

Consultation comments and responses

Document number: Client safety assurance of high integrity software-based systems for railway applications

Consultation closing date: **19 April 2022**

1. Responders to consultation

No	Name	Company				
1	David Warwick	Network Rail				
2	Orry King	Network Rail				
3	James Wilson	First Group				
4	Mark Molyneux	RDG				
5	Richard Stainton	Network Rail				
6	Yuki Ohashi	Angel Trains				
7	Stephen Trigg	GWR				
8	lan Cuthbertson	Lner				
9	Peter Morris	Hitachi Rail				
10	Lucia Capogna	AEGIS Certification Service				
11	Olufemi Okeya	Network Rail				

2. Summary of comments

Code	Description	Total
-	Consulted	
CE	Critical errors	
ED	Editorial errors	
TY	Typographical errors	
ОВ	Observations	
-	Total comments returned	

Classification codes for a way forward:

- DC Document change
- NC No change

3. Collated consultation comments and responses

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
1			General Comment: I think this is a well developed document which will provide useful guidance in the area intended.		1	NC			Noted with t
2			General Comment: This document is not software specific and is more system related.	It would be great to have more guidance on the software side, that explains how the existing standards should be applied and what are the evidence a Client should request to suppliers based on that.	10	NC			Noted. The RIS is int which includ The standard standard life the software
3		General	Who is the client		11	DC		1.1 G 2.3	The term clie organisation procuremen system. Section 1.1 h Proposer (ty client organi Further expl change of cli Working exa from the ind future versio
4		General	What is deemed high integrity system?		11	NC		1.2.1	For the purp systems, are have a safet Performance ISO 13849 se primarily del out in clause
5	7	1.1	The first paragraph explains what is in the standard but could be improved by explaining why the document should be followed.	Include reference to the legal requirements to manage risk and how following the standard assists in demonstrating compliance.	2	DC		1.1.3 and 1.1.4	A new parag legal require standard ass 1.1.3 The He legal respon- managemen at Work regu employers a 1.1.4 The Ra Regulations safety mana client organi (SMS), to ass integrity sof



thanks.
tended for high integrity software-based systems de both software and hardware. d will be periodically reviewed as part of the ecycle. The need for inclusion of more guidance on e side could be considered when next reviewed.
ent refers to the group of people within the client's n who are collectively responsible for the nt and the use of a safety-related software based
has been expanded relating the client role to that of /pically IM and RU) and to include more guidance on isations. lanation of client organisation in relation to the lient organisation was provided in section G 2.3 amples of client organisations have been sought dustry, which could be developed and included in a on of the RIS-0745-CCS.
bose of this RIS, high integrity software-based those systems that deliver functions assessed to y integrity level (SIL) greater that basic integrity, or e Level (PL) at b, c, d and e as set out in the BS EN eries, and where the functionality of the system is elivered through the execution of software (as set e 1.2.1)
graph added to section 1.1 with reference to the ements. Existing 1.1.3 expanded to include how the sists in demonstrating compliance. (now 1.1.4)
ealth and Safety at Work, etc. Act (HASAW) places asibilities on organisations regarding the at of safety. The Management of Health and Safety ulations reinforce HASAW, placing duties on and employees to manage health and safety.
ailways and Other Guided Transport Systems (Safety) (ROGS) require transport operators to maintain a agement system. This standard can be adopted by a isation under their safety management system sist the management of risks relating to high ftware-based systems.

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
6	7	1.1	Whilst introduction of the role of client links to the RAIB report that gave rise to the new standard, it would be useful to put it into context of terms used elsewhere in the industry.	Relate the client role to that of Proposer in CSM RA legislation – this may assist later in the document when CSM RA risk management is referenced.	2	DC		1.1.5 - 1.1.7 Definitions	The followin 1.1.5 Common Assessment proposers of that affects as significant, t applying the 1.1.6 In man undertaking proposers in who is respond vehicles. 1.1.7 When a the client or proposer of Added the for proposer One of the for a) a railwa b) an entit c) a contra i)
									Source: CSM



ng have been added to section 1.1:

on Safety Method for Risk Evaluation and (CSM RA) provides a standard approach for f a technical, operational or organisational change safety to evaluate and assess risk. If a change is the proposer is responsible and accountable for cCSM RA process.

y circumstances, the proposer will be a railway (RU) or infrastructure manager (IM). Other types of aclude an entity in charge of maintenance (ECM) possible for the maintenance and modification of rail

a high integrity software-based system is procured, ganisation could be the RU or IM who would be the the change for CSM RA purposes.

ollowing in Definitions:

ollowing:

y undertaking or an infrastructure manager y in charge of maintenance

acting entity or a manufacturer which invites:

- an approved body or a designated body to apply the UK verification assessment procedure in
- accordance with regulation 17 of and Schedule 4 to the Railways (Interoperability) Regulations 2011; or
- an EU notified body to apply the EC verification procedure in accordance with Directive 2008/57/EC or a designated body according to Article 17(3) of
- that directive.

I RA

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
7	7	1.1.2	It is not clear if the scope of this RIS is intended to cover Train Operating Companies and vehicle owners. This could lead to confusion in the industry.	Examples of client organisations could be provided.	9	DC		1.1	In general, a (or parts of F licence holde consultation effective me Any rail indu choose to ad procedures of Section 1.1 h Proposer and Further expla- change of cli Working exa from the ind future version The following Comment No 1.1.5 Common Assessment proposers of that affects of significant, tl applying the 1.1.6 In man undertaking proposers in who is responvehicles. 1.1.7 When a the client org proposer of the
8	7	1.1.4	BS EN 50128:2001 is listed, however the latest version of this standard is EN 50128:2011 + A2:2020	To amend with the latest EN 50128 version.	10	DC		1.1.8	Revised. The was an e 50128:2011,
9	7	1.1.4	It states, "The standard is structured to align with the 12-phase lifecycle set out in BS EN 50126-1:2017".	I would expect this standard to be structured on the EN 50128 and EN 50657 lifecycle phases. This generates confusion.	10	NC			BS EN 50126 Command, C Installations' for systems, BS EN50126 BS EN 50128 protection a Board Rolling The scope of systems.



a licence holder is only required to comply with RISs RISs) that are applicable to its licenced activities. The er does not have to comply with a RIS if, following h, it has adopted and is complying with an equally easure.

ustry company that is not a licence holder can dopt all or part of a RIS through company or contract conditions.

has been expanded relating the client role to that of d to include more guidance on client organisations.

lanation of client organisation in relation to the ient organisation was provided in section G 2.3 amples of client organisations have been sought

dustry, which could be developed and included a on of the RIS-0745-CCS.

ng have been added to section 1.1, (in response to o 6)

on Safety Method for Risk Evaluation and (CSM RA) provides a standard approach for f a technical, operational or organisational change safety to evaluate and assess risk. If a change is the proposer is responsible and accountable for cCSM RA process.

y circumstances, the proposer will be a railway (RU) or infrastructure manager (IM). Other types of aclude an entity in charge of maintenance (ECM) possible for the maintenance and modification of rail

a high integrity software-based system is procured, ganisation could be the RU or IM who would be the the change for CSM RA purposes.

editorial error. It was intended to be BS EN as listed in the reference section.

5 'is applicable to railway application fields, namely Control and Signalling, Rolling Stock and Fixed S' to the specification and demonstration of RAMS including software.

addresses system issues on the wider scale, while 3 only covers software aspect of railway control and applications, and BS EN 50657 covers Software on g Stock.

f RIS-0745-CCS covers both on-board and trackside

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
10	8	1.2.1	It states, "RIS-0745-CCS issue one covers high integrity software-based systems, specifically those systems that deliver functions assessed to have a safety integrity level (SIL) greater than 0". Please note that the concept of SIL 0 has been replaced with Basic Integrity in all Standards listed in Clause 1.1.4. It is also noted that G2.1.11 states: "Systems that are determined to have a SIL of 0 are referred to in BS EN 50126-1:2017 as 'basic integrity'".	Please amend to read "RIS-0745-CCS issue one covers high integrity software-based systems, specifically those systems that deliver functions assessed to have a safety integrity level (SIL) greater than BI "	10	DC		1.2.1 And G 2.1.11	1.2.1 Revise RIS-0745-CC systems, spe assessed to integrity (BI in the BS EN system is pr Also, first pa The suite of requiremen have a basic this standar because
11	8	1.2.1	Does control logic controller meet this definition or software application in a wheel lathe		11	NC			RIS-0745-CC specifically t have a safet performance functionality execution of The perform performance the RIS show these system
12	8	1.2.2	Not sure why we mention on track separately. I would change the wording	RIS-0745-CCS issue one applies to systems used in railway applications, primarily infrastructure, trains, on- track machines and plant and their operation to deliver a service especially where software controls safety functions.	7	NC		1.2.2	The on-track mentioned s machines ar engineering Machinery (of the base already be s 13849 series systems on and BS EN 6
13	8	1.2.2	Does the standard apply to portable transportable and mobile plant, fixed plant and depot plant?		11	NC			RIS-0745-CC specifically t have a safet Performance functionality execution of If the portate deport plan infrastructur performance then the RIS where the d 1.2.3.



ed. Replaced with 'basic integrity (BI)', now reads: CS issue one covers high integrity software-based becifically those systems that deliver functions o have a safety integrity level (SIL) greater than basic I), or performance level (PL) at b, c, d and e as set out N ISO 13849 series, and where the functionality of the rimarily delivered through the execution of software.

art of G 2.1.11 rewrite to replace 'SIL 0':

f railway software standards places a reduced set of hts on the design and development of systems that c integrity. However, many of the activities set out in rd could be beneficial even at basic integrity

CS covers high integrity software-based systems, those systems that deliver functions assessed to ty integrity level (SIL) greater than basic integrity, or the level (PL) at b, c, d, and e, and where the y of the system is primarily delivered through the f software.

nance level of the lathe software will fall within the e levels set out in 1.2.1 of RIS-0745-CCS. However, uld only be applied where the develop and use of ms are as set out in 1.2.3.

ck machines (OTM) and on-track plant (OTP) are separately, because the control systems on these re generally derivatives of those used on civil g machines that need to comply with the Supply of (Safety) Regulations 2008 (as amended). Also, most machines are from European manufacturers that will supplying control systems compliant with EN ISO es and EN 61508 series. Therefore, the control these machines will use the BS EN ISO 13849 series 51508 series.

CS covers high integrity software-based systems, those systems that deliver functions assessed to ty integrity level (SIL) greater than basic integrity, or ce Level (PL) at b, c, d, and e, and where the cy of the system is primarily delivered through the of software.

ble transportable and mobile plant, fixed plant and are to be used on Network Rail managed re, and that the performance level fall within the e levels set out in RIS-0745-CCS draft 1f clause 1.2.1, 5 applies. However, the RIS should only be applied levelop and use of these systems are as set out in

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
14	8	1.2.2	NTH Plant suggests referencing relevant existing RIS for On-track machines and on-track plant which adequately addresses the same risk or reference to these standards. They are RIS 1530 PLT for OTP and		11	DC			On Track Ma control syste support the
			RIS 1702 PLT for OTM.						RIS-1530-PLT and Their As software in c 5.11.7 All soft documented performance system as de
									RIS-1530-PLT community t wording in th machines an requirement
									of RIS-1530-I '5.14.2.2 Sof All safety rel validated and checks that a included and and EN 6150
									1.2.2 now re RIS-0745-CC applications, to deliver a s
									G2.2.5 updat The Supply o by the 'Produ Exit) Regulat within contro plant. Requin set out in RIS
15	8	1.2.3	How about off the shelf systems proven in service which are already in use? Is this standard retrospective.		11	NC			1.2.3 a) of th to 'the devel developmen which there generic prod therefore off
									This standard and dates ha of internal pr Clause 1.3.1 not been spe procedures of expected to organisation



achines and On Track Plant are fitted with complex ems, therefore RIS-0745-CCS could be useful to safety assurance of the systems.

T Issue 6 'Technical Requirements for On-Track Plant sociated Equipment and Trolleys', currently covers clause 5.11.7:

ftware and software systems shall be validated and d. All software incorporated into a system with a e level of d shall meet the requirements of a SIL 2 efined in BS EN 61508:2010.

T is being revised and at the request of the plant the section on software will be aligned with the he recently published EN 15746-2:2020 'Road-rail nd associated equipment Part 2: General safety ts', where the reference to SIL 2 in the current issue .PLT will be avoided:

ftware

lated software and software systems shall be ad documented. The software validation shall include all foreseeable sequence of operations have been d validated as set out in EN ISO 13849-1:2015, 4.6 D8:2010.'

eads

S issue one applies to all systems used in railway , primarily infrastructure, trains, and their operation service.

ted to refer to RIS's for OTP and PLT

of Machinery (Safety) Regulations 2008 as amended luct Safety and Metrology etc. (Amendment etc.) (EU tions 2019' applies to the safety-related software rol systems used by on-track machines and on-track irements for control systems on these machines are S-1530-PLT and RIS-1702-PLT.

he RIS states the requirements in this standard apply lopment of a generic product or system where the t is commissioned by a client, excluding systems for is no client distinct from the supplier (for example, lucts being developed by a supplier for the market)', f-the-shelf systems are not in scope of the standard.

d is not retrospective, the compliance requirements ave not been specified because these are the subject rocedures or contract conditions.

states 'Compliance requirements and dates have ecified because these are the subject of internal or contract conditions.' RIS's are normally not be retrospective, however it is up to the client to decide when and how to apply.

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
16	9	1.3	If OTM and OTP are in scope, should applications for these assets not come to NTH Plant if he/she were to mandate this RIS via NR/L2/RMVP/0200, 'Infrastructure Plant Manual'?		11	NC			The licence a licence ho with a RIS, t alternative r consultatior It is for Netw added to the
17	10	G 2.1.1	Introduce the issue of hazards being introduced by the work being undertaken.	"Increased complexity and hazards arising from"	2	DC		G 2.1.1	Updated as
18	10	G 2.1.2	'Safety risk' is used regularly in the document.	Add to definitions section.	2	DC		Definitions	The followir safety risk Risk related
19	10	G 2.1.2	Isn't this also the case with software upgrades. Should we add this	Controlling the safety risk associated with software defects and upgrades involves an extension to the approaches used to control the safety risk associated with older technologies because the way in which software fails is different.	7	NC		G 2.1.2	Yes, the soft upgrades. The fundam other syster
20	10	G 2.1.2	The text is clear but concludes stating that "Controlling the safety risk associated with software defects involves an extension to the approaches used to control the safety risk associated with older technologies because the way in which software fails is different ." Actually the software is subject to systematic failures. Also the HW can have systematic failures	I suggest to explicitly mention the Software is subject to systematic failures and given that exhaustive testing is impossible to demonstrate the qualitative aspects are fundamental. This should connect very well with the next paragraph (G2.1.3)	10	NC			Agree that s hardware ca of section 2 director leve specific tech G 2.1.3 expl different to
21	10	G 2.1.3	Additional software systems in additional equipment fitted to a vehicle can also render the software unreliable or extenuate a failure mode or vulnerability		7	NC		G 2.1.3	Agreed. This usage scena
22	10	G 2.1.5	Reference to 'expensive' encourages comparison to cost of safety.	"tends to use more resources be more expensive"	2	DC		G 2.1.5	Updated as
23	10	G 2.1.5	It may not always introduce a defect though. It could still work as intended and still remain compatible with the existing system but give an adverse outcome to the added system		7	NC		G 2.1.5	G 2.1.5 refe software to possible to o testing all po Defect in so result in a d behaviour o system shou
24	10	G 2.1.5	line 3 typo - 'using'		11	NC			No typo fou



condition require compliance with applicable RISs if olders plan to do something that does not comply they may identify and use an equally effective measure to achieve the purpose of the RIS, after n with those who are likely to be affected. work Rail to decide whether RIS-0745-CCS should be ne list of mandated standards in NR/L2/RMVP/0200.

suggested

ng definitions are added:

to human health or to the environment.

tware defects could arise from new development or

ental point is that software fails in different ways to ms.

software is subject to systematic failures, and can have systematic failures. However, the intention 2.1 is to include introductory material that aims for vel readers or others who have limited knowledge in hnological terminologies.

lains in detail the way of how software failure is hardware.

s could be one of the failure modes captured by rios as required by 4.4.1.

suggested

rs to the use of proven and rigorous techniques for introduce fewer defects, as it is generally not confirm the behaviour of software-based systems by ossible combinations of input.

ftware, is an error, mistake or inaccuracy that could eviation from the intended performance or if the software. Giving an adverse outcome to the uld be clarified as a defect.

nd; possible later version has fixed this.

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
25	10	G 2.1.6	Reference is first made to the 'suite of software railway standards' but there are only explained in G 2.2.4.	Move the wording 'For brevity the standards BS software standards in this document' to G 2.1.6.	4	DC		G 2.1.6	The 'suite of introduced i G 2.1.6 revis explanation with existing G 2.1.6 For each 50657:2017 50126-2:202 for controlli based system
26	10	G 2.1.6	It states, "The extent to which functions of a system relate to safety is often expressed in terms of the SIL as set out in BS EN 61508 and associated standards". 61508 is not railway specific. Why does this paragraph not reference EN 50126?	To reference EN 50126 instead of 61508.	10	NC			EN 50126 fo BS EN 61508 G 2.1.6 intro EN 61508. Relationship in the next s
27	11	G 2.1.7		As such, safeguards to control the risk of hardware systems failing are also applied.	2	DC		G 2.1.7	Updated as
28	11	G 2.1.7	Software based systems simply cannot function without hardware.	Amend to read 'Software-based systems operate on hardware and'	4	DC		G 2.1.7	Updated:
29	11	G 2.1.9	Typo - 2 nd sentence (erroneous 'it')	Amend to read 'leading to circumstances where what is specified is'	4	DC		G 2.1.9	'it' removed
30	12	G 2.2.2	The two standards contain very similar requirements but are applicable to different sorts of systems. A new standard is under development, prEN50716:2021, which is intended to supersede both BS EN 50128:2001 and BS EN 50657:2017 Is there a projected timescale for the production of this combined standard?	Documenting the proposed publication date for this standard may be useful	8	NC			BS EN 50716 (according t However, th therefore w
31	12	G 2.2.4	BS EN 50128:2001 is listed, however the latest version of this standard is EN 50128:2011 + A2:2020. See also comment No.1	To amend with the latest EN 50128 version.	10	DC		G 2.2.4	Revised. The was an 50128:2011
32	12	G 2.2.5	Noted		11	NC			G 2.2.5 has conformanc 2008 as ame (Amendmer
33	12	G 2.2.6	Current performance level requirements for OTM and OTP achieves this		11	NC			Noted. Assu [G 2.2.6 The software wi does not car electronic h hardware do



f railway software standards' was first briefly in 1.4.

sed to include these standards, with the further retain in the section (2.2) regarding 'Relationship g standards and legislation'

SIL, the suite of railway software standards (BS EN , BS EN 50128:2011, BS EN 50126-1:2017, and BS EN 17) provides guidance on the techniques to be used ng the risk in the design of safety-related softwarems.....

orms part of the railway sector specific application of 8.

oduced the term SIL which was originated from BS

o with existing standards and legislation are set out section (2.2) of the document.

suggested

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.6 is expected to be published on 22/06/2023 to the BSI website).

he date is unconfirmed and is subject to change, vas not added to the reference.

editorial error. It was intended to be BS EN , as listed in the reference section.

been added recognising the alternative way of ce to the Supply of Machinery (Safety) Regulations ended by the 'Product Safety and Metrology etc. nt etc.) (EU Exit) Regulations 2019'.

ime this is against G2.2.6 in Draft1e. e focus of this standard is on ensuring that the thin high integrity software-based railway systems use hazards. This software will run on programmable ardware, and it is equally important to ensure the oes not cause hazards.]

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
34	13	G 2.2.12 & G 2.2.13	Legislation requires the risk of the change to be managed. CSM RA is required by legislation to be used for significant projects although Network Rail require CSM RA to be used for non-significant change too – refer HSMS V6 section 3.1.2: "NRIL has adopted the principle that for any change (technical, operational and organisational) proposed, it applies the risk management framework defined in the CSM RA, including as its methods of safety verification."	Strengthen advice to use CSM RA to manage hazards arising from the changes being implemented and those that are existing.	2	DC		G 2.2.12 & G 2.2.13	G 2.2.12 & G RA. G 2.2.12 The managemen technical, op system. Gui technical ch are significa independen for CSM RA G 2.2.13 Sor the requiren particularly it is efficient safety assure
35	13	G 2.2.13	States 'if the CSM RS applies to the project' – however, hazard management should always apply. This should be the theme throughout this document. The only decision to be made is whether or not to use CSM RA, if not mandated within the client organisation e.g., NR HSMS.		2	DC		G 2.2.12&13	Section 1.1 l requirement G 2.2.12 & C use CSM RA
36	14	G 2.3.5	Some client organisations may wish to procure engineering services rather than directly employing staff. They may wish to use this procured resource to carry out the client defined actions. This may be necessary because the client organisation is very small, or alternatively it may be a choice taken within an organisation.	Amend the clause to confirm that it is possible to use procured resources, but that the responsibility remains with the client. In addition G 3.2.1.6 could be amended by adding it is possible to close a resource gap by procuring suitable external resource.	3	NC		G 2.3.5	Clause G 2.3 'The Client s accommoda Significant c of requirem It is howeve competence
37	15	G 2.4.3	2nd sentence - Wording could be improved.	Amend to read 'Requirements for client action during'	4	DC		G 2.4.3	Updated
38	15	G 2.4.4	1st sentence - Wording could be improved.	Amend to read 'specific requirements for client action during'	4	DC		G 2.4.4	Updated
39	15	G 2.4.5	1st sentence - Wording could be improved.	Amend to read 'specific requirements for client action during'	4	DC		G 2.4.5	Updated
40	15	G 2.4.6	1st sentence - Wording could be improved.	Amend to read 'specific requirements for client action during'	4	DC		G 2.4.6	Updated



6 2.2.13 revised to strengthen the advice to use CSM

e CSM RA regulation sets out a harmonised risk nt process used to assess the impact on safety from perational and organisational changes to the railway idance on CSM RA is set out in GEGN8646. If the anges related to introducing the software or system nt, as defined in article 4 of the CSM RA, then an t assessment of the risk assessment is undertaken as set out in 3.6 of this document.

ne of the requirements of this standard overlap with nents of legislation and of other standards,

the CSM RA. If the CSM RA applies to a project then t to align the safety assurance activities set out in the rance strategy with those for the CSM RA.

has been revised to Include reference to the legal ts to manage risk. (See response to Comment No 5)

G 2.2.13 has been revised to strengthen the advice to . (see response to comment No 34)

8.5 explains the two different phrases used in the RIS shall' and "The Client shall require that" to ate the different management arrangement. considerations were given so that only minimum set ents are using 'the client shall'.

r up to the client organisation of how to make resources available for any projects.

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
41	16	G 2.5.1	Note: generally cyber-security of a system is concerned with preventing unauthorised people accessing confidential data on it or causing it to stop working or causing it to do something unwanted." It is understood why this note has been added for the "Unauthorised access" hazard within the table, however it is felt that the comment can be misleading. Whilst cyber-security does cover preventing unauthorised access, it also could cover events that occur due to personnel with authorised access making an error or acting with malicious intent. I feel having this statement within a RIS could lead to people regarding cyber-security as only being related to unauthorised access.	The removal of the "generally" is proposed. A suggestion on the wording of this note is: "One area of cyber-security is the prevention of unauthorised people accessing"	6	DC		G 2.5.1	The note in Note: one a unauthorise it to stop wo
42	17	G 2.6.3	Figure 2, General Blue box, 3.4 Convene stage gate reviews can not be delegated. I believe some clients will not be able to competently do this.		11	NC			Assume it is Significant of of requirem It is essentia of the safety how to mak If a client is compliance something t and use an of purpose of t to be affecto Any rail induced
43	17	G 2.6.4	Paragraph doesn't read correctly. Should there be a full stop between "controlled" and "That"?		7	NC		G 2.6.4	The full stop sentence re effective co
44	19	3.1.1	System Assurance Strategy – could be linked to CSM RA to start baking in hazard management using a defined process.		2	NC		3.1.1	The intentio client organ managemer The link to C Part 2 of the
45	19	3.1.1 .1	The safety assurance strategy is very generic and not software specific. A more detailed SW specific list would support better the organisations	To be more SW specific.	10	NC			The intention of a client as software-bas support com but do not r The high int software an
46	20	G 3.1.1.11	Typo – 2 nd sentence	Amend to read 'alteration'	4	DC		G 3.1.1.11	Amended



the table has been revised accordingly.

rea of cyber-security is the prevention of ed people accessing confidential data on it or causing orking or causing it to do something unwanted.

- now against G 2.6.4 in Draft1f
- considerations were given so that only minimum set nents are using 'the client shall'.
- al for a client to convene stage gate reviews as part by management. It is up to the client organisation of ke competence resources available for any projects. a licences holder, the licence condition require with applicable RISs. if a licence holders plan to do that does not comply with a RIS, they may identify equally effective alternative measure to achieve the the RIS, after consultation with those who are likely
- ed. ustry company that is not a licence holder can idopt all or part of a RIS through company
- or contract conditions
- o is need. 'That assurance' at the start of the second fer to the assurance that safety risk has been ntrolled referenced in the first sentence.
- on of this standard is to identify the activities for hisations to undertake as part of the safety nt of high integrity software-based systems.
- CSM RA has been strengthened in section 1.1 and e document.
- on for the RIS is to identify the activities for the role as part of the safety management of the high integrity ased systems. The requirements in this standard mpliance with the suite of railway software standards replace or overrule any part of them.
- egrity software-based systems includes both d hardware.

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
47	20	G3.1.1.1	Bullet a) states: "a maximum tolerable rate for hazard occurrence". Software is subject of systematic failures. This is not applicable in the SW context.	 Please make it SW specific. Please also consider aligning with the new EN 50126, the terminology adopted seems to be related to the old version of the standard. THR and SIL Allocation are outside the scope of the SW as per EN50128 and EN50657 (see also 3.1.3.1 bullet b)). 	10	NC			Assume the The high int software an ways of defi which one t 3.1.3.1 b) re for safety as and hardwa Clause 4.3 o integrity lev the basis of associated v
48	20	G3.1.1.5	This clause makes an important point that would usefully be introduced in the opening paragraphs of the document.		2	NC		G3.1.1.5	Section 1.1 requiremen
49	21	3.1.2	This is already determined for OTM and OTP hence reason to refer to existing RIS that cover them G 3.1.2.4; G 3.1.2.5 & G 3.1.2.6		11	NC			Noted. It wo activities set hazard man
50	21	G 3.1.2.2		"in a way that will efficiently yield the greatest"	2	DC		G3.1.2.2	Updated.
51	22	G 3.1.2.12	States 'if the CSM RS applies to the project' – however, hazard management should always apply. This should be the theme throughout this document. The only decision to be made is whether or not to use CSM RA, if not mandated within the client organisation e.g., NR HSMS.		2	NC		G 3.1.2.12	See respons
52	22 & 43	3.1.3.1 & 4.5.1.1	It is unclear what level of requirements should be recorded / managed here. For example if procuring an ETCS system, a client would probably specify at the level of ERA standards. However those standards contain many requirements, such as those defining how to calculate the braking curves. An ETCS supplier would then probably take the ERA standard requirements and further develop them to produce software requirements.	Clarify the requirement level that should be managed by the client. Is it acceptable to manage to the top level in the example given if anything below that is covered by a Software Assessment Report from an Assessor?	3	NC		3.1.3.1 & 4.5.1.1	Clause 3.1.3 the system a The importa safety assur This require defined acti possible for action to an accountabili
53	23	G 3.2.1.5	It states: "Key competencies for roles in the system development process are defined in Annex G of BS EN 50126-2:2017 and Annex B of BS EN 50128:2001 which might be relevant if the client organisation is carrying out tasks associated with these roles."	Please add EN 50657 Annex B	10	DC		G 3.2.1.5	Added BS Ef G 3.2.1.5 no Key compet are defined 50128:2011 relevant if th with these r



comment is against G 3.1.1.4.

tegrity software-based systems includes both nd hardware. G 3.1.1.4 provides guidance for various fining target for safety. The guidance does not specify to use.

efer 'the SIL determination for each safety function' ssurance records. This is necessary for both software are elements.

of BS EN50128 states 'The required software safety vel shall be decided and assessed at system level, on f the system safety integrity level and the level of risk with the use of the software in the system.'

has been revised to Include reference to the legal nts to manage risk. (see response to comment No 5)

buld be efficient to align the safety assurance t out in this standard with those for other safety and agement processes.

se to comments No 35.

3.1 referred to safety function of the system, it is at and functional level.

ant aspect of this requirement is to establish the rance records and maintain traceability.

ement is in case of 'The client shall require that [some ion is taken]', as defined in G 2.3.5, which means 'it is r the client organisation to delegate the defined nother organisation provided that it retains lity for the performance of this action.'

N 50657:2017 Annex B.

w reads:

tencies for roles in the system development process in Annex G of BS EN 50126-2:2017, Annex B of BS EN and Annex B of BS EN 50657:2017 which might be he client organisation is carrying out tasks associated roles.

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
54	23	3.2.2.1	To enable the supplier to accurately cost the scope of this work, the client should provide its own assurance strategy for the project.	Recommend that there is an additional point that the client should distribute its own assurance strategy to the supplier.	9	NC			Section 3.2. The require engaged in s to them in t The safety a of the syste project wou strategy.
55	23	G 3.2.2.4	Specific requirements for the SW Independent assessor are detailed in EN 50128 and EN 50657	Please add a reference to SW Standards	10	DC		G 3.2.2.4	Replaced th railway soft G 3.2.2.4 no If the project then the sui responsibility the project
56	24	3.3	It should be made clear that it is the client's responsibility to ensure that they have sufficient contractual arrangements to enforce this RIS.	Recommend adding the following guidance: 'The client can effectively apply the safety assurance strategy only if it has contractual arrangements in place to do so. This would should include explicit reference to this RIS and the suite of standards'	9	DC		G 3.3.1.2	The safety a justification applied on t The required client shall ensure cont (3.3.1.1a) an safety assur The suite of Additional r The client ca only if it has
57	24	3.3	This is not a technical requirement, I suggest wording be relaxed if it is to be left in this technical standard. Ultimately the organisation paying would determine how they manage their contracts		11	NC			The contract safety risk a safety assur strategy. If a client is compliance something t and use an of purpose of t to be affect Any rail induction procedures
58	24	3.3.1.1	It would be beneficial if the clients own assurance strategy for the project was contracted too.	Recommend adding the client's safety assurance strategy to the contract terms list.	9	NC			The relevant process/stat has already 3.3.1.1b).



- .2 includes requirements on supply selection.
- ement on client to place contract terms on suppliers safety-related activities, for these activities assigned the safety assurance strategy is set out in 3.3.1.1a).
- assurance strategy is maintained throughout the life em, it is expected all organisations involved in the uld need to share information to support this
- ne reference to BS EN 50126-2:2017 with the suite of tware standards.
- ow reads:
- ct includes an Independent Safety Assessors (ISA) ite of railway software standards places a specific ity on them for the evaluation of the competency of staff and organisation.
- assurance strategy (3.1.1) requires the definition and n of how the requirements of this standard are being the project.
- ement on contract terms (3.3.1) uses the phrase "the ..." so it is clear it is the client's responsibility to tract terms are in place for relevant activities nd process/standards (3.3.1.1b) identified in the rance strategy.
- f standards is induced in 3.3.1.1 d).
- rationale added to start of G 3.3.1.2:
- an effectively apply the safety assurance strategy s contractual arrangements in place to do so. ...
- ct terms placed on suppliers supports the control of and the provision of evidence that supports the rance strategy and other standards identified in the
- a licences holder, the licence condition require with applicable RIS's. if a licence holders plan to do that does not comply with a RIS, they may identify equally effective alternative measure to achieve the the RIS, after consultation with those who are likely ted.
- ustry company that is not a licence holder can idopt all or part of a RIS through company or contract conditions
- nt activities assigned to the supplier and andards identified in the safety assurance strategy been included in the contract term list (3.3.1.1a and

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
59	24	3.3.1.1	Similar to point 3 above, the list should include clear reference to the RIS and the suite of standards.	Recommend the list includes a reference to this RIS.	9	NC			The safety a the required project. The relevan process/sta has already 3.3.1.1b). In general. a (or parts of licence hold consultation effective me Any rail indu choose to a procedures
60	24	G 3.2.2.6	It states: "Key competencies for roles in the system development process are defined in Annex G of BS EN 50126-2:2017 and Annex B of BS EN 50128:2001"	50128:2001 should be replaced with the latest version of this standard and EN 50657 should be added.	10	DC		G 3.2.2.6	Added BS El G 3.2.2.6 nc Key compet are defined BS EN 50123
61	26	3.5	This section should also refer to hazard management and hazards arising from the change being implemented. Often these changes require further hazard identification work focusing on the change to scope or programme that is being implemented.		2	DC		G 3.5.1.6 e)	This section throughout activities mid design Requiremen evaluation' record is pro- identification relevant new occur.' G 3.5.1.6 e) G 3.5.1.6 e) Once a confany propose the change of the change
62	26	3.5	This would aid the PA process and reduce the need for relevant PA certs to be updated every time a change is made to software. Current wording for PA certs was developed when the railway was hardware intensive and is not suitable for software systems. This section or standard can help amendment of relevant PA requirement for significant changes to be reflected on PA for all assets(including software).		11	NC			Noted, this Acceptance



assurance strategy (3.1.1) defines and justifies how ments of this standard are being applied on the

nt activities assigned to the supplier and andards identified in the safety assurance strategy v been included in the contract term list ((3.3.1.1a and

a licence holder is only required to comply with RISs RISs) that are applicable to its licenced activities. The der does not have to comply with a RIS if, following in, it has adopted and is complying with an equally reasure.

lustry company that is not a licence holder can adopt all or part of a RIS through company s or contract conditions.

N 50657:2017 Annex B.

ow reads:

tencies for roles in the system development process I in Annex G of BS EN 50126-2:2017, Annex B of 28:2011 and Annex B of BS EN 50657:2017.

n is about change control that is applicable t the lifecycle. Without change control, safety night not be carried out on a consistent version of the

nt in 4.3.2 (now 4.3.3) 'Ongoing risk analysis and refers to need for the client to require that 'hazard roduced to record the results of system hazard on and risk assessment and is kept up-to-date as ew information becomes available and changes

has been updated as follows:

Change control

figuration item has been included within a baseline, ed change to it is fully assessed and approved before is made and tracked to completion. The assessment ge includes safety analysis of the impact of the

comment is about Network Rail's internal Product process.

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
63	26	3.5.1.1	Some safety systems (eg. ASDO, TSRs) rely on databases to function. While changing the database does not impact the actual software code it can affect the safe operation of the system. Some database changes are required at short notice, or even immediately in the case of an ESR/TSR. Changes to such databases need special consideration given the immediate / short term nature of the change.	Add a requirement for the client to ensure a robust process is in place for managing changes to databases, including the validation & verification element. For example in an ASDO system: if data for a single platform is modified, can a process be put in place to ensure that no other data was erroneously changed in the database? Propose a test at the platform in question before rollout of the new database.	3	NC		3.5.1.1	Noted and a changes to o The term 'co data that de and its desir Clause 1.2.4 that the soft configuratio The existing are establish applications data, includ The 'configu- configuratio change cont
64	26	G 3.5.1.4	Focus the project team on the proposed changes by altering the wording as suggested.	Only the key effected items	2	NC		G 3.5.1.3	Assume this Change cont than just the
65	28	G3.5.1.1 0	Not sure this clause is relevant – would all users of this RIS have access to NR/SE/001 anyway?		7	DC		G 3.5.1.10	This was inc that NR doc Clause revis reference is Further guic handbook (I
66	29	3.6	How about when the client is simply buying a compliant off the shelf product? In this case they will have a product and a certificate - what would the client be assessing or assuring? Most software modules with safety critical function are either bought or certificed by a specialist, what would be assessed or assured in this scenario without duplicating initial compliance and purchase scrutiny activity by the client (Converter or Vehicle Owner?)		11	NC			 1.2.3 a) of the to 'the developmer' which there generic procetor therefore of 4.5.2 of the pre-existing railway soft use.
67	30	Part 4	Is it the aim of this part of the RIS to provide clarity to the clients activity? Do the authors believe BS EN 50126-1:2017 is not clear enough for clients to interpret it on their own? This Part will not apply to OTM and OTP if reference is made to existing standards that adequately fulfills the purpose of this RIS. Section comment made on clause 1.2.2.		11	NC			The RAIB rep 2017 highlig implement a associated g installation a systems'. The report. This part ide on during sp If safety asso following ex safety assure other safety are no dupli



agreed the need for process in place for managing data.

onfiguration data' is used in the standard referring to efines the environment in which the system will run red behaviour.

I states 'It is important that the safeguards to assure tware is correct are extended to cover the on data as well.'

requirement in 3.5.1.1 covers the need for process ned for configuration management of the system, its , its components and associated documentation and ing arrangement for controlling change

uration data' is listed as one of the typical on items' in Clause G 3.5.1.4, which is subject to trol as set out in G 3.5.1.6 e).

is for G3.5.1.3.

trol and configuration management applies to more terms being modified or effected.

luded to acknowledge contribution of material from ument.

ed to refer to further guidance instead, so that the only for readers wishes to get more information.

dance is set out in Network Rail System Engineering NR/SE/001).

the RIS states the requirements in this standard apply elopment of a generic product or system where the nt is commissioned by a client, excluding systems for e is no client distinct from the supplier (for example, ducts being developed by a supplier for the market), ff-the-shelf systems are not in scope of the standard.

RIS requires safety justifications are provided for subsystems or software elements. The suite of ware standards also contains guidance relating to re-

port on Cambrian Coastline incident on 20 October ghts the need to for the rail industry to 'develop and a mandatory safety assurance procedure (and guidance) for its client role on projects involving and modification of high integrity software-based ne RIS has been developed in response to the RAIB

entifies specific requirements placed on client to act pecific phases of the system lifecycle.

urance activities have been carried adequately isting standards, it would be efficient to align the ance activities set out in this standard with those for and hazard management processes, so that there cated efforts.

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
68	30	G 4.1.1	Typo – 2 nd sentence	Amend to read 'system lifecycle is described'	4	DC		G 4.1.1	Done
69	32	Table 2	Typo – 4.5 'Relevant client's activities' box	Amend to read 'Engage with the decisions taken'	4	DC		Table 2	Done
70	32	Table 2	Typo – 4.8 'Relevant client's activities' box	Amend to read 'Liaise with stakeholders inside and outside the client's organisation''	4	DC		Table 2	Amended
71	33	G 4.2.1.3	1 st sentence – Wording can be improved	Amend to read 'The deliverables identified in section 7.3.3 of BS EN 50126-1:2017 are a system'	4	DC		G 4.2.1.3	Amended.
72	33	G 4.2.1.3	It states: "The deliverables identified by BS EN 50126- 1:2017 (7.3.3) are a system definition, a safety plan, and a RAM plan. Guidance on these deliverables and the activities needed to produce them is provided in the suite of railway software standards" Please note these documents are not deliverable of any specific SW Standard such us EN 50128 EN 50657. This creates an inconsistency with the Railway standards	Please consider amending this section to list planning documents requested by SW Standards, e.g. SQAP (SW Quality Assurance Plan, SW verification and Validation Plan, SW Configuration Management Plan, etc	10	NC			The RIS is in which includ the lifecycle The plannin already cove 50128. Thes and validation involvement to approve
73	33	4.2.2.1 a)	This statement contradicts G 2.4.6 which states Phase 12 (Decommissioning) is out of scope of this standard.	Please clarify.	4	DC		G 2.4.6 4.2.2.1 a)	There is no o no requirem requires the demands th 8, 9, 11 and G 2.4.6 has This standar act during P considered f consider ho design, and concepts du
74	36	4.3.1	Include requirement to undertake risk analysis and evaluation for potential failure modes.		2	NC		4.3.2	The required consider 'th roles, lifecyo Potential fai out in 4.4.1



tended for high integrity software-based systems de both software and hardware, and it aligns with and deliverables from BS EN 50126-2:2017.

ng documents as listed are software specific and vered by specific software standards such as BS EN se documents would be needed for the verification ion of the software design, where the client nt is set out as a general requirement in 3.4 of the RIS phased deliverables.

contradiction: G.2.4.6 states that this standard puts ment for client action in Phase 12; Clause 4.2.2.1 e development of lifecycle concepts in Phase 2 which he consideration of the approach to lifecycle phases 12.

been revised to clarify:

rd contains no specific requirements for the client to Phase 12 because the activities during that phase are to be out of scope. However, it is necessary to ow the decommissioning phase impacts the system I this is covered by the production of lifecycle uring Phase 2.

ement in 4.3.1 (now 4.3.2) refers to the need to he full scope of system functions, interfaces, user vcle concepts, and usage scenarios'

ilure modes are included in 'usage scenarios', as set of the standard.

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
75	38	G 4.3.1.16	 Place this clause at the beginning of 4.3 since the whole of 4.3 explains fundamentals of hazard management that should be implemented using CSM RA on the mainline railway network. CSM RA provides a framework for risk analysis and evaluation that provides for change to be integrated into the operational network or other projects/railway organisations. It also allows migration of a project that begins with a limited scope that develops into a more complex project. By placing the contents of G 4.3.1.16 at the end of section 4.3, the reader may conclude that CSM RA is additional to the hazard management previously described in section 4.3. This may result in duplicate work, un-necessary expenditure, and confusion. 	Reiterate legislation in UK mandates CSM RA to be used for managing hazards throughout the project lifecycle for all significant changes to mainline railway. This standard, RIS 0745-CCS, is aimed at managing risk in connection with technology which, by its' very nature, is novel, complex and safety critical. Any change to such infrastructure is nearly always significant under the CSM regulations. On mainline railway, CSM RA should also be applied to non-significant changes when required by the owner, e.g. Network Rail, although an independent assessment body is not necessarily required.	2	DC		G 4.3.1.1 G 4.3.1.2	Guidance G reworded: Compliance through the guidance on There might the requiren it is efficient safety assure
76	38	G 4.3.2.1	Include changes to scope and programme require the system definition to be updated and the hazard identification to be revisited to consider the changes. Such changes may result in unintended interfaces or operation situations, e.g. interim or temporary operating methods and practices.		2	NC		G 4.3.3.1	Agreed. The hazard i indicated in The safety a through the of the system external syst The strategy to the scope controlled a 3.5.
77	39	4.3.3.1	Wording can be improved	Amend to read 'The client shall require that a register of safety -related conditions on the application of the system is prepared (known as the register of safety- related application conditions)	4	DC		4.3.4.1	Existing G 4. safety-relate 4.3.3.1 (now The client sh conditions o
78	39	4.3.3.2	Wording can be improved	The client shall require that the conditions in the register of safety-related application conditions are respected at all times.'	4	NC		4.3.4.2	It is not nece 4.3.4.2).
79	40	G 4.4.1.3	Should include normal operating environment. For example, operating in temperature extremes or exposure to weather in the components usual location		7	NC		G 4.4.1.3	'Normal ope Also, the exp hardware fa relating to R in Table 1 in
80	40	Between G 4.4.1.5 and G 4.4.1.6	In order to ram home the need for specific guidance on incident investigation, a new clause should be added here.	Add 'Incident investigation covers the provision of facilities to retain system data to support the identification of root cause in the event of an occurrence that needs to be investigated'	4	DC		G 4.4.1.6	New guidan Incident inve system data adverse eve



4.3.1.16 moved to the beginning of 4.3 and

- with CSM RA is required in GB for duty holders safety management system under ROGS. Further CSM RA is provided in GEGN8646.
- be overlap between activities undertaken to meet nents of this standard and those needed by CSM RA. to align the safety assurance activities set out in the ance strategy with those for the CSM RA.

- identification to be revisited if change occurs is G 4.3.2.1 (now 4.3.3.1).
- assurance strategy set out in 3.1.1 that is maintained e lifecycle of the system, includes 'a) the description m in terms of its functions, users, and interfaced stems;'
- v would need to be updated if there are any changes e of a project. These changes would also need to ccording to the change control process in set out in
- .3.3.7 (now G 4.3.4.1) already provides guidance on ed application conditions.
- 4.3.4.1) revised:
- nall require that a register of safety-related on the application of the system is prepared.
- essary to include 'at all time' for 4.3.3.2 (now
- eration' was included in G 4.4.1.3
- posure to weather etc relates more to specific ilure, which are normally covered by standards teliability, Availability and Maintainability, as shown RIS-0745-CCS.
- ce added as G 4.4.1.6:
- estigation covers the provision of facilities to retain to support the identification of root cause of nts.

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
81	41	G 4.4.1.12	1 st sentence, wording could be improved.	Amend to read 'those key safety functions, whose correct behaviour'	4	DC		G 4.4.1.10	Assume the The process scenarios w functions, w
82	42	G 4.4.2.9	Further clarification to be added.	Add 3 rd sentence 'However, it is important that the software-based system remains safe with data values that are outside 'normal bounds' and this should be confirmed'	4	DC		G 4.4.2.9	Software-ba include a sig the environ its desired b system will values. How remains safe and mitigati defects.
83	42	G 4.4.3.6	 [Minor] "Integration finds problems at interfaces between systems." Is it "Integration" that finds problems at interfaces, or would it be the next step "System Validation"? I assume that the risks associated with interconnected systems are to be highlighted in stage 3 Risk Analysis and Evaluation? Therefore is the purpose of the sentence trying to guide the client to think about the tests that can be performed to check if there are any problems at the interfaces? 	Is the sentence required? – proposed it is deleted. Or "Integration considers problems at interfaces between systems"	6	DC		G 4.4.3.7	A new parag the sentence Integration If a system h everything i very difficult
84	44	4.5.2	Pre-existing SW is already regulated by specific requirement of EN50128 and EN50657.	Please align with SW Standards.	10	NC			Agreed pre- BS EN 50128 It is not the adequately on identifyir
85	44	G. 4.5.2.2	A key aspect missing from this list are any hardware differences	Add f) evidence that the hardware being used to run the software element is identical to the pre-existing use case	4	NC		G. 4.5.2.2	The required The wording element und In case of a that the har justification element on subsystems. In case of pr software), the could be idee the use of the
86	44	G 4.5.2.3	Wording can be improved	Amend to read 'If this analysis was not carried out it might	4	DC		G 4.5.2.3	Amended: If this analys that the sub hazard.



comment is against G 4.4.1.10

of checking system requirements against the usage ill allow the identification of those key safety whose correct behaviour...

ased systems are often highly configurable and gnificant amount of configuration data which define ment the system is intended to operate in as well as behaviour. It is rarely possible to demonstrate that a work for every combination of configuration data vever, it is important that the software-based system fe with data values that are outside 'normal bounds' cions are in place for safety risks associated with data

graph should have started from 'Integration finds ...'. e also revised as suggested.

considers problems at interfaces between systems. has interfaces with many external systems and s put together at the same time, problems can be t to find....

existing software already covered by 8:2011 and Annex B of BS EN 50657:2017. intention of the RIS to repeat what has been covered by other standards, rather to concentrate ng activities for client to act on.

ment does not preclude hardware element.

g in 4.5.2.2 referring 'the subsystem or software der consideration' includes hardware.

pre-existing software element is proposed, it is likely rdware to run the software is different, safety need to be provided for running the software other hardware, and/or within other software

re-existing subsystem (with both hardware and he hardware being used to run the software element entical, however safety justification is required for he subsystem as a whole.

sis was not carried out it might be discovered later osystem or software requirements could cause a

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
87	49	G 4.6.10	The use of operational mitigations in the case of a pre- commissioning defect would not be a course of action that I would support lightly.	This should be considered as a last resort and only consider when the source of the defect has been identified. A key issue in the past has been putting a system into use restricts the access to investigate and rectify the underlying problem thus further extending the defect period and potentially the cost impact.	1	DC		G 4.6.10	G 4.6.10 Gui Defects iden to rectify. Th the use of th system to co permanent, validation ac a last resort defect has b restrict the a problem thu potentially t
88	50	4.8	The scenario described in appendix G.B.2.9 where a failure of the type that caused an incident of a similar nature had been identified with a related system in operation on another administration.	There should be some guidance that it is desirable to have in place a process where such defects are shared with interested parties. Realistically the onus needs to be on the supplier to identify this situation as only they have an overview where the equipment concerned has been deployed.	1	NC			Clause 3.3.1. suppliers for
89	50	4.8.1	Lifecycle requirements	Consider adding as guidance: Ensure that any activities put in place to satisfy an SRAC are still in place and being executed.	3	DC		4.8.1.6	G 4.8.1.6 rev Activities pla include those (4.2.2 of this this docume These activit usual proces
90	50	G 4.8.1.2	Typo – 2 nd sentence	Amend to read 'impact safe operation is identified quickly.'	4	DC		G 4.8.1.2	'are' replace
91	51	G 4.8.3.4	It is already accepted nomenclature on the railway for the D in DRACAS to represent 'Defect'	Amend to read 'scope of a Defect Recording Analysis'	4	DC		G 4.8.3.4	Updated.
92	54	G A.4.2	Further clarification to be added.	Add 'Has the system been confirmed to react in a safe manner with data values that are outside 'normal bounds.'	4	DC		G A.4.2j)	The list in G be consider The followin j) Have requi data values t
93	55	G A.5.2	A key aspect missing from this list are any hardware differences	Add 'Is the pre-existing software element running on the same hardware as previously deployed?'	4	NC		G A.5.2	The list relat See response
94	56	G A.7.2 – h)	Missing word	Amend to read ' which could create the potential for an incident'	4	DC		G A.7.2 – h)	Added 'the'
95	59	G B.2.9	Туро	Amend to read ' but had the chance been implemented then'	4			G B.2.9	Replaced 'be



idance has been revised:

ntified during system validation are often expensive the client might choose to put in place restrictions on the system to mitigate these defects and allow the portinue into operation. These restrictions might be or temporary until the fault is fixed and the ctivity repeated. Operational mitigations are used as and are only considered when the source of the been identified, as putting system into use might access to investigate and rectify the underlying us further extending the defect period and the cost impact.

.1.f requires the client to place contract terms on r provision of incident information through-life.

vised to include activities in place for SRAC

anned and carried out under this requirement will be identified in the maintenance lifecycle concept s document) and related usage scenarios (4.4.1 of ent). Activities to satisfy SRACs will remain in place. ties will often be an integral part of the business-assses for the system's operator and maintainer.

ed with 'is'

A.4.2 relates to 4.4.1 'User scenarios' that need to when looking for missing system requirements.

ng has been added:

irements been defined to deal with defect data or that are outside boundaries?

tes to pre-existing subsystems or software elements. e to No 85.

before 'potential'

e' with 'been'

No	Page	Clause	Comment	Suggestion	Ву	Way forward	Page	Clause	Response
96	59	B.3 Railway power disruptio n	Please remove this example. It incorrectly gives the impression that this is a greater than SIL 0 system. It isn't. Please also review BS EN 50562. This states "A SIL-allocation for functions of electric traction systems is not required within the framework of EN 50562."	Delete	5	DC		B.3 Railway power disruption	Deleted.
97	61	Table 5	Typo (Why are the [] here?)	Amend to read 'Change Control Processes'	4	DC			Section B.3
98	62	Table 6	Typo (Why are the [] here?)	Amend to read 'Change Control Processes'	4	DC		Table 5	Removed br 'Change cor
99	66	G C.1.3	Туро	Amend to read 'scenarios that cover all modes'	4	DC		G C.1.3	Done.
100	67	G C3.1.1. c)	Suspected wording error. Not clear why 'Inconsistent or incomplete specifications of any of the interfaces could lead to failures' is presented here.	Please clarify where this statement should appear in the document.	4	DC		G C3.1.1.2	This statem C.3.1.1 Updated.
101	69	DRACAS Definitio n	It is already accepted nomenclature on the railway for the D in DRACAS to represent 'Defect'	Amend to read 'Defect Recording Analysis'	4	DC		DRACAS Definition	Definition u
.02	73		Please remove reference to GLRT1210 and BS EN 50163:2004. Neither of these standards have any SIL or software requirement	Delete	5	DC			The two doo Removed.
103	73		BS EN 61508 missing from refences	Add missing reference	5	DC		References	Added: BS EN 61508 programma
.04	73	RSSB 2022	This is cited as an RSSB document. There seems to be something missing from the definition.	Please clarify.	4	DC		RSSB, 2021	This informa dated 2021, Reference r RSSB, 2021



deleted (see response to No 96)

racket in the table, changed the subtitle in 3.5.1 to ntrol processes'

ent should appear as a separate paragraph after G

pdated.

cuments were only referenced from B.3.

8-1:2010 Functional safety of electrical/electronic/ ble electronic safety-related systems.

ation on A400M incident summary, and is a report , and is downloadable from a RSSB web page. revised:

> A400M disaster 2015, RSSB, 2021 [Online]. Available from www.rssb.co.uk [Accessed 7 Jan 2022]