Common Safety Method for risk evaluation and assessment

Guidance on the application of Commission Regulation (EU) 402/2013

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1. Introduction

Background

1.1 Commission Implementing Regulation (EU) 402/2013 (the Regulation on a common safety method (CSM) for risk evaluation and assessment [or “the CSM RA”]) is part of a wide-ranging programme of work by the European Railway Agency (ERA) and the European Commission (the Commission) to bring about a more open, competitive rail market while seeking to ensure that safety levels are maintained, and, if reasonably practicable, improved. In the past, safety requirements may have been used as a barrier to open competition across the EU. The intention of the CSM RA is to harmonise processes for risk evaluation and assessment and the evidence and documentation produced during the application of these processes. By applying a common process, it will be easier for an assessment undertaken in one EU Member State to be accepted in another with the minimum of further work. This is referred to as mutual recognition.

1.2 The CSM RA is a framework that describes a common mandatory European risk management process for the rail industry and does not prescribe specific tools or techniques to be used. The processes are intended to complement requirements in other legislation, for example on interoperability or safety certification, and not to duplicate them. The broad principles of how these requirements fit together are explained in the following paragraphs.

1.3 There is other domestic UK legislation that requires suitable and sufficient risk assessments to be undertaken, such as the Management of Health and Safety at Work Regulations. ORR is of the view that there is no conflict between the domestic requirements for a risk assessment to be suitable and sufficient and the level of risk assessment required by the risk management process of the CSM RA. In practice, therefore, when any significant safety related change of a technical, operational or organisational nature is proposed to the mainline railway, compliance with the risk management process of the CSM RA should produce a suitable and sufficient risk assessment for that change. ORR has published a policy statement on the relationship between the CSM RA and other risk assessment requirements.

1.4 The CSM RA applies when any technical, operational or organisation change is being proposed to the railway system. A person making the change (known as ‘the proposer’) needs to firstly consider if a change has an impact on safety. If there is no impact on safety, the risk management process in the CSM RA need not be applied and the proposer must keep a record of how it arrived at its decision.

1.5 If the change has an impact on safety the proposer must decide on whether it is significant or not by using criteria in the CSM RA (see Annex 1 of this guidance). If the change is significant the proposer must apply the risk management process. If
the change is not significant, the proposer must keep a record of how it arrived at its decision.

1.6 The Rail Safety and Standards Board (RSSB) in its publication Taking Safe Decisions has suggested applying the risk management process of the CSM RA even if a change not significant. This is to avoid the need to have duplicate risk assessment processes.

1.7 So, even though it is not mandatory to apply the risk management process if a change is not significant a proposer may choose to apply it. In these circumstances some elements of the risk management process (such as the need for independent assessment) can be omitted.

1.8 The framework of the risk management process is based on the analysis and evaluation of hazards using one or more of the following risk acceptance principles:

- application of codes of practice;
- comparison with similar systems (reference systems); and
- explicit risk estimation.

**Purpose of this guidance**

1.9 This guidance summarises and explains the main requirements of the CSM RA, to whom it applies, and specific points on compliance in the UK.

1.10 This is the third issue of this guidance. It has been updated to reflect the coming into force of the CSM RA on 30 April 2013. This amends the original Regulation (EC) 352/2009, which came into force on 19 July 2010 and has been applicable from July 2012 to all significant changes which impact on safety. The amendments apply from 21 May 2015 and are mostly concerned with the accreditation and recognition of assessment bodies. Regulation (EC) 352/2009 will be repealed on 21 May 2015 but its provisions will continue to apply in relation to projects which are at an advanced stage of development. This guidance has also been updated to reflect developments in other related legislation. It will continue to be updated as further revisions to the CSM RA come into force or if there are changes to other processes that impact on how the CSM RA should be applied. (The CSM RA will be revised in 2015 in relation to one of the risk acceptance principles and this guidance will be amended to reflect the changes – see Box 1 in paragraph 3.47).

1.11 The full text of the CSM RA is available on the Commission’s website. As a Commission Regulation, it applies directly and does not need to be transposed into UK law. The CSM RA primarily applies to railway undertakings (RUs), infrastructure managers (IMs) and entities in charge of maintenance (ECMs) but also applies to
Further information and references

Commission Regulation (EC) 352/2009

Commission Regulation (EU) 402/2013

ERA guidance to the application of the CSM

ERA collection of examples of risk assessments and some possible tools

ORR policy statement on the relationship between the CSM and other risk assessment requirements

RSSB guidance: Taking Safe Decisions

1.12 ERA has also produced guidance on the application of the CSM RA. This is in two parts: the first is intended as further explanation (‘Guide to the Application of the CSM’); and the second is a collection of examples of risk assessments, processes and applications that were used in some Member States prior to the introduction of the CSM RA. The main aim of the second part is to illustrate the types of tools and techniques that may be used to apply the CSM RA.

1.13 The Railway and Other Guided Transport Systems (Safety) Regulations 2006 (as amended) (ROGS) require RUs and IMs to develop safety management systems (SMS) to manage the risks associated with their activities and to meet specific criteria. One of the criteria for the SMS is that it must apply the relevant parts of CSMs. (In addition to the CSM RA, there are two other CSMs applicable to RUs and IMs. Please see ORR’s website or Taking Safe Decisions for further details.) ORR will check compliance with CSMs when we examine applications from duty holders for safety certificates or authorisations and when we subsequently supervise those duty holders.

1.14 The Railways and Other Guided Transport Systems (Miscellaneous Amendments) Regulations 2013 removed from ROGS the requirement for a written safety verification scheme by RUs or IMs in certain circumstances. This was to prevent duplication following the introduction of the CSM, which achieves a similar outcome.
2. Applying the CSM RA

When does the CSM RA apply?

2.1 The CSM RA applies when any technical, operational or organisational change is being proposed to the railway system. A person making the change (known as ‘the proposer’) needs to firstly consider if a change has an impact on safety. If there is no impact on safety, the risk management process in the CSM RA need not be applied and the proposer must keep a record of how it arrived at its decision.

2.2 If the change has an impact on safety the proposer must decide on whether it is significant or not by using criteria in the CSM RA (see Annex 1 of this guidance). If the change is significant the proposer must apply the risk management process (see Chapter 3). If the change is not significant, the proposer must keep a record of how it arrived at its decision.

2.3 This process is summarised in Figure 1.

2.4 In addition to structural, operational or organisational changes, application of the CSM RA may be required

- by a Technical Specification for Interoperability (TSI) when structural sub-systems falling within the scope of the Railways (Interoperability) Regulations 2011 (as amended) (RIR) are constructed or manufactured, or upgraded or renewed; or
- when placing in service a structural sub-system to ensure that it is integrated into the existing system in a safe manner.

2.5 Structural sub-systems (as described in Directive 2008/57/EC) are:

- rolling stock;
- infrastructure;
- command control and signalling; and
- energy.

2.6 For those projects at an ‘advanced stage of development’ on 21 May 2015 the provisions of Commission Regulation 352/2009 shall continue to apply. Projects can be considered by the proposer to be at an ‘advanced stage of development’ if the planning/construction stage has reached a point where a change in the technical specifications would not be viable on economic, contractual, legal, social or environmental grounds.
What are technical, operational and organisation changes?

Technical changes

2.7 Technical changes are changes to a structural sub-system. Technical changes should also be reviewed to determine whether they introduce changes to the operation of the sub-system under consideration.
Operational changes

2.8 Operational changes are:

- changes to the operation of a structural sub-system;
- changes to the operation of the railway system; or
- changes to the operating rules of the railway system.

2.9 Operational changes are often the result of technical changes to a sub-system. Indeed, technical changes are frequently made for the purpose of delivering a desired operational change. In these cases, the technical change and its effect on

- the operation of the sub-system;
- the wider railway system; or
- the operating rules of the railway,

must be considered and assessed together.

2.10 For example, a change of the command, control and signalling (CCS) system from fixed marker signals (for example TVM) to a cab-based system (for example ETCS) is a significant safety-related technical change that should be assessed in accordance with the risk management process of the CSM RA. Such a change will also involve changes to the operation of the CCS sub-system and changes to the wider operating rules. These operational changes must be assessed together with the significant safety-related technical changes as part of the risk management process of the CSM RA.

2.11 Of course, changes to

- the operation of a sub-system; or
- the operation of the railway system; or
- the operating rules of the railway system,

can also be introduced without a related technical change. If these changes are safety-related, the proposer should consider whether they are significant or not. Only if they are significant should the risk management process of the CSM RA be applied to them.

Organisational changes

2.12 Organisational changes are changes to the organisation of an actor in the railway system which could impact on the safety of the railway system. The ‘actor’ is most likely to be an IM or a RU, but it could be an ECM or any other organisation that affects the safety of the railway system.
2.13 An example could be a change to the Safety Management System (SMS) - moving from a structure and culture based on a large number of prescriptive standards to a risk-based system relying on trained and competent staff using a small number of key principles. This could be a significant safety-related change and should be assessed using the CSM RA.

2.14 Further guidance on organisational changes can be found in Annex 4.

**Who has duties under the CSM RA?**

2.15 The CSM RA places duties primarily on the proposer of a change. Proposers are those in charge of projects who wish to implement a change to a technical, operational or organisational aspect of the railway system.

2.16 In many circumstances, proposers will be RUs or IMs. This aligns with the Safety Directive 2004/49/EC which places the main responsibilities for safety on these two key players. An ECM will also become a proposer in relation to changes to its maintenance system or if it is responsible for the modification of vehicles.

2.17 However, the CSM RA allows other bodies to act as the proposer. This could apply, for example, to project entities and manufacturers who lead projects where they are required to engage a Notified Body (NoBo) or a Designated Body (DeBo), or an applicant for an authorisation for placing in service under RIR.

2.18 In some circumstances a manufacturer will act as the proposer at the start of a project (for example if they want to market a new or altered product). Once the product is placed on the market, that ‘change’ is complete. An RU or IM wishing to use the new or altered product in a specific application or location will then be the proposer of a new change, for CSM RA purposes. The RU or IM’s risk assessment will focus on such matters as route-specific technical compatibility and safe integration (and will not need to repeat the manufacturer’s risk assessment).

2.19 The proposer must ensure that risks introduced by its suppliers and its service providers, including their subcontractors are also managed through application of the CSM RA. This may require participation in the risk management process of the CSM RA through contractual arrangements coordinated by the proposer.

**Where on the railway system does the CSM RA apply?**

2.20 The CSM RA has the same scope as the mainline railway as defined in ROGS. Therefore, the CSM RA does not apply to a railway if

a) ORR determines under regulation 2A (1) of ROGS that it falls within one or more of these categories:
   - metros and other light rail systems;
- networks that are functionally separate from the rest of the mainline railway system and intended only for the operation of local, urban or suburban passenger services, as well as transport undertakings operating solely on these networks; or
- heritage, museum or tourist railways that operate on their own networks; or
  b) ORR determines under regulation 2A(2) of ROGS that heritage vehicles that operate on the mainline railway and comply with national safety rules are part of a non-mainline operation; or
  c) it is privately owned infrastructure that exists solely for use by the infrastructure owner for its own freight operations.

2.21 Rail systems that fall under (a) and (b) above are contained in an Approved List on our website.

2.22 The CSM RA also does not apply to RUs operating vehicles (for example On-Track Machines) within a possession. If vehicles operate within a possession and subsequently leave the possession to operate on the mainline railway the CSM RA will apply. The risks arising from operating OTMs within a possession can be managed through other measures, such as the Management of Health and Safety at Work Regulations 1999.

How does the proposer determine the significance of a change?

2.23 If a proposed change has an impact on safety, the proposer must determine the significance of the change by examining the criteria in Article 4(2) of the CSM RA (see Annex 1 of this guidance). Note that the assessment body (see Chapter 4) assesses the application of the risk management process of the CSM RA but cannot question the proposer’s significance decision.

2.24 If a change is deemed to be non-significant, application of the risk management process of the CSM RA is not mandatory and the change should be managed under the change management processes as described in the proposer’s SMS or by carrying out a risk assessment which is required as part of compliance with other legislation, such as the Management of Health and Safety at Work Regulations 1999. However, there is nothing to prevent the proposer voluntarily applying the CSM RA risk management process for a non-significant change.

2.25 ORR, or the safety authority in another EU Member State, may check the process that RUs or IMs have used to determine whether or not to apply the CSM RA. Proposers, therefore, must document their decisions, particularly in relation to the test for significance.
2.26 The CSM RA contains six criteria which should be examined to determine 'significance'. These are:

- **failure consequence**: credible worst-case scenario in the event of failure of the system under assessment, taking into account the existence of safety barriers outside the system;

- **novelty used in implementing the change**: this concerns both what is innovative in the railway sector, and what is new just for the organisation implementing the change;

- **complexity of the change**;

- **monitoring**: the inability to monitor the implemented change throughout the system life-cycle and take appropriate interventions;

- **reversibility**: the inability to revert to the system before the change; and

- **additionality**: assessment of the significance of the change taking into account all recent safety-related modifications to the system under assessment and which were not judged as significant.

2.27 The CSM RA gives no order or priority on how to use the “significance” criteria, nor any thresholds to evaluate and make the decision. To help proposers work through the process, a UK industry proposal for how to determine significance is included at Annex 1. This approach is only one way of applying the criteria and is not mandatory.

**Additionality**

2.28 Additionality can be described as considering other changes that have been made since the entry into force of the CSM RA (30 April 2013) or since the last application of the risk management process (whichever is later), which, when combined with the change being considered, could become significant. If there are other safety-related changes that have been made ‘recently’, the test for significance should be made for all the changes as a whole rather than for just the individual change being considered.

2.29 Annex 1 suggests that additionality should be considered first as this defines the scope of the change that is to be assessed. It also proposes a method of addressing how far back to look when examining a series of changes.

2.30 Breaking down a significant change into a series of smaller changes, which individually are not significant so that the risk management process is then not applied to the overall significant change, is not permitted by the CSM RA.
Novelty and complexity

2.31 If a proposed change is novel or complex there could be an increase in the likelihood that, once implemented, the changed structural sub-system, operation or organisation will not behave as predicted and that unforeseen hazards will arise. Classifying such changes as significant and applying the risk management process, including the requirement for an independent assessment, will provide additional assurance and should help to identify measures to mitigate any potential increase in the risk.
3. Applying the risk management process of the CSM RA

What does the risk management process involve?

3.1 The risk management process is contained in Annex I of the CSM RA. The main phases are illustrated in Figure 2 and further details are set out below. The process illustrated is not static or linear as the proposer may undertake iterations of all or part of the process. The proposer should also integrate the process into the project lifecycle, rather than carrying it out in isolation. The process begins with a system definition and ends when the proposer is content that for each hazard the identified safety requirements and measures have been complied with by applying defined risk acceptance principles (see paragraphs 3.26 to 3.52). If the proposer decides to change the system definition throughout the process, it may need to start again from the beginning.

3.2 An assessment body must carry out an independent assessment of the risk management process and the results obtained from carrying it out.

3.3 The processes required by Annex I of the CSM RA will be familiar to many in the UK and are probably already in use in their risk management systems. The key requirements are examined below. Potential proposers who need to comply with the risk management process should review their current processes and procedures and make any necessary adjustments.

What are the main phases of the risk management process?

Preliminary system definition

3.4 In order to assess whether the change is significant or not, the proposer should conduct a preliminary system definition. This ‘preliminary system definition’ is in effect an analysis of what is being changed and a preliminary risk assessment of that change. The ‘preliminary system definition’ should

- give a clear statement on what is being changed and the scope of the change; and
- address the information described in paragraph 3.10(a) to (d) to the extent necessary to enable the proposer to determine the significance of the change.

System definition

3.5 The risk management process starts with the system definition (which can use information from the preliminary system definition). This provides the key details of
the system that is being changed - its purpose, functions, interfaces and the existing safety measures that apply to it. In most cases, the hazards which need to be analysed will exist at the boundary of the system with its environment.

3.6 The definition is not static and during iterations of the risk management process, it should be reviewed and updated with the additional safety requirements that are
identified by the risk analysis. It therefore describes the condition (or expected condition) of the system before the change, during the change and after the change.

3.7 The system definition may change due to factors other than the specification of safety requirements, such as

- changes in scope;
- changes in client requirements;
- increasing design definition; and
- implementation of changes proposed by contractors and suppliers.

3.8 Such changes may necessitate iteration of the risk management process.

3.9 Equally, changes to the system definition for other reasons may require the proposer to repeat all or part of the process and discuss with the assessment body the implications.

3.10 The risk management process states that the system definition should address at least the following issues:

a) system objective, e.g. intended purpose;

b) system functions and elements, where relevant (including e.g. human, technical and operational elements);

c) system boundary including other interacting systems;

d) physical (i.e. interacting systems) and functional (i.e. functional input and output) interfaces;

e) system environment (e.g. energy and thermal flow, shocks, vibrations, electromagnetic interference, operational use);

f) existing safety measures and, after iterations, definition of the safety requirements identified by the risk assessment process; and

g) assumptions which shall determine the limits for the risk assessment.

3.11 The system definition needs to cover not only normal mode operations but also degraded or emergency mode.

3.12 Consideration of interfaces should not be restricted to physical parameters, such as interfaces between wheel and rail. It should include human interfaces, such as the user-machine interface between the driver and driver displays in the cabs of rail vehicles. It should also include interfaces with non-railway installations and organisations. For example, the interface with road users at level crossings.
3.13 Operational rules and procedures, and staff competence should be considered as part of the system environment. This is in addition to the more usual issues such as weather, electromagnetic interference, local conditions such as lighting levels, etc.

3.14 A good test of whether the system definition is complete and sufficient is if the proposer can describe the system elements, boundaries and interfaces, as well as what the system does.

3.15 The description can effectively serve as a model of the system and should cover
- structural issues (how the system is constructed or made up); and
- operational issues (what it does, and how it behaves normally and in failure modes).

3.16 The existing safety measures, which may change as the risk assessment process progresses, can be added after the structural and operational parts of the model are complete.

3.17 For some projects, the proposer may not know all the environmental or operational conditions in which the altered or new system will operate. In these circumstances, they should make assumptions on the basis of the intended or most likely environment. These assumptions will determine the initial limits of use of the system and should be recorded. When the system is put into use, the proposer (who may be different to the original proposer) should review the assumptions and analyse any differences with the intended environmental and operational conditions.

Hazard Identification

3.18 The purpose of the hazard identification is to identify all reasonably foreseeable hazards which are then analysed further in the next steps.

3.19 The hazard identification should be systematic and structured, which means taking into account factors such as
- the boundary of the system and its interactions with the environment;
- the system's modes of operation (i.e. normal/degraded/emergency);
- the system life cycle including maintenance;
- the circumstances of operation (e.g. freight-only line, tunnel, bridge, etc.);
- human factors;
- environmental conditions; and
- relevant and foreseeable system failure modes.
3.20 While the risk management process does not require that any specific tools should be applied, many of the more well-known techniques will be relevant, including

- structured group discussions;
- checklists;
- task analysis;
- hazard and operability studies (HAZOPs);
- hazard identification studies (HAZIDs);
- failure mode and effects analysis (FMEA);
- fault trees; and
- event trees.

3.21 Whichever technique is used, it is important to have the right mixture of experience and competence while maintaining impartiality and objectivity. Correct hazard identification will underpin the whole risk management process and give assurance that the risks will be managed in the project.

3.22 The risk management process uses the term ‘broadly acceptable’ to identify those hazards which need not be analysed further. In this context, ‘broadly acceptable’ applies to those hazards where the risk is, to all intents and purposes, insignificant or negligible. This could be because the hazard is so unlikely to arise that there are no feasible control measures that could be used to control the risk it creates (e.g. earthquakes if in a low vulnerability area) or where there is a credible failure mode but the consequences are negligible. By screening out the ‘broadly acceptable’ hazards at this stage, the risk analysis can focus on the more important hazards to manage. It is unlikely that many hazards will be screened out in this way.

3.23 The level of detail of the hazard identification depends on the system that is being assessed and needs to be sufficient to ensure that relevant safety measures can be identified. If, following a high level hazard identification, it can be successfully demonstrated that a hazard can be controlled by application of one of the three risk acceptance principles required by the risk management process (see paragraph 3.26), then no further hazard identification is necessary. If it is not possible to have sufficient confidence at this stage, then further analysis of the causes of these high level hazards is undertaken to identify relevant measures to control the risks arising. The risk management process continues until it can be shown that the overall system risk is controlled by one or more of the risk acceptance principles.

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1 ‘Broadly acceptable’ in the Regulation does not have the same meaning as it has in the HSE tolerability of risk framework (see ‘Reducing Risks, Protecting People’).
3.24 Hazard identification is still necessary for those changes where the hazards are to be controlled by the application of codes of practice or by comparison to reference systems. Hazard identification in these cases will serve to check that all the identified hazards are being controlled by relevant codes of practice or by adopting the safety measures for an appropriate in-use system. This will also support mutual recognition and transparency. The hazard identification can then be limited to verification of the relevance of the codes of practice or reference systems, if these completely control the hazards, and identification of any deviations from them. If there are no deviations, the hazard identification may be considered complete.

3.25 The purpose of risk analyses and evaluation is to identify those safety requirements and measures that are necessary to control the risks arising from the identified hazards.

### Risk acceptance principles

3.26 Hazards can be analysed and evaluated using one or more of the following risk acceptance principles:

- the application of codes of practice;
- a comparison with similar systems (reference systems); or
- an explicit risk estimation.

3.27 In the UK, you can choose any of these three risk acceptance principles. However, if a proposer is seeking mutual recognition in another EU Member State, they should check whether there is a notified national rule restricting the choice of risk acceptance principle. If there is, only the required principle(s) must be applied.

3.28 Individual hazards can be closed out by the application of one of the three principles but it is likely that, for most major projects, a combination of all three will be used. Any risk assessment conducted under the CSM RA should always be proportionate to the extent of the risk being assessed.

3.29 The CSM RA has been introduced to ensure that levels of safety are maintained or improved when and where necessary and reasonably practicable, in accordance with the requirements of the Railway Safety Directive (2004/49/EC). Applying one or more of the three risk acceptance principles correctly for all identified hazards means that the risk has been reduced to an acceptable level. In these circumstances, ORR will not normally require further evidence that the residual risk is acceptable.

### Codes of Practice

3.30 Standards and rules have to meet all the following criteria to be used as a code of practice for the risk management process:
be widely accepted in the railway sector or otherwise justified to the assessment body;

- be relevant for the control of the specific hazard; and

- be available to an assessment body so that it can:
  - assess the suitability of the how the CSM RA is applied and the results of applying it; or
  - mutually recognise any safety assessment report on the same system (see paragraph 4.8).

3.31 Standards and rules that are widely accepted in the railway sector include

- TSIs or other mandatory European standards, for example those used in other EC verifications;
- notified national safety rules;
- notified national technical rules (NNTRs); and
- Euro standards or ISO standards.

3.32 Domestic or UK standards can also be used where they meet the requirements in paragraph 3.30 and are not in conflict with mandatory standards. In particular, Railway Group Standards (RGSs) are widely acknowledged in the UK railway industry. There are a number of other domestic standards that are available to all railway actors that could be considered as codes of practice in certain circumstances such as

- **ATOC standards** for passenger rail services or passenger rail vehicles;
- Rail Industry Company Standards;
- codes of practice relating to plant produced by the Mechanical and Electrical Engineers Networking Group for the rail industry; or
- relevant British Standards issued by the [British Standards Institution](https://www.britishstandards.co.uk); or
- other rail industry standards.

3.33 This list is not exhaustive.

3.34 It is also possible to use standards or codes of practice from other sectors, for example aviation and maritime, but these have to be justified and be acceptable to the assessment body (see paragraphs 3.65 - 3.80). The proposer will have to demonstrate that they are effective in controlling the risks from the relevant hazards in a railway context.

3.35 To be satisfied that a code of practice is relevant for the control of the specific hazards in the system, the proposer needs to
a) know what the hazards are;

b) be able to demonstrate that the code(s) of practice are relevant to the hazards; and

c) be able to demonstrate that application of the code(s) of practice control the hazards.

3.36 In evaluating whether a code of practice controls one or more of the hazards, proposers will need to check, with the support of other affected parties, that it covers the intended application of the system under assessment.

3.37 Deviations from codes of practice are possible where the proposer can demonstrate that at least the same level of safety will be achieved. Mandatory standards such as TSIs and Railway Group Standards include a process for deviating from them. For example, a Railway Group Standard deviation certificate could be used as part of the demonstration that the system maintains the same level of safety.

3.38 Most non-mandatory standards do not have a process for deviating from them. If one or more conditions of the code of practice are not fulfilled, the proposer may have to conduct an explicit risk estimation on those hazards where the code of practice is not relevant for the control of the hazards in the system under assessment. Alternatively, other codes of practice or reference systems could be used.

Reference systems

3.39 Reference systems can be used to derive the safety requirements for the new or changed system. For an existing system to be used as a reference system, a proposer needs to demonstrate that

- it has been proven in use and has an acceptable safety level;
- it is accepted in the Member State where the change is to be introduced; and
- the system being assessed is used under similar functional, operational and environmental conditions and has similar interfaces as the reference system.

3.40 For technical changes, it is unlikely that evidence of in-service history alone can prove that a high integrity system has an acceptable safety level, given the low failure rates required of such systems. Evidence that sufficient safety engineering principles have been applied in the development of the reference system will need to be confirmed for each new application.

3.41 The proposer must use the support of other affected parties to analyse whether one; several; or all hazards are appropriately covered by a similar reference system. If the reference system meets the requirements in paragraph 3.39, and those in paragraph 3.40 for technical changes, the hazards and associated risks covered by that system are considered as acceptable. If there are deviations, the safety requirements can
still be used for the hazards that are covered by the reference system, providing the same level of performance can be demonstrated. This may involve further risk assessment and evaluation. If the same performance or better cannot be reached, additional safety measures need to be identified by applying one of the other two risk acceptance principles.

**Explicit risk estimation**

3.42 Explicit risk estimation is an assessment of the risks associated with hazard(s), where risk is defined as a combination of the rate of the occurrence of the hazard or hazardous event causing harm (the frequency) and the degree of severity of the harm (the consequence).

3.43 The estimation can be qualitative, semi-quantitative or quantitative. The choice will be determined by factors such as the availability of quantitative data and confidence in such data. Any analysis should be proportionate to the potential risks. Any risk assessment should follow a systematic and structured process.

3.44 A typical risk assessment process in the UK rail industry for the type of projects that are likely to be significant would be

- identifying the hazardous events which have the potential to cause injury or death to
- passengers;
- workers; or
- members of the public who are directly or indirectly exposed to the technical, operational, or organisational change being assessed;
- identifying the precursors (i.e. the component, sub-system or system failures, physical effects, human error failures or operational conditions), which can result in the occurrence of each hazardous event;
- identifying the control measures that are in place to control or limit the occurrence of each precursor that cannot be eliminated;
- estimating the frequency at which each precursor and hazardous event can occur;
- estimating or analysing the consequences in terms of injuries and fatalities that could occur for the different outcomes that may follow the occurrence of a hazardous event;
- estimating the overall risk associated with each hazardous event;
- identifying any additional control measures required to ensure that risk is reduced so far as is reasonably practicable; and
providing clear and comprehensive documentary evidence of the methodologies, assumptions, data, judgements and interpretations used in the development of the risk assessment and the analysis of its results (The results may also need to be accompanied by sensitivity and uncertainty analyses, particularly where the assessment is quantitative and where different safety measures need to be evaluated).

3.45 Explicit risk estimation can be used where

- a proposer is unable to address the hazards identified in the hazard identification stage of the risk management process via a code of practice or comparison with a reference system;
- deviations are necessary from codes of practice or reference systems; or
- a proposer needs to analyse the hazards and evaluate design principles or safety measures.

3.46 The CSM RA does not impose any specific tools and techniques to be used in an explicit risk estimation. But proposers may find the following key documents produced by the UK rail industry or standards committees useful:

- RSSB guidance on the use of cost-benefit analysis when determining whether a measure is necessary to ensure safety so far as is reasonably practicable
- GE/GN8640 - Guidance on Planning an Application of the Common Safety Method on Risk Evaluation and Assessment
- GE/GN8641 - Guidance on system definition
- GE/GN8642 – Rail Industry Guidance Note on hazard identification and classification
- GE/GN8643 – Rail Industry Guidance Note on risk evaluation and risk acceptance
- GE/GN8644 – Rail Industry Guidance Note on safety requirements and hazard management
- GE/GN8645 - Guidance on independent assessment
- RSSB guidance: Taking safe decisions
- EN 50126:1999 Railway applications – The specification and demonstration of reliability, availability, maintainability and safety (RAMS) applicable to electro and electro-mechanical subsystems
Risk acceptance criteria for explicit risk estimation

3.47 Risk acceptance criteria (RAC) are used to judge whether the risk is sufficiently reduced to allow the proposer to accept and implement the change. RAC can be based on domestic or European legislation. For the UK, this will mean that risks should be reduced ‘so far as is reasonably practicable’ (see ORR SFAIRP guidance).

Box 1: Revision of the CSM RA

The CSM RA is being revised to provide additional risk acceptance criteria to be used as design targets for technical systems (RAC-TS). To avoid confusion between the RAC-TS and any other type of risk acceptance criteria (e.g. operational or organisational RAC) used in risk assessments, the RAC-TS terminology is being changed to ‘CSM design targets’ (CSM-DT) for technical systems.

The guidance below relates to the existing CSM RA but will be amended to reflect the changes in the revised CSM RA once it comes into force later in 2015.

3.48 An important exception relates to the RAC for technical systems (RAC-TS) in the CSM RA. Proposers should first consider

- whether the change relates to a technical system for which the failure of functions has a direct potential for a catastrophic consequence; and, if so
- if the change needs to be mutually recognised by other Member States or the proposer wishes to use the RAC-TS as the acceptance criteria.

3.49 If both apply and the proposer can demonstrate that the railway sub-system being assessed has a failure rate no greater than $10^{-9}$ per operating hour, then that sub-system must be mutually recognised in other EU Member States. This is providing that the operating conditions and interfaces in those countries are the same as those assumed in the analysis of the sub-system (with the exception at paragraph 3.51).

3.50 Demonstrating compliance with the RAC-TS means that the proposer does not have to undertake further assessments to show that risk has been reduced so far as is reasonably practicable.
3.51 The CSM RA allows the application of a less demanding risk acceptance criterion for these functions if the proposer can show that the national safety level in the Member State can be maintained. This can be done by showing that the railway sub-system complies with domestic risk acceptance criteria. In these circumstances, if the railway sub-system is subsequently put on the market or operated in another Member State, further risk analysis may be required. In the UK, this means the proposer will need to demonstrate that the risk is reduced so far as is reasonably practicable.

3.52 It is possible for an EU Member State to notify a national rule to ERA which would require a more demanding criterion than $10^{-9}$ per operating hour. The UK has no such national rule and at the time of publication, our understanding is that no other Member State had notified a rule.

Hazard record

3.53 The proposer has to create and maintain a hazard record for the system (or part system) that is to be changed. Its purpose is to track progress of the risk assessment and risk management process for the project. The CSM RA requires that it contains certain information but does not mandate any particular format.

3.54 The hazard record should concentrate on key issues. To aid transparency and consistency, it needs to contain the safety measures relating to the identified hazards and the assumptions taken into account in the definition of the system. It needs to include details of the risk assessment principles used and the actors in charge of controlling each hazard.

3.55 When the change has been ‘accepted’ by the proposer, and is successfully embedded in the system, the hazard record should be integrated by the IM or RU operating the system into its SMS. This may be examined by the national safety authority (NSA) as part of its inspection of a duty holder’s SMS.

3.56 The hazard record itself should be updated if

- other significant changes occur that affect the system;
- a new hazard is discovered;
- there are new accident and incident data; or
- assumptions about the system are changed.

3.57 The hazard record, if kept updated, may also be of value where the system is later used as a reference system.

3.58 There may be more than one hazard record if there are several bodies participating in the change. If separate hazard records are maintained during the project, the proposer is responsible for co-ordinating the production of an overall record.
Other documentation

3.59 The CSM RA places some minimum requirements on proposers to document certain information to assist the assessment body. These are

- a description of the organisation and the experts appointed to carry out the risk assessment process;
- the results of the different phases of the risk assessment and a list of all the necessary safety requirements to be fulfilled in order to control the risk to an acceptable level;
- evidence of compliance with all the necessary safety requirements; and
- all assumptions relevant for system integration, operation or maintenance, which were made during system definition, design and risk assessment.

Demonstration of system compliance

3.60 The proposer ‘accepts’ the change in the system and is responsible for its safe integration and operation in the wider railway system. This means ensuring that the system is designed, validated and accepted against the safety measures identified to control the hazards. Before acceptance, the proposer needs to demonstrate that the risk assessment principles have been correctly applied and that the system complies with all specified requirements. The proposer has overall responsibility for coordinating and managing the demonstration that the safety requirements are met. Other organisations involved will need to demonstrate that they have met the safety requirements and implemented safety measures at the lower level for the part of the system which they are responsible.

3.61 The proposer allocates the safety requirements to each part of the system that was defined in the system definition, but these can also be transferred to other organisations. If that happens, it should be recorded as such in the hazard record. Contracts may be required to reflect these agreements.

3.62 Many hazards, and the risks arising, will be at shared interfaces and cooperation will be needed to ensure that such risks are properly assessed and controlled.

3.63 The demonstration of compliance can involve further activities including causal analyses, testing, etc. It is also possible that new hazards may be identified during the validation phase which will need to be analysed further. Where a non-compliance with safety requirements is discovered, then the proposer must be notified. The proposer must then further notify others who are affected and responsible for the same or similar subsystems so that they can take the appropriate action.
Independent assessment

3.64 The CSM RA requires an independent assessment of

- how the risk management process is applied; and
- the results from the risk management process.

3.65 An assessment body must carry out the independent assessment.

3.66 The proposer is able to choose (subject to certain restrictions) the assessment body, unless there is a national rule in an EU Member State that requires certain bodies or persons to be used. There is no such national rule in the UK.

3.67 The proposer is required to appoint an assessment body at the earliest appropriate stage of the risk assessment process. However, ORR recommends that the assessment body is involved from the beginning of the project so that it can monitor the development of the hazard record, consider other relevant material (such as a safety plan) and possibly ask to observe tests. This may also include the detailed design stage or the manufacturing stage of the project.

3.68 The assessment body must meet the criteria set out in the CSM RA (included in this guidance at Annex 2). It must be either accredited, recognised, or an NSA. However, if the proposer does not require the significant change to be mutually recognised in one or more other EU Member State the CSM RA allows the proposer to appoint an assessment body meeting relaxed criteria agreed by the NSA. ORR has developed relaxed criteria for the UK and these are set out in Annex 3 of this guidance. A proposer (or assessment body) wishing to use the relaxed criteria may do so without further recourse to ORR. However, the proposer must provide ORR with details of any assessment body it engages which makes use of the relaxed criteria. See paragraphs 3 – 7 of Annex 2 for further details on the relaxed criteria.

3.69 The proposer can appoint an assessment body external to the organisation or an in-house assessment body. Factors that enable the proposer to demonstrate that an in-house assessment body is independent include

- different line management;
- no involvement with the development of the safety measures associated with the system under assessment; and
- freedom from undue commercial influence or bias.

3.70 The assessment body can be made up more than one organisation.

3.71 The scale and complexity of any given project may determine whether an external or in-house assessment body is used. For more complex projects, or those where the
proposer is unfamiliar with the technical analytical skills needed for the assessment, access to external independent assessment may be needed.

3.72 The process for taking the decision about use of internal or external assessment bodies should be recorded. Relevant factors include

- evidence to satisfy the proposer that the assessment body is independent and competent;
- absence of financial pressure or incentives on the assessment body (noting that the proposer cannot control financial pressure or incentives from third parties);
- checks that the assessment body has civil liability insurance, if it is an external organisation; and
- appropriate policies relating to confidentiality rules, if the assessment body is an external organisation.

3.73 At the conclusion of the independent assessment, the assessment body produces a safety assessment report and this should support the proposer in taking the decision on the safety of the system. If the proposer disagrees with any part of the safety assessment report it must keep a record of this with clear justification for its disagreement.

**Declaration by the proposer**

3.74 When the proposer receives the safety assessment report at the end of the risk management process it must produce a written declaration confirming that all identified hazards and associated risks are controlled to an acceptable level.

3.75 If the change to the system requires an authorisation for placing in service the proposer’s declaration will be accepted by the

- NoBo when delivering a conformity certificate (unless it justifies and documents its doubts about the assumptions made or the appropriateness of the results from the assessment); and
- NSA in its authorisation decision (unless it can demonstrate the existence of a substantial safety risk).

3.76 If the change to the system does not require an authorisation for placing in service, then the proposer’s declaration must be kept as part of its records.

**Avoiding duplication of assessment processes**

3.77 There are a number of assessment processes required under different laws:

- assessment of conformity with TSIs (by a NoBo);
- assessment of conformity with NNTRs (by a DeBo);
- assessment of safety certificates for RUs (by an NSA);
- assessment of safety authorisations for IMs (by an NSA);
- independent assessment under the CSM (by an assessment body); and
- assessment of the system of maintenance of ECMs (by a certification body).

3.78 ORR’s position is that there should not be duplication when these processes are carried out, and there are opportunities for businesses to avoid duplication by being aware of the following points:

- A NoBo can act as an assessment body as long as it meets the criteria in the CSM RA. So, if the significant change concerns sub-systems that are covered by TSIs, it is possible to appoint a NoBo that meets the criteria for independent assessment so that it can carry out the CSM assessment as well as the assessment of conformity with TSIs. Similarly it is possible to appoint a DeBo that meets the criteria for independent assessment so that it might carry out the CSM assessment as well as the assessment of conformity of NNTRs.

- If ORR has issued a safety certificate or authorisation, then the assessment body does not need to examine the general processes for risk assessment during the application of the CSM RA, but should look only at how the processes are applied for the specific change. However, if the assessment body finds that there are issues with the general processes for risk assessment these should be reported to the NSA and the proposer.

- If the proposer does not have a safety certificate, safety authorisation, or ECM certificate, then quality management systems may give the assessment body assurance about the general processes for change management and risk assessment within the proposer’s organisation.

- If the proposer does not have a safety certificate or safety authorisation, the proposer should as far as possible apply equivalent change management and risk assessment processes to those of the duty holder (IM or RU) who is likely to introduce that significant change onto the railway system.

3.79 The CSM RA allows, but does not oblige, NSAs to act as an independent assessment body when a significant change also concerns

- an authorisation for placing a structural sub-system or vehicle into service; or
- an update or revision of a safety certificate or safety authorisation.

3.80 ORR does not intend to act as an assessment body in these circumstances.
Further information and references

**ORR guidance**

ORR guidance on assessing whether risks on Britain's railways have been reduced so far as is reasonably practicable

**Industry guidance**

RSSB guidance: Taking Safe Decisions

RSSB guidance on preparing and using company risk assessment profiles
http://www.safetyriskmodel.co.uk/Pages/default.aspx

RSSB guidance on the management of change (including six complementary Rail Industry Guidance Notes)
http://www.rssb.co.uk/improving-industry-performance/management-of-change

RSSB guidance on the use of cost-benefit analysis when determining whether a measure is necessary to ensure safety so far as is reasonably practicable
4. The role of the assessment body

What is the role of the assessment body?

4.1 The assessment body is appointed by a proposer to carry out independent assessment of

- how the risk management process in the CSM RA is applied; and
- the results obtained from the risk management process.

4.2 This could involve a sample or vertical audit to check

- the correct application of the processes to the specific change (but not the question of whether the change is significant or not);
- adequate definition of the part of the system that is being changed;
- robust process for hazard identification and that the hazard identification appears to be complete;
- justified classification of hazards associated with a broadly acceptable risk;
- correctly applied risk acceptance principles (see paragraph 3.26);
- satisfactory demonstration of compliance with safety requirements;
- the hazard record contains the right information about: the hazards and their associated safety measures; and the responsibilities of the main parties involved for those hazards; and
- hazards and the associated safety measures are closed and validated.

4.3 To carry out the independent assessment, the assessment body must

- ensure that it has a thorough understanding of the significant change based on the documentation provided by the proposer;
- conduct an assessment of the processes used for managing safety and quality during the design and implementation of the significant change, if those processes are not already certified by a relevant conformity assessment body; and
- conduct an assessment of the application of those safety and quality processes during the design and implementation of the significant change.

4.4 Once the assessment body has completed its assessment as described in paragraph 4.3 it must deliver the safety assessment report as described below.

4.5 The proposer is required to appoint an assessment body at the earliest appropriate stage of the risk assessment process. However, ORR recommends that the
The assessment body is involved from the beginning of the project so that it can monitor the development of the hazard record, consider other relevant material (such as a safety plan) and possibly ask to observe tests. This may also include the detailed design stage or the manufacturing stage of the project. The assessment body must ensure that its involvement in these activities does not jeopardise its independence. The assessment body’s role in oversight does not remove the responsibility of the proposer for overall safety. In all cases the proposer remains responsible for safety and takes the decision to implement the proposed change.

Safety assessment report

4.6 At the conclusion of the assessment, the assessment body produces a safety assessment report and this should support the proposer in taking the decision on the safety of the system. If the proposer disagrees with any part of the safety assessment report it must keep a record of this with clear justification for the disagreement.

4.7 If the change to the system also requires an authorisation for placing in service, then the safety assessment report should also be submitted to the NSA with the technical file and other documentation. The NSA will take this into account in considering the authorisation. If there is an authorisation for placing in service and the proposer disagrees with any part of the safety assessment report it must keep a record of this on the technical file with clear justification for the disagreement.

4.8 Where an assessment body has delivered a safety assessment report, that report must be mutually recognised by any other assessment body, providing the system is used under the same conditions and equivalent risk acceptance criteria are applied.

4.9 In accordance with Annex III of the CSM RA the safety assessment report must contain as a minimum the following information:

a) identification of the assessment body;

b) the independent assessment plan;

c) the definition of the scope of the independent assessment as well as its limitations;

d) the results of the independent assessment, including in particular:

i) detailed information on the independent assessment activities for checking the compliance with the provisions of the CSM RA; and

ii) any identified cases of non-compliance with the provisions of the CSM RA and the assessment body’s recommendations; and

e) the conclusions of the independent assessment.
5. Miscellaneous requirements for specific duty holders

Railway undertakings and infrastructure managers

5.1 RUs and IMs should undertake periodic audits of the application of the CSM RA as part of their SMS arrangements.

5.2 As part of their annual safety report to ORR, RUs and IMs must include
  - a summary of experience in applying the CSM RA; and
  - a summary report on the decisions related to significance of change.

Entities in charge of maintenance

5.3 All ECMs should undertake periodic audits of the application of the CSM RA as part of their maintenance system as referred to in regulation 18A of ROGS.

5.4 As part of their annual maintenance report to the certification body, ECMs responsible for freight wagons must include a summary of experience in applying the CSM process.

5.5 ECMs responsible for vehicles that are not freight wagons must also share their experience with ERA, which will coordinate the sharing of this information with NSAs.

Supervision by national safety authorities

5.6 ORR, or the safety authority in another EU Member State, may check the process that
  - RUs;
  - IMs; and
  - ECMs not responsible for freight wagons but registered in the national vehicle register,

  have used to determine how to apply the CSM RA. Proposers must therefore keep a record of how they have arrived at their decisions, particularly in relation to the test for significance.

5.7 The process that freight wagon ECMs use may be checked by ORR, or another certification body, as part of its surveillance activities.
Annex 1: Determining the significance of a change

1. When a proposed change has an impact on safety, the CSM RA requires the proposer to decide, by expert judgement, the significance of the change based on stated criteria (Article 4[2]).

2. These criteria are:
   - **failure consequence**: credible worst-case scenario in the event of failure of the system under assessment, taking into account the existence of safety barriers outside the system;
   - **novelty** used in implementing the change: this concerns both what is innovative in the railway sector, and what is new just for the organisation implementing the change;
   - **complexity of the change**;
   - **monitoring**: the inability to monitor the implemented change throughout the system life-cycle and take appropriate interventions;
   - **reversibility**: the inability to revert to the system before the change;
   - **additionality**: assessment of the significance of the change taking into account all recent safety-related modifications to the system under assessment and which were not judged as significant.

3. The CSM RA does not prescribe how to use the criteria, or the priority or weighting given to any of them. The method described here may be useful to proposers and provide some structure for taking these decisions.

Methodology for using the criteria

4. It is likely that the proposer will need to undertake some preliminary work to identify and understand the relevant hazards before applying the significance test. A good overall understanding of all the hazards will help with identifying the most appropriate risk acceptance principle.

5. For a significant change the proposer must produce “a written declaration that all identified hazards and associated risks are controlled to an acceptable level”. The proposer must also be confident that risk is controlled to an acceptable level if a change is not significant.

6. Taking the criteria together, it would be reasonable to conclude that a change is not significant if the proposer
is confident that it has identified all significant hazards (i.e. those that give rise to non-negligible risk); and either

- knows how it will control the associated risk to an acceptable level; or
- is confident that it will be straightforward to identify and implement the measures required to control the associated risk to an acceptable level.
7. If the proposer chooses to apply the criteria more explicitly, it is possible to group and sequence the criteria in a way that assists their application. Figure 3 shows a flowchart, which illustrates a proposed application of the criteria.

**Additionality**

8. Additionality is considered first, as this defines the scope of the change that is to be assessed.

9. When a change ‘A’ is proposed, other recent changes (B, C, …) should be considered and, if necessary, included within the scope of the change subject to the test of significance (that is, if necessary, the change whose significance is to be decided is A + B + C …)

10. Additionality can be described as considering other changes that have been made since the entry into force of the CSM RA (30 April 2013) or since the last application of the risk management process (whichever is later).

11. Once a change is established and is working successfully, the change can be regarded as fully implemented and does not need to be included in the consideration of additionality.

12. This would achieve the intention of the CSM RA (which refers to ‘recent’ safety-related changes), whilst being practical and not imposing an arbitrary time limit.

**Novelty and complexity**

13. Novelty and complexity can be thought of as measures of the uncertainty of outcome or the likelihood that the proposed change, once implemented, will or will not behave as predicted. Clearly, the more novel and the more complex a change is, the higher the likelihood that it may behave in an unpredicted, and possibly undesirable, way. Therefore, the more novel and the more complex a change is, the more significant it is likely to be.

**Failure consequence**

14. Failure consequence (or consequence of failure) is straightforward. This is asking the question “What is the worst that could happen if the system behaves in an undesirable way following the introduction of the proposed change?”

**Combining uncertainty of outcome and consequence of failure**

15. Risk is usually understood to be likelihood x consequence. Similarly, ‘uncertainty of outcome’ x ‘consequence of failure’ can be thought of as a factor measuring the potential scale of a change with respect to safety. The ‘uncertainty of outcome’ is judged by reference to novelty and complexity.
Judging significance

16. It is possible to develop a simple matrix, to assist in making a judgement about whether a proposed change is ‘significant’ (high uncertainty, high consequence) or ‘non-significant’ (low uncertainty, low consequence) or where the additional criteria (ability to monitor and reversibility) need to be applied to make a final decision.

Monitoring and reversibility

17. Monitoring and reversibility are additional criteria that should be considered where the decision about whether the change is ‘significant’ or ‘non-significant’ cannot be made on the basis of the ‘uncertainty of outcome x consequence of failure’ test.

18. The criterion in relation to monitoring is ‘the inability to monitor the implemented change throughout the system life-cycle and take appropriate interventions’. In essence, this is asking the question “Can I see what is going on and react in time?”
19. But a more complex question to ask when thinking about monitoring as a criterion is “Is it possible and practicable to introduce a system of monitoring that gives sufficient warning early enough to permit effective intervention to prevent or mitigate any hazard arising from the change I have made?” Note that it is not sufficient, for example, to simply install monitoring equipment. Supporting operational procedures are necessary to take note of, and react to, warnings generated by the equipment.

20. Reverting to the system before the change is one possible intervention, though one that is not usually available in the case of engineering change. It should therefore be thought of in the wider sense of:

   The ability (or otherwise) to intervene in a timely manner to prevent or mitigate any hazard arising from the change you have made, when such intervention is indicated by the monitoring arrangements.

21. If it is not possible to adequately monitor the effects of a change so as to be able to ‘take appropriate interventions’; or if it is impossible to reverse the effects of a change, it is likely that the change should be considered significant.

22. An example of a possible matrix is shown in Figure 4. Others (3 x 3 or 5 x 5 for example) are possible.
Annex 2: Criteria for assessment bodies

1. The assessment body must be either
   - accredited by a national accreditation body; or
   - recognised by a recognition body (see paragraph 8 below); or
   - the national safety authority (NSA).

2. In the UK the national accreditation body (the United Kingdom Accreditation Service) has been asked to establish an accreditation scheme.

3. Alternatively, a proposer may appoint an assessment body that meets the relaxed criteria in the CSM RA (Article 12) if a significant change does not need to be mutually recognised in one or more other EU Member State. (Mutual recognition is explained in paragraph 13 of Annex 4). The benefit of this is where the appointment of an accredited or recognised assessment body would be less economical. For example, it could be used for changes that affect only the domestic market (parts of the railway system where international trains would never operate). However, the downside is that using the relaxed criteria does not contribute to establishing mutual trust in the same way that accreditation and recognition does. It does not provide the same level of assurance for the different parts of the railway system concerning the independent assessment of the application of the risk management process and the results obtained. The safety assessment report of an assessment body using the relaxed criteria cannot therefore benefit from mutual recognition enjoyed by accredited or recognised assessment bodies (see paragraph 13).

4. An assessment body making use of the relaxed criteria must meet at least the competency, independence and impartiality requirements in Annex II of the CSM RA when the risk assessment for a significant change is not to be mutually recognised. Other requirements may be relaxed in agreement with the NSA in a non-discriminatory way. ‘Non-discriminatory’ means that any assessment body fulfilling the same relaxed criteria and requirements should be allowed to be appointed on the considered significant change.

5. ORR has developed, in consultation with industry, the relaxed criteria set out in Annex 3 of this guidance. An assessment body, or a proposer selecting an assessment body, may use the relaxed criteria without further recourse to ORR. It is for
   - the assessment body to satisfy itself that it meets the relaxed criteria; or
   - the proposer selecting an assessment body to satisfy itself that the assessment body meets the relaxed criteria.
6. ORR will not provide an approval role in a proposer’s decision to appoint an assessment body meeting the relaxed criteria. However, the proposer must provide ORR (rogsguidance@orr.gsi.gov.uk) with details of any assessment body it engages which makes use of the relaxed criteria. We will publish details of the assessment body on our website. The proposer’s determination of whether or not an assessment body meets the relaxed criteria in Annex 3 may be checked by ORR as part of its supervision role (see Chapter 5).

7. Even if a proposer does not require a significant change to be mutually recognised in one or more other EU Member State, it may decide to choose an accredited or recognised assessment body over using the relaxed criteria.

8. An assessment body may be accredited or recognised for one, several or all of the areas of competence listed in Box 2.

Box 2: Accreditation and recognition

1. The assessment body has to be accredited or recognised for the different areas of competence within the railway system, or parts of it, for which an essential safety requirement exists. This includes the area of competence involving the operation and maintenance of the railway system.

2. The assessment body has to be accredited or recognised for assessing the overall consistency of the risk management and the safe integration of the system under assessment into the railway system as a whole. This must include competence of the assessment body in checking the following:

   **Organisation**
   
   The arrangements necessary to ensure a coordinated approach to achieving system safety through a uniform understanding and application of risk control measures for sub-systems.

   **Methodology**
   
   Evaluation of the methods and resources deployed by various stakeholders to support safety at sub-system and system level.

   **Technical aspects**
   
   The technical aspects necessary for assessing the relevance and completeness of risk assessments and the level of safety for the system as a whole.

9. The CSM RA allows for recognition of an assessment body by the EU Member State or NSA as follows:

   - recognition by the Member State of:
     - an entity in charge of maintenance (ECM);
an organisation or part of it;

or an individual;

- recognition by the NSA of the ability of:
  - an organisation or part of it; or
  - an individual
  to conduct independent assessment through the assessment and supervision of the SMS of an RU or an IM;

- recognition by the NSA as ECM certification body of the ability of:
  - an organisation or part of it; or
  - an individual
  to conduct independent assessment through assessment and surveillance of the system of maintenance of an ECM; or

- recognition by a recognition body designated by the Member State of the ability of:
  - an ECM;
  - an organisation or part of it; or
  - an individual
  to conduct independent assessment.

10. In any of the cases above the person acting as assessment body must be sufficiently independent from the project that it is engaged in (see paragraphs 3.64 to 3.72).

11. ORR, an NSA in another EU Member State, or an ECM certification body has to accept accreditation, or recognition by a EU Member State, as proof of the ability of:

- an RU to act as an assessment body when granting a safety certificate;
- an IM to act as an assessment body when granting a safety authorisation; or
- an ECM to act as an assessment body when granting an ECM certificate.

12. ORR has to accept accreditation or recognition in another EU Member State as proof of the ability of an organisation to act as an assessment body under the CSM RA. This includes when the CSM RA is used when authorising the placing into service of a sub-system.
Can all assessment bodies work EU-wide?

13. The safety assessment report of any assessment body accredited or recognised in an EU Member State in accordance with the requirement of the CSM RA must be recognised across the EU.

14. An assessment body accredited in an EU Member State in accordance with the requirements of the CSM RA can carry out independent assessment in the whole of the EU.

15. An NSA recognised by its Member State as an assessment body under the CSM RA cannot provide independent assessment in another EU Member State, unless there is a bilateral agreement between the two Member States.

16. An assessment body recognised under the CSM RA cannot provide independent assessment in another EU Member State. However, the expectation from ERA is that these types of assessment bodies do not carry out independent assessment outside their own organisation.

17. An assessment body using relaxed criteria cannot provide independent assessment in another EU Member State.
Annex 3: Relaxed criteria where a significant change is not to be mutually recognised

Introduction

1. Article 12 of the CSM RA requires that where the risk assessment for a significant change is not to be mutually recognised, the proposer shall appoint an assessment body meeting at least the competency, independency and impartiality requirements of Annex II. The other requirements of paragraph 1 in Annex II (see Box 3) may be relaxed in agreement with the national safety authority in a non-discriminatory way.

2. The objective is to avoid unnecessary costs being incurred by a proposer when engaging an assessment body in a risk assessment for a significant change that would never require mutual recognition in one or more other EU Member State.

3. The logic, therefore, is that it is the requirements of ISO/EN17020:2012 which are to be relaxed, and also paragraphs 2, 3 and 4 of Annex II of the CSM RA.

4. ISO/EC 17020:2012 contains the following elements:
   - Section 1: Scope;
   - Section 2: Normative References;
   - Section 3: Definitions;
   - Section 4: General Requirements

Box 3: Paragraph 1 of Annex II of the CSM RA

Paragraph 1 of Annex II says the following:

“The assessment body shall fulfil all the requirements of the ISO/IEC 17020:2012 standard and of its subsequent amendments. The assessment body shall exercise professional judgment in performing the inspection work defined in that standard. The assessment body shall fulfil both the general criteria concerning competence and independence in that standard and the following specific competence criteria:

(a) competence in risk management: knowledge and experience of the standard safety analysis techniques and of the relevant standards;

(b) all relevant competences for assessing the parts of the railway system affected by the change;

(c) competence in the correct application of safety and quality management or in auditing management systems.”
5. Sections 1, 2, 3 and 5 are largely administrative and are concerned with what the standard covers and what the relevant definitions are, as such they may be relaxed within the terms of Article 12.

6. Some elements of Sections 7 and 8 may be relaxed provided that the requirements in paragraph 1(a) – (c) of Annex II the CSM RA are met.

**Sections of ISO/IEC 17020:2012 which must be fulfilled**

7. Section 4 (General Requirements) covers independence and impartiality; Section 6 on Resource Requirements deals with the competence aspects of employing the correct personnel; and Annex A deals with independence requirements for inspection bodies. These sections of the standard cannot therefore be relaxed.

8. Using the principles outlined below, it is possible to create a proportionate assessment structure which meets industry needs for assessing a significant change where mutual recognition is not required.

**Principles**

*(i) Facilities and Equipment*

The assessment body shall have directly available to it, or should be able to access, all facilities and equipment required to carry out a proper assessment.

This means that the assessment body shall either have, or be responsible for, all the facilities and equipment needed to carry out an assessment, including anything which is required to be calibrated before use, or it shall have the ability to contract for such services as are required to carry out a full and proper assessment. In this latter case the assessment body or its parent organisation will have to conduct all necessary checks to make sure that the services provided by third parties meet the required quality.

*(ii) Sub-contracting*

An assessment body should carry out the assessments it is contracted to undertake. However, in some cases sub-contracting of specialist activities may be allowed.
This means that for this form of assessment the expectation is that the designated in-house assessment body would carry out assessments for the purposes of an assessment of a significant change that does not require mutual recognition. However, in some circumstances sub-contracting of specialist functions may be appropriate. If this route is taken the sub-contractor’s roles and responsibilities should be clearly specified and the assessment body should satisfy itself that the contractor is competent to carry out the specified duties.

(iii) Assessment Methods and Procedures

The assessment body should use assessment methods appropriate to the scale and extent of the change being assessed.

The assessment body should clearly set out the methods used and the reasoning behind the decision. The assessment body shall have documented instructions for carrying out assessments safely.

(iv) Handling samples and Items

The assessment body shall have in place appropriate procedures and processes for handling assessment samples and items.

There shall be appropriate documentation which allows for the accurate identification of samples and other items which are required as part of the assessment.

(v) Safety Assessment Reports

All safety assessment reports should be produced in a retrievable format and be in line with the format set out in the CSM RA.

If the report includes any information derived from work by sub-contractors this should be clearly specified.

(vi) Management Requirements

An assessment body should have in place an organisation and management structure appropriate to the scale and extent of the change being assessed.

This means having an organisation which allows the proper fulfilment of safety assessment functions. The organisation should be clearly set out and the relationships between the various functions involved described. There should be a designated competent manager in charge of the assessment team, with competent staff in that team and having appropriate job descriptions for the roles involved. There should be a robust document control system in place.

9. Annex B of the standard concerns inspection reports. As these are optional they could be omitted from the reports of an assessment body engaged in the risk assessment of a significant change which is not to be mutually recognised.
Annex 4: Guidance on organisational change

Purpose

1. This Annex provides high-level guidance on the application of the CSM RA when assessing significant organisational changes.

What is a significant organisational change?

2. It is a requirement of the CSM RA that, when making any technical system, operational or organisational changes which could impact on the safety of the operational railway system, consideration should be given to whether or not the change is 'significant' by applying the six criteria described in the CSM RA.

3. The reasons for the decision that a change is, or is not, significant must be documented. The documentation of this assessment is particularly important where it is decided that a change is not significant, as this may be required to be reviewed should the change be implicated in a safety incident in the future.

4. It is not possible to define explicitly what a significant organisational change is in terms of a particular type of change. A change that is significant for one company/circumstance may not be significant for another company/circumstance. Each change has to be assessed individually in the context in which it is being applied.

5. The first consideration is whether the organisational change is within the scope of the CSM RA – could it impact on the operational or maintenance processes of the railway system?

6. The second consideration is whether the change affects safety, either directly or indirectly. If the organisational change does not affect safety then no further consideration needs to be given in relation to the application of the CSM.

7. If an organisational change does affect safety, one method for assessing whether a change is significant is offered in Annex 1 of this guidance.

Assessing the change

8. The CSM RA presents three 'risk acceptance principles' by which the hazards associated with a significant change can be analysed and evaluated. These are:

   a) the application of codes of practice;
   b) a comparison with similar systems (reference systems); and
   c) an explicit risk estimation.
9. The most likely acceptance principle to be applied to significant organisational change is explicit risk estimation. This can be qualitative. Quantitative risk assessment of the proposed organisational change is not necessarily required.

10. Risk assessment associated with significant organisational changes is not an exact science; it is about managing and organising people, therefore a qualitative or semi-quantitative risk ranking method for assessing organisational changes should meet the requirements of the CSM RA.

11. Most companies already have structured safety validation processes for organisational changes within their existing SMSs which are likely to meet the requirements of the CSM RA. In broad terms for significant organisational changes this would include:

   a) definition of the extent of the change being made;
   b) preparation of disposition statements indicating where the safety responsibilities are transferred from one job description to the job description of the new role;
   c) checking that the new job roles specify the correct competency levels for the safety functions that have been transferred;
   d) carrying out a risk assessment commensurate with the scale of the change to determine the potential impact of the change and that adequate mitigation measures have been put in place;
   e) recording and maintaining the outputs of the risk assessment in a hazard record;
   f) establishing the go-live criteria that need to be achieved before the organisational change is implemented; and
   g) documentation of records relating to (a) to (f) above.

Risk Acceptance criteria

12. The quantitative risk acceptance criteria defined in paragraph 2.5.4 of Annex I of the CSM RA only apply to significant changes relating to technical systems and therefore do not have to be considered in the context of significant organisational changes.

Mutual recognition

13. One of the main principles introduced by the CSM RA is that of mutual recognition. This principle is designed to reduce industry costs by not having to redo risk assessment work when the change can be applied to more than one company in any EU Member State, i.e. once a significant change has been assessed and subject to an independent assessment by an assessment body, the change should be acceptable anywhere in the EU Member States without additional assessment providing the same application conditions apply.
Independent Assessment

14. The CSM RA requires that all significant changes, including organisational changes, are independently assessed by an assessment body, which produces a safety assessment report.

15. The role and requirements of an assessment body are described in Chapter 4 of this guidance. The key to a successful independent assessment is getting the assessment body involved at the early stages of the risk assessment process, including attendance at some or all of the workshops/safety review meetings, as long as independence is maintained and they don’t become involved in the design of the change. This will ensure that the assessment body has a good insight into the risk assessment process and the development of the hazard records. Early feedback from the assessment body can help in the development and refining of the risk assessment process being used.

16. The assessment body is required to review the adequacy of the risk assessment process used and determine if the conclusions of the assessment are reasonable based on the results obtained from the assessment. The assessment body does not sign off that the change being made is acceptable from a safety risk perspective. This remains the responsibility of the proposer of the change.

Documentation

17. All stages of the application of the CSM RA should be documented and the hazard record established for use through the implementation of the change.

Risk assessment process

18. There is no defined methodology currently available for risk assessment of organisational change. A qualitative risk assessment based on a structured workshop process and the management of a hazard record derived from the workshops should be adequate to meet the requirements of the CSM RA.

19. This Annex provides an overview of an approach that could be used, based on the risk assessment work that was done for the review of the organisational changes associated with the establishment of the South West Trains/Network Rail Wessex Alliance.

20. The purpose of the workshops would be to identify whether the organisational changes could introduce safety concerns/issues and consider the measures that need to be put in place to control/mitigate any increase in risk. The extent of the workshops depends on the scale of the change, the number of people affected and their role in influencing safety.
21. The workshop(s) will enable individuals who will be affected by the change to better understand the objectives of the change and provide proactive input to the consideration of the safety implications of the change and any additional mitigating measures. The method should involve:

a) clearly defining the change being made;

b) identifying who is affected by the change and needs to be consulted including:
   i) staff;
   ii) representative bodies e.g. trades unions;
   iii) interface organisations; and
   iv) other stakeholders

c) facilitating the structured workshop(s) involving representatives of the groups that could be affected by the change;

d) the independent assessor attending some or all or the workshops; and

e) development and maintenance of a hazard record, including the measures to be taken to mitigate the risk from each identified hazard and the current status of the implementation of the control measures.

22. The workshop(s) should be structured into topic areas that could be influenced by the organisational change rather than just a general brainstorming of the issues. The topic areas could include the potential influences on:

a) the way the SMS is implemented and managed;

b) the different risk areas such as train accident risk, station risk, on-train risk and infrastructure risk;

c) management of risk interfaces:
   i) incident/emergency management (on-track, at station, on-train);
   ii) degraded operations - for example, failed train and station safety (e.g. platform-train interface); and
   iii) safety reporting, safety meetings, risk reviews, accident investigation, etc.;

d) communications;

e) safety decision making;

f) operational strategy; and

g) maintenance strategy.
Identification of safety concerns

23. Attendees should be asked to brainstorm the safety concerns they perceive against each of the topic areas in relation to the proposed organisational changes. The use of post-it notes can be useful here to ensure that each attendee has the opportunity to note down their own perceived issues. This will assist the facilitator in the collation of similar safety concerns into agreed safety concern statements.

24. Given the difficulty in assigning meaningful likelihood and consequence rankings to each safety concern for organisational changes, a simple high, medium and low vulnerability ranking can be considered such as:
   a) High = Major concern – potential for significant degradation in safety;
   b) Medium = Some concern – potential for some degradation in safety; and
   c) Low = Minimal concern – unlikely to significantly affect safety but should be reviewed.

25. As each topic area is reviewed, participants should write their perceived safety concerns and associated vulnerability ranking onto individual post-it notes and place them on a flip chart/wall poster for the topic area divided into the high, medium and low vulnerability rankings.

26. Once all the post-it notes have been put on the relevant category poster the comments should be collated by the workshop facilitator and discussed by the group to produce agreed safety concern statements, including the overall perceived vulnerability ranking for each statement.

Identification of control measures

27. Having identified the safety concerns into agreed safety concern statements and their associated vulnerability rankings, the project team can develop a ranked hazard record. The relevant control/mitigation measures required to address each hazard can then be identified.

28. This can either be done in the workshop environment (if there are not too many safety concerns raised) or as a separate exercise by the project team and fed back to the participants for review.

29. The hazard record containing
   - the agreed safety concern statements with their associated vulnerability rankings;
   - control/mitigating actions;
   - actions required;
person(s) responsible for the actions; and

- the status of the actions

can then be managed throughout the implementation phase to ensure the identified control/mitigation measures are put in place.

30. A requirement that the actions from the hazard record relevant to the development and start-up phases are completed should be part of the go-live criteria necessary to be addressed before the organisational change is implemented.
## Annex 5: Glossary of terms and acronyms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Accreditation</td>
<td>An attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.</td>
</tr>
<tr>
<td>Actors</td>
<td>All parties which are, directly or through contractual arrangements, involved in the application of the CSM RA.</td>
</tr>
<tr>
<td>Advanced stage of development</td>
<td>When the proposer considers that the planning/construction stage of a project has reached a point where a change in the technical specifications would not be viable on economic, contractual, legal, social or environmental grounds.</td>
</tr>
<tr>
<td>Assessment body</td>
<td>The independent and competent external or internal individual, organisation or entity which undertakes investigation to provide a judgement, based on evidence, of the suitability of a system to fulfil its safety requirements.</td>
</tr>
<tr>
<td>ATOC</td>
<td>Association of Train Operating Companies</td>
</tr>
<tr>
<td>Catastrophic consequence</td>
<td>Fatalities and/or multiple severe injuries and/or major damage to the environment resulting from an accident.</td>
</tr>
<tr>
<td>Code of practice</td>
<td>A written set of rules that, when correctly applied, can be used to control one or more specific hazards.</td>
</tr>
<tr>
<td>DeBo</td>
<td>Designated Body</td>
</tr>
<tr>
<td>Designated Body</td>
<td>A person appointed under regulation 31 of RIR as a designated body.</td>
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</tbody>
</table>
ECM  Entity in charge of maintenance

Entity in charge of maintenance  Any person or organisation that is responsible for the safe maintenance of a vehicle and is registered as an ECM in the national vehicle register. This can include people or organisations such as transport undertakings, infrastructure managers, a keeper (usually the owner of a rail vehicle) or a maintenance organisation.

ERA  European Railway Agency

ETCS  European Train Control System

Functional sub-systems  Traffic operation and management; maintenance; and telematics applications for passenger and freight services.

Hazard  A condition that could lead to an accident.

Hazard identification  The process of finding, listing and characterising hazards.

Hazard record  The document in which identified hazards, their related measures, their origin and the reference to the organisation which has to manage them are recorded and referenced.

IM  Infrastructure Manager

Interfaces  All points of interaction during a system or subsystem life cycle, including operation and maintenance where different actors of the rail sector will work together in order to manage the risks.

Interoperability constituent  Any elementary component, group of components, subassembly or complete assembly of equipment that is incorporated or intended to be incorporated into a sub-
system upon which the interoperability of the rail system depends directly or indirectly; and the concept of a “constituent” covers both tangible objects and intangible objects such as software.

<table>
<thead>
<tr>
<th><strong>ISO/IEC 17020:2012</strong></th>
<th>An international standard which specifies requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>National accreditation body</strong></td>
<td>The sole body in a Member State that performs accreditation with authority derived from the State.</td>
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<tr>
<td><strong>National vehicle register</strong></td>
<td>A database of vehicles authorised or operated in Great Britain under RIR.</td>
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<tr>
<td><strong>NNTRs</strong></td>
<td>Notified National Technical Rules</td>
</tr>
<tr>
<td><strong>NoBo</strong></td>
<td>Notified Body</td>
</tr>
<tr>
<td><strong>Notified Body</strong></td>
<td>A body which is responsible for assessing the conformity or suitability for use of the interoperability constituents or for appraising the ‘EC’ procedure for verification of the sub-systems</td>
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<tr>
<td><strong>NSA</strong></td>
<td>National safety authority</td>
</tr>
<tr>
<td><strong>Proposer</strong></td>
<td>One of the following: (a) a railway undertaking or an infrastructure manager which implements risk control measures in accordance with Article 4 of Directive 2004/49/EC; (b) an entity in charge of maintenance which implements measures in accordance with Article 14a(3) of Directive</td>
</tr>
</tbody>
</table>
(c) a contracting entity or a manufacturer which invites a notified body to apply the ‘EC’ verification procedure in accordance with Article 18(1) of Directive 2008/57/EC or a designated body according to Article 17(3) of that Directive;
(d) an applicant for an authorisation for the placing in service of structural sub-systems.

RAC Risk acceptance criteria

Recognition An attestation by a national body other than the national accreditation body that the assessment body meets the requirements set out in Annex II to the CSM RA to carry out the independent assessment activity specified in Article 6(1) and (2).

Reference system A system proven in use to have an acceptable safety level and against which the acceptability of the risks from a system under assessment can be evaluated by comparison.

RGS Railway Group Standard

RIR Railways (Interoperability) Regulations 2011

Risk The frequency of occurrence of accidents and incidents resulting in harm (caused by a hazard) and the degree of severity of that harm.

Risk acceptance criteria The terms of reference by which the acceptability of a specific risk is assessed; these criteria are used to determine that the level of a risk is sufficiently low that it is not necessary to take any immediate action to reduce it further.

Risk acceptance principle The rules used in order to arrive at the conclusion whether or not the risk related to one or more specific
hazards is acceptable.

<table>
<thead>
<tr>
<th>Term</th>
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<tbody>
<tr>
<td>Risk analysis</td>
<td>Systematic use of all available information to identify hazards and to estimate the risk.</td>
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<tr>
<td>Risk assessment</td>
<td>The overall process comprising a risk analysis and a risk evaluation.</td>
</tr>
<tr>
<td>Risk estimation</td>
<td>The process used to produce a measure of the level of risks being analysed, consisting of the following steps: estimation of frequency, consequence analysis and their integration.</td>
</tr>
<tr>
<td>Risk evaluation</td>
<td>A procedure based on the risk analysis to determine whether an acceptable level of risk has been achieved.</td>
</tr>
<tr>
<td>Risk management</td>
<td>The systematic application of management policies, procedures and practices to the tasks of analysing, evaluating and controlling risks.</td>
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<tr>
<td>ROGS</td>
<td>Railways and Other Guided Transport Systems (Safety) Regulations 2006</td>
</tr>
<tr>
<td>RSSB</td>
<td>Rail Safety and Standards Board</td>
</tr>
<tr>
<td>RU</td>
<td>Railway Undertaking (also referred to as Transport Undertaking under ROGS)</td>
</tr>
<tr>
<td>Safe integration</td>
<td>The action to ensure that incorporating an element of a system into a bigger system does not create an unacceptable risk for the resulting system.</td>
</tr>
<tr>
<td>Safety</td>
<td>Freedom from unacceptable risk of harm.</td>
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<tr>
<td>Safety assessment report</td>
<td>The document containing the conclusions of the assessment performed by an assessment body on the system under assessment.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>Safety management system</td>
<td>The organisation and arrangements established by an infrastructure manager or a railway undertaking to ensure the safe management of its operations.</td>
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<tr>
<td>Safety measures</td>
<td>A set of actions either reducing the frequency of occurrence of a hazard or mitigating its consequences in order to achieve and/or maintain an acceptable level of risk.</td>
</tr>
<tr>
<td>Safety requirements</td>
<td>The safety characteristics (qualitative or quantitative) of a system and its operation (including operational rules) and maintenance necessary in order to meet legal or company safety targets.</td>
</tr>
<tr>
<td>SFRAIP</td>
<td>So far as is reasonably practicable</td>
</tr>
<tr>
<td>SMS</td>
<td>Safety management system</td>
</tr>
<tr>
<td>Structural sub-systems</td>
<td>Rolling stock; infrastructure; command control and signalling; and energy.</td>
</tr>
<tr>
<td>Sub-system</td>
<td>The whole, or as the context requires, part of a subdivision of the rail system as specified in sections 1(a) and 1(b) of Annex II to Directive 2008/57/EC - namely structural sub-systems and functional sub-systems and includes a structural or functional sub-system that is intended to become the whole or part of a subdivision of the rail system.</td>
</tr>
<tr>
<td>System</td>
<td>Any part of the railway system which is subjected to a change whereby the change may be of a technical, operational or organisational nature.</td>
</tr>
<tr>
<td>Technical specification for</td>
<td>A specification adopted in accordance with Directive 2008/57/EC by which each subsystem or part subsystem is covered in order to meet the essential requirements and ensure the interoperability of the rail system.</td>
</tr>
<tr>
<td>interoperability</td>
<td></td>
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</tbody>
</table>
Technical system

A product or an assembly of products including the design, implementation and support documentation; the development of a technical system starts with its requirements specification and ends with its acceptance; although the design of relevant interfaces with human behaviour is considered, human operators and their actions are not included in a technical system; the maintenance process is described in the maintenance manuals but is not itself part of the technical system.

TSI

Technical specification for interoperability

TVM
