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6. Material Defect Identified During Inspection

a) Generally, Purchase Dep. and Inward Inspection QC Dep. is responsible for usage of non conformity raw materials. This situation will be handle by QC people along with help of top managament.

Steps to evaluate the impact

* reviewing & analysing the non conformity
* Determine the cause of the non conformity including, as applicable, those related to human factors.
* Determine if similar non conformities exist.
* Implament the proper corrective action measure.

b) The difference in chemical composition can be identified by cross verifying the test report of the previous batch with the defective batches.

The composition of the chemical will vary from the respective batch through the respective test reports.

c) Preventive measure:

* Make changes to QMS, if necessary.

* The corrective action requirements to an external provider when it is determined that the external provider is responsible for the non-conformity.

* Set a proper time line to recheck the corrective action which is implemented.

* The organization shall maintain the documented information that defines the non conformity & action plans (eg. specification, log sheets etc).

* The organization shall retain the document as evidence of the results of any corrective action.

* The process should be improved continously.

support.

7 a) The organization shall determine, provide and maintain the infrastructure necessary for the operation of its process & to achieve conformity of products. (e.g. Lid, container).

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2. a) Quality control purchase dep. is responsible to counterfeit on production.

- Actions:
  * Training of appropriate person
  * application of a parts obsolescence monitoring program.
  * monitoring of counterfeit parts reporting from external sources
  * quarantine & reporting of suspect.
  * Valid verification & test methodologies to detect counterfeit part.
  * requirement for assuring traceability of parts & components

(24)

b) The purchase should address this issues to the external supplier and arrange of replacement or re supply of conformity product.

The qc should cross check the re-supply product with validated report and then by conforming the product is original with respect to AS9001D.

(V)

c) * customer communication
* Determing the requirement of product + services.
* review of requirement of product + services.

(VI)

The review shall be coordinated with applicable function of organization
* acceptance report & validation report are covered.

3. a) The organization shall determine provide & maintain the environment necessary for the operation of its process & to achieve conformity of product & services.

i) social

ii) psychological

iii) physical

b) The organization shall determine the internal & external communication relevant to QMS. including

a) on what it will communicate

i) what to communicate

ii) with whom communicates.

iv) how to communicate

v) who communicate.

communication should include internal | external feedback relevant to QMS.

c). i) Purchase Dept:

* The chemical should be procured from approved vendors with suitable regulation policy & certificates.

ii) QC:

The chemical should be subjected to relevant analysis method to know the risk of the chemical & also its composition

iii) ~~R & D dept and production dept:~~

The respective people should be aware of handling of chemicals

Documents:

* Test report, specification, work instruction etc.

The process should comes under regulatory compliance.

4. a) Top management to address the compliant.

Analysis + Evaluation

↓

Internal audit

↓

(2x) Management review

↓

MR Input

↓

MR output

b) The result of analysis shall be

(2x)
i) conformity of product & services
ii) degree of customer satisfaction
iii) if planning has been implemented
iv) the performance of internal provider
v) the need for improvement to QMS

vi) the performance & effectiveness of QMS.

vii) the effectiveness of actions taken to address risk & opportunities.

~~e) → plan, nsta~~

c) Improvement

→ General

→ Non conformity & corrective action

→ when a non conformity occurs, including any arising from complaints

i) react to non conformity & as applicable

2) evaluate the need for action to eliminate the cause of the non conformity.

3) implement any action needed

4) review the effectiveness of any corrective action

5) update risks & opportunities determined

6) make changes to QMS.

7) flow down corrective action requirements to an external provider.

8) take specific action when timely effective corrective action

* the organization shall retain documented information as evidence

* continual Improvement.

d) Clause NO. 9.

(3) i) control, updating & provision of technical document.

ii) warranting;

iii) analysis report.

iv) RDC.

1) ~~e) Quality control~~

a) claim 9.

c)

5. a) those item having significant affection the provision + use of the product + service including safety, performance, form fit, function, producibility, service life etc.

Purchase + procurement department will be responsible for this insure

b) The organisation shall ensure when required that customer designated (or) approved external provider including process sources.

* the orgnization shall periodically review external provider performance including process, products & service conformity & on time delivery performance.

* Type + extent of control.

The organisation shall ensure that externally provided process remain within the control of QMS.

* define both the controls that it intends to apply to an external provider.

* take into consideration, the results of the periodic review of external provider performance.
* determine the verification.
* Information for external provider.

a). the process, products & services to be provided including the identification of relevant technical data

b) the approval of product & services, method, process & equipment, the release of product & services.

c) competence, including any required qualification of person

d) design & development control

e) special requirements critical item(or) key characteristics.

i) test, inspection & verification

7. a) Development of new vendors for the product.

b) The organization shall periodically review external provider performance including process, product & service conformity & on time delivery performance.

(4)

d) i) assessment of hazards & management of associated risk

ii) Managment of safety critical items

iii) analysis & reporting of occured events affecting safety

iv) communication of lessons learnts and training of persons.

v)

Choose the correct answer

1) a) 7

2) a)

3) c)

4) a)