To: Beloved Dr. Krishat Kumar Sir

TKES

Ch. Mohit Syam Sai
1655.
1 of 4.

Choose the Correct Answers:-

1. A ✓
2. E ✓
3. C ✓
4. A ✓

4
4.4/4

Question & Answers

1).

(a) the 1st thing that we need to do after getting the test failure in LeakTest is to raise NC [Non-conformance] against the failure.

Clause : 8.7 :- Control of Non conforming outputs. will come in this case.

The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The "NC outputs" include & Non Conforming Product or Service generated internally.

(b) Aft Step1:- NC [Non-conformance] Needs to be raised.

Step2:- A NC meeting for the raised Nc needs to be held in which the respective departments Like [Qc, Production, Process, Design, Purchase (if req)]. will be present in the meetings.

Step-3:- The departments needs to discuss about the leak test failure and all departments will give their Inputs and based on the Inputs the raised Nc will be taken forward [Pto]

Step-4: Taking actions necessary to contain the effect of the Non Conformity on other process, will check how many regular intervals does this leak Problem is raising.

Step-5: reviewing the Effectiveness of any corrective action taken.

Step-6: by the reviewing we will check & if any changes rq- we will update the Procedure. if necessry.

Step7: Making the changes in the QMS. if required.

then the "NC" will give a note to change ~~if~~ in work Instruction or Procedure [if req]. and after the update we will close the Problem. and we will ~~Empr~~ have Continual Improvement.

(2): Quality Control is responsible for All Steps But Anyone can raise the "NC" & so they will also be responsible.
& All departments who are invdved are responsible.

---

(2). ~~Brete Cou~~ Clause: 8.1.4:- Prevention of counterfeit Parts is to be followed.

~~Counterfeit P.~~

Counterfeit Parts: An unauthorized copy or a duplicate version. which is knowingly misrepresented as a genuine or orignal Part of an authorized Manufacturer.

The organization Shall plan, implement & control Processes appropriate to the organization and the product, for the Prevention of counterfeit or Suspect Counterfeit Part use and their inclusion in Products delivered to the customer.

(P.T.O)

(A) Training the Appropriate Persons in the awareness & prevention of Counterfeit Parts

(B) application of Parts obsolescence monitoring program.

(C) Controls for acquiring Externally provided product from original (or) authorized manuf.; distributers.

(D) requirement for assuring traceability of parts & components to their original (or) authorized manufacturers

(E) Verification & Test to detect Counterfeit Parts.

(F) Monitoring of counterfeit parts reporting from External Sources

(G) Quarantine & reporting of Suspect (or) detected counterfeit parts.

(B). The role of purchase (1) Is to verify the vendor, his previous orders to other Companies

(2) Visiting his Company & Confirming whether he is giving original (or) Counterfeit Part

(3) Doing the Vendor Assessment for verifying & Approving the Vendor.

The role of Q.C:- the role of the Qc is to verify verifying whether the Vendor who is supplying whether is giving original (or) Counterfeit Product.

→ If they Identify the counterfeit Part they will Quarantine the Product & they will keep under their custody.

(C) If we find any counterfeit Parts then we will recall all the products in which we have used.

the clause 8.5.5:- Post-Delivery Activities we need to recall the from the Customer.

PT-O

6. the responsible department & Steps to Evaluate impact on production

Q. Timelines the QA & material verification department.
handle the Non conforming materials.

Ans Steps:-

1. Quarantine the defative batch to Prevent it from entering Production
2. Conduct a root cause analysis to determine the Severity of deviation
3. Compare material Properties with the required Specification & assess the indoor battery performance
4. Checking the Stores if any alternative batches available.
5. If any delay in Production with them & will see, Coordinate with the Supplier if to give a replacement batch

b. Verification of Similar material Usage in previous batches:

i. Review the incoming inspection records of previous batches.
ii. Conducting the Chemical Analysis & testing on present Sample of previously used batch
iii. Cross check the Supplier Lot No. & Certificates of analysis for consistency
iv. Verify "manufacturing records" to identify 'NC' material work -

c. Preventive measures to avoid recurrences :-

i. Implement Strict Supplier audits to ensure Compliance with material
ii. Need to take the Certificate from the vendor before Shipping
iii. Need to make more Sample tests for getting Conformance that this is a good Product.
iv. Establishing the Corrective actions as per the QMS.

P.T.O3

7. After detecting the alternative Component (or) materials.

A

1. Engage with the Vendor (or) Supplier with the Substitut.
2. Conducting the ~~Comparing~~ Comparision analysis of materials, testing the materials to Evaluate the impact reviewing their
3. Reviewing the ~~Vendor~~ Vendor Standards and his regulatory for which Standards he is using and following for making the Product.

B. Validating the alternative Compatibility with the Existing design.

i. We can verify the Conducting the Mechanical tests if this and ~~their~~ Chemical test to Ensure if it is a good Product (or) not.

ii. Conducting a test battery to check whether it can achieve the desired output that were required.

iii. & Comparing the results with the other batteries & Validating whether the Component is Pass (or) Not.

C. i. We Providing the Note to the customer about the material changes.

iv. Share the technical Impact assessment and the qualification test results.

v. giving the alternative Solutions to minimize the issue to the Vendor.

iv. maintaining the transparent and a healthy Communication with the vendor through Vendor Assessment tech.

D. for managing the risk with using new Component in different conditions.

i. ~~Conduct~~ making a failure mode & Effect Analysis ~~(~~ to assess risk.

ii. Implementing the redundant testing to verify Performance reliability.

[P.T.O]

(iii) Ensuring the regulatory & military Compliance for critical Application.

(iv) Making a plan incase the alternative material fails.

3. (a) By updating the regulatory Compliance, revising the Supplier requirements; changing or updating the Procurement rules/Policies, and making a meeting with the Procurement, Purchase, Stores to Educate about the new Environmental rules. and Explaining what we need to do about the regulatory Compliance & if any thing is required to Purchase we will buy and then we will make the arrangement for incorporating in the QMS.

(b) we will Communicate by Sending a letter/ Mail to the customers Vendors and we will updating the terms & Conditions to them and we will audit the Vendors and Confirm whether they are following the new regulations after Confirmation we will make a new ~~aggrem~~ agreement with the Customer & Vendor.

(c) The necessary Steps to be taken ~~of~~ Education of departments.

(i) updating the Confirmity of the Compliance reports.

(iv) In the Procurement document we will Update the Customer Qualification

(iii) In Quality we will Update how to Inspect the Product & it's present Standards

(iv) giving a Note to the Customer that we are changing this Environmental regulations. So Please check the all.

[PT-O]

4

a. the responsible departments to address the Compliant are the Customer Service and the Quality Assurance (QA) whom will Sign the document Ensuring that the Product from our Company which Came to you is a proven Product they are responsible.

(i) Tracking the Product until the raw material Stage & Checking if Everything is OK (or) Not

(ii) Making a root cause Analysis for the failure & Investigating the Possible Outcomes of the Product

(iii) Implementing the Corrective actions & Checking the results

(iv) If the results are ok then the monitoring of the Process is Completed

(v) Reporting this to the Customer.

b. Identifying the failure mode by dismantling the battery & Investigating the cause. and by that we can be know Sure the if there are any regulatory effects on the battery and we will make the Process Improvements.

c. Strict this can be done by Inspecting in the raw material Stage and making Ensuring that we can make the Product qualities, Enhanced testing FMEA, Employee training, design changes (if required.

d. As per AS9100D clause 10.2: Non Conformity & Corrective Action,

(1) Keeping "NC";

(2) Updating 'Work Instructions'

(3) Changing the Inspecting Care Plan for Testing ;.

(4) ~~Alert~~

(PTO).

5. a. the responsible departments for the Shortage: the main

i) Procurement

ii) Quality Assurance

iii) ~~Regulators~~ Production planning.

iv) Vendor Assessment ~~Comm~~

b. Supplier Qualification is to be done by the Vendor Assessment department by following steps

i) Inspecting the vendor and Auditing the Certificates.

ii) Testing the materials in chemical, mechanical Standards and Confirming the Product by making a test battery / Prototype.

iii) Checking Whether the Vendor is meeting the Military Standards Standards which he used approved by.

iv) After all was Pass the Vendor Assessment department will make meeting with design, Production, Procurement, QA & Showing the results and asking whether they are ok with the Performance and the members will approve the to the ~~to~~ Approved Vendor

v) Making the vendor and recording him the Approved Vendor and making a file for him and re inspecting him in Excel and Every 3-4 months and inspecting him Whether he is okay (or) Not : and Whether it is Okay for the Vendor development