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**Railway Industry Supplier Approval Scheme BRIEFING NOTE**

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**Subject:**            **Methodology for addressing “Out-of-Course”  
Supplier Issues**

**Advice to:**            Railway Industry Supplier Approval Bodies (RISAB's)

**Reference:**            Standard: RISAS/003                    Issue: 4

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**Applies when:**        'Intelligence' is received or identified which could affect the efficacy of supplier RISAS Approval.

**Note's Purpose:**        To provide clarification and guidance on the methodology for addressing 'Out-of-Course' Supplier Issues which could affect the efficacy of their RISAS Approval.

**Background:**            RISAS is intended as a managed approval and both RISABs and suppliers have obligations as outlined in RISAS/003 Part A, 4.4. This includes an appropriate response to an 'Out-of-Course' incident (i.e. occurring during the period of validity of the supplier's current RISAS certificate, in-between planned assessment visits by the RISAB).

Within RISAS/003 Part A 4.4, clauses 4.4.5 - 4.4.7 provide the general instruction for such instances; however, arising from the RSSB-led axle bearing NIR investigation (report dated August 2014), recommendation 11 supports the production of a more detailed intervention methodology for 'Out-of-Course' supplier issues.

This note therefore provides a more detail process and instructions in support of clauses A.4.4.5 – 4.4.7 of RISAS/003.

**1 Intelligence received/identified**

1.1 An out-of-course event can be as a result of a significant change instigated by or otherwise affecting the supplier (e.g. a change of organisation / ownership, location, production facilities, etc.) or as a result of an incident affecting the supplier (eg issue of an NIR implicating a product produced by the supplier).

1.2 The scheme requires that the supplier should advise its RISAB when such events occur; however sometimes this is not case and the RISAB either identifies the incident through review of industry intelligence (for example RISAS website feedback, RAIB reports, CIRAS, NIRs, etc.) or is advised from other sources.

1.3 Such alternative advice can come from the supplier's customers or RSSB's own monitoring of industry notifications (eg National incident log, ORR & HSE Enforcement Notices, EU Alerts etc).

- 1.4 In addition to the above, the RISAS Scheme Manager, Accreditation Agency, Suppliers and Customers are required to provide feedback regarding any serious issues related to RISAS certificated suppliers which may have wider industry implications, via the RISAS website, helpdesk or scheme manager.
- 1.5 In such matters, safety of the running railway should be of the utmost priority regardless of contractual or other issues.

## **2 Assessment of risk arising from out-of-course event**

- 2.1 The RISAB shall carry out an initial review of the information received to ensure the 'who', 'what', 'where', 'when', 'how' and, if known, the 'why' of the issue.
- 2.2 Where necessary the RISAB shall request further information to enable the issue to be more clearly understood.
- 2.3 It should be noted that the supplier should already have processes to review either type of out-of-course event described in paragraph 1.1 above and these processes will have already been assessed by the RISAB. There is therefore an expectation that the RISAB should see an output accordingly.
- 2.4 The RISAB shall review the information received and assess the risks to the efficacy of supplier's certification. The key decision to be made is 'can we continue to support the current approval in the light of this new information'?

## **3. Actions arising from the assessment of risk**

- 3.1 Where the outcome of the above assessment establishes that no further action is required the RISAB shall record its decision (referencing any relevant evidence / documentation in support of this decision) and advise the supplier accordingly. Other than ongoing monitoring (and consideration of paragraph 4.5 below), no further action should be required.
- 3.2 Where it is not possible to determine whether the efficacy of the current approval is compromised based on the supplied information alone, the RISAB shall then undertake additional assessment work of its own to fully establish the circumstances surrounding the out-of-course event – this might include a visit to the supplier's premises. This should be undertaken in a timely and efficient manner commensurate with the level of risk exposed.
- 3.3 Where this requires the co-operation of the supplier, then this shall be agreed with the supplier, including any commercial arrangements (RISABs are strongly advised to ensure that its contractual terms and conditions cover such events). Any failure to agree such additional assessment activities renders the supplier likely to have its approval suspended and to place the situation in dispute.
- 3.4 Additional assessment activities should be undertaken in a similar manner to a full assessment (ie a visit plan, checklists, etc) and recorded accordingly.
- 3.5 Any issues identified shall be raised as required actions and an action plan provided from the supplier in a similar manner as a normal assessment. Following the visit, the existing Executive Summary on the RISAS website shall be updated or renewed as necessary to record the assessment activity

#### **4. Monitoring or amending the Approval**

- 4.1 Where the efficacy of the current approval is potentially compromised, either directly arising from the supplier's information or as a result of the RISAB's additional assessment work, the RISAB shall determine whether the current approval can still be supported going forward.
- 4.2 Where the RISAB decides it cannot support the current approval then it shall amend, suspend or withdraw its certificate and advise the supplier accordingly. The supplier's right to appeal shall be highlighted.
- 4.3 Where the RISAB decides it can continue support the current approval (in spite of it being potentially compromised), then the RISAB shall decide the conditions for the approval going forward and advise the supplier accordingly.
- 4.4 Conditions can include placing limitations against one or more of the product groups and / or emphasising the completion of required improvement actions within defined timescales.
- 4.5 Where the out-of-course event is the result of a NIR being issued, then the instigator of the NIR should be encouraged to update the NIR information with the output from the above process (so that industry may be assured over the management of the issue by RISAS).

#### **5. Timescales and Communication**

- 5.1 Experience has shown that in the vast majority of cases, timely and appropriate action / communication greatly enhances the investigation process and the resulting assurance provided to industry.
- 5.2 The following timescales (relative to the date when intelligence was received or an out-of-course event was identified) are suggested for action to be taken and communicated:
  - Within five working days – RISAB to have established the facts surrounding the event and conducted an initial assimilation to determine the scale and impact of the event in terms of the efficacy of the current RISAS approval
  - Within ten working days – RISAB to have fully determined the scale / impact and made a decision as to what, if any out-of-course action needs to be taken to support the efficacy of the current RISAS approval (central 'decision diamond' on flowchart refers)
  - Within one month – RISAB to have undertaken any out-of-course action (including any additional site assessment) to establish whether the current RISAS approval can be maintained (possibly with conditions) (right-hand 'decision diamond' on flowchart refers)
  - Within two months – RISAB to provide interim update communication
  - Within three months – RISAB to confirm that any short term remedial action has been undertaken and longer term action plans established to address the out-of-course event / issue

## **6 Definitions**

- 6.1 The main definition of terms used in RISAS is contained in RISAS/001, Principles of RISAS.

**Contact:**

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BN-002 Process Flowchart

