

QUESTION 6

ISO 9001 contains eight sections or clauses of which the first three contain an introduction to the standard, and Clauses four to eight contain the requirements.

- (a) ISO 9001 Clause 2 sets out an explanation of exclusion from the quality management system. Describe with **one** example the meaning of this clause. (5 marks)
- (b) Identify **five** requirements that ISO 9001 states should be included in the Quality Policy. (15 marks)

QUESTION 7

To meet legal requirements before being sold within the European Community many products, such as equipment, toys and medical devices, must carry CE marking. This provides a self-declaration made by the manufacturer that the product meets European legislation for health, safety and environmental requirements.

Explain why some products carry both a national and CE mark, and describe what is involved in the CE marking process.

(20 marks)



Chartered Quality Institute

CQI Examinations June 2015

Unit 302

Management System Models (Level 3)

26 June 2015

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 two 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

Standards, in many forms, are used as support for various functions within an organisation.

- (a) Compare the difference between a company standard and an international standard referred to in a statute or regulation. (4 marks)
- (b) Explain **three** benefits of using standards within an organisation. (12 marks)
- (c) Explain the difference between formal and informal standards. (4 marks)

QUESTION 2

Conformity assessment involves a number of processes used to demonstrate that a product, service or management system meets the requirements of a standard.

- (a) Explain the difference between internal and external conformity assessment. (8 marks)
- (b) Within the process of conformity assessment, explain the interface between testing and product certification. (6 marks)
- (c) Explain the difference between accreditation and certification. (6 marks)

QUESTION 3

An integrated management system is one that combines internal management practices into one system, although not as separate components.

- (a) Provide **three** examples of standards that might be included in an integrated management system together with a simple diagram. (8 marks)
- (b) Setting meaningful objectives is an important process in an integrated management system. For each of the standards identified in 3(a) suggest **two** possible objectives. (12 marks)

SECTION B – ANSWER TWO QUESTIONS ONLY

QUESTION 4

There are a number of quality standards and models that an organisation may decide to implement to manage and improve its business.

- (a) Identify **four** quality standards or models that may be used by an organisation. (8 marks)
- (b) Describe the process a national standards body may use in developing a new standard. (12 marks)

QUESTION 5

There are many reasons why an organisation may choose to implement an integrated management system.

- (a) Explain **three** benefits of an integrated management system to an organisation. (12 marks)
- (b) Briefly explain why the following are important additional shared procedures:
- 1) Risk assessment
 - 2) Regulations management
 - 3) Programme management
 - 4) Public awareness.
- (8 marks)