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1. a. clause 8. operation.

In clause 8.7. i.e Control of non conforming outputs.

The organisation shall take appropriate action based on the nature of nonconformity.

Doumented made as per AS9100D.

→ defining the responsibility and authority for the review & disposition of nonconforming outputs and process for approving persons making these decisions.

→ Taking actions necessary to contain the effect of the nonconformi on other processes, products, or services.

→ Defining corrective actions for nonconforming products and services as per (clause 10.2).

b) when a non conformity occurs,

* React to the non-conformity and as applicable
  1. take action to control and correct it
  2. deal with consequences.
* evaluate the need for action to eliminate the cause
  1. Reviewing and analyzing
  2. Determining the causes of non conformity
  3. determining if similar non conformities exist or could potential occur.
  4. Implement any action needed.
  5. update the risks and opportunities determined during planning, if necessary.

a. flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for non conformity

b. Take specific actions when timely and effective corrective actions are not achieved.

Corrective actions shall be appropriate to effect of the non-conformities encounted.

c) Quality control is responsible for each step.

2 a. Clause 8.1.4

prevention of counterfeit part.

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

→ Training of appropriate persons on the awareness and prevention of counterfeit parts.

→ Application of a parts obsolencence monitoring program.

→ Controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors

→ Verification and test methodologies to detect counterfeit part

→ Monitoring of counterfeit parts reporting from external sources.

→ quarantine and reporting of suspect or detected counterfeit parts.

b. purchase will traceable the parts and components to their original or abuthorized manufactures.

→ QC will inspect whether the quality of product whether they receive original product from authorized manufactures.

→ Store department will identify the counterfeit product when they receive.

3 As per clause 7.5 (Documented Information)

a. Documented information required by this International Standard

b. The documented information determined by the organisation as being necessary for the effectiveness of QMS.

7.5.2 creating and updating

a. Identification and description.

b. Format

c. Review and approval for suitability and adequacy.

7.5.3 control of documented information.

a. It is available and suitable

b. It is adequately protected.

c. Storage and preservation, including preservation of legibility.

d. retention and disposition.

b.) * providing information relation product.

* handling enquiries, contracts or orders, including changes

4. a. If the customer Compleent about the thermal Battery failure.

The Design and development department is responsible and also production & Quality control.

b. management reviews. Inputs.

→ The status of actions from previous management reviews

→ changes in external & internal issues that are relevant to QMS.

→ Information on the performance and effectiveness of QMS. Including.

1. Customer Specification
2. extent to which quality Objective have been met
3. process performance & conformity of product & services
4. Nonconformities and corrective actions.
5. monitoring and measurement results.
6. audit results.
7. Opportunities for improvement.

c. Improvement.

These includes.

* Improving products and services to meet requirement as well as address future needs and expectations.
* correcting, preventing, or reducing undesired effects.
* Improving the performance and effective of QMS

d. In clause 10.2.2 the organisation shall retain documented information as evidence of.

→ nature of non conformities and any subsequent action taken.

→ the results of any corrective action.

5. As per clause 4. (4.2)

Expectations of interested parties.

a. Interested parties that are relevant to QMS.

b. The requirements of these interested parties are relevant to QMS.

4.3 · determing the scope of QMS.

a. The external and internal issues

b. Requirement of relevant interested parties

b. ~~Clause 8(8.1)~~. 4.4

(4) Organisation shall determine the process needed for QMS and their application

→ Determine the input required.

→ Determine the sequence and interaction of these process.

→ determine & apply the criteria and methods

→ determine the resources needed for these processes & ensure their availability.

Q. a. production and Quality control are responsible to handle non conforming materials.

[→ Design verification
→ process control
→ Engaging representatives of affected organisation functions. for operation planning.
→ Determing the process and resources to support the use and a maintences ]

7.1.5.2 Measurabent Traceability

when the measurement trability as a requirement or is consider by organisation to an essential

One organisation shall establish, implement and maintain a process for recall of monitoring and measuring equipment requiring verfication.

b. By traceing the results, there capability measuring specifications.

1. ~~7~~
2. d.
3. b.
4. a.

(2)

7 planning.

4.1. understanding the organisation and its context

4.2 understanding the needs and expectations of interested parties.

(5)

→ Action to address risk & opportunities

→ when planning for oms

→ give assurance ~~that~~ oms can achieve

→ Enhance desirable effects.

→ prevent, or reduce, undesired effects.

→ Evaluate the effectiveness of these actions