



MACHAKOS UNIVERSITY

University Examinations 2022/2023

SCHOOL OF PURE AND APPLIED SCIENCES

DEPARTMENT OF PHYSICAL SCIENCES

SECOND YEAR FIRST SEMESTER EXAMINATION FOR
BACHELOR OF SCIENCE (ANALYTICAL CHEMISTRY)

SAN 201: QUALITY ASSURANCE AND LABORATORY MANAGEMENT

DATE:

TIME:

INSTRUCTIONS:

- The paper consists of **two** sections.
- Section **A** is **compulsory** (30 marks).
- Answer any **two** questions from section **B** (each 20 marks).

SECTION A

QUESTION ONE (30 MARKS)-COMPULSORY

- (a) Differentiate between the following terms as used in the perspective of quality assurance in the laboratory
- Quality and quality management system ISO 9001 (2 marks)
 - Method validation and method verification as used in qualitative and quantitative analysis. (2 marks)
 - Precision and accuracy as used in qualitative and quantitative analysis. (2 marks)

- iv. ISO 15189:2007 and ISO/IEC 17025:2015 as used in understanding quality assurance/management. (2 marks)
- (b) Define the term EQA and explain the five principal characteristics of EQA. (6 marks)
- (c) Employees should have a periodic formal appraisal of their overall performance in the laboratory. This is broader than competency assessment in the laboratory. State four elements which should be appraised. (4 marks)
- (d) Successful purchasing and inventory management requires that policies and procedures be established for managing all critical materials and services.
- i. Define the term quantification. (2 marks)
- ii. Explain two methods of quantification as applied in purchasing and inventory management. (4 marks)
- (e) Dr. Azariah is an analytical chemist working with Kenya Bureau of Standards in the Chromatography laboratory. His daily activities involve analysis of pesticide residues. Prior to testing his samples, it is important to evaluate the performance of new equipment to ensure it is working correctly with respect to accuracy and precision. Name and elaborate the two techniques applied in checking performance of laboratory instruments. (6 marks)

QUESTION TWO (20 MARKS)

- (a) Hospital laboratories should establish sample rejection criteria and follow them closely. It is sometimes difficult to reject a sample, but remember that a poor sample will not allow for accurate results. It is the responsibility of the hospital laboratory to enforce its policies on sample rejection so that patient care is not compromised. Explain two categories of samples that can be rejected by the hospital laboratory. (2 marks)
- (b) Assessment or auditing of a laboratory is a very critical exercise for confirming the performance of a laboratory with regards to provision of quality services to its customers or provision of reliable results.
- (i) Explain the terms external audits.
- (ii) Internal audits
- (iii) Assessment as used in checking the performance of a laboratory. (6 marks)

- (c) Assuring accuracy and reliability throughout the path of workflow depends on good management of all of the 12 quality essentials. Provide and explain 6 important quality essentials used in ensuring quality assurance in the laboratory. (6 marks)
- (d) Quality control materials are run to quantify the variability and establish a normal range, and to decrease the risk of error. The variability of repeated measurements will be distributed around a central point or location. Explain three commonly calculated measures of central tendency and measure of variability in the laboratory. (6 marks)

QUESTION THREE (20 MARKS)

- (a) Proficiency testing is a critical technique for ensuring accurate and reliable test results in the laboratory. Name two disadvantages of proficiency testing as a technique. (2 marks)
- (b) Name and explain the purpose of four personal protective equipment (PPEs) used in the laboratory for safety (4 marks)
- (c) The laboratories of a research institution must be equipped with the state of art equipment for smooth operations. A great deal of thought and planning should go into equipment management. Discuss three elements which should be considered by the laboratory implementing an equipment management programme (6 marks).
- (d) External and internal audits are critical steps in the laboratory assessment process. The quality manager or other designated qualified personnel should organize the internal audit following certain steps for a comprehensive assessment and quality of work. Name and discuss the eight steps the quality manager should undertake to organize the internal audit. (8 marks)

QUESTION FOUR (20 MARKS)

- (a) A periodic visit by evaluators for on-site laboratory assessment is a type of EQA that has been used when other methods of EQA are not feasible or effective. State three advantages of on-site visit of laboratory by evaluators (3 marks)
- (b) State three benefits of accreditation to a laboratory (3 marks)
- (c) Explain the working of the Levey-jennings charts in interpreting reliability of laboratory test results (8 marks)

- (d) The laboratory should keep a register of all incoming samples. A master register may be kept, or each laboratory may keep its own sample register. Name and explain six contents which must be included in the sample register when considering laboratory quality assurance (6 marks)

QUESTION FIVE (20 MARKS)

- (a) Explain what you understand by the terms. (4 marks)
- i. Training
 - ii. Retraining
 - iii. Cross-training
 - iv. Continuing education as used in developing laboratory competency
- (b) Accreditation is critical for any laboratory seeking international and national recognition for its activities. Explain the accreditation steps detailing the activities involved in each step. (6 marks)
- (c) Quality assurance in the laboratory involves commitment of all personnel working in the laboratory. Name and state three roles of each personnel working in the laboratory. (6 marks)
- (d) In order to understand whether client needs are being met, a laboratory needs to employ tools for gaining information. It needs to actively seek information from customers, rather than just waiting for customers to contact the laboratory with a complaint. Explain four ways which can be used to obtain customer satisfaction. (4 marks)