

FACULTY OF ENGINEERING AND THE BUILT ENVIRONMENT

November Examination 2015

PROGRAMME

BTECH: QUALITY

DEPARTMENT

QUALITY & OPERATIONS MANAGEMENT

MODULE

QUALITY AUDITING TECHNIQUES 4

CODE

QAT44-2

DATE

: SUMMER EXAMINATION 2015

9 NOVEMBER 2015

DURATION

: (SESSION 2) 12:30 - 15:30

TOTAL MARKS

120

EXAMINER

MRS M GOUNDEN / MRS N SUKDEO

EXTERNAL MODERATOR

MR A INDERLAL

NUMBER OF PAGES

5 PAGES (including cover page)

INSTRUCTIONS TO CANDIDATES:

- This is a closed book assessment.
- Read the questions carefully and answer only what is asked.
- Number your answers clearly.
- Write neatly and legibly.
- Structure your answers by using appropriate headings and sub-headings.
- Attached are the clauses of ISO 9001.
- The general University of Johannesburg policies, procedures and rules pertaining to written assessments apply to this assessment.

Question 1 - 60 marks

During a stage one audit, you were selected as a lead auditor together with your audit team to conduct a Quality Management System (ISO 9001:2008) audit on JESH Manufacturing organization. The following activities took place during the audit:

- a) During a Quality Management System (QMS) document review, you noted the organization procedure QAP 05, revision 3 states that when testing raw material RH 2005 for acceptance, the results became unreliable if the test samples are taken closer than 20 inches apart on the material. In the receiving inspection lab you notice an inspector carrying out an acceptance test on material RH 2005. You ask the inspector how the sample position on the material is selected. The inspector replies that they are taken 6 inches apart to avoid wasting material. Upon inquiring about the procedure, you were shown the inspector's copy of QAP 05, revision 2 on a shelf near the inspector's desk.
- b) In the maintenance department, work instruction TDWI 05 issue 3 which is clearly displayed at all work stations, five of the ten people in the department were not wearing the issued safety glasses when operating machinery equipment.
- c) In the quality manager's office, one of your audit team member's asks to see the schedule for internal audits. This schedule shows that each of the eight QMS processes is audited every six months. The auditor asks the quality manager how the prioritization of audits was decided. The manager says the system was set up three years ago and the organization has kept to this original schedule.
- d) In the QA department you saw three defective products on a desk. The QA Manager explains that these products came from products came from the production department because of problems in manufacturing. There is no identification on any of the three defective products or any indication of their inspection status. Further investigation was unable to locate any inspection records relating to the defective products.
- e) In the engineering department, your audit team member is shown procedure SOP P7.3 ENG which requires that all engineering drawings must be signed off by the draftsman and the engineering manager to prior to issue. He randomly examines a drawing, DWG 1446, revision 3 on the manager's desk and noticed that the 'compiled by' and 'approved by' boxes on it were not yet signed off. Later, in the mail room he comes across the same drawing with a distribution list attached.
- f) In the Quality Management Representative's (QMR) office, you flip through the management review minutes for the past year. You notice the last minutes was dated 28/11/2012 and the previous one dated 13/06/2010. When asked about the frequency of these reviews, the QMR said they were done when senior management were in town and definitely before an external audit.
- g) The jig fixture used for checking stamped plates on the production lines was badly maintained. Guide pins were unstable causing misalignment and the reflection surface for underside inspection was very dirty.
- h) On the drum filling line, the requirement of 50 drums per hour to be inspected was not being met. An average of 10 drums per hour was inspected between 3pm and 12 midnight.
- 1.1 Define the audit objectives and criteria with regards to the above case study. (5)
- 1.2 Produce an audit report stating the non-conformity, type of non-conformance (Major, Minor or Critical) and state the clause number from the ISO 9001:2008 standard which is/are not being implemented for each incident. (40)

1.3 In the Quality Management Representative's (QMR) office, you read through the management review minutes for the past year. You notice the last minutes was dated 28/11/2012 and the previous one dated 13/06/2010. When asked about the frequency of these reviews, the QMR said that they were done when senior management were in town and definitely before an external audit.

Study the non-conformance above and design and complete a corrective/preventative action report form. (10)

Note: Complete the root cause of the non-conformance, requirements for effective resolution and proposed action plan to correct the non-conformance.

1.4 State the overall conclusion of the audit conducted at JESH organization.

(5)

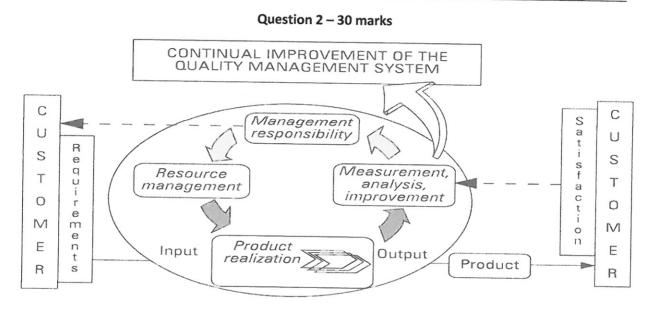


Figure 1

2.1 Discuss the quality management system identified in Figure 1.

- (10)
- 2.2 During the preliminary review, documentation is requested. Discuss **any five** of the documentation to be reviewed and investigated in this process. (10)
- 2.3 Interviews are important means of collecting information and should be carried out in a manner adapted to the situation and the person being interviewed. What aspects must be considered when conducting an interview? (10)

Question 3 - 30 marks

3.1 Auditors should possess the knowledge and skills necessary to achieve the intended results of the audits they are expected to perform. All auditors should possess generic knowledge and skills as well as discipline and sector specific knowledge and skills. Discuss in detail the generic knowledge and skills of management system auditors. (26)

3.2 "Greater costs arise when an audit is performed by untrained or unsuitable auditors". Critically analyse this statement.

Summary of ISO 9001:2008 Clauses

1.1 General

1.2 Application

All requirements of this international standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

4. Quality MS

4.1. General requirements

4.2 Document requirements

- 4.2.1 General
- 4.2.2 Quality Manual
- 4.2.3 Control of documents
- 4.2.4 Control of records

5. Management Responsibility:

- 5.1 Management Commitment
- 5.2 Customer focus
- 5.3 Quality Policy

5.4 Planning

- 5.4.1 Quality Objectives:
- 5.4.2 Quality Management System Planning

5.5 Responsibility, authority and communication

- 5.5.1 Responsibility and Authority
- 5.5.2 Management representative
- 5.5.3 Internal communication

5.6 Management Review

- 5.6.1 General
- 5.6.2. Review Input
- 5.6.3 Review Output

6. Resource Management

6.1 Provision of resources

6.2 Human Resources

- 6.2.1 General
- 6.2.2 Competence, awareness and training

6.3 Infrastructure

6.4 Work Environment

7. Product Realization

7.1 Planning of product realization

7.2 Customer-related processes

- 7.2.1 Determine of requirements related to the product
- 7.2.2 Review of requirements related to the product
- 7.2.3 Customer Communication

7.3 Design and development

- 7.3.1 Design and development planning
- 7.3.2 Design and development inputs
- 7.3.3 Design and development outputs
- 7.3.4 Design and development review:
- 7.3.5 Design and development verification
- 7.3.6 Design and development validation

7.4 Purchasing

- 7.4.1 Purchasing process
- 7.4.2 Purchasing information
- 7.4.3 Verification of purchased product

7.5 Production and service provision

- 7.5.1 Control of production and service provision
- 7.5.2 Validation of processes for production and service provision:
- 7.5.3 Identification and trace ability
- 7.5.4 Customer property
- 7.5.5 Preservation of product

7.6 Control and monitoring and measuring devices:

8. Measurement, Analysis and improvement

8.1 General

8.2 Monitoring and measurement

- 8.2.1 Customer Satisfaction
- 8.2.2 Internal Audit
- 8.2.3 Monitoring and measurement of processes
- 8.2.4 Monitoring and measurement of product

8.3 Control of non-conforming product

8.4 Analysis of data

8.5 Improvement

- 8.5.1 Continual improvement
- 8.5.2 Corrective Action
- 8.5.3 Preventative action