



RIS

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Rail Industry Standard for Verification of Conformity of Engineering Change to Rail Vehicles

Issue record

Issue	Date	Comments
One	March 2016	Original document. Replaces GMRT2000 issue three, GMRT2001 issue two, PS305-04 issue one and GEGN8565 issue one. This RIS takes the relevant text of the above documents and places it in the context of the prevailing industry legislation affecting verification of conformity of rail vehicles.

Superseded or replaced documents

The following Railway Group documents are superseded or replaced, either in whole or in part as indicated:

Superseded documents	Sections superseded	Date when sections are superseded
GMRT2000 issue three Engineering Acceptance of Rail Vehicles	All	04/06/2016
GMRT2001 issue two Design Scrutiny for the Engineering Acceptance of Rail Vehicles	All	04/06/2016
PS305-04 issue one Specification for Vehicle Acceptance and Conformance Certification Bodies	All	04/06/2016
GEGN8565 issue one Guidance on the Retention of Design Information, Validation of Technical Change and Configuration Management	All	04/06/2016

GMRT2000 issue three, GMRT2001 issue two, PS305-04 issue one and GEGN8565 issue one cease to be in force and are withdrawn as of 04 June 2016.

Supply

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Part 1 Introduction

1.1 Purpose of this document

- 1.1.1 The purpose of this Rail Industry Standard (RIS) is to set out a process which can be adopted by organisations that are undertaking projects that require verification of conformity of an engineering change to rail vehicles against applicable requirements and by organisations that carry out the verification work.
- 1.1.2 In particular, this RIS can be used as a regime to demonstrate conformity with Railway Group Standards (RGSs) applicable to rail vehicles.
- 1.1.3 The following vehicle types are considered to be outside the scope of this document:
- a) On-track machines (OTMs) – travelling and working modes (alternative process outlined in RIS-1710-PLT).
 - b) On-track plant (OTP) (alternative process outlined in RIS-1710-PLT).
 - c) Vehicles registered for operation outside Great Britain (GB) prior to the implementation of the Railways (Interoperability) Regulations (RIR) 2006 (requirements covered by RIR 2011 (as amended), Cross-Acceptance agreements or UIC503).

Aspects of Part 4 of this document can however provide methods that can be adopted as part of the verification of the above vehicle types.

1.2 Application of this document

- 1.2.1 A member of RSSB may choose to adopt all or part of this document through internal procedures or contract conditions. Where this is the case, the member of RSSB will specify the nature and extent of application.
- 1.2.2 Therefore, specific compliance requirements and dates have not been specified since these will be the subject of internal procedures or contract conditions.

1.3 Health and safety responsibilities

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1.4 The structure of this document

- 1.4.1 This document is set out as a series of requirements, in some cases followed by relevant guidance. The guidance is indicated by prefixing the paragraph number with the letter 'G'.
- 1.4.2 Part 2 of the document introduces the principles of verification in the rail industry, as set out in other parts of this document.
- 1.4.3 Part 3 provides requirements and guidance on the degree of independence when undertaking verification work.
- 1.4.4 Part 4 provides requirements and guidance on the methodology for the verification processes to assess design conformity and construction conformity.
- 1.4.5 Part 5 provides requirements and guidance on the compilation of verification records.
- 1.4.6 Part 6 provides requirements and guidance on the production of an attestation statement.

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1.6 Approval and authorisation of this document

- 1.6.1 The content of this document was approved by Rolling Stock Standards Committee on 15 January 2016.
- 1.6.2 This document was authorised by RSSB on 20 January 2016.

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Part 2 Guidance on Verification in the Rail Industry

2.1 Introduction

2.1.1 The purpose of verification, in its widest sense, is to objectively confirm that an organisation has met its responsibilities in terms of complying with relevant legislation and regulations (including those relevant to safety), its own management systems, and associated requirements or processes that it may be required to, or has decided to, adopt.

G 2.1.1.1 Legislation relevant to verification of conformity of engineering change to rail vehicles includes:

- a) The Railways and Other Guided Transport Systems (Safety) Regulations (ROGS) 2006 (as amended) (implementing the Railway Safety Directive 2004/49/EC).
- b) RIR 2011 (as amended) (implementing the Railway Interoperability Directive 2008/57/EC).
- c) Commission Implementing Regulation No 402/2013/EU (as amended) establishing a Common Safety Method for Risk Evaluation and Assessment (CSM RA).
- d) Commission Implementing Regulation No 445/2011/EU concerning Entities in Charge of Maintenance (ECM).

G 2.1.1.2 Guidance relevant to the above legislation includes:

- a) Office of Rail and Road (ORR) guidance on the application of ROGS and CSM RA.
- b) RSSB guidance notes on the CSM RA GEGN8640 through to GEGN8645.
- c) The ATOC Guide to Vehicle Change (ATOC/EC/GN/002).
- d) Commission Recommendation 2014/897/EU.

2.1.2 For engineering changes to rail vehicles (modifications) that are not deemed renewed or upgraded as defined in RIR 2011 (as amended) the level of verification is managed by the Proposer of the change.

G 2.1.2.1 For projects that are for new, renewed and upgraded vehicles or structural subsystem(s) RIR 2011 (as amended) sets out where third party verification is required. 'Renewal' and 'upgrading' are specifically defined types of modifications under RIR 2011 (as amended) and in this context do not mean any wider definitions that can be used in industry.

G 2.1.2.2 Further explanation on modifications can be found in clauses 110 to 116 of Commission Recommendation 2014/897/EU on matters related to the placing in service and use of structural subsystems and vehicles under Directives 2008/57/EC and 2004/49/EC.

2.1.3 Under ROGS 2006 (as amended), railway undertakings (RUs) are required to have an approved Safety Management System (SMS), which includes details of its change management process, including carrying out risk evaluation and implementing risk control measures – this includes changes made to rolling stock (vehicles) that it operates and compliance with any applicable requirements (see 2.4) and other associated standards, for example GERT8270.

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2.1.4 The requirements and guidance contained within this RIS are intended for the verification of conformity of an engineering change where no process exists within a standard or other normative document containing applicable requirements (see 2.4) which applies to the project. The requirements and guidance of this RIS may be applied in the following situations:

- a) A rail vehicle engineering change project for which RIR 2011 (as amended) does not apply.
- b) When a Designated Body (DeBo) is engaged to verify conformity against National Technical Rules (NTRs) as part of a project which is in scope of RIR 2011 (as amended).
- c) To verify conformity with a code of practice when it is chosen as the risk assessment principle when applying the full risk management process prescribed in the CSM RA.

2.1.5 Various principles associated with verification of conformity of engineering change to rail vehicles are explained below to put the content of this RIS into context.

2.2 Role of the Proposer and the Assessment Party

2.2.1 In the context of this RIS, the roles of the Proposer and Assessment Party are described as follows:

- a) Proposer – responsible for initiating and undertaking the engineering change project, providing evidence of compliance and specifying the verification requirements, including the appointment of an Assessment Party.
- b) Assessment Party – responsible for undertaking the verification of conformity of the engineering change project, in accordance with the defined verification requirements and with an appropriate degree of independence.

G 2.2.1.1 The descriptions in 2.2.1 a) and b) are referring to roles. It can in fact be the same organisation that undertakes both of these roles.

G 2.2.1.2 The Proposer can be:

- a) An RU.
- b) An alternative organisation nominated by an RU (an authorised representative); in such a case, the accountability remains with the RU.
- c) A manufacturer or installer of an engineering change.
- d) A vehicle owner / keeper, where vehicle enhancements (for example, interior refreshment) are being undertaken either as part of a lease agreement or to prepare the vehicles for leasing to a new or alternative RU.
- e) An ECM, responsible for the safe maintenance state of the vehicle(s).

G 2.2.1.3 The role of the RU as the train operator, responsible for safely reintroducing the vehicle(s) into service following completion of the engineering change, is outside the scope of this RIS. However, it is summarised in 2.2.3 to place it into context.

G 2.2.1.4 An explanation of the types of Assessment Party and their degree of independence is provided in Part 3.

G 2.2.1.5 The responsibilities of the Assessment Party are generally limited by the 'scope of the verification work', not the 'scope of the engineering change'.

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2.2.2 Consultation with affected parties can assist with appropriate exchange of information regarding the engineering change project, taking into account the likely risks, complexity and impact of the proposed change.

G 2.2.2.1 Where there are multiple stakeholders, a lack of engagement can lead to a situation whereby design information is not fully shared or updated.

2.2.3 The responsibilities of the Proposer and the RU (as train operator) are summarised in the following table:

	Responsibility of the Proposer	Responsibility of the RU
Description	Undertaking the actual engineering change affecting the vehicle	Reintroducing the vehicle(s) to operational service following the engineering change
Task	Conform with the applicable requirements	Confirming that the vehicle(s) remain operationally safe (SMS processes)
Output	Attestation statement (produced by the Assessment Party) see Part 6	Safety acceptance
Potential associated tasks	Other verification activities outside the scope of this RIS. Update vehicle records (see Part 5)	Technical compatibility at route level (methodology set out in GERT8270). Mandatory data update (advise RSL)

Table 1 Summary of the responsibilities of the Proposer and the RU

- G 2.2.3.1 The highlighted (shaded) Task / Output indicates the scope of this RIS within the wider context of verification and approvals processes within the UK rail industry.
- G 2.2.3.2 Depending on the scale of the engineering change project and the extent of verification required (see 2.3), it can be the case that some or all of the other aspects outlined in Table 1 are not relevant.
- G 2.2.3.3 An analogy to aid understanding of the principle outlined in Table 1 is given as follows:
- 'Undertaking the actual engineering change affecting the vehicle' completes the engineering change work within the maintenance shed and places the vehicle within the depot / shed yard.
 - 'Reintroducing the vehicle to operational service' takes the vehicle from the depot / shed yard out onto the GB mainline network.
- G 2.2.3.4 The role of the Proposer as described in this RIS is not as extensive as the 'proposer' as described in the CSM RA, as the latter also has responsibility for implementing the change that has been subject to the application of the CSM RA.

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2.3 Extent of verification and degree of independence

2.3.1 The 'Verification Triangle' (Figure 1) illustrates the extent of verification and degree of independence.

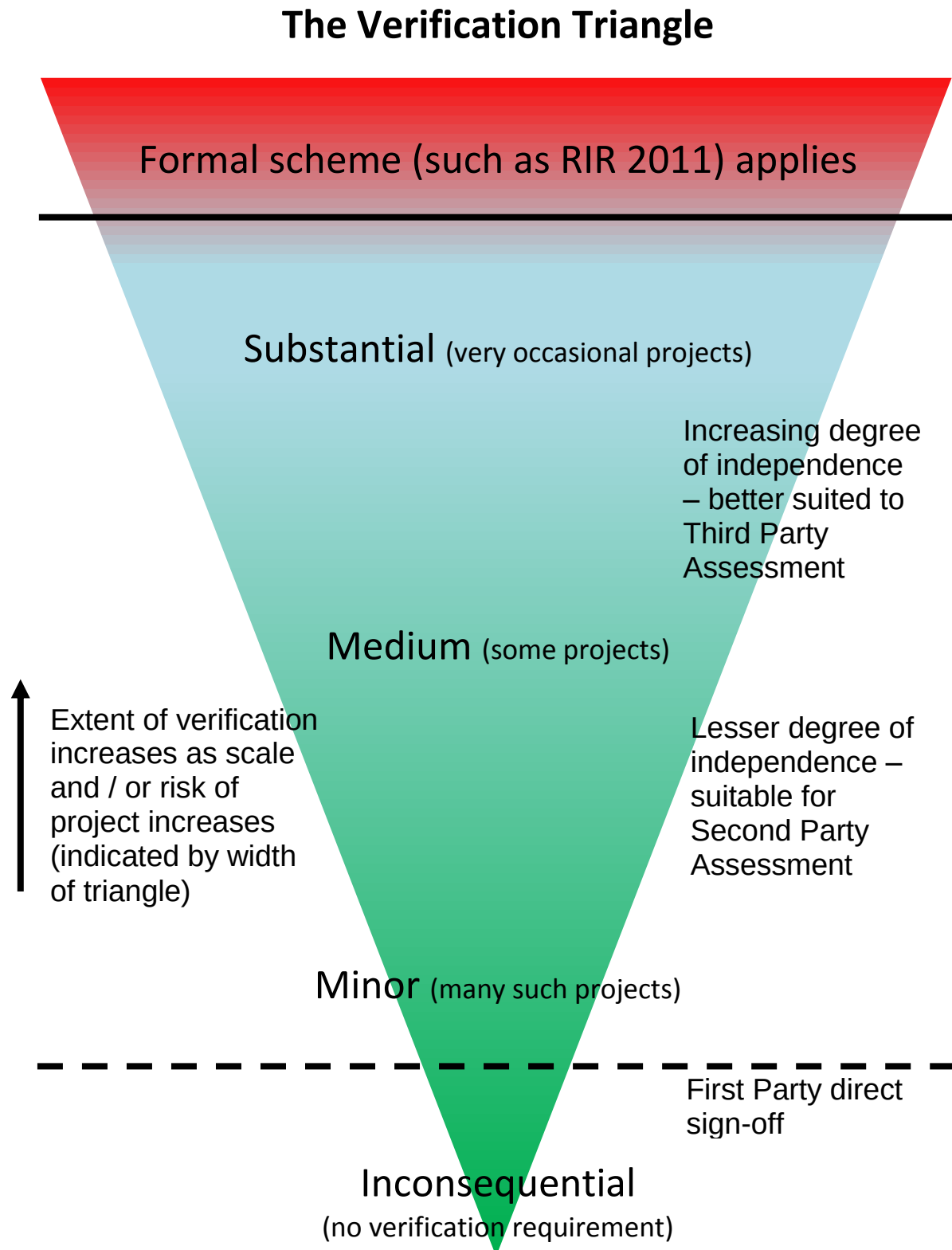


Figure 1 Diagram illustrating the extent of verification and degree of independence

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- G 2.3.1.1 The key principle highlighted is that the extent of verification increases in proportion to the scale and / or risk of the engineering change being undertaken.
- G 2.3.1.2 Risks associated with engineering change can arise from a number of factors, including:
- a) Scale of the change and its impact on the existing vehicle (interfaces).
 - b) Complexity and novelty of the design and / or use of technology.
 - c) Consequence of failure, error or omission
 - d) Effect on the design configuration and interfaces with existing systems.
 - e) The proposed installation programme (who? where? capability?).
 - f) Involvement of supplier(s) of critical materials, components and / or services (competence / assurance arrangements).
 - g) Any transient phases of the project, such as testing and controlled trials.
- G 2.3.1.3 Typically, the level of risk increases with the scale of the engineering change; but there can be examples where a small scale change involves a disproportionately high risk (for example, a change in brake block type or a software update). The converse can also be true where a large-scale change is otherwise routine in nature (for example, a vehicle interior refurbishment using already proven / accepted materials and fittings).
- G 2.3.1.4 It is expected that the Proposer would have considered such risks when devising the engineering change. The Assessment Party may challenge any assumptions to be sure that the risk profile for the engineering change project is understood and accepted.
- G 2.3.1.5 A greater degree of independence is usually associated with an engineering change project where the scale and / or risk is greater; however, this does not necessarily have to be the case. For example, a large organisation undertaking a substantial engineering change can have sufficient engineering resources such that it can also undertake the verification work without compromising the requirements for independence (see Part 3).
- G 2.3.1.6 For engineering changes that are towards the upper end of the 'Verification Triangle', a greater synergy with defined verification processes (such as those required under RIR 2011 (as amended)) is considered to be beneficial.
-

2.4 Applicable requirements

- 2.4.1 Verification is undertaken against the defined / agreed list of applicable requirements for the engineering change project.

-
- G 2.4.1.1 Applicable requirements are contained within standards and other normative documents as set out in G 2.4.1.2, some of which can include a verification process by which conformity with the requirements of the document concerned are to be assessed. Where no such process is indicated, this RIS can provide suitable methods.

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- G 2.4.1.2 The applicable requirements can include:
- a) NTRs relevant to the engineering change being undertaken; for rail vehicles these are typically contained within rolling stock RGSs. The verification processes outlined in this RIS are particularly suitable for these types of documents.
 - b) Technical Specifications for Interoperability (TSIs). Where the engineering change is being undertaken on a vehicle that has an authorisation under RIR 2011 (as amended) (see G 5.3.1.1.1 c)), there can be an impact on the criteria within a TSI that define the basic design characteristics of the rolling stock subsystem. This is explained further in 2014/897/EU.
 - c) Euro-Norms (ENs) contain requirements covering specific component or systems on rail vehicles. These can be referenced directly in the TSIs.
 - d) Voluntary railway industry standards (for example RSSB RISs) can contain requirements which an organisation has chosen to adopt.
 - e) There can also be other standards and normative documents, including non-railway specific requirements that need to be considered or further voluntarily requirements (for example, customer requirements).
- G 2.4.1.3 As part of their licence conditions and Statement of National Regulator Provisions (SNRP), RUs are required to comply with the relevant RGSs (condition 9).
-

2.5 Principle of due diligence

- 2.5.1 Both ROGS 2006 and RIR 2011 (as amended) include the defence of due diligence in terms of compliance with the requirements of the legislation.
-

- G 2.5.1.1 In respect of engineering change, for an organisation's actions to be regarded as 'duly diligent', it is considered reasonable for the extent of verification involved to be proportionate to the scale and / or risk from the engineering change being undertaken (see 2.3.1).
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Part 3 Role of Independent Verification

3.1 Verification roles and independence

3.1.1 The following guidance is provided on the issue of independence when undertaking verification work.

-
- G 3.1.1.1 Verification work is categorised as first, second or third party as follows (refer also to the 'Verification Triangle' diagram in 2.3.1):
- a) Third party – undertaken by a different company (separate legal entity), therefore offering full independence. Suitable for medium changes and recommended for substantial changes.
 - b) Second party – a separate department or separate personnel of the same company (legal entity) as the Proposer, therefore offering limited independence. Suitable for minor and medium changes; possible for substantial changes if the appropriate level of peer review and independence is available.
 - c) First party – effectively a self-declaration and therefore no degree of independence involved. Only suitable for engineering changes of an inconsequential nature.
- G 3.1.1.2 The level of independence is indicated by whoever issues the attestation statement (see Part 6) at the completion of the verification work.
- G 3.1.1.3 Guidance on the degree of independence required for the verification of conformity of an engineering change project is given in G 2.3.1.5.
-

3.2 Role and Independence of Assessment Party

3.2.1 Role of the Assessment Party

3.2.1.1 An Assessment Party shall be designated to verify conformity of an engineering change project to a rail vehicle(s) to an appropriate level of independence.

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- G 3.2.1.1.1 A flowchart summary of the considerations when designating an Assessment Party is provided at the end of this section 3.2, see Figure 2.
-

3.2.2 First party verification

3.2.2.1 For a first party verification, the Proposer shall approve the work without the need for independence.

-
- G 3.2.2.1.1 Many examples of engineering change typically occur towards the lower end of the 'Verification Triangle' diagram (see 2.3.1), and therefore the extent of verification required may be similarly proportionate.
- G 3.2.2.1.2 Where an engineering change can be classified as not being affected by any applicable requirements, defined as 'inconsequential' within the context of this RIS, independent verification activity is not required.
- G 3.2.2.1.3 Where it is considered that a simple first party assessment is sufficient, a nominated engineer / manager within the Proposer's organisation may 'sign off' the engineering change to take direct responsibility for the verification of conformity of the engineering change project.
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3.2.2.2 The decision that the verification of conformity of an engineering change project is to be regarded as first party shall be recorded, together with the rationale behind the decision.

G 3.2.2.2.1 The ORR's guidance on the CSM RA emphasises that, where a decision is taken that a change is not significant and thus no independent assessment is required, that decision is required to be recorded, together with the rationale behind the decision.

3.2.3 Second party verification

3.2.3.1 If a second party approach to verification is to be adopted, then the Proposer shall manage the verification work such that the required degree of independence is maintained.

G 3.2.3.1.1 A 'second party' approach to verification can include using internal resources from a separate and identifiable part of the organisation and which are otherwise independent of the engineering change work being carried out; this constitutes the Assessment Party for the project. This approach may also include contracting out elements of the assessment work to an independent body (provided that the ultimate verification remains in the name of the Proposer).

G 3.2.3.1.2 Where an independent body is contracted to undertake elements of the assessment work, such a body can be any organisation that the Proposer has undertaken assurance checks on and considers suitable (see 3.3.3). This is distinct from the guidance on full, third party independent bodies given in G 3.2.4.2.2 to G 3.2.4.2.5.

G 3.2.3.1.3 Guidance on the degree of independence and the link between the extent of verification and the risk profile of the engineering change project is given in G 2.3.1.1 to G 2.3.1.5.

G 3.2.3.1.4 It is recommended to consult with any other interested parties on the approach to verification, where appropriate (for example, the vehicle owner if the Proposer is the RU).

3.2.3.2 The documented management system of the Proposer shall include the processes that control the verification work.

G 3.2.3.2.1 Under the terms of ROGS, an RU is granted a safety certificate by the ORR on the basis of having a suitable SMS, which includes processes for change management. An ECM for freight wagons is certificated on the basis of having a suitable maintenance system, which includes processes for change management. Other organisations, such as a vehicle owner / keeper or manufacturer, can operate in accordance with an ISO9001 Quality Management System (QMS) which can include change management.

G 3.2.3.2.2 The following factors are relevant when considering the suitability of an SMS / QMS (or equivalent) to support a 'second party' verification:

- a) Does the Proposer have access to personnel of the appropriate competence to carry out verification work?
- b) Are the nominated personnel independent of the work that has been carried out? Independence would be compromised if the personnel designated to verify conformity of an engineering change project were also involved in the generation of submitted evidence in support of the verification.

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- c) Do the timescale and resource implications for the project allow such internal resources to be deployed?
- d) Is there a documented process to cover the verification activities required (for example, audit, inspection, peer review, etc)?
- e) Are there procurement arrangements to cover the use of external resources to undertake some / all of the assessment work in support of verification?

G 3.2.3.2.3 This does not preclude designated assessors and / or verifiers from undertaking other activities for the company or related organisation, provided that these activities do not compromise the objectivity and impartiality of the verification work.

3.2.4 Third party verification

3.2.4.1 If a third party approach to verification is to be adopted, then an Assessment Party that is a different company (separate legal entity) from the Proposer shall be appointed to undertake the full verification work.

3.2.4.2 The Proposer shall confirm that the Assessment Party has the required capability to meet the scope of verification and that the principle of independence is not compromised.

G 3.2.4.2.1 The third party independent body with a recognised accreditation (for example ISO17065, ISO17020 Type A) to undertake such work provides the greatest assurance of capability. In the UK, the United Kingdom Accreditation Service (UKAS) is the organisation with authority to issue such accreditations.

G 3.2.4.2.2 Under the various legislative frameworks outlined in G 2.1.1.1, third party independent bodies such as Notified Bodies (NoBos), DeBos or Assessment Bodies (AsBos) are accredited against a defined scope of work. This may be taken as suitable evidence of independence and competence to undertake verification work as outlined below. This also provides a degree of assurance over confidentiality.

G 3.2.4.2.3 In particular, a DeBo, accredited by UKAS under RIR 2011 (as amended), is deemed to be a suitable organisation to undertake third party verification work (subject to its scope of accreditation covering the type of vehicle(s) concerned) as they have a recognised accreditation as competent to verify conformity with NTRs.

G 3.2.4.2.4 For a third party independent body with a UKAS accreditation, the schedule of accreditation can be checked on the UKAS website (www.ukas.org) to confirm that the body has the required capability to meet the scope of verification.

G 3.2.4.2.5 In the context of this RIS, third party independent bodies holding an accreditation as a NoBo, DeBo or AsBo are not acting as such when undertaking verification work that is outside of the formal certification scheme for which such an accreditation is held.

G 3.2.4.2.6 The principle of independence can be compromised, particularly in cases where the independent body is related to a common body or by another organisational relationship that can conflict with their independence of judgement and integrity in relation to their verification activities. In certain circumstances, personal relationships or previous career history can compromise the required independence.

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- G 3.2.4.2.7 In circumstances where a related organisation of the third party verification body has been involved with the design and / or installation of the engineering change (often referred to as a 'turn key' approach), independence can be compromised. The guidance given in G 3.2.3.2.2 b) is considered to be relevant in this instance.
- G 3.2.4.2.8 An approach under the terms of this RIS whereby an independent body undertakes all the assessment work, but the Proposer then issues the attestation statement under their own SMS, is regarded as a variant of the second party approach within the context of this RIS.

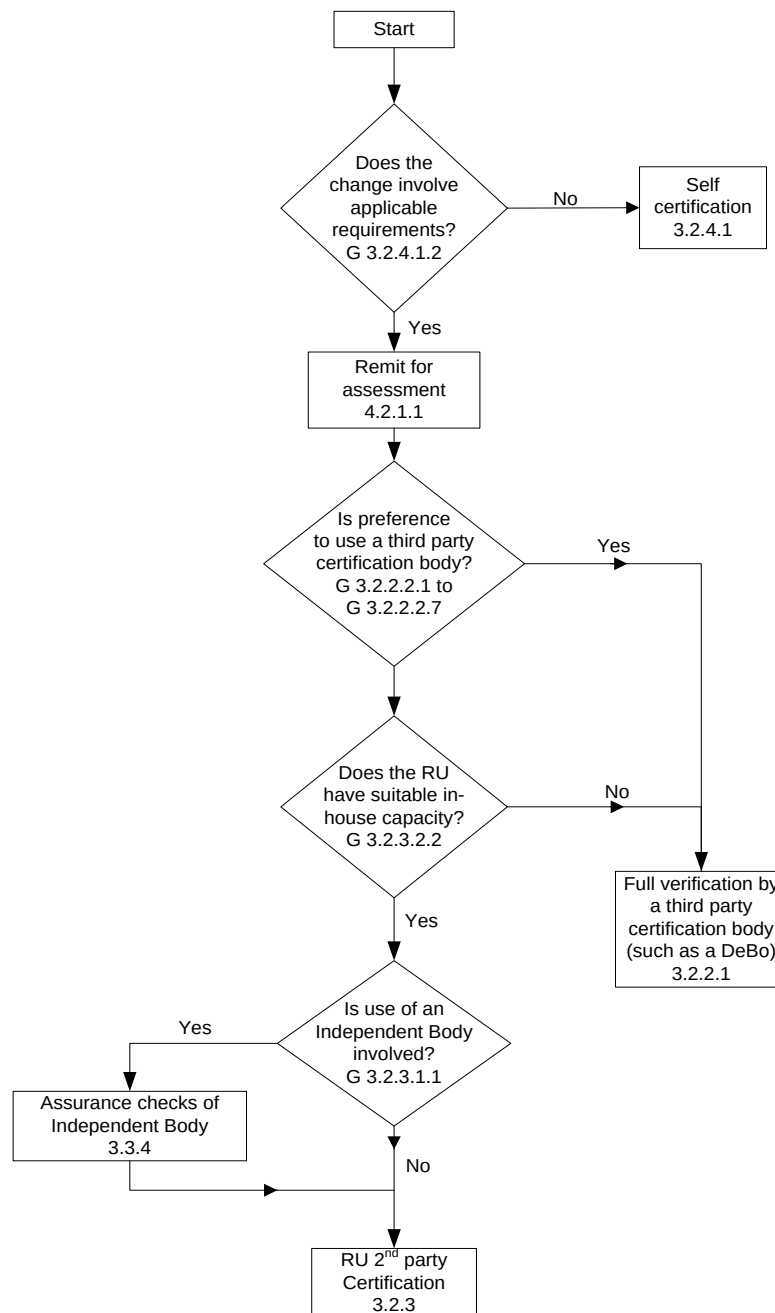


Figure 2 Summary of the considerations when designating an Assessment Party