

INDIAN STATISTICAL INSTITUTE
SQC & OR Unit, Hyderabad

MS in Quality Management Science : 2014 - 2016
III SEMESTER : FINAL EXAMINATION

Subject : Quality Assurance

Date : 23.10.2015 (Friday)

Duration : 3 hrs

Max. Marks : 100

INSTRUCTIONS

This paper carries questions for 124 Marks. Answer as much as you can. But the maximum you can score is 100 Marks.

- I. Within the scope of ISO 9000:2005, ISO 9004:2009, ISO 9001:2015, ISO 14001:2015 & OHSAS 18001:2007(or IS 18001:2007), state whether the following statements are TRUE or FALSE. Give brief justification to your answer.

(10 x 3 = 30 Marks)

- a) Soft copies of Operating Instructions given by the customer can be considered as customer property.
- b) All measuring equipments shall be calibrated against measurement standards traceable to national/international measurement standards.
- c) Nomination of Management Representative(MR) is mandatory as per ISO 9001:2015 standard.
- d) Every Nonconformity is a Defect.
- e) Share holder of an organization can be considered as interested party
- f) Purchased services under maintenance procedures shall conform to the organization's OH&S requirements.
- g) The organization need not safeguard all property of external providers while it is under the organization's control.
- h) The Organization shall take action to prevent or mitigate the consequences of potential environmental impacts.
- i) Transport services of an organization fall under the scope of Infrastructure.
- j) HIRA need not be carried out for the facilities at the company premises which are provided by external agencies.

II. Briefly explain any SEVEN of the following

(7 x 5 = 35 Marks)

- a) What are the constellations available in CMMI V 1.3? Explain their applicability.
- b) In a staged representation of CMMI V 1.3, provide details of maturity levels and the number of Process Areas (PA's) in each of the constellations.
- c) Define Generic Goal, Generic Practice, Specific Goal and Specific Practice in CMMI V 1.3
- d) What is the suggested method for CMMI V 1.3 appraisals? Provide details of the different classes of appraisals?
- e) What are organizations that can use COPC standard? Give COPC standard frame work with points.
- f) What is CE Marking & list out at least 5 directives?
- g) What is the definition of Manufacturer? What are his responsibilities?
- h) Who can be an authorized representative and what is his role.
- i) Define and explain essential safety requirements.

III. Write short notes on any FOUR of the following :

(4 x 6 = 24)

- a) List out appropriate Statistical Techniques applicable under any three different clauses of each of ISO 9001, ISO 14001 & OHSAS 18001(or IS 18001). Briefly explain with examples and assumed data.
- b) Write short notes on Emergency preparedness and response under Health and Safety management.
- c) Write short notes on Environmental objectives, with examples.
- d) Briefly explain the four types of audits viz., Random, Horizontal, Vertical and Trail following audits with two examples for each one of them. What is the best sequence of auditing an organization.
- e) Briefly explain hierarchy of Risk control in Health and Safety management.
- f) Briefly explain questioning techniques in carrying out audits

IV. Answer any FIVE of the following questions.

(5 x 7 = 35)

The following are the audit observations made in the context of ISO 9001:2015 or ISO 14001:2015 or IS 18001:2007(or OHSAS 18001:2007) in an organization. State whether each observation is a NC or not. If NC, then mention the relevant Standard, Clause #, justify with brief explanation, suggest Correction and Corrective Action. If it is not an NC, give justification of compliance to the clause.

- a) The Inspector Mr.Naidu's job is to carry out inprocess inspection of products by collecting random sample as per a sampling plan to verify whether the sample conforms to specification limits or not. The Auditor Mr.Kumar, on careful examination of finds that the method of inspection is invalid.
- b) As per the QA Manual Internal audits have to be conducted quarterly. In January 2015 Internal Audits were conducted in the Maintenance dept by Stores Incharge. However, in the next round of Internal Audits conducted by Marketing Manager in April 2015, he finds that two NCs are still not closed within one week(as mentioned in the NCR format) despite availability of required resources.
- c) The noise level during day/night within the production area/workers colony is not being monitored as per the six monthly schedule specified in the relevant procedure.
- d) Effluents exceeding the permissible values of(the local municipality) the characteristics such as BOD, COD, SS, chlorides etc. are being let outside the factory premises.
- e) OH & S policy is defined, documented and approved by Top management. Reviewed half-yearly. OH&S policy boards are displayed at several locations in the plant premises. The Health & Safety Policy of the company is covered in all Trg Prgs in English and local language. All employees/contractors/visitors are distributed H&S policy cards.
- f) HIRA studies were carried out for all routine and non-routine activities, including facilities at the work place which are provided by the company. The activities of all personnel having access to workplace(including visitors & subcontractors) are also covered. The results of assessments and effects of controls are considered while setting OH&S objectives. This info is documented and updated.
- g) The organization has been externally communicating information relevant to the EMS, as established by it's communicating processes and as required by it's compliance obligations.