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38

Answers

1) a) If a Thermal Battery is ~~failed~~ in leak Test. it is a Non-conforming product, and AS 9100D ~~with some~~ requires the organization to take corrective action and preventive action.

The Relevant AS9100D Clauses applicable in this case are:

1. clause 8.7 – control of Non conforming outputs
2. clause 10.2 – Non conformity and corrective Action
3. clause 8.5.1.2 – validation and control of special process
4. clause 8.4 – control of Externally provided process, Product and services

~~The~~ The Required Documents is

1. Non-conformance Report (NCR)
2. corrective Action Report
3. Supplier Deviation Request
4. updated WI and process control Documents

b) The sequence of steps and WI / procedures

1. Detection and Reporting of Leak Failure
2. Immediate containment Action
3. RCA and Investigation
4. corrective and preventive action Implementation
5. Review and validation of Leak Testing Process
6. Final Approval and ~~closure~~ ~~close~~ closure

WI and procedures covered:

* Leak Test procedure Document
* WI for Rework or scrap.
* Material Review Board.
* Non-conformance Management
* Root cause Analysis and corrective Action.

c) Responsibility of Each step

Step	Responsible person / Team
* Leak test failure detected	QC Inspector
* Non-conformance Document	QA Team
* segregation of Defective products	production supervisor
* Root cause Analysis (RCA)	quality Engineer & process Engineer
* Corrective Action Implement-ation	Manufacturing & quality Team
* Review of process changes	Engineering & QM
* supplier communication	procurement & supplier quality
* MRB approval for disposition	MRB Members
* Updating WI	process Engineering Team
* Training on revised procedures	Training & quality Team
* closure & final approval	quality Manager & production Head

2) Counterfeit parts can lead to

* Product failure and safety risks
* Increased rework and scrap
* Delays in production schedules.
* Damage to the organization's reputation.
* Increased costs due to recalls and replacements.
* Legal Liabilities

The clause for counterfeit part as per As9100D is 8.1.4

a) * If a counterfeit part is found, the following deparments are responsible.

* Procurement / Purchasing: Responsible for supplier selection and verification.
* QC / Inspection: Responsible for incoming inspection and verification of parts
* Engineering: Responsible for defining part requirements and specification.
* Material Management: Responsible for proper storage and Handling.

Actions to prevent counterfeit

* Implement a robust counterfeit parts prevention plan.
* purchase parts from authorized distributors
* verify supplir credentials and Traceability
* conduct thorough incoming inspections
* Maintain detailed records of part traceability
* provide Training to personnel on CP awareness.

b) Roles of purchase department

* Select and evaluate suppliers based on their abailitys
* Maintain suppliers lists
* Negotiate contracts that address counterfeit part prevention
* Ensure PO include clear requirements for traceability and authentication.

Role of QC

* Develop and implement Inspection process to detect counterfeit parts
* utilize appropriate inspection equipment and Techniques
* Maintain Records of Inspection results
* Isolate and quarantine suspected counterfeit parts

Role of ~~Logistics~~ Material Management

* Ensure proper ~~sto~~ storage and Handling of Parts to maintain Traceability
* control access to Inventory

c) Steps:

* Immediately notify the customer and relevant authorities
* conduct a thorough investigation to determine the extent of problem
* Implement CA and PA (write full forms)
* Provide replacement parts of products as necessary
* Maintain detailed ~~Rec~~ds of the incident and CA

3) A change in new environmental regulation impacts the use of specific chemicals in ~~your~~ Thermal Battelies must be integrated into the quality Management system (QMS)

a) Incorporating into QMS

Identify & Assess:

* Analyze the regulation, determine its impact on your Product and processes
* update risk assessments to reflect potential non-compliance risks

update documentation:

* revise relevant specification and your regulatory compliance matrix
* Integrate the regulation into your QMS.

b) communication

Suppliers:

Inform suppliers of the regulation, request compliance documentation and update supplier agreements

customer

Notify customers of product/process changes, provide updated specifications and address concerns

c) Steps, Responsibilities and Documents

* steps

1. Regulatory Analysis
2. Impact Assessment
3. Material/process change
4. Documentation update
5. Supplier/customer communication
6. Training
7. Implementation/Monitoring
8. Internal audit

Responsibilities

1) TOP Management
2) Environmental / Legal
3) Engineering
4) Procurement
5) Production
6) Quality
7) Sales

Documents

1) Regulatory compliance matrix
2) Risk assessments
3) Revised specifications / procedures
4) customer notifications
5) Training records
6) Internal audit reports
7) MSDS for new materials

4 a) Responsible department:

The primary responsible department is typically Quality Assurance / Quality control, working closely with Engineering, production and customer service.

Sequence of steps

1. Complaint Reception and documentation
2. Initial Assessment and containment
3. Failure Analysis
4. Corrective Action planning
5. Implementation of corrective Action
6. Verification of Effectiveness

(3)

b) Analysis:

1. conduct a detailed root cause Analysis (RCA) using tools like 5 whys, Fishbone diagram etc.
2. Analyze manufacturing records, inspection data and test results
3. Evaluate the battery's design, materials and manufacturing processes
4. Consider Environmental factors and usage conditions

(3)

Risk consideration

1. Safety Risk
2. Financial Risk
3. Reputational Risks
4. Production Risk
5. Regulatory Risk

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c) changes to prevent recurrance

* Strengthen incoming material Inspection
* Enhance process controls and monitoring
* update manufacturing procedures and WI

2

2) Applicable clauses is 8.7, 8.5.1, 8.3, 8.4, 8.5.2, 8.5.6, 10.2 and 9.1.2

Necessary documents

1. Customer complaint form
2. Failure analysis report
3. RCA Report
4. Training records

Choose the correct Answers

1) a
2) e
3) e
4) e

4