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SUPPLIER QUALITY MANUAL

SUPPLIER QUALITY ENGINEERING

Departmental Business Manual

HRE-SQA-DBM-001 Issue 3.0

Author	
Head of UK Supplier Quality Control Andy Cole	05/11/2024
Reviewer	
Head of Maintenance Quality Control Keith Snell	05/11/2024
Reviewer	
Head of Manufacturing Quality Control Graeme Ketley	05/11/2024
Approver	
Quality Director Andy Radford	05/11/2024

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HRE-SQA-DBM-001 Issue 1.0	16-Oct-2017	First Issue of the SQA Manual	Lee Costello
HRE-SQA-DBM-001 Issue 2.0		Removal of 6M format	
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Distribution List

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Referenced Document

Document Reference	Document Title
HRE-PRC-PRO-0008	Supplier Selection Procedure
HRE-SQA-PRO-0004	UK Vehicles SQC – Supplier Performance Management
HRE-SQA-PRO-0005	Supplier Audit Procedure
HRE-SQA-PRO-0006	UK Vehicles SQC – Supplier Surveillance and Development Procedure
HRE-SQA-PRO-0007	UK Vehicles SQC – Part or Service Approval Procedure
HRE-SQA-PRO-0008	UK Vehicles SQC – Supplier Non Conformity Management Procedure

Appendices

Document Reference No.	Document Title
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Forms/ Records

Document Reference No.	Document Title	Location/ Retention Period
HRE-SQA-FOR-0001	FAI Form	Singlepoint then Teams site for archive
HRE-SQA-FOR-0013	Application for a Technical Query	Singlepoint
Safety Culture Templates	Safety Culture PPAP Templates	Safety Culture

Definitions

Terms	Definitions
Hitachi Rail	Hitachi Rail Limited

ISO/TS 22163:2017	International standard incorporating requirements of ISO9001:2015 with additional rail sector specific requirements for business management systems
IAF	International Accreditation Forum, which oversees the overall accreditation scheme for ISO 9001 and other management system certifications
On-site Audit	Organised audit on the site (manufacturing and / or strategic) of the supplier that is connected to Hitachi Rail's business
Audit	Scheduled, independent, impartial, documented, 2nd party assessment realised by qualified staff of Hitachi Rail, based on the TS22163, ISO9001 standards and requirements of this document
Surveillance	A visit to review the continued product validation
8D	Eight disciplined approach to problem solving. It establishes a permanent corrective action based on statistical analysis of the problem and on the origin of the problem by determining the root causes
5-Why	An interrogative technique used to explore the cause-and-effect relationships underlying a particular problem
SQE	Supplier Quality Engineer
SQA	Supplier Quality Assurance – responsible for Audits and Approvals
SQC	Supplier Quality Control – responsible for Product Validation and Non Conformity
APQP	Advanced Product Quality Planning – A structured method of defining and establishing the steps necessary to assure that a product satisfies the customer requirements
FMEA	Failure Mode Effects Analysis – An analytical methodology used to ensure that potential problems have been considered and addressed throughout the product and process development process
Control Plan	A document describing the actions required at each step in the production process to assure that all process outputs will be in a state of control. Through this system of monitoring and control, customer / design requirements will be met and the product or process variation will be reduced.
SPC	Statistical Process Control – Feedback system for continuous improvement of a manufacturing system to avoid the production of non-conforming product
FAI	First Article Inspection – Activity performed by the supplier in support of the part approval process
PPAP	Production Part Approval Process - Manufacturing inspection process that verifies a supplier's ability to consistently produce parts.
RVMF	Rail Vehicle Manufacturing Facility
TMC	Train Maintenance Centre
Verification	The process by which the quality of the assessment process and the systems and procedures which underpin it are independently assured
Safety Critical Material	A Safety Critical material is an individual piece of equipment, a control system or an individual protection device which in the event of a single point failure may

result in a hazardous situation which could lead to an accident or directly cause an accident that results in injury or fatality, or damage to the infrastructure

Contents

1 Introduction & Purpose

1.1 Purpose

The purpose of this Supplier Quality Manual is to

a) Set out clear requirements for the Supplier to be considered and to qualify for Hitachi Rail projects.

b) Set out the clear requirements for the Supplier to remain qualified for Hitachi Rail projects

c) To support supplier development and the continuous improvement of the supplier's business management system, emphasizing defect prevention and defect reduction in Hitachi Rail's supply chain.

1.2 Scope

This Supplier Quality manual shall apply to all parts, manufactured, assembled, serviced, overhauled and shipped by the supplier, to any Hitachi Rail sites.

This document specifies requirements for inclusion in the Supplier's system which enable the Supplier:
a) To demonstrate that at least the minimum requirements are achieved, in order to be selected.
b) To enhance Hitachi's satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
c) To record how the Supplier submits formal queries to Hitachi Rail

1.3 Policy

This Supplier Quality Manual is categorised as a Hitachi Rail policy and therefore all Suppliers are contractually bound to comply with the requirements set out below.

2 Requirements

2.1 Quality management system

QMS Requirements

All Suppliers shall have a quality management system, certified to ISO 9001:2015, which is issued by an IAF recognized registrar. As the globally recognised standard within the railway industry, Hitachi Rail also expects its Suppliers to work towards obtaining ISO/TS 22163:2017 certification within an agreeable timescale.
The scope of the requirement affects subassembly, sequencing, sorting, re-work and calibration services in addition to direct material suppliers.

Suppliers and sub-suppliers who are identified as special process providers are also required to adhere to the specific requirements, as set by Hitachi Rail. (See Section 3).

Suppliers of critical materials and services for the overhaul of assets and components for rail vehicles, may be required to comply with additional standards, regulatory requirements and approval schemes, appropriate for the country in which those vehicles operate. Such requirements will be specified by Hitachi Rail and notified to Suppliers as and when required.

Suppliers are responsible for maintaining and updating their certification status. Suppliers shall immediately communicate any change in certification or status to their allocated Category Manager and Supplier Quality Engineer (SQE).

In order to demonstrate the effectiveness of a quality management system, Suppliers should be able to demonstrate that the following internal processes, are in use within their organisation;

- Internal audit plan covering all areas of the business
- Comprehensive KPI's suite monitoring data from all relevant areas of the business
- Proven system for analysis of process and product data
- Regular, documented management review meetings with recorded actions and action plan
- Business and product risk management procedure
- Strategic risk management including business contingency plan
- Dedicated and focused management team who meet regularly to discuss and improve business and part quality
- Staff training and competency management
- Documented processes and demonstrable interaction with all staff
- Regular feedback on company performance to all levels of the business
- Performance data accessible to staff in process
- A business management team which reviews the QMS through regular meetings, feedback from staff and monitoring of KPI's
- Senior management shall appoint members of their team who, irrespective of other responsibilities, shall have responsibility and authority that includes:
    - Ensuring that processes needed to satisfy customer requirements are established, implemented and maintained
    - Reporting to senior management and Hitachi Rail on the performance of these processes and any need for improvement and

- Ensuring the promotion of awareness of customer satisfaction throughout the organisation and related training

Suppliers should appoint competent, qualified and dedicated Hitachi Rail representatives, as key contacts for support in the following areas;

- Problem solver as a quality representative in respect of quality concern notifications and provider of resolutions.
- Part approver for planning of activities, collection and presentation of part approval records.
- System improver for identification and implementation of continuous improvement activities, internal surveillance and improvement plans

Hitachi Rail must comply with all applicable laws, regulations and rules in the countries in which it operates. Hitachi Rail suppliers are therefore expected to and must comply with all applicable laws and regulations. These include the health and safety of workers, environmental protection, use of toxic and hazardous materials and free trade. Suppliers should recognize and comply with applicable laws and regulations in the country of manufacture as well the country receiving the products and the final country of sale. Hitachi Rail also expects its Suppliers to contribute to meeting any applicable Corporate and Social Responsibility (CSR) requirements.

Health, Safety and Environmental Protection

Our Suppliers shall be actively engaged with environmental concerns and establish and adhere to environmental management as per ISO 14001 or other equivalent standard. This does not release the Supplier from complying with all relevant national and international regulations.
Hitachi Rail promotes strong relationships with its Suppliers and the supply chain to minimize Health, Safety and Environmental (HS&E) risks and impacts and prevent business interruption and damage to our reputation. These relationships should also be used to reduce total costs by carefully considering all costs; direct and indirect, associated with the acquisition of goods and services.
HS&E performance shall be included in the criteria for the selection and continued use of Suppliers and must be assessed as part of the Supplier Quality Assurance (SQA) process. HS&E requirements should be considered similar to any other specification and Supplier's conformance to them documented accordingly. Hitachi Rail's HS&E criteria are described as follows:

1. Customer Requirements – Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Compliance

    a. Suppliers with chronic non-performance may be put on bid suspension and/or new business hold.

    b. Suppliers must submit REACH Unife substance declaration as part of the required Production Part Approval documentation.

2. International Standards - ISO 14001 Certification

    a. Suppliers shall demonstrate compliance through certification from a recognised accreditation body.

2.2 Supplier Audits

New suppliers who wish to be a supplier to Hitachi Rail shall:

1. Demonstrate compliance at a minimum to ISO9001:2015
   (New suppliers, who have not yet obtained rail acceptability certification ISO TS22163, may be awarded business on the condition, unless otherwise specified by a customer to Hitachi Rail, that they successfully pass the Supplier Audit and have an accepted plan to achieve rail acceptability certification).
2. Meet all commercial and financial requirements of Hitachi Rail
3. Complete and return the Supplier Assessment form (HRE-SQA-FOR-0003)
4. Successfully pass a Supplier Audit performed by Supplier Quality Assurance (SQA)

New locations for approved suppliers to Hitachi Rail shall:

1. Demonstrate compliance at a minimum to ISO9001:2015.
2. Complete and return the Supplier Assessment form (HRE-SQA-FOR-0003)
3. Successfully pass a Supplier Audit performed by Supplier Quality Assurance (SQA)

During supplier selection (iaw HRE-PRC-PRO-0008) and surveillance, Hitachi Rail will perform various audits (iaw HRE-SQA-PRO-0005) to confirm supplier capability beyond the certification level. Suppliers that initially do not score acceptably will be allowed to develop action plans and timelines to correct any deficiencies and then request a re-audit to verify implementation of these actions.

By prior notice, suppliers shall allow Hitachi Rail and its customers' access to both their facilities and their supplier's facility for the purpose of evaluating parts, processes, documents (i.e., FMEA, Control Plan, Instructions, records, etc.), methodologies and systems used in the manufacturing of products supplied.
Hitachi Rail may, at its discretion, use 3rd Party independent auditors. These individuals represent Hitachi Rail and will audit the supplier's processes to establish conformance to validated quality systems.

2.3 Project Management

Project Management Requirements

All suppliers, shall use a disciplined project management and launch process, appropriate to the level of risk and apply resource with an Advanced Product Quality Planning approach. Suppliers should provide status reports for new products, to ensure program objectives are met, including reporting on quality, cost, performance and timing. Suppliers to Hitachi Rail are responsible for managing their new product introduction process and participating in reviews with the Hitachi Rail Supplier Quality Engineer's and Category Manager.

Project management can involve comprehensive risk management using process flow charts, FMEA, control plans and SPC. Risk analysis should be communicated throughout the Supplier's project team with relevant actions. Risk analysis should be continually reviewed and updated throughout the project. Design reviews should be conducted regularly until the point of design freeze and all design development must be documented.

Customer requirements shall be cascaded to sub-suppliers using approved drawings. All project changes should be managed through change management processes.
Any delays against the project plan must be immediately communicated to the customer and escalated appropriately. Contingency planning should be in place to avoid disruption to customer in case of project deviation or non-conformity.

2.4 Sub-Supplier Management

Sub-Supplier management must be a function of the Supplier's business quality assurance organisation. There must be demonstration of evidence based decision making for sub-supplier selection. Strategic sub-supplier management should be based on audits, component approvals and NCR management. Sub-supplier performance must be monitored through established metrics, with regular feedback to sub-suppliers on quality performance.
Evidence of sub-supplier component approval is required for all sub-tier components and must include a material certification. In addition to this certificate, any sub-tier component that influences a characteristic specified on Hitachi Rail drawings must also include an approved part approval in line with the suppliers' internal processes.
A system for guaranteeing the conformity of incoming parts must be agreed with sub-supplier.
The Supplier shall prevent the purchase of counterfeit parts and parts from unapproved sources, prevent the delivery of counterfeit parts to Hitachi Rail and control parts identified as counterfeit or suspected to be counterfeit. Any occurrences shall be investigated, documented and reported as appropriate.
Where customer NCR's are deemed to be a sub-suppliers liability, Suppliers are expected to manage concerns with sub-suppliers in the same way that customer concerns are managed between the Supplier and Hitachi Rail.

2.5 Product Assurance

Process Controls

Suppliers should implement process controls for characteristics deemed to be 'predictors of process stability and feedback' and these should be identified in the Supplier's Control Plan. These features may relate to product safety, product performance, the ability to assemble product and/or customer satisfaction.
For any special characteristics designated on design drawings, the Supplier shall apply appropriate process controls, to ensure on-going conformance is maintained. In areas where statistical process control is implemented, the Supplier shall create an action plan that defines the containment and process improvements, for any special characteristics out of control. Hitachi Rail may evaluate the capability of all special characteristics and the validity of studies. In order to ensure this, capability reports should include a histogram, control charts and a normality test.

Part Approvals

Suppliers shall ensure that part approval documentation and sample submissions meet the requirements defined by Hitachi Rail. Suppliers shall only submit part approval packages for approved drawings and copies of these drawings shall be included in the submission package. Each Supplier is responsible for meeting all these requirements before submitting the part approval package to Hitachi Rail, including obtaining Hitachi Rail approvals for any change requests.
Suppliers will be requested to submit the part approval package in an electronic format by a Hitachi Rail quality representative iaw HRE-SQA-PRO-0007.

HS2 PPAP
HS2 Product is to follow Production Part Approval Process (PPAP). A part approval submission checklist is available and is to be used to assure the submission meets Hitachi Rail's expectations. Evidence of customer part approval will be provided to the Supplier, by issue of a signed PPAP checklist.

FAI
Hitachi Rail may require Suppliers to submit additional documents and forms beyond those required by FAI. In addition, the Supplier is responsible for all sub-tier submissions and approvals, including those suppliers Hitachi Rail has directed a Supplier to use. A part approval submission checklist is available and is to be used to assure the submission meets Hitachi Rail's expectations. Evidence of customer part approval will be provided to the Supplier, by issue of a signed FAI review form, (HRE-SQA-FOR-0001).

Part Identification and Traceability

Part Identification are appropriate markings applied to each individual product, wherever possible, permanently and in a suitable position for reading (markings, punch marks, tags, adhesive tags, stickers, etc.) to recognize the type and version of the various products during the production process.

Part Traceability is defined as an adequate system that allows each product and associated documentation to be distinguished and recognized from other identical products which are produced separately and in different conditions and time.
The Supplier will identify all materials and components during the whole production cycle and will ensure traceability is achieved.

Upon delivery to Hitachi Rail, all products shall be able to be identified and tracked using by way of example: marking, stamping, decals, adhesive tags. The following data must be contained in text and barcode formats:

SUPPLIER'S COMPANY NAME
NUMBER/REFERENCE TO HITACHI RAIL ORDER and relative revision
HITACHI RAIL CONTRACT
HITACHI RAIL Part Number (P/N) and relevant revision index
NUMBER OF THE LOT, or MANUFACTURING DATE (where applicable) and Serial Number
DESCRIPTION OF THE COMPONENT

Specific part labelling requirements may be issued by the Hitachi Rail receiving site, to ensure that all supplier deliveries comply with inbound supply policies.

Producers of a material that is subject to expiration will identify a suitable system for recording parameters (e.g. Temperature / humidity) in order to guarantee the material remains valid, throughout the entire supply chain, and therefore from its site to the delivery site in Hitachi Rail. The parameters to guarantee validity will be the same units reported in the Product Data Sheet, written and conceived by the supplier.

2.6 Inspection, Testing and Warranty

It is important that error proofing and visual aids are employed to ensure the correct material is used during serial production. Guidelines should be applied during the APQP process to establish proper controls in the process. It is the Supplier's responsibility to ensure ongoing adherence and control during production.

- Inspection and test parameters may be defined by customer requirements, using approved drawings and specifications; this must be evidenced in the Control Plan.
- Responsibility and authority for inspection and testing should be defined within the Control Plan.
- Batch sizes for inspection and testing must be established within the QMS and adhered to on all projects.
- Systematic testing and inspection must be conducted throughout each project with concise reports completed for each activity.
- Up to date approved test procedures should be available at the appropriate workstations.
- Results from inspection activities must be traceable to an individual part or batch.

The recorded inspection data should be used to analyse trends in production performance. The Supplier should be able to use data to anticipate failures before they occur.
Where applicable, specific inspection and non-destructive testing (NDT) must be performed in accordance with the standards and controls prescribed within requirements for control of special processes, (See section 3). The Supplier is responsible for ensuring the supplied product meets the requirements specified by Hitachi Rail and/or regulations and standards applicable within the country of operation.

Within any applicable warranty period there must be a commitment from Supplier to provide spare parts and qualified service staff, at the fastest possible lead time in event of failure. The Supplier should be committed to providing onsite support and spare parts where required. The Supplier should have qualified personnel on staff with established procedures in place to meet the customers warranty requirements.

2.7 Control of Non-conforming Product

Supplier identified non-conforming product

Suppliers are required to use competent quality personnel to implement sufficient controls which identify non-conforming product and prevent further processing or delivery to its customer. Scrap material and rejected product must be clearly identified and segregated from serial production. There shall be a formal system to determine the disposition of rejected material.
Rework processes should be documented and authorisation obtained from Hitachi Rail before conducting repairs or rework which is outside of the standard manufacturing process.
The amount of non-conforming material and product should be recorded and monitored within the Suppliers KPI's.

In case of defect escape, the Supplier shall immediately notify all impacted Hitachi Rail sites upon discovery that they might have shipped nonconforming or suspect product to Hitachi Rail. Notification shall go to the Supplier Quality Manager and the Materials Manager, or in their absence, the Category Manager within Hitachi Rail. The Suppliers shall notify all Hitachi Rail facilities receiving the same or similar affected product, within 24 hours.

Hitachi Rail identified supplier non-conforming product

law HRE-SQA-PRO-0008, Hitachi Rail will notify Supplier of Non-Conforming product through release of Quality Notification/Fault Notices. Suppliers are required to adhere to Fault Notices requirements listed below:

Rank 1 – Very High

1hr – Please provide email confirmation of acceptance of QN/FN with details of what actions have been taken to prevent the delivery of further reject parts into Hitachi Rail.

Max 24hrs – Read across to similar parts explored with initial analysis for escape understood (non-detection) and adequate temporary countermeasures introduced.

Max 7 days – according to the contract, see warranty conditions, the rectification works (containment actions) shall be carried out.

In 7 days completed 8D Report with closed short term corrective actions and proposed long term corrective actions.

For each discipline objective proofs shall be provided.

Rank 2 – High

12hr – Please provide email confirmation of acceptance of QN/FN with details of what actions have been taken to prevent the delivery of further reject parts into Hitachi Rail.

Max 24hrs – Read across to similar parts explored with initial analysis for escape understood (non-detection) and adequate temporary countermeasures introduced.

Max 7 days – according to the contract, see warranty conditions, the rectification works (containment actions) shall be carried out.

In 30 days completed 8D Report with closed short term corrective actions and proposed long term corrective actions.

For each discipline objective proofs shall be provided.

Rank 3 – Medium

24h – email confirmation of acceptance of QN/FN with details of what actions have been taken to prevent the delivery of further reject parts into Hitachi Rail

Max 7 days – Read across to similar parts explored with initial analysis for escape understood (non-detection) & adequate temporary countermeasures introduced.

Max 7 days – according to the contract, see warranty conditions, the rectification works (containment actions) shall be carried out.

In 30 days completed 8D Report with closed short term corrective actions and proposed long term corrective actions.

For each discipline objective proofs shall be provided.

Rank 4 – Low

7 days – email confirmation of acceptance of QN/FN with details of what actions have been taken to prevent the delivery of further reject parts into Hitachi Rail

Max 7 days – Read across to similar parts explored with initial analysis for escape understood (non-detection) and adequate temporary countermeasures introduced.

Max 7 days – according to the contract, see warranty conditions, the rectification works (containment actions) shall be carried out.

In 30 days completed 8D Report with closed short term corrective actions and proposed long term corrective actions.

For each discipline objective proofs shall be provided.

2.8 Supplier Change Management

Suppler Change Requests

The Supplier who, for any reason, feels it necessary to propose changes to the approved product or manufacturing process, can propose a "change request" to Hitachi Rail.
Suppliers shall submit a written request to all Hitachi sites affected by the proposed product or process change. In addition, Suppliers shall ensure they receive an acknowledgement of receipt from Hitachi Rail and obtain Hitachi Rail approval prior to implementing the change. This includes changes at sub-suppliers throughout the supply chain. Additionally, suppliers are also required to submit all supporting validation data including necessary dimensional reports, capability studies, performance testing, before/after process parameters, updated documentation (PFMEA/Control Plan), indications on safety aspects, environmental impact and RAM parameters and a detailed timeline demonstrating proper change control, that identifies necessary safety stock/bank requirements, including timing for Customer validation timing and designated resources to manage the change. Changes shall not be implemented prior to the receipt of written approval from Hitachi Rail. Verbal requests will not be accepted.
The Supplier's internal change management process shall include the requirement to notify the customer and obtain approval before implementing a product or process related change.
Supplier personnel responsible for communication of product or process related changes must be identified and authorised to act on behalf of the Supplier. Change management activities should be managed by dedicated personnel, within a Change Review Board (CRB)/Change Control Board (CCB).

Authorisation to ship production material shall be given after the change is communicated, through a signed part approval package. For HS2 this would be a signed Part Submission Warrant as part of a PPAP checklist. For other projects this would be an FAI review form (HRE-SQA-FOR-0001). Once Hitachi Rail has approved the part approval package, for the requested change, that change is co-ordinated through the Hitachi Rail facility or facilities.

Supplier Concession

Suppliers shall request, in writing, a deviation (or concession) before shipping any non-conforming material to Hitachi Rail. The concession should be supported with a report identifying root cause and corrective actions for the deviation. Material shipped under an approved deviation shall be labelled with the deviation number and its expiration date.

2.9 Customer Concern Management

Hitachi Rail has the right to reject non-compliant products or to request correction by repair or rework. The supplied products found non-compliant will be returned to the Supplier or, where possible, will be repaired or reworked by the Supplier itself, at their own expense. Any rejected products shall not be submitted to Hitachi Rail again. The Supplier shall have a system established to evaluate returned parts, from their customers.

If Hitachi Rail believes that a defect may have occurred with respect to any products supplied by the Supplier, the supplier shall, if requested by Hitachi Rail, ensure that an appropriately qualified engineer arrives at the place at which such products are located within five (5) days after a request from Hitachi Rail. The Engineer shall remain at such place for such period as is agreed by Hitachi Rail, to investigate the defect and to carry out the rectification of that defect.

Any non-conformity found by Hitachi Rail at its site during incoming material inspection, during installation or testing of the material supplied, will be notified by Hitachi Rail through Non Conformity Reports (NCRs) or Quality Notifications (QNs). To this end, upon receiving this type of notification, the supplier accepts to consider the NCR/QN as acknowledged and accepted upon its receipt. The Supplier shall promptly send to Hitachi Rail, for acceptance, its proposal for solution.

Upon receiving a Hitachi Rail concern for a quality, launch or delivery issue or non-conformance, suppliers shall implement an immediate containment action. The supplier shall have a system to implement 100% sorting activity as a containment action and should ensure that sorting activities are maintained until permanent corrective actions are implemented and verified. Concerns can be raised at differing levels reflecting the severity of the issue. Standard response targets will be specified upon issue of a non-conformance, but the initiator of the concern can establish other target dates, if needed. Within the time specified, the supplier shall submit a corrective action plan or a reasonable approach to developing one in case of complex issues.

Customer quality management should be performed by competent quality engineers. Suppliers shall use a systematic problem solving method such as 8D, fishbone diagram, 5-WHY, etc., for documenting an investigation. This analysis should consider the 3 root causes of the issue, the technical root cause, the detection system root cause and the root cause of the quality system.

Upon receiving a Hitachi Rail concern for quality, launch or delivery, Suppliers shall have a well-defined procedure with time frames for corrective actions and responses, with concerns managed by a formal approval, closure and tracking process. A dedicated customer concern management database should be used for administrative purposes.
Suppliers shall have a process for communicating responses to Hitachi Rail, obtaining and tracking approvals for formal closure of NCR's. Customer concern status should be included within a Suppliers monthly management review.

Suppliers are responsible for all costs and expenses created as a result of any defect on the material supplied and/or late delivery and Hitachi Rail may recover these costs from the responsible supplier.

2.10 Continuous Improvement

Hitachi Rail defines supplier continuous improvement as a holistic approach to overall quality management system improvement. Suppliers should develop plans which improve internal systems that support the flawless launch of new products/components/sub-systems, value enhancements and cost competitiveness and achievement of agreed quality targets, along with a plan to reduce defects in support of on-going operational excellence. This plan should include lessons learned from previous launch, cost and quality issues and how these lessons have been incorporated into respective continuous improvement processes (i.e., read across matrix). Suppliers should also be prepared to discuss their intent to maintain or achieve strategic status including a plan to 'grow' with Hitachi Rail globally. Hitachi Rail will carry out regular surveillance visits iaw HRE-SQA-PRO-0006.

The Supplier should also continually improve the effectiveness of the quality management systems through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews.

3 Special Processes

3.1 Definition

The term Special Process means a process the results of which cannot be completely ascertained by successive controls, inspections or tests on the product and the deficiencies of which can be disclosed only when the product is used. Hitachi Rail considers all those processes to which the definition above, can be applied as Special Processes.

3.2 Audit

Where applicable, Suppliers will be required to ensure conformity of each special process, used in the manufacture of its product. This shall be demonstrated by quality audit conducted by Hitachi Rail or directed 3rd party to verify that proper documentation exists for full implementation of process qualification, process specification and personnel qualification. Suppliers are expected to conduct surveillance on special processes as part of an internal audit plan, with a minimum frequency of 12 months.

3.3 Specific Requirements

Specific requirements for certain Special Process will be provided by Hitachi Rail, as required. This includes but is not restricted to the following;

- Bonding & Sealing
- Casting
- Crimping
- Force Fitting or Shrink Fitting
- Forging
- Heat Treatment
- Laminating (Composites)
- Moulding
- Potting (e.g. Electronics)
- Riveting
- Stress Relief Treatment
- Surface Treatment (Painting, coating, chemical, electro-chemical treatment)
- Torque Tightening/Bolt Tensioning (for Preload application)
- Welding (Including Soldering and Brazing)
- 3D Printing