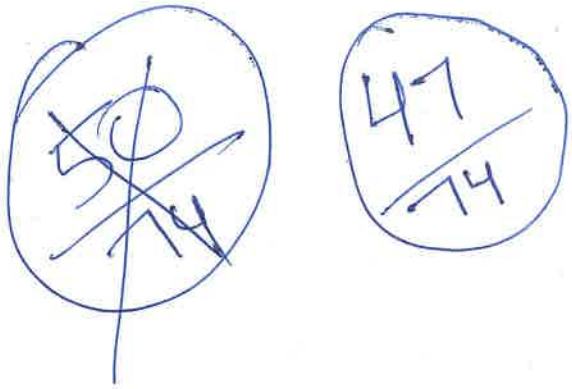
S. Lekhana 1667



Choose the correct answers:-

1) a ✓
2) e ✓ (3)
3) b ✓
4) e ✓

QIA's:-

1) (a) The clause this situation comes under is 10th clause i.e., Improvement.

Actions should be taken:-

→ Improving products & services to meet requirements as well as to address future needs.

→ correcting, preventing undesired effects.

→ Improving performance & effectiveness of quality management system.

→ The improvement can include correction, corrective action, continual improvement.

(b) Documents made to AS9100D for stopping non-conformance:-

→ The organisation shall maintain documented information that defines non-conformity & corrective action management process.

→ The organisation shall retain documented information as evidence of:-

a) the nature of non-conformities.

b) the results of any corrective action.

(b) Sequence of steps to be Undertaken:-

i) Observing failure in leak test.

ii) Raising Non-conformance.

iii) Conducting ~~Corrective~~ NC Meetings.

iv) Implementing corrective actions that are discussed in NC meetings.

Work Instructions that are covered:-

→ Leak test Work Instruction.

→ Control of QC. Procedure document.

3

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2) To prevent counterfeit, the clause needed as per AS9100D is Clause 3, Terms & definitions & Clause 8 i.e, operations.

a) Purchase department is responsible to counterfeit.

Actions should be taken to prevent counterfeit:-

→ Training of appropriate persons in awareness.

→ Controls for acquiring externally provided product from original (or) authorized manufactures.

→ Requirements for traceability of components to their original (or) authorized manufacturers.

→ Verification & test methodologies to detect counterfeits.

→ Monitoring of counterfeits from external sources.

2

b) Role of purchase, QC & other departments:-

→ purchase should identify & track the manufacturer.

→ QC should verify the product given by the manufacturer, to see if they're misrepresenting knowingly.

2

c) → Steps to be taken if counterfeit parts are discovered:-

→ Approching the manufacturer.

→ Explaining our problem.

→ We shouldnot contact the manufacturer for further requirement.

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3) a) I incorporate this change into QMS as per clause 7 i.e., 7.1.4. Environment for the Operation of processes.

b) I communicate these changes to our customers & suppliers as per clause 8 i.e., 8.2.1 Customer communication by providing information related to change in regulation impacts.

c) i) Preparing document regarding new environmental regulation.

ii) Reviewing & Approving the Document by CRQ & CCB members.

iii) Releasing the document and educating operators.

iv) Communicating with Customers.

Responsiblities of Each Dept:-

→ R&D - Material Validation

→ QC - Verifying

→ Asst. MR - preparing the necessary Document.

→ MR - Reviewing & approving the document.

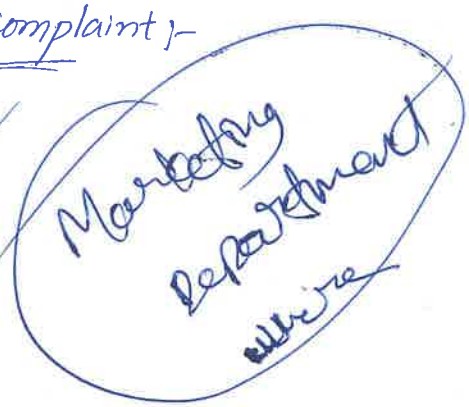
Necessary Documents:-

→ Environmental regulation should be documented in an procedural document so, that everyone can know what are the impact of using specific chemicals on the environment.

Customer compliant about a thermal battery failure.

4) a) Responsible department to address complaint :-

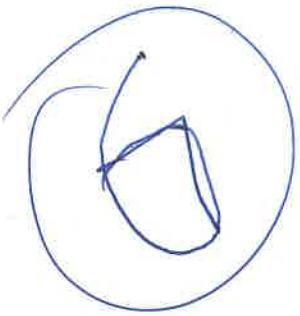
→ QC Department
→ Purchase Department
→ Production Department
→ D&D Department.



Sequence of steps to be taken :-

→ Identifying root cause by performing cut open of failed battery.
→ Preparing a report by attaching pictures & all other necessary data of that particular battery.
→ Preventing the cause by not repeating it again.

b) → Enhancing desirable effects.
→ Preventing, reducing the undesired effects.
→ Achieving improvement.
→ Eliminating the risk source.
→ Changing the likelihood (or) consequence.



c) → Improving process.
→ Updating Work instructions according to the reason of failure.
→ Enhancing the sampling process done by QC.
→ Explaining the root cause of failure of battery to the operators.

d) → The clause applicable is Clause 6 → Planning.

Clause 6.1 :- Actions to address risks & opportunities.

Necessary Documents :-
→ Root Cause Analysis Report.
→ NC Report.

5)
a) If a key supplier for critical materials faces a shortage, responsible departments to address :-

→ Purchase Department
→ Planning Department
→ Production Department.

(2)

b) Evaluating alternate suppliers

→ Inspection & audit at external provider's premises.
→ Reviewing required documents.
→ Reviewing of production part approval process data.
→ Inspection of products (or) verification of services.
→ Results of production process verification.

The clause of AS9100D that is applicable to this situation is Clause 8→Operations.

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6) Material defect identified during inspection.

a) Responsible department to handle nonconforming :-

→ QC department
→ Production department
→ Process department
→ Purchase department

(4)

Steps to be taken :-

→ To contact the supplier and explaining the problem.
→ Asking them to visit our company for verification.
→ Replacing these raw materials with new ones.
→ Preparing a sample battery with new raw materials.

→ Analyzing the results.

→ ~~Decidin~~

b) By traceability we can verify whether similar material from the supplier has been used.

Traceability requirements can include :-

→ Identification to be maintained throughout product life.

→ for an assembly, the ability to trace its components to the assembly & then to next higher assembly.

→ for product, a sequential record of its production to be retrievable.

c) Preventive measures to avoid reoccurrence :-

Clause 9 :- Performance Evaluation

9.1 Monitoring, Measurement, Analysis & Evaluation :-

The org. shall determine :-

a) what needs to be monitored.

b) Methods for monitoring, analysis & evaluation needed to ensure valid results.

Clause 8.4 :- Control of Externally provided process, products & services :-

→ During external provider evaluation & selection, the organization can use quality data from objective and reliable external sources, as evaluated by organisation.

→ ~~Use of data~~ Maintain a register of its external provider that includes approval status (eg :- approved, conditional disapproval) and the scope of approval (eg :- product type, process).

7)

a) It is considered as the requirement for products and servies.

as per clause 8.2.2.

→ ~~Verifying~~ Asking suggestion from the supplier for the alternative component.

→ Design department :- taking advice by design department for the alternative component.

→ Making a trail battery by that alternative component.

→ Analysing the results.

b) → Validating if the alternative component can be fit in the design.

→ Dimensions of it.

→ Making a trail battery.

→ Monitoring the results & performance of the trail battery.

→ Re-updating the drawing of this component, if it is not compatible with existing design.

c) As per clause 8.2.1 customer communication, I will communicate potential delays (or) product changes.

Customer communication shall include:-

a) providing information relating to product & services.

b) handling equires.

c) providing information about potential delays in supply of batteries.

d) As per clause 8.1.1 Operational Risk Management

→ Assignment of responsibilities for risk.

→ Defining of risk assignment criteria

Eg:- likelihood, consequences, risk acceptance.

6

→ Identification of risk.

→ Communication of risks throughout operations.

→ Mitigating risks that exceed the defined risk acceptance criteria.

→ Acceptance of risks remaining after implementation of mitigating actions.

5) Clause 8.4.2 Type & Extent of Control

ⓑ Verification activities of externally provided processes, products and services shall be performed according to risks identified by the organization. These shall include inspection (or) periodic testing.

3

→ Customer Verification activities performed at any level of supply chain doesn't absolve the org. of its responsibility to provide acceptable processes, products & services to comply with all requirements.