



MACHAKOS UNIVERSITY

University Examinations for 2021/2022 Academic Year

SCHOOL OF PURE AND APPLIED SCIENCES

DEPARTMENT OF PHYSICAL SCIENCES

SECOND YEAR FIRST SEMESTER EXAMINATION FOR THE DEGREE OF

BACHELOR OF SCIENCE (ANALYTICAL CHEMISTRY)

SAN 201: QUALITY ASSURANCE AND LABORATORY MANAGEMENT

DATE: 8/12/2021

TIME: 11:00 – 1:00 PM

INSTRUCTIONS:

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

QUESTION ONE COMPULSORY (30 MARKS)-~~compulsory~~.

- a) Differentiate between the following terms as used in the perspective of quality in the laboratory
- (i) Laboratory handbook and Path of workflow (2 marks)
 - (ii) Method validation and method verification as used in qualitative and quantitative analysis. (2 marks)
 - (iii) Repeatability and reproducibility as used in understanding quality assurance/management. (2 marks)
- b) Assuring accuracy and reliability throughout the path of workflow depends on good management of all of the 12 quality essentials. Name and briefly explain 6 important quality essentials used in ensuring quality assurance in the laboratory. (6 marks)
- c) Safety in the laboratory is critical for all stakeholders involved with the view of accurate and reliable results. Name and explain four ~~factors, that~~ factors that must be part of a quality management of facilities and safety. (4 marks)
- d) To identify where improvements in laboratory design may be needed in order to prevent or reduce risks of cross-contamination, one needs to follow the path of the samples ~~it~~ moves through the laboratory during examination phases of analysis. Name and explain four critical pathways of samples during examination. (4 marks)
- e) Engineer Azariah is a chemical engineer 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)
- f) 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)

Commented [DN1]: Workflow path or path of workflow?

Commented [DN2]: Move marks to the end for all questions

QUESTION TWO (20 MARKS):

- a) Accurate laboratory test results depend on staff being competent in performing a range of procedures that occur throughout the entire examination process. Explain your understanding on the terms competency and competency assessment. (2 marks)
- b) Poor performance in the laboratory may not always be due to technical incompetence. Explain other six factors that may cause poor performance in the laboratory. (6 marks)
- c) In order to understand whether client needs are being met, the laboratory will need to employ tools for gaining collecting this information through active engagement of. The laboratory needs to actively seek information from customers rather than just waiting for customers to contact the laboratory with a complaint. Name and explain six tools which can provide important information on customer satisfaction. (6 marks)
- d) If the laboratory performs poorly on EQA, the problems may lie anywhere along the path of workflow requiring. All the aspects of the process will need to be checked. Identify Some six examples of problems that may be associated with poor performance on EQA. (6 marks)

Commented [DN3]: Provide the full name for EQA

QUESTION THREE (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. Explain four advantages of using on-site evaluation as an EQA method. (4 marks)
- b) When the quality control sample that is used in a test run is out of the acceptable range, the run is considered to be out of control. Name and explain two steps that must be followed by the laboratory when results are out of control. (4 marks)
- c) Machakos University is an institution of higher learning mandated to offer quality teaching and research. To execute this mandate, the laboratories must be equipped with the state of art equipment for smooth operations. A great deal of thought and planning should go into equipment management. Name and explain three elements which should be considered by the laboratory in implementing an equipment management programme. (6 marks)

- d) The internal audit is a valuable tool in a quality management system. Name and explain six benefits that result from internal audit as a tool in ensuring quality assurance in the laboratory. (6 marks)

QUESTION FOUR (20 MARKS)

- a) Explain the working of the Levey-jennings charts in interpreting reliability of laboratory test results. (4 marks)
- b) Using examples, differentiate between quality control materials and calibrators. (4 marks)
- c) 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)
- d) An occurrence is any event that has a negative impact on an organization, which includes personnel, product, equipment or the environment. The laboratory should develop a system for prompt investigation of every laboratory problem or error. State the six steps involved in management of occurrences in the laboratory. (6 marks)

QUESTION FIVE (20 MARKS)

- a) In many laboratories, a simple computerized system can be set up for management of inventory reagents and consumables. There are many advantages of using computerized inventory management. Name and explain five advantages of using the computer to manage laboratory reagents and consumables. (4 marks)
- b) 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~~ laboratory. (6 marks)

- c) 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)
- d) All laboratory staff must understand the importance of customer satisfaction. Laboratory personnel must always interact with customers in a way that is appropriate, providing needed information, and being courteous. Name and explain four factors that are required while seeking customer satisfaction. (4 marks)