

FACULTY OF ENGINEERING AND BUILT ENVIRONMENT

Main 2019

DEPARTMENT OF QUALITY AND OPERATIONS MANAGEMENT

PROGRAMME BTECH: QUALITY

MODULE QUALITY AUDITING TECHNIQUES

CODE QAT44-2

DATE 21 November 2019

DURATION 3 hours

TIME 12h30

TOTAL MARKS 100

EXAMINER MR VM MOFOKENG

<u>INTERNAL MODERATOR</u> DR N SUKDEO

EXTERNAL MODERATOR PROF K RAMDASS

NUMBER OF PAGES 6 PAGES including cover page and Annexures

INSTRUCTIONS TO CANDIDATES:

- Please answer all questions.
- Question papers must not be handed in.
- 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.
- Annexure A Clauses of ISO 9001:2015
- The general University of Johannesburg policies, procedures and rules pertaining to written exam apply.

...Cont/

QUESTION ONE

During a stage one of the audit, you have been selected as a lead auditor together with your audit team to conduct a Quality Management System (ISO 9001:2015) audit on JC Manufacturing organization. The following activities occurred during the audit:

- a) During a Quality Management System (QMS) document review, you noted that the organization procedure QAP 05 revision 3, states that when testing raw materials for acceptance, the results became unreliable if the test samples are taken closer than 20 inches apart on the material RH 2005. In the receiving inspection laboratory, you notice an inspector conducting 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.
- 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 are audited every six months. The auditor asks the quality manager how the prioritization of audits are 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 mailroom 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 conducted 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 poorly 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.

Questions:

- 1.1 Draft an agenda for the opening meeting. [6]
- 1.2 Formulate an audit plan for the audit process of JC Manufacturing. [8]

| 1.3 | Identify <i>five</i> non-conformities observed at JC Manufacturing, and cross-r findings to ISO 9001:2015. | eference your [20] | | |
|------|--|---|--|--|
| | For each of the non-conformities that you have identified, briefly explain findings in the format as per the table below: | | | |
| Cl | nding ause assification orrective action | | | |
| 1.4 | Generate an agenda for the closing meeting and conclude on the findings. | [10] [44] | | |
| | QUESTION TWO | | | |
| 2.1 | Explain the principles of a quality audit. | [10] | | |
| 2.2 | In developing their internal audit programmes organisation should effectiveness of their audit process and minimise their audit risk by adopting approach to auditing. Examine how an organisation can achieve this. | | | |
| 2.3 | Distinguish between: | | | |
| | 2.3.1 preventive action and corrective action | [2] | | |
| | 2.3.2 auditor and auditee | [2] | | |
| | 2.3.3 audit criteria and audit evidence | [2] | | |
| | 2.3.4 conformity and nonconformity | [2] | | |
| | 2.3.5 audit scope and audit plan | [2] | | |
| | | [30] | | |
| | QUESTION THREE | | | |
| Refe | r to Figure 1 | | | |
| 3.1 | With reference to clause 5.3.3 in ISO 19011:2012, determine the procedure to be addressed in an audit programme. | /ith reference to clause 5.3.3 in ISO 19011:2012, determine the procedures which need be addressed in an audit programme. [8] | | |
| 3.2 | According to clause 6.8 in ISO 19011:2012, discuss how an audit follow up | According to clause 6.8 in ISO 19011:2012, discuss how an audit follow up is conducted? [6] | | |
| 3.3 | With reference to clause 7.2.3.4 in ISO 19011:2012, critique the knowledge a quality management systems audit team leader. | and skills of [7] | | |

The following non-conformances were noted during an audit of XYZ Industries. Identify

the clause that is applicable to the following non-conformances:

3.4

Eg: A – 8.1

[5]

| Α | There was not enough light in the lab to determine whether measuring | | |
|---|---|--|--|
| | instruments were reading correctly. | | |
| В | The sales department did not inform despatch that the client had changed the | | |
| | delivery date to an earlier date, due to pending international order. | | |
| С | The purchasing department does not always include all required information | | |
| | on purchase orders. | | |
| D | Production work instructions were kept in the Production manager's office but | | |
| | the office is closed during the night shift. | | |
| Е | Flammable products were not stored in accordance with regulatory | | |
| | requirements. | | |

[26]

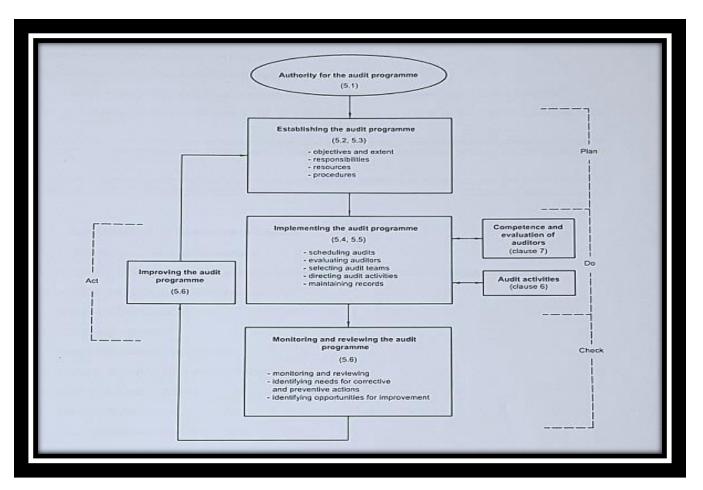


Figure 1

Annexure A

Summary of ISO 9001:2015 Clauses

1. Scope

Describes the scope of the management system

2. Normative reference

References other relevant standards which a valuable for the implementation of this document

3. Terms & definitions

Section 3 contains definitions some of which are common. All terms & definitions are contained in ISO 9000:2015

4. Context of the organisation

- 4.1 Understanding
- 4.2 Understanding needs & expectations of interested parties
- 4.3 Determining scope of the quality management system
- 4.4 QMS and its processes

5. Leadership

- 5.1.1 Leadership & commitment to the quality management system
- 5.1.2 Customer focus

5.2 Policy

- 5.2.1 Developing the quality policy
- 5.2.2 Communicating the quality policy
- 5.3 Organisational roles, responsibilities & authorities

6. Planning

- 6.1 Actions to address risk & opportunities
- 6.2 Quality objectives & planning to achieve them
- 6.3 Planning of changes

7. Support

7.1 Resources

- 7.1.1 General
- 7.1.2 People
- 7.1.3 Infrastructure
- 7.1.4 Environment for the operation of processes

7.1.5 Monitoring & measuring resources

- 7.1.5.1 General
- 7.1.5.2 Measurement traceability
- 7.1.6 Organisational knowledge

7.2 Competence

- 7.3 Awareness
- 7.4 Communication

7.5 Documented information

- 7.5.1 General
- 7.5.2 Creating & updating
- 7.5.3 Control of documented information

8. Operation

8.1 Operational planning & control

8.2 Requirements for products & services

- 8.2.1Customer communication
- 8.2.2 Determination of requirements for products & services
- 8.2.3 Review of products & services
- 8.2.4 Changes to requirements for products & services

8.3 Design & development of products & services

- 8.3.1 General
- 8.3.2 Design & development planning
- 8.3.3 Design & development inputs
- 8.3.4 Design & development controls
- 8.3.5 Design & development outputs
- 8.3.6 Design & development changes

8.4 Control of externally provided processes, products & services

- 8.4.1 General
- 8.4.2 Type & extent of control of external provision
- 8.4.3 Info for external providers

8.5 Production & service provision

- 8.5.1 Control of production & service provision
- 8.5.2 Identification & traceability
- 8.5.3 Property belonging to customers or external providers
- 8.5.4 Preservation
- 8.5.5 Post-delivery activities
- 8.5.6 Control of changes
- 8.5.7 Control of non-conforming process outputs, products & services

8.6 Release of products & services

9.1Monitoring, measurement, analysis & evaluation

- 9.1.1General
- 9.1.2 Customer satisfaction
- 9.1.3 Analysis & evaluation

9.2. Internal audit

9.3 Management review

- 9.3.1 General
- 9.3.2 Management review inputs
- 9.3.3 Management review outputs

10. Improvement

- 10.1 General
- 10.2 Non-conformity & corrective action
- 10.3 Continual improvement