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Guidance on System Definition

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Rail Industry Guidance Note

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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Superseded documents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, this guidance is intended to assist infrastructure managers (IMs) and railway undertakings (RUs) in undertaking system definition.

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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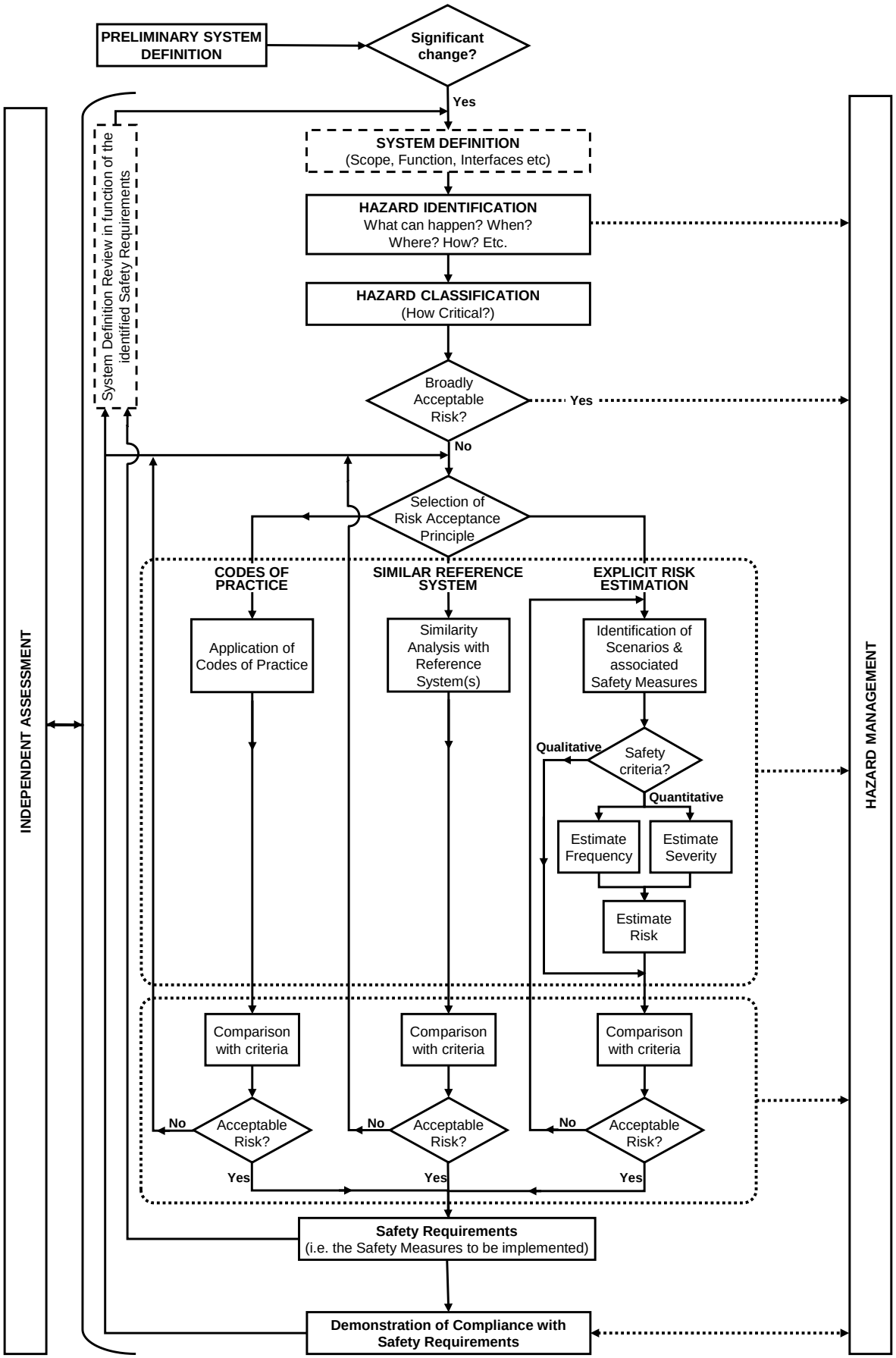

Figure 1 The risk management and independent assessment process from the CSM RA

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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 into 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).

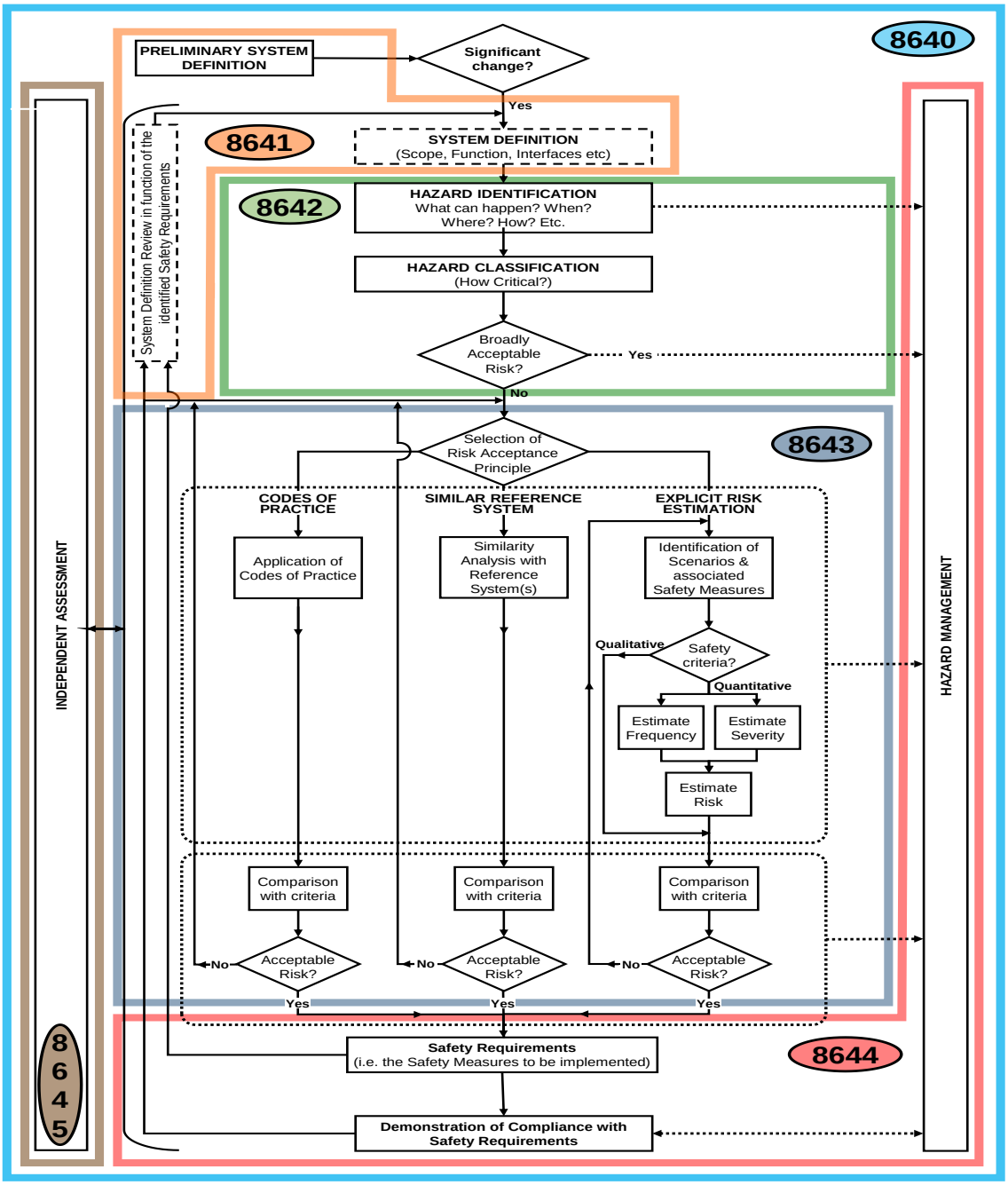

Figure 2 The set of guidance notes on the application of the CSM RA, and the process elements to which they relate

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