



Accreditation of Approval Bodies within the Railway Industry Supplier Approval Scheme

Submitted by

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RISAB Accreditation Manager

Approved by

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Accreditation of Approval Bodies within the Railway Industry Supplier Approval Scheme

Rail Safety and Standards Board

RISAS/004/01

Issue Two

Date 12th May 2006

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Part A

Issue Record

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

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Draft	February 2006	Original Draft Document developed from PS105/02 November 2005
One	7 th April 2006	Final draft
Two	12 th May 2006	First issue

Revisions in any reissued document will be marked by a vertical black line in the right hand margin adjacent to the revision.

Technical Content

Approved by:

Maurice Wilsdon, Head of National Initiatives, Rail Safety & Standards Board

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Compliance

This is not a Railway Group standard and is therefore not mandatory. However, for RISAS participants the relevant requirements detailed in this specification shall be complied with by the dates detailed below.

The requirements for Accreditation of RISABs, transfer of responsibility or need for re-accreditation are to be complied with from the date of award of Certification of the RISAB

Supply

Controlled and uncontrolled copies of this document may be obtained from the Communications Department, Rail Safety & Standards Board, Evergreen House, 160 Euston Road, London NW1 2DX.

Part B Requirements for Organisations Acting or seeking to Act as a RISAB

1 Introduction

B1.1

This specification defines the requirements that an organisation shall satisfy in order to obtain and retain Accreditation as a Railway Industry Supplier Approval Scheme Approved Body (RISAB). All RISABs shall be required to demonstrate ongoing compliance with the requirements of this specification.

B1.2

This section is to help prospective applicants understand what is involved in seeking to act as a RISAB and to give additional guidance.

B1.3

The RISAS working documents, the Supplier Approval Module (SAM) (RISAS/003/01) and this document, contain detailed requirements for prospective and existing Approved Suppliers and Approval Bodies. The Assessment of these bodies against these requirements is reliant on both simple factual assessments but also, importantly, on a significant level of professional judgement. The effectiveness of the scheme is very dependent on the involvement of experienced people with the appropriate skills, background and attitude. Appendix A contains guidance on what is expected of the RISAB's Assessment Team.

2 Definitions

B2.1

The scheme definitions are listed in the Principles of the Railway Industry Supplier Approval Scheme, RISAS/001/01.

3 General Requirements

B3.1

In order to approve under the scheme a body must be accredited by the RISAS Accreditation Agency.

B3.2

Access to the services of the RISAB shall be available to all Suppliers. The procedures under which the RISAB operates shall be applied and administered in a non-discriminatory manner with no undue financial or other conditions to restrict the application of the process for Supplier Approval.

B3.3

Where a Supplier's documentation is not in English or key personnel do not speak English, a RISAB may require translators or interpreters.

4 Administration and Legal Structure

B4.1

The RISAB shall be impartial and independent in decision making from other commercial interests within any parent organisation. RISAS Approval activity shall be independent of other activities of the organisation. This does not preclude those involved in RISAS undertaking other activities for the parent organisation, provided that these activities do not compromise the objectivity and impartiality when undertaking RISAB activity.

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B4.2

The RISAB is not required to be a Notified Body but many of the requirements in this specification are in line with what is required of a Notified Body and in accordance with EN45011.

B4.3

The documented structure shall define the responsibilities and authorities of individuals with respect to approval work and allow only those so authorised to participate in approval work.

B4.4

The organisation must have the necessary impartiality. This does not preclude a railway company or Supplier having a RISAB within its organisation, but it does mean that certain constraints are placed on the organisational structure so as to demonstrate the necessary independence underpinned by a recognised Quality Management system.

B4.5

The RISAB shall describe its legal status in regard to the activities within its scope especially where the RISAB is part of a larger organisation or group providing other Products.

B4.6

The RISAB must have a working understanding of how it is empowered to carry out Supplier Approval work; its knowledge will be expected to encompass the legislative background as outlined in the "Principles of RISAS" RISAS/001/01, and the "RISAS Supplier Assessment Module", RISAS/003/01.

5 Rights of Access

B5.1

The RISAB shall provide the Accreditation Agency with reasonable right of access to any area of the RISAB or Sub-contractor's premises to verify compliance with this specification and Mandatory Requirements. The RISAB's personnel shall be made available as required to assist with this process.

6 Outline of Approval System Requirements

B6.1

The RISAB shall have documented approval system procedures setting out the way in which it complies with this specification and the Supplier Assessment Module and other RISAS documentation. See Part D for more details.

B6.2

The RISAB may have some aspects of its approval system within other systems' documentation, such as its quality manual but it must ensure that these are clearly cross-referenced so that the total requirements of the system can easily be located. The information supplied within the approval system shall include as a minimum:

B6.2.1 Introduction

Brief details regarding the company and its activities.

B6.2.2 Amendments

Page(s) detailing changes to the system and procedures, and the method employed to identify them within the documents.

B6.2.3 Policy Statement

The management with executive responsibility shall define and document its RISAB policy, including objectives and commitment. The Policy Statement shall

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be relevant to the RISAB's organisational goals and the expectations and needs of its customers. The RISAB shall ensure that the policy is understood, implemented and maintained at all levels. The Policy shall be reviewed and updated annually to ensure it continues to reflect the company's organisational goals and expectations. When any significant change is made to the Policy Statement the Accreditation Agency should be notified.

B6.2.4 Confidentiality

The RISAB shall have adequate arrangements to ensure confidentiality of the information obtained in the course of its Supplier Approval at all levels of its organisation. Information received by the RISAB in support of approval shall not be disclosed to any party other than the submitter, the Accreditation Agency, the system administrator, the RISAS Board and any other RISAB contractually involved in the process, without the express written permission of the applicant.

B6.2.5 Independence and impartiality of RISAB personnel

The RISAB must be independent and impartial in its Approval activities and RISAB personnel must be able to operate in such a way as to be free from the control of personnel who have a direct commercial interest in the Products that are within the scope of the proposed approval. In order to satisfy these requirements on independence and impartiality a number of general principles should be followed:

- a) Any Signatory, Lead Assessor, Assessor and Technical Expert should have no direct commercial interest in the Products that are within the scope of the proposed approval
- b) Where any of these personnel is employed by an organisation which supplies Products to the railway industry, he or she should have no direct responsibility for these but should hold a position within the company where independence and impartiality can be demonstrated
- c) Any person involved in RISAB activities should not respond or report directly to a manager or head of department who is responsible for the generation of evidence in support of approval, and shall not have participated in the generation of that evidence.

7 RISAB Organisation and Responsibilities

B7.1

The RISAB shall have and maintain:

- a) An up to date organisation chart showing clearly the responsibility and reporting structure of the RISAB.
- b) Defined and documented details of the responsibilities, authority and interrelation of personnel who manage, perform and verify Approval work.
- c) The means to identify resource requirements and provide adequate resources, including the assignment of trained personnel for management, performance of work and approval activities.
- d) Details of the appointment by the management of a dedicated member of its own management team with executive responsibility who, irrespective of other responsibilities, shall have defined authority for ensuring the Approval System is established, implemented and maintained in accordance with this specification and the requirements of RISAS. This member shall report on the performance of the approval system at the management review meetings.

- e) A registered User designated to be the RISAB's major interface with the RISAS IT application.

B7.2

The RISAB shall have or make available the necessary expertise to conduct the approval Assessment process.

B7.3

The Assessors, Technical Experts and other personnel of the RISAB shall be competent for the functions they undertake.

B7.4

Personnel undertaking RISAB activities shall have available to them, and be able to demonstrate their knowledge and understanding of clear documented instructions pertaining to their duties and responsibilities. These instructions shall be maintained up-to-date.

8 The RISAB's Management Systems

B8.1 Management Systems

The Accreditation Agency will examine the management systems that are relevant to the application of RISAS. These follow in sub-sections 8.2 to 8.16. Sub-sections 8.2 – 8.6 relate to different aspects of competence and training.

B8.2 Competence Management System and RISAS

The potential, or existing, RISAB must demonstrate that it has competent staff possessing the appropriate knowledge, skills and experience in respect of the process for Supplier Approval in general and in the specific technical disciplines and Product Groups for which Accreditation is being sought as follows:

B8.2.1

Personnel involved in RISAB activities shall be subject to a Competence Management System (CMS) and this will be examined during the Accreditation process. The RISAB, personnel shall be able to demonstrate, appropriate knowledge and understanding of:

- a) The process for Supplier Approval, its limits of applicability and its interface with other rail industry processes.
- b) The company's procedures by which the process for Supplier Approval is operated, and of the responsibilities which this imposes on RISAB and its role as Assessor and Approver
- c) The overall roles of the RISAB within the process for Supplier Approval.
- d) The application of risk management techniques in support of RISAS.
- e) The overall framework of railway safety legislation, the Safety Management System interfaces between HSE, Rail Safety & Standards Board, the Train Operating Companies and suppliers, and the position of the process for Supplier Approval within this framework.
- f) The identification and application of the relevant Mandatory Requirements including where appropriate Railway Group Standards, European Technical Specifications for Interoperability (TSIs) and Euronorms
- g) The use of relevant Assessment/audit techniques

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B8.2.2

Lead Assessors shall also be able to demonstrate their technical knowledge and experience of the categories of Product Groups for which they intend to approve suppliers. Lead Assessors should be able to demonstrate that they are aware of their limitations with regards to technical expertise and can specify and arrange technical support as necessary.

B8.2.3

Technical Experts shall also be able to demonstrate their technical knowledge and experience of the categories of Product Groups for which they intend to support the Approval of Suppliers.

B8.2.4

The RISAB Signatory must be a chartered engineer or equivalent.

B8.2.5

Throughout RISAS/004/01 references to the Assessment Team, their competencies and how these will be verified, will be expected to be in accordance with those in the following matrix, or similar. The RISAB shall be able to demonstrate that personnel approved to undertake approval activities continue to satisfy the requirements. Each role must be independent of others and the RISAB Signatory must not be in the Assessment Team:

Guidance on Qualifications and Experience:

Role	Activities undertaken	Required Competence (Qualifications/ Work experience/Training)	Method of verification	Comments
RISAB Manager	Manage RISAB internally and interface with the Accreditation Agency	Senior Manager may be a Chartered Engineer	Discussion	Likely to lead meeting on RISAB's Management Systems
RISAB Signatory	Set scope, agree assessment details, approve report and sign authorisation of certification on IT Application	Chartered Engineer with rail industry and audit experience and understanding of Risk Management	Review documentation and interview	May be interviewed on RISAB's Management Systems
Lead Assessor	Lead all aspects of supplier assessments and recommend Approval	Minimum 10 years experience in engineering preferably railway, with HNC, have experience and qualification as a lead auditor and have passed an IRCA registered course. An understanding of railway standards and risks and general risk management	Review documentation and interview a % of Lead Assessors determined by the Accreditation Agency (initially this would be expected to be 100%)	Will lead a minimum two person assessment team with the appropriate experience for all products/services to be considered for Approval
Assessor	Assess suppliers in support of Lead Assessor working towards lead assessor with route agreed with RISAS Manager	Minimum 5 years experience in engineering preferably railway, understanding of railway standards and risks, experienced auditor	Check on CMS and a % sample interviews, determined by the Accreditation Agency (initially this would be expected to be 100%)	
Technical Expert	Giving technical support to Assessors	Minimum 10 years railway engineering experience with understanding of railway standards and risks, Experience of the product groups to be assessed is essential	Review documentation and interview a % of Technical Experts determined by the Accreditation Agency (initially this would be expected to be 100%)	

B8.3 Competence Management System and Risk

RISAB Signatories and Lead Assessors should have a good understanding of risks in the railway industry and have experience in risk management techniques. They should also be able to demonstrate a good understanding of the principles behind section 4.1 of the Supplier Assessment Module.

B8.3.1

For those involved in Assessments for Engineering Change a good understanding of Risk Management and Engineering Change must be able to be demonstrated.

B8.3.2

Assessors and Lead Assessors who are to carry out risk assessments as part of the approval process should possess an appropriate formal qualification or be able to provide evidence of attendance at a Risk Assessment course together with evidence of practical application of such techniques.

B8.4 Appropriate Competencies

It is not expected that all organisations applying for Accreditation will have competencies covering the whole matrix of Product Groups. It is therefore acceptable to be accredited for specific activities within the overall product Group range. An organisation might, for example, limit its activities to the issue of *'Engineering Change Supplier of repaired or overhauled brake equipment, excluding software'*. There are no limits on the combinations of Approval and Product Groups for which an organisation can be accredited, provided it can demonstrate that it has the appropriate systems, facilities and competencies to carry out the task in each case.

B8.5 Ongoing monitoring of Competence of RISAB Personnel

The RISAB CMS must include ongoing monitoring of its RISAB personnel and the RISAB is required to be able to demonstrate that its personnel continue to satisfy the requirements including:

B8.5.1

The process for monitoring the competence of RISAB personnel may be linked to the RISAB's own internal audits which should be scheduled on a risk basis.

B8.5.2

The RISAB must maintain competence records of the personnel who work on RISAB activities. These must be made available as required during the Accreditation process.

B8.6 Continued Professional Development Log

All members of Assessment Teams are required to maintain a Continued Professional Development (CPD) log. The CPD log shall include the following sections as a minimum:

- a) Professional Review Paper (an extended Curriculum Vitae updated annually or on change of responsibility, accountability, or position within the company), including qualifications and information on experience of the technical disciplines relevant to RISAS and related levels of responsibilities

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- b) An Assessment log and for Lead Assessors, an Index of Certificates recommended
- c) Their work related to applicable industry standards including reviewing and drafting
- d) Knowledge and understanding of relevant industry issues and interfaces, and the ongoing development of these, eg noting seminars attended
- e) Training completed appropriate to the process of Assessment of Suppliers.

B8.6.1

The CMS should cover all aspects of RISAS related training including training needs analysis, training records, briefings and training should be included within management review. Details relating to training needs of a CMS are described in Principle A8 of RSPG 3A.

B8.7 Management review

A RISAB Manager, with executive responsibility, shall review its arrangements for applying the Approval System at defined intervals sufficient to ensure its continuing suitability and effectiveness in satisfying the requirements of this specification and the RISAB's Policy Statement and objectives. Records of such reviews shall be maintained as follows:

B8.7.1

As a minimum the review shall cover the following topics:

- a) Internal audits and external assessments of the RISAB
- b) System evaluation including training needs and subcontractor performance and covering Assessment Team CPD logs and assessment logs
- c) Any available appeals, complaints and accolades and other customer feedback
- d) Consideration of previous supplier assessments
- e) Progress on Required Actions and preventive actions
- f) Efficacy of the interfaces with the RISAS Accreditation Manager and the data base
- g) Policy statement & objectives continued validity

8.7.2

Actions required as a result of the review should be recorded and adequately addressed to specified timescale.

B8.8 Contract review

The RISAB shall establish and maintain documented procedures for Contract Review and for the co-ordination of these activities, as follows:

B8.8.1

Before acceptance of an order or contract with a Supplier the order or contract shall be reviewed to ensure that the requirements are adequately defined and that the RISAB has the capability or resources to meet laid down criteria as defined by its scope of Accreditation.

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B8.8.2

The RISAB shall identify how an amendment to a contract is made and correctly transferred to the functions within its organisation.

B8.8.3

Records of all contract reviews shall be maintained. These records shall be sufficiently detailed to ensure appropriate analysis can be completed.

B8.9 Document and data control

The RISAB shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this specification for Supplier Approval under the RISAS process As follows:

B8.9.1

All documents and data shall be reviewed and approved for adequacy by authorised personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and / or obsolete documents. Documents of external origin such as standards, drawings and technical literature shall also be controlled as required.

B8.9.2

Issues of appropriate documents shall be available at all locations where operations essential to the effective functioning of the RISAB are performed.

B8.9.3

All obsolete documents should be removed from all points of issue or suitably identified to prevent unintended use.

B8.9.4

When practical, the nature of any document or data change shall be identified either within the document or the appropriate attachments. All documents and data, where possible, shall be reviewed and approved at an appropriate frequency by the same function / organisation that performed the original review and approval.

B8.9.5

A controlled copy of documented procedures in support of the Supplier Approval process shall be made available to the Accreditation Agency if requested when visiting the RISAB's premises and changes to the arrangements or documentation shall be notified to the Accreditation Agency for its review.

B8.10 Control of records

The RISAB shall maintain a record system applicable to its particular requirements and to satisfy the requirements of the process for Supplier Approval as follows:

B8.10.1

The records including the reports on suppliers shall demonstrate the way in which each approval was undertaken including any result. Copies of the reports shall be forwarded to the RISAS database and these will be subject to restricted access.

B8.10.2

All records shall be securely stored, as in B8.11.1, for an adequate period consistent with the scope of the assessment and any notes produced by the

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Assessment Team justifying decisions made during the Assessment are to be maintained for at least three years.

B8.10.3

All records shall be stored in such a manner as to provide security, ease of retrieval and in the case of electronic data to prevent corruption or loss.

B8.10.4

The RISAB shall identify the method of identification, collection, indexing, maintenance and disposition of all pertinent records.

B8.10.5

In the event of a RISAB ceasing to operate, all records associated with the process for Supplier Approval shall become the property of the Scheme Administrator.

B8.11 Appeals and Feedback

The RISAS Appeals process is described in detail in the Principles document RISAS/001/01 and the RISAB shall have processes to allow it to comply with these details as follows:

B8.11.1

In particular, the RISAB shall establish and maintain documented procedures to define the actions taken on the receipt of an appeal against previous decisions or feedback (positive or negative).

B8.11.2

The Accreditation Agency will provide a RISAB with any complaints raised against it where this is considered appropriate. Confidentiality of the Supplier will be maintained where requested. A record of complaints shall be held for three years and these shall detail any remedial action and subsequent corrective and preventive actions.

B8.11.3

The RISAB shall notify the Scheme Administrator, in writing, of any complaints and shall pass on any appeals received, and shall keep the Accreditation Agency informed of all actions taken to resolve such feedback.

B8.11.4

The RISAB shall, on a regular basis, seek the views of its clients, eg via review meetings, or write to invite documented feedback to determine the effectiveness of the Approval services it has provided. Results of review shall be presented to the Management Review. The RISAB should regularly check for feedback on the IT Application and results from reviewing these should be included in its management review. Other possible sources of feedback include surveys and questionnaires on completion of Approvals.

B8.12 Internal audits

The organisation concerned must demonstrate that it has an auditable system for ensuring Supplier Compliance with Mandatory Requirements and its own RISAB processes prior to Approval of Certification, and for keeping records of Approval work undertaken. This shall be in accordance with the following:

B8.12.1

The RISAB shall establish and maintain procedures for planning and implementing internal audits to verify whether activities and related results associated with the Supplier Approval process satisfy its requirements and comply with planned arrangements to determine the effectiveness of the Approval system.

B8.12.2

Audits shall be scheduled on the basis that all RISAB activities, including the undertaking of RISAS Assessments, will be audited at least once in any twelve-month period. The audit frequency for members of the Assessment Team shall not be less frequent than annually.

B8.12.3

Audits shall be scheduled on the basis of the status and importance of the activity to be audited.

B8.12.4

The results of audits shall be recorded and brought to the attention of those concerned with RISAS activities and follow up action shall verify and record the implementation and effectiveness of the corrective action taken and where known also preventative action.

B8.12.5

Results of all audits both internal and external and any actions taken shall be presented to the Management Review

B8.13 Control of non-conformance

Procedures shall be in place for the correction of non-conformance detected during internal audit, accreditation meetings, peer review or other sources.

B8.14 Engineering Change

Engineering Change includes changes in the areas listed at the start of Section B9 of RISAS/003/01. These include:

- Overhaul / maintenance / repair specification
- Materials specification
- Manufacture/ repair techniques
- Software
- Manufacture/ repair sub-suppliers
- Works / Manufacturing site
- Introduction of a new part, design or procedure,
- Personnel competence requirements

And the following requirements on Engineering Change apply:

B8.14.1

Accreditation for Approval of Engineering Change Suppliers requires a generally higher level of capabilities. This applies to the capabilities of the RISAB to assess and to the Supplier to deliver Engineering Change. The Supplier requires appropriate procedures, capabilities and competencies as identified in Supplier Assessment Module (RISAS/003/01)

B8.14.2

The RISAB requires appropriate capabilities to assess Engineering Change suppliers as follows:

- a) Procedures that set out how to measure and approve all of the supplier capabilities in the Supplier Assessment Module.

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- b) Personnel who are competent to assess appropriate aspects of the supplier capabilities.
- c) Managers who are capable of ensuring that competent assessment teams assess all the supplier capabilities for the Product Groups requiring Approval.

B8.14.3

RISAB staff involved in approval of suppliers for Engineering Change should be familiar with the requirements of documentation, such as the following, where relevant:

- Validation of Organisational Change, GH/RT4003
- Engineering Safety Management (Yellow Book)
- Engineering Acceptance of Rail Vehicles, GM/RT2000,
- ATOC/EC/ACOP01006, Inter-company Train Engineering Change approval Process

B8.15 Sub-contractor control

The following requirements shall apply where the RISAB uses Sub-contractors or self employed personnel in the performance of activities associated with the approval process:

B8.15.1

The RISAB shall establish and maintain documented procedures to ensure that the purchased sub-contract service conforms to specified requirements.

B8.15.2

The RISAB shall evaluate and select Sub-Contractors or self employed personnel on their ability to meet the requirements of this document and ensure that the Sub-contractor has personnel who are competent to undertake the work allocated. The type and extent of control exercised shall be dependent on the requirements of the service.

B8.15.3

The RISAB shall establish and maintain an approved Sub-Contractor list along with suitable records relating to each contracted individual to determine their suitability.

B8.15.4

Contract documents (RISAB to sub-contractor) shall contain all relevant data on assessments including the details of the Product Groups to be approved

B8.15.5

Where work is subcontracted the RISAB shall ensure that relevant records of its sub-contractor's activities shall be retained by the RISAB as evidence.

B8.15.6

Where applicable, the RISAB shall undertake verification at its Sub-contractors' premises and the RISAB will be afforded reasonable right to carry out verification of the sub-contracted activities and personnel.

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B8.16 Risk Management

The RISAB shall ensure that its systems are risk based and that staff are appropriately trained in risk management. Section 8.3 makes specific references to risk management and competence.

9 Relationship of RISAS/004/01 with PS305/04 and ISO: 9001

B9.1

Some requirements of this specification are similar to the requirements of PS305/04 relating to the Specification for VAB and CCB and to BSEN ISO: 9001:2000, Quality Management Systems Requirements. These are:

Title	RISAS/004 /01	PS305/04 reference	ISO 9001 reference
Certification (Approval) System	Part D 3	6.0	4
Policy Statement	Part B: 6.2.3	6.2.3	5.1
Organisation/ Responsibilities	7.1	6.2.6	5.5.2
Training	8.2-8.6	7.11	6.2.2
Management Review	8.7	7.4	5.6
Contract Review	8.8	7.5	7.2.2
Document & Data Control	8.9	7.6	5.5.6
Control of Records	8.10	7.9	5.5.7
Title	RISAS/004 /01	PS305/04 reference	ISO 9001 reference
Internal Audits	8.12	7.10	8.2.2
Control of Non-conforming Product/Service	8.13	7.8	8.3
Subcontractor Control	8.15	8.1	7.4.1

B9.2

Where a RISAB, or its parent organisation operates a quality management system in accordance with the applicable standard in the ISO 9000 series or EN45011, or another reputable system, whose scope covers aspects of RISAS activity, evidence of compliance with that standard will be taken into account when planning and assessing compliance with the requirements of this specification.

10 Related Documents

B10.1

RISAS has a suite of documents for the different aspects of the scheme

B10.2

The Principles of RISAS are detailed in RISAS/001/01

B10.3

The RISAS Board Arrangements are described in RISAS/002/01

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B10.4

The requirements for Supplier Approval are defined in the RISAS Supplier Assessment Module (SAM) RISAS/003/01.

11 Appeals Process

B11.1

Following a refusal to grant Accreditation to a potential RISAB, the applicant has the right in the first instance to appeal to the RISAS Board and details of the process are included in RISAS/001/01

12 Further Information

B12.1

Guidance on RISAS is available on the RISAS web site.

B12.2

Further enquiries regarding the process for Accreditation of RISABs and guidance on the interpretation of this standard can be obtained from:

RISAS Accreditation Manager
Rail Safety & Standards Board
Evergreen House, 160 Euston Road,
London NW1 2DX Tel: 020 7904 7687

Part C Accreditation

1 Accreditation of the RISABs

C1.1 Gaining and Maintaining Accreditation to act as a RISAB

The Accreditation process is managed on behalf of the RISAS Board by the Accreditation Agency and will be conducted in line with the SAM and this specification.

C1.2 Stages of accreditation

The stages in gaining Accreditation will be generally as follows:

C1.2.1

Discussions between the prospective RISAB and the Accreditation Agency on the scope of Accreditation which is sought.

C1.2.2

Preparation by the Accreditation Agency of a formal proposal setting out the commercial arrangements for the Assessment and any agreed ongoing surveillance of the organisation's activities as a RISAB.

C1.2.3

Submission by the prospective RISAB to the Accreditation Agency of a formal Application for Accreditation which signifies commercial agreement.

C1.2.4

Issue by the Accreditation Agency of controlled copies of this document, or referral to the RISAS web site, which gives full details of the requirements for an organisation to be accredited as a RISAB.

C1.2.5

Start up Assessment by the Accreditation Agency, principally at the candidate company's premises, of the Approval System to be employed. This Assessment includes a review of all policy statements and documented procedures associated with the Approval System and an Assessment to determine the level of compliance with of this specification, especially Part B, the company's procedures and in particular its CMS, and applicable Mandatory Requirements.

C1.2.6

Subject to agreement by the company to close out Required Actions within an agreed time scale, and provided that the CMS for the personnel involved in RISAB activities (including sample interviews of potential members of the Assessment Teams) is found to be acceptable, the company may be Accredited to act as RISAB, from an agreed date, for a defined period of time of between six months and three years.

C1.2.7

Prior to the expiry of the time period for addressing Required Actions, a follow up assessment may be conducted by the Accreditation Agency at the candidate company's premises in order to establish that the required control systems have now been established and that the organisational structure is such that the necessary assurance can be given. Subject to close out of Required Actions by the date of any follow up Accreditation Assessment, the company Accreditation may be confirmed for a period of between six months and three years.

C1.2.8

The Accreditation period and the scope of the Accreditation in terms of Product Groups levels 1 and 2, Engineering Change or Standard and any other relevant

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information, such as exclusions, will then be registered on the RISAS IT Application, for prospective RISAS Suppliers to see.

C1.2.9

The decisions on the granting of Accreditation and the period granted will depend on the assessment of the RISAB and the reasons for the decision should be recorded. Factors for consideration may include: confidence in the management systems (in particular competence management) and personnel, previous record of Product Group approval (for same Product Group and others), the risks involved and the norms for the industry.

C1.3 After Accreditation

The RISAS IT Application will automatically notify the RISAB prior to the expiry of the time period of Accreditation that re-accreditation is due. It is then the responsibility of the RISAB to request re-accreditation if desired:

C1.3.1

If so, a formal assessment will be conducted by the Accreditation Agency at the company's premises in order to consider re-accreditation of the RISAB. This assessment will include a full review of Supplier Approval work undertaken by the RISAB.

C1.3.2

Once accredited, a RISAB should inform the RISAS Scheme Administrator if it takes on additional staff performing RISAB activities. The RISAB's management systems are assumed to give the necessary assurance on competence; however, the RISAS scheme administrator may determine whether or not to interview such staff and will certainly interview new RISAB Signatories.

C1.3.3

The Accreditation Agency may undertake surveillance visits and observe new RISABs on their first assessments or may apply other forms of monitoring as felt appropriate (eg reviewing assessment reports).

C1.3.4

The Accreditation Agency may conduct such surveillance visits to a RISAB up to once per year as part of its general monitoring of RISAS or in response to any concerns it may have, eg after review of reports.

C1.4 Changes to Scope of Accreditation

At any time following the granting of Approval the RISAB can make a request to the Accreditation Agency for a change in the Scope of Accreditation. Such a change in scope will be regarded as an addition to the commercial agreement with the Accreditation Agency, and a further proposal and application will be necessary.

2 Assessment of Personnel Undertaking RISAB Activities

C2.1

Every RISAB will have a defined Scope of Accreditation. Before this Scope can be granted the RISAB will have demonstrated effective management systems, especially a CMS covering all staff involved in RISAB activities. All of these personnel do not need to have knowledge and experience of all of the Product

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Groups covered by the Scope but the RISAB must have access to competencies covering all of these groups to a satisfactory depth.

C2.2

Technical Experts are used to complement the expertise of the Assessors where necessary. They do not require to be experts in the Supplier Approval process but must have an expertise in the fields in which they assist the Assessors.

C2.3

Further guidance on the qualifications and experience necessary for a person to be considered as a member of an Assessment Team is given in B8.2-8.6.

C2.4

During the Accreditation process members of Assessment Teams may be interviewed in order to verify the management systems, in particular the CMS. Interviews will focus on competence issues and may include consideration of:

- a) The Supplier Approval and Product Groups to be considered and the individual's knowledge and understanding of the process for Supplier Approval.
- b) CPD logs, assessment logs, and other relevant documentation
- c) The individual's career history to determine their knowledge and experience of the products under consideration and the techniques (e.g. risk assessment) required during the Approval process.
- d) The individual's knowledge and understanding of the applicable legislation and regulations
- e) Audit reports and RISAS Assessments already undertaken or contributed to by the individual

C2.5

The interviewers will summarise their findings and feed back any observations to the interviewee.

C2.6

It is intended that the interviews be a one-to-one session to allow a straightforward assessment of the individual, however it is permissible for a management representative of the RISAB to be present to witness part of the discussions in order to help establish any further training or experience which the individual might require

C2.7

In addition to reviewing the RISAB's internal audit, Competence Management System and training records relating to RISAB personnel, the Accreditation Agency may monitor individuals during surveillance visits.

C2.8

In the event that there are doubts regarding an individual's continuing competence, it may be necessary for the Accreditation Agency assessor to review the categories of certificates which may be accredited with the RISAB's management and/or for the individual concerned to undergo a further interview to establish the current level of knowledge and experience.

C2.9

Where an individual working on RISAB activities cannot demonstrate the required levels of knowledge and overall competence the RISAB will be set an agreed timescale to take appropriate action.

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3 Measuring the Effectiveness of the Approval Process

C3.1

Once a RISAB has been operating it should keep records on its effectiveness. The Accreditation Agency shall review RISAB performance during surveillance visits and when re-accrediting should see records such as the following:

- a) The RISAB speed of response to the initial enquiry by the customer;
- b) The speed with which the approval work was carried out;
- c) How quickly Certification was awarded on completion of the Approval work;
- d) The professionalism and competence of Approval staff during the process;
- e) If approval was refused, was the customer advised of the reason(s) for this?
- f) The professionalism in determining the scope of Certification;
- g) Were the costs of Approval considered by the customer to be reasonable?
- h) How easy was it for the customer to obtain guidance on the process for Supplier Approval from the RISAB and/or from the Accreditation Agency?
- i) Were the quoted time-scales adhered to and any declared deadlines met?

C3.2

The list shown above is not exhaustive and Accreditation Agency will review RISAB procedures to determine compliance with the requirements.

4 Product Groups

C4.1 Product Groups

The list of Product Groups, showing levels 1, 2 and 3 is included as an appendix to the Supplier Assessment Module RISAS/003/01 and is available on the IT Application.

Part D The Approval Process

1 Approval Assessment Procedures

D1.1

The RISAB shall establish and maintain suitable documented procedures that identify, plan and control its approval process.

D1.2

The procedures shall encompass all stages of the approval process from the receipt of Supplier approval requests, tendering for (RISAB-supplier) contract, acceptance of the contract, to the award of Certification and any agreed follow up.

D1.3

In particular, the procedures shall include the processes for:

- a) Receipt of requests for Supplier approval
- b) Identification, recording and reviewing new and emerging Mandatory Requirements to determine their effect on existing and future contracts.
- c) Review of contract and technical specifications and the determination of the scope of the Assessment and the Certification provisionally determining the scope of the Supplier Approval after consultation details of the Product Groups and the necessary competencies for the Assessment Team
- d) Determining the initial scope and then producing the required detailed assessment arrangements, eg checklists and a programme,
- e) Detailed consideration of the questions in the Supplier Assessment Module to determine, via a risk based approach, the questions to ask
- f) Obtaining the necessary evidence to demonstrate that all aspects of the SAM relating to the scope of the Assessment have been met, clearly documenting the results which demonstrate conformance.
- g) Preparation and use of appropriate Risk Assessment techniques including the documentation of such assessments.
- h) Defining of Required Actions (Note definition in RISAS/001/01
- i) Definition of the scope for approval (possible amended during the assessment) , including the period of its validity, including Product Groups, timescales, limitations and Required Actions to be closed out
- j) Peer review of the Assessment Team's output, completed by the RISAB Signatory prior to the authorisation of the RISAB Certification to confirm the validity and scope of the Assessment in light of the scrutiny undertaken.
- k) Writing a concise report which describes the Assessment process applied and the Assessment findings

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2 The Assessment Process

D2.1.

The RISAB is required to manage the Supplier Approval Assessment which is described in the "Supplier Assessment Module" RISAS/003/01

D2.2

In planning and conducting the Assessment and in the writing of the Approval Scope careful consideration should be given to the site/s that the Approval covers.

3 Approval Assessment Reports

D3.1

The RISAB's approval Assessment reports shall cover the requirements of the Supplier Assessment Module sections B1 to B9.2 and should preferably be structured on the same basis and as a minimum clearly referenced so that reports can be easily viewed for good practice. It shall also meet the timescale requirements specified in RISAS/003/01 Section 2.5.

D3.2

The report shall contain an executive summary, conclusions and recommendations and will make clear the scope of the Approval being recommended noting 'Engineering Change' on 'Standard' supplier. Details of the Product Groups covered by the assessment should also be included and the period/s of approval must be made clear. These periods can be between 6 months and 3 years but for the first assessments one year would normally be the maximum period.

D3.3

The Assessment reports shall be treated confidentially and shall only be available (hard copy and electronically) to the RISAB, the assessed Supplier, the Scheme Administrator, and the RISAB Board.

D3.4

The Assessment report will make clear whether the approval being granted is dependent on close out of Required Actions or whether approval may be granted before closeout. In the latter case the monitoring and the closeout requirements and dates must be made clear.

4 Certification Control

D4.1 Award of Certification

The RISAB shall exercise proper control over the issue of the Certification of Suppliers on the IT Application. The RISAB Signatory will add an electronic signature on the IT Application giving them the authority to certify a Supplier for each of the Product Groups for which they have been successfully assessed. The IT Application is the primary means for demonstrating a Supplier's certificated status. Hard copies of the list of a Supplier's Certificated Product Groups may be printed out by a Supplier which could be used as a Certificate for presentational purposes if desired

D4.2

After the Assessment Team has undertaken the Assessment the Lead Assessor recommends the final scope of Approval. This may be different from the proposed scope of the Assessment initially requested by the Supplier. The

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RISAB Signatory will confirm the final scope of Certification by peer review of the report prior to the electronic authorisation on the IT Application.

D4.3

The Certification of a Supplier without the necessary justification, or where the requirements of the Supplier Approval process have not been met, shall be sufficient grounds for immediate suspension or cancellation of the RISAB's Accreditation.

D4.4

The Certification of a Supplier by a RISAB confirms compliance with RISAS requirements and that a systematic and risk based check has been carried out over the whole range of relevant requirements using selected Product Groups that are representative of the overall Product Group/s approved in the final scope.

D4.5

The Certification details on the IT Application for each Product Group include:

- a) The Number code for each Product Group see Appendix B of RISAS/003/01
- b) The name of the Product Group
- c) The date of Certification for the Product Group
- d) The date that the Certification for the Product Group expires
- e) Whether the Supplier has been approved as an "Engineering Change" or a "Standard Supplier" for that Product
- f) Name of Signatory and RISAB
- g) Any limitations or restrictions eg locations

D4.6

The IT Application will allow the records of Certification awarded to be interrogated and listed by relevant fields, eg Product Group.

D4.7

The RISAB shall have documented procedures for the withdrawal and cancellation of Certification. This requirement is outlined in RISAS/001/01

Appendix A

Guidance on the Application of Professional Judgement

Assessors should be able to:

- Detect whether and how statement of high level commitment is reflected in shop floor attitude and action
- See how the 'big picture' is likely to impact on the shop floor
- Understand the risks to the railway posed by the Products included in the Assessment
- See what is important and what is less so
- Know when to leave alone and when to dig deeper
- Identify the root causes of problems and anticipate what else they might impact on
- Understand the likely impacts of change including across interfaces
- See beyond the systems and paper to actual practice
- Have sufficient knowledge of the product and it's key design/manufacturing aspects to be able to prioritise scrutiny of likely problem areas
- Have an appropriate and commercial awareness of the operational railway (001, 3.3.3)
- Identify where other expertise is needed to support the Assessment
- Recognise the relevance of existing certification to the range of RISAS requirements and assess accordingly
- Be able to get interviewees 'on your side' as much as possible
- Be able to suggest remedies and anticipate likely responses and outcomes
- Be able to judge, after all the above (and noting the criteria in 001, 4.2.4 and 004, C1.2.9), how long the assessed company should be left before they are assessed again

The above applies equally to the RISAB Assessment Team and the Accreditation Agency but, in particular, to the Lead Assessor. The Accreditation Agency also has to assess the prospective RISAB on the above.