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56/74 ①

1) There is a Failure in leak test in thermal battery.

a) So, what action should be taken and what documents are made according to the AS 9100 D for stopping the non-conformance which Clause of AS 9100 D will come in this case.

1 Containment Action (Clause 8.7)

Ans: · Immediate Responce.

· Stop future processing of the affected batch.

· Inform relevant Personal - Including Quality team and Engineering team.

2. Non conformity and Corrective Action. (Clause: 10.2)

- Investigate the root Cause of the leak test failure
- Implement Corrective actions to prevent recurence.
- maintain documented evidence of corrective action.

3. Control of externaly provided process. (Clause 8.4)

4. Validation and Control of special process. (Clause: 8.5.1.2)

Document:

a) Non conformance Report.

b) Corrective action Report

c) Updated work Instructions.

b) Total sequence of steps to be undertaken and what work Instuctions / procedures are covered.

1. Detection & Reporting of Leak Failure (8.7)

- Identify and record the Leak Test Failure
- Isolate the affected batch.

2. Immediate Containment Action.
3. Root Cause Analysis and Investigation. (10.2)
4. Corredive and preventative action Implementation.
5. Review and Validation of Leak Testing proceer.
6. Final approval and closure.

Work Instruction and procedures Coverd:

a) Lids Timing / Soldering.
b) ~~Lids~~ & Battery welding
c) Battery Leakchecking.

C) who is responsible for each step:

	Responsible	Step.
1)	QC	Leak Test Failure detected
2)	QA	NCR
3)	production	Seregation of defective products
4)	Quality Engineer	Root Cause Analysis
5)	Quality Team	Corrective Action Implemation
6)	procurement	Supplier Communication

2) Effects of Counterfit on production and which Clause as per AS 9100D need to be followed to prevent Counterfiet.

* Effects of Counterfeit parts on production:

production Can have serious Consequence, Including.

a) product Failure and safety RisKS.

b) Regularity and Legal Issue.

c) Reputation Damages.

d) production delays.

* Clause AS 9100D.

- Clause 8.1.4 – prevention of Counterfiet parts.
- Clause 8.4.2 – Control of Externelly provided products and servies.
- Clause 8.7 – Control of Non conforming outputs.
- Clause 10.2 – Non Conformity and correlive Action.

9)

* prevent Counterfeit parts:

a) Supplier verfication and Selection.

b) Incomming Inspection and Authentication.

c) Tranning and Awarenss.

d) Tracability and DOcumention Control.

* Responsible Department and Action for counterfiet prevention.

Department	Responsibility.
purchase	approved suppliers. Certificates of Conformity.
Qc	Verified and approved.
production	Defines Critical components requesting Stringent verifications to avoid Counterfit risks.
design.	

b) What is the role of purchase, Qc and any other department?

Department	Role in Counterfit prevention
1) purchase –	Source components from approved vendors, ensures proper documentions, and performs supplier back back ground checks.
2) Quality –	Conducts Incoming Inspection, verifies materials authenticity and reports Counterfit Susicoins.
3 production –	Uses only approved, Inspection parts during assembly.
4. Engineering Team –	Specifies Critical parts needing additional verification and suggeststs.

C) what are the steps to be taken if counterfit parts are discovered to have been used after delivery of the product. (3)
which work Instruction | procedure are Coverd.

* After product delivery Counterfit parts :
  - Inform to Customer and Correct the issue.
  - Immediate Containment and Investigation (8.7 and 10.2)
  - Customer Notification and Recall process (8.4.2 and 8.7)
  - Corrective action (10.2)
  - Supplier Investigation and Blacklist (8.4)
  - Internal process Review and Improvement (8.1.4)

* work Instruction and procedure covered.
  - Supplier Approval process (sop)-
  - Non Conformining material hadling procedure.
  - Receiving Inspection procedure.
  - Customer Communication and Recall SOP.
  - Root cause Analysis and Corrective action.
  - Supplier Blacklist and monitoring SOP.

3) A new environmental regulation impacts the use of specific Chemicals in your batteries.

A Change in Environmental regulations affecting the use of Specific Chemicals in the thermal batteries.

a) How do you incorporate this into your (QMS)?

Clause 4.1 - Understanding the Orgnization and context. (Process material)

Clause 6.1 - Actions to Address Risks and opportunits. (FMEA)

Clause 8.3 - Design and Development (material Selection).

Clause 8.4 - Contool of Externally provided process and Services

Clause 8.5.6 - Contool of changes

Clause 7.2 and 7.3 - Compentence and Awareness

Clause 10.2 - Non Conformity and corrective action.

b) How do you Communicate these changes to your Customers and Supplier?

To Customer:

a) via Formal Communication email, letter or Contractual amendment
b) material Safety data sheet.
c) design alternatives.

To supplier:

a) Engineering Change Notes, Specifying the banded Chemical
b) Supplier Contracts to include new environment Compliance Clause.
c) Supplr audit.

4) Customer Complaint About a Thermal Battery Failure.

A structured Investigation, risk assessment, Corrective action and preventive measures must be Implemented to ensure Compliance with.

a) Responsible department to address the Complaint and sequence of steps to be taken.

Responsibility	Department.
- Analyze design-related failure	Engineering and R&D.
- Check - process deviations	production - manufacturing.
- Investigative Supplier-related defects	Purchase
- Receive and log the complaint, Inilative Investigation.	Quality.

b) How would you analyse and address this complaint while Considering risk to your organization ?

1. Production Risks - If Failure is widespred. It may halt production. leading to Financials losses.
2. Safety Risks - If failure leads to safety hazards. Issue a recall If necessary.
3. Reputation Damages - Ahigh Failure rate effetites Customer trust.

c) what Changes would you Implement to prevent recurrence ?

- Modify materials sections and battery Chemistry if needed.
- Improve assembly techniques, leak test or welding, assembly.
- Supplier audits, testing outside, and materials traceability.

c)

– Additional functions and stress testing.

d) which Clause of AS 9100 D is applicable. what are necessary documents need to be made?

Clause – 8.7 – Control of non Conforming outputs.

Clause – 10.2 – Non Conformity and Corrective action.

Clause – 8.5.1 – Control of production and Service provision

Clause – 8.3 – Design and Development Changes.

5) a) If a key Supplier for Critical materials faces a shortage, responsible departments to address the issue?

Department	Responsibility.
* purchase –	Identifies alternate suppliers, Negotiates contracts.
* Quality –	Ensures Incoming materials inspection and Compliance.
* Engineering R&D –	Assesses materials alternatives for Compatability.

b) How do you evalute alternate Suppliers while maintaining Compliance with Customer and regulatory requirments? Explain each step in sequence. which Clause of As 9100D is applicable?

– To ensure that alternative Supplier meet regulatory and Customer requirments. and Supplier evalution.

Step.	Action	Department:
1. Identify and List alternative supplies	- approve dvendor - he have Infastrutture.	purchase.
2. preliminary Screening	- Check Certifications of IS 9001-2017 (or) AS 9100D	purchase.
3. Risk Assesment	- Quality, cost, delivery Compliance issues	purchase.
4. Sample Testing & Validation	Test material for mechanical Chemicals and durability properties	QC

Relevant AS 9100D Clauses

1. 8.4 – Control of Externaly provided process
2. 8.1 – Operational planning and Control.
3. 8.5.6 – Control of Changes
4. 10.2 – Non Conformity and corrective action.
5. 7.1.5 – monitoring and measuring

6) Material Defects Identified during Inspection (6)

A batch of raw material eg lithium. Ca, Sodium alloy) used in Thermal batteries fails incoming inspection duels a deviation in Chemical Composition Qns.

a) Responsible department to handle non conforming materials in this situation ?

Department	Responsibility.
1. Quality Control (QC)	Detect and segregate defective materials.
2. purchase	Coordinate with supplier for replacement
3. Design.	Impact on product design and performance.
4. production	Determine if production delays needed.

b) How do you verify whether similar materials from the supplier has been used in previous batches ?

1. Check Incoming material Inspection Report.
2. Retrieve material Batch Records.
3. Review Finished goods.
4. Verify Supplier Certificate of Conformance.
5. Conduct random retesting of old batches.
6. Inform customer If needed.

c) what preventive measure would you Implement to avoid resaurence (Supplier audits, additional tests)? explain all the above AS9100D standard clauses.

1. Strength Supplier Audits and Qualifications.
2. Implement Advanced Incoming Inspection.
3. Improve Tranceability and Batch Segregation
4. Require materials Certification and Testing from Suppliers.

(2)

Clauses:

1) 8.4.2 - Supplier Control and selection
2) 8.4.3 - Supplier performance monitary
3) 8.6 - Verification of purchased products
4) 7.1.5 - measured and monitoring
5) 8.5.2 - Identification and traceability.
6) 8.4.2 - Supplier Control and Evaluation.

7) A key material used in thermal battery manufacturing is being phased out by the supplier. (7)

a) How do you Identify alternative Components or materials?

1. Conduct market Research
2. Review material specifications
3. Check Regulatory Compliance
4. Verify Supplier Certification
5. Perform Initial risk assesment

(2)

b) What steps would you take to Validate the alternative's Compatability with existing designs?

1. material Testing and Lab analysis.
2. Prototype manufacturing.
3. Functional Testing.
4. Relibility.
5. Customer and regulatory approval.

(3)

c)

SECtion – B

1, a ✓

2, e ✓

3, c ✓

4) e ✓

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