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Guidance on Independent Assessment

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Rail Industry Guidance Note

Guidance on Independent Assessment

Issue record

Issue	Date	Comments
One	June 2014	This guidance was developed as part of the RSSB research project T955 and provides guidance on the application of the Common Safety Method on Risk Evaluation and Assessment required by Commission Regulation (EC) No 352/2009.

Superseded documents

This Rail Industry Guidance Note does not supersede any other Railway Group documents.

Supply

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Part 1 Introduction

G 1.1 Purpose of this document

- G 1.1.1 This document gives practitioner level guidance on the application of the risk management process set out in the 'Common Safety Method on Risk Evaluation and Assessment' (CSM RA). Specifically, it gives guidance on commissioning and managing an independent assessment by an assessment body.
- G 1.1.2 This document is primarily focussed on the application of the process by practitioners within an RU or IM. Others, who need to apply the process or interact with it in some way, should also find it useful. Further guidance for other actors (for example, manufacturers) may be developed over time.
- G 1.1.3 The CSM RA (Commission Regulation (EC) No 352/2009) has applied since 01 July 2012 to all significant changes to the railway system – 'technical' (engineering), operational and organisational, or if required as the risk assessment process by a Technical Specification for Interoperability (TSI).

G 1.2 Background

- G 1.2.1 Commission Regulation (EC) No. 352/2009 ('the regulation') established a 'common safety method on risk evaluation and assessment' (the CSM RA). The CSM RA, contained in Annex I to the regulation, sets out a mandatory risk management process for the rail industry that is common across Europe. The CSM RA has applied to all significant changes to the railway system since 01 July 2012. The changes may be of a technical (engineering), operational or organisational nature (where the organisational changes could have an impact on the operation of the railway). The CSM also applies if a risk assessment is required by a technical specification for interoperability (TSI); and is used to ensure safe integration of a structural subsystem into an existing system in the context of an authorisation for placing in service in accordance with the Railway Interoperability Directive 2008/57/EC.
- G 1.2.2 Commission Implementing Regulation (EU) No 402/2013 establishes a revised common safety method for risk evaluation and assessment. The revised CSM RA has been in force since 23 May 2013 (meaning it can be used from that date), and will apply from 21 May 2015 (meaning that it must be used from that date), at which time Commission Regulation (EC) No. 352/2009 is repealed. The principal amendments relate to the acceptability of codes of practice, the documentation provided to an assessment body, the content of the safety assessment report and the recognition and accreditation of assessment bodies.
- G 1.2.3 If a project is expected to continue beyond 21 May 2015, the proposer can continue to use the 2009 regulation, provided the project is at 'an advanced stage of development within the meaning of ... Directive 2008/57/EC'.
- G 1.2.4 All references in this document to 'the regulation' refer to Commission Regulation (EC) No 352/2009, unless otherwise stated.

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G 1.4 Approval and authorisation of this document

G 1.4.1 The content of this document was approved by a Multifunctional Standards Committee on 25 March 2014.

G 1.4.2 This document was authorised by RSSB on 09 May 2014.

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Part 2 **Guidance on Common Safety Method on Risk Evaluation and Assessment**

G 2.1 General introduction

- G 2.1.1 The CSM RA applies to *'any change of the railway system in a Member State ... which is considered to be significant within the meaning of Article 4 of the Regulation'* that is Commission Regulation (EC) No 352/2009 [the CSM RA itself]. Those changes may be technical, operational or organisational, but are those which could impact the operating conditions of the railway system. The proposer of a change is responsible for applying the risk management process set out in the CSM RA. In many circumstances, proposers will be RUs or IMs. However, a manufacturer may want or need to apply the CSM RA in order to place a new or altered product or system on the market. Once the product is placed on the market, an RU or IM wishing to use the new or altered product or system in a specific application or location will be the proposer of a new change.
- G 2.1.2 Detailed advice on the regulation's requirements, its scope and the significance test that triggers the requirement to apply the risk management process in full, is set out in the Office of Rail Regulation's (ORR's) guidance on the CSM RA. In this section an overview summary of the regulation and its requirements is provided, for the purposes of setting out the context of this guidance and allowing a quick point of reference to the main principles for practitioners.
- G 2.1.3 Figure 1 shows the risk management process defined in the CSM RA. The process essentially consists of the following steps:
- a) The proposer of a change produces a preliminary definition of that change, and the system to which it relates. It then examines it against the significance criteria in the regulation. If a change is deemed to be significant, then the regulation requires you to apply the risk management process in Annex I and appoint an independent assessment body to assess application of the process. However, the CSM RA risk management process is a sound one and you may choose to apply some or all of it more generally.
 - b) The CSM risk management process starts with the 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. This system definition will be kept live for the duration of the project.
 - c) All reasonably foreseeable hazards are identified and their risk is classified and / or analysed.
 - d) Safety requirements are identified by application of one or more of the three risk acceptance principles to each hazard.
 - e) A hazard record for the system that is to be changed is produced and maintained. Its purpose is to track progress of the project's risk management process.
 - f) Before acceptance, the change proposer demonstrates that the risk assessment principles have been correctly applied and that the system complies with all specified safety requirements.
 - g) The assessment body provides its report to the proposer. The proposer remains responsible for safety and takes the decision to implement the proposed change.

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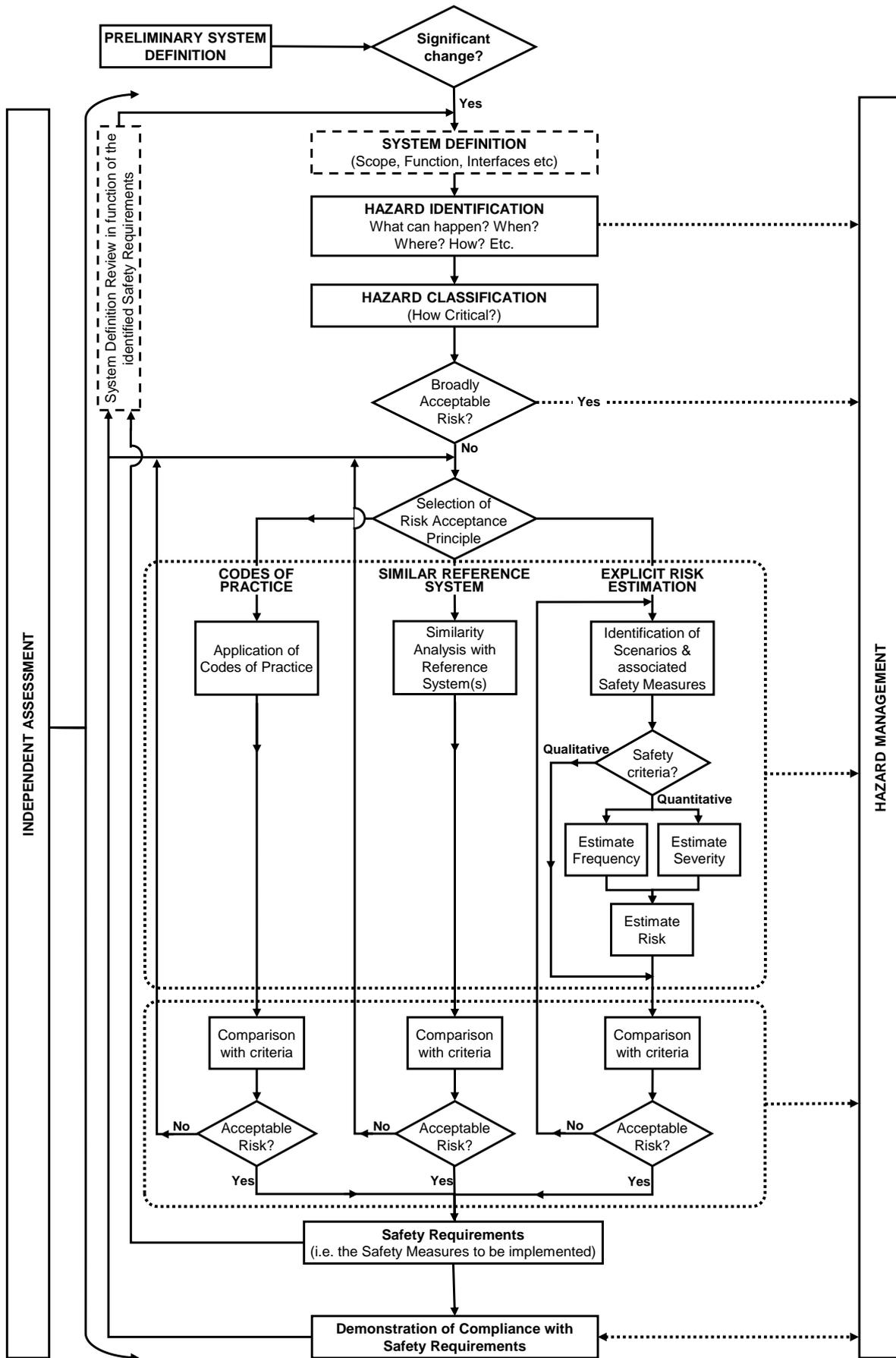


Figure 1 The risk management and independent assessment process from the CSM RA

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G 2.2 Guidance documents

G 2.2.1 This guidance forms part of a suite of six documents that address the different elements of the risk management process. The guidance notes are numbered below and Figure 2 shows how each one fits in to the whole:

- Guidance on Planning an Application of the Common Safety Method on Risk Evaluation and Assessment (GE/GN8640).
- Guidance on System Definition (GE/GN8641).
- Guidance on Hazard Identification and Classification (GE/GN8642).
- Guidance on Risk Evaluation and Risk Acceptance (GE/GN8643).
- Guidance on Safety Requirements and Hazard Management (GE/GN8644).
- Guidance on Independent Assessment (GE/GN8645).

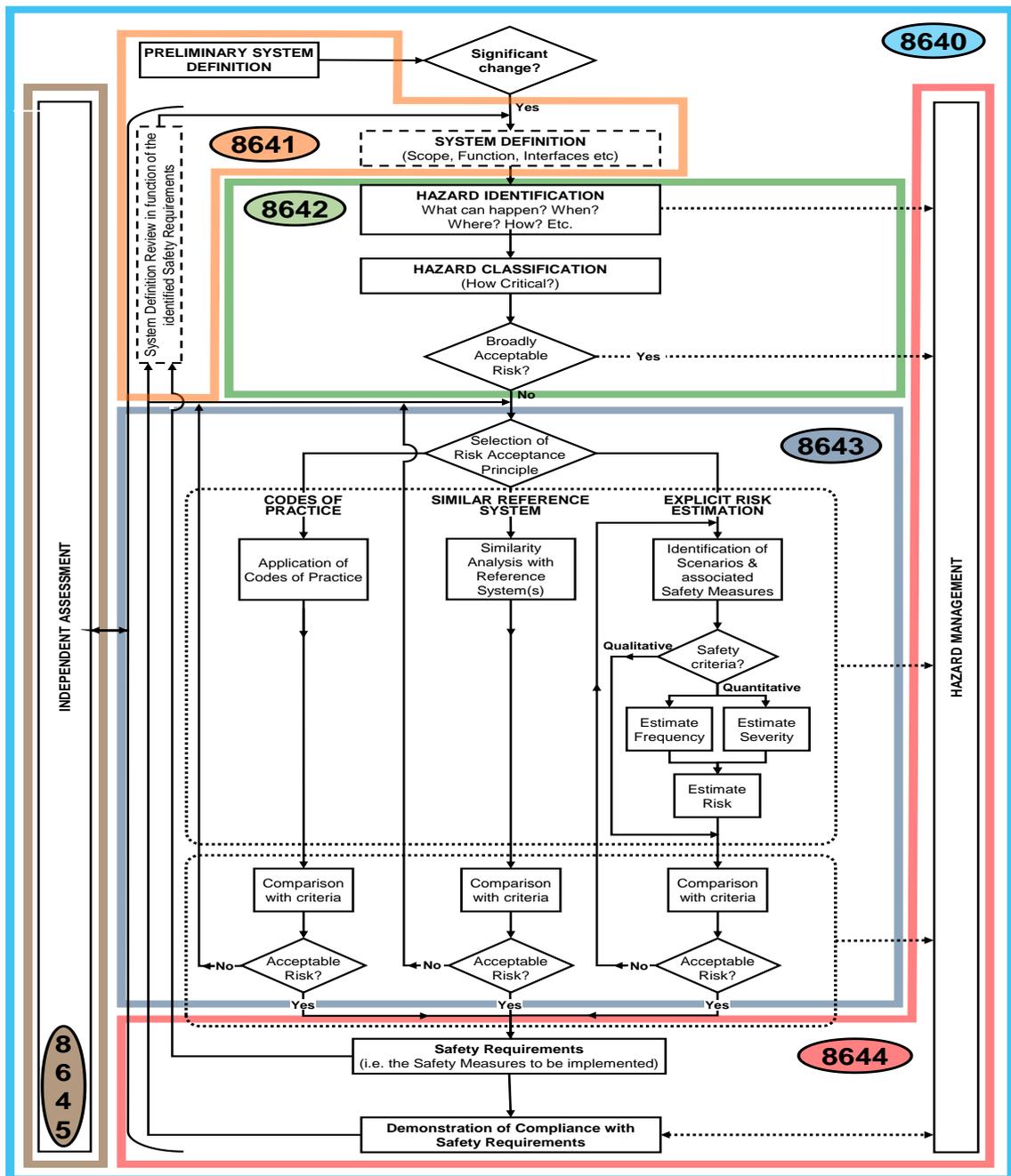


Figure 2 The set of guidance notes on the application of the CSM RA, and the process elements to which they relate

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G 3.1 Key points

G 3.1.1 It is a mandatory requirement of the regulation that:

G 3.1.2 *An independent assessment of the correct application of the risk management process [...] and of the results of this application shall be carried out by [an assessment] body.*
(Article 6, clause 1) Reference to 'results' is taken to mean that they are reviewed to the extent necessary to support the assessment body's judgement of how the process has been applied.

G 3.1.3 The ORR Guidance (Dec 2012) states that:

'The proposer remains responsible for safety and takes the decision to implement the proposed change.' (ORR Guidance (Dec 2012), clause 3.68)

Therefore it is not the assessment body's role to judge whether the change is safe.

G 3.1.4 The regulation sets out requirements that the assessment body must meet, including requirements on competence and independence. The assessment body may be a separate company, but it is possible for a proposer to meet these requirements while using a department of its own organisation as the assessment body.

G 3.1.5 A good assessment will be one that provides early engagement and timely feedback to the proposer thereby encouraging a rigorous and efficient application of the risk management process.

G 3.2 The role of the assessment body

G 3.2.1 In broad terms, to perform the assessment, the assessment body's role is to:

- a) Ensure it has a thorough understanding of the significant change based on the documentation provided by the proposer.
- b) 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.
- c) Conduct an assessment of the application of those safety and quality processes during the design and implementation of the significant change.
- d) Deliver the safety assessment report.

These activities will become mandatory under the revised regulation (402/2013), see G 3.9.3.

G 3.2.2 It is important that the proposer build the regulation's risk management process for significant change into their processes used for managing safety and quality.

G 3.3 Selecting and appointing an assessment body

G 3.3.1 In the UK, it is the responsibility of the proposer of a significant change (see Article 6, point 1 of the regulation) to appoint an assessment body.

G 3.3.2 Given that a 'significant change' is being made, if the assessment body role is being performed by persons from within the proposer's organisation, consideration needs to be given to the appropriate degree of separation between responsibilities for project delivery and responsibilities for conducting the assessment.

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- G 3.3.3 In other cases, such as where there is a need for a greater degree of independence, the proposer may appoint a separate organisation as an assessment body. More information is provided in the ORR Guidance (Dec 2012) from clause 3.58.
- G 3.3.4 The proposer can appoint any suitable person or organisation as an assessment body, provided that the person or organisation meets the requirements of Annex II of the regulation on competence, independence and other matters.
- G 3.3.5 The following requirements on competence are set out in the regulation:
- 'The assessment body must carry out the assessment with the greatest possible professional integrity and the greatest possible technical competence [...].*
(Annex II, clause 2)
- 'The assessment body must possess the means required to perform adequately the technical and administrative tasks linked with the assessments; it shall also have access to the equipment needed for exceptional assessments.* (Annex II, clause 3)
- 'The staff responsible for the assessments must possess: proper technical and vocational training, a satisfactory knowledge of the requirements relating to the assessments that they carry out and sufficient practice in those assessments [and] the ability to draw up the safety assessment reports which constitute the formal conclusions of the assessments conducted.'* (Annex II, clause 4)
- G 3.3.6 The following requirements on independence are set out in the regulation:
- 'The assessment body may not become involved [...] in the design, manufacture, construction, marketing, operation or maintenance of the system under assessment.*
(Annex II, clause 1)
- 'The independence of the staff responsible for the independent assessments must be guaranteed. No official must be remunerated either on the basis of the number of assessments performed or of the results of those assessments.'* (Annex II, clause 5)
- G 3.3.7 If the assessment body is not part of the proposer's organisation, then the regulation states that it *'must have its civil liability ensured'*, for example by carrying insurance and be *'bound by professional secrecy with regard to everything [it learns] in the performance of [its] duties.'* (Annex II, clause 6).
- G 3.3.8 For most significant changes it will be necessary to form a team to act as the assessment body, because no individual will possess all the necessary training, knowledge and experience.
- G 3.3.9 It is possible to create a team to act as an assessment body with members taken from both the proposer's organisation and an independent organisation, and this may be a practical way of assembling the necessary skills for the team where these include specialist skills that are in short supply, provided that the necessary level of independence can be maintained.
- G 3.3.10 In entering into an agreement with an assessment body the proposer of a change will need to clearly define the scope of the assessment. An example template for an assessment remit is set out in Appendix A.
- G 3.3.11 The following two options allowed by the regulation have not been taken up in the UK:
- a) The regulation allows national safety authorities to act as assessment bodies under certain circumstances (see Article 6, point 3). The ORR, which is the national safety authority in the UK, has said that it does not intend to do this (see the ORR guidance (Dec 2012) paragraph 3.66).

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- b) The regulation allows for assessment bodies to be restricted in national legislation (see Article 6, point 1). There is no such restriction in the UK and therefore any assessment body that meets the requirements in Annex II may be used (see the ORR Guidance (Dec 2012) paragraph 3.58).

G 3.4 Avoiding duplication

- G 3.4.1 Depending upon the nature of the project, some other form of independent assessment may be required by other aspects of UK and European law, such as assessment of conformity with TSIs and assessment of safety certificates (for RUs) or safety authorisations (for IMs). The regulation states that duplication of work between these types of assessment and the assessment required by the regulation 'shall be avoided'. See further information in the ORR Guidance (Dec 2012) paragraph 3.63.
- G 3.4.2 Directive 2004/49/EC is the Railway Safety Directive. In the UK, the ORR performs the conformity assessments of the safety management systems operated by IMs and RUs. In order to avoid duplication between a CSM RA independent assessment and one of these conformity assessments, the ORR Guidance (Dec 2012) suggests that an assessment body looking at the processes operated by an IM or RU with a valid safety certificate of safety authorisation need not examine processes in general but only the way that they are applied on the project (see paragraph 3.64).
- G 3.4.3 If aspects of a change fall under the scope of the Interoperability Directive 2008/57/EC, then these aspects are subject to assessment by a notified body and where applicable a designated body. The risk of duplication can be reduced by:
- a) Using the TSI and national rules as codes of practice for the purpose of applying the 'Codes of practice' risk assessment principle (as set out in GE/GN8643).
- And / Or
- b) Ensuring each assessment uses work done on the other.
- G 3.4.4 There may be outputs from other relevant independent assessments available, for example assessments against European reliability, availability, maintainability and safety (RAMS) standards. There is an opportunity to use these outputs to efficiently demonstrate that elements of risk management process have been applied.
- G 3.4.5 It is in the business interests of the proposer to avoid duplication because this reduces the costs of assessment and also the risk of receiving inconsistent advice from differing assessment bodies.
- G 3.4.6 Co-ordinating the planning of different assessments should be helpful in eliminating duplication. In some cases it might be practical and efficient to appoint the same organisation to carry out multiple assessment roles. The regulation does not prohibit such an arrangement.
- G 3.4.7 Where assessments are carried out by more than one organisation, duplication may be avoided by co-ordinating the activities of the assessment bodies so that, where appropriate, one assessment body makes use of the results of assessments performed by another assessment body. For example, the reports produced by another assessment body may be passed to the assessment body as evidence for compliance with safety requirements.
- G 3.4.8 Appointing the same organisation as notified body and assessment body, if an organisation can be found with the necessary attributes to act in both roles, may make it easier to re-use work between the assessments.

G 3.5 The safety assessment report

- G 3.5.1 Article 7 of the regulation requires that the assessment body provides the proposer with a safety assessment report.

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- G 3.5.2 The regulation describes an independent assessment as an assessment '*of the correct application of the risk management process [...] and of the results of this application*'. (Article 6, clause 1). Furthermore the regulation defines safety acceptance as the status given to change by the proposer based on the safety assessment report provided by the assessment body.
- G 3.5.3 The safety assessment report is provided before bringing the new or changed system into service. It will form an important part of the grounds for the proposer's decision to proceed with bringing it into service, and in some cases it will be provided when seeking an authorisation for placing in service under Directive 2008/57/EC.
- G 3.5.4 When a change is to be brought into service in stages, multiple safety assessment reports (or multiple versions of the safety assessment report) may be required, each covering one or more stages of introduction.
- G 3.5.5 The form of the safety assessment report will be the result of discussion between the proposer and the assessment body. An example template for a safety assessment report is set out in Appendix A. Under the revised regulation (402/2013) there is a core set of required information, see G 3.9.5.
- G 3.5.6 The safety assessment report is the final product of the assessment. In a well-run assessment, it should contain no surprises because any issues should have already been brought to the proposer's attention and resolved. Arrangements for making this happen are discussed in the next section.

G 3.6 Managing an assessment programme

- G 3.6.1 The regulation states that:
- 'The risk management process used to assess the safety levels and compliance with safety requirements shall be documented by the proposer in such a way that all the necessary evidence showing the correct application of the risk management process is accessible to an assessment body. The assessment body shall establish its conclusion in a safety assessment report.'* (Annex I, clause 5.1)
- G 3.6.2 In order to review sufficient information to support its conclusion without incurring excessive cost, an assessment body will normally operate a strategy for inspecting a sample of the evidence made available to it.
- G 3.6.3 The members of an assessment body's team may sample evidence by various activities, including:
- a) Inspecting documents.
 - b) Attending meetings.
 - c) Witnessing tests.
 - d) Inspecting equipment.
 - e) Carrying out audits to collect information about process operation.
- G 3.6.4 It will often be more efficient and effective to use a mixture of most or all of these activities, because different activities will provide insight into different aspects of the project.
- G 3.6.5 If the proposer and the assessment body agree at the beginning of the process the number and types of assessment activities that the assessment body is expected to perform, this will provide clarity on the expected cost and depth of the independent assessment.

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G 3.6.6 At the end of the assessment, non-compliances are included in the safety assessment report. However, by the time that the safety assessment report is written, it may be too late to resolve any significant non-compliances and therefore it is good project management that:

- a) An assessment body should be appointed at or near the outset of the project. The revised regulation (402/2013) makes it mandatory to appoint the assessment body at the '*earliest appropriate stage of the risk assessment process.*' (Article 6, clause 1)

And

- b) The proposer of a change should work with the assessment body to set up arrangements for ensuring that any non-compliances arising from the assessment are promptly raised and dealt with. A proven arrangement for doing this is to make use of a three-part form, with parts for the original non-compliance, the project's response and the assessment body's response to the project's response. An example template for such a form is set out in Appendix A.

G 3.6.7 The earlier that any non-compliances are brought to the proposer's attention, the easier it should be to resolve them. It will be in the proposer's interest to agree arrangements with the assessment body, which expose significant decisions to the assessment body's review, as early as practical. However, the final versions of documents passed to the assessment body should be subject to robust review first because, otherwise, they may give rise to many non-compliances, which is likely to increase the costs of the assessment without increasing the value that it adds.

G 3.6.8 It is possible that the proposer of a change may find that it disagrees with the assessment body. This would be an unfortunate situation and one in which the proposer and the assessment body should make every effort to reach agreement. If the disagreement centres upon facts or upon how the system will behave in the future it can, in principle, be resolved through the collection of further data and further analysis. If the disagreement is not resolved, then it would be advisable for the proposer to discuss this with the ORR, so that any implications for the proposer's safety certification, safety authorisation or authorisation to place into service may be identified and dealt with. Section G 3.9.8 discusses requirements on the proposer under the revised regulation (402/2013) in the circumstances where the disagreement is not resolved.

G 3.7 Involving others

G 3.7.1 The guidance above has been written for the situation where the proposer is carrying out the project itself. However, there is no fundamental difference if the proposer of a change sub-contracts aspects of the delivery of the project, except that:

- a) The proposer needs to ensure the assessment body can access parts of the project being carried out by others. It may need to place clauses in its contracts with suppliers to require co-operation with the assessment process.

And

- b) When non-compliances are raised that relate to a contractor's activities, the proposer should pass them to its contractors and agree a response with them.

G 3.7.2 It may also be the case that other RUs and IMs have to implement safety requirements, in order to ensure that risk is acceptable. In this case the proposer co-operates with these other RUs and IMs to ensure that the assessment body has access to evidence that these safety measures have been correctly implemented.

G 3.8 Planning an assessment programme

G 3.8.1 The programme of activities required to perform an independent assessment may be complex and will require significant co-ordination between parties. The programme is likely to be carried out in a more efficient and timely manner if a plan is written for it.

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G 3.8.2 A plan for an assessment will usually be drawn up by the assessment body, but it will have to be drawn up in conjunction with the proposer and the other actors involved in the project because they will have to support the activities in the plan.

G 3.8.3 An example template for an assessment plan is set out in Appendix A.

G 3.9 Forthcoming changes to the CSM RA

G 3.9.1 A revised CSM RA has been published 'European Commission. Regulation 402/2013 on the common safety method for risk evaluation and assessment', which came into force on 23 May 2013. Therefore, a proposer may use the revised CSM RA if they wish after this date. The revised CSM RA will apply from 21 May 2015; this is the date on which the revised CSM RA must be used and the 352/2009 revised regulation will be repealed on this date.

G 3.9.2 The revised regulation will introduce parallel processes for 'accreditation' and 'recognition' of assessment bodies (see definitions). When the revised version comes into force, it will only be legal to use assessment bodies which are accredited or recognised. The revised version of the regulation requires that assessment bodies must fulfil the requirements of ISO/IEC 17020: 2012 if the change is intended to be mutually recognised between member states. If mutual recognition is not a requirement then the condition of compliance with ISO/IEC 17020:2012 may be relaxed by the National Safety Authority.

G 3.9.3 The assessment body has a better defined set of tasks that they need to undertake under the revised regulation. Specifically, Regulation 402/2013 Article 6, requires:

'To perform the independent assessment, the assessment body shall:

- (a) ensure it has a thorough understanding of the significant change based on the documentation provided by the proposer;*
- (b) 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;*
- (c) conduct an assessment of the application of those safety and quality processes during the design and implementation of the significant change.'*

G 3.9.4 The revised regulation also provides more detail on the documentation produced by the proposer to the assessment body. Although not necessarily more onerous in practice, the revised regulation provides more clarity on what is supplied. Specifically, Regulation 402/2013 Annex I, clause 5.2, requires:

'The documentation produced by the proposer under point 5.1 shall at least include:

- (a) a description of the organisation and the experts appointed to carry out the risk assessment process;*
- (b) 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;*
- (c) evidence of compliance with all the necessary safety requirements;*
- (d) all assumptions relevant for system integration, operation or maintenance, which were made during system definition, design and risk assessment.'*

Under the 2009 regulation, only (a) and (b) were explicitly stated.

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- G 3.9.5 Annex III of the revised regulation includes detailed requirements on the content of the safety assessment report by the assessment body. The template report included in Appendix G A.3 of this document includes those mandatory fields. Regulation 402/2013 Annex III states:
- ‘The safety assessment report of the assessment body shall contain at least 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 this Regulation;*
 - (ii) any identified cases of non-compliances with the provisions of this Regulation and the assessment body’s recommendations;*
 - (e) the conclusions of the independent assessment.’*
- G 3.9.6 If the CSM RA assessment is being called up within a TSI as the relevant risk assessment to be used; then under the revised regulation (Regulation 402/2013 Article 15 4), a notified body in charge of delivering the conformity certificate must accept the declaration by the proposer [required by Article 16 of the 2013 regulation] unless it justifies and documents its doubts concerning the assumptions made or the appropriateness of the results.
- G 3.9.7 Under the revised regulation (Regulation 402/2013 Article 6, clause 1):
- ‘The proposer shall appoint its own assessment body at the earliest appropriate stage of the risk assessment process.’* This is more explicit than the 2009 regulation about when the assessment body is appointed.
- G 3.9.8 Under the revised regulation, if the proposer and assessment body disagree over an element of the process as documented in the safety assessment report, then the proposer has an additional requirement:
- ‘The proposer shall be responsible for determining if and how to take into account the conclusions of the safety assessment report for the safety acceptance of the assessed change. The proposer shall justify and document the part of the safety assessment report for which the proposer eventually disagrees.’* (Regulation 402/2013 Article 15, clause 1).

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Appendix A Templates

G A.1 Assessment remit template

G A.1.1 This section sets out a suggested template for an assessment remit. Table G A.1 suggests section headings and indicates the content of each section.

Background	Background information about the context of the change, which is required in order to understand the rest of the document.
The assessment sought	A statement of the nature of the assessment sought, making clear that the requirements of the CSM RA apply and indicating whether the 2009 or 2013 regulations are to be used. If the CSM RA assessment is to be combined with some other sort of assessment, such as EC verification, as required by the Interoperability Regulations, this should be made clear.
The scope of the assessment	A precise account of what is to be assessed, including a definition of the change being made and the system of which it forms part (possibly by appending the system definition).
Safety assessment report(s)	A statement of whether a single safety assessment report is required or whether multiple reports are required (for example, when the change is to be brought into service in stages) and requirements placed on the report(s), including the requirements placed by the CSM RA.
Timescales	The projected timescales for the project, including the dates upon which safety assessment reports are required.
Management arrangements	Arrangements for scheduling tasks, transferring documents, access for the assessment body to the proposer's premises and, as necessary, the premises of suppliers, participation in meetings, passing on non-compliances, escalating issues and so forth. This may usefully include a requirement for the assessment body to develop the information in this section and the previous one into an assessment plan.
Competence	A statement of the areas in which the assessment team should possess technical competence.
Commercial terms	As required, including requirements for treating information supplied in confidence.

Table G A.1 Assessment remit template

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G A.2 Assessment plan template

G A.2.1 This section sets out a suggested template for an assessment plan. Table G A.2 suggests section headings and indicates the content of each section. The plan should seek to demonstrate how the remit will be met.

Background	Background information about the context of the change, which is required in order to understand the rest of the document.
Remit	A restatement of the purpose and scope of the assessment, as understood by the assessment body, including any clarification and amendments agreed since the remit was issued.
Activities	A description of the programme of activities to be carried out by the assessment team.
Management arrangements	Arrangements for scheduling tasks, transferring documents, access for the assessment body to the proposer's premises and, as necessary, the premises of suppliers, participation in meetings, passing on observations, escalating issues and so forth. These arrangements should include a scheme for categorising non-compliances such as that included in the template non-compliance form provided at G A.4 below.
The assessment team	A list of the members of the assessment, defining the role to be performed by each member and stating relevant aspects of each member's experience and knowledge and how these meet the competence requirements. An indication of how the team will be organised, typically with a lead assessor to which the others report. Where the assessment team is part of the proposer's organisation, then: a) The manager to whom the team reports should be identified so that it can be confirmed that the requirements on independence are met. And b) It should be confirmed that no team member has taken part or will take part in the activities of the project.
Reports	A list of the points at which safety assessment reports will be produced and, if there is more than one report, the scope of each. The information to be provided in each report.
Dependencies	Identification of the dependencies that the assessment team has upon the proposer and others, including access to information, people and premises.
Timescales	The expected times at which activities will be carried out and reports will be produced.

Table G A.2 Assessment plan template

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G A.3 Safety assessment report template

G A.3.1 This section sets out a suggested template for a safety assessment report based on mandatory elements as required by the regulation (EU) No 402/2013, Annex III, and suggested good practice. Table G A.3 suggests section headings and indicates the content of each section.

G A.3.2 The mandatory elements are as indicated below with an asterisk (*).

Identification*	Identification of the assessment body
Remit	A restatement of the purpose and scope of the assessment, as understood by the assessment body, including any clarification and amendments agreed since the remit was issued.
Plan*	The independent assessment plan
Scope / Limitations*	The scope of the assessment as well as its limitations
Activities	A summary of the assessment activities carried out to support the assessment offered.
Results*	The results of the assessment in particular: <ul style="list-style-type: none"> i) Detailed information on the independent assessment activities for checking the compliance with the provisions of the regulation. ii) Any identified cases of non-compliances with the provisions of the regulation and the assessment body's recommendations.
Conclusion*	The conclusion reached by the assessment body. This should include a conclusion about whether or not the CSM RA has been correctly applied, as required by the CSM RA and should also respond to any other areas where the assessment body's opinion has been sought in the remit. The conclusions may be contingent upon clearance of open issues.
Appendix: Documents reviewed	A list of the documents reviewed, including their issue numbers, so that it can be confirmed that the assessment has been based upon information current at the time.
Appendix: Non-compliances / recommendations	A list of the non-compliances and their current status, and any recommendations.

Table G A.3 Safety assessment report template

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G A.4 Non-compliance form template

G A.4.1 This section sets out a suggested template for a form for documenting non-compliances raised by the assessment body and the responses to them. Table G A.4 suggests headings and indicates the content expected below that section. The template may be used in two different ways, either:

- a) Each non-compliance may be set out on a separate form, in which case the headings may be used as section headings.

Or

- b) Several non-compliances may be provided together as separate rows in a table, in which case the headings may be used as column headings.

Identifier	A unique identifier for the non-compliance, which can be used to refer to it concisely and unambiguously; perhaps a serial number.
Non-compliance	A description of the non-compliance against the application of the risk management process as set out in the regulation.
Category	An indication of the significance of the non-compliance to assist the project in prioritising its response. For example: <ol style="list-style-type: none">a) Class I, if, in the assessment body's opinion, the non-compliance represents a material departure from compliance with the CSM RA and urgent action is required by the project to resolve it.b) Class II, if, in the assessment body's opinion, the non-compliance represents a material departure from compliance with the CSM RA but a response is less urgent.
Status	<ol style="list-style-type: none">a) Open, if a further response from the project is required.b) Resolved, if a satisfactory response from the project has been received, but the actions required have not yet been carried out.c) Closed, if a satisfactory response from the project has been received and all actions required have been carried out.
Project response	The project's response to the non-compliance, including, as appropriate: actions undertaken, additional information provided and areas of disagreement. This section may be added to on more than one occasion.
Assessment body's response	The assessment body's response to the project's response. This section may be added to on more than one occasion. The final response should close the non-compliance.

Table G A.4 Non-compliance form template

Guidance on Independent Assessment

Definitions and Abbreviations

Accreditation (of an assessment body)

As defined in Article 2 of Regulation (EC) No 765/2008 and referenced in the revised regulation (402/2013):

'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.'

Actor

Any party which is, directly or through contractual arrangements, involved in the application of the risk management process.

Assessment body

An independent and competent person, organisation or entity which undertakes investigation to arrive at a judgement, based on evidence, of the suitability of a system to fulfil its safety requirements.

CSM RA 'the regulation'

The Common Safety Method on Risk Evaluation and Assessment. Commission Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment as referred to in Article 6(3)(a) of Directive 2004/49/EC of the European Parliament and of the Council.

Declaration by the proposer

As defined in the revised regulation (402/2013):

'written declaration that all identified hazards and associated risks are controlled to an acceptable level.' (Article 16)

ESM

Engineering Safety Management.

Hazard

A system condition that could lead to an accident.

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.

Infrastructure manager (IM)

As defined in the ROGS 2006: *'infrastructure manager' means the person who -*
(a) in relation to infrastructure other than a station, is responsible for developing and maintaining that infrastructure or, in relation to a station, the person who is responsible for managing and operating that station, except that it shall not include any person solely on the basis that he carries out the construction of that infrastructure or station or its maintenance, repair or alteration; and
(b) manages and uses that infrastructure or station, or permits it to be used, for the operation of a vehicle'. (Part 1, clause 2)

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Project at an 'advanced stage of development'

As defined in Directive 2008/57/EC and referenced in the revised regulation (402/2013):

“project at an advanced stage of development’ means any project whose planning/construction stage has reached a point where a change in the technical specifications would be unacceptable to the Member State concerned. Such an impediment may be legal, contractual, economic, financial, social or environmental in nature and must be duly substantiated.’

Proposer

As defined in the regulation:

“proposer’ means the railway undertakings or the infrastructure managers in the framework of the risk control measures they have to implement in accordance with Article 4 of Directive 2004/49/EC, the contracting entities or the manufacturers when they invite a notified body to apply the ‘EC’ verification procedure in accordance with Article 18(1) of Directive 2008/57/EC or the applicant of an authorisation for placing in service of vehicles.’ (Article 3, clause 11)

Railway undertaking (RU)

As defined in Directive 2001/14/EC, and any other public or private undertaking, the activity of which is to provide transport of goods and / or passengers by rail on the basis that the undertaking must ensure traction; this also includes undertakings which provide traction only.

Recognition (of an assessment body)

As defined in the revised regulation 402/2013:

‘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 this Regulation to carry out the independent assessment activity specified in Article 6(1) and (2)’. (Article 3, clause 31)

Risk analysis

The systematic use of all available information to identify hazards and to estimate the risk.

Risk assessment

The overall process comprising a risk analysis and a risk evaluation.

Risk evaluation

A procedure based on the risk analysis to determine whether the acceptable risk has been achieved.

Safety assessment report

The document containing the results, recommendations and conclusions of the assessment performed by an assessment body on the system under assessment.

Safety measure

As defined in the regulation:

‘A set of actions that either reduce the rate of occurrence of a hazard or mitigate its consequences in order to achieve and / or maintain an acceptable level of risk.’ (Article 3, clause 10)

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Safety requirement

As used in this guidance: A characteristic of a system and its operation (including operational rules) necessary in order to deliver acceptable risk.

As defined in the regulation:

“safety requirements’ means the safety characteristics (qualitative or quantitative) of a system and its operation (including operational rules) necessary in order to meet legal or company safety targets.’ (Article 3, clause 9)

System

That part of the railway system which is subject to a change.

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References

The Catalogue of Railway Group Standards gives the current issue number and status of documents published by RSSB. This information is also available from www.rgsonline.co.uk.

RGSC 01 Railway Group Standards Code
RGSC 02 Standards Manual

Documents referenced in the text

RSSB documents

GE/GN8640 Guidance on Planning of an Application of the CSM on Risk Evaluation and Assessment
GE/GN8641 Guidance on System Definition
GE/GN8642 Guidance on Hazard Identification and Classification
GE/GN8643 Guidance on Risk Evaluation and Acceptance
GE/GN8644 Guidance on Safety Requirements and Hazard Management

Other references

(EC) No 352/2009 Commission Regulation on a Common Safety Method on risk evaluation and assessment (2009)

(EU) No 402/2013 Commission Regulation on a Common Safety Method for risk evaluation and assessment (2013)

ISO/IEC 17020:2012 Conformity assessment -- Requirements for the operation of various types of bodies performing inspection

2001/14/EC Allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification.

2004/49/EC Railway Safety Directive
2008/57/EC Interoperability Directive
ORR Guidance (Dec 2012) ORR guidance on the application of the common safety method (CSM) on risk assessment and evaluation (December 2012)

ROGs 2006 Railways and Other Guided Transport Systems (Safety) Regulations 2006

Other relevant documents

Other references

ERA/GUI/02-2008/SAF European Railway Agency Collection of examples of risk assessments and of some possible tools supporting the CSM Regulation