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

GUIDE TO THE APPLICATION OF SAFETY VERIFICATION

HMRI Inspector Guidance

May 2007
PREFACE

This guidance explains how Duty Holders (Railway Undertakings (RUs) or Infrastructure Managers (IMs)) arrive at the decision to apply, or not apply, Safety Verification (SV). By explaining the principles of SV, it gives guidance to Inspectors on how to review the management arrangements and in some cases, determined by the Rail Guidance Document on Operational Policy, the application of Safety Verification. It covers the transition arrangements of projects from Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994 (ROTS) to SV and Safety Management System (SMS) change management processes.

Safety Verification is a provision (Regulation 5(4)(a) and 6(4)(a)) within The Railways & Other Guided Transport Systems (Safety) Regulations 2006 (ROGS) that came into force on 10 April 2006. Schedule 4 of ROGS details written SV scheme requirements. Refer to Appendix 2.

The transition from ROTS to ROGS creates a major change in the way of working for the Office of Rail Regulation Her Majesty’s Railway Inspectorate Directorate (HMRI) and Industry. HMRI recognise that all stakeholders will initially go through a learning process in understanding:

- how SV is understood and applied by Duty Holders
- how frequently and by whom
- what support HMRI needs to offer in the short term, during the learning process, to ensure SV is applied consistently

For further advice or information please contact HMRI at the address below.

HMRI
Office of Rail Regulation
One Kemble Street
London
WC2B 4AN

Switchboard: 0207 282 2000
CONTENTS

Introduction 4
1. Scope 5
2. Background 5
3. The principle behind SV 6
4. When SV should be applied 7
5. What ROGS requires of an SV Scheme 9
6. Initial integrity and verification of Systems Critical to Safety 10
7. HMRI involvement in SV schemes 13
8. Relationship between ROGS and Interoperability Regulations 15
9. Transition arrangements 16
10. Enforcement 17
Appendix 1 - Illustrations of the SV process 18
    Transitional Process 18
    Interoperability or ROGS? 19
    Process for Safety Verification 20
Appendix 2 - Schedule 4 Regulation 5(4)(a) and 6(4)(a) 21
    HMRI ROGS Regulations Guidance on SV process 22
Appendix 3 - Independent Competent Person 23
Appendix 4 - Example of a typical rolling stock project managed under a Safety Management System (SMS) Change Management Process 25
Appendix 5 - Glossary 27
Guide to the Application of Safety Verification

Introduction

The Railways & Other Guided Transport Systems (Safety) Regulations 2006 (ROGS) implement the EU Railway Safety Directive 2004/49/EC. ROGS came into force on 10 April 2006. The coming into force was followed by a transition period ending on 30 September 2006, for mainline railways. ROGS includes a provision requiring, in certain circumstances, the introduction of new or altered infrastructure or rolling stock to be subject to Safety Verification (SV).

Audience

This document is primarily intended as internal guidance for use by HMRI Inspectors and support staff. It is intended to provide information on the SV process, when it should apply and summarises the arrangements for the transition between Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994 (ROTS) and SV, and the requirements for the review of the application of SV.

Links to related documents:

Railways and Other Guided Transport System (Safety) Regulations 2006 (“ROGS”)

The Railways and Other Guided Transport Systems (Safety) Regulations 2006 Guidance on Regulations


The Railways (Interoperability) Regulations 2006

The Railways (Interoperability) Regulations 2006 guidance (DfT Guidance)

HMRI Interoperability Guidance – link to be added

Rail Guidance Document on Safety Verification Operational Policy – link to be added
1. **Scope**

This guidance explains how Duty Holders arrive at the decision to apply or not apply SV. In addition it gives guidance to Inspectors on the application of SV. It addresses the requirements for the transition between ROTS to SV and gives an example of a routine scenario for projects managed under Safety Management System (SMS) change management processes.

**It does not cover the assessment of the provisions for SV made in the SMS submitted as part of an application for the issue of a Certificate or Authorisation under ROGS.** This is covered in a separate manual: HM Railway Inspectorate Safety Certificate and Authorisation Assessment Manual.

**Level Crossings**

Any level crossing covered by the requirements of the Level Crossing Act 1983 are excluded from the requirements of SV. The LC Act continues to apply.

**Heritage and Tramways**

There are extended transitional arrangements for ROTS under ROGS for Tramway and Heritage operators. New Heritage and Tramway systems can continue to be submitted to HMRI under ROTS until 1 Oct 2008 provided that the anticipated Approval and bringing into use under ROTS is by 1 Oct 2010.

From March 2007 Heritage and Tramway operators must have an SMS but there is no requirement for the SMS, or SV provisions in the SMS, to be assessed or certified by ORR. Regulations 4(3)(a) and (b) and 4(4) of the ROGS regulations refer.

In the absence of a transport operator a ‘responsible person’ will be required to undertake the duties of the transport operator i.e. establishing a written SV scheme and appointing a competent person to undertake the SV. ROGS Regulation 6(4) and (6) refer.

2. **Background**

A significant change that ROGS brings about is the withdrawal of the safety regulator, ORR, formerly HSE, from the initial approval of new or altered infrastructure or rolling stock (due to the revocation of ROTS by ROGS).

ROGS offers an approach to providing assurance on initial integrity risks that is similar to the Interoperability EC verification process using Notified Bodies (NoBos), required under The Railways (Interoperability) Regulations 2006 (Interop Regs), whilst remaining proportionate to the actual risks involved. Duty Holders (DH), referred to as Transport Undertakings (TU) and Infrastructure
Managers (IM) under ROGS, are required to have a certificated SMS and this must include high level details of the management arrangements - procedures and methods for carrying out risk evaluation and implementing risk control measures when new or altered infrastructure and rolling stock is to be introduced.

3. The principle behind SV

The purpose of SV is to provide assurance regarding the control of risks arising from the changes brought about by the introduction of new or altered infrastructure and rolling stock, where there is the potential to significantly increase the risk arising from the operation of the railway.

The process of SV can be viewed as having distinct levels:

- the management arrangements as described above;
- the verification scheme as described below in 5.3 and 6;
- the project – the works plant or equipment.

A written SV scheme allows for the examination of the risk associated with all aspects of the project but in particular the arrangements for managing components and systems critical to safety to ensure that risk mitigation is suitable and sufficient, so far as is reasonably practicable (SFAIRP), when the project is brought into use.

The SV scheme would be expected to identify errors or failures in areas such as:

- the specification and selection of appropriate standards; and
- the design, construction and testing of systems, which have been identified as safety-critical, so that appropriate preventative or remedial action can be taken prior to bringing into use.

Under ROTS assurance was provided by the involvement of the independent safety regulator, HMRI. Under ROGS this independent scrutiny is provided by involvement of an “independent competent person” (ICP) at all stages of a project subject to the SV process. An ICP can be an individual or an organisation, a member of the organisation applying SV (2\textsuperscript{nd} party) or an external organisation (3\textsuperscript{rd} party). Refer to Appendix 3 - Independent Competent Person.

The principle of using second or third parties to provide technical safety and compatibility assurance in relation to the integrity of new or altered
infrastructure or rolling stock is already familiar to the mainline rail industry through the role of Vehicle Acceptance Bodies (VAB)*, usually on a contractual basis, Independent Safety Assessors (ISA) and Technical Competent Authorities (TCA) working with Duty Holders to support applications made to Network Rail’s Acceptance Board (NRAB)* and other certification processes. It is also commonly used in high-risk sectors such as the oil and gas industries. In addition third party authorities have been used extensively for many years in the shipping industry.

*  The entire acceptance process involving VABs and NRAB has changed under ROGS to self-certification and Duty of Co-operation respectively.

Whilst independent assurance is commonly seen as solely relevant to safety, and in the case of ROGS this is its sole purpose, it can be, and is, used by many businesses as a key part of their business risk control measures. This is especially so in relation to design appraisal, given that the costs of rework at the design stage are considerably less than once construction has started.

4. When SV should be applied

The primary means by which the risks arising from the introduction of new or altered infrastructure or rolling stock are controlled are the provisions in a Duty Holders SMS for the management of change. Details of what the SMS requires in this regard can be found in Schedule 1, para 2(d) of ROGS (Railways and Other Guided Transport System (Safety) Regulations 2006).

Railway Safety Case holders will already have a formal change management process that will help them fulfil the management of change requirement. Refer to section 7 - HMRI Involvement in SV schemes.

Note: Duty Holders who hold a deemed safety certificate or safety authorisation under ROGS from 1 October 2006, can only apply SV if they have amended their SMS to include the provisions required for SV and notified HMRI of this under reg. 13, or have obtained a full safety certificate or safety authorisation.

4.1 SV applies when a Duty Holder wishes to place into service new or altered vehicles or infrastructure the design, construction, or testing of which:

- incorporates significant changes compared to any vehicle or infrastructure already in use on the transport system; and
would be capable of **significantly** increasing an existing risk or creating a **significant** new safety risk

In coming to a view on the application of SV Duty Holders should therefore apply a two-stage “test”.

The SV process will not apply unless the new or altered equipment is **both** novel to the transport system and is likely to give rise to a significant new risk or a significant increase in an existing risk.

**The project must meet both of the following criteria:**

- **Difference Test:** the risk arising from the design is new, or novel to the transport system; and
- **Risk Test:** there will be a new significant safety risk or a significant increase in risk

The difference test considers the likelihood of risk arising because of the novelty of the new or altered infrastructure or rolling stock to be introduced. Where the design, construction or mode of operation of equipment is new to a particular transport system there is a greater likelihood that potential safety risks will not be properly identified. For example, failure modes and their effect on the particular transport system may not be properly understood even where the technology has been used on other transport systems. Similarly, where, for example, existing technology is used outside previous operational limits the effects on safety of design decisions may not be fully understood.

If the difference test is satisfied, the Duty Holder then needs to consider the second test i.e. the consequence of any failure, or risk created by the way the design is operated. If there is a significant new risk to safety, or a risk is significantly increased, then SV must be applied.

ROGS requires (in regulation sections 5(4) and 5(7)), that the Duty Holder must, before new or altered vehicles or infrastructure are placed into service:

- establish a written safety verification scheme which meets the requirements and contains the elements set out in **Schedule 4 of ROGS**;
- appoint an independent competent person to undertake that safety verification;
- ensure that the independent competent person has undertaken the safety verification.

**4.2 SV is intended to address only those situations where there are**
significant changes and those changes have the potential to significantly increase the risk of operating the railway. SV is not intended to address risks that are already understood and managed, i.e. where there are well developed, established, industry recognised identification and risk control measures throughout the project - from initial design integrity, through construction, installation, testing, commissioning, bringing into use, operation and arrangements for maintenance. These risks would be dealt with by the Safety Management System (SMS) Change Management Processes. (Refer to Appendix 4 for a typical rolling stock project managed under a SMS Change Management Process).

4.3 The types of project more likely to lead to the application of SV are those where:

- novel technology is being introduced or the use of technology that is entirely new to the transport system;
- existing technology is being used in novel ways or situations;
- existing technology is being required to deliver very significant increases in performance or output.

Examples of specific situations that might be considered novel are:

- the introduction of existing vehicles new to a route;
- the introduction of selective door opening using Global Positioning Systems;
- the use of automated/driverless vehicles.

In summary where a Duty Holder is dealing with novel and potentially significant risk SV must be applied to provide assurance that these potential risks are being properly identified and adequately controlled.

5. What ROGS requires of an SV Scheme

The requirements for SV schemes are set out in Schedule 4 of ROGS. The Guidance on the Regulations provides interpretation of those requirements. However, in broad terms, the requirements of ROGS are set out below. Refer to Appendix 1 for an illustration of a typical Safety Verification process.

5.1 Once it has been decided that a project meets the requirements to apply SV the first step in setting up a scheme is the appointment of an “Independent Competent Person (ICP)”. An ICP can be either an individual or a corporate entity. There are two key aspects to being a competent person:
objectivity, largely evidenced by independence from the procurement and implementation of the project; and

competence in the matters being considered, in terms of skills, knowledge and experience.

ROGS defines Independence in terms of:

- the degree of responsibility the competent person has had in relation to the matters they have to consider; and
- the extent to which they are outside the management system, which is responsible for the introduction of the new infrastructure and rolling stock.

Refer to Appendix 3 - Independent Competent Person for further definition of ICP.

5.2 The competent person must be appointed sufficiently early on in the project so that they can be involved in establishing:

- the design process;
- the criteria to be used in the verification process; and
- an inspection plan/audit programme.

5.3 The SV scheme must be written down and must include adequate arrangements for:

- communication with the ICP to ensure they have access to all the information they need to undertake the verification;
- identifying the standards and criteria to be applied in the verification process;
- identifying the methods of controlling risks during any testing and trials;
- process for review and revision of the scheme;
- process for making and preserving records; and
- communicating with the appropriate level in management system of the Duty Holder.

Refer to Appendix 2 for Schedule 4 of ROGS Regs for SV scheme requirements.

6. Initial integrity and verification of Systems Critical to Safety

The SV process can be considered to have three distinct levels:

- the management arrangements for SV which the Duty Holder has in place;
• the SV scheme - the work undertaken by an ICP and
• the project – the works plant or equipment.

Management Arrangements – the high level, auditable safety management system (SMS) wording, which describes how schemes will be managed and how the Duty Holder will engage and work with the Independent Competent Person (ICP).

These written arrangements are assessed by HMRI as part of the application for the issue of a Safety Certificate or Authorisation under ROGS. However, these written arrangements may be audited, either as part of a general SMS inspection or as part of a detailed assessment of an SV scheme. The HMRI Operational Policy Rail Guidance Document will define the audit process.

Safety Verification Scheme – the auditable written correspondence between DH and ICP is likely to include, and should demonstrate:

• the DH’s initial decision making rationale for applying SV - the methodology and results of the risk and difference tests and engagement of an ICP;
• the technical scope (and commercial/contractual scope if 3rd party) produced by the DH for the ICP;
• the ICP’s verification assessment and written inspection reports, design scrutiny, drawings, calculations and recommendations to the DH on the project design, construction, installation and testing.
• the DH responses to the ICP recommendations.

See also Section 5.3.

The SV scheme – general requirements

The Duty Holder must make certain that their written SV scheme documentation for each project ensures that components critical to safety are suitable for their intended purpose. To undertake this requirement the Duty Holder must have a process and an effective SMS in place to deliver it.

The Duty Holder, in conjunction with the ICP, must devise a written scheme of verification which satisfies the requirements of ROGS. The ICP will be expected to audit and inspect, against an agreed plan, the project methodology and the actual project design, installation, and testing arrangements.

The ICP assessment should be sufficiently detailed to identify any errors or failures in the design and construction of the components critical to safety that could prevent them from achieving their intended safety functions.
The ICP assessment could comprise audits or inspections of designs, specifications, certificates, CE marking, suppliers or supply chain, contractors and other documents or standards relating to the systems critical to safety.

Project – the physical works, plant or equipment to be manufactured or altered as proposed by the DH and to be independently scrutinised by the ICP.

6.1 What should the Duty Holder make available to the ICP?

In order for the ICP to carry out this inspection the Duty Holder must make available any relevant documentation, as required, which could include some, or all, of the items below for each system critical to safety:

1. Specification documentation;
2. Design documentation;
3. Certificates of Conformity for material used, test certificates etc.;
4. Other documentation e.g. risk assessments, compliance with Common Safety Methods (CSMs), Preliminary Hazard Analysis (PHA), HAZOP and HAZID reports, Safety Integrity Levels assessments (SIL), Fault Tree Analysis (FTA) and Failure Modes Effects Criticality Analysis (FMECA) and similar documentation relating to modifications;
5. Evidence of compliance with current standards, derogations and non-compliances. Departures from standards indicate areas where improvements may be required in order to ensure risks are reduced So Far As Is Reasonably Practicable (SFAIRP). Changes in technology, standards etc. relevant to the systems critical to safety need to be considered to ensure that an opportunity to reduce risks SFAIRP is not missed.
6. Evidence that the change has been considered under ROGS Duty of Co-operation, after affected parties have been consulted and the interfaces of the change are demonstrated to be compatible with the system into which it is being introduced.

6.2 How much evidence should the ICP examine?

The ICP will need to establish, through audit and inspection, that the design meets relevant standards, or has necessary derogations, that it is ‘safe’ (SFAIRP) and that it has been properly constructed, installed, tested and has operational procedures and maintenance arrangements. The depth and breadth of examination by the ICP depends on the combination of the variables that make up the project; its size, scope, potential risk, novelty, complexity,
interfaces, stakeholder involvement etc. In some circumstances a vertical audit would be sufficient to establish that the Duty Holder’s risk mitigation arrangements and identification of new or increased existing risks brought about by the introduction of the project are appropriate and reduced SFAIRP. In other cases a broader, more in depth assessment may be required. The ICP would need to examine sufficient evidence of a system critical to safety to be confident that the Duty Holder has identified and mitigated both new and increased existing risks.

Note: It is the Duty Holder who owns and retains the risk. The ICP is purely an Independent Verifier.

7. HMRI involvement in SV schemes

There is no requirement in ROGS for a project subject to SV to be notified to or given prior consent or approval by HMRI.

ROGS does not provide for Inspectors to be involved in the drawing up or approval of SV schemes, or to be involved in the detailed aspects of the design or specification of design.

Inspector involvement with an SV scheme does not involve verification of the initial integrity of the new equipment - this is the role of the ICP. HMRI will be targeting a sample of Duty Holder’s Verification schemes to check that these are working.

However, during the initial stages of the use of SV, audits of SV schemes during their application may be made at any point. The HMRI Operational Policy Rail Guidance Document will define the audit process.

7.1 Gathering intelligence about SV schemes

Inspectors are likely, through routine liaison meetings with Duty Holders, to become aware of schemes being planned or ongoing under SV. Intelligence provided by Duty Holders will be recorded by HMRI and built into future SMS intervention work and business planning processes. Inspectors should make a point of asking Duty Holders for details of ongoing schemes or plans to implement an SV scheme. The Operational Policy will define how intelligence will be captured.

HMRI may also become aware of SV schemes under the provisions of ROGS Regulation 13 entitled ‘Notice of changes by holders of a safety certificate or safety authorisation’. This information will be fed into the business planning processes.
As part of the Delivery Plan, Inspectors may choose to review the evidential audit trail retained by Duty Holders of a sample of schemes where a project has not met the requirements to apply SV but has been implemented under the change management processes of the Duty Holder’s SMS. See Section 7.4.

The Account Manager and NET Manager will select the schemes to be audited from intelligence gathered from the Industry. The Operational Policy will set the sample size and specific criteria for this audit. Schemes selected for audit may involve both Area and NET Inspectors.

7.2 Frequency of intervention with SV

It is not yet fully known how widely or often SV will be applied across Industry and therefore the frequency and depth of HMRI intervention is not fixed. For example, SV is likely to be applied more frequently by London Underground as the Interoperability Regulations do not apply to metros.

It is recognised that Duty Holders will need support to understand how to apply SV in the early stages and that intervention and support will be greater initially. It is also recognised that different sectors will need varying levels of support. The transitional period for ROTS and extended arrangements for the Heritage and Tramway sector will have an effect on the frequency of application of SV. The Operational Policy will define the intervention strategy for the mainline railway.

7.3 Level of intervention with SV schemes

The only planned intervention envisaged by ORR with an SV scheme is a post certification/authorisation review of a representative sample of Safety Verification management arrangements to verify compliance with the requirements in ROGS. It is anticipated that this review will be undertaken by Area Team inspectors familiar with the audit of management systems.

However, on a sample of schemes, this will include an in depth audit. The Operational Policy will set the sample size and specific criteria for this audit. An important point that Inspectors should check is that the Duty Holder is not relying solely on the ICP for the management of safety.

The Duty Holder is responsible for the management of the SV scheme and resolution of issues raised by the ICP during the SV process.

7.4 Changes managed under SMS Change Management Processes

Where the scope of modifications (changes) to vehicles or infrastructure - particularly to new rolling stock (post placing into service) where reliability or
availability targets need to be met - are not caught by the interoperability regulations or SV, or where an existing project has been requested to be removed from ROTS, then these projects will need to be managed under the SMS change management procedures.

A typical example of a process that would be followed by a Duty Holder under this sort of change is detailed in Appendix 4 - Safety Management System (SMS) change management process.

Inspectors need to be mindful that although SV may not be widely applied it is likely that changes under SMS managed projects will be. Intelligence on these projects needs to be captured and reported back to HMRI to be fed into business planning processes for consideration in SMS inspection planning.

8. Relationship between ROGS and Interoperability Regulations

The Railways (Interoperability) Regulations 2006 (Interop Regs) implement the EU Conventional Interoperability Directive and the Amendment Directive. In addition they replace the Railways (Interoperability) (High Speed) Regulations 2002 (High Speed Regs) which implemented the EU High Speed Directive. The Interop Regs came into force on 2 April 2006, when the High Speed Regs were revoked. The Interop Regs provide for, in certain circumstances, the introduction of new or altered infrastructure or rolling stock, to be subject to an EC verification process conducted by a Notified Body (NoBo).

The Interop Regs place the decision, initially with the Contracting Entity (Duty Holder) but ultimately with the Competent Authority (CA), (the Department for Transport (DfT) in the UK), as to whether new or altered infrastructure or rolling stock should be constructed in compliance with European wide Technical Specifications for Interoperability (TSIs), where these are published, and be subject to the standard EC Interoperability verification process undertaken by NoBos. See Appendix 1 for flow diagram.

These matters are dealt with in detail in the DfT’s Guidance on the Interoperability Regs (The Railways (Interoperability) Regulations 2006 guidance) and HMRI’s own guidance on Interoperability (link to be added).

Where the DfT decides not to require application of the EC Interoperability verification process it must consult the Safety Authority, Office of Rail Regulation (Her Majesty’s Railway Inspectorate) in the UK, to see whether it considers the Authorisation process should be applied on safety grounds.

If HMRI decides that the new or altered infrastructure or rolling stock does not pose a significant safety risk, in the context of the
Interoperability Regs, and does not require Authorisation on safety grounds then the project will have to be managed under ROGS.

The Contracting Entity should then consider if the project needs be managed under the SV process or managed under their SMS, by applying the risk tests. Their decision can be informed by the Safety Authority's decision to not require Authorisation on safety grounds. If the Contracting Entity decides that the project does not pose significant risk then it will only need to be managed under their Safety Management Scheme.

The SV process will not apply if a project (or works) is subject to an Interoperability Authorisation under the Interoperability Regulations. An Authorisation under the Interoperability Regs is deemed to satisfy the requirements in ROGS as a ‘verification’ suitable to control the risk.

Where a project involving the introduction of new or altered infrastructure or rolling stock is subject to the EC verification process (Interoperability), this is considered sufficient to provide assurance on safety matters, including the interface between the new or altered infrastructure or rolling stock and the existing system into which it is being introduced.

ROGS does not require the application of SV to be considered at all where the Interoperability EC verification process is being applied, except for any elements of a wider scale project generally subject to the Interoperability EC verification process that fall outside of the requirements of interoperability (i.e. lineside signalling). Where there is an ‘open point’ in the TSIs, i.e. within scope of the TSI but not yet developed or defined, or no TSIs have been written, then National Notified Technical Rules (NNTRs) will need to be applied, under the interoperable process.

For transition diagram see Appendix 1.

9. Transition arrangements

ROGS revokes ROTS. However, there are transitional arrangements. ROGS allow Duty Holders to request to HMRI that current projects under ROTS be transferred to the Duty Holder to complete under SV or SMS change management process.

If the project transfers to the SV process the Duty Holder will need to consider how this affects his proposed SV scheme given that ideally the competent person should have been involved from the design stage. Duty Holders transferring a project part way through the project process, will need to
consider what evidence exists of work done at the earlier stages and what the ICP needs to do in order to satisfy itself that adequate precautions have been taken, for example, at the design stage.

The allowed transition for Interoperability ended August 2006. A small number of projects being processed under ROTS prior to August 2006 have, if the Contracting Entity (CE) decided that the project is a new or major upgrade/renewal on the TENs network and so caught by the Interop Regs, switched process to Interoperability. In such cases the requirements of ROGS are satisfied.

The CE may approach DfT for a decision as to whether a major upgrade or renewal on the TENs network requires Authorisation under the Interoperability Regs.

Projects already being dealt with under ROTS that do not transfer to the Interoperability Authorisation process may continue to be processed in accordance with the provisions of ROTS so long as they will be completed before 1 October 2008. Projects that will not be completed by 1 October 2008 will need to transfer to either an SV scheme or be dealt with under the Duty Holders SMS change management procedures.

New applications for metros and mainline railways that do not come under the Interoperability Regs, could be submitted under ROTS until 1 October 2006 and continue to be processed in accordance with the provisions of ROTS so long as they are completed before 1 October 2008.

For tramways and heritage railways the transition dates in the paragraph above are extended by 2 years i.e. projects can be submitted under ROTS until 1 October 2008 and be processed in accordance with the provisions of ROTS so long as they will be completed before 1 October 2010.

The flow chart Appendix 1 summarises the transition arrangements.

10. **Enforcement**

Where inspection, or post incident investigation of SV projects, identifies non-compliance it may be appropriate to consider enforcement to remedy specific shortcomings, or systematic management failings, applying the criteria in ORR Health & Safety Enforcement Policy Statement.
Appendix 1 - Illustrations of the SV process

Transitional Process

The application of ROGS/Safety Verification for existing ROTS and High Speed Interoperable Projects

Transitional arrangements for ongoing and new applications on mainline and other transport systems excluding tramways and heritage railways

```
Existing HSI 2002 regs project

Is project dormant/abandoned?
Yes
Send HMRI letter of abandonment and close file
No

Project can continue to Authorisation under 2002 HSI regs

Will project be placed into service before 31/7/2006?
Yes

Projects 'Ongoing Requirements' must comply with 2006 regs including all projects previously Authorised under the 2002 HSI regs
No

RI transfers relevant project info to CE and NoBo

Existing ROTS project

Does project fall within scope of 2006 Interoperability Regs?
Yes

Does TU/IM want to continue with ROTS?
No

RI acknowledges, closes record and file. Makes project info available if required

No

Yes

CE appoints NoBo by 1/7/2006

Project to be Authorised under 2006 Interoperability Regs

Duty Holders can make an application under ROTS until 1/10/06

Will project be placed in service by 1/10/2006?
Yes

RU/IM updates SMS or applies for full certificate/authorisation

No

Yes

RU/IM writes to HMRI to confirm SV to be used

Is project both new AND significantly increasing risk?
Yes

RU writes to confirm SMS to be used

No

No

RI acknowledges, closes record and file. Makes project info available if required

Yes

RU/IM writes to HMRI to confirm SV to be used

Does TU/IM have current processes to handle SV/ SMS?
Yes

Project transfers to ROGS SMS or SV if not completed by 30/9/2008

No

Project continues under ROTS

RU/IM updates SMS or applies for full certificate/authorisation

Existing 2002 HSI project

Does project fall within scope of 2006 Interoperability Regs?
Yes

Does TU/IM want to continue with ROTS?
No

RI transfers relevant project info to CE and NoBo

Is project dormant/abandoned?
Yes

Send HMRI letter of abandonment and close file

No

Project to be Authorised under 2006 Interoperability Regs

Will project be placed in service by 1/10/2006?
Yes

RU/IM updates SMS or applies for full certificate/authorisation

No

Yes

RU/IM writes to HMRI to confirm SV to be used

Is project both new AND significantly increasing risk?
Yes

RU writes to confirm SMS to be used

No

No

RI acknowledges, closes record and file. Makes project info available if required

Yes

RU/IM writes to HMRI to confirm SV to be used

Does TU/IM have current processes to handle SV/ SMS?
Yes

Project transfers to ROGS SMS or SV if not completed by 30/9/2008

No

Project continues under ROTS

RU/IM updates SMS or applies for full certificate/authorisation

```
Interoperability or ROGS?

Interoperability
Authorisation

Yes

DfT Confirmation?

No

ORR (NSA)
Safety Issues?

Yes

No

Is it on the TEN?

Yes

Borderline
/unsure

No

Is it new or major
upgrade or
renewal?

Yes

Is safety likely to be affected in terms of
significant risk?*

* Does design, construction or testing
incorporate significant changes compared with
any vehicle already in use on the transport
system, and would be capable of significantly
increasing an existing risk or creating a
significant new safety risk?

No

ROGS SMS (Change
Management)

No
HM Railway Inspectorate
Guide To The Application Of Safety Verification

Process for Safety Verification

Typical Safety Verification Process
Timeline

Safety Verification Stage

Duty Holder (Transport Undertaking/ Infrastructure Manager)

Independent Competent Person (2nd or 3rd Party) ICP

HMRI (ORR) Safety Authority

Initial Concept Feasibility Study

Applies risk tests
Decides SV applies
Appoints ICP
Develops project scope

Provided with project scope interfaces, risk identification and control strategy

Design & Integrity Check

Provides info on project design selection process, standards and verification criteria
Develops written SV scheme

Audits and reports on suitability and robustness of SV scheme
Draws up inspection plan

Test verification/ Commission

Provides info on testing strategy and results of compatibility testing/verification

Appropriate auditing and reporting activity

At any point in the SV process and during the lifecycle of the project HMRI may audit the SMS arrangements and sampled SV schemes

Manufacture/ Design/ Install

Provides info on manufacture/strategy

Appropriate auditing and reporting activity

Bringing Into Service

Provides info on arrangements for compatibility, bringing into service and maintenance
Review and revision of scheme
Making and preserving records

Audits arrangements for bringing into service

Post bringing into service for lifetime of project

The SMS operational management plan is applied

Retains records/ reports
ICP involvement ends

Note: Not all stages have to be followed for all projects
Appendix 2 - Schedule 4 Regulation 5(4)(a) and 6(4)(a)

Written Safety Verification Scheme Requirements

Information to be Included in a Safety Verification Scheme

1.—(1) The arrangements for the selection, appointment and retention of the competent person, which arrangements should at least provide for:

(a) the appointment of the competent person at an early stage in the design selection process;

(b) the involvement of the competent person in the establishing of the criteria to be applied in the verification process and the design selection process; and

(c) the communication to the competent person of information necessary for the proper implementation, or revision, of the verification scheme and which information is necessary in order for the competent person to undertake the verification.

(2) The arrangements for the examination and testing of new or altered vehicles or infrastructure, which arrangements should at least provide for:

(a) the means of controlling risks that arise during the carrying out of any testing or trials prior to placing in service; and

(b) the standards and criteria to be applied in the verification process.

(3) The arrangements for the review and revision of the verification scheme.

(4) The arrangements for the making and preservation of records showing—

(a) the examination and testing carried out to the new or altered vehicles or infrastructure prior to its being placed in service;

(b) the findings of that examination and testing;

(c) any remedial action recommended as a result of that examination and testing; and

(d) any remedial action performed.

(5) The arrangements for communicating the matters contained in sub-paragraphs (1) to (4) of this Schedule to an appropriate level in the management system of the transport operator or responsible person as the case may be.
HMRI ROGS Regulations Guidance on SV process

From: HMRI ROGS Regulations Guidance:

‘The foundation of a safety verification scheme is the timely appointment of an independent competent person. The transport operator or responsible person should draw up the scheme taking into consideration the advice of the competent person. Clearly failure to appoint a competent person early on in the process will make this difficult and undermine the effectiveness and suitability of the scheme. The competent person should be involved in the establishment of the verification criteria. In this case a competent person could be an individual or a corporate body.

It is important that those carrying out the verification work have appropriate levels of impartiality and independence from pressures, especially of a financial or operational nature, which could affect sound judgment. They should not verify their own work, and their management lines should be separate from those people whose work they are checking. For instance, it is acceptable in principle for a transport operator’s in-house team to check work done elsewhere in the same organisation. However, it would influence objectivity if that team’s management chain included the manager responsible for meeting targets that might be adversely affected by the outcome of the verification process.

In many cases the testing process itself has the potential to introduce risk onto the transport system. It is important that the verification scheme takes account of such risks and ensures that controls are in place to mitigate them.

The actual standards and criteria utilised in the verification process should be agreed and recorded to give transparency to the process and provide an audit trail.

The governance arrangements for making changes to the verification scheme should be recorded and where any changes are made they too should be recorded.

The retention of a written record of the verification undertaken is an essential part of the process. The records should be retained for the life of the subject of the verification scheme.

To ensure effective governance of the safety verification process the key information should be communicated to the appropriate management level. An appropriate level is that with sufficient authority to ensure that any action required in relation to the safety verification is taken.’
Appendix 3 - Independent Competent Person

From: HMRI ROGS Regulations Guidance:

Competent Person

1. A Competent Person is responsible for undertaking the safety verification on behalf of the transport operator (known as the ‘responsible person’).

2. A competent person is defined as:

"a person with sufficient practical and theoretical knowledge as well as experience of the particular task, plant, machine, procedure, equipment (etc) involved to enable them to thoroughly examine and identify any defects or weaknesses during examinations, and to assess their importance in relation to the safety, function and continued use of the plant, machine, procedure, (etc again) and to be aware of their own particular limitations with regard to the task to be undertaken."

Competence

3. A competent person should have:

• Demonstrable auditable qualifications, for example, BSc/ Chartered Engineer;
• Experience in industry in the type of work and workplace where they are to be deemed competent;
• Knowledge of, for example, the vehicle acceptance process (rolling stock) or participation in system renewal panels (signalling);
• Knowledge of applying regulatory process –
  a. standards compliance;
  b. what evidence is required to be presented;
• Knowledge of up to date best practice;
• An awareness of their limitations.

Independence

4. To be independent a competent person should have;

• No conflict of interest;
• The ability to demonstrate impartiality e.g. if an independent competent person is ‘in house’ (second party), they are not part of the design team and they report only to senior management.

5. It is essential that the competent person is sufficiently independent and
impartial to allow objective decisions to be made. This does not mean that competent persons need to be employed from an external company (third party). If employers and others within their own company have the necessary competence they can use it. However, if they do, they will need to ensure that their ‘in house’ or second party examiners have the genuine authority and independence to ensure that examinations are properly carried out and that the necessary recommendations arising from them are made without ‘fear or favour’.
Appendix 4 - Example of a typical rolling stock project managed under a Safety Management System (SMS) Change Management Process

This type of change happens frequently in depots and is a form of safety verification operating at a lower level. In practice, the use of in-house independent signatories who are competent and empowered to approve changes using established company procedures, referred to in railway safety cases, is common - particularly where new rolling stock is extensively modified to meet reliability and availability targets.

On occasions the change may be felt to infringe upon group standards and a call or email to a Vehicle Acceptance Body (VAB) will be required to clarify.

In the absence of an in-house independent signatory then an independent, competent third party could fulfil this role. Typically this would be a member of a VAB or engineering consultancy.

There can be financial benefits in using in-house expertise. However, under SV, demonstrating independence from the production environment may prove more of a challenge than in the past.

Example Project

Assume that the project is deemed to be outside the scope for Approval under ROTS, is not interoperable and does not meet the risk tests to qualify it for Safety Verification. Implementation will be under change management procedures. This is an example of a Rolling Stock Project.

The Signatory Responsibilities process for Infrastructure projects will be similar.

1. Background

Consider a requirement to improve the ability to bleed air locks on the under-seat heater system on a diesel multiple unit. The modification will improve saloon heater efficiency in the winter and reduce depot downtime. The modification has the consent and financial support of the Leasing Company.

2. Development Process

The design is developed according to the principles, laid down in the company modification/change control procedure, by technically competent technical staff and converted into a work package.

The work package is presented to the competent in-house signatory,
typically a Chartered Engineer or similar, such as a Fleet Engineer for approval leading to a prototype trial or fleet fitment.

3. Signatory Responsibilities

The signatory will check that the following has been considered:

The change modification/change control procedure has been followed, in particular:

- Modification costs are correctly allocated and benefits have been estimated;
- The design does not affect railway group standards and therefore does not require vehicle acceptance body design scrutiny and engineering acceptance certification;
- A programme has been developed identifying the project duration and during which maintenance interval the change will be applied;
- A modification procedure/method statement illustrates how the modification is applied and identifies the hazards of applying the change;
- The competency requirements of the staff responsible to apply the modification have been identified and if the work is sub-contracted then a check that the contractors are accredited;
- A hazard analysis identifies potential risks and mitigation of the design throughout the vehicle life cycle;
- Suitable engineering drawings have been produced to compliment the modification procedure;
- Suitable maintenance instruction amendments have been prepared;
- Guidance or training material for maintenance and operational staff has been updated to reflect the change;
- Material used for the modification has been procured from approved suppliers;
- Stores have been notified to amend stock levels during the change and order new parts;
- A regime is in place to record the change and monitor its performance;

Only after these points have been satisfied does the signatory approve the change for a prototype trial or fleet fitment.
Appendix 5 - Glossary

Note: The following list is a glossary of some terms and abbreviations used in this Guidance and elsewhere in connection with ROGS, ROTS, safety verification and interoperability and related topics.

Authorisation
Under the Interoperability Regulations Authorisation is the permission sought by the Contracting Entity from the Safety Authority prior to placing into service a structural subsystem. (This is not to be confused with a Safety Authorisation issued to an Infrastructure Manager under ROGS)

Certificate of Conformity
A certificate supplied with goods identifying batch numbers, delivery references, order numbers, product details and statements and its level of conformance

Change Management Process
Provision within Railway Safety case whereby Duty Holders described, at high level, their arrangements for the management of change. Working level procedures translate the high level description

CoCoSig
Control Command and Signalling

Common Safety Methods (CSMs)
The methods being developed to describe how safety levels, achievement of safety targets and compliance with other safety requirements are assessed

Competent Authority (CA)
Secretary of State (Department for Transport) in UK, excluding Channel Tunnel where it is Intergovernmental Commission (IGC); Department for Regional Development for Northern Ireland (DRDNI) in Northern Ireland
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent Person</td>
<td>See ICP – Independent Competent Person</td>
</tr>
<tr>
<td>Contracting Entity (CE)</td>
<td>The organisation responsible for the design or manufacture of works for a new subsystem or major works to upgrade or renew a subsystem</td>
</tr>
<tr>
<td>Deemed Safety Certificate</td>
<td>A transition arrangement between Safety Cases and ROGS for a Railway Undertaking. See paragraph 1(a) of Schedule 5 of the ROGS Regs</td>
</tr>
<tr>
<td>Deemed Safety Authorisation</td>
<td>A transition arrangement between Safety Cases and ROGS for an Infrastructure Manager. See paragraph 1(a) of Schedule 5 of the ROGS Regs.</td>
</tr>
<tr>
<td>Design Stage</td>
<td>This is the stage when a complete and robust engineering design for the project is produced - one that allows risks, costs, timescales, resources and benefits to be fully understood prior to commitment to implement</td>
</tr>
<tr>
<td>DfT (Rail)</td>
<td>Department for Transport (Rail Group)</td>
</tr>
<tr>
<td>Duty Holder</td>
<td>A Duty Holder is a person appointed by the company to have overall responsibility for railway operations under their Railway Safety Case</td>
</tr>
<tr>
<td>HAZID</td>
<td>HAZID (HAZard IDentification) is a high-level, systematic assessment of a plant, system or operation intended to identify potential hazards. This method is often used as a basis for risk assessment</td>
</tr>
<tr>
<td>HAZOP</td>
<td>HAZOP (HAZard &amp; OPerability analysis) is a well established method for identifying potential safety and operational problems associated with the design, maintenance or operation of a system. A HAZOP is a formal and</td>
</tr>
</tbody>
</table>
objective process, where a group assesses the different parts of a given system with the aid of "guidewords". This ensures a systematic and well documented evaluation of potential problems/hazards. Also used for 'identifying potential hazards and operability problems' caused by 'deviations from the design intent' of both new and existing process plants.

Heritage railway

Means a railway which is operated to –

a) preserve, re-create or simulate railways of the past, or;

b) demonstrate or operate historical or special types of motive power or rolling stock;

and is exclusively or primarily used for tourist, educational or recreational purposes.

HMRI

Her Majesty's Railway Inspectorate

HSE

Health & Safety Executive

HSW

Health & Safety at Work Act 1974

Independent Competent Person (ICP)

From the ROGS Regulations, "competent person" means a person who–

a) has sufficient skills, knowledge, experience and resources to undertake the safety verification in relation to which he is appointed

b) has not borne such responsibility in relation to any of the matters he has to consider in undertaking that safety verification that might compromise his objectivity; and

c) is sufficiently independent of a
management system, or a part thereof, which has borne responsibility for any of the matters he has to consider in undertaking the safety verification, to ensure that he will be objective in carrying out the safety verification for which he is appointed

Infrastructure

Means fixed assets used for the operation of a transport system which shall include—

a) its permanent way or other means of guiding or supporting vehicles;

b) any station; and

c) plant used for signalling or exclusively for supplying electricity for operational purposes to the transport system

Infrastructure Manager (IM)

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

Initial Integrity

Process for checking safety by design

ISA

Independent Safety Assessor is the formation by a qualified expert of a
judgement, separate and independent from any system design, development or operational personnel, that the safety requirements for the system are appropriate and adequate for the planned application and that the system satisfies those safety requirements

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mainline railway</td>
<td>Term used in Guidance to refer to that part of the UK network which is already, or is intended to be in future, covered by TSIs. It is made up of the high speed railway, the conventional railway and the domestic railway. It excludes light rail, trams, metros etc</td>
</tr>
<tr>
<td>Mainline railway system</td>
<td>Means the mainline railway and the management and operation of the mainline railway as a whole</td>
</tr>
<tr>
<td>Management Arrangements</td>
<td>High level, auditable Safety Management System wording, which describes how SV schemes will be managed and how the Duty Holder will engage and work with the Independent Competent Person.</td>
</tr>
<tr>
<td>Manufacture Stage</td>
<td>The stage which delivers the asset to the appropriate specification and provides confirmation that the asset and system work in accordance with their design. A NoBo must be appointed before this stage begins, if not earlier upon completion of the design stage (compare design stage)</td>
</tr>
<tr>
<td>National safety rules</td>
<td>With respect to the Interoperability Regulations, legislation, other than national notified technical rules, notified to the EC such as the Health and Safety at Work Act, ROGS, RIDOR, CDM etc</td>
</tr>
</tbody>
</table>
NRL  Network Rail Limited
NoBo  Notified Body
Notified Body  Body notified to European Commission by Member State as being competent to undertake verification assessment procedures, issue certificates of conformity and prepare technical files for defined sub-systems under Interoperability Regulations 2006
Notified National Technical Rules  Standards, etc, notified to the Commission by the UK to fill gaps where TSIs do not exist, or to fill a declared “open point” within a published TSI. (The High-Speed Regulations referred to these as notified national standards)
NNTRs  Notified National Technical Rules
NRAB  Network Rail Acceptance Board – multi-discipline panels of NRL experts responsible for assuring that projects brought before it have been properly managed to agreed standards and do not import risks onto the infrastructure
ORR  Office of Rail Regulation. The Safety Authority for GB (except the Channel Tunnel system) and the enforcing authority for GB
Pre-design stage  Also known as concept/feasibility stage. The stage in a project prior to the design stage (see above). This is the stage during which a selected single option is developed to the point of engineering scope freeze and in sufficient detail to allow finalisation of the business case and scheduling of implementation resources
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project</td>
<td>For the purposes of this guidance project refers to the new or altered works</td>
</tr>
<tr>
<td>Railway Undertaking</td>
<td>Train Operating Company, Freight Operating Company</td>
</tr>
<tr>
<td>Responsible person</td>
<td>Means in relation to any relevant infrastructure or vehicle, any person who— a) has contracted with another person for the manufacture or construction by that other person of that infrastructure or vehicle; or b) manufactures or constructs that infrastructure or vehicle for his own use, or for sale to, or use by, another person but not where he is contracted to do so by a person falling under sub-paragraph (i), and includes an authorised representative established in Great Britain of such a person</td>
</tr>
<tr>
<td>RGS</td>
<td>Railway Group Standards</td>
</tr>
<tr>
<td>Risk</td>
<td>Means in Parts 1 and 2 of ROGS, a risk to the safety of a person</td>
</tr>
<tr>
<td>Rolling Stock</td>
<td>Rolling stock has the meaning in section 83(1) of the Railways Act 1993 - any carriage, wagon or other vehicle used on track and includes a locomotive</td>
</tr>
<tr>
<td>RSC</td>
<td>Railway Safety Case (superseded by</td>
</tr>
</tbody>
</table>
the Safety Management System through the application of ROGS

RSSB
Rail Safety and Standards Board (co-ordinates UK input into TSI drafting process)

ROGS
Railways and Other Guided Transport Systems (Safety) Regulations 2006. Amongst other things, the ROGS Regulations implement a major part of the Safety Directive

ROTS
Railways and Other Transport Systems (Approval of Works, Plant & Equipment) Regulations 1994

Safety Authorisation
Means a safety authorisation issued by HMRI (ORR) in accordance with ROGS regulation 10 or 12 to Infrastructure Managers

Safety Authority (SA)
ORR in GB, Inter-Governmental Commission (IGC) for the Channel Tunnel; Department for Regional Development for Northern Ireland (DRDNI) in Northern Ireland. Authority established by the Member State under Article 16.1 of the Safety Directive - ‘This authority may be the Ministry responsible for transport matters and shall be independent in its organisation, legal structure and decision making from any railway undertaking, infrastructure manager, applicant and procurement entity’

Safety Certificate
Means a safety certificate issued by HMRI in accordance with regulation 7 or 9 of ROGS to Transport Undertakings

Safety Directive
Also referred to as "Railway Safety Directive". Refers to Directive
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Management System</td>
<td>System for managing safety risks which Duty Holders are required to have under ROGS</td>
</tr>
<tr>
<td>Safety Verification</td>
<td>Requirement in the SMS for assessing significant safety risks which may be brought about by changes to the network or rolling stock and controlling them through verification</td>
</tr>
<tr>
<td>Scheme</td>
<td>For the purpose of this guidance the scheme refers to the written process of Safety Verification established between the Duty Holder and ICP</td>
</tr>
<tr>
<td>SFAIRP</td>
<td>“SFAIRP” is short for “so far as is reasonably practicable”. The term means at its core is the concept of “reasonably practicable”; this involves weighing a risk against the trouble, time and money needed to control it. Thus, SFAIRP describes the level to which workplace risks are expected to be controlled</td>
</tr>
<tr>
<td>Significant safety risk</td>
<td>Means, in relation to new or altered infrastructure or a new or altered vehicle the design or construction of which incorporates significant changes compared to any infrastructure or vehicle already in use on that transport</td>
</tr>
</tbody>
</table>
system, the capability of significantly increasing an existing risk or creating a significant safety risk to—

i) passengers on the transport system in question; or

ii) members of the public in [roads] [streets] and any other location where the transport system in question operates and to which the public have access

SIL

Safety Integrity Levels (SIL) are measures of the safety of a given process. Specifically, to what extent can the end user expect the process in question to perform safely, and in the case of a failure, fail in a safe manner? Usually applies to electronic systems particularly software and firmware architecture

SMS

Safety Management System

SV

Safety Verification

System/Component Critical to Safety

A system or component in a system whether hardware or software (whether computer, electronic, electromechanical, mechanical, pneumatic or hydraulic) whose failure may cause injury or death to human beings. E.g. rolling stock braking system software or signalling system solid state interlocking controls

TEN

Trans-European Network

Train

Includes any rolling stock

Tramway

means a system of transport used wholly or mainly for the carriage of passengers and employing parallel rails
which—

(a) provide support and guidance for vehicles carried on flanged wheels, and

(b) are laid wholly or mainly along a street or in any other place to which the public has access (including a place to which the public has access only on making a payment)

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transport Operator</td>
<td>Means any transport undertaking or infrastructure manager</td>
</tr>
<tr>
<td>TSI</td>
<td>Technical Specification for Interoperability. TSIs set out how &quot;subsystems&quot; meet the &quot;essential requirements&quot; of the Interoperability Directives</td>
</tr>
<tr>
<td>Transport Undertaking (TU)</td>
<td>Means any person who operates a vehicle in relation to any infrastructure but shall not include a person who operates a vehicle solely within an engineering possession</td>
</tr>
<tr>
<td>VAB</td>
<td>Vehicle Acceptance Body. In relation to rolling stock acceptance under Railway Group Standards, VABs determine whether or not RGS has been complied with</td>
</tr>
</tbody>
</table>