Approach to authorisations under the Railways (Interoperability) Regulations 2011

September 2017

Summary

This policy statement sets out ORR’s approach to interoperability authorisations under the Railways (Interoperability) Regulations 2011 (as amended) (the Regulations).

Introduction

1. The Regulations have been in force since 16th January 2012. One of the core requirements is that no structural subsystem can be put into use on or as part of the rail system in the UK unless the Office of Rail and Road (ORR) has given an interoperability authorisation for the placing in service of that subsystem.

2. Experience and feedback provided by stakeholders over the last three years on the current approach to authorisations, particularly in relation to large infrastructure programs where work to upgrade or renew infrastructure is separated into different packages or projects, has prompted ORR to review its approach and how we, and industry, currently apply the Regulations.

3. We have therefore developed this policy statement to set out our approach to interoperability authorisations under the Regulations, in particular in determining the point at which an authorisation will be required.

4. A glossary of terms is set out in Annex D.
Background

5. Directive 2008/57/EC on the interoperability of the rail system within the Community\(^1\) (the **Interoperability Directive**) sets out the conditions to be met to achieve interoperability.

6. The purpose of interoperability is to promote the single market in the rail sector. An interoperable rail system not only enables trains to move safely and without interruption between Member States but also prevents barriers to trade by promoting a single European market for railway products and services. Further, the standardisation of structural subsystems (such as rolling stock and infrastructure) delivers benefits through economies of scale and enables the costs of the railway to be reduced. The benefits provided by interoperability enable the rail sector to effectively compete with other transport modes.

7. The Interoperability Directive has been transposed into domestic legislation by the Regulations. Under the Regulations an interoperability authorisation must be obtained for the placing in service of a structural subsystem (which includes infrastructure and rolling stock) before that subsystem is put into use on or as part of the rail system in the UK.

8. An interoperability authorisation provides confirmation that, to the extent required, new, upgraded or renewed structural subsystems meet the essential requirements\(^2\) and comply with all relevant and applicable legal requirements, including Technical Specifications for Interoperability (**TSIs**\(^3\)), Common Safety Methods (**CSM**\(^4\)) and Notified National Technical Rules (**NNTR**\(^5\)).

9. The Safety Authority for each Member State is responsible for issuing interoperability authorisations. ORR is responsible for issuing such authorisations in the UK.

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\(^1\) The Interoperability Directive has been recast and will be replaced by Directive 2016/797/EU, which must be transposed by 16 June 2019. This will result in changes to the Regulations. However, until such time as the Directive is transposed, the provisions of the current Interoperability Directive and the Regulations will continue to apply.

\(^2\) The essential requirements are conditions relating to safety; reliability and availability; health; environmental protection; technical compatibility and accessibility. These are set out in more detail in Annex II of the Interoperability Directive.

\(^3\) TSIs set out all the conditions with which structural subsystems must conform and the procedure to be followed in assessing conformity.

\(^4\) CSMs are a single, European Union wide, approach setting out how safety levels, achievement of safety targets and compliance with other safety requirements are assessed. CSMs apply whenever any technical, operational or organisational change is being proposed to the railway system.

\(^5\) NNTR are a technical standard used to ensure the rail industry is safe, efficient and sustainable. NNTRs can perform a number of functions, such as making a provision to deal with specific cases for particular circumstances prevailing in a member state; filling in where gaps have been identified in the TSIs and setting requirements to maintain technical compatibility with existing assets that do not conform to the requirements of TSIs.
The authorisation process

10. The Safety Authority can only issue an authorisation for the placing in service of a structural subsystem where it is satisfied that the:

- EC verification declaration, if required, has been drawn up in accordance with Annex V of the Interoperability Directive;
- structural subsystem is technically compatible with the rail system into which it is being integrated; and
- structural subsystem has been so designed, constructed and installed as to meet the essential requirements relating to that subsystem when placed in service.

11. To assist the Safety Authority in determining whether these requirements have been met, new, upgraded and renewed structural subsystems are subject to third party verification and assessment procedures.

12. The diagram in Annex A summarises the process for seeking an authorisation for new, upgraded or renewed structural subsystems under the Regulations, including the work of third party assessment bodies. Annex B sets out the indicative process for obtaining authorisations while Annex C sets out the indicative process for obtaining a single authorisation where separate packages of work are grouped together in one submission.

Approach to authorisation under the Regulations

13. An authorisation for placing in service is required before a structural system can be put into use. Previously, when making applications for interoperability authorisations, industry has focused on individual packages of work without reference to the wider context. Each individual package of work has therefore been regarded as a separate structural subsystem requiring its own authorisation even where it is a component part of a wider project or program of work that is being undertaken. This approach has meant that where work on a wider project or program of work to upgrade or renew a structural subsystem is undertaken in separate stages, multiple, separate authorisations are sought and obtained.

14. Having carefully considered the authorisation provisions of the Regulations, ORR is of the view that when considering the question of authorisation, consideration should be given to what constitutes the 'structural subsystem' within the context of the

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6 See regulation 7(2).
particular project or program of work that is being undertaken rather than just focussing on each individual package of work in isolation.

15. This approach means that where there is a project or program of work to upgrade or renew a structural subsystem which is being carried out in stages, applicants can propose grouping together what would currently be separate authorisation applications into one single authorisation submission on the basis that the project or program of work should be treated as a single structural subsystem notwithstanding that the upgrade or renewal work is being carried out as separate packages of work in stages.

16. This approach will require, a judgement to be made by ORR as to what constitutes the structural subsystem in each case taking into account the wider context. This will involve an assessment by ORR of:

- The scale and scope of the works:
  - It should be noted that the definition of upgrade/renewal under the Regulations is limited to major works.

- The complexity of the works:
  - ORR will consider whether the proposed works may adversely affect the overall safety of the structural subsystem or the wider rail network.
  - ORR will pay particular regard to whether the applicant has given the necessary level of assurance to ORR that safety will not be compromised.

- Any other factors which ORR considers relevant to the particular context.

17. Accordingly, where an applicant wishes to group packages of work together for the purpose of seeking a single authorisation for all the works combined, it will need to liaise with ORR prior to commencing any work to construct, renew or upgrade a structural subsystem. ORR will also require appropriate assurance from the applicant that the point at which a project or program of work requires an authorisation is embedded into an applicant's safety management system and/or arrangements when making its assessment.

18. Depending on ORR’s assessment of what constitutes the structural subsystem in each case, the applicant may be able to obtain a single authorisation upon completion of the entire project or program of work (or alternatively to obtain authorisations upon completion of key milestones of the overall project or program of work) rather than applying for separate authorisations upon completion of each individual stage of work. This approach will mean there is the possibility for an applicant to obtain fewer authorisations in respect of an overall project or program of work.
19. Whichever approach is followed, applicants will continue to remain responsible at all times for the safe management of any construction or upgrade/renewal work and for ensuring the safe and appropriate operation and maintenance of the structural subsystem in accordance with the appropriate TSIs CSM, NNTRs and other applicable legislation.

**Key principles**

20. We have set out below the key principles of this approach:

- Under the Regulations no structural subsystem can be ‘*put into use*’\(^7\) unless an interoperability authorisation has been obtained for the ‘*placing in service*’\(^8\) of that structural subsystem.

- ‘subsystem’ is defined under the Regulations as:
  - “…the whole, or, as the context requires, part of a subdivision of the rail system…namely structural subsystems and functional subsystems…” (emphasis added).

- What constitutes a structural subsystem in each case will therefore be a question of context, taking into account the scale, scope and complexity of the works and whether any of these may affect the overall safety of the subsystem or the wider rail network.

- Where there is a project or program of work which is being carried out in stages, the applicant may propose to ORR that it considers the overall project or program of work should be treated as a single structural subsystem.

- ORR will agree with the applicant an authorisation plan, i.e. how many authorisations will be required and at what point they must be obtained. ORR will determine this based on what is set out in an applicant’s proposal. It is therefore important an applicant submits a detailed plan which sets out why the combined packages of work should be treated as a single structural subsystem.

- In considering an applicant’s proposal, ORR will consider whether each package of work within a project or program of work is a structural subsystem in its own right or whether it is simply a component part of a project or program of work:
  - If each package of work is considered to be a structural subsystem in its own right each package of work will require an authorisation at the point it is placed in service and put into use.

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\(^7\) A structural subsystem is put into use when it is first used on or as part of the rail system in the UK for the transportation of passengers or freight or for the purpose for which it was designed.

\(^8\) Placing in service means all the operations by which a structural subsystem is put into its design operating state.
If each package of work is considered to be a component part of the project or program of work, then either a single authorisation can be obtained at the point the upgrade/renewal of the structural subsystem has been completed in its entirety or authorisations can be obtained upon completion of key milestones of the overall project or program of work (as determined by ORR).

- It is for the applicant to provide adequate assurance to ORR that it has identified all risks and has taken or put in place appropriate processes and procedures to adequately manage risk and safety issues:
  - ORR may seek specific assurances from the applicant that risks have been identified and are being managed appropriately.
  - ORR will only permit separate packages of work to be grouped together and approved under a single authorisation where it is satisfied all safety aspects are being properly managed.

- If the context in relation to a project or program of work changes (for example, delay in the project, a change of scope, or where the standard of the completed works could impact on the overall safety of the subsystem or the wider rail network) ORR will revisit the authorisation process. This could result in ORR requiring an applicant to obtain additional authorisations upon completion of individual packages of work or upon completion of agreed milestones.

**Example:** In the case of a project or program of work to upgrade or renew 100 miles of track, which is being carried out in 5 separate phases of 20 miles each, an applicant may propose to ORR that the project or program of work should be treated as a single structural subsystem, thereby only requiring a single authorisation upon completion of all 5 phases of work.

ORR will consider the applicant’s proposal. As part of its assessment ORR will consider the scale, scope and complexity of the works and whether each 20 mile section of track should be regarded as a structural subsystem in its own right or whether the structural subsystem in this case is the entire 100 miles of track, with each 20 mile section of track being a component part of that structural subsystem.

If ORR considers that the scale, scope and complexity of the works requires each phase to be regarded as a structural subsystem in its own right, the applicant will need to seek an authorisation for each 20 mile section of track. The authorisation will need to be obtained on completion of the upgrade/renewal of each phase at the point at which each 20 mile section of track is placed in service and put into use.
If, however, ORR considers that the scale, scope and complexity of the works is such that the structural subsystem in this context means all the component parts taken together, i.e. all 5 sections of track, the applicant will likely only need to obtain a single authorisation in respect of the 100 miles of track. This would be obtained upon completion of the upgrade or renewal of all 100 miles of track at the point it is placed in service and put into use in its entirety.

Where such an approach is agreed with ORR it will mean that each 20 mile section of track can be brought into use without an authorisation as that section of track will only be put into use on the rail system at such time as the upgrade or renewal of the entire 100 miles of track has been completed. Where this is the case the applicant will be required to follow the processes and governance requirements established by ORR in order to provide sufficient assurance to ORR on risk and safety management by the applicant.

**Note:** Depending on ORR’s assessment, it may be that while ORR determines that each individual package of work does not need to be authorised, ORR nonetheless determines that the applicant must obtain authorisations upon completion of key milestones rather than a single authorisation upon completion of the entire project or program of work.

21. We do not consider that this revised approach will result in any substantive changes to how and when authorisations are currently obtained for smaller projects or programs of work to upgrade/renew a structural subsystem, rolling stock or the construction of new structural subsystems. This is because in these scenarios work tends to either be undertaken in one go or, where it is carried out in stages, such subsystems are only placed in service and put into use once the project or program of work has been completed in its entirety.

**Governance**

22. Where there is a project or program of work which is being carried out in phases and an applicant considers it meets the criteria to enable it to obtain a single authorisation upon completion of the entire project/program of work, the applicant must make a proposal to ORR and obtain ORR’s agreement that this approach is appropriate prior to the commencement of any work.

23. Where ORR confirms this approach is appropriate in the circumstances, the applicant will need to comply with such requirements as ORR determines is necessary. This is to give ORR the necessary assurance that the work is being carried out in accordance with the applicable legal requirements.

24. The requirements with which the applicant must comply will include (but may not be limited to):
The provision of an authorisation plan (agreed in advance with ORR) setting out how the project or program of works will be undertaken and the point at which authorisations must be obtained:

- The authorisation plan will identify the programme stages where ISVs and SARs will be integrated together and submitted for authorisation with the technical file and verification declarations.
- ORR will conduct supervision against the applicant’s authorisation plan in a proportionate manner.
- ORR will expect the applicant to promptly inform ORR if it considers it can no longer meet the requirements set out in the authorisation plan.

For each phase of a project or program of work, the applicant must continue to:

- Employ Conformity Assessment Bodies who will provide ISVs for each individual phase of work at either the design stage, production stage, or at both stages. These should be collected by the project manager at the completion of each phase of work and submitted to ORR as part of the technical file for the overall authorisation.
- Obtain an appropriate ISV from the assessment body, which will need to be supported by a (positive) Safety Assessment Report;
- Obtain Common Safety Method Safety Assessment Reports, which align with, and support the ISVs and project stages. These will have to appear in the technical file to underpin the applicant’s Article 16 Declaration of Control of Risk and demonstrate safe integration of this work with the wider rail system.

25. Where the applicant is Network Rail, in addition to the above, Network Rail will need to demonstrate to ORR’s satisfaction that it has the appropriate governance arrangements in place. This includes:

- Amending its internal Safety Management System Network Rail Assurance Panel (NRAP) 100 series processes and guidance to reflect the introduction of a phased approach for certain projects and programs of work to upgrade/renew infrastructure.
- Endorsement through their Project Authorisation Strategy, System Definitions and accompanying plan by the System Review Panel (SRP). The relevant route must have a functioning competent SRP. NRAP must endorse the approach following SRP agreement.
Implementation

26. We will review this policy no later than two years after the date of publication to ensure it remains fit for purpose.

27. We may, from time to time, revise this policy following appropriate consultation.
Annex A: Authorisation Process - third party assessment

Applicant seeking interoperability authorisation requires third party verification

**Assessment body (AsBo)**
Assesses compliance with the common safety method on risk assessment and evaluation

**Notified body (NoBo)**
Provides third party certification at different points in the project lifecycle as to whether a structural subsystem conforms to the required TSIs

**Designated body (DeBo)**
Assesses compliance with NNTRs

Assessments result in the following being issued to the applicant

**Safety assessment report (SAR)** based on the applicant’s hazard identification and risk mitigations

**Intermediate Statements of Verification (ISV)** for the design and/or production stages of a structural subsystem and **Certificate of verification (CoV)** in relation to a structural subsystem

Intermediate Statements of Verification (ISV) for the design and/or production stages of a structural subsystem and Certificate of verification (CoV) in relation to a structural subsystem

**Applicant produces a declaration of control of risk and EC declaration of verification**

Applicant must submit all of the above documentation to the Safety Authority as part of the complete technical file to obtain an authorisation.
Annex B: Indicative process for obtaining authorisations

1. Initial engagement with ORR and DfT regarding project.
2. Applicant obtains internal approval to undertake project.
3. Applicant produces a plan setting out the key milestones and the ISVs and SARs which will be produced to support the authorisation application.
4. Third party assessors are appointed by the project/program.
5. Project work is undertaken and third party assessment work is carried out.
6. Applicant submits application for authorisation. This will include the technical file.
7. ORR issues authorisation subject to review of technical file.
Annex C: Indicative process where packages of work are grouped together for the purpose of obtaining a single authorisation

<table>
<thead>
<tr>
<th>Initial phase</th>
<th>Planning and approval</th>
<th>Delivery</th>
<th>Submission for authorisation</th>
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<tr>
<td><strong>Initial engagement with ORR and DfT regarding project.</strong></td>
<td><strong>Applicant produces a plan setting out the stages of the project/program of work, the key milestones, the ISVs and SARs which will be produced to support the authorisation application.</strong></td>
<td><strong>Third party assessors are appointed by the project/program.</strong></td>
<td><strong>Applicant submits application for authorisation in accordance with the agreed plan. This will include the technical file demonstrating the integration of stages or work packages.</strong></td>
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<td><strong>Example: For Network Rail the proposal must be written into the Project Authorisation Strategy and CSM System Definition prior to the program seeking a scoping decision at NRAP or route SRP.</strong></td>
<td><strong>ORR will consider the plan and the context of the project/program in order to determine whether an a single authorisation is appropriate or the point at which authorisations must be obtained. This will be agreed with the applicant prior to commencement of the project/program.</strong></td>
<td><strong>The applicant should send completed ISVs and SARs to ORR to demonstrate the progress of work. These will be used by ORR to determine the applicant’s adherence to the agreed plan.</strong></td>
<td><strong>ORR authorises program subject to review of technical file.</strong></td>
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<tr>
<td><strong>ORR acknowledges internal approval and awaits sight of project/program plan.</strong></td>
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<td><strong>ISVs, and SAR’s should be produced at the design and / or production stages and collated by the applicant.</strong></td>
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## Annex D: Glossary of terms

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<th>Acronym</th>
<th>Definition</th>
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<tr>
<td>AsBo</td>
<td>An Assessment Body is an independent and competent external or internal individual, organisation or entity which undertakes investigation to provide a judgement, based on evidence, of the suitability of a system to fulfil its safety requirements.</td>
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<tr>
<td>CAB</td>
<td>A Conformity Assessment Body performs conformity assessment activities including calibration, testing, certification and inspection.</td>
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<tr>
<td>CoV</td>
<td>Certificate of Verification is a document drawn up by a Notified Body (NoBo) or a Designated Body (DeBo) in relation to a structural subsystem as part of the verification assessment procedure.</td>
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<tr>
<td>CSM</td>
<td>Common Safety Methods are a single, European Union-wide, approach to describe how safety levels, achievement of safety targets and compliance with other safety requirements are assessed. They apply whenever a change of the operating conditions or new material imposes new risks on infrastructure or operations.</td>
</tr>
<tr>
<td>DeBo</td>
<td>A Designated Body is an independent third party appointed by the Secretary of State to assess and verify conformity of projects with Notified National Technical Rules (NNTRs) in the United Kingdom. It operates in tandem with Notified Bodies which assess and verify conformity with Technical Specifications for Interoperability (TSIs).</td>
</tr>
<tr>
<td>Functional Subsystems</td>
<td>Functional subsystems are those which deal with traffic operation and management, maintenance and telematics applications for passenger and freight services.</td>
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<tr>
<td><strong>Infrastructure</strong></td>
<td>Infrastructure subsystems include, for example, track, points, engineering structures (bridges, tunnels, etc.), associated station infrastructure (platforms, zones of access, including the needs of persons with reduced mobility, etc.), safety and protective equipment. However, power supply and signalling are also often included.</td>
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<tr>
<td><strong>ISV</strong></td>
<td>Intermediate Statements of Verification enable checks to be carried out in stages – see section 2.2 of Annex VI of the Interoperability Directive.</td>
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<tr>
<td><strong>NNTR</strong></td>
<td>Notified National Technical Rules are the standards, technical specifications and technical rules which the United Kingdom has notified to the Commission for this purpose. Compliance with NNTRs must be verified by a Designated Body (DeBo).</td>
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</table>
| **NoBo** | A Notified Body is an independent third party appointed by, the Secretary of State or another European Union Member State which meets the criteria of competence, integrity and independence set out in Annex VIII of the Interoperability Directive.  

NoBo's assess and verify conformity of project subsystems to the Technical Specifications for Interoperability (TSIs). They operate in tandem with Designated Bodies (DeBos) who assess and verify conformity with Notified National Technical Rules (NNTRs). |
<p>| <strong>ORR</strong> | The Office of Rail and Road is the independent safety and economic regulator for the rail industry in Great Britain. It is responsible for the enforcement of the Regulations. |
| <strong>Renewal</strong> | Renewal means any major substitution work on a structural subsystem or part of a structural subsystem which does not change the overall performance of the structural subsystem. |
| <strong>SAR</strong> | Safety Assessment Report contains the conclusions of the assessment performed by an assessment body on the system. |</p>
<table>
<thead>
<tr>
<th><strong>Structural Subsystem</strong></th>
<th>Structural subsystems are those which deal with rolling stock, infrastructure, energy or control and command and signalling.</th>
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<tr>
<td><strong>Subsystem</strong></td>
<td>A categorisation of the rail system into separate elements for convenience in the context of interoperability. The term is used to refer to the whole, or any part of “structural” or “functional” subsystems.</td>
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<tr>
<td><strong>TSI</strong></td>
<td>Technical Specifications for Interoperability outline the specification to be met by a subsystem, or part of a subsystem, in order for it to meet the essential requirements and achieve interoperability.</td>
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<tr>
<td><strong>Upgrade</strong></td>
<td>Upgrade means any major modification work on a structural subsystem or part of a structural subsystem which improves the overall performance of the structural subsystem.</td>
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