



Railway Industry Supplier Approval Scheme

Supplier Assessment Module

Submitted by

Authorised by

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Issue record

This document will be updated when necessary by distribution of a complete replacement.

Issue	Date	Comments
One	7 th April 2006	Original document
Two	12 th May 2006	Replaces issue one
Three	15 th Mar 2012	Replaces issue two
Four	1 st June 2015	Updated to subsume BN-004 and incorporate ECM generic requirements

Revisions have been marked by a vertical black line

Technical Content

Approved by:

The RISAS Board on 18th March 2015.

Suggestions to improve the contents of this document should be directed to the Scheme Manager at the following address:

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Application

This is not a Railway Group standard and is therefore not mandatory. However, for participants in the RISAS Scheme, the relevant requirements detailed in this document shall be regarded as mandatory and will be identified as obligations within the relevant contracts. This document comes into force and is to be complied with from 15th June 2015.

Supply

Copies of this document may be obtained from:

The RISAS Scheme Administrator,
Rail Safety and Standards Board,
The Helicon, 1 South Place,
London EC2M 2RB.

E-mail: risas.admin@rssb.co.uk

Or from the RISAS website www.risas-online.org

Definitions

Definitions of the terms used in the RISAS documents are given in Appendix A of RISAS/001, Principles of the Railway Industry Supplier Approval Scheme.

Throughout this document the phrase 'Product Group' refers to all groupings within the scheme. These are Materials (M-code) or Services (S-code) Product Groups.

References / related documents

RISAS documents

RISAS/001	Principles of the Railway Industry Supplier Approval Scheme
RISAS/002	Arrangements for the Board of the Railway Industry Supplier Approval Scheme
RISAS/004	Accreditation of Approval Bodies within the Railway Industry Supplier Approval Scheme
RISAS/005	Railway Industry Supplier Approval Scheme Operations and Management

Briefing Notes as published on the RISAS website

Railway Group Standards

GM/RT2450	Qualification of Suppliers of Safety Critical Engineering Products and Services
GM/GN8565	Guidance on the retention of design information, validation of technical change and configuration management

ATOC Codes of Practice

ATOC ACOP/EC/1003	National Railway Materials and Supply Accreditation Scheme
ATOC ACOP/EC/1006	Inter-Company Train Engineering Change Approval Process

International Standards

ISO 9000:2000	Quality Management Systems Fundamentals and Vocabulary
ISO 9001:2008	Quality Management Systems Requirements
ISO 9004:2009	Managing for sustained success of an organisation – A Quality Management Approach
ISO 10005:1995	Quality Management Systems -- Guidelines for Quality Plans
ISO/IEC 17021:2011	General Requirements for Bodies Operating Assessment and Certification / Registration of Quality Systems
ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
ISO/IEC 17050-1:2004	Conformity Assessment Supplier's Declaration of Conformity Part 1: General Requirements
ISO/IEC 17050-2:2004	Conformity Assessment Supplier's Declaration of Conformity Part 1: Supporting Documentation

Legislation

S.I. 2006 No. 599 The Railways and Other Guided Transport Systems (Safety) Regulations 2006 ('ROGS')

EU No 402/2013 European Commission Regulation on the Common Safety Method for Risk Evaluation and Assessment.

ORR guidance and documents

Railway Safety Publication No.1, Developing and Maintaining Staff Competence

Industry guidance and documents

Securing Supplier Assurance, Guidance on the principles of Supplier Assurance and how to engage with existing arrangements for today's GB mainline rail industry.

'Engineering Excellence into Competence' Guidance for developing a Competence Management Systems.

Part A RISAS Supplier Approval Process

1 Overview of Assessment Process

1.1

This document is one part of the Railway Industry Supplier Approval Scheme (RISAS) which is described in RISAS/001. It defines the requirements that a supplier shall meet to obtain and maintain approval under RISAS. Its purpose is to ensure that suppliers of critical products to the rail industry have the appropriate systems, processes, competence, resources and procedures. Assessment of a supplier against these requirements provides a duty holder with an appropriate level of assurance against the requirements of ROGS, in respect of risks related to the supply of maintenance and material (Regulation 5(1)(d)(i)).

1.2

RISAS has been established initially for suppliers of critical materials and services in the market for the overhaul of assets and components for rail vehicles – this includes new manufacture where required to supply or replace a component as part of an overhaul (eg a new monobloc wheel as part of the overhaul of a wheelset). A supplier that wants to provide critical products to a duty holder, or other customer under this Scheme, will first need to request an assessment by an accredited RISAS Approval Body (RISAB).

1.3

All applications for assessment and details of any approval subsequently granted are administered via the RISAS website www.risas-online.org. The website gives details of the scheme including the current list of (critical) product groups, accredited RISABs, approved suppliers and their product group scope. Further details are available in RISAS/005.

1.4

The RISAB will carry out an assessment of the supplier against the requirements of this document according to an agreed scope. Specifically, the requirements laid out in Part B of this document constitute the standard that the supplier has to meet in order to be awarded a RISAS certificate.

1.5

The award of a RISAS certificate is subject to a review by the RISAB Signatory of the work of the assessment team, its findings and recommendation(s). The RISAB Signatory will not otherwise have been involved in the assessment itself, thereby making the endorsement of the assessment team's recommendation an independent judgement.

1.6

Following successful assessment the RISAB will award certification for the supply of some or all of the product groups that were included in the scope of the assessment (as determined by the outcome of the assessment). An overview of the RISAS approval process is shown in the process flow diagram in Appendix A.

1.7

Technical Specifications for Interoperability (TSIs) take precedence over national standards and the Supplier and RISAB shall take account of this in meeting the requirements of this document.

Note: The objectives of Interoperability and RISAS are not the same and both schemes can therefore be applicable to suppliers of critical product (for example wheelsets)

1.8

Suppliers should recognise any RISAS approval held as a long term commitment. They should also look to build and develop the scope of their approval over time. RISABs should recognise that they have an ongoing obligation to monitor the efficacy of approvals granted, so long as they are held in their name, responding to issues as they occur.

1.9

Each approval granted to a supplier is based on an assessment by a RISAB and has a finite life, as determined by the expiry date. Thereafter further approval is conditional upon a new, full assessment (RISAS is not designed as a continuous assessment scheme). The RISAB

may however propose to make an approval subject to supplementary surveillance activity during the term of that approval.

2 Pre-assessment Planning

2.1 Introduction

Suppliers and the RISAB assessment team shall prepare fully in advance to ensure that all appropriate requirements for the assessment are identified and that the assessment is planned such that all those requirements are covered.

2.1.1

The purpose of the pre-assessment planning is to agree the scope of the proposed assessment, the product groups covered by the assessment and the representative products to be selected. The current list of available product groups can be viewed on the RISAS website www.risas-online.org.

2.1.2

The application by a supplier for assessment should be made through the RISAS website. Without this, it will not be possible to issue a certificate of approval (see 4.3.4 below).

2.1.3

In agreeing commercial terms for any assessment work, the RISAB's terms and conditions for supply of RISAS assessment services shall be consistent with the rules and principles of the RISAS scheme.

2.1.4

The assessment shall be planned on the basis of assessing the supplier as a 'Standard' or 'Engineering Change' supplier and this should be determined at the time of contract award so that the assessment can be planned accordingly (assessment of a supplier for 'Engineering Change' requires additional assessment activity as reflected by several additional assessment requirements in Part B of this document).

2.2 Preparation

In preparation, the RISAB should gather sufficient supplier information relating to the proposed scope of approval as an input to the pre-assessment planning meeting.

2.2.1

As much of the documentation in relation to the supplier profile in Part B.1 of this document as possible should be provided to the RISAB as part of the planning process.

2.2.2

The supplier shall provide a list of recent contracts and specifications to which they have been working. This is to enable the RISAB to select suitable products and specifications which are representative of the supplier's work for the industry as a basis for assessment.

The selection of representative products should consider the different types and variety of industry customers such that the samples chosen give good coverage and thus confidence to the industry at large (for example has freight interests been covered as well as passenger?). Consideration should be given to reviewing more than one type for a product group where appropriate to achieve this objective.

2.2.3

For each representative sample, the key technical documentation should be identified and copies of all such documents shall be provided to the RISAB to assist in preparation.

Technical documentation shall include (as appropriate):

- A brief description of each product and its criticality.
- Pertinent contract details.
- A list of the technical (overhaul) specifications, legislation, and standards etc. including issue status relevant to the critical product.
- Any product specific facilities or equipment.

- Drawings and parts lists including OEM parts within component (for example 'O' rings in valves).
- Process instructions and/or procedures to demonstrate how the requirements of specifications, standards and legislation are met.

This list is not exhaustive.

2.2.4

The supplier should also identify any significant sub-supplier involvement with the product group(s) to be assessed. A decision should be made to either visit the sub-supplier to assess the sub-contracted overhaul work directly or to assess that the supplier has suitable assurance arrangements in place through its own procurement process – note that this would require the RISAB to field a procurement expert within its team (see clause 2.4.2 below). This latter assessment of procurement is considered to be more in-depth than routine procurement activity arrangements as covered in Part B, 5.2.

If the supplier merely acts as a 'post box' for particular products then approval cannot be given for the product groups concerned (an example would be the sub-supplier of replacement monobloc wheels to a supplier overhauling wheelsets). Any RISAS approval for such supplied product should be based on an assessment of the sub-supplier instead and be issued in their name.

Where a significant sub-supplier holds a current RISAS approval for the sub-contracted product(s) or service(s) then this provides the necessary presumption of conformity.

2.2.5

The RISAB assessment team shall review all available information pertinent to the supplier and its products, including details of any previous assessments, NIRs, RAIB and CIRAS reports, ORR enforcement actions and general railway safety intelligence. Any such information gathered should be used as an input to pre-assessment planning, querying it with the supplier if appropriate.

2.3 Pre-assessment meeting

2.3.1

The supplier and the RISAB should hold the pre-assessment planning meeting in sufficient time (typically at least one month) before the day(s) of the assessment to ensure that both parties are properly prepared.

2.3.2

It is permitted to hold a telephone / video conference call in lieu of an actual face-to-face meeting where circumstances dictate (for example overseas supplier). The RISAB should support this decision in a clearly documented risk-based statement.

2.3.3

For subsequent assessments the RISAB shall decide whether there is a need for a pre-assessment meeting. Considerations should include:

- relative stability of the organisation;
- any incidents arising with critical products from the supplier;
- extent of required actions raised at previous assessments;
- requests for extension to scope of approval and / or significant new contracts / customers

(this list is not exhaustive)

2.3.4

Suppliers should ensure that a senior manager will be available for an introductory meeting (as per 3.1.2 below), either at the pre-assessment meeting or near the start of the assessment. They shall also ensure that suitable representatives will be made available at the assessment itself to deal with the assessment of the management systems and of each relevant product group area.

2.3.5

There may be instances where there is no current work for a particular product group (for example intermittent bogie overhaul contracts) or where a supplier is preparing to undertake work in a new product group area (for example where RISAS approval is required as a condition of contract award).

In such circumstances, the RISAB and the supplier shall look for suitable alternatives to ensure coverage of the product group concerned and plan this into the assessment work. Acceptable approaches include potentially 'reading across' capability demonstrated through other similar work or setting up a simulation using a spare or scrap component.

Where a supplier has not previously supplied to the UK market, evidence of supply of equivalent products in Europe (or to European / AAR requirements) may provide a feasible option to demonstrating compliance with specified requirements. Alternatively (or possibly in addition), the requirements of briefing note BN-006 may be applicable.

2.3.6

Where not already pre-supplied, the RISAB shall ensure that all supplier information, as outlined in Part B.1, has been obtained by the close of the pre-assessment meeting. If the RISAB believes that they have not been provided with the required information or access to appropriate personnel then the assessment will not be able to take place until they have been provided.

2.3.7

Where possible, visits and the deployment of the assessment team should be planned to fit in with the supplier's normal production schedules. An optimum time for the visit should be agreed accordingly; however, suppliers should be prepared to accept a certain amount of disruption in order to facilitate witnessing of any specific activities that are required to complete the assessment and confirm approval for the product groups concerned.

For a particularly complex product group activity (for example where the work is completed over several weeks and / or there are multiple shifts) it is recommended that the assessment be conducted over a number of separate visits to ensure that all critical stages of the product group activity are witnessed.

2.3.8

The salient points arising from the meeting should be documented and a brief resume included in the main assessment report.

2.4 Assessment plan

The RISAB assessment team should carry out detailed planning utilising data / information gathered at the pre-assessment meeting. Appropriate assessment techniques and audit methodology should be planned for known assessment scenarios.

2.4.1

Where more than one product group is to be assessed, then the examination of systems and other product groups should be planned in a way that minimises unnecessary repetition, while ensuring an adequate breadth and depth of assessment to justify the scope of approval.

2.4.2

The make-up of the assessment team should be carefully considered, especially where a complex product group scope is involved. There may be a need for both technical and non-technical experts, for example to cover disciplines such as procurement and contract management (for which the requirements of BN-007 apply).

Specific railway technical specialism should be recognised; for example, for manufacture of replacement wheelset components, a qualified metallurgist competent in cast and forged steel making processes and the defects that can result from inadequate manufacture (eg hydrogen embrittlement and wheel tread occlusions). Other examples include welding specialist and NDT specialist.

The allocation of time allowed for the lead assessor to coordinate and manage the assessment work on site, as opposed to undertaking assessment work themselves, should be considered where a complex product group scope is involved. In such cases, the use of supplementary assessors to assist the lead assessor is recommended.

2.4.3

Checksheets (or their equivalent), together with any supplementary assessment criteria, should be focussed around collection of evidence to demonstrate compliance against Part B of this document. A risk-based approach should be used to prioritise critical areas based on the review of the information gathered during pre-assessment.

2.4.4

The RISAB lead assessor is responsible for the overall co-ordination of the assessment plan. The system assessment ('top down') and product assessment ('bottom up') activities should be integrated so that the areas of critical risk can be fully assessed and verified.

2.4.5

The completed assessment plan, including any checklists and supplementary assessment criteria, should be agreed and finalised amongst the RISAB team and endorsed by the nominated signatory. A copy of the finalised assessment programme should be sent to the supplier prior to the assessment visit(s).

3 During the Assessment

The lead assessor shall ensure that the assessment is undertaken in accordance with the agreed programme and the prepared assessment plan. The assessment will review the management systems in place and examine in detail representative samples covering all product groups applied for.

3.1 Opening meeting

The assessment shall commence with an opening meeting chaired by the lead assessor.

3.1.1

The opening meeting shall include:

- Confirmation of assessment programme and agreement of any variations.
- Re-confirmation of availability of suitable examples for each representative critical product as detailed in the assessment programme.
- Availability of documentation packs for each representative critical product (where not already received during pre-assessment planning meeting).
- Explanation of categorisation for assessment findings.

3.1.2

Following the opening meeting, a brief introductory meeting shall be held with a senior manager, if this has not already occurred at the planning meeting. This shall explore the following high level issues:

- The main recent changes in the company.
- Company performance.
- The organisational structure of the company (including legal ownership) and any key vacancies.
- The structure of the company's policies and documentation (including safety).
- The company's strengths and concerns.
- Improvement plans currently in place.

3.1.3

This meeting should assist in giving the assessment team a good starting point to put their assessment findings in context.

3.2 Assessment methodology

3.2.1

The assessment shall identify the management systems in place and review their application to the physical production of selected products representative of the scope of approval being sought. This shall include the effectiveness of procedures / processes in place (which may be determined through analysis of the applicable outputs of internal auditing, management review, policy / objectives, performance monitoring, etc).

3.2.2

The assessment shall confirm that the critical products reviewed during the assessment are representative of the capability of the supplier. This is particularly relevant for a first assessment of a supplier under RISAS.

3.2.3

The RISAB assessment team shall ensure that the assessment covers all critical stages of the production and delivery of selected products (as identified during planning) against the selected contract(s) and applicable specifications, as referenced in the detailed assessment plan. This shall include the assessment of actual work in progress (especially key activities critical to product safety) against the relevant contract.

3.2.4

All assessment work should be focussed on demonstration of compliance against the assessment requirements (see Part B), as outlined in 3.3 below. Assessment (inadvertent or intentional) against other requirements (for example ISO 9001) is not considered a valid approach. RISAS is specifically designed as a risk-based scheme and compliance against its requirements should be complementary to and not a repeat of the requirements of other schemes.

3.2.5

If it is not possible to cover the assessment of a particular product group, then approval for that product group should either be deferred until a subsequent assessment visit or controlled by a limitation, as outlined in 4.3.1 below.

3.3 The assessment requirements

Part B of this document identifies the core requirements that a supplier shall meet to become a RISAS approved supplier. The clauses at the start of each section summarise the key requirements which shall be met.

3.3.1

The assessment tables in Part B are set out in three columns:

- Column 1 Requirements that a supplier need to meet to become a certified RISAS approved supplier.
- Column 2 Examples of suitable objective evidence that an assessor requires to confirm that the supplier is meeting the requirements.
- Column 3 Assessment comments for use by the RISAB team during the assessment to record the main findings.

The titles and descriptive clauses at the start of each of the nine sections (and sub-sections) are part of the requirements.

3.3.2

The requirements in Part B, supplemented by contract / product group specific supplementary assessment criteria, form the scope of the assessment.

3.3.3

The assessment team shall seek suitable and sufficient objective evidence of conformance (and, where appropriate, non-conformity) with the assessment requirements to support the assessment result.

3.3.4

All findings identified during assessment should be referenced against the applicable clause of the assessment requirements (Part B). Where other standards / requirements are called up (for example through contract requirements) they must be linked back to a requirement within Part B of this document for them to be a valid assessment finding.

3.4 Cooperation of supplier

3.4.1

The supplier shall provide access to production facilities and staff for each product group for which approval is sought and arrange their production schedules as appropriate to ensure that selected samples (as identified and agreed during pre-assessment) are available for review.

The assessment team should ensure that there is sufficient flexibility to respond to the supplier's production dynamics 'on the day' to ensure that all critical processes previously identified are witnessed.

3.4.2

Where unavoidable, it is permitted for the RISAB to undertake the assessment of a product group based on an alternative sample to that which was pre-selected or 'read across' a demonstration of capability from other related products, subject to the following conditions:

- the alternative sample or related product shall involve equivalent repair and inspection techniques
- the assessment shall complete the review of the relevant technical documentation for the original product group selected (including the review of the consistency of in-house overhaul documentation against the contract / specification).

3.4.3

Lack of supplier co-operation shall be reported to the lead assessor, with a view to resolving any issues as quickly as possible during the assessment.

3.5 Assessment approach

3.5.1

A typical approach to assess compliance with requirements is to run parallel 'system' and 'product' assessments; however the lead assessor should ensure that such activities are complementary and never carried out in isolation to each other. Many of the requirements necessitate input from both 'systems' (top down) and product (bottom up) to ensure compliance is fully verified.

3.5.2

RISAB assessment team members shall actively engage with staff carrying out the tasks. The assessment team shall use a combination of assessment techniques to confirm conformance with the requirements specified in the assessment plan for example:

- Interview.
- Simulation.
- Observation.
- Demonstration.
- Document and data review.

3.5.3

As the assessment progresses any areas of non-conformance identified by the assessment team shall be discussed and agreed with supplier representatives.

3.5.4

The scope of the assessment team's work is defined by the requirements of this standard. However, should the assessment team identify issues against any relevant national and European legislation, including health and safety in the workplace and environmental legislation, then it has an implicit duty of care to raise these with the supplier during the assessment.

3.5.5

If during the course of the assessment the RISAB considers that processes and practices are such that the supplier's products pose a serious risk to the railway, then the RISAB shall inform the supplier's most senior representative on site. The RISAB shall discuss its conclusions with the supplier at the close-out meeting and ask the supplier what action they intend to take and whether they intend to appeal. In such cases, the RISAB should immediately inform the RISAS scheme manager and urgently complete its report (see RISAS/005). If appropriate, arrangements for issue of a National Incident Report, in accordance with GE/RT8250, should be considered.

3.6 Provision of documentation

3.6.1

In addition to the information supplied as part of pre-assessment, the supplier shall have prepared the appropriate technical documentation to enable the RISAB to assess the processing of selected critical product in accordance with customer requirements. The supplier shall clearly define which documents have been supplied by the customer and which are owned by the supplier so that the responsibility for specifying the scope of the overhaul activity is clearly understood. The documentation shall cover all applicable production stages from receipt of order, commencement of work, for example maintenance, repair, overhaul or test, through implementation to order delivery.

3.6.2

In addition to the items detailed in 2.2.3 above, examples of additional technical documentation provided during assessment are:

- Reports and statistics to demonstrate how the requirements of specifications, standards and legislation are met.
- Records and results of overhaul, examinations carried out.
- Test procedures and reports.
- After sales reports.

3.7 Sub-suppliers

Where Sub-suppliers are involved in the production of a product group, the supplier shall meet the supply chain requirements of this document before approval for that product group is granted.

3.7.1

In exceptional circumstances, for example where a sub-supplier provides a significant proportion of the product, the assessment plan should include a visit to the sub-supplier (this should already have been identified and agreed during pre-assessment).

3.7.2

If no manufacturing / overhaul of the product group concerned takes place at the main supplier then the requirements outlined in 2.2.4 shall apply.

3.8 Review of progress

3.8.1

The assessment team shall hold regular review meetings as identified in the assessment programme to discuss:

- Progress against the assessment plan.
- Team findings.
- Programme issues.
- Information exchange, lead sharing and / or comparison where lateral and vertical assessments have crossed.
- Emerging issues.

3.8.2

End of day / phase review meetings with the supplier shall be held to review progress with the programme and present key findings and non-conformities. The opportunity should also be taken to compliment the supplier on areas of good practice highlighted.

3.9 Close-out meeting

3.9.1

A close-out meeting shall be held at the end of the assessment. The assessment team shall summarise the degree of compliance against the assessment requirements (Part B) and report its findings including examples of good practice. Any proposed required actions should also be presented.

3.9.2

Acceptance of required actions is a condition of any approval. In the event of a supplier being unable to understand or refusing to accept a finding, the lead assessor shall endeavour to ratify this by reference to the objective evidence and the witnessing of the issue in relation to the clause of the assessment requirements against which the finding has been raised.

If, after discussion, the lead assessor still considers the finding valid but the supplier still refuses to sign the required action, the lead assessor shall endorse the required action as such, advise the supplier that approval cannot be granted and explain the route to appeal (as outlined in RISAS/005).

3.9.3

The assessment team shall give an indication of their conclusions and proposed scope and conditions of approval, including:

- The scope to be recommended for approval noting 'standard' or 'engineering change'.
- The identification of any inclusions or exclusions as appropriate, such as software.
- Required actions and their status (categorisation), ie any such Required Actions where granting approval is dependent on their closure
- Where appropriate, timescales for the approval to be granted.
- Any limitations / restrictions.
- The approval period for each product group (see 4.3.2 below).

The above are subject to agreement by the RISAB signatory.

3.9.4

It might be the case that an assessment is undertaken on a supplier that already has a RISAS certificate which is due to expire, and findings are raised that require closure prior to a new approval to be put in place. In such circumstances, the RISAB should endeavour to agree with the supplier suitable short term (containment) measures to contain the risk, together with suitable controls (limitation) over any longer term actions required to support any new approval recommendation.

3.9.5

It might be the case that unusual circumstances prevent a new approval being put in place prior to the existing approval expiring, (for example illness delaying the assessment). In such circumstances, the RISAB should consider recommending an interim approval (maximum duration six months).

Such a decision should be supported by evaluation of risk (eg stability of the organisation, degree of compliance at previous assessment and the supplier's response to any Required Actions that were raised). This rationale should be documented and reported to the RISAS website in support of any interim approval.

3.9.6

When neither of the above options is appropriate and the current certification will lapse, the RISAB should ensure the supplier is fully aware of the circumstances and the reasoning behind it and explain the route to appeal (as outlined in RISAS/005).

4 Post Assessment

4.1 Assessment report

4.1.1

The assessment team shall complete the assessment report as soon as possible after the assessment (typically within 5 - 10 working days).

4.1.2

The assessment report shall clearly describe all the assessment activities including pre-assessment. The basis on which the approval is to be recommended, both in terms of the core requirements and each product group for which approval is sought should be clearly indicated and linked to evidence gathered during the assessment activities. Compliance with any applicable briefing notes shall also be referenced.

4.1.3

The report shall make clear whether approval is to be recommended dependent on closure of required actions or whether approval can be granted before closure. In the latter case monitoring and closure requirements shall be made clear.

4.1.4

The RISAB shall ensure that the report content complies with the minimum requirements outlined in RISAS/004, Part D.3.

4.2 Response to required actions

4.2.1

For each required action raised, the supplier should propose suitable close-out actions, together with appropriate timescales for closing out. Where appropriate, the supplier shall provide an action plan in response to required actions to support any recommended approval.

Such responses shall be to the satisfaction of the RISAB in order for the approval to proceed.

4.2.2

The report and response to the required actions should be submitted for final approval concurrently (ideally, this should be within 15 working days of the end of the assessment).

4.3 Signatory review and confirmation of approval

4.3.1

The RISAB signatory shall independently review the assessment report and the response to the required actions and determine the final decision on approval. Factors for consideration should include:

- The assessment has considered each requested product group to sufficient depth, commensurate with a risk-based approach.
- The report content and format is suitable and sufficient to support the recommended approval
- Supplier's response to any required actions requiring closing out prior to approval have been completed effectively (this is likely to require an element of verification, possibly even a follow up close-out visit from the assessment team)
- For other required actions, the supplier's response is acceptable and supported by a time-based action plan.
- Issues arising from the assessment that require control via a limitation

4.3.2

Certification validity will be for a period of not less than six months and no greater than three years. This is at the discretion of the RISAB and should reflect the level of risk associated with the approval. The RISAB may choose to make an approval dependent on interim surveillance activity (see 4.4.1 below) but this is not mandatory.

Factors for consideration in determining the length of an approval should include the relative stability of the supplier's organisation and its operations and the degree of compliance demonstrated against the assessment requirements. For a first assessment, certification validity shall not normally be longer than one year.

4.3.3

Where certification is to be granted with required actions outstanding, the RISAB shall make it clear to the supplier that the scope and timescale of approval is dependent on the required actions being completed as intended. This shall include any surveillance and / or close-out activities required to confirm completion. The limitations facility on the RISAS website should be used to confirm such situations.

The limitation field can also be used for clarifying the scope of approval within the product group structure listing where necessary

4.3.4

When all issues have been resolved (including any appeals being heard), approval shall be confirmed by the RISAB responding to the application made by the supplier on the RISAS website (see 2.1.2 above). For each confirmed product group covered by the approval, the RISAB shall enter the approval expiry date and any relevant limitations. The certificate of RISAS approval is automatically generated by subsequent reference to the supplier's page on the RISAS website.

4.4 Management of the approval

RISAS is intended as a 'managed' approval and both RISAB and supplier have obligations accordingly, as outlined below.

4.4.1

Where an approval is linked to periodic surveillance activities, then the RISAB shall ensure that these are undertaken in accordance with the agreed monitoring programme and with the full cooperation of the supplier. Failure to undertake such activities in a timely manner may render any approval invalid.

4.4.2

Where an approval is linked to the completion of required actions (see 4.2.1), the supplier shall provide regular and timely updates to the RISAB to enable the RISAB to close out any outstanding required actions.

The principle should be that all required actions are completed prior to the next assessment (otherwise a supplier would have been non-compliant for the entire duration of an approval).

4.4.3

Where progress against action plans becomes unsatisfactory, the RISAB and supplier should resolve any issues as appropriate. Where circumstances dictate that action plans become unachievable, the RISAB should give consideration to a modified response.

4.4.4

Where a supplier fails to close out one or more of the required actions as intended, the RISAB shall reserve the right to modify, suspend or withdraw the scope of approval accordingly (for example reduce the approval period to invoke a further assessment earlier than original planned). The supplier's right to appeal should be explained in such circumstances (as outlined in RISAS/005).

4.4.5

Should the validity of a RISAS approval be called into question at any stage (for example customer complaint, issue of a national incident report (NIR), etc), the supplier shall feed back this information to the RISAB and facilitate any reasonable request from the RISAB to

investigate further. BN-002 provides further detail on the requirements of this clause and clauses 4.4.6 & 4.4.7 below.

4.4.6

The RISAB shall monitor the efficacy of a RISAS approval through review of industry intelligence (for example RISAS website feedback, RAIB reports, CIRAS, NIRs, etc. The RISAS Scheme Manager can assist with some of this monitoring).

The supplier shall advise the RISAB of any significant changes to its operation (for example change of location, organisation / ownership, production facilities, etc) during a period of approval. In response, the RISAB shall consider the impact on the on-going validity of the current certification.

4.4.7

Where significant changes or any investigations into incidents arising provide a justifiable reason, the RISAB shall reserve the right to undertake out-of-course assessment activity and / or modify the scope of approval accordingly. Other out-of-course assessment activity may be as directed by the RISAS board or at the supplier's request due to a significant change.

4.4.8

Suppliers should ensure that they are re-assessed prior to the expiry of their RISAS certificate to avoid their approval lapsing.

4.4.9

If a supplier fails a subsequent assessment or there is some other valid reason for suspension / withdrawal of certification, the RISAB shall withdraw the supplier's certification in accordance with the requirements of RISAS/001 via update of the RISAS website and upload of a notification advice.

4.4.10

Any decisions arising from surveillance or out-of-course interventions (including issue of any out-of-course CARs and modification of approval scope or status) should be subject of signatory review in a similar manner to the granting of the original approval (as outlined in section 4.3 above).

Part B - Assessment Requirements

1 Supplier Profile

Suppliers shall provide baseline information for reporting purposes. As much of this information as possible should be supplied to the assessment team in advance in order to assist with preparation and to maximise the efficiency of the assessment itself.

	Requirements	Examples of suitable evidence	Assessment comments
1	History including date of establishment.	Company literature.	
2	Current work relationships for example associated, parent or group companies	Group / corporate organogram. Legal ownership of the company for example company registration documentation, contact details for the organisation, contact details for the facilities and national identification for example VAT number.	
3	Human resources (both management and staff) necessary to carry out the work related to the relevant product groups for which approval is sought.	Organisation chart with key roles and responsibilities. Staff turnover, any key vacancies, succession planning. Identification of future organisational change	
4	Facilities, plant and equipment for relevant product group.	Production location, for example name of location(s) to be assessed. Statement of capability, site and facility layout plans, access and egress for persons, materials, services, asset register (RISAS Briefing Note BN-001 provides further guidance in this area)	
5	Detailed scope of supply, including critical product review and capacity	Types of critical product produced and product related activities, how many, who for, when etc. (ensure supply to UK has been within the last 2 years)	
6	Details of contracts in place for relevant product group	Recent and relevant contracts (to enable RISAB to identify suitable contracts for assessment).	

	Requirements	Examples of suitable evidence	Assessment comments
7	Details of existing assurance qualifications.	Registration / qualification (for example Link-Up, Plan Assure, ATOC-ACOP/EC/01003). Certifications held (eg ISO 9001, ISO 14001 / 18001, IRIS), process-specific approvals (eg NDT, welding, calibration), customer approvals, TSI certification)	

2 Management Systems

2.1 ISO 9001: 2008 certificated suppliers

Where the supplier has a quality management system that meets the requirements of ISO 9001:2008 then this will be taken into consideration during the assessment with the intention of minimising the duplication of assessments. The ISO 9001 certification shall have been carried out in accordance with ISO 17021:2011 by a certification body that holds appropriate accreditation for the rail industry and the scope of supply relevant to the product group(s) being assessed.

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier's certification to ISO 9001:2008 shall cover the work involved in the supply of the particular product group and the efficacy of the current approval should be reviewed.	<p>ISO 9001 certificate, the scope of which covers the work and procedures, required for the supply of the particular product group.</p> <p>Review of previous third party assessment reports, demonstrating that there are no open major non-compliances or issues that might compromise the certification of the product groups being assessed.</p>	

2.2 Supplier not certificated to ISO 9001: 2008

The supplier shall have in place a documented management system that is relevant to the product group(s) being assessed. Certification to other standards that meet the principles of ISO 9001:2008, for example ISO / IEC 17025:2005, or adoption of good practice such as ISO 9004:2009, shall be taken into consideration by RISABs.

	Requirements	Examples of Suitable Evidence	Assessment Comments
1	<p>If the supplier does not have certification to ISO 9001:2008, the supplier shall demonstrate that it has a quality plan consistent with the requirements of ISO 10005:2005 which covers the work involved in the supply of the particular product group(s).</p> <p>Assessment of the supplier's management system should take into account any other approvals held relevant to the product group(s).</p>	<p>A quality plan consistent with the requirements of ISO 10005:2005 which demonstrates the work and procedures for the product group(s).</p> <p>Manual containing comprehensive and robust written procedures.</p> <p>Review of the supplier's management system.</p> <p>Evidence that the supplier is working to the procedures.</p> <p>An alternative third party certificated or accredited management system or product approval.</p>	

2.3 All suppliers

The supplier shall have in place appropriate and effective systems to ensure critical products are processed in accordance with customer requirements

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall demonstrate effective systems (as evidenced through its internal audit programme) which provide confidence that the production of critical product will continue to meet customer requirements.	<p>An internal audit programme substantially being met.</p> <p>Results from other, recognised audits.</p> <p>Minutes of meetings where audit output is discussed and progress monitored.</p> <p>Progress in addressing internal and external audit recommendations and other actions in response to audits on a prioritised basis, dependent on risk.</p> <p>Note: The assessment team should use the findings from such audits not only as endorsement of the supplier's processes but also for audit trails as part of their own assessment.</p>	
2	The supplier shall have processes in place for change management such that any changes are implemented in a controlled manner (risk-based*) so as not to adversely affect critical product. (*consistent with the requirements of Commission Regulation No 402/2013 (Common Safety Method for Risk Evaluation and Assessment) in regard to any changes being made.	<p>A defined process, recognising 402/2013/EC, for managing change (organisational or major personnel change); change of location, facilities, plant/equipment (including start-up of mothballed equipment / facilities); change of production processes; change in supply chain; change in legislation) – including advice to the RISAB in accordance with BN-002 where appropriate.</p> <p>Records of management and implementation of changes (project management meeting minutes, staff training records, equipment homologation testing, consideration of 'significant' in accordance with 402/2013/EC, etc)</p> <p>Advice to customers where such changes require consultation.</p> <p>Guidance on the application of 402/2013/EC is provided on the RSSB website at: http://www.rssb.co.uk/improving-industry-performance/management-of-change</p>	

3 Customer Specific Requirements

A supplier shall be able to demonstrate how they have complied with customer requirements. The supplier shall have a quality plan (or equivalent) which implements specific customer requirements which will be set out in each customer's contract and specification. The quality plan should identify specific instances where the customer requires intervention or monitoring of the supplier's deliverables. It shall demonstrate an effective procedure to control contract variations and ensure the effective cascade of customer requirements to the supply chain.

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall demonstrate that customer specific requirements are reviewed appropriately prior to a commitment to supply and that 'who supplies what' is clearly understood. Where requirements are not clear clarification should be sought with the customer.	<p>Records of tender / bid review, contract review, meeting minutes etc.</p> <p>Agreement over provision of key technical specifications (overhaul instructions, drawings, parts lists, etc) and the format in which they be submitted.</p> <p>Customer agreement (for example e-mail or meeting minutes) confirming acceptance of 'best alternative'.</p>	
2	The supplier shall have appropriate management procedures to ensure that customer specific requirements are met.	<p>Formal processes and procedures</p> <p>Quality plan (or equivalent). Copies of documents called up such as appropriate drawings and standards, to the correct date and issue number. Also agreed final inspection and release of product, including certificates of conformity where required.</p> <p>Project management minutes, contract enabling minutes.</p> <p>Manufacturing instructions that reflect requirements of specifications.</p> <p>Production planning that takes into account requirements derived from the customer specification and appropriate co-ordination of internal resources / activities.</p>	

	Requirements	Examples of suitable evidence	Assessment comments
3	<p>Sub-suppliers in the supply chain shall have sufficient knowledge (commensurate with risk) of the main supplier's quality plan to ensure that the customer specific requirements are met.</p> <p>The supplier shall demonstrate how it has satisfied itself that sub-suppliers are able to supply in accordance with customer requirements</p>	<p>Back-to-back contract requirements, supplier sign-off of sub-supplier quality plans, supplier issue of its quality plan to sub-suppliers (typically for higher value contracts), meeting minutes etc.</p>	
4	<p>For each appropriate specification (as pre-selected by the assessment team) the supplier shall demonstrate how they have complied with the specification for the product groups concerned.</p> <p>Note: The work of the technical experts within the assessment team will typically provide the evidence required to confirm compliance with this requirement</p>	<p>For both material (M-code) and services (S-code) product groups: Procedures and product comply with specification. Awareness of appropriate personnel to the requirements of the specifications. Review customer feedback for evidence of compliance with specification and close-out of any issues raised.</p> <p>For materials (M-code): Drawings, documents, procedures, instructions, components / materials and working and testing practices for the critical product during all stages of supply and test which prove that the work of the supplier meets the requirements of the specifications and that they have been interpreted correctly.</p> <p>For services (S-code): Demonstrate the employment of personnel competent in the relevant disciplines (including supply and test of critical product). These may be in-house, consultants or from a sub-supplier's personnel.</p>	
5	<p>For the selected specifications, the supplier shall be able to demonstrate that they have ensured the appropriate control of contract variations, including liaison with customers.</p>	<p>Where available, appropriate contract variations associated with the specification. This should include variations initiated by either party (for example change of scope from customer, change of critical sub-supplier, additional work found during inspection, etc)</p>	

	Requirements	Examples of suitable evidence	Assessment comments
6	<p>The supplier shall demonstrate that the successful supply of a critical product for one contract is not compromised by work on another contract.</p> <p>The supplier shall demonstrate that it is capable of delivering different customer specific requirements at the same time. If the supplier cannot demonstrate this, then it shall demonstrate that it has appropriate controls to ensure that this does not happen.</p>	<p>Examples of delivering against more than one specification at the same time and any obstacles that had to be overcome.</p> <p>Supplier awareness of their operational capacity constraints (as expressed in capability statement), ability to cope with perturbations to production plans.</p> <p>Delivery under pressure doesn't compromise quality.</p>	
7	<p>The supplier shall demonstrate that it has procedures to ensure that sufficient personnel and resources are provided to meet customers' requirements.</p>	<p>Appropriate procedures for the management and control of production volumes. Examples of delivering the volumes required.</p> <p>Examples of customer requirements that have been considered. Engineering assessment of the capability to deliver the production volumes required and consequent provision of personnel and resources (including tools, equipment and facilities, etc).</p>	
8	<p>Working environment, including plant, facilities, tools and equipment shall be appropriate and suitable for the product group.</p>	<p>Appropriate facilities, for example buildings / storage areas, heating / lighting, crane-age / lifting / handling, designated areas for critical activities (for example inspection booths, clean rooms, etc), IT provision and office accommodation.</p> <p>Suitable arrangements for inspecting and maintaining site facilities (for example PPM regime, data security and back-up)</p>	

4 Document Control

4.1 Supplier not certificated to ISO 9001:2008

The supplier shall demonstrate effective management and control of all documents pertinent to the critical products it supplies to ensure that the requirements of customers and all relevant standards are met.

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier's document control procedure shall identify the documents requiring control on a selected rail industry contract for the supply of critical product(s).	Documents and document control procedures on a selected rail industry contract for the supply of critical products.	
2	The supplier shall identify the names of the personnel who authorise and carry out the reviews of the necessary documentation.	List of authorised signatories and their competency, evidence of appropriate signatures on documents.	
3	The supplier shall review external documents and ensure that their impact on internal documents is assessed and required amendments actioned.	Review documentation control system and schedule and evidence of competency.	
4	Document changes shall be identified and recorded and cascaded throughout the supplier's organisation.	Evidence that changes to customer and supplier documentation, new standards, legislation etc are identified and communicated to personnel	
5	Documents shall be controlled and issued effectively to points of use in particular multi-sites. The supplier shall have an effective process for feedback on individual documents to the document controller and, where appropriate, the document originator.	Document control procedure, master list, acknowledgement slips, document sampling, evidence of feedback forms and close out of issues raised etc.	
6	The supplier shall have appropriate procedures to handle and manage withdrawn and superseded documents.	Document control procedure, master list, acknowledgement slips, document sampling etc.	

	Requirements	Examples of suitable evidence	Assessment comments
7	The supplier shall have appropriate procedures to record controlled documents and show document status.	Document control procedure, master list, acknowledgement slips, document sampling etc.	

4.2 Document control: all suppliers

All documents and media, which are necessary for the supply of critical products, shall be held by or be readily accessible to the supplier and its personnel and be provided for the assessment team upon request. These should include, but are not limited to: technical specifications, drawings, test and inspection standards, and work instructions, together with training and competence standards. It shall be apparent that such documentation is known and duly used.

	Requirements	Examples of suitable evidence	Assessment comments
1	All the documents and media for the supply of the critical product shall be readily accessible to the relevant personnel.	Industry standards, technical specifications, drawings, test and inspection standards readily accessible to relevant personnel and made available to the assessor.	
2	Documentation and media shall be current and supplied in a controlled manner.	Documentation with correct issue number and indication of control status (for example 'controlled', 'for reference', etc). Electronic media with appropriate access rights and version number. Absence of spurious, unofficial notices, 'aide memoirs', etc that could lead to loss of data control.	
3	Documentation and media, provided to support the supply of critical products, shall be known and duly used.	Readily apparent use of provided documentation (as witnessed by the assessment team), interviews with artisans demonstrating knowledge of the content of the documentation. Absence of artisans working to alternative methods, contrary to the supplied documentation.	

4.3 Document control: engineering change certificated suppliers

	Requirements	Examples of suitable evidence	Assessment comments
1	<p>The supplier shall have the appropriate awareness of statutory, mandatory and industry requirements to be able to determine which standards apply to the work carried out for the production of the product group and to be able to interpret them correctly.</p>	<p>For materials: Drawings, documents, Industry Standards (Railway Group/Industry Standards, Guidance Notes, inter-business (IB) technical specifications, etc), Euronorms, procedures and working and testing practices for the critical product during all stages of supply and test.</p> <p>For services: Demonstrate the employment of personnel competent in the above issues. These may be in-house, consultants or from a sub-supplier's personnel.</p> <p>For both: Working practices at all stages of production on the shop floor which demonstrate compliance with standards and legislation.</p>	

5 Risk Management

5.1 Risk management: all suppliers

The products groups identified under RISAS are all considered to present key risk issues associated with the supplier's processing of the product, which need to be managed by the supplier (and, where relevant, its supply chain). The supplier (and, where relevant, its supply chain) shall demonstrate their understanding of the key risks, which need to be managed and that they have production control procedures for controlling the specified risk and responding to external industry risk issues (for example NIRs) as they arise. This section in particular requires an overall, considered judgement by the assessment team based on evidence gathered / seen throughout the whole visit.

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall be able to demonstrate appropriate awareness of the criticality of the product.	Documentation, including part number, details, reference to its safety or business criticality. Answers of relevant personnel. Risk assessments for the supply of critical products.	
2	The supplier shall demonstrate its procedures and methods that control risk whilst processing critical product	Personnel engaged on production activities with appropriate competence and aware of relevant mitigation measures. Provision and use of appropriate tools and equipment. Availability and control of materials and components. Observed production practice for example control of storage conditions, handling, adherence to procedures and instructions, identification, segregation and traceability, recording of work done; sign-off and release of product.	
3	The supplier shall demonstrate its procedures and methods, appropriate to product risk, for monitoring and checking the compliance of critical product during production activities and at the point of release for use.	Procedures and instructions for inspection activities. Use of appropriate calibrated equipment for undertaking prescribed measurements and tests, including non-destructive testing. For measuring equipment relying on computer software, the methods used to ensure the ability of the software to perform the desired task has been confirmed prior to initial use and reconfirmed as necessary.	

	Requirements	Examples of suitable evidence	Assessment comments
		<p>Personnel with authority to check and inspect, including the final inspection prior to product release.</p> <p>Identification and processing of non-compliant product (this can include re-inspection / recall procedures when an item of measuring equipment is found to be out of calibration).</p>	
4	The supplier shall have appropriate procedures to uniquely identify critical products and their components to avoid inadvertent use that might create a risk scenario.	<p>Evidence of suitable catalogue numbers on critical products and in literature (for example on PADS for rolling stock).</p> <p>Suitable identification, traceability and configuration control of product and components during production processing.</p>	
5	The supplier shall have an effective system for responding to in-service incidents occurring to supplied product and for monitoring the results from national incident reports (NIRs) (issued in accordance with GE/RT8250) relevant to their product group, and identifying and carrying out any resulting corrective action they need to take.	<p>Records of response to in-service problems and failures including warranty claims, investigations to establish the cause of the failure and actions for improvement. Co-operation with NIR investigations, in accordance with BN-002</p> <p>Relevant records from review of NIRs, such reviews being carried out at the time of issue of the NIR.</p> <p>Appropriate procedures for dissemination of NIRs and responding to them.</p> <p>Examples of corrective / preventive action undertaken as a result of NIR review.</p>	

5.2 Risk management: control of the supply chain

Risk to provision of critical product is affected by interaction with the supply chain (ie associated products / services not supplied by the organisation being assessed). The supplier shall demonstrate that this element of risk has been controlled through appropriate procurement processes to manage the risk throughout its supply chain such that equivalent assurance is provided notwithstanding supply chain involvement.

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall demonstrate that it has assessed and managed the risks for the supply of critical products throughout its supply chain.	<p>Procurement policy and its understanding by key personnel.</p> <p>Risk assessment of supply chain, including capability, risk management plan.</p> <p>Arrangements for registration, qualification and certification of sub-suppliers (risk-based audit plan, verification of certifications / approvals, first article inspection). Those sub-suppliers holding an appropriate RISAS approval in their own right have a presumption of conformity.</p> <p>List of approved suppliers.</p> <p>Monitoring of supplier performance, including addressing and resolving issues raised (for example resident engineer).</p> <p>NOTE: Guidance is provided in RSSB document 'Securing Supplier Assurance', available at www.rssb-safp.com.</p>	
2	Where materials and repair / overhaul components are sourced from sub-suppliers, the supplier shall have processes to ensure that that these materials / components comply with the contracted specification and any relevant national / international rules (RGS, ENs, etc).	<p>Purchasing procedure.</p> <p>Contract / specification requirements identified on purchasing documentation.</p> <p>Inwards inspection and test of incoming. Products; sampling levels; tolerances.</p> <p>Supplied conformance documentation.</p> <p>Control and storage of components on site.</p>	

5.3 Risk management: engineering change certificated supplier

The supplier should understand the criticality of the product, have appropriate awareness of the critical product and its function within the rail system, and employ personnel with the competence to make risk-based judgements related to the technical configuration of critical product.

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall demonstrate appropriate awareness of the criticality of the product group and the function and risks of the critical product within the system (or systems) of which it will form a part.	<p>For Materials: Documentation, including part no. details, reference to its Safety Criticality and the system for which the part is relevant.</p> <p>For Services: Demonstrate the employment of competent personnel. These may be in-house consultants or a sub-supplier's personnel. Understanding of personnel.</p> <p>For Both: Answers of relevant personnel. The risk assessment for the critical product including the assessment of risks associated with any changes or the impact of defective critical products on the railway system. Awareness of the Risk Management Process outlined in Annex I of 402/2013/EC. Engagement with customer / customer information where relevant.</p> <p>Guidance on the application of 402/2013/EC is provided on the RSSB website at: http://www.rssb.co.uk/improving-industry-performance/management-of-change</p>	
2	The supplier shall demonstrate compliance with the four competencies listed in GE/GN8565.	<p>Systems to control the four competencies listed in GE/GN8565:</p> <ol style="list-style-type: none"> 1. The 'know why' of a system. 2. Retention of information. 3. Ability to make an informed judgement on the validation of technical change. 4. Management of configuration levels. <p>Answers of relevant personnel, appropriate training and appropriate records.</p>	

6 Management Communication

6.1 Communication within the supplier's organisation

The supplier shall demonstrate its arrangements for ensuring that it receives and disseminates relevant information appropriately. This could relate to customer, product specific or industry wide information and regulatory requirements. This shall include the internal cascade and effective briefing of information. This section is intended to be complementary to the requirements in section 3 'Customer Specific Requirements'; any communication that takes place between the supplier and the customer in terms of agreeing the contract and specification for work should not be regarded as evidence of compliance with this section 6.

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall have effective processes in place for the timely dissemination and briefing of information related to critical product to appropriate personnel.	Evidence of effective processes (campaigns, written, verbal, audio visual, tool box talks etc.). Where such communications are as a result of issues arising these should be undertaken promptly (eg all staff briefed within a month) Effective inter-departmental communications (e-mails, meeting minutes, etc).	
2	The supplier shall demonstrate that information communicated is relevant to the work activity for the supply of the critical product.	Content of briefings and other communications to include: <ul style="list-style-type: none"> • Customer feedback / information (alerts, notifications, bulletins, contract amendments, etc). • Product specific information (for example specification changes). • Railway industry risk issues (including NIRs, RAIB / CIRAS reports). • Regulatory requirements, etc. <p>Note: General company information (financial performance, corporate news, etc) is not considered sufficient to address this requirement.</p>	
3	Personnel who determine the type of information to be communicated and the target audience shall have the appropriate competencies	Training, management supervisory skills / qualifications etc.	

	Requirements	Examples of suitable evidence	Assessment comments
4	The supplier shall have processes to ensure that briefings are understood by personnel and that appropriate records are maintained.	Meeting minutes, briefing note with signed attendance register etc. Talking with personnel.	
5	<p>The supplier shall have appropriate processes to encourage comments, suggestions and feedback to the appropriate level and issuing authority. This should include briefing issues raised and defect reporting.</p> <p>It shall be demonstrated that such feedback is appropriately responded to.</p>	<p>Verbal / written feedback, suggestion box, e-mails, management review etc.</p> <p>Involvement of staff representatives in determining and disseminating information related to critical product.</p> <p>Examples of responses to feedback</p>	

6.2 Communication throughout supply chains

The supplier shall demonstrate that it has systems for cascading relevant risk related information to the sub-suppliers in its supply chains according to the scope of their supply and their risk management processes (see 5.2). Sub-suppliers should also be required to communicate product-related risk information back to the supplier in a timely manner. Such communication should complement the standard procurement activity.

	Requirements	Examples of suitable evidence	Assessment comments
1	Where applicable, the supplier shall have effective systems in place for on-going communication of risk-related information to sub-suppliers relevant to the critical product they supply.	Letters / e-mails, briefing notes, minutes of meetings, etc where risk related issues are discussed as they arise. Advice of relevant industry risk information (for example NIR), changes to procurement requirements (specification, configuration, documentation, etc) clearly recorded in such communications.	
2	The supplier shall ensure that their sub-suppliers have appropriate monitoring and review procedures and that there are effective feedback loops to highlight new areas of risk identified.	Terms and conditions of supply include requirement for sub-suppliers to communicate pro-actively with supplier. Examples of sub-suppliers having communicated risk issues back to the supplier.	

6.3 Communications with customers

The supplier shall demonstrate that it has an effective system for feeding back pertinent information to and encouraging exchange of safety-related information with its customers according to the scope of their supply and their risk management processes. This is essential for the effective management of risk and to facilitate continual improvement.

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall have effective processes to ensure feedback of pertinent information to customers and exchange of safety-related information. (Such information should form an input to the monitoring and review activities in section 8) NOTE: The assessment of the above requirements is intended to be separate from the requirements for contract review in section 3.	Documented feedback for example e-mails, letters, minutes of review meetings, etc. containing details of such issues as defect / reject rates, failure modes, specification anomalies related to critical product. Evidence of exchange of information on safety-related malfunctions, accidents, incidents, near-misses and other dangerous occurrences as well as on any possible restriction on use. Contract issues log and improvement action plans.	

7 Competence Management

The competence of personnel working on critical products is essential to the safe operation of the railway. The supplier shall ensure that the training and allocation of competent personnel are appropriate for the tasks required for reliably and consistently producing the critical products. For management / technical staff, this should also include business critical competences.

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall be able to demonstrate that it has a competence management system (CMS) consistent with the requirements of ORR's Railway Safety Publication No.1, 2007 'Developing and Maintaining Staff Competence' and have undertaken a self-assessment against the checklist in the RISAS Competence Management System Guidance document.	<p>Documented CMS and personnel competence records.</p> <p>Completed checklist from the RISAS Competence Management System Guidance document.</p> <p>NOTE 1 – The RISAS guidance document 'Engineering Excellence into Competence' Guidance for developing a Competence Management System is available on RISAS website. The checklist is set out in pages 19-21 of the document (2012 edition)</p> <p>NOTE 2 – It is recognized that in some non-UK countries, arrangements for competency are influenced by national conditions (eg work permits). Where such situations exist, equivalence to the requirements of RSP1 and the RISAS guide should be established.</p>	
2	The supplier shall be able to identify the competencies for the supply of the critical product and demonstrate that the relevant personnel have the appropriate competencies.	<p>Obtain list of competencies for product supply and check against the CMS and a selection of sample personnel.</p> <p>Observation and inspection of work in progress, personnel interviews to verify technical competence, whether they are working to procedures, etc.</p>	
3	The supplier shall be able to demonstrate that work has been carried out by competent personnel and that they have effective controls to ensure that	Records to show that work has been carried out by competent personnel.	

	Requirements	Examples of suitable evidence	Assessment comments
	personnel do not carry out work for which they are not competent.	<p>Controls so that personnel do not carry out work for which they are not competent.</p> <p>Answers of relevant personnel.</p>	
4	The supplier shall be able to demonstrate that key management / technical personnel possess the requisite competencies to support the supply of the critical product.	<p>Identification of required managerial and technical competencies (leadership, engineering, procurement, project management, etc).</p> <p>Training records, curriculum vitae, performance review (or equivalent) process, with evidence that such skills are evaluated and developed.</p>	

8 Monitoring, Review and Development

To ensure that critical product meets the requirements of the customer, the supplier shall define and implement efficient and effective measuring, monitoring and recording procedures. Review and development processes should be based on input from such information and ultimately lead to continuous improvement in support of risk free performance.
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	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall have procedures to ensure that the production of the critical product continues to meet the specification.	Key performance indicators (KPIs) for product quality, records of measurements made in accordance with the quality plan, defect / reject rates, in-service problems and failures including warranty claims (see 5.1(5) above) Procedures for the recovery or recall of defective products.	
2	The supplier shall demonstrate that records of work carried out are produced and readily available in the format agreed in the relevant specification. Where appropriate, the supplier shall make available such records on request to the customer. This is to enable the customer to maintain a whole life history of maintenance, overhaul / repair and modification data.	Records (data) at least include those required by the specification, suitably retained / retrievable, traceable (by reference to component / vehicle serial number). Certificates of conformity (consistent with the requirements of ISO 17050-1:2010), release to service notice, with information on any restrictions on use, etc. Examples of records / data supplied to customer as part of contract requirements.	
3	The supplier shall demonstrate that performance against a contract is subject to periodic review based on recorded data. Actions arising from review should be subject to sustainable action plans to demonstrate commitment to continual improvement and risk mitigation	Analysis of data arising from processing of critical product and services (KPIs, measurements made in accordance with quality plan), customer feedback / exchange of safety-related information (see 6.3). Review meeting minutes where such analysis is discussed. Focussed (SMART) improvement actions. Subsequent review to confirm effectiveness of actions (for example improved KPI record) Evidence of a structured approach to continuous improvement through long term adoption of preventive	

	Requirements	Examples of suitable evidence	Assessment comments
		<p>or corrective measures linked to analysis of feedback data, designed to maintain or improve the performance levels (including safety) of critical product.</p> <p>NOTE – Effectiveness of such actions can be judged by reference to RSSB guidance document 'Measuring Safety Performance', available on the RSSB website http://www.rssb.co.uk/SiteCollectionDocuments/pdf/reports/Research/T852_guide_final.pdf</p>	

9 Control of Design

This section is concerned with design work (modifications, drawings, technical instructions, specifications, software, etc) that supports the overhaul of critical product. For an 'engineering change' supplier, design control may include the development of technical data and / or physical product which might be to improve reliability, safety performance and cost effectiveness. Such activities should be supported by planning, review, verification and validation before delivery to the customer.

9.1 Standard supplier

For the standard supplier, design work is not allowed, except where it is particularly identified and appropriate authorisation is obtained from the relevant customer(s).

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall have robust procedures to ensure that no design work takes place without authorisation having been obtained from their customers.	Engineering / technical procedures and documents including correspondence to and from customers.	
2	Where relevant, the supplier shall have appropriate evidence of processes for concessions, deferred work and work arising and be able to demonstrate their application including obtaining agreement of customers.	Procedures and examples of agreements with customers on concessions and work arising. Examples of assessing the risk impact of deferred work, evidence that deferred work is carried out as quickly as possible and is not forgotten.	

9.2 Engineering change certificated supplier

Design work for a critical product is allowed where a supplier has been approved for the relevant critical products for having the competence, product knowledge and understanding of the ultimate use of its critical product by a duty holder. The supplier will therefore know for which design work it shall still seek authorisation from the customer.

	Requirements	Examples of suitable evidence	Assessment comments
1	The supplier shall demonstrate how they decide which design work needs to be referred back to the customer for authorisation. Its procedures shall be sufficient to ensure that this process is routinely and consistently followed on every occasion.	Design change procedures and documents. Correspondence with customers where changes to the design and / or the technical data of critical product are discussed (including authorisation requirements). Risk assessments and assessments of whether authorisation from a customer is required.	

	Requirements	Examples of suitable evidence	Assessment comments
2	<p>The supplier shall have personnel competent to assess whether a change is necessary and whether authorisation needs to be sought from the customer.</p> <p>Such personnel shall review the impact of the change and undertake the necessary design work (including review and authorisation)</p>	<p>Are the competency standards set adequate for the tasks?</p> <p>Do the relevant personnel have the appropriate competences? (know-what, know-why and know-how of critical product and systems)</p> <p>Are personnel following the requirements of procedures?</p> <p>Answers of relevant personnel to procedural questions.</p> <p>Note: Evidence as above should be considered in conjunction with the responses to section 5.3.</p>	
3	<p>The supplier shall demonstrate how any design work is carried out in accordance with industry good practice guidance (eg that given in ATOC ACOP/EC/1006).</p>	<p>Examples of design work undertaken (drawings, calculations, etc), risk reviews (FMEA, HAZOP, etc).</p> <p>Evidence of review, approval and authorisation by the appropriate personnel in the supplier's organisation.</p> <p>Examples of evidence submitted to customers for a design change request together with calculations, risk assessments and other evidence submitted to customers.</p>	

Appendix A: RISAS approval process overview



