
QUESTION 5

ISO 9001 (8.2.2) requires the selection of auditors and the conduct of audits to ensure objectivity and impartiality of the audit process and for auditors not to audit their own work.

Describe why the selection of auditors is important in relation to the above requirement of the standard, taking into account their objectivity and impartiality, why these qualities are important and how they are demonstrated by the auditor.

(20 marks)

QUESTION 6

ISO 9001 (8.2.2) requires a documented procedure to be established to define responsibilities and requirements for planning and conducting audits and for establishing and reporting results.

a) List **four** aspects an Audit Summary Report includes to summarise the audit prior to receipt of the final written report, given by the Lead Auditor.

(4 marks)

b) Briefly describe **eight** topics that should be addressed in the Audit Report.

(16 marks)

QUESTION 7

Within section 8 of ISO 9001 there are requirements for control of non-conformity, corrective action and preventive action.

a) Compare and contrast the terms corrective and preventive action and explain why there is confusion between them.

(6 marks)

b) Explain the term remedial action.

(2 marks)

c) Discuss the differences between potential non-conformance, actual non-conformance and suspected non-conformance.

(12 marks)



Chartered Quality Institute

CQI Examinations June 2013

Unit 306

Management Systems Audit (Level 3)

19 June 2013

Time: 9.40 – 12.10
(2½ hours)

Notes for candidates

At 9.30, you have 10 minutes preparation time before the exam begins. Your exam booklet will be handed out at 9.40.

Attempt **ALL THREE questions** in **Section A**. Attempt **any TWO** questions from **Section B**. If you attempt three or more questions in Section B, only the first two will be marked.

Questions may be attempted in any order. All questions carry equal marks. The maximum marks for each part of each question are shown.

Begin each question at the top of a fresh side of paper. Do not write in the margins.

If you use any additional sheets (i.e. graph paper or additional answer booklet) please write your CQI student number, examination name and date on each sheet.

SECTION A – ANSWER ALL QUESTIONS

QUESTION 1

Within ISO 9001 (8.2.2) there is a requirement for the planning and conducting of audits. As part of this requirement, aids can be used to help the auditor. One such tool is a checklist.

- a) Compare the advantages and disadvantages of using checklists. (16 marks)
- b) List **four** benefits of using checklists if developed for a specific audit and used correctly. (4 marks)

QUESTION 2

An ISO 9001 audit requires third party auditors to obtain a good understanding of the organisation's quality management system (QMS) and the nature of its business. This is why it is beneficial for an organization to be visited prior to its certification audit and for a first stage audit to be conducted. This first stage audit is primarily for scoping and planning a certification audit (the stage two audit) and to allow the auditor to obtain an understanding of the organisation.

Explain what activities are performed at a preliminary first stage audit. (20 marks)

QUESTION 3

During an audit, conformity to the standard (ISO 9001) must be demonstrated.

a) Trying to show compliance to a standard often brings people back to using checklists, where an auditor is able to check-off the requirements of the standard one-by-one, making sure that all the requirements have been covered. The use of a generic checklist might prevent an auditor from collecting evidence of effective interfacing between processes.

Explain why this might be the case. (2 marks)

b) There is no statistical or mathematical formula to establish the right number of samples to be taken during an audit to demonstrate it is efficient or to ensure conformity.

List **three** reasons why this does not ensure conformity and give an explanation for each reason. (15 marks)

c) It is important that the audit reports to the auditee only contain important information for the auditee, for example information regarding possible improvements, positive observations, and nonconformities to the standard.

As the lead auditor, explain the main disadvantage of using auditor notes when compiling the audit report. (3 marks)

SECTION B – ANSWER TWO QUESTIONS ONLY

QUESTION 4

ISO 9001 requires that auditing includes verification of competence

a) To satisfy the competence/effectiveness of a product realisation process audit under ISO 9001, describe the actions the organisation typically needs to undertake to demonstrate verification. (8 marks)

b) In auditing an organisation's compliance with the competence and training evaluation requirements, an auditor would typically be seeking evidence that the following issues are addressed:

- (1) required competency
- (2) competent people assigned
- (3) the need to evaluate the effectiveness of the actions taken
- (4) verification that some form of effective monitoring process exists.

Give a brief description of what each of the above issues means in terms of meeting ISO 9001 requirements and the evidence required to show compliance. (12 marks)