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1) (a)

Actions to be taken for stopping Non conformances report :-

- i) ~~Identify~~ Identify and segregate the non conforming product.
- ii) Take immediate action to prevent unintended use on delivery.
- iii) Raise Non Conformances report.
- iv) Investigate the root cause.
- v) Take corrective actions to prevent it from happening again.
- vi) Document everything.

Documents required :-

- i) Non conformance report
- ii) Corrective actions report
- iii) The root cause analysis report

Below are the AS9100D clauses which will come in this case :-

- i) Clause 8.7: Control of Non Conforming outputs
- ii) Clause 10.2: Non conformity and corrective action
- iii) Clause 10.3: Continual improvement.

1) (b) Sequence of steps and work instructions ~~are~~ covered:

- (i) Detection and reporting of leak failure. (Raise NC)
- (ii) segregating defected unit.
- (iii) Check whether rework is possible.
- (iv) Use different root cause analysis methods like 5 whys, Fishbone diagram.
- (v) Implementing preventive actions.
- (vi) Review of preventive actions
- (vii) Final approval of preventive actions

2) (c) Responsibility for each step:

(i) Quality control → step (i) & (ii)

(ii) Production → step (iii)

(iii) Quality control, production and D&D → step (iv)

(iv) Change review group → step (v) & (vi)

(v) Change control board → step (vii)

3) ~~Effects~~ Effects of Counterfeit on production

(i) Product failure and safety risks.

(ii) Regularity and legal issues

(iii) Production delays

(iv) Reputation damage

(v) Financial loss

Clauses of AS9100D to prevent Counterfeit:-

- (i) Clause 8.1.4 → Prevention of counterfeit parts
- (ii) Clause 8.4 → Control of externally provided, processes products and services.
- (iii) Clause 8.5.2 → Identification and traceability.
- (iv) Clause 8.7 → Control of Non conforming outputs
- (v) Clause 8.2.1 → Customer Communication.

2) (a) (i) Procurement department is responsible for procuring right materials from right vendor.

(ii) Vendor management is responsible for choosing correct vendor.

(iii) Quality Control is responsible for inspecting the input materials properly.

All ~~departments~~ the above departments needs to make sure that no counterfeit is being introduced in production.

Actions to be taken to prevent counterfeit.

- (i) ~~Sup~~ Vendor Assessment.
- (ii) Incoming inspection.
- (iii) Traceability.
- (iv) Awareness.

2) (c) steps to be taken if counterfeit parts are discovered to have been used after delivery of the produce

- (i) Customer notification and recalling the products.
- (ii) Documenting all communication with customer.
- (iii) Root cause analysis.

IV Supplier Investigation

~~V~~

Work instructions covered under this

- i Incoming inspection work instruction.
- ii Vendor Assessment work instruction.
- iii Customer Communication

3) a Incorporating Environmental regulation into QMS

- i Conduct a impact assessment on product due to chemical change.
- ii If environmental regulation bars ^{or limit the use of} a specific chemicals which was used then find alternative chemicals to comply with regulation
- iii Develop change product design to get the desired results with alternate chemicals
- iv ~~can~~ Inform purchasing department and ensure suppliers comply with regulations.
- v Update manufacturing work instructions.
- vi Awareness in employees on ~~new~~ ~~chemical~~ environmental regulation of chemical.

b Communicating changes with customer

- i Provide information about environmental regulation.
- ii Obtaining feedback from customer relating to environmental regulation and changes introduced due to environmental regulation.

Communicating changes with suppliers

(i) New contract to be placed to ~~the~~ implement environment regulations. ✓

(ii) Vendor assessment for the specific chemicals.

3) (c) Necessary steps to be taken and responsibilities of each department.

(i) Review new regulation and how it affects battery performance. (Management and D&D department)

(ii) ~~Mod~~ Modify battery design to comply with regulation (D&D department)

(iii) ~~Custom~~ Communicating exchanges to customers and ~~supplier~~ (Sales & Customer service department)

(iv) Communicating changes to suppliers. (Procurement department)

(v) Updating work instruction. (Production department)

(vi) Training Employees on safety and handling. (Production department)

Documents required

(i) ~~Regul~~ Environmental regulation compliance report

(ii) & design change report

(iii) Updated purchase contract ✓

(iv) Customer Notification letter.

(v) Updated work instructions.

- 4) (a) Responsible department
- (i) Quality Control
 - (ii) Production

Sequence of steps

- (i) Receiving the complain
- (ii) Separating the ^{affected} batch
- (iii) Conducting failure analysis
- (iv) Implementing corrective actions
- (v) Informing customer about corrective actions
- (vi) Conducting internal audit at planned intervals to avoid failures.

4) (b) Risks :-

- (i) Safety risks
- (ii) Reputation damage
- (iii) Legal Risks

Addressing the risks

- (i) Analysis of performance and ~~dissect~~ post mortem of battery.
- (ii) Testing other batteries from same batch.
- (iii) Improving Quality check methods.
- (iv) Communicating to customer about each step to give them confidence.

4) (C) Changes to prevent recurrence

- (i) ~~Design~~ Improving design to eliminate problems.
- (ii) Enhancing process control.
- (iii) Improving quality test methods.

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4) (d)

- (i) Clause 8.2.1 → ~~Regularly~~ Customer communication
- (ii) Clause 8.5.5 → Post delivery activities
- (iii) Clause 9.1.2 → Customer satisfaction.
- (iv) Clause 9.1.3 → Analysis and Evaluation.
- (v) Clause 8.5.1 → Control of product and service provision.

5) (a) Purchasing department and Vendor ~~as~~ development department.

(b) Evaluation of alternate suppliers:

(i) Products and services provided by supplier.

(ii) Methods, processes and equipments

(iii) @ Supplier interactions with organization.

(iv) Monitoring of performance of supplier. Like Rejection, supplying product in time, etc.

(v) Verification on validation activities of suppliers.

clauses:-

(i) Clause 8.4.1

(ii) Clause 8.4.2

(iii) Clause 8.4.3

(iv) Clause 7.1.5

6) (a) Quality control department and purchase department steps to evaluate the impact on production timelines.

(i) Segregating the batch of the material. ~~to stop it~~

(ii) Raising Non conformance report.

(iii) Communicating about defect to supplier (purchase department)

(iv) Finding alternate supplier to reduce impact on production timeline

6) (b) (i) Communicate with supplier about when this deviation was used.

(ii) ~~Verify~~ ~~at~~ Confirm whether any batch with deviation was supplied or not earlier.

(iii) If doubt about earlier batches, then ~~recheck~~ ^{requalify} those batches.

(iv) Tests some batteries from previous batches. ~~#~~

6) (c) (i) Rigorous supplier audits (Clause - 8.4.2)

(ii) Improving incoming inspection (Clause - 8.6)

(iii) Material certification from Test labs. (Clause 7.1.5)

→ Choose the correct answers

1) (a) 7 ✓

2) (e) All A, B & C ✓

3) (c) Process owner ✓

4) (e) Only A & C. ✓

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