AS9100D

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* Choose the correct answers:

1) [a] ✓

2) [e] ✓

3) [a] ✗

4) [a] ✓

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28+8/14

S. Greeshma

1) Ans:

→ There is a failure in leak test in thermal battery.

a) The organization shall retain documented information as evidence of:

1) the nature of the nonconformities and any subsequent actions taken

2) the results of any corrective action.

→ clause 10: Improvement and sub clause: 10.2: Nonconformity and corrective action of AS9100D will come this case.

b) when a nonconfirmity occurs, including any arising from complaints, the organisation shall:

→ react to the nonconfirmity and, as applicable:

a) take action to control and correct it.

b) deal with the consequences.

→ Evaluate the need for action to eliminate the cause(s) of nonconfirmity, in order that it does not recur or occur elsewhere, by:

a) reviewing and analyzing the nonconformity

b) determining the causes of the nonconformity, including, as applicable, those related to human factors.

c) implement any action needed

d) review the effectiveness of any corrective action taken.

e) update risks and opportunities determined during planning, if necessary

f) make changes to the Quality Management system, if necessary.

g) flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconfirmity.

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h) take specific actions when timely, and effective corrective actions are not achieved.

c) External provider and QC is responsible for each step.

2) Ans:

→ Effects of counterfeit on production.

→ Clause 8: Operation

Sub clause 8.1.4: prevention of counterfeit parts.

a) "QC" is responsible to counterfeit and counterfeit part prevention

processes should consider:

But procurement department is primarily responsible

1) training of appropriate persons in the awareness and prevention of counterfeit parts.

2) application of a parts obsolescence monitoring program

3) controls for aquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources.

4) requirements for assuring traceability of parts and components to their original or authorized manufacturers.

5) verification and test methodologies to detect counterfeit parts.

6) monitoring of counterfeit parts reporting from external sources.

7) quarantine and reporting of suspect or detected counterfeit parts.

b) purchase: The purchase department will be first select one or two external provider. They will verify all the data and information from External provider. If the supplier is have good knowledge on these the purchase department will be select and communicate with them.

QC: The QC is responsible for measuring, monitoring, analysing and evaluation needed to ensure valid results.

c) The organisation shall plan, implement, and control processes, appropriate to the organisation and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in products delivered to the customer.

3) Ans:

a) The organisation shall determine, provide, and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

→ A suitable environment can be a combination of human and physical factors, such as:

1) social [Ex: non-discriminatory].

2) psychological [Ex: burnout prevention]

3) physical [Ex: Temperature, heat, humidity, light, airflow, noise).

b) Communication with customers will be:

→ providing information relating to products and services.

→ handling enquiries, contracts or orders, including changes.

c) QC: calibration or verification of monitoring and measuring equipment shall be carried out under suitable Environmental conditions.

Design and development: D&D shall consider the ability to provide verify, test and maintain products and services.

→ The organisation's quality management system shall include:

1) documented information required by this international standard.

2) documented information determined by the organisation as being necessary for the effectiveness of the quality management system.

3) Identification and description

4) Storage and preservation

5) Control of changes

4) Ans:

a) 'purchase and QC is responsible for this complaint.

b) The results of analysis shall be used to evaluate:

→ conformity of products and services

→ the degree of customer satisfaction

→ the performance and effectiveness of QMS.

→ if planning has been implemented effectively.

→ the effectiveness of actions taken to address risks and opportunities.

c) The organisation shall monitor customer's perceptions of the degree to which their needs and expectations have been fulfilled.

d) clause 9.1.2 customer satisfaction.

Sub clause 9.1.3: Analysis and Evaluation.

5) Ans:

a) QC is responsible for this issue.

b) The requirements for the products and services are defined, including:

→ any applicable statutory and regulatory requirements.

→ those considered necessary by the organisation.

→ the organisation can meet the claims for the products and services it offers;

→ special requirements of the products and services are determined.

→ Operational risks (Ex: new technology, ability and capacity to provide, short delivery time frame) have been identified.

clause 8: Operation

Sub clause 8.2.2: Determining the requirements of products and services are applicable.

7) Ans:

b) For processes where the resulting output cannot be verified by subsequent monitoring or measurement, the organisation shall establish arrangements for these processes including, as applicable:

→ definition of criteria for the review and approval of the processes.

→ determination of conditions to maintain the approval.

→ approval of facilities and equipment.

→ use of specific methods and procedures for implementation and monitoring the processes.

c) * providing information relating to products and services.

* handling enquiries, contracts or orders, including changes.

d) The organisation shall implement production process verification activities to ensure the production process is able to produce products that meet requirements.

→ These activities can include risk assessments, and control plans.