

1) a) When a failure is happened at leak test in a thermal battery, first raise a non-conformance with all information like, where did it happened, what is the actual value, observed value, describe the issue.

42
74

→ "Clause 8.7" Control of Nonconforming outputs will come in this case.

b) → Conduct a NC meetings, by forming a group containing a personnel from each department (production, Quality, D&D, process)

→ Review the NC, Note the reasons for failure.

→ Note the corrective actions to be done based on the reason for failure

→ If required, the Tig welding (WI) (WI-PRD-09), needs to be changed by following control of change procedure.

c) → NC can be raised by any personnel when an Non-conforming output is identified. (In this case QA will raise)

→ NC meeting to be conducted by NC Coordinator

→ Corrective actions needs to be followed by production, process will look over the parameters that are changed.

→ Verification of corrective action is done by QA, after successful Verification, the WI gets updated by following control of change procedure.

→ Determining if similar non conformities exist, or could potentially occur.

2)

a) Counterfeit Part :-

An unauthorized copy, imitation, substitute (or) modified part (e.g., material part, component), which is knowingly misrepresented as a specific genuine part of an original (or) authorized manufacturer.

- "Clause 8.1.4" need to be followed to prevent counterfeit.
- The effect of the counterfeit part on production may lead to

less performance.

→ purchase, QC (Inward) is responsible to the counterfeit.

→ Actions to be taken to prevent counterfeit :-

1) Training of appropriate persons in the awareness and prevention of counterfeit parts.

2) Verification and test methodologies to detect counterfeit parts.

3) Quarantine and reporting of suspect (or) detected counterfeit parts.

4) Monitoring of counterfeit parts reporting from external sources.

5) Organisation should consider requirements for assuring traceability of parts and components to their original (or) authorized manufacturers.

b) purchase needs to report the suspected / detected counterfeit part to the supplier.

→ QC needs to train appropriate persons to prevent counterfeit parts.

→ QC needs to quarantine the counterfeit part.

→ Organisation shall plan, implement and control processes, appropriate to the organization and the product, for the prevention of counterfeit part used and their inclusion in product(s) delivered to the customers.

→ purchase department should identify a vendor of a product which is required.

→ They need to assess the vendor, whether they are able to meet our requirements.

→ If met, then they need to add vendor into their list.

c) Management has to review if counterfeit parts are discovered that have been used in the product i.e. delivered to customers.

② → If possible the management has to recall the delivered goods from the customer immediately.

→ When problems are detected after delivery, the organisation shall take appropriate action including investigation and reporting.

g)

a) Incorporating into QMS :-

→ Update the regulatory compliance, revise the purchase/procurement policies, conduct audits internally.

b) → Issue the change notice to the customer and the alteration to the supplier agreement.

→ Update the compliance reports.

c)

→ Revise the supplier qualification criteria needs to be done by purchase.

QC needs to update the material inspection reports.

→ Issue the change request for the material change if applicable.

→ Implement into the QMS.

4)
a) On a customer complaint on failure of a thermal battery, the Quality, Business development team record a complaint, investigate the issue.

② → perform root cause analysis by raising a non conformity, corrective actions to be taken at the earliest.

b) Identify failure mode, assess risks related to regulatory & financial, initiate through the process improvements

c) To prevent recurrence, improve the testing / samples required for testing

① → Training to the employees

→ Modifications to the design of the product

→ Control on the material supplied by external provider

d) "clause 10.2" Non conformity and corrective action is applicable

→ react to the non conformity and take an action to control & correct it.

② → deal with consequences

→ determining if similar non conformities exist (or) could potentially occur.

Documents need to be made: NC document, RCCA, Corrective action, update w2's

5)

a) purchase, planning are responsible departments to address the issue, if a key supplier for critical materials faces a shortage ✓

b) → Supplier Qualifying ÷ Auditing the supplier, compliance with specification (or) not, reviewing the certification of the supplier. ✓

→ Testing the material i.e. provided by the supplier.

→ Analysis to be done if it is either chemical component ✓

(or) a mechanical component.

(5) → Compliance with regulatory and industry requirements

→ Approval of the product as per spec by QA (or) other departments if applicable.

→ Having an additional supplier in spare, if the previous vendor is unable to provide the material which is critical.

→ Add the supplier/vendor to the approved list, attach the material test reports, compliance certificate.

→ "Clause 8.4" Control of Externally provided processes products & services. ✓

→ Organisation shall require that external providers apply appropriate controls to the direct and sub-tier external providers to ensure that requirements are met.

6)

a) Quality department should handle non conforming materials.

→ Quarantine the defective batch to prevent it from entering production.

→ Conduct a root cause analysis

→ Compare material properties

2 → check inventory whether an alternate batch is available

→ coordinate with the supplier for batch replacement.

b)

→ Review the inspection records of previous batches

2 → check the supplier lot numbers and test reports for consistency

→ Conduct chemical analysis & testing

c)

→ Implement the regular supplier audits.

1 → Ask for detailed material certificate before the shipment only.

→ Increase sample testing frequency during inward inspection.

7)

a) A key material used in thermal battery manufacturing is being phased out by the supplier.

1) → Identifying alternate materials (or) components

→ Talk with the suppliers/ industry experts to identify the substitute material.

b) → Conduct analysis on the material properties

2) → Review for the compliance with industry & regulatory standards.

→ Conduct test on the sample material to assess the performance.

c) → Give information to customer about material change

3) → Share the technical details, test result

→ Maintain a proper communication channel b/w the customer & organisation.

d) → Conduct FMEA to assess risks

4) → Verify the reliability of the material & its performance

→ Establish another plan if the alternate material fails.

→ Ensure statutory / regulatory requirements are met.

Choose the correct answers

1) a ✓

2) e ✓

3) c ✓

4) a ✓

(4)