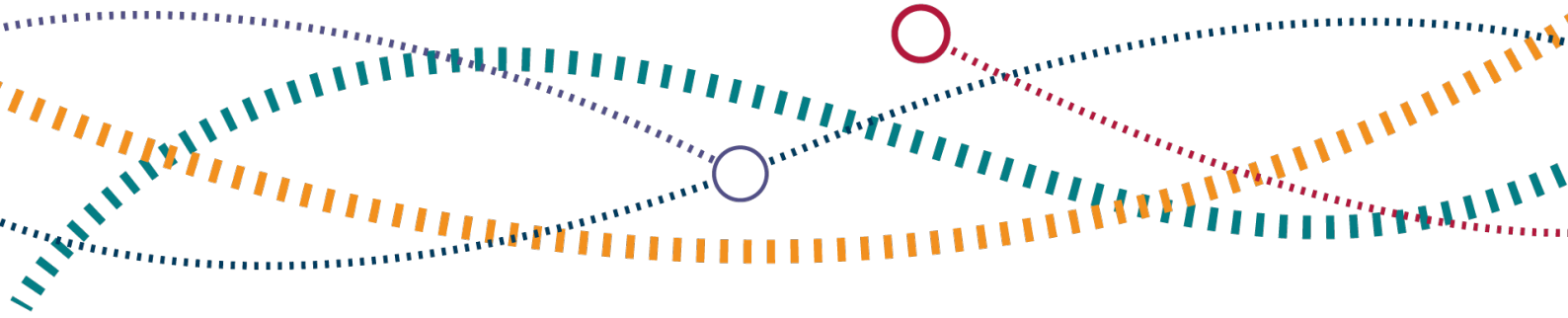
OFFICE OF RAIL AND ROAD

Approach to Authorisation under the Interoperability Regulations

Guidance for Applicants

28 July 2021



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Foreword

This new guidance has been developed following a formal investigation into the effectiveness of the authorisation process that was completed in consultation with railway experts and questionnaires posed to key duty holders in late 2019. It replaces the **Approach to authorisations under the Railways (Interoperability) Regulations 2011 - Updated July 2020**.

This guidance clarifies the expectations we have of those making authorisation applications and provides a recommended process for engaging with us in developing the authorisation submission. In this process we focus on engaging with applicants early in the project design phases, so that potential barriers to a successful application can be identified and resolved earlier in the project.

The early engagement process described here should therefore provide confidence to applicants that authorisation will not be a barrier to meeting project timescales, will help spread workload associated with authorisation applications more evenly across the project lifecycle, and substantially reduce (or eliminate) the number of conditions we apply to authorisations through enhancing application quality.

Whilst this new process is not mandatory, we believe that applicants choosing to follow the approach outlined in this document will be able to better integrate authorisation applications in their project planning. Applicants following this process are therefore more likely to receive authorisations from us without conditions in a timely manner, making the whole process more efficient for everyone involved.

Introduction

1.1 The Railways (Interoperability)(Amendment)(EU Exit) Regulations 2019 ensure that there is a clear and accessible technical standards framework in place from 1 January 2021, and that the railway interoperability regime is maintained.

1.2 These regulations amend the Railways (Interoperability) Regulations 2011 (RIR 2011), which transposed EU Directive 2008/57/EC on the interoperability of the European rail system ('the Interoperability Directive').

1.3 One of the core requirements of the EU Interoperability Directive (2008/57/EC) and associated Interoperability Regulations was that no structural or vehicle subsystem can be put into use on or as part of the GB rail system unless the Office of Rail and Road (ORR) has provided an interoperability authorisation for the placing in service of that subsystem.

1.4 We have developed this guidance document to set out our approach to interoperability authorisations under the 2019 Regulations, formalise the expectations of the ORR, and provide a framework to facilitate the submission of authorisation applications of a high quality.

1.5 This guidance provides a framework for enhanced engagement with Applicants throughout the authorisation process and should improve the clarity of the application requirements for different types of subsystem.

1.6 This guidance is not mandatory, however it is intended to effectively support the Applicant throughout the authorisation process leading to a de-risked approach for the applicant, resulting in the imposition of fewer conditions to the authorisation and benefiting all stakeholders.

1.7 Applicants choosing not to follow this recommended approach, should produce an application to an equal standard, in a systematic and assessable format. Further clarification on this guidance and the authorisation processes can be sought from the ORR.

1.8 General information about interoperability can be found in Appendix A.

References

2.1 Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community

2.2 Directive (EU) 2016/797 (recast of Directive 2008/57/EC) Interoperability Directive, including Amendments

2.3 Railways (Interoperability) Regulations 2011 (RIR 2011) (SI 2011/3066)

2.4 Railways (Interoperability) (Amendment) (EU Exit) Regulations 2019 (SI 2019/345)

2.5 The Railways and Other Guided Transport Systems (Safety) Regulations 2006 (ROGS)

2.6 List of NTSNs at: https://www.rssb.co.uk/standards/understanding-and-applying-standards/national-technical-specification-notices

2.7 RSSB Managing the issues log for the application of NTSN for Interoperability in UK

2.8 RSSB Guidance on the use of Intermediate Statements of Verification during the movement or testing of vehicles

2.9 RSSB Technical checklist for Technical Specifications for Interoperability

2.10 RSSB Taking Safe Decisions

2.11 A Request for Help can be submitted to RSSB to:

- Ask for help in interpretation in any requirements in the NTSN or NTRs
- Get something on the NTSN issues log

2.12 Common Safety Method for Risk Evaluation and Assessment Guidance on the application of Commission Regulation (EU) 402/2013

2.13 Route Compatibility guidance

ORR Involvement

This chapter sets out the ORR's involvement in the application process, including early engagement and in the submission and approval process. It describes:

- The Authorisation Process
- Pre-Application Engagement (for new subsystems)
- Stage Gate reviews throughout the process (for both new subsystems and upgraded or modified subsystems)
- Submission of Application and Approval

The Authorisation Process

3.1 Under the Railways (Interoperability) Regulations 2011 "no **structural subsystem** can be **put into use** unless an interoperability authorisation has been obtained for the **placing into service** of that **structural subsystem**".

- 'subsystem' is defined as "…the whole, or, as the context requires, part of a subdivision of the rail system…namely structural subsystems and functional subsystems…"
- "Put into use" means that the structural subsystem is functional and able to be used by others.
- 'Placing in service' means all the operations by which a structural subsystem is put into its design operating state.
- The definition of 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 itself and the wider rail network.

3.2 Throughout a project the Applicant must:

- Ensure that Conformity Assessment Bodies (CABs) are engaged for individual phases of work at the design and/or production stages of the project. Any reports or comments from the CABs should be collected by the

project manager at the appropriate phase of work and submitted to ORR as part of the technical file for the overall authorisation.

- Provide the ORR with appropriate intermediate statements of verification (ISVs) from the assessment body (where these are being produced), which will need to be supported by a (positive) Safety Assessment Report (SAR).
- If the change is considered significant, obtain CSM-RA Safety Assessment Reports (SARs), which align with, and support the ISVs and project stages. These must be included in the technical file and demonstrate safe integration with the wider railway system.

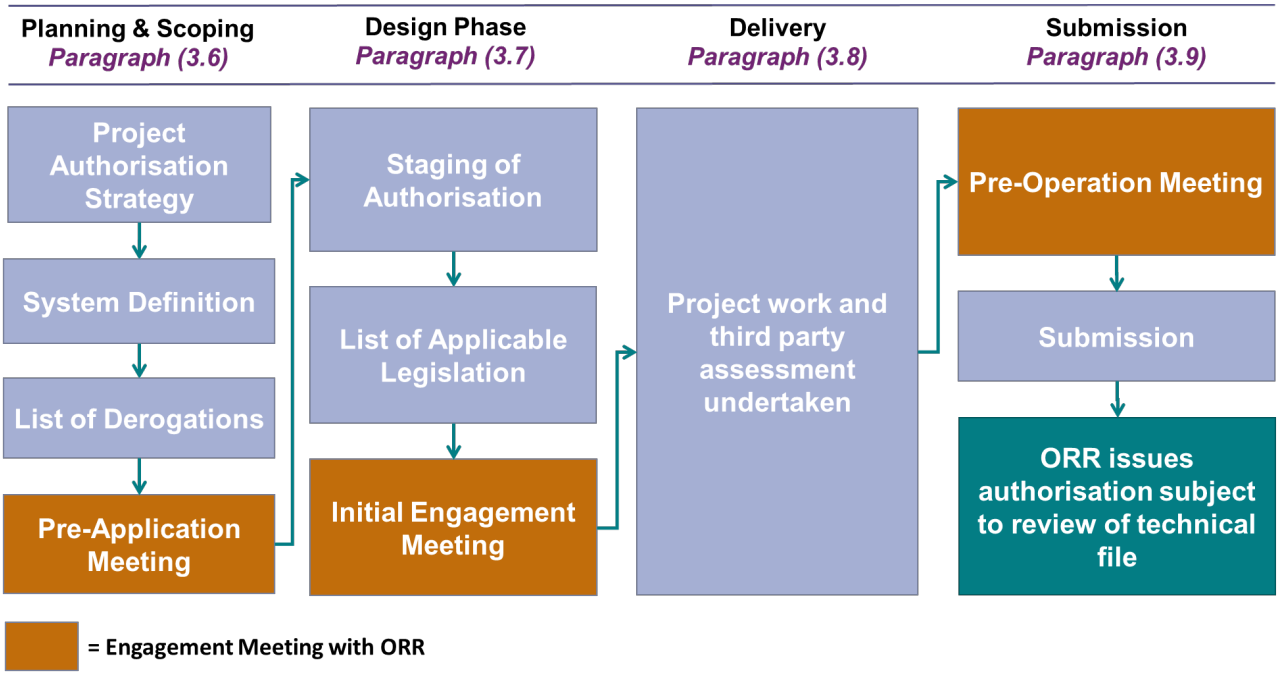
3.3 The ORR can only issue an authorisation for placing a sub-system into service where it is satisfied that all of the following are demonstrated by the Applicant:

- A UK declaration of verification has been drawn up that complies with Schedule 5 of the Railways (Interoperability)(Amendment)(EU Exit) Regulations 2019. The requirements of Schedule 5 are given in Appendix F.
- The project sub-system is technically compatible with the rail system it is being integrated into.
- The Applicant has satisfactorily completed tests in accordance with the Regulations.
- The Applicant has prepared a technical file (as defined by the Regulations) containing all the information and documents where they have been required by ORR.

3.4 In the event that the ORR is not satisfied that these requirements have been met they can either reject the application, or authorise subject to conditions, which are additional constraints on operation of the sub-system.

3.5 An illustrative process for obtaining authorisation is given in Figure 3.1. Note that not all steps will be applicable for every authorisation application, particularly in the case of upgraded or modified systems.

Figure 3.1 Process for obtaining Authorisation highlighting areas of engagement



3.6 When the Applicant believes that authorisation is required for a project or programme of work, they should begin to plan and scope their project through producing a **Project Authorisation Strategy (PAS)**, **System Definition**, and a **List of Possible Derogations**, which should be brought to a **Pre-Application Meeting with ORR (Initial Engagement meeting for upgraded / modified subsystems).**

3.7 After this, as part of the draft PAS, the Applicant should produce the **Staging of Authorisation** i.e. a plan setting out the key milestones and the ISVs and Assessment Reports to be produced, in addition to producing a **list of Applicable Legislation** to be brought to an **Initial Engagement Meeting**.

3.8 The Applicant should then **undertake project work and independent assessment** for their project or programme of work.

3.9 The Authorisation process concludes with a **Pre-Operation Meeting**, in advance of the ORR review of the technical file and subsequent authorisation.

3.10 Additional guidance specific to infrastructure and rolling stock projects is given in Paragraphs 4.8 to 4.17.

3.11 The Applicant should send completed ISVs and SARs to ORR at stage gate intervals to demonstrate the progress of work. These will be used by the ORR to assess the Applicant's adherence to the agreed plan.

3.12 The Project Authorisation Strategy (PAS) should give a clear approach for how the Applicant intends to obtain authorisation and should be followed by all project members throughout the project lifecycle. If changes occur (such as to the project scope) then it should be revised in line with these changes.

3.13 The PAS should identify the programme stages where any required Intermediate Statements of Verification (ISVs) and Safety Assessment Reports will be submitted. The PAS should also cover how the evidence will be integrated and submitted for authorisation in the final technical file and verification declarations.

3.14 For all applicants, we expect to see evidence that internal assurance process has been followed. For details see Appendix B.

Note: Where Network Rail is not the project entity, the Network Rail Assurance Panel (NRAP) may still be required to confirm Network Rail's obligations under RIR are upheld. Projects where this is the case will be required to provide a submission to NRAP for endorsement under NR sponsor's liaison.

3.15 Where the project or programme of work covers the upgrade or renewal of a structural subsystem that is being carried out in stages, it may be possible to group together what would otherwise be separate authorisation applications.

3.16 Paragraph 4.17 describes how the Applicant should treat such a project or programme of work as a single structural subsystem.

Pre-Application Engagement

3.17 When the Applicant knows that authorisation is required for a new subsystem to be put into service, they should consult with the ORR in a Pre-Application meeting (Initial Engagement meeting for upgraded / modified subsystems) to discuss the main features of the project or programme, including:

- System Definition (SD) including subsystem purpose and project / programme scope
- Risk management approach for design, testing and operation of the subsystem
- Planned project / programme schedule
- Project Authorisation Strategy (PAS)

3.18 At this meeting the ORR will seek to understand:

- The scale and scope of the project / programme
- The technical and operational complexity of the subsystem
- Potential impact of the project / programme on the safety of the railway network

3.19 The ORR will pay particular attention as to whether the Applicant can provide sufficient assurance that safety will not be compromised by the project or programme.

3.20 This meeting will involve review of the PAS, setting out how works will be undertaken and the point at which authorisation must be obtained:

3.21 Full guidance on the structure of the Pre-Application meeting for new subsystems, including what the Applicant should present, is given in Appendix C. For guidance on the Initial Engagement meeting for upgraded / modified subsystems see Appendix D.

3.22 The following two sections provide more detailed guidance on how the ORR can engage with Applicants for both new subsystems and upgraded / modified subsystems through a series of meetings and document reviews.

3.23 The ORR will provide feedback from these meetings and document reviews to the Applicant through a table of comments.

3.24 When preparing for these meetings Applicants should understand that their purpose is not for the ORR to confirm whether or not they are meeting the requirements for approval; but rather that they are an opportunity to get early feedback from the ORR on potential challenges and opportunities in the authorisation process.

3.25 In both cases Applicants should consider the checklist in Appendix E when preparing interim submissions. When following the checklist for preparing interim documents, Applicants should update the contents of previously submitted documents before the final submission (e.g. updating the *Project Lifecycle* at later stages of the project).

Stage Gate Reviews – New Subsystems

3.26 For new subsystems, the Applicant should take part in **three formal engagement meetings** with the ORR throughout the project or programme lifecycle, to discuss major developments and milestones with the ORR where these could have an impact on authorisation. The suggested early engagement meetings are at three points in the project or programme:

- **Pre-Application Meeting:** Before Conceptual design
- **Initial Engagement Meeting:** Before Detailed Design
- **Pre-Operation Meeting:** Before Commissioning/Trial Operation

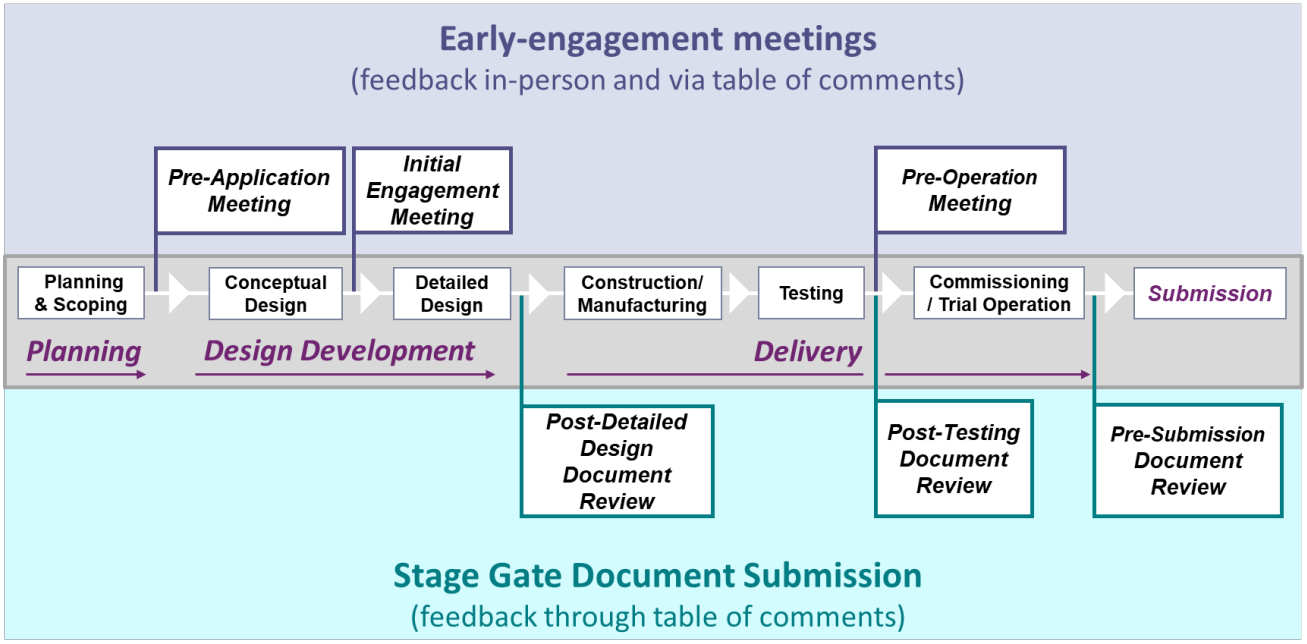
3.27 A suggested agenda for each of these three meetings, is given in Appendix C.

3.28 For new subsystems, Applicants are encouraged to produce **three interim document submissions** at three defined stage gates during the process, to enable early quality and completeness checks prior to the final submission. These suggested points are:

- **Post-Detailed Design Review:** After Detailed Design / Before Delivery
- **Post-Testing Review:** After Testing, before commissioning / trial operations
- **Pre-Submission Review:** Either towards the end of, or after, commissioning / trial operations, but prior to APIS.

3.29 Where project timescales mean that the post-testing review and the pre-submission review have significant overlap, the Applicant may consider merging the requirements of the Post-Detailed Design Review and Pre-Submission Review into one review, at the discretion of ORR.

Figure 3.2 Engagement Timeline for New Subsystems



Stage Gate Reviews – Upgraded or Modified Subsystems

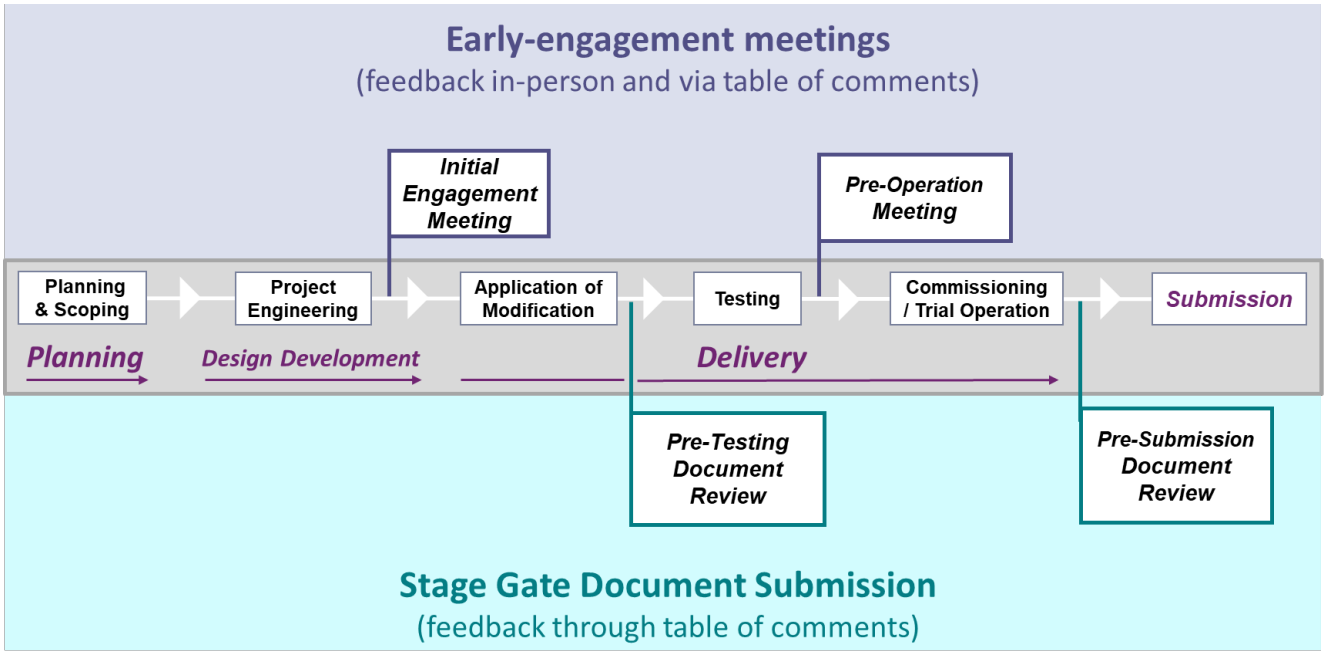
3.30 Where the structural subsystem is subject to an upgrade, renewal or substantial modification, the Applicant should take part in **two formal engagement meetings** at the following points in the project or programme:

- **Initial Engagement Meeting:** After Project Engineering
- **Pre-Operation Meeting:** Before Commissioning/Trial Operation

3.31 Where the structural subsystem is subject to an upgrade, renewal or substantial modification, Applicants are encouraged to produce **two interim document submissions** at the following points in the project or programme:

- **Pre-Testing Review:** After Modification Application, before Testing
- **Pre-Submission Review:** At least three months before the final document submission

Figure 3.3 Engagement Timeline for Upgrades & Renewals



Technical File submission and approval

3.32 The Applicant should ensure that their submission is supported by sufficient evidence before submission to the ORR. This means applications should include at least the following items:

- A presentation of technical descriptions, technical drawings, test methods and results, simulations, calculations, and operation and maintenance requirements
- Declarations of verification (written in English, not the country of origin)
- Any derogations obtained from the requirements (and associated conditions where applicable)
- Reports from the third-party assessors should support that issues raised have been addressed.

3.33 All submitted documents should be written in English and should be submitted in standard file formats, such as Microsoft Word or PDF format, on A4 size paper.

3.34 The Applicant should submit a statement that all identified hazards and associated risks are controlled and will continue to be monitored after approval, with a

strategy for doing so. Where applicable, this should acknowledge requirements from other regulations. CSM-RA Regulation 16.

3.35 To ensure that the subsystem can be placed into service in line with project or programme timescales, the Applicant should allow sufficient time in the project schedule for evaluation by third-party assessors and at least four weeks for ORR review during final submission.

3.36 After receiving the formal application, ORR will inform the Applicant as soon as possible about whether they consider the application to be incomplete. If an application is incomplete, the ORR will request supplementary information, along with a reasonable deadline for its provision.

3.37 The time it takes for ORR to review submissions will depend on the effectiveness of early engagement, the quality of the original submission, novelty, scale and complexity of the system, and the associated requirements to prove that compliance with safety requirements and risk control has been maintained.

Note: The Applicant should develop a process to escalate and resolve any changes to project schedules that impact the review time for the Approved Body or NoBo / DeBo / ORR. We recommend the following rating system:

“Green” = All reviews will start in line with the planned schedule

“Amber” = Approved Body / DeBo / ORR reviews will start later than planned, but durations remain the same.

“Red” = The duration for Approved Body / DeBo / ORR reviews shortens OR the gap between Approved Body / DeBo / ORR reviews is removed completely OR the gap between ORR review and APIS is removed completely.

Approach to Authorisation

This chapter sets out the Approach to Authorisation Applicants should follow under specific circumstances. It describes:

- Assessing the change under CSM-RA
- Authorisations for Fixed Infrastructure
- Authorisations for Rolling Stock
- Authorisations for Large Packages of Work
- Interfaces between systems

Assessment of the change

4.1 To determine the approach applicable to the project, the Applicant should:

- determine the importance of the change
- determine the category of work to which the project belongs

4.2 Choosing the right approach is important because the process differs depending on the type of project envisaged, such as whether it is an infrastructure or rolling stock subsystem, or the type of change envisaged such as new equipment, or changes to existing equipment.

4.3 If the Applicant is unsure if authorisation is required, they should consult the DfT who, as a competent authority, will provide their opinion.

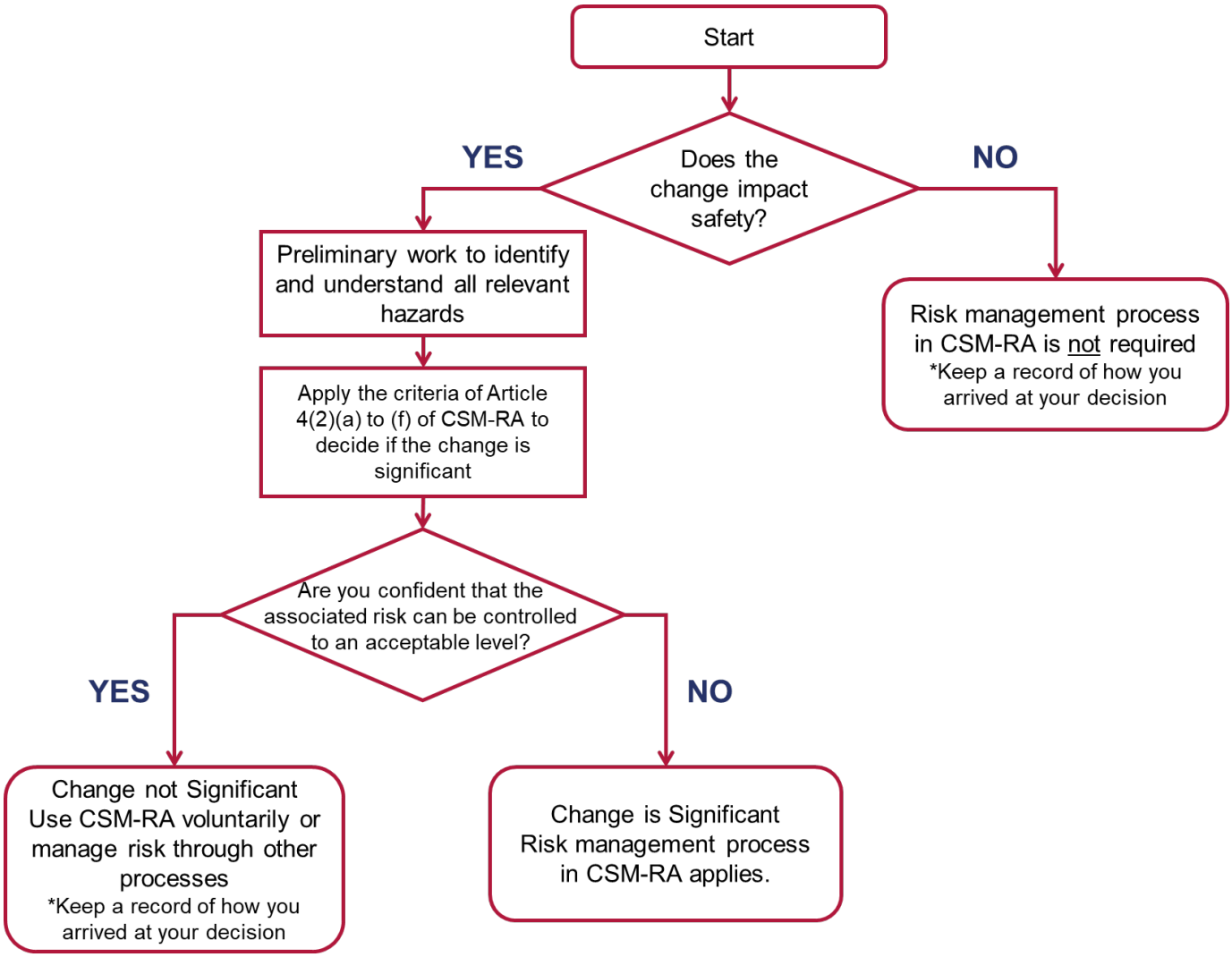
4.4 To determine the importance of the change the Applicant should consider the impact of the proposed change on safety. For guidance on what constitutes a "significant" change Applicants should refer to Section 2 of the Common Safety Method for Risk Evaluation and Assessment.

4.5 Where the change is not significant then it is recommended that the risk management process described in CSM-RA is applied, as described in Section 3 of the Common Safety Method for Risk Evaluation and Assessment

4.6 The creation of any new subsystem that requires an interoperability authorisation will likely have an impact on safety and will usually (though not in all cases) be considered to be significant.

4.7 The flowchart in Figure 4.1 in addition to criteria delineated within Article 4 of the CSM regulation should be used to determine the significance of the change to assess whether the CSM-RA applies to the project or programme.

Figure 4.1 Significance of a change



Note: In the case of organisational changes, only those likely to have an impact on the operation or maintenance activities should be considered.

Authorisations for Fixed Infrastructure

4.8 Fixed infrastructure authorisations fall into four categories;

(a) New infrastructure – Commissioning of a new subsystem in the absence of a pre-existing subsystem

(b) Upgrades and renewals – 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

(c) Maintenance – Preservation of the existing infrastructure

(d) Removals – Decommissioning of either a complete subsystem or part of it

4.9 For infrastructure designed to earlier TSI standards, the Applicant should consult the ORR for guidance. The ORR will provide guidance on authorisation in these cases on an ad-hoc basis, taking into account relevant Health and Safety legislation.

4.10 For 'New infrastructure' and 'Upgrades and Renewals' authorisations, the Applicant should follow the submission content structure set out in Appendix E.

4.11 In the case of 'Maintenance' and 'Removals', an application for authorisation is not required and the Applicant should take any reasonable opportunity to meet current standards in accordance with their own standards and processes.

Authorisations for Rolling stock

4.12 The Applicant should consider additional factors for rolling stock authorisations that depend on the circumstances of their project or programme.

4.13 Rolling stock authorisations fall into three broad categories;

(a) New rolling stock - Rolling stock that is not authorised for GB railway and does not have a valid authorisation under the EU TSI regulations.

(b) Existing rolling stock - Rolling stock that is not authorised for the GB railway but has valid authorisation under the EU TSI regulations.

(c) Substantially modified rolling stock – Rolling stock that may or may not be already authorised for the GB railway and is modified in a substantial way that brings it into scope.

4.14 For all categories of rolling stock, the Applicant should follow the content structure set out in Appendix E.

4.15 For existing rolling stock, the Applicant should focus on reviewing the published data for that rolling stock and any deviations from the NTSNs and NTRs. This includes:

- A copy of the authorisation for placing in service within another network
- Where applicable, maintenance history of the subsystem and any technical modifications made since authorisation was granted

4.16 For substantially modified rolling stock, the Applicant should focus on the impact of the modifications and how safety and compliance with NTSNs and NTRs will be maintained. This includes:

- Clear definition of the scope of modification, including any changes to interfaces with other subsystems.
- Description of intent to the modification.
- Description of the functional and technical elements affected by the modification.

4.17 For rolling stock designed to earlier standards, the Applicant should consult the ORR for guidance. The ORR will provide guidance on authorisation in these cases on an ad-hoc basis, taking into account relevant health and safety legislation.

Large packages of work

4.18 Projects or programmes of work that are used to deliver large packages of work in multiple discrete phases, may sometimes be treated as a single structural subsystem to avoid multiple authorisations being required.

4.19 Applicants who wish to combine multiple projects or programmes together under one authorisation application must consult the ORR before following this approach to ensure that it is a suitable course of action. Applicants should also make it clear with the ORR during the Initial Engagement Meeting that they wish the project/program of work to be regarded as a single subsystem.

4.20 An Applicant wishing to group packages of work together should focus on what makes up the ‘structural subsystem’ within the context of the particular project or programme of work.

4.21 When following this approach, a judgement will need to be made as to what constitutes the structural subsystem in each stage of work by taking into account the wider context.

4.22 In assessing an Applicant's proposal, the ORR will consider whether each package of work within a project or programme of work is:

(a) a structural subsystem in its own right, in which case each package of work will require an authorisation at the point it is placed in service and put into use; or

(b) a component part of the structural subsystem, in which case an authorisation can be obtained (as determined by ORR) either upon completion of key milestones, or at the point the upgrade/renewal of that structural subsystem has been completed in its entirety.

4.23 The ORR will confirm in writing if approach (b) can be used by the project and will agree with the Applicant how many authorisations will be required and at what point they must be obtained.

4.24 Where ORR agrees this approach is appropriate, the Applicant will need to comply with such requirements as ORR determines is necessary.

Interfaces Between Systems

4.25 The nature of the modern railway network is that subsystems are highly interconnected and will often impact on other subsystems already in operation. This is particularly notable where there are large packages of work comprised of multiple subsystems.

4.26 The interfaces between subsystems are not the subject of a separate authorisation but should be considered in the authorisation application for a subsystem.

4.27 The Applicant should identify how the changes in interfaces due to the introduction of the new subsystems impact on safety and operability as part of their project design and risk management processes.

4.28 The Applicant should make a record of any "cross-interface risks" that the introduction of the new subsystem could lead to and ensure that these are addressed as part of their authorisation application.

4.29 For examining the interface, the general safety demonstration principles in Appendix E remain the same.

Regulatory Environment

This section of the guidance sets out the main regulatory requirements placed on Applicants under the interoperability regulations. It describes:

- Regulations applicable to interoperability
- The role of the Common Safety Method for Risk Evaluation & Assessment (CSM-RA) in interoperability
- The role of Independent assessors
- Expectations of Applicants

Interoperability Regulations

5.1 The National Technical Specification Notices (NTSNs) are UK standards defining the technical and operational standards that must be met by each subsystem in order to meet the essential requirements specified in RIR (2011) and ensure the interoperability of the railway system.

5.2 The NTSNs replace the Technical Specifications for Interoperability (TSIs) that defined the essential requirements for interoperability during the period that the UK was a Member State of the EU.

5.3 The various NTSNs apply to specific ‘structural’ subsystems such as infrastructure and rolling stock, to functions such as operations and telematics, across a number of subsystems such as the NTSN for accessibility for persons with reduced mobility, or define requirements for conformity assessment.

5.4 References to NTSNs are not provided in this policy as they are frequently updated. Applicants should identify NTSNs that are specific to their process and use the applicable version with correct amendments of the NTSNs.

5.5 If a project or programme of work is at an advanced stage of development and a relevant NTSN is updated then the Applicant should assess the impact of complying with the revised NTSN. Where the impact is significant then they should consult the competent authority for guidance.

5.6 To submit a valid application for authorisation an Applicant must:

- engage an Approved Body to carry out the UK verification assessment procedure.
- ensure that an Approved Body continues to be engaged throughout the project once appointed.
- engage a Designated Body (DeBo), to perform an assessment of verification against UK specific rules. If no UK specific rules are applicable to the project then this does not apply.

Note: Applicants should ensure adequate interoperability expertise is maintained throughout the project. The amount of expertise needed will vary across the project lifecycle and Applicants should consider where they will obtain expertise from at each project stage. This could either be within the project team or through external subject matter experts.

5.7 The Applicant must draw up a UK declaration of verification in relation to the project subsystem that complies with Schedule 5 of the Regulations, a summary of which can be found in Appendix F.

5.8 National Technical Rules (NTRs) provide controls in addition to National Technical Specification Notices (NTSNs) to ensure that the essential requirements specified in RIR (2011) are met.

5.9 NTRs are provided in situations to fill 'open points' in NTSNs, support UK specific cases in NTSNs, and to set out the requirements to maintain technical compatibility between assets that do not conform to the requirements of NTSNs.

5.10 In this context "open points" are defined as *technical aspects corresponding to the essential requirements that are not explicitly covered in the NTSN*.

5.11 Derogations from NTRs in exceptional cases are analysed by the RSSB on a case-by-case basis.

5.12 The ORR understands that for current applications, there may be an element of TSIs involved as a result of interoperability constituents that were verified by a European Notified Body (NoBo), therefore structural subsystems authorised in this way will be permitted for the GB railway up to the deadline of December 2021.

5.13 Applicants are encouraged to develop a measure of NTSN compliance risk, to be updated periodically and reported to the ORR. This measure should consider

factors such as a) number of issues raised by the Approved Body or NoBo and the Designated Body (DeBo), b) Contingency in schedule for the ORR review (we recommend this risk measure is reported as a red / amber / green (RAG) status of ease of use).

The role of CSM-RA in Interoperability

5.14 The Applicant must ensure that risks associated with the technical, operational or organisational change associated with the introduction of the new or changed subsystem are evaluated and assessed as part of their risk assessment and management processes.

5.15 Any technical, operational or organisational change must be assessed as to whether or not it is a significant change under the Common Safety Method for Risk Evaluation & Assessment (CSM-RA) as described in Paragraph 4.4.

5.16 The risk management process described in CSM-RA is an iterative process for managing risk and is based on four stages (see article 1.1.1. of Appendix I of CSM-RA Regulation):

(a) definition of the system under assessment;

(b) systematic hazard identification, covering identification of;

(i) the hazards,

(ii) the risks,

(iii) the associated safety measures,

(iv) the resulting safety controls which must be met by the system under assessment;

(c) demonstration of the system's compliance with the safety requirements;

(d) management of all identified hazards and associated safety measures.

5.17 The Applicant should document and implement appropriate controls in accordance with the risk acceptance criteria outlined in CSM-RA, which is to implement suitable safety requirements so as to reduce the risk ‘so far as is reasonably practicable’ (SFAIRP)

5.18 Risks can only be considered SFAIRP when all possible risk reduction options have been evaluated in one or more of the following ways:

- the application of recognised industry good practice standards
- comparison with one or more reference systems
- explicit risk estimation (qualitative and / or quantitative).

5.19 For projects subject to CSM-RA, where the change is deemed to be significant, the Applicant must appoint an Assessment Body (AsBo) to independently assess their risk management processes.

5.20 The Applicant must produce a written statement indicating that relevant hazards have been identified and that associated risks are controlled to an acceptable level. (See Article 16 of CSM-RA).

5.21 The risk management process must be traceable throughout the design, construction and operation of the project, and Applicants must maintain a hazard record throughout the system's life after being granted authorisation.

The role of Independent assessors

5.22 Applicants should appoint competent organisations to perform activities of independent assessment. This includes appointment of an Assessment Body (AsBo) for significant changes, as well as a Designated Body (DeBo) and an Approved Body (formerly NoBo under the European interoperability regime).

Assessment Body (AsBo)

5.23 The AsBo makes an assessment of compliance with CSM-RA (where change is significant). The AsBo:

- Produces a Safety Assessment Report (SAR) in accordance with the requirements of Appendix III of the CSM-RA Regulation
- Reports on compliance, which can be either 'supportive' or 'non-supportive'. A non-supportive SAR is essentially a rejection of application in which case the Applicant must provide further evidence to close-out any remaining non compliances with CSM.
- The Applicant should address recommendations and ask the assessor to update their response accordingly.

Approved Body (Formerly NoBo)

5.24 The Approved Body (or ApBo) provides independent certification at specific stages in the project lifecycle as to whether a structural subsystem conforms to required NTSNs. The NoBo or Approved Body:

- Produces a Certification of Verification (CoV) that references the national rules against which conformity has been examined.
- Can optionally produce Intermediate Statements of Verification (ISVs) that reference NTSNs against which the conformity has been examined.

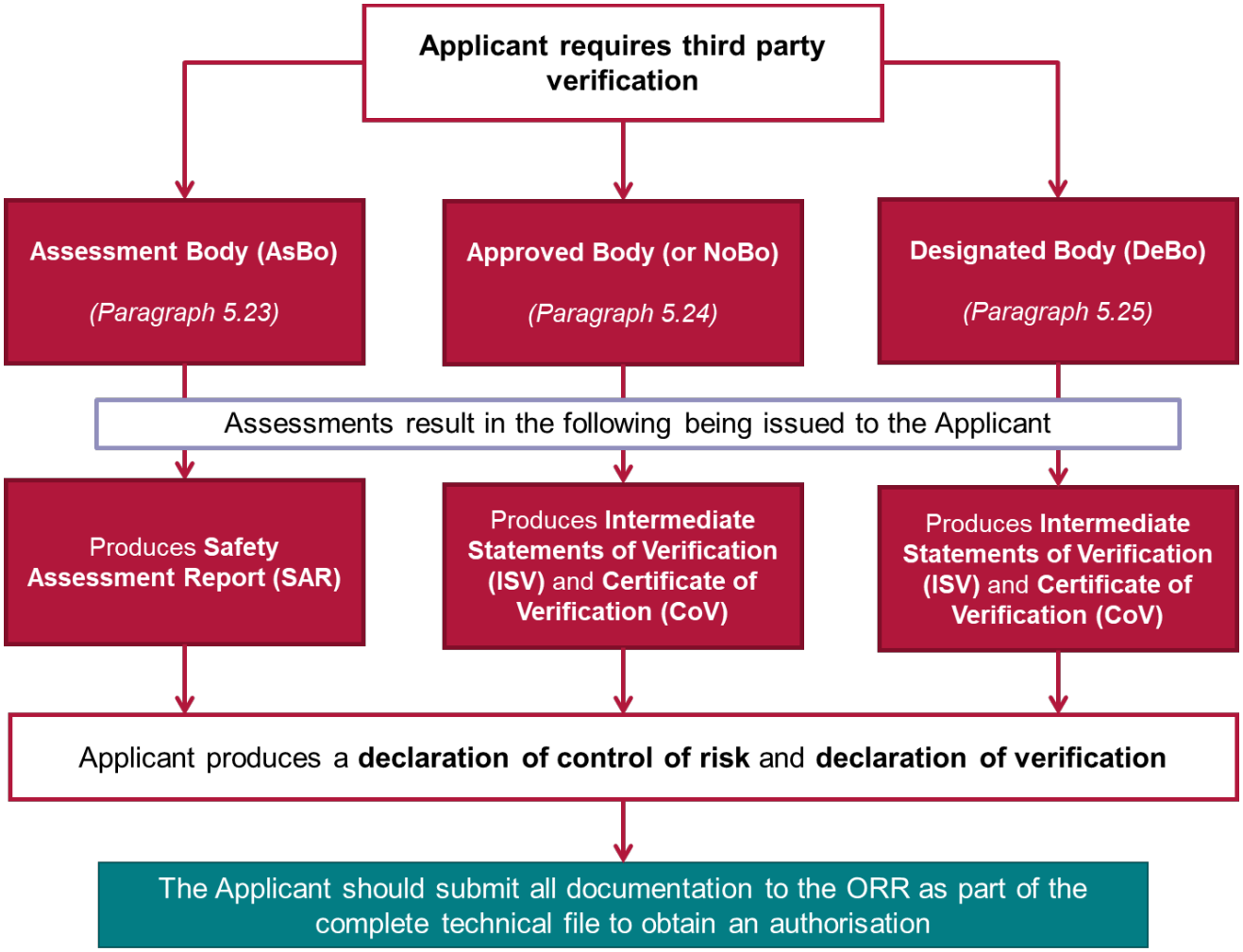
Designated Body (DeBo)

5.25 The DeBo assesses compliance with NTRs (National Technical Rules). The DeBo:

- Produces a Certification of Verification (CoV)
- Can optionally produce Intermediate Statements of Verification (ISVs) at the design and/or production stages.
- Report should not cover aspects falling within the Approved Body's area of competence

5.26 The Applicant should produce a Declaration of Control of Risk (DoCoR) and a UK declaration of verification to submit as part of the technical file.

Figure 5.1 The roles and duties of Independent assessors



5.27 To avoid recommendations or conditions being carried forward to the next stage of review, the Applicant should allow sufficient time between review and beginning the next stage to find solutions to issues and close them out accordingly.

5.28 Applicants should focus on obtaining tangible evidence to solve conditions and recommendations that Independent assessors provide, rather than focussing on finding a form of words to satisfy assessors that issues have been resolved.

5.29 Independent assessors can raise queries or recommend good practices to Applicants throughout the process; Applicants should consider these and seek to understand the reasons behind them before accepting or rejecting them.

Note: The Applicant should develop a dated and resourced plan in the event of non-supportive NoBo / Approved Body / DeBo assessment. This plan should set out how the Applicant will obtain a supporting assessment. For example, it could include: a) process map for obtaining evidence to close out issues, b) Methodology for contacting other project teams which dealt with similar issues, c) List of contacts for specialists who may be required to close out conditions and recommendations.

Expectations of Applicants

5.30 Applicants are responsible for planning, managing, monitoring and coordinating health and safety on their worksites. They must also ensure that the system can be operated and maintained to prevent (SFAIRP) danger to the public, employees' subcontractors and third parties.

5.31 The Applicant is responsible for defining the scope of assessment for all independent assessors. Applicants must ensure each body has its own field of competence and that their responsibilities do not overlap.

5.32 Applicants should promptly inform the ORR in the following events:

- The scope of the project, project stages, or approach to authorisation changes
- The Applicant considers it can no longer meet the requirements set out in the authorisation plan
- The standard of the completed works could impact on the overall safety of the subsystem or the wider rail network

5.33 Any of these circumstances could result in ORR requiring an Applicant to obtain additional authorisations upon completion of individual packages of work or upon completion of agreed milestones, or agree changes to the authorisation plan.

5.34 The ORR may also request specific assurances from the Applicant that risks have been identified and are being managed appropriately.

Glossary & Definitions

AsBo	**Assessment Body**	An independent and competent third-party, organisation or entity that undertakes investigation to provide a judgement, based on evidence, of the compliance of an organisation with the requirements of CSM-RA	Common Safety Method for Risk Evaluation and Assessment - Guidance on the application of Commission Regulation (EU) 402/2013
	Applicant	The organisation applying for authorisation to place into service.	
	Approved Body	An approved UK-specific independent appointed by the Applicant. They assess and verify conformity of project subsystems to the National Technical Specification Notices (NTSNs). They operate in tandem with Designated Bodies (DeBos) who assess and verify conformity with National Technical Rules (NTRs).	Railways (Interoperability) (Amendment) (EU Exit) Regulations 2019 (SI 2019/345)
CoV	**Certificate of verification**	A document drawn up by an Approved Body or a Designated Body (DeBo) in relation to a structural subsystem as part of the verification assessment procedure.	Railways (Interoperability) (Amendment) (EU Exit) Regulations 2019 (SI 2019/345)
CSM-RA	**Common Safety Method for Risk Evaluation & Assessment**	Single, European Union-wide, regulation to describe how the safety impacts of significant changes are assessed. This includes requirements for system definitions, risk management processes and third-party assessment	Commission Implementing Regulation (EU) 2015/1136 of 13 July 2015 amending Implementing Regulation (EU) No 402/2013 on the common safety method for risk evaluation and assessment
DeBo	**Designated Body**	An independent appointed by the Applicant to assess and verify conformity of projects with	Railways (Interoperability) (Amendment)

		National Technical Rules (NTRs) in the United Kingdom. It operates in tandem with Approved Bodies which assess and verify conformity with National Technical Specification Notices (NTSNs).	(EU Exit) Regulations 2019 (SI 2019/345)
DoCoR	**Declaration of Control of Risk**	Declaration confirming all identified hazards and risks are controlled to an acceptable level.	
	Infrastructure	Railways assets including 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.	
ISV	**Intermediate Statements of Verification**	Enable checks to be carried out in stages – see section 2.2 of Annex VI of the Interoperability Directive.	Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community
NoBo	**Notified Body**	The EU equivalent of a UK Approved Body. They are an independent appointed by the Applicant that meets the criteria of competence, integrity and independence set out in Annex VIII of the Interoperability Directive. They assess and verify conformity of project subsystems to the National Technical Specification Notices (NTSNs). They operate in tandem with Designated Bodies (DeBos) who assess and verify conformity with National Technical Rules (NTRs).	Railways (Interoperability) Regulations 2011 (RIR 2011) (SI 2011/3066)
NRAP	**Network Rail Assurance Panel**	Provides review on behalf of the Network Rail Executive prior to structural subsystems being put into service.	

NTR	**National Technical Rules**	The rules to satisfy for the design, upkeep and maintenance of installations planned for service on the GB rail network.	
NTSN	**National Technical Specification Notices**	Replaces the EU TSIs (Technical Specifications for Interoperability). Outline the specification to be met by a subsystem, or part of a subsystem, for it to meet the essential requirements and achieve interoperability.	Railways (Interoperability) (Amendment) (EU Exit) Regulations 2019 (SI 2019/345)
ORR	**Office of Rail and Road**	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.	
	Open Points	Certain technical aspects corresponding to the essential requirements that are not explicitly covered in the NTSN	
	Placing in Service	All the operations by which a structural subsystem is put into its design operating state.	
	Put into use	The structural subsystem is functional and able to be used by others.	
	Renewal	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.	
SAR	**Safety Assessment Report**	Contains the conclusions of the assessment performed by an assessment body on the system.	
SRP	**System Review Panel**	For most infrastructure schemes and systems requiring assessment, NRAP delegates the review to the SRP.	
	Structural Subsystem	Rolling stock, infrastructure, energy or control and command and signalling	
	Subsystem	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.	
TSI	**Technical Specifications**	Replaced by NTSNs (National Technical Specification Notices) in the UK. Outline the specification to be met by a subsystem, or part	Railways (Interoperability) Regulations 2011

	for Interoperability	of a subsystem, in order for it to meet the essential requirements and achieve interoperability.	(RIR 2011) (SI 2011/3066)
	Upgrade	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.	

Appendices

Appendix A: General Information about Interoperability

Directive 2008/57/EC on the interoperability of the rail system within the European Community (the Interoperability Directive), and associated regulations (The "Interoperability Regulations"), set out the conditions required to achieve interoperability.

The purpose of interoperability is to ensure technical compatibility of trains and infrastructure across GB and establish common standards and assessment processes for new, upgraded or renewed rail vehicles, infrastructure and components such that they meet the essential requirements for interoperability. These essential requirements include safety, reliability, accessibility and environmental protection.

The standardisation of structural subsystems (such as rolling stock and infrastructure) removes barriers to trade, delivering 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 compete more effectively with other transport modes.

Under the Regulations, an interoperability authorisation must be obtained for the placing in service of a structural subsystem (which may be infrastructure or rolling stock) before that subsystem is put into use for the purpose it was designed or as part of, the GB rail system.

An interoperability authorisation provides confirmation that new, upgraded or renewed structural subsystems meet the essential requirements for interoperability and comply with the relevant applicable legal requirements, including National Technical Specification Notices (NTSNs), Common Safety Methods (CSMs) and National Technical Rules (NTRs).

New, upgraded and renewed structural subsystems are subject to independent assessment body verification and assessment procedures. These assessments assist the ORR in determining whether requirements for interoperability have been met.

Appendix B: Additional Requirements for Network Rail

Where the project entity is Network Rail additional evidence will be required to satisfy ORR that the Network Rail governance processes have been applied to the project. This includes meeting the requirements of:

(i) Internal Health & Safety Management System (H&SMS) and Network Rail Assurance Panel (NRAP) process.

(ii) Network Rail processes and guidance regarding the use of a phased approach for certain projects and programmes of work to upgrade/renew infrastructure.

(iii) Endorsement through their Project Authorisation Strategy (PAS), System Definitions and accompanying plan by NRAP and then the System Review Panel (SRP) (in accordance with Network Rail internal standards). NRAP must endorse the approach ahead of SRP.

(iv) Resubmission to NRAP for agreement in the event of any changes to project scope or approach.

(v) Consultation with the ORR after submission of the project to NRAP (Network Rail Assurance Panel) for review and endorsement of the project authorisation strategy and system definition that has been agreed with NRAP.

Appendix C: Structure for Early Engagement for New Subsystems

Timings	1. **Pre-Application:** 1 meeting before conceptual design 2. **Initial Engagement:** 1 meeting before detailed design 3. **Pre-Operation:** 1 meeting before commissioning/trial operation
Attendees	■ **ORR:** Assigned lead for this project; ■ **Applicant:** Project Manager / Director; Project Sponsor; Subject experts from project team; ■ **Approved Body (NoBo in EU) / DeBo:** Optional, but recommended

Suggested Agenda Items

Meeting	Clarifications	Project Definition	Project Status
1: Pre-Application	■ Clarify **roles and responsibilities** of ORR, Applicant, assessors, DfT ■ Manage expectations for initial engagement meeting ■ Clarify "**what good looks like**", e.g. complete technical file and no conditions on authorisation ■ Confirm Applicant has **access to NTSN expertise** and has a method of assessing NTSN compliance risk ■ Confirm **Applicant is aware** of self-assessment checklist / stage gate intervals	■ **System Definition:** including scope and purpose, maps/plans, interfaces, possible future benefits, technical and functional characteristics of the subsystem and its interfaces ■ **Project authorisation strategy**: Present preliminary schedule, planned commissioning date ■ Preliminary **feasibility study** and preliminary **safety impact analysis**	■ **Request** for authorisation ■ **Confirm 'significance'** of change and type of authorisation ■ **Risks & Issues log** – showing path to obtain evidence of compliance for each item

Suggested Agenda Items

Meeting	Clarifications	Project Definition	Project Status
2: Initial Engagement	■ Clarify **contingency plans** (in case of non-supportive SARs) ■ Clarify **document control strategy** ■ Manage **expectations for post-detailed design report**	■ List **applicable legislation** (NTSNs, any NTRs, any other Codes of Practice, etc.) ■ **Timelines**, critical path activities, key milestones (including Approved Body/DeBo timelines) ■ **Staging of authorisation**, ISVs, derogations, and possible tests	■ Review project **NTSN RAG status** ■ Discussion of **open third-party assessor queries** and recommendations ■ Discuss **supplier competence** and contracts (check NTSN evidence is being provided) ■ **Risks & issues log**
3: Pre-Operation	■ Clarify **activities to monitor compliance** ■ Clarify **contingency plans** (in case of non-supportive SARs)	■ Discuss **Operations & Maintenance strategy** after handover ■ Discuss **change management** process and anticipated changes	■ Review **project NTSN status** e.g. RAG ■ Discussion of **open third-party assessor queries** and recommendations
Minutes of meeting are taken to ensure that there is a shared understanding of what was discussed and agreed			
Things to avoid at the meeting	■ Presenting only ‘good news’ or optimistic views of risks. The aim of these meetings is to discuss problem areas and find a way forward – not just to reassure either party. ■ The assumption that “it’s too early to discuss the details” at Initial Engagement. While technical components might not be finalised, the staging and relevant NTSN clauses must be understood in detail.		
ORR to review before meetings	■ ORR Authorisation leads to check with ORR colleagues for any concerns about the project ■ ORR Authorisation leads to review internal lessons learned from previous authorisations of similar projects (e.g. new station PRM, new OLE etc.)		

Appendix D: Structure for Early Engagement for Upgrades & Renewals

Timings	1. **Initial Engagement:** 1 meeting before application of modification 2. **Pre-Operation:** 1 meeting before commissioning/trial operation
Attendees	■ **ORR:** Assigned lead for this project; ■ **Applicant:** Project Manager / Director; Project Sponsor; Subject experts from project team; ■ **Approved Body (NoBo in EU) / DeBo:** Optional, but recommended

Suggested Agenda Items

Meeting	Clarifications	Project Definition	Project Status
1: Initial Engagement	■ Clarify **roles and responsibilities** of ORR, Applicant, assessors, DfT ■ Manage expectations for initial engagement ■ Clarify "**what good looks like**", e.g. complete technical file and no conditions on authorisation ■ Confirm Applicant has **access to NTSN expertise** and a method of assessing NTSN compliance risk ■ Confirm **Document Control Strategy** ■ Clarify **contingency plans** (in case of non-supportive SARs) ■ Clarify **document control strategy** ■ Manage **expectations for post-detailed design report** ■ Confirm **Applicant is aware** of self-assessment checklist and stage gate intervals	■ **System Definition:** including scope and purpose, maps/plans, interfaces, possible future benefits, technical and functional characteristics of the subsystem and its interfaces ■ **Project authorisation strategy**: Present preliminary schedule, planned commissioning date ■ **Staging of authorisation**, ISVs, derogations, and possible tests ■ List **applicable legislation** (NTSNs, any NTRs, any other Codes of Practice, etc.) ■ **Timelines**, critical path activities, key milestones (including Approved Body/DeBo timelines)	■ **Request** for authorisation ■ **Confirm 'significance'** of change and type of authorisation ■ **Risks & Issues log** – showing path to obtain evidence of compliance for each item ■ Discussion of **open third-party assessor queries** and recommendations ■ Review project **NTSN RAG status** ■ Discuss **supplier competence** and contracts (check NTSN evidence is being provided)

Suggested Agenda Items			
Meeting	**Clarifications**	**Project Definition**	**Project Status**
2: Pre-Operation	■ Clarify **activities to monitor compliance** ■ Clarify **contingency plans** (in case of non-supportive SARs)	■ Discuss **Operations & Maintenance strategy** after handover ■ Discuss **change management** process and anticipated changes	■ Review **project NTSN status** e.g. RAG ■ Discussion of **open third-party assessor queries** and recommendations
Minutes of meeting are written to ensure that there is a shared understanding of what was said			
Things to avoid at the meeting	■ Presenting only ‘good news’ or optimistic views of risks. The aim of these meetings is to discuss problem areas and find a way forward – not just to reassure either party. ■ The assumption that “it’s too early to discuss the details” at Initial Engagement. While technical components might not be finalised, the staging and relevant NTSN clauses must be understood in detail.		
ORR to review before meetings	■ ORR Authorisation leads to check with ORR colleagues for any concerns about the project ■ ORR Authorisation leads to review internal lessons learned from previous authorisations of similar projects (e.g. new station PRM, new OLE etc.)		

Appendix E: Stage Gate and Submission Checklist

Note: This stage gates in this submission refer to authorisations for new structural subsystems**.** Where the timing of interim submissions vary for upgrades and renewals, differences in what the Applicant should produce is highlighted in turquoise.

When using the checklist for stage gate submissions, applicants should update the contents of previously submitted documents before each submission. The complete application is therefore made up of three submissions with continuous updates.

Section	Contents of file	More Information
The following documents should be submitted for review as part of the Post-Detailed Design document review		
Introduction	• **System Definition:** scope, purpose, required type of authorisation (new, upgrade, or renewal), maps/plans, interface with other projects, etc. • Provisional **project schedule** including planned commissioning date • **Project Lifecycle Plan**, including definition of project lifecycle phases • **Approach** to project including possible future benefits	• Paragraph 3.13 • Paragraph 3.13 • Paragraph 3.13 • Paragraph 3.13
Project Description	• Description of the **significance of the change** • Technical and functional **characteristics** of the subsystem • **Interfaces** with other systems and the environment • List of **applicable national NTSNs and rules** and derogations • Information on **appointed Approved Body, DeBo and AsBo** (if applicable) and their activities	• Paragraph 1.1 • Paragraph 3.32 • Paragraph 4.24 • Paragraph 5.1 • Paragraph 5.22
Where the project or programme of work is an upgrade or renewal, the Applicant should submit their **Testing procedures** in addition to the above documents at the *Pre-Testing Document Review*		
The following documents should be submitted for review as part of the Post-Testing Document Review		
	High level versions of all the above documents, plus	

Safety deliverables	• Description of **risk management process** • **Documents required by CSM-RA**, where applicable, including system definition, identified hazards, risks, and mitigation measures • **Risk tolerability** thresholds and acceptance criteria • **Declaration of verification**	• Paragraph 5.16 • Paragraph 5.14 • Paragraph 5.14 • Paragraph 5.26
Testing	• **Testing** procedures • **Test results** including calculations and simulations • Independent **SARs**	• Paragraph 3.33 • Paragraph 3.33 • Paragraph 5.22
The following documents should be submitted for review as part of the Pre-Submission Document Review		
	High level versions of all the above documents, plus	
Operation & Maintenance	• **Description of requirements** for operation, maintenance, removal and decommissioning under normal and exceptional circumstances	• Paragraph 3.32
Technical File	• **Process for monitoring and control** of all identified hazards and associated risks after approval. • **Demonstration that operation is safe** under internal and external influences • **Demonstration of compliance** with NTSNs / TSIs and NTRs • Confirmation that **identified risks have been addressed** • Intended **activities to monitor compliance** • **Independent SARs**, DeBo Technical File, Approved Body Technical File • **Declaration of Verification** and **Declaration of control of risk** • **Derogation outcomes** and conditions (if applicable)	• Paragraph 5.21 • Paragraph 3.33 • Paragraph 3.33 • Paragraph 3.34 • Paragraph 3.34 • Paragraph 5.22 • Paragraph 5.26 • Paragraph 3.6
Where the project or programme of work is an upgrade or renewal, the Applicant should combine the Post-Testing and Pre-Submissions as one "*Pre-Submission*" Document		
Conclusion	• **Summary** of findings	

Appendix F: Schedule 5 UK Declaration of Verification of Subsystems

The UK declaration of verification must contain at least the following:

a) the reference to these Regulations, NTSNs and applicable NTRs,

b) the reference to the NTSN(s) or their parts to which conformity has not been examined during the UK verification procedure and to the GB specific rules which have been applied in the case of an exemption, partial application of NTSNs for upgrade or renewal, transitional period in an NTSN or GB specific case,

c) name and address of the project entity applying for an authorisation under these Regulations (specifying the trade name and full address; in the case of the authorised representative, specifying also the trade name of the contracting entity or manufacturer),

d) a brief description of the subsystem,

e) name(s) and address(es) and the identification number(s) of the approved body or bodies which conducted the UK verification assessment procedure,

f) if applicable, name(s) and address(es) and identification number(s) of the EU notified body or bodies which conducted the EC verification assessment procedure,

g) name(s) and address(es) and the identification number(s) of the body or bodies which conducted an assessment of conformity with any other applicable enactment or rule of law,

h) name(s) and address(es) of the designated body or bodies which conducted the UK verification assessment procedure in relation to UK specific rules,

i) name and address of the assessment body or bodies which established the safety assessment reports related to the use of the CSM on risk assessment referred to in paragraph 2.4(e) of Schedule 4,

j) the references of the documents contained in the technical file accompanying the UK declaration of verification,

k) all the relevant temporary or final provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions,

l) the identity of the signatory (i.e. the physical person or persons authorised to sign the declaration).

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