated body**" - to refer to a body that has been designated to verify UK NNTRs (see section 3.32);

"**determination of type**" - to refer to a Safety Authority process to recognise that an authorised subsystem is a "type", which in turn can be recognised for further authorisation of subsystems that are described by that type (see section 3.8);

"**European vehicle number**" - to replace the term "ID code", which is used in relation to the National Vehicle Register (see section 3.40);

"**infrastructure register**" - to refer to the register of infrastructure, as required by Article 35 of the new Directive (see section 3.39);

"**keeper**" - to refer to certain railway entities ("actors") on the rail system that use railway vehicles, but may or may not own them, and whose details are entered onto the National Vehicle Register - the term has also been introduced to the Railway Safety Directive (see section 3.40);

"**network**" - to refer to the extended scope of the new Directive, in relation to facilities on the rail system (e.g. terminals);

"**Official Journal"** - to refer to the Official journal of the EU;

"**rail system**" - to refer to the current scope of the new Directive (this definition relies on the scope as described in the new Directive);

"**safety assessment report**" - to refer to the report generated by the process of applying the CSM on risk evaluation and assessment;

"**structural subsystem**" - has been added to demarcate the two types of subsystem and bring consistency (the current Regulations already define both "subsystem" and "functional subsystem"); and,

"**vehicle**" - to refer to single vehicles, using the definition in the Directive, but adapting it to limit it to vehicles that run on railway lines with a track gauge of at least 350mm (consequently, any provision that relies on the term "vehicle" is not applied to miniature railways).

3.2.4 The following terms are **substantively modified** versions of terms in the current Regulations:

"**contracting entity**" - to add 'keepers' to the types of railway actors that can also be contracting entities;

"**project subsystem**" - to add provision for projects that are not subject to mandatory authorisation to be permitted to undergo voluntary authorisation;

"**renewal**" - to substitute the term "improve" with "change", in relation to the impact of a project on the overall performance of the subsystem being renewed (this adopts a change in wording in the new Directive);

"**rolling stock**" - to specifically include fixed formations of vehicles (as a single unit of rolling stock), as opposed to specifically excluding them, as is the case under RIR 2006 (single vehicles are treated as such in the definition of "vehicle");

"**trans-European rail system**" - to absorb and consolidate the references to the trans-European high speed and conventional rail systems (as described in section 3.2.2 above)**;** and,

"**TSIs**" - to simplify the definition used in RIR 2006 by removing the reference to the Official Journal of the EU.

3.2.5 This section (above) has been provided for information and we are not asking a question in relation to changes to the definitions in the draft Regulations. It should be noted that draft Regulation 2 includes the definitions that can be used to interpret the whole set of draft Regulations. However, some individual draft Regulations also include clauses that are intended to define terms as they arise or to support interpretation of those terms.

3.3 Regulation 3: Application (i.e. scope of application)

3.3.1 Draft Regulation 3(1) sets the overall scope of the proposed RIR 2010 so that it applies to:

- the "rail system" in the United Kingdom;
- railway subsystems located, operated or intended to be operated in the United Kingdom; and,
- Interoperability Constituents that are placed on the market in the European Union and (implicitly) used or intended to be used in the United Kingdom.

Extension of scope

3.3.2 The use of the term “rail system” (described in draft Regulation 2) captures a much wider geographic scope than the current “High Speed” and “Conventional” Trans European Networks (TENs) as the base scope of the draft Regulations because the definition now “includes” the current TENs, as opposed to being explicitly defined and limited by the current TENs. This reflects the new Directive’s potentially wide base scope, which includes the whole range of European rail “systems”, anywhere in the territory of the European Union. A much wider range of *technical* systems is also potentially caught, depending on the future introduction of TSIs that define such technical systems. This approach allows for the future introduction of new TSIs including, principally, TSIs with a geographical scope extended beyond the existing TEN, to be made directly applicable by the Regulations, without recourse to further implementing measures (i.e. national legislation).

Exclusions from scope

3.3.3 The new Directive allows Member States to decide to reduce the potentially very wide scope of implementing Regulations by making available a range of exemptions. The exemptions largely mirror the exemptions that are available in the Railway Safety Directive. Draft Regulation 3(2)-(5) includes two processes to enable exclusion from the scope of mandatory requirements to take effect, i.e.:

- by reference to an ***Approved List of excluded railway systems***, that explicitly details excluded railway infrastructure and vehicles, including:
    - in Regulation 3(2)(a): metros, trams and other light rail systems;
    - in Regulation 3(2)(b): dedicated local, urban and suburban passenger networks that are functionally separate from the rest of the rail system; and,
    - in Regulation 3(2)(c): infrastructure and vehicles that are reserved for a strictly local, historical or touristic use.
- through ***blanket exemption***, directly cited as a broad category in the Regulations, including:
    - privately owned and exclusively operated (i.e. unshared) freight infrastructure and vehicles (in draft Regulation 3(5)(a)); and,
    - railways with a gauge of less than 350mm, which are effectively considered to be touristic in nature, or in the very least, highly unlikely to ever be subject to the technical scope of a future TSI (provided for in draft Regulation 3(5)(b)).

3.3.4 Regulation 3(3) allows for the Approved List of exclusions that applies in Great Britain to be added to via a determination by the Secretary of State that a proposed railway system meets the criteria in Regulation 3(2). Regulation 3(4) requires the Secretary of State to keep the Approved List of exclusions published and up to date. In Northern Ireland, the determinations are made by DRDNI and the Approved List is published by DRDNI, as provided for in draft Regulation 3(7).

3.3.5 Exclusion from the scope of application from all or part of the Regulations can be determined in other ways, for example, through the explicit definition of "vehicle", which is delimited by not including vehicles that have a track gauge of under 350mm. More generally, exclusion from scope of application can also be determined through the operation of specific provisions in the Regulations, for example, where an engineering change to the railway or the introduction of infrastructure or engineering plant is not covered by the term "subsystem" or not within the intended scope of TSIs.

The Approved List of exclusions

3.3.6 A draft Approved List of exclusions is included in this Consultation Document at Annex C. The list includes details of railway networks and systems that have been positively identified as meeting the description of being a metro system, tram system, light railway, historical railway, touristic railway or functionally separate dedicated local urban or suburban passenger railway, and are therefore proposed to be made automatically exempt from the scope of the draft Regulations.

3.3.7 Vehicles that are not totally restricted for use on the above exempted systems but are principally used on such systems are considered to be exempt by reference to the rail system that they are normally used on. Where it is absolutely necessary, individual vehicles or explicit classes of vehicles (where appropriate) can be individually listed (e.g. Class 08 & Class 09 shunters used in Great Britain, which are considered to be only for strictly local use). For mainline infrastructure, the default position is to not exclude, however, infrastructure that has been designated as part of a *Community Railway* and appears to meet the description of "strictly local" has been added to the draft Approved List (but the proposed exemption does not apply to the vehicles used on that infrastructure).

3.3.8 The Department would like to thank stakeholders that have assisted in the population of this draft Approved List, however, ***if there are any other systems that should be included in the Approved List, please advise the Department as soon as possible*** (through the policy contact in section 1.10, or please include reference to such systems as part of your response).

3.3.9 The Approved List (for Great Britain) will be published on DfT's website once it has been approved by the Secretary of State. Further additions can be made through a determination by the Secretary of State, as and when new projects are proposed (for example, tramway schemes), or when stakeholders apply for inclusion on the List. Any significant additions and removals from the Approved List could be made subject to a short consultation with potentially affected stakeholders.

Please Note: A new draft Help Note describing the processes to exclude rail systems by adding them to the Approved List has been included in Annex D of this Consultation Document.

Please Note: This issue is also described in the partial Impact Assessment which is attached to this Consultation Document at Annex E.

3.3.10 ***Wholly private freight networks and vehicles:*** The Department considers that the option to exclude wholly private freight networks (e.g. enclosed railway systems entirely within a steelworks) do not need to be included on the Approved List. Such systems should be easily identifiable as meeting the description used in Article 1(3)(c) of the new Directive, which is reproduced in draft Regulation 3(5)(a)) as a blanket exemption.

3.3.11 ***Infrastructure:*** The Department's strategy for interoperability is to consider the development of the infrastructure first, and by default, to make all of it available for UK and European operators to place vehicles into service onto it, using the European harmonised interoperability process. Existing mainline infrastructure that should be made subject to the planned application of the draft Regulations will ultimately be included in the proposed process for Implementation Plans, as described in section 3.8-3.9. New mainline infrastructure is considered to be caught by the Regulations by default (see the definition for "network"), subject to any appropriate and reasonable derogation. However, the proposed Approved List for Great Britain does include a list of railway lines (infrastructure only) that have been designated as Community Railways, and which are considered to be out of scope of the Regulations, in relation to the infrastructure only.

Question 2: Do you agree with the proposed approach for scoping out specific railway systems from the Regulations through the use of an Approved List? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

Question 3: Do you agree with the proposed approach to provide a blanket exemption from scope for wholly private freight networks and vehicles? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

RIR 2010 PART 2: SUBSYSTEMS

3.4 Regulation 4: Requirement for authorisation

3.4.1 Draft Regulation 4 introduces the *mandatory requirement* for authorisation of subsystems that are in scope of the draft Regulations and are to be placed into service on the *rail system*. Regulation 4(1) explicitly extends the geographical scope of the mandatory authorisation process (compared to RIR 2006) from the TEN to the whole rail system, to the extent that a TSI applies to any other part of the rail system beyond the TEN. This enables the mandatory application of any TSIs that have their geographical scope extended beyond the existing TEN to apply beyond the TEN. If, for a given project, a subsystem is impacted by more than one TSI, but only one of the TSIs is extended in geographical scope, then the scope of *mandatory* authorisation would still be limited to the scope of the individual TSIs.

3.4.2 Draft Regulation 4(2) effectively defines the placing into service of a subsystem as the first time that it is used for transportation of passengers and freight, carrying over the existing definition in Regulation 4(10) of RIR 2006.

3.4.3 It is proposed that the existing Regulation 4 in RIR 2006 now be broken down into three separate Regulations covering the authorisation requirement (in draft Regulation 4), the application process (in draft Regulation 5) and the decision process (in draft Regulation 6). This new structure is intended to provide additional clarity, particularly given the need to transpose additional authorisation provisions (on Type Authorisation and reauthorisation) that are provided for in the new Directive.

3.5 Regulation 5: Application for authorisation

3.5.1 Draft Regulation 5 sets out the conditions under which an application for an authorisation can be submitted to the Safety Authority. These conditions include (in draft Regulation 5(1)(a)) a process to support the mandatory requirement for authorisation under draft Regulation 4, but also makes the authorisation provisions available, on a voluntary basis, for subsystems that are entirely out of scope of the Regulations, are scoped out due to exemption, or are partially out of scope (principally geographically, but could also include technical scope).

3.5.2 Draft Regulation 5 includes *three* new scenarios under which an application for authorisation for a project can be made on a *voluntary basis*, if desired by the Contracting Entity:

- in draft Regulation 5(1)(b) - for a project or part of a project that is not within the scope of any TSIs, but voluntary authorisation for the part of the project that is out of scope is desired by the Contracting Entity, for example, a project that:
    - is *entirely* out of the geographical scope of all of the TSIs;
    - is not generally within the technical scope of most of the relevant TSIs, but where authorisation is desired for some part of the project, for example, the fitment of ETCS to a steam engine; or
    - crosses the (mandatory) scope boundary of one or more TSIs, where the Contracting Entity desires a single authorisation that covers those parts of a project that are within the mandatory scope (geographically) *and* those parts of a project that are outside of the mandatory scope - this could also include a project that is subject to multiple TSIs that, incidentally, have different geographical scopes.
- in draft Regulation 5(1)(c) - for projects that are not in the mandatory scope of the draft Regulations, for example:
    - vehicle or infrastructure subsystems that are subject to blanket exemption under draft Regulation 3(5)(a); or,
    - vehicle or infrastructure subsystems that are on the Approved List of excluded railway systems, as provided for in draft Regulation 3(2).
- in draft Regulation 5(1)(d) - for subsystems that have already been authorised in another Member State (voluntary reauthorisation).

Question 4: Do you agree with the approach taken in the draft Regulations to provide a voluntary process of authorisation for subsystems to include parts of such subsystems that are outside of the geographical scope of an existing TSI? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

New documents to be included in applications for authorisation

3.5.3 Draft Regulation 5(2)-(6) provides the core processes to support the application for an authorisation to the Safety Authority, and the provisions are largely unchanged compared to RIR 2006. The key exceptions are that draft Regulation 5(2)(a) now makes explicit provision for the Contracting Entity's application to include:

- evidence of compliance with Notified National Technical Rules (NNTRs) through the inclusion of a *certificate of conformity with notified national technical rules*; and,
- a *safety assessment report* generated by the process of applying the CSM on risk evaluation and assessment.

3.5.4 The requirement for a certificate of conformity to NNTRs is needed as a consequence of the Department's proposals to limit the scope of the NoBo assessment to TSIs, whilst retaining the NoBo's duty to complete the Technical File, i.e. it is not a requirement for the NoBo to include NNTR evidence in the Technical File. The proposals for the remit for NoBo verification are discussed in section 3.16. The requirement to include the safety assessment report results from the coming into force of the EC Regulation on the CSM on risk evaluation and assessment, which applies to significant rail system changes, and should be carried out prior to authorisation of subsystems under the interoperability process. The role of the CSM on risk evaluation and assessment is discussed in more detail in section 3.15, which describes how essential requirements are to be met.

3.5.5 Draft Regulation 5(6) points the reader to draft Regulations 7, 9 and 10, for the specific modifications that are made to the general process for application for an authorisation, for the new processes for Type Authorisation (in draft Regulations 9 and 10) and for the new voluntary process for re-authorisation in draft Regulation 7.

3.6 Regulation 6: Authorisation decision

3.6.1 Draft Regulation 6 includes the general requirement on the Safety Authority to determine whether or not to authorise a railway subsystem. The draft Regulation retains most of the wording in the equivalent provisions in the current Regulations, but now includes a new discretion for the Safety Authority to include conditions in its authorisation. These conditions, which are described in Regulation 6(4), include restrictions or limitations on the use of a subsystem and/or requirements that must be met by a time specified in the authorisation.

3.6.2 Stakeholders have advised us that it would be useful for all subsystem authorisations, particularly infrastructure subsystems, to potentially be subject to similar conditions. Although the ability of the Safety Authority to impose conditions could appear to provide an additional burden or risk to Contracting Entities, the policy intention is actually the opposite, i.e. it is designed to provide further flexibility in an otherwise potentially rigid authorisation process.

3.6.3 The new Directive explicitly allows for *vehicle* subsystem authorisations to stipulate restrictions and limitations and we are proposing to implement this, as a minimum, for vehicle subsystems:

Question 5: Do you agree with the approach taken in the draft Regulations to permit the authorisation to stipulate limitations and restrictions for authorised vehicles? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.6.4 The Department proposes that the policy on creating provisions for the stipulation of conditions to an authorisation be expanded to cover *all* subsystems. This is not explicitly provided for in the Directive. Such an approach could allow for a more limited authorisation to be granted by the Safety Authority, for example, a time-limit to place into service ("use or lose").

3.6.5 An authorisation could stipulate conditions to be met in circumstances where it is reasonable for an infrastructure upgrade/renewal project to be placed into service even though the subsystem is not yet in full conformity with the TSIs and national notified rules that it has been assessed against, or where the verification and certification has not yet been formally completed, but where the subsystem is otherwise safe for use. In addition, the application of the CSM on risk evaluation and assessment could demonstrate that such an approach would be safe. If the conditions of the authorisation are not met by the time stipulated, then the enforcing authority would be able to take enforcement action in respect to the breach of the condition.

3.6.6 The Department believes that by providing this flexibility in the draft Regulations that there would be a reduced risk that an incomplete upgrade/renewal project would effectively shut down an exiting railway line beyond a planned possession, for example, when engineering works over-run in unforeseeable circumstances, but where the line can be safely be brought back into service. Consequently, the risk of applying the interoperability process of authorisation is reduced, making its application more attractive.

Question 6: Do you agree with the approach taken in the draft Regulations to permit the authorisation to stipulate limitations and restrictions for all authorised subsystems, including subsystems other than vehicles? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.7 Regulation 7: Authorisation for rolling stock already authorised in another Member State ("reauthorisations")

3.7.1 The new Directive includes provisions (in Articles 23 and 25) that explicitly prevent Member States from requiring a repeat of certain checks already undertaken on vehicles already authorised in another Member State. However, each Member State may still require a vehicle to be authorised to be placed into service on its territory (in order to check, for example, that compatibility with the national network has been verified). The UK's general policy, in transposing the 2004 Railway Safety Directive (which included optional reauthorisation requirements) and the interoperability Directives has been to not require, on a mandatory basis, such a further authorisation. The Department proposes that this approach is perpetuated, but given the new clarity on the limits to which a Member State may grant a further authorisation (a "reauthorisation") it is proposed that a Contracting Entity should be able to make an application for reauthorisation on a voluntary basis.

3.7.2 Draft Regulation 5(1)(d) therefore makes provision for Contracting Entities that would like to *voluntarily* apply for a reauthorisation of rolling stock. The first authorisation in another Member State is recognised in draft Regulation 4(1)(c) as being sufficient for placing vehicles into service in the UK as required by draft Regulation 4, i.e. it is proposed that a further *statutory* authorisation by the Safety Authority is not required in the UK on a mandatory basis.

3.7.3 Under the new Interoperability Directive another Member State is allowed to require a "reauthorisation" covering national technical rules (for example, as cited in Specific Cases in TSIs), or to ensure local compatibility with a national network. Although the new Regulations make reauthorisation available on a voluntary basis, a compatibility check in cooperation with the relevant infrastructure manager will still be necessary for such a vehicle to operate on UK networks, and the relevant Notified National Safety Rules should be applied.

3.7.4 When rolling stock is undergoing a statutory reauthorisation, draft Regulation 7 applies, so that the application need only address those areas described under Articles 23 and 25 of the Directive. Under Articles 23 and 25, the scope of a reauthorisation is limited to:

- a technical compatibility check between a vehicle and the new network, including the national rules that address open points in relation to compatibility; and
- national rules applicable in the new Member State that address open points in the TSIs or are applicable to national specific cases that are identified in TSIs.

3.7.5 After the adoption of the Reference Document referred to in Article 27 and Annex VII of the new Directive, additional verification in pursuit of a reauthorisation is strictly limited to the verification of national rules that are included in that Reference Document (known as "Group B" and "Group C" rules for cross acceptance). Broadly speaking, Group C rules are specific national rules concerning compatibility with infrastructure and Group B rules are all other national rules (Group A rules are those rules that are mutually acceptable between the Member States concerned with the proposed cross-border operation). If a voluntary reauthorisation is being sought by a Contracting Entity (likely to be a train operator), then it has a right to rely on a reauthorisation that only includes verification of the Group B and Group C rules, before placing its vehicle into service.

3.7.6 The Contracting Entity is not obliged, under our proposals, to obtain a reauthorisation. However, an operator would still have to ensure, as part of its duties to ensure safety, that compatibility of its vehicle with the network is demonstrated before gaining access to it. Any national rules or requirements applied to a vehicle that is not being reauthorised should, in theory, be identical to those rules and requirements under the reauthorisation process. However, in practice, should the rules included in the Reference Document be different to those applied in practice when a reauthorisation is not sought, then the Contracting Entity should be able to fully rely on the statutory reauthorisation process as an open, transparent and non-discriminatory way to obtain access to the railway infrastructure in any Member State (where that infrastructure is covered by the scope of the interoperability regime).

Please Note: A new draft Help Note describing cross acceptance and reauthorisation has been included in Annex D of this Consultation Document.

3.7.7 Reauthorisation and cross acceptance processes are not new to the UK's railways. For example, UIC leaflets have historically applied to freight vehicles principally designed to operate on the European mainland, but which occasionally access the GB network. Also, Article 14 of the 2004 Railway

Safety Directive provided for the option for a Member State to require a reauthorisation (for safety purposes) for vehicles "authorised" in another Member State. In GB, Article 14 was not implemented so as to require a mandatory reauthorisation, however, the bi-national Regulation implementing the Railway Safety Directive for the Channel Tunnel explicitly included the Member State *option* to reauthorise as an automatic *mandatory requirement* on the face of those Regulations.

Voluntary reauthorisation of vehicles using the Channel Tunnel

3.7.8 The provisions in Article 14 of the Railway Safety Directive have now been repealed and substantively transferred to the new Interoperability Directive (to Articles 23 and 25). Given that our proposals for implementing the new interoperability Directive cover the whole of the UK, including the British half of the Channel Tunnel, then our proposals for voluntary reauthorisation potentially represents a change in approach in relation to the Channel Tunnel. It could be argued that the nature of the original RSD Article 14 reauthorisation provision has changed from being a "safety reauthorisation" to that of being an "interoperability reauthorisation", and primarily intended to support fair and open access to railway infrastructure, according to a harmonised process for assessing technical rules. The Department's view is that by *making available* a non-discriminatory voluntary process of reauthorisation that the intention of the new Directive would be fully met for cross-accepted vehicles and that this is sufficient for the Channel Tunnel (as with all other UK railway infrastructure).

3.7.9 Operation in the Channel Tunnel is currently subject to specific safety requirements, compatibility requirements and operational requirements. Such requirements should be listed as Notified National Safety Rules (NNSRs) or Notified National Technical Rules (NNTRs) and should be applied by duty-holders when introducing new vehicles to the Channel Tunnel. The infrastructure manager that operates the Channel Tunnel is incentivised to ensure that relevant safety requirements are met by vehicles that enter onto its infrastructure, in order to maintain its own safety obligations. Under the proposed UK Regulations implementing the new Directive, if an operator elects to not apply for a reauthorisation to place his vehicle into service in the Channel Tunnel, and is not satisfied that the technical rules and safety rules required by the infrastructure manager for access to that infrastructure are non-discriminatory, then the operator can choose to apply for a voluntary statutory reauthorisation according to clear and transparent rules. The reauthorisation process available in the draft Regulations would require, upon adoption of the Reference Document, for the checks to be limited to those Group B and Group C rules that are listed for the Channel Tunnel in the Reference Document (which would include NNSRs and NNTRs).

Question 7: Do you agree with the approach taken in the draft Regulations to provide for a voluntary process of statutory reauthorisation? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.8 Regulation 8: Determination of type

3.8.1 The new Directive includes new provisions for rolling stock that allow for vehicles to be placed into service through the use of a "Type Authorisation", which is broadly equivalent to the use of a form of "type approval". Draft Regulation 8 implements part of these new provisions (from Article 26 of the new Directive) by allowing for a process of statutory type approval of authorised subsystems. The recognition of a "type" is done through the Safety Authority's "determination of type", and the use of the determination of type to authorise *subsequent* subsystems, with a fast-tracked "Type Authorisation" process is described in draft Regulation 9 (in the section below).

3.8.2 The Department is keen to maximise the potential for these new provisions in order to reduce duplication by limiting the need for repeated use of the full authorisation process for a series of identical (or even, broadly similar) subsystems. It should be noted that a Type Authorisation can only be granted for a subsystem that has been authorised under the proposed draft Regulations, and where such a subsystem has been subject to a determination of type. It is not proposed that determinations of type can be given to existing authorised subsystems, as the enabling provisions only become available upon transposition of the new Directive.

3.8.3 Under RIR 2006 it has been a requirement for new batches of rolling stock to go through the full authorisation process for each batch, unless follow-on orders are subject to options in the original contract to design and build, and even then, with certain limitations, for example, time limits. RIR 2006 also requires that all subsystems be authorised to be placed into service according to the full process.

3.8.4 The provisions in the new Directive on Type Authorisation are principally designed for use with rolling stock, and were developed at the European level with the support of the UK. As with the proposed provisions in the draft Regulations that allow the Safety Authority to stipulate restrictions and limitations for all subsystem authorisations, it is proposed that the

provisions for Type Authorisation should also be applied to all other subsystems, including infrastructure subsystems, in the event that there is any potential for the process to be used in an effective and economic way for non rolling stock subsystems.

Question 8: Do you agree with the approach taken in the draft Regulations to allow the Safety Authority to issue a determination of type for all subsystems, including those other than rolling stock subsystems? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.8.5 Draft Regulation 8(1) requires the Safety Authority to make a determination of type for every new authorisation it issues that is related to a rolling stock subsystem, unless that authorisation is being made as a result of an application for authorisation that relies on an existing determination of type, i.e. a "Type Authorisation", as provided for under draft Regulation 8(7).

3.8.6 Draft Regulation 8(2) *allows* the Safety Authority to make a determination of type for all other (non rolling stock) subsystems, but the draft Regulations do not mandate it (as it might be needed only rarely). Under draft Regulation 8(3) a Contracting Entity can ask for a new non rolling stock subsystem build to be recognised as a Type, and to request the Safety Authority to issue a determination of type.

3.8.7 As set out in draft Regulation 8(4), a determination of type is a document that describes the *basic design characteristics* of the subsystem, as covered by an EC-type examination certificate. The flexibility for future use of a type determination (to obtain Type Authorisations) largely depends on the description of the subsystem in that certificate and in the description in the determination of type. If the certificate describes the subsystem in relatively wide terms, then it is hoped that there is, as a minimum, a potential for production run variants (i.e. variants created during the ongoing production of a batch) to rely on the certificate, and potentially for subsequent builds (of say, the same "class" of vehicle), but with new minor design modifications that fall within the basic design, to rely on the same certificate. The standard format of the "determination of type" is for the Safety Authority to create, but it is envisaged to be a certificate or letter recognising the initial build of a type, the date that the type was first authorised to be placed into service, the "technical characteristics" and other information, as referred to in Article 34(2) of the new Directive (i.e. an extract of the register information for

the Type), plus a reference to the EC-type examination certificate(s) that describes the build.

3.8.8 Draft Regulation 8(5)-(6) requires the Safety Authority to notify the European Railway Agency of any new determinations of type that it has made (with respect to rolling stock only) and the new Directive requires the Agency to maintain a register of authorised types of vehicles. This provides visibility across Europe of the available design types, although the determinations of type are only valid in the Member State that has issued them. Draft Regulation 8(5)-(6) also allows the Safety Authority, in light of standards change (TSIs or NNTRs) to modify, suspend or withdraw any determinations of type that it has made. These provisions could be used, for example, to make an existing determination of type unavailable, in the event that a TSI or NNTR incorporates a significant new safety requirement that should be met by all new vehicles. If the Safety Authority chooses to modify, suspend or withdraw a determination of type, then the draft Regulations require the Safety Authority to notify the European Railway Agency, in order to assist the Agency in maintaining its register of authorised types (of vehicles).

3.8.9 In the event that determinations of type are made for subsystems other than rolling stock subsystems, it would be helpful if the Safety Authority made available a list of such type determinations in order to provide full visibility of the types available in the UK (a list of rolling stock types should be available in the European Railway Agency's register). However, we do not think that the creation of a list of non-rolling stock determinations of type should be an explicit requirement in the proposed Regulations.

Question 9: Do you agree that the Safety Authority should maintain a list of determinations of type for non-vehicle subsystems, but that this does not need to be an explicit requirement in the Regulations? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.9 Regulation 9: Type authorisation

3.9.1 The proposed draft Regulations enable an existing determination of type to be used by Contracting Entities for the repeated subsequent authorisation of new builds of an existing recognised type of subsystem, according to a fast-tracked authorisation process. This is the process known as "Type Authorisation", which is described in draft Regulation 9.

3.9.2 To make use of a determination of type, the Contracting Entity is required, under draft Regulation 9(1) to submit an application for an authorisation to place the subsystem in service. The application must include a *declaration of conformity to type*, which is an attestation by the Contracting Entity that the subsystem conforms to the basic design characteristics set out in the determination of type for the subsystem type in question. As described in the section above, there is potential for a determination of type to be used for a design variant. However, there is another variable to consider, in that the new Directive requires the Type Authorisation process to take account of any standards change (TSIs or NNTRs) that has taken place since the original determination of type has been made by the Safety Authority.

3.9.3 Our policy intention that deals with the impact of standards change on Type Authorisation is to enable determinations of type to be used (and reused), as far as is reasonable, despite standards change. To make the process work, draft Regulation 9(2) requires the Contracting Entity to supplement the declaration of conformity to type with a statement describing the standards change that has taken place and to describe how those changes impact on the new subsystem's conformity with the type in question.

3.9.4 Draft Regulation 9(1)(a) and draft Regulation 9(3) are intended to direct the Contracting Entity to declare conformity to type by reference to the impact on the new subsystem's capability to meet the Essential Requirements. Put another way, if the Contracting Entity wishes to rely on an existing determination of type, but the design has been varied and/or the standards have changed since that type was created, but the new subsystem is not *materially different from the original type with respect to its ability to meet the Essential Requirements*, and/or the change in standards is not relevant to the design, then the new subsystem should be Type Authorised. With respect to safety, the Contracting Entity can assure itself that it can rely on a determination of type through the use of the CSM on risk evaluation and assessment - the output of this process (the safety assessment report) is required as part of the evidence to be submitted in the application for Type Authorisation, as provided for in draft Regulation 9(2)(d).

3.9.5 Draft Regulation 9(4) requires the Safety Authority to consider an application for an authorisation of a subsystem that relies on a determination of type (i.e. a Type Authorisation), taking into account the evidence provided in the application according to draft Regulation 9(2).

3.9.6 In the event that the Safety Authority is satisfied that standards have not changed in such a way as to materially affect the application for authorisation, and that the requirements in draft Regulation 9(4) have been met (i.e. that the subsystem conforms to the description in the determination of type, meets the Essential Requirements, and will be compatible with the

network it is to be placed into service on), then the Safety Authority must authorise the subsystem.

3.10 Regulation 10: Type authorisation (changes to TSIs)

3.10.1 If standards have changed, then under draft Regulation 9(4) the Safety Authority can only authorise the proposed subsystem described in the Contracting Entity's application if it is satisfied that the changes to standards do not materially impact on the application (i.e. ultimately, the subsystem's ability to conform with the Essential Requirements).

3.10.2 If the Safety Authority is not satisfied, then under draft Regulation 10(1) the Safety Authority must inform the Contracting Entity, via a notice, of the (standards) changes that it believes impact on the validity of the determination of type for the proposed subsystem project. If this happens, then according to draft Regulation 10(2), the Contracting Entity can only continue its application by verifying that the subsystem is in conformity with the specified changed standards. The Contracting Entity must then, in accordance with Safety Authority's notice, supplement its original application for a Type Authorisation with:

- a copy of the updates to the Technical File;
- a certificate of verification (in relation to the verification of those parts of the TSIs that have changed);
- a certificate of conformity to NNTRs (in relation to the verification of those parts of the NNTRs that have changed);
- a verification declaration (in relation to the verification of those parts of the TSIs and NNTRs that have changed); and,
- if necessary (for example, if the changed TSIs or NNTRs relate to compatibility), a revised safety assessment report that addresses the changes to standards and the impacts that they have on the rest of the subsystem and the rail system.

3.10.3 After receiving the further material required by the notice in Regulation 10(1), the Safety Authority can still require further checks (under draft Regulation 10(3)) with respect to the changes identified in its notice, if it believes that despite conformity with the standards, etc., that the Essential Requirements are not met by the subsystem - this is part of the normal process for a full initial authorisation of a subsystem, primarily intended to act as a safeguard for flagging deficiencies in the regulatory or standards framework.

3.10.4 It is anticipated that when TSIs have changed, that the limited additional TSI verification process could result in the production of a supplement to the original EC-type examination certificate. When the two certificates are combined, and the new subsystem that takes account of standards change is authorised, the Safety Authority has effectively authorised a *new* type, and should therefore issue a new determination of type. Despite the creation of the new type, subsequent proposed projects (to a variant design or operation) might still be able to wholly rely on the original determination of type, despite the change in standards, and it should therefore not be "withdrawn" by default when issuing the new determination of type.

3.10.5 As an aside, the Safety Authority might use the experience gained from applications for Type Authorisations to withdraw or suspend existing determinations of type, for example, if the change in standards since an original determination of type was created are to such an extent that:

- there is little prospect for any new subsystems to wholly or substantially rely on it (i.e. if there is little value in applying the process under Regulation 10 because the extent of additional verification required means that there is little value in applying it compared to applying the full authorisation process); or,
- it would be demonstrably unsafe to allow the original determination of type to be used again by any future project (i.e. if there is a critical fault in the TSI or NNTR requirements, but the fault has not yet been addressed or removed in the current version of the specification or standard).

Please Note: A new draft Help Note describing the processes for Type Authorisation and has been included in Annex D of this Consultation Document.

Question 10: Do you agree that the draft Regulations have adequately provided for a process of Type Authorisation that can be realistically applied to real projects, resulting in less duplication of the authorisation process? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.11 Regulation 11: Revocation of authorisation

3.11.1 Draft Regulation 11 introduces a new power for the Safety Authority to revoke an authorisation (to place into service) that it has made under the proposed Regulations, as drawn from the provisions in Article 21 of the new Directive. The power to revoke can be applied to authorisations made under RIR 2006, although it is probable that such subsystems would have already been placed into service.

3.11.2 The power to revoke an authorisation made under the proposed Regulations has *no impact* on the operation of a subsystem that has already been placed into service, it merely serves as a power to retract an authorisation, in the event that before the subsystem is placed into service the holder of the authorisation no longer satisfies the conditions of the authorisation, for example, an operational condition (e.g. compliance with the Operations TSI). The authorisation could also be withdrawn, for example, if a condition of the authorisation is that the subsystem should be placed into service by a particular time, and that the time limit has expired.

Overview of authorisation processes in the proposed Regulations

3.11.4 As described in the sections above, the proposed Regulations make significant changes to the existing authorisation processes, including a range of new requirements and provisions. In summary, these changes include:

- voluntary authorisation for subsystems or parts of subsystems that are outside the geographical scope of TSIs;
- the ability to authorise (any) subsystem with restrictions and limitations;
- a new process of Type Authorisation, applied to all subsystems;
- a new process for voluntary reauthorisation of rolling stock subsystems; and,
- a new power for the Safety Authority to revoke authorisations to place into service.

3.11.5 Regulation 4 of RIR 2006 has also been restructured (in draft Regulations 4-10) to separate out the requirement for authorisation, the application process and the decision making process, and to include the new processes for Type Authorisation. The Department believes that all of the above proposals, when considered together as a whole package, provide a complete, flexible and balanced suite of authorisation requirements and

provisions that will help enable the roll-out of interoperability in accordance with the Department's strategy for interoperability.

Question 11: Do you agree that the draft Regulations provide a complete and balanced suite of provisions for the authorisation of railway subsystems, to be placed into service in the UK? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.12 Regulation 12: List of projects for the renewal or upgrading of subsystems

3.12.1 Draft Regulation 12 incorporates the Department's proposals for the introduction of TSI Implementation Plans, in support of its strategy on interoperability. The Department's proposals were discussed in detail in the first Consultation Document and were widely supported by stakeholders.

3.12.2 The creation of Implementation Plans, for each TSI, is intended to support the rail industry's planning process for the development of the railway in the UK. Implementation Plans could therefore include aspects of strategy, transport policy, proposals for entirely new railway lines, migration strategies for upgrading existing lines, forecasts for network utilisation and demand, cost benefit analyses, technical information on capacity or design, etc. The Implementation Plans could also take account of UK Specific Cases in TSIs and the UK's migration strategy towards full compliance with specific TSI specifications.

Please Note: A new draft Help Note describing the planned use of Implementation Plans and has been included in Annex D of this Consultation Document.

Please Note: This issue is also described in the partial Impact Assessment which is attached to this Consultation Document at Annex E.

3.12.3 Draft Regulations 12 and 13 facilitate the use of Implementation Plans to specifically list projects and types of projects that are considered by the Competent Authority to be "upgrades" to or "renewals" of the existing UK railway system, where such projects are considered to be significant enough to warrant the application of the interoperability process of authorisation. Draft Regulation 12 sets out the mechanisms for creating the list of projects

and draft Regulation 13 sets out how the draft Regulations apply to upgrade and renewal projects that are specified on the list.

3.12.4 Draft Regulation 12(1) allows the Competent Authority (DfT, DRDNI or IGC) to publish an Implementation Plan for each TSI, and if such an Implementation Plan is created, then it should include a list called the "*Regulation 12 List*". Draft Regulation 12(2) requires the list to include those projects and type of projects that have been determined by the Competent Authority to be an "upgrade" or a "renewal" and such projects will be formally treated as such and be subject to the requirements on upgrades and renewals. Draft Regulation 12(4) requires the Competent Authority to keep any published Regulation 12 List up to date.

3.12.5 The effect of draft Regulation 12 is to provide the equivalent of an advance "screening decision" on the application of the Regulations to upgrades and renewals (when compared to RIR 2002), or to replace the Contracting Entity's judgement on whether such a project is "major" and should write to the Competent Authority for a "Reg 5 Decision" on the extent of application of TSIs (when compared to RIR 2006). When all such "screening decisions" are coalesced into one plan, the application of the Regulations to upgrades and renewals can be more sensibly planned for at both a national and European level, compared with decisions on a case by case basis.

3.12.6 Draft Regulation 12(3) sets out the criteria for deciding whether a project or type of project should be included on the list. A key criterion for deciding whether a project, type of project, or even group of projects, should be included on the list is the scale of a project in terms of economic cost and benefit. The criteria also include:

- impacts on the rail system, having regard to (the essential requirements for) safety, reliability and availability, health, environmental protection and technical compatibility;
- impact on the accessibility of the rail system to passengers; and,
- impact of the application of TSIs to the (railway) subsystem and any interfacing subsystems.

3.12.7 The Department would like to start work with stakeholders on the development of the Implementation Plan for the Infrastructure TSIs as the first priority, and, if possible, to complete the first version of the Implementation Plan by mid 2011. If this timescale is met then it should be possible to integrate the Implementation Plan with industry and Government planning processes, for example, the development of Network Rail's Strategic Business Plan and Route Utilisation Strategies, and for specific projects or

types of project to be specified under the next phase of the High Level Output Specification (HLOS II).

Question 12: Do you agree that the factors in draft Regulation 12(3), to be considered by the Competent Authority for the inclusion of projects and types of projects in each TSI Implementation Plan, are suitable? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.13 Regulation 13: Authorisation requirements for the renewal or upgrading of subsystems

3.13.1 Draft Regulation 13 replaces the current RIR 2006 Regulation 5 with the addition of a new provision to incorporate the use of Implementation Plans. Until an Implementation Plan is published for a TSI the current RIR 2006 Regulation 5 process applies, i.e. the Contracting Entity should write to the Competent Authority for a decision on whether an authorisation will be required for projects that are an upgrade or renewal. This provision is replicated in draft Regulation 13(1), and the Contracting Entity is still, in effect, left to judge whether the project meets the description of “upgrade” or “renewal”.

3.13.2 Under the new draft Regulation 13(2), if a TSI Implementation Plan has been published, and the Implementation Plan’s Regulation 12 List includes a specific project or type of project, then no judgement is required by the Contracting Entity regarding whether the project is an upgrade or renewal, and the direction in draft Regulation 13(1) directly applies to the project. More significantly, if a TSI Implementation Plan has been published, and its list *does not include* a specific project or type of project, then no judgement is required by the Contracting Entity, and the Contracting Entity can be sure that the project is not subject to the rest of the requirements in draft Regulation 13, with respect to that TSI.

3.13.3 Draft Regulation 12(3)-(9) replicates RIR 2006 Regulation 5(2)-(8) with minor changes to modernise the drafting (for example, substituting “shall” with “must”). Also, in draft Regulation 13(3)(b), the Contracting Entity is now simply required to assess whether there are any new or changed safety risks resulting from the works, and how the risks will be managed (as opposed to assessment of “adverse effect” as required under the current RIR 2006). This would be consistent with the application of the CSM on risk evaluation and

assessment to the project. In summary, the existence of an Implementation Plan is intended to provide certainty on whether the existing RIR 2006 "Reg 5" process applies to a project, although the process itself (submitting a project file, etc. to the Competent Authority, and requesting a decision on the extent of the application of TSIs) has not changed.

3.13.4 The Department believes that the best approach to Implementation Plans is to create an Implementation Plan for each individual TSI. If a project or type of project is determined to be an upgrade or renewal, and is subject to multiple TSIs, then it should be listed in each TSI Implementation Plan.

3.13.5 It has been suggested, however, that an alternative approach (not incorporated into the draft Regulations) would be to create Implementation Plans for each *subsystem*, instead of each TSI. This approach has the potential to decrease the number of Implementation Plans needed (as each subsystem can have multiple associated TSIs). However, the Department considers that the subsystem approach would not provide the same clarity as individual TSI Implementation Plans. Also, the individual TSIs include their own "implementation strategies", which inform the application of the TSIs to upgrades and renewals, and are therefore relevant to the creation of individual TSI Implementation Plans.

Question 13: Do you agree that Implementation Plans should be developed for each TSI, rather than for each subsystem? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.14 Regulation 14: Exemption from need to conform with TSIs (derogations)

3.14.1 Draft Regulation 14 carries forward the provisions in RIR 2006 Regulation 6 with some changes in line with changes to Article 9 of the new Directive. The changes that reflect the changes in the new Directive include:

- explicitly enabling the application of all existing types of derogation to all subsystems (as opposed to, in certain cases, limiting derogations to "railway lines");
- an expansion of the applicability of the derogation type that relates to rail networks that are separated or isolated by the sea to now include networks that are "separated as a result of special geographical

conditions" (as provided for in Article 9(1)(c) and transposed at draft Regulation 14(2)(c));

- the inclusion of a new derogation type to the draft Regulations for "vehicles coming or going to countries outside the European Union, the track gauge of which is different from that of the main rail network within the European Union" (as provided for in Article 9(1)(f) and transposed at draft Regulation 14(2)(f));

- the inclusion, in draft Regulation 14(3), of a reference to Schedule 8 of the draft Regulations (reproducing Annex IX of the new Directive), which sets out the details that need to be included in a project file to be sent to the European Commission by the Competent Authority before the Competent Authority grants any derogation (in practice the compilation of this file will be done by the Contracting Entity that is requesting a derogation); and,

- the inclusion of a provision for derogations that rely on a decision by the European Commission to automatically consider permission to derogate to be granted (by the Commission) in the event that the Commission has not decided on a request within six months of that request being submitted.

3.14.2 The above changes are not considered to be controversial and are expected to provide a benefit to stakeholders by either increasing the flexibility for the application of derogations (application to all subsystems where relevant) and by improving the consistency for decision making (through the use of Annex IX criteria), or they are expected to have no impact for the UK at all (e.g. derogation for non EU vehicles).

3.14.3 In addition to the changes described above, the reference in RIR 2006 Regulation 6(1) that allows derogations to apply to Interoperability Constituents has been removed in draft Regulation 14(1). The Department has never processed a request for derogation from TSI requirements for an Interoperability Constituent and cannot foresee the need for provisions that would allow it. Derogation for an Interoperability Constituent would appear to have no purpose as permission is not required from a statutory authority to place them onto the market. Further to this, for an Interoperability Constituent to be placed onto the market, it must first be verified as being TSI compliant (and therefore mutually acceptable across Europe), and can therefore not be subject to a derogation. In the event that a future subsystem incorporates a component that could be described as an Interoperability Constituent, but that component does not comply with TSIs, then a derogation can still be applied for with respect to the subsystem, if appropriate.

3.14.4 It should be noted that it is also proposed as part of this consultation, at draft Regulation 49, that the Competent Authority be given the power to grant derogation from UK NNTRs. This proposal is described in more detail in section 3.49.

3.15 Regulation 15: Essential requirements for project subsystems

3.15.1 Draft Regulation 15 carries forward the provisions in RIR 2006 Regulation 7 with drafting changes (making it more explicit that the provision is intended to "deem" that Essential Requirements are met, for the purpose of other provisions in the draft Regulations, if certain conditions are met) plus an additional clause at draft Regulation 15(1)(b) that requires the Essential Requirements to be met through the implementation of:

- any necessary measures identified by the risk management process undertaken during the application of the Common Safety Method (CSM) on risk assessment and evaluation; and,
- any necessary measures identified in the safety assessment report (the output of the CSM process, which is needed for demonstrating on going conformity with Essential Requirements).

3.15.2 The proposed requirement to apply the CSM is in addition to the existing requirement to achieve conformity with applicable TSIs and NNTRs (as in draft Regulation 15(1)(a)). Although this appears to be an additional requirement on industry, in practice duty-holders are generally required to make risk assessments for safety in general health and safety legislation, and it is expected that railway operators and infrastructure managers already carry out this kind of activity when introducing engineering change to the railway system. The EC Regulation on the CSM (EC Reg No. 352/2009) comes into force on 19 July 2010 with direct effect (coinciding with the transposition deadline for the new Directive), and will therefore become a harmonised legal requirement for all railways across the European Union.

3.15.3 Article 15(1) of the new Directive on interoperability makes it clear that safe integration of railway subsystems (including meeting the Essential Requirements) is to be done in accordance to Article 6(3) of the Railway Safety Directive, which calls up the requirements of the CSMs. The application of the CSM on risk assessment and evaluation therefore has particular significance for demonstrating compatibility with national networks.

3.15.3 The CSM is designed to be applied whenever there is a significant change to the railway system and Article 2(2) of the Regulation that mandates it makes it explicit that the requirement to apply the process is triggered by the authorisation of a structural subsystem under the new Directive on

interoperability (including authorisation of upgrades and renewals, as well as new subsystems). The Department is therefore proposing to "hardwire" the requirement to apply the CSM into the authorisation process (for example, it will be a requirement to produce a safety assessment report as part of the evidence for an application for authorisation).

3.15.4 The Contracting Entity will therefore need to ensure that when making an application for authorisation, that its project subsystem is in conformity with all applicable TSIs and NNTRs, and that the CSM on risk assessment and evaluation has been applied. This is relevant for all authorisations, including Type Authorisations and reauthorisations (when they are applied for).

3.15.5 It is anticipated that the application of the CSM will be particularly useful for providing a sustainable process for Contracting Entities to identify the alternative requirements that need to be complied with in order to meet the Essential Requirements, for example, when derogation from the application of TSIs, or indeed NNTRs, is sought for a project subsystem.

3.15.6 In summary, it is reasonable for any European railway operator to expect to have to apply the harmonised CSM on risk assessment and evaluation, given that the EC Regulation that brings it into force (EC Reg No. 352/2009) requires its use whenever a subsystem is authorised using interoperability processes, and that the Directive on interoperability requires (in Article 15) that subsystems are to be placed into service in accordance with such CSMs. The Department therefore proposes, in the interests of transparency and for the proper implementation of the CSM with respect to its application to interoperability, to build the requirements directly into the proposed draft Regulations.

3.15.7 Before answering the question below, the reader is asked to read through to section 3.20 of this Consultation Document (and particularly section 3.18.5), for further information, consideration and discussion on the application of the CSM on risk assessment and evaluation.

Question 14: Do you agree that the application of the CSM on risk assessment and evaluation should be hard-wired into the proposed Regulations? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach).

3.16 Regulation 16: Duties on a contracting entity

3.16.1 Draft Regulation 16 carries forward the provisions in RIR 2006 Regulation 8 with some minor drafting changes but also includes an amended set of provisions (compared to existing Regulations) that enables a significant new policy proposal to:

- limit the role of the Notified Body to the verification of TSIs and the checking of compatibility only by reference to the registers of infrastructure and rolling stock; and
- require the verification of NNTRs to be done by a Designated Body (or "DeBo").

3.16.2 The proposed policy on NoBos and DeBos explicitly manifests itself for the first time in the body of the draft Regulations at draft Regulation 16(1), although the term "designated bodies" is actually introduced in draft Regulation 2, where it is defined. Draft Regulation 16(1) requires the Contracting Entity to appoint a Notified Body to carry out the verification assessment procedure, but *not* in relation to NNTRs. Draft Regulation 16(1)(c) requires the Contracting Entity to appoint a DeBo to carry out verification of NNTRs, but includes a transition provision to allow a NoBo to carry out that the task for a project where that NoBo has been appointed within a year of the draft Regulations coming into force (i.e. by 19 July 2011) - i.e. the transition provisions enable NoBos to carry on their work on NNTRs:

- on existing projects until those projects have been finished;
- on new projects only if they have been appointed to work on a project by 19 July 2011; and,
- on new projects, after 19 July 2011, only if that NoBo has also been designated as a DeBo (this transitional provision is included at draft Regulation 16(4)).

3.16.3 The introduction of the proposed policy on DeBos is reflected in further provisions in other parts of the draft Regulations that amend existing provisions in RIR 2006. These changes impact on:

- draft Regulation 15 (on Essential Requirements);
- draft Regulations 16-20 (with respect to the duties of the Contracting Entity);
- draft Regulation 32 (appointment of NoBos and DeBos by the Secretary of State);
- draft Regulations 33 & 34 (functions of NoBos and DeBos); and,

- draft Regulation 35 (NoBo certificate of verification of TSIs and DeBo certificate of conformity for NNTRs).

Cross references to the necessary changes to the existing Regulations are discussed below in the sections on draft Regulations 17-20 (readers are therefore advised to read through these all of these sections, which discuss the policy in more detail, before answering the questions at the end of section 3.19).

3.16.4 The Department considers that its proposed policy to appoint DeBos to assess NNTRs is more consistent with the Directive's intentions, and broadly aligns to the process that is used in most other Member States.

3.17 Regulation 17: Project subsystems: verification assessment procedure

3.17.1 Draft Regulation 17 carries forward the provisions in RIR 2006 Regulation 9 and implements the new provisions in Article 18(2) of the new Directive which states that the verification of the interface of the subsystem (by a NoBo) should be based on the information available in the relevant TSI and in the registers provided for in Articles 34 and 35 (the European register of authorised types of vehicles and the register of infrastructure, respectively). Consequently, the provision on the extent of the NoBo verification has been amended at draft Regulation 17(2)(b) to explicitly include (in addition to verification of TSIs) the verification of the interface of the subsystem with the rail system, but to limit the extent of that assessment only to the information available in the TSIs and the relevant registers, as described in the new draft Regulation 17(3).

3.17.2 It should be noted that draft Regulation 17(2) requires the Notified Body to complete the Technical File (this is unchanged from RIR 2006 Regulation 9), but that the contents of the Technical File, as added to and kept by the Contracting Entity under draft Regulation 19, includes material relevant to NNTRs (that the NoBo does not verify).

3.18 Regulation 18: Project subsystems: verification declaration

3.18.1 Draft Regulation 18 carries forward the provisions in RIR 2006 Regulation 10 and the text has not substantively changed from that in RIR 2006. The provision at draft Regulation 18(1) assumes that when a Contracting Entity makes its declaration to the Safety Authority that its project subsystem has been verified, and that the project subsystem should be taken

to meet the Essential Requirements. Draft Regulation 18 makes reference to, and is therefore reliant on changes to draft Regulation 15 (on Essential Requirements), which now incorporates the application of the CSM on risk assessment and evaluation, as well as project subsystem conformity with TSIs and NNTRs (as discussed earlier in section 3.15).

3.18.2 The effect of draft Regulation 18 has also been modified by the policy proposal to split the verification of TSIs and NNTRs between NoBos and DeBos (respectively). The verification declaration, as part of the package of information required for an application for authorisation, is therefore impacted by the extent that the NoBo's certificate of verification provides for presumption of conformity with Essential Requirements (which would, under these proposals, now only be in relation to TSIs). To recap, the information required in an application for authorisation under draft Regulation 5(2) includes:

- the NoBo certificate of verification of TSIs (under draft Regulation 5(2)(a));
- the DeBo certificate of conformity to NNTRs (under draft Regulation 5(2)(a));
- the complete Technical File (under draft Regulation 5(2)(a));
- the safety assessment report produced as a result of applying the CSM on risk assessment and evaluation (under draft Regulation 5(2)(a)); and,
- the verification declaration (under draft Regulation 5(2)(b)).

3.18.3 Given that it is proposed that the NoBo's role in relation to the verification of standards is to be limited to TSIs, its certificate of verification must therefore also be limited to TSIs (as a mandatory requirement). Consequently, draft Regulation 35 on NoBo certificates of verification (which substantively carries forward the current RIR 2006 Regulation 27) has been amended so that draft Regulation 35(2) no longer requires the NoBo to be satisfied that the project subsystem conforms to NNTRs. Proposed changes to the compilation of the Technical File are described in section 3.19 below.

3.18.4 The certificate of verification provided by the NoBo only provides for presumption of conformity to Essential Requirements with respect to the verified TSIs (under the process of EC verification). There is no (European wide) presumption of conformity with Essential Requirements for any other part of the verification (NNTRs, etc.) for a specific project subsystem. Under the proposed draft Regulations, the Contracting Entity should apply the NNTRs that are suitable for the project, and ask a DeBo to verify that the

project subsystem is in conformity with them. By splitting the verification between these two bodies, the only participants in the process of authorisation that have oversight of the whole verification process are the Contracting Entity and the Safety Authority. This is a significant change from the current Regulations, in which the NoBo also has oversight (and attests to it through its certificate of verification covering both TSIs and NNTRs). Consequently, under the proposed draft Regulations, the Contracting Entity, when producing its verification declaration, is more clearly responsible as the integrator of the verification process.

Application of CSM on risk assessment and evaluation

3.18.5 Additionally, with the incorporation of the CSM on risk assessment and evaluation in the proposed draft Regulations, the Contracting Entity would be compiling and providing a more complete package to the Safety Authority to assess, when making its application for the authorisation of a subsystem to be placed into service. It is proposed that the safety assessment report that results from the process of applying the CSM, can be verified, in accordance to Article 6 of the EC Regulation on the CSM, by:

- an internal department within the Contracting Entity (which is suitably removed from the initiator of the project);
- an external body, such as an Independent Safety Assessor (ISA);
- the Safety Authority; or,
- the Notified Body (NoBo), with respect to TSI verification, when appointed to the task by the Contracting Entity.

This means that a further level of integration is required by the duty-holder (the Contracting Entity), and, implicitly, a wider range of checking will be required by the Safety Authority when assessing an application for authorisation.

3.18.6 The obligation to apply CSMs, more generally, is required by the Railway Safety Directive, which is transposed into separate pieces of national legislation in the UK, and only applies to certain railway “actors” in the system - for example, in Great Britain, the obligation falls on duty-holders under ROGS. However, a Contracting Entity under the proposed draft Regulations for interoperability does not necessarily need to be a duty-holder under the various Regulations on railway safety. The Department’s proposal to incorporate relevant requirements of the CSM on risk assessment and evaluation in the proposed draft Regulations for interoperability would catch other stakeholders not covered by ROGS (etc.) and would provide for a more complete and consistent implementation of the EC Regulation on the CSM.

Regulation 19: Technical file and retention of documents

3.19.1 Draft Regulation 19 carries forward the provisions in RIR 2006 Regulation 11 and the text has not substantively changed from that in RIR 2006, with the following key exceptions:

- the Technical file should include the "certificate of conformity to notified national technical rules", to be inserted by the Contracting Entity;
- the Technical File should include the safety assessment report that results from the application of the CSM on risk assessment and evaluation; and,
- if the application for authorisation involved a Type Authorisation in accordance with draft Regulation 9, then the declaration of conformity to type must be included in the Technical File.

Summary of the policy proposal to split TSI and NNTR verification

3.19.2 The consequences of the proposed policy to remove the verification of NNTRs from the NoBo's remit, and to separately designate bodies for the verification of NNTRs, are that:

- the Contracting Entity is given increased flexibility to choose which bodies verify national rules;
- there is a potential reduction in duplication of assessment by a NoBo when national rules are first assessed by a national body, and then by a NoBo (as the NoBo must assure itself, under the current Regulations, that the project subsystem conforms to NNTRs - this would no longer be relevant);
- although nothing in the current Regulations explicitly prevents a non-UK NoBo from verifying UK NNTRs, an explicit designation by the Secretary of State for foreign NoBos to be appointed for that task should provide Contracting Entities with more confidence in appointing them for verifying project subsystems;
- the NoBo will only be involved in compatibility checks in the "European domain", i.e. where it is relevant to TSI verification, or where the information necessary for the checks are in the TSIs or in the European vehicle register or register of infrastructure;
- if a Contracting Entity appoints a DeBo that is not already a NoBo, then it will need to be more proactive in setting out the scope of verification for both the NoBo and DeBo, and be able to integrate evidence of design verification and any assessments associated with compatibility

checks before making a verification declaration to the Safety Authority; and,

- the Safety Authority will need to be mindful that the Contracting Entity is the integrator of the evidence that demonstrates that Essential Requirements have been met, as opposed to the NoBo (which is implicit under the current Regulations).

Question 15: Do you agree that in the future, only Designated Bodies should be appointed by Contracting Entities to verify UK NNTRs?

Question 16: Do you agree that the role of the Notified Body should be limited to checking conformity with TSIs and, with respect to compatibility, should be limited to only checking the interface with infrastructure as defined in Article 18(2) of the Directive?

Question 17: Do you agree that the Contracting Entity should be (more explicitly) responsible for integrating the verification evidence for project subsystems and for the integration of the subsystem with the rail network, as opposed to the NoBo (on the Contracting Entity's behalf)?

(Please explain your answers, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach)

Regulation 20: Duty on operator to ensure essential requirements are met

3.20.1 Draft Regulation 20 carries forward the provisions in RIR 2006 Regulation 12 (as amended) and the provisions have not substantively changed from that in RIR 2006 (as amended), with the exception that when a safety assessment report has been produced to support an application for authorisation, that any necessary measures identified by the risk management process continue to be implemented (as described in draft Regulation 20(2)(e)).

Please Note: Draft Regulation 20(3)-(6) incorporates the amendments that were made to RIR 2006 by the Rail Vehicle Accessibility (Interoperable Rail System) Regulations 2008 (SI No. 2008/1746), with respect to exemption orders.

Regulation 21: Fees payable to the Safety Authority

3.21.1 Draft Regulation 21 carries forward the provisions in RIR 2006 Regulation 13 and the provisions have not substantively changed from that in RIR 2006.

Regulation 22: Fees payable to the Competent Authority

3.22.1 Draft Regulation 22 carries forward the provisions in RIR 2006 Regulation 14 and the provisions have not substantively changed from that in RIR 2006.

RIR 2010 PART 3: INTEROPERABILITY CONSTITUENTS

Regulation 23: EC declaration of conformity or of suitability for use

3.23.1 As described in the Government response to the first Consultation Document, stakeholders were broadly content that nothing in the current Regulations needed to be addressed regarding Interoperability Constituents.

3.23.2 The new Directive has not significantly changed with respect to requirements for Interoperability Constituents, other than to make provisions for the use of spare parts (see draft Regulation 25(2)). That said, there are two key changes to RIR 2006 in relation to Interoperability Constituents. Firstly, as described in section 3.14, RIR 2006 made provision for derogation for Interoperability Constituents, and this has now been removed. Secondly, the Department considers Interoperability Constituents to be "products" within the meaning of European harmonisation legislation for products, and therefore the provisions in the EC Regulation on Accreditation and Market Surveillance (EC Regulation 765/2008) apply - this is described in sections 3.43-3.45.

3.22.3 Draft Regulation 23 carries forward the provisions in RIR 2006 Regulation 16 and the provisions have not substantively changed from that in RIR 2006.

Regulation 24: Effect of conformity and suitability declarations

3.24.1 Draft Regulation 24 carries forward the provisions in RIR 2006 Regulation 17 and the provisions not substantively changed from that in RIR 2006.

Regulation 25: Assessment procedure for interoperability constituents

3.25.1 Draft Regulation 25 carries forward the provisions in RIR 2006 Regulation 18. Draft Regulation 25(2) has been added in order to transpose the new provision in Article 11(4) of the new Directive that exempts "spare parts" from being subject to the EC verification procedure.

3.25.2 The exemption applies to spare parts that are to be used in subsystems that have been placed into service before a relevant corresponding TSI has come into force, i.e. where that TSI explicitly

describes those spare parts (perhaps as Interoperability Constituents) and explicitly makes their use mandatory in a subsystem. There is an ongoing discussion between the European Commission, the European Railway Agency and Member States on whether the incorporation of Interoperability Constituents into subsystems is mandatory or voluntary.

Please note: The intention in the new Directive appears to be to consider incorporation as mandatory (when defined in TSIs) as Article 11(5) guides TSI drafters to make provision in TSIs for a transition period to allow the use of rail products that have already been placed on the market when a TSI enters into force.

Regulation 26: Prohibition on placing interoperability constituents on the market

3.26.1 Draft Regulation 26 carries forward the provisions in RIR 2006 Regulation 19, and the provisions have not substantively changed from that in RIR 2006, other than to make future provision for “the market” to be extended beyond the current TEN networks, should TSIs have their geographical scope extended.

Regulation 27: Duties on operators

3.27.1 Draft Regulation 27 carries forward the provisions in RIR 2006 Regulation 20, and the provisions have not substantively changed from that in RIR 2006.

Regulation 28: Position after placing on the market

3.28.1 Draft Regulation 28 carries forward the provisions in RIR 2006 Regulation 21, and the provisions have not substantively changed from that in RIR 2006.

Regulation 29: Recognition of assessments of other Member States

3.29.1 Draft Regulation 29 carries forward the provisions in RIR 2006 Regulation 2, and the provisions have not substantively changed from that in RIR 2006.

Regulation 30: Notification to the Commission of incorrect declaration

3.30.1 Draft Regulation 30 carries forward the provisions in RIR 2006 Regulation 23, with one minor amendment, requiring the Safety Authority to notify the European Commission of any action it has taken to withdraw an Interoperability Constituent from the market, where the Safety Authority has found that Interoperability Constituent to not meet the Essential Requirements. This is in addition to notifying the European Commission of the action the Safety Authority has taken to prohibit or restrict the use of such Interoperability Constituents, as provided for under RIR 2006 (as amended).

RIR 2010 PART 4: NOTIFIED AND DESIGNATED BODIES

Regulation 31: Notified bodies

3.31.1 Part 4 of the Regulations concerns the duties of Notified Bodies and Designated Bodies, and their appointment by the Secretary of State. The proposed creation of Designated Bodies as bodies to assess NNTRs, and the operative impact of this proposal is discussed earlier in this document in sections 3.16-3.20.

3.31.2 Draft Regulation 31 carries forward the provisions in RIR 2006 Regulation 24 and these provisions have not substantively changed from that in RIR 2006. The Regulation has been adapted slightly, at draft Regulation 31(d), to recognise Notified Bodies that have been appointed by other Member States under the new Directive, as well as the two previous Directives (in draft Regulation 31(c)).

Regulation 32: Appointment of notified bodies and designated bodies

3.32.1 Draft Regulation 32 carries forward the provisions in RIR 2006 Regulation 26 and the provisions for statutorily appointing NoBos have not substantively changed from that in RIR 2006. Draft Regulation 32 includes additional requirements for the appointment of a Designated Body (DeBo) by the Secretary of State, and these generally mirror the provisions for the NoBo, except that:

- under draft Regulation 32(12), the Secretary of State need not notify the European Commission and other Member States of the appointment of a DeBo or the termination of a DeBo's appointment; and,
- under draft Regulation 32(13), the Secretary of State need not notify the European Commission and other Member States regarding the performance of a DeBo, in accordance with the criteria in Schedule 2 of the Regulations (these criteria only strictly apply to NoBos).

Regulation 33: Requirement on notified bodies to carry out functions

3.33.1 Draft Regulation 33 carries forward the provisions in RIR 2006 Regulation 26 and these provisions have not substantively changed from that

in RIR 2006. The requirements on NoBos, which apply to all NoBos in Europe, do not apply to DeBos (which are only appointed in the draft Regulations with respect to their operations in the United Kingdom).

Regulation 34: Requirement on designated bodies to carry out functions

3.34.1 Draft Regulation 34 mirrors the requirements in draft Regulation 33 on NoBos and applies them to DeBos, with the exception that DeBos are explicitly required to verify NNTRs.

Regulation 35: Notified bodies and designated bodies: certificates, etc.

3.35.1 Draft Regulation 35 carries forward the provisions in RIR 2006 Regulation 27 and the provisions as they apply to NoBos have not substantively changed from that in RIR 2006, except that the draft Regulations no longer require the NoBo to be satisfied that a subsystem conforms to NNTRs. This is key to the policy proposal that verification of TSIs and NNTRs should be split between NoBos and DeBos (respectively), as discussed in sections 3.16-3.20.

3.35.2 Under draft Regulation 35(4) the responsibility for verifying NNTRs is given to the DeBo, which is also required to provide a “certificate of conformity to NNTRs”.

Regulation 36: Duties on notified bodies to consult

3.36.1 Draft Regulation 36 carries forward the provisions in RIR 2006 Regulation 28 and these provisions have not substantively changed from that in RIR 2006. The requirements on NoBos to consult with each other (in the European NoBo forum known as “NB Rail”), applies to all NoBos in Europe, but does not apply to national DeBos (which are only appointed in the draft Regulations with respect to their operations in the United Kingdom).

Regulation 37: Fees of notified bodies and designated bodies

3.37.1 Draft Regulation 37 carries forward the provisions in RIR 2006 Regulation 29 and the provisions for NoBos have not substantively changed from that in RIR 2006. Draft Regulation 37 includes additional provisions for DeBos to charge fees, mirroring the existing provisions for NoBos.

Regulation 38: Fees of the Secretary of State

3.38.1 Draft Regulation 38 carries forward the provisions in RIR 2006 Regulation 30 that allow the Secretary of State to charge fees for activities under draft Regulation 32 - these provisions have not substantively changed from that in RIR 2006.

RIR 2010 PART 5: REGISTERS

Regulation 39: Register of infrastructure

3.39.1 Draft Regulation 39 includes requirements for the registers of infrastructure (known as "infrastructure registers" in the draft Regulations), as provided for under Article 35 of the new Directive. The draft Regulation retains the overall structure of RIR 2006 Regulation 31, but with the following key changes:

- the draft Regulation only applies to *infrastructure* - RIR 2006 Regulation 31 currently applies to authorised rolling stock and authorised infrastructure - however, the requirements for vehicle registers are now more fully covered (separately) under draft Regulation 40, which implements the (now developed) requirements to create a National Vehicle Register;
- the requirement to retain a register is now placed on the *infrastructure manager*, as opposed to the infrastructure *owner* (this only has practical effect when the infrastructure manager and the owner are different);
- the infrastructure manager is required to publish, on a publicly available website; any infrastructure register that he retains, and to keep that information up to date;
- the Secretary of State's obligation to publish and send to other Member States a copy of any (vehicle and) infrastructure registers (under Regulation 32 of RIR 2006) has been removed from the proposed draft Regulations (although the infrastructure manager is still obliged to notify the Competent Authority (Secretary of State in GB) whenever the infrastructure manager has infrastructure authorised, becomes responsible for authorised infrastructure or when authorised infrastructure is taken permanently out of use); and,
- the requirements to retain an infrastructure register are also applied to existing infrastructure that has not yet been authorised and requires the infrastructure register to include any information that is required by any TSI.

3.39.2 The changes described above (particularly the second bullet point) are in line with the Government's response to the first consultation, which described the overall stakeholder support for the option that the infrastructure manager should be made responsible for making the register of infrastructure available.

3.39.3 The information to be included on the infrastructure register, i.e. the correlation of the basic parameters with the features laid down in TSIs (in draft Regulations 39(3)(a)(ii) and 39(3)(b)(i)) should effectively define the gap between the state of that infrastructure and a fully TSI compliant infrastructure. If the infrastructure is fully TSI compliant, the register will be empty, but where there are non-compliances, the register should detail those non-compliances.

3.39.4 Transition periods are provided for the creation of the infrastructure register (12 months), and any necessary updates following the adoption of a new or revised TSI that imposes information requirements on the register (12 months), in line with draft Regulations 39(3)(a)(iii) for authorised infrastructure and draft Regulation 39(3)(b)(ii) for all other infrastructure.

3.39.5 When an infrastructure register is in place, and work is carried out on the infrastructure that affects the accuracy of the data in the register, then an updated version of the register should be provided to the Competent Authority within 21 days of that work being carried out. The updated register should also be provided to the Competent Authority within 21 days after:

- any infrastructure is authorised under the draft Regulations;
- any infrastructure is taken permanently out of use; and,
- the infrastructure manager becomes responsible for any infrastructure.

Question 18: Do you agree with the approach taken in the draft Regulations to implement the new Directive's requirements for the register of infrastructure? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach)

Regulation 40: National vehicle register

3.40.1 Draft Regulation 40 includes requirements for a National Vehicle Register (NVR) of authorised rolling stock. Current requirements in RIR 2006 Regulation 37 for individual owner registers of authorised rolling stock are now considered to be redundant, and such provisions are not included in the proposed draft Regulations (refer to section above regarding registers of infrastructure for more information).

3.40.2 RIR 2006 Regulation 33 cites requirements for a NVR, and these provisions have been refined with minor amendments in the proposed draft Regulations. The most significant changes, which are still relatively insubstantial, include:

- references to a vehicle's ID Code (in RIR 2006) are now replaced with references to the European Vehicle Number; and,
- the National Vehicle Register must conform to the common specifications in the "NVR Decision" (i.e. EC Decision 2007/756/EC).

3.40.3 The Department's policy position regarding the NVR on requirements from the new Directive was described in detail in the first consultation document, and the continuing assumption is that there is little impact for GB's railways due to the existence of the Rolling Stock Library.

Question 19: Do you agree with the approach taken in the draft Regulations to implement the European requirements for the National Vehicle Register? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach)

RIR 2010 PART 6: APPEALS AND ENFORCEMENT

3.41.0 Part 6 of the draft Regulations includes substantial new additions to the provisions of the existing RIR 2006, including:

- a new process for appeals (with entirely new provisions for RIR 2010);
- a continued approach with enforcement under the Health and Safety at Work, etc. Act 1974 (HSWA) regime, but with minor changes to the provisions of RIR 2006 to reflect changes to the HSWA provisions regarding offences under health and safety law; and,
- new enforcement powers to allow the enforcing authorities to require the withdrawal and/or recall of interoperability constituents that have been placed on the market in the United Kingdom.

Regulation 41: Appeals

3.41.1 The Government's response to the first Consultation Document indicated that the Department's preferred approach to handling appeals against Safety Authority decisions was to refer them to an Industrial Tribunal or Employment Tribunal - an approach that was widely supported by stakeholders. However, there was equally significant stakeholder support for the Secretary of State (SoS), in Great Britain, to hear such appeals, as is currently done in the ROGS Regulations on railway safety.

3.41.2 The tribunal route of appeal was considered in detail as the potential frequency of appeals cases was initially considered to be reasonably high because the Department had proposed that *all* Safety Authority decisions under interoperability (and not just those cited in the Interoperability Directive) should be made subject to appeals. However, given the approach to make the Regulations more flexible for all subsystems, the frequency of appeals should be reduced, and the costs associated with setting up a tribunal that might rarely or even never be used are not justifiable at this point in time.

3.41.3 The proposed approach in the draft Regulations to handle appeals is now to align the interoperability process with the process in ROGS - i.e. for the SoS or an independent expert appointed by the SoS to hear appeals (in Great Britain). If this appeals process is tried, tested, and proven to not be appropriate or functional, the Department will revisit an approach involving a tribunal, if it appears to be the best option at the time.

3.41.4 Draft Regulation 41 includes the proposed appeals process. The draft Regulations provide for the SoS, or a person nominated by the SoS, to hear the appellant (in Great Britain). The appeals process, as currently drafted in the proposed Regulations, applies to decisions by both of the GB Safety Authorities, including ORR (GB mainland) and IGC (in relation to the Channel Tunnel). The appeals process to be used in Northern Ireland, i.e. appeals against a decision made by the DRDNI in its capacity as Safety Authority, is still under development, and for the purposes of the draft Regulations enclosed in this Consultation Document, the appeals process in draft Regulation 41 is not applied to DRDNI, by the disapplication in draft Regulation 41(10).

3.41.5 In summary the appeals process, as drafted in the proposed Regulations, includes the following key features:

- draft Regulation 41, overall, closely follows the standard statutory appeals mechanism for health and safety licensing related appeals, and therefore closely follows the provisions in Regulation 27 of ROGS on the granting of safety certificates and safety authorisations;
- draft Regulation 41(1) applies the appeals process to decisions of the Safety Authority in relation to draft Regulations 5-11, i.e. authorisation decisions, including revocation of an authorisation, and allows the Secretary of State to hear such an appeal; and,
- draft Regulation 41(2) allows the Secretary of State to nominate someone to hear the appeal on the Secretary of State's behalf.

3.41.6 In the case of Northern Ireland, it is possible that DRDNI, in its capacity as Competent Authority, or the relevant DRDNI Minister, would hear any appeals made against a decision of DRDNI in its capacity as Safety Authority, and that such an approach could mirror the proposed process for GB. Alternatively, a process where Ministers in Northern Ireland appoint an ad hoc panel of experts could be used. Another approach would be to ask the European Railway Agency (ERA) to provide an opinion on a decision by the Safety Authority in Northern Ireland, as provided for in Article 21(10) of the new Directive, although the Directive only anticipates ERA's involvement if an appeals body requests an opinion.

3.41.7 In any event, the case for setting up a standing industrial tribunal as an appeals body in Northern Ireland is weaker than the case for setting it up for the GB mainline railway, given the likely infrequency of such appeals in Northern Ireland. If the proposed draft Regulations do not provide a specific process for Northern Ireland, then the default method of appealing against a Safety Authority decision in Northern Ireland would be for the aggrieved to

seek a Judicial Review, which is regarded as being wholly disproportionate, unless there is a critical flaw in the Regulations.

Please note: The appeals mechanisms related to enforcement provisions are provided for in draft Regulation 42 and 43.

Regulation 42: Enforcement in Great Britain

3.42.1 The proposed approach in the draft Regulations, with respect to enforcement, is to generally maintain the status quo, and to use the HSWA regime. Draft Regulation 42 substantively reproduces the current RIR Regulation 34 and applies various sections of HSWA 1974 to the draft Regulations for enforcement purposes. This section of the draft Regulations has been expanded to include:

- more specific references to the sections and sub-section of HSWA 1974 which are relied on to provide enforcement provisions (for example, s.21 and s.22 provide powers for improvement and prohibition notices, as cited in draft Regulation 42(3)(b)); and,
- the addition of a substantial new piece of text and a reference table, to fully explain the application of s.33 of HSWA 1974, following its amendment by the HSWA Offences Act 2008 - the table describes the mode of trial and penalties (which have been modified for RIR 2010) that can be applied on conviction, for each offence under HSWA.

Regulation 43: Enforcement in Northern Ireland

3.43.1 Draft Regulation 43 follows the same approach as draft Regulation 42, except that it is applied to Northern Ireland instead of Great Britain, and applies the provisions in the NI equivalent of HSWA 1974, i.e. the Health and Safety at Work (Northern Ireland) Order 1978. As such, the draft Regulation largely reproduces Regulation 35 of RIR 2006, and expands on the information on the provisions in the NI Order in a similar way to draft Regulation 42.

Regulation 44: Notices relating to interoperability constituents not meeting the essential requirements

3.44.1 Draft Regulation 44 carries forward the provisions in RIR 2006 Regulation 36, and the provisions have not substantively changed from that in RIR 2006, except for one significant new addition. A new draft Regulation 44(1)(b) now allows enforcing authorities (ORR for Great Britain including the UK half of the Channel Tunnel and HSE Northern Ireland in Northern Ireland) to serve a notice requiring the withdrawal or recall of Interoperability Constituents that present a serious risk. In draft Regulation 44(1)(b) the intended recipient of such a notice is someone using or intending to use an Interoperability Constituent. This draft Regulation implements Article 14(1) of the new Directive, in relation to "withdrawal" of Interoperability Constituents from the European market.

3.44.2 Draft Regulation 44(1)(b) also implements a "Market Surveillance Authority" (MSA) power under the new EC Regulation on Accreditation and Market Surveillance or "RAMS" (EC Regulation 765/2008). RAMS provides a common template for MSA enforcement powers to be used for all European harmonising legislation concerning products (consumer products and non-consumer "goods").

3.44.3 The UK's approach to implementing RAMS is, broadly speaking, to consider whether existing harmonising Directives (and the transposed national legislation) already make provision for the full suite of RAMS provisions, and where there is a gap, to amend all relevant UK Regulations with a single Statutory Instrument (SI), to be introduced in 2010. Since the new Interoperability Directive is a fairly modern Directive it already includes modern MSA provisions, with the exception of the power to require a (product) recall and the power to render (products and goods) inoperable or destroy (them).

3.44.4 The approach taken with the draft Regulations (on interoperability) is to implement the power of recall directly in draft Regulation 44(1)(b) (and in draft Regulation 45(2)(c)(iii), dealt with in the next section) and apply it only to Interoperability Constituents, as they are the only "products" under interoperability that are directly placed onto the European market. Given the wide range of interventions available in the regulatory framework for railways, we do not consider it necessary to give enforcing authorities a new explicit additional power to render railway Interoperability Constituents inoperable (including the power to do this by destroying them), in order for them to be able to effectively carry out monitoring and enforcement activities. Draft Regulation 44(2)(c) clarifies that a notice served under draft Regulation 44(1) can now direct that the Interoperability Constituent must be recalled or withdrawn (from the market), in addition to directing that it not be used or that its use is restricted (as is the case under the current RIR 2006).

Regulation 45: Notice of improper drawing up of the EC declaration of conformity for an interoperability constituent

3.45.1 Draft Regulation 45 carries forward the provisions in RIR 2006 Regulation 37, and the provisions have not substantively changed from that in RIR 2006 except for the inclusion of a new power for enforcing authorities to issue a notice requiring the withdrawal or recall of an interoperability constituent. Provision is made for this in draft Regulation 45(2)(c)(iii) and the approach is similar to that described in the section above on draft Regulation 44, except that the recipient of the notice is intended to be the manufacturers and their representatives (including suppliers).

Regulation 46: Defence of due diligence

3.46.1 Draft Regulation 46 carries forward the provisions in RIR 2006 Regulation 38 and these provisions have not substantively changed from that in RIR 2006.

RIR 2010 PART 7: SUPPLEMENTARY

3.47 Part 7 of the proposed draft Regulations includes transitional provisions, provisions to revoke the existing RIR 2006 and savings provisions in relation to provisions under RIR 2006 and the previous Directives on interoperability.

Regulation 47: Deemed authorisation (for existing vehicles)

3.47.1 Draft Regulation 47 carries forward the provisions in RIR 2006 Regulation 4A, and these provisions have not substantively changed from the existing consolidated RIR 2006 (as amended). The existing Regulation 4A was added to RIR 2006 in 2008 as a consequence of mainline railway vehicles being carved out of the Rail Vehicle Accessibility Regulations (RVAR) regime (following the introduction of the PRM TSI).

3.47.2 RIR 2006 Regulation 4A brought mainline vehicles that were previously subject to RVAR 1998 (or RVAR (NI) 2001)) and placed in service between 31 December 1998 and 1 August 2006 into the scope of RIR 2006, so that continuing compliance with the relevant accessibility standards could be enforced. To put this into effect, such vehicles are "deemed" to be authorised under RIR 2006. Regulation 47 achieves this by categorising all existing vehicles that have undergone an assessment under RVAR as having a "deemed authorisation". This means that such vehicles, when enforced under the interoperability regime, are bound by the duties to maintain compliance to the standards to which they were (deemed to be) "authorised".

3.47.3 It is proposed that draft Regulation 47(1)(b) should refer to Part 1 of Schedule 1 of the new RVAR 2010, which will substantially reproduce RVAR 1998, which, in turn acts as the relevant NNTR for any deemed authorisations (i.e. the RVAR 1998 requirements fulfil the role of a NNTR, as if the vehicle was authorised to a PRM TSI composed entirely of "open points"). The Department has been careful, when producing the new RVAR 2010 to ensure that none of the amendments to Schedule 1, Part II, will allow deemed vehicles to become non-compliant.

Regulation 48: Accessibility for people with reduced mobility

3.48.1 Draft Regulation 48 carries forward the provisions in RIR 2006 Regulation 4B, and these provisions have not substantively changed from the existing consolidated RIR 2006 (as amended). The existing Regulation 4B was added to RIR 2006 in 2008 as a consequence of the setting of the "end

date" for existing railway vehicles to achieve compliance with standards for accessibility by 2020.

3.48.2 Achieving the desired level of accessibility by 2020 can be done in a number of different ways, depending on when the vehicle was assessed, and to what standards (RVAR or the PRM TSI). All new vehicles will have to apply the PRM TSI, as the TSI has been brought into force. Existing vehicles on the network will have varying levels of compliance including:

- full compliance to the PRM TSI (if authorised under RIR 2006, with the PRM TSI in force);
- full compliance with RVAR;
- partial compliance with RVAR, because the vehicle had been granted an exemption allowing non-compliance with part of RVAR; and,
- no compliance (but the vehicle is still regulated, and is expected to comply by 2020).

3.48.3 For vehicles that are not fully compliant, they will be required to achieve:

- a greater level of compliance at the point of upgrade/renewal, through compliance with the PRM TSI for those parts of the vehicle that are being upgraded or renewed and which are not yet compliant with RVAR or the PRM TSI; and/or,
- in any event, full compliance with the PRM TSI by 1 January 2020, for those parts of the vehicle that are not yet compliant with RVAR or the PRM TSI.

Regulation 49: Dispensation from notified national technical rules

3.49.1 A new proposal in the draft Regulations is to include a new power for the Competent Authority to grant derogation from NNTRs. This power is reflected in draft Regulation 49 and would be implemented as a new national provision, as the new Directive is silent with respect to derogation from national rules.

3.49.2 The management of NNTRs in individual Member States is left (implicitly) within the Member State's competence, given that the Member State is given the role of notifying nationally applicable NNTRs. A derogation process for national rules that are also Railway Group Standards (RGS) currently exists under the current regulatory and standards frameworks in GB, however, this process is not easily applicable to, or appropriate for:

- the full spectrum of potential NNTRs, other than RGS in Great Britain;
- NNTRs that apply in Great Britain, but not to Network Rail controlled infrastructure (for example, HS1); or,
- standards used in the rest of the UK, particularly in Northern Ireland or the Channel Tunnel.

3.49.3 Given that it is a requirement for notification of NNTRs to be handled at the Member State level, it is considered to be reasonable for Contracting Entities that require derogation from NNTRs to be able to make representations to the notifier of NNTRs at the Member State level, or equivalent. It is therefore proposed that the Competent Authority be given this function, although it should be pointed out that the duty to ensure that Essential Requirements are met by a project taking advantage of derogation would wholly remain with the Contracting Entity, and that the Safety Authority would still be required to satisfy itself that Essential Requirements are met before authorising a subsystem to be placed into service.

Question 20: Do you agree with the proposal for a new national provision to be included in the draft Regulations that gives the Competent Authority the power to grant derogation from NNTRs? (Y/N)

(Please explain your answer, citing specific examples, including information on any additional costs or benefits that you consider to arise from the proposed approach)

Regulation 50: Revocation and savings

3.50.1 Draft Regulation 50 revokes RIR 2006 (as opposed to amending RIR 2006) at draft Regulation 50(1). Draft Regulation 50(2) preserves (saves) the appointed status of Notified Bodies appointed under RIR 2006. Draft Regulation 50(3) preserves the status of subsystems authorised under and RIR 2006 and recognises that Interoperability Constituents that have already been placed on the market are still placed on the market.

3.50.2 Draft Regulation 50(4) saves the provisions in RIR 2006 to allow for the placing into service of identical vehicles that are subject to a contract for follow-on orders - this saving will “sunset” in line with the time limits in the existing RIR 2006 Regulation 4.

3.50.3 Draft Regulation 50(5) recognises that a derogation granted by the Secretary of State, pursuant to the requirements in the old Directives, continues to have the status of a derogation, as if it were granted under the proposed draft Regulations.

3.51 Regulations in RIR 2006 not carried forward in draft RIR 2010

(RIR 2006) Regulation 15: (Transitional projects in 2006)

3.51.1 Please note: It is proposed that Regulation 15 in the current RIR 2006 is not needed in the proposed draft Regulations. Regulation 15 provided transitional arrangements for projects on the conventional TEN and for renewal projects on the high speed TEN that had reached design stage shortly after RIR 2006 came into force, but where a NoBo had not yet been appointed. The Regulation required NoBos, appointed to the project under RIR 2006, to have (reasonable) regard to any evidence provided to it by the Contracting Entity. These transitional arrangements are no longer needed. The existing Regulation 15 of RIR 2006 has therefore not been carried forward to the proposed draft Regulations.

(RIR 2006) Regulation 39: (Liability of persons other than the principal offender)

3.51.2 Please note: It is proposed that Regulation 39 in the current RIR 2006 is not needed in the proposed draft Regulations. Regulation 39 in RIR 2006 simply replicates existing provisions in UK health and safety law (i.e. section 36(1)&(2) of HSWA 1974 and Article 34(1)&(2) of HSWO 1978). The existing Regulation 39 of RIR 2006 has therefore not been carried forward to the proposed draft Regulations.

(RIR 2006) Regulation 40: (Revocation, transitional provisions and savings)

3.51.3 Please note: Regulation 40 in the current RIR 2006 has been replaced by draft Regulation 50. None of the transitional provisions in Regulation 40 of RIR 2006 need to be continued, however, certain savings made by RIR 2006 (from RIR 2002) have effectively been carried over in draft Regulation 50, particularly in relation to recognising that:

- a subsystem that has been authorised to be placed into service (prior to RIR 2006) is still an authorised subsystem under RIR 2010; and,
- an Interoperability Constituent placed on the market (prior to RIR 2006) is still recognised as an Interoperability Constituent that has been placed on the market.

3.52 Responding to the questions in this Consultation Document

3.52.1 The rest of this Consultation Document is presented as a series of annexes, starting with Annex A, which includes a consolidated list of consultation questions that appear throughout the document. There may be issues that are either:

- discussed in this Consultation Document, but the questions provided do not provide a suitable prompt for you to raise them in your response; or
- not fully covered in this Consultation Document, but you believe they are relevant to the UK's transposition of the new Directive.

3.52.3 In the event that you would like to add to your response to the questions provided, you are invited to include any additions in your response to the following question using the response form at Annex J:

Question 21: Are there any other issues that you would like us to consider, with respect to the transposition of the new Directive that are not covered by the other questions in the Consultation Document?

(Please provide details of the issue that you would like us to consider, describing why it is relevant, citing practical examples where appropriate, and including any relevant information on costs or benefits)

3.53 Guidance

3.53.1 Annex D includes proposed draft Guidance in the form of Help Notes, and we welcome any feedback on them that will help us to help you to understand the regulatory framework for interoperability. You are invited to provide comments on the Help Notes using the response form at Annex J:

Question 22: A number of new Help Notes have been produced to cover revised or new provisions. Please consider these and let us have any comments on the proposed text.

3.54 Impact Assessment

3.54.1 Annex E includes a partial Impact Assessment that considers the key features of the proposals in the draft Regulations presented in this Consultation Document. We welcome any feedback that you can provide on

the information provided in the partial Impact Assessment, however we are also particularly keen to receive any:

- quantitative data that you might have on costs and benefits;
- estimates of cost and benefit for realistic scenarios where the proposed draft Regulations might have an impact (positive or negative); and,
- where necessary, qualitative information that can be reasonably considered to inform the assessment of the impact of the proposed draft Regulations.

You are invited to provide your comments on the Help Notes using the response form at Annex J:

Question 23: Do you have any quantitative data, or any other information, that should be considered in the partial Impact Assessment, in order to determine the likely costs, benefits and other impacts of the proposed draft Regulations in this Consultation Document?