MACHAKOS UNIVERSITY

University Examinations 2019/2020Academic year

SCHOOL OF PURE AND APPLIED SCIENCES

DEPARTMENT OF PHYSICAL SCIENCES

THIRD YEAR FIRST SEMESTER EXAMINATION FOR

BACHELOR OF SCIENCE IN ANALYTICAL CHEMISTRY

SAN 201: QUALITY ASSURANCE AND LABORATORY MANAGEMENT

DATE: **TIME:**

INSTRUCTIONS TO CANDIDATES

1. **This paper contains five (5) questions.**
2. **Answer question one (compulsory) and any other two questions.**

QUESTION ONE (30 MARKS) COMPULSORY

a) Differentiate between the following terms as used in environmental analysis of samples

   a) Qualitative Management and Quality System as defined by ISO 9001 (2 marks)

   b) Precision and accuracy as used in qualitative and quantitative analysis (2 marks)

   c) ISO 9001:2001 and ISO/IEC 17025:2005 as used in understanding quality assurance/management (2 marks)

b) Name any three officers who are critical in ensuring safety of the laboratory and explain at least two roles undertaken by each one of them (6 marks)

c) Successful purchasing and inventory management requires that policies and procedures be established for managing all critical materials and services. Name and explain six key components applied for successful purchasing and inventory management in a laboratory (6 marks)

d) Dr Ndege is a chemical analyst 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)

e) As with quantitative procedures, it is important to verify that results of qualitative and semi-quantitative examinations are correct prior to reporting them to the requesting health care provider. Conducting quality control for many of these tests is not as easily accomplished as with quantitative tests. Therefore, it becomes essential that other processes within the quality system are carefully conducted, in addition to traditional QC methods. Name and explain some six important overarching concepts for quality that apply to qualitative and semi-quantitative tests. (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 Nairobi hospital laboratory to enforce its policies on sample rejection so that patient care is not compromised. Explain four categories of samples that can be rejected by the Nairobi hospital laboratory (4 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. Explain the terms external audits, internal audits and assessment as used in checking the performance of a laboratory (6 marks)

c) Sampling is a very critical step in ensuring quality of laboratory results. Explain the terms stratified sampling and random sampling as used in sampling process (4 marks)

d) 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 when the laboratory putting in place an equipment management programme (6 marks)

QUESTION THREE (20 MARKS).

a) Graphical representation for control ranges is important for reliability of test results. Once the appropriate range of control values has been established, the laboratory will find it very useful to represent the range graphically for the purpose of daily monitoring. The common method for this graphing is the use of Levey–Jennings charts. Explain what you understand by Levey-Jennings charts as a method (4 marks)

b) Name and explain the purpose of four personal protective equipment (PPEs) used in the laboratory for safety (4 marks)

c) Differentiate between quantitative examination and qualitative examination as used in quality control principle (4 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) Proficiency testing, or PT, has been in use by laboratories for many years. It is the most commonly employed type of External Quality Assessment, as it is able to address many laboratory methods. PT is available for most of the commonly performed laboratory tests, and covers a range of chemistry, hematology, microbiology and immunology testing. Most laboratorians are familiar with the PT process, and many laboratories employ some kind of PT. Explain what you understand by the term PT and also explain the activities of undertaking a PT process (6 marks)

b) Define material safety data sheet (MSDS) and name at least three critical contents which must be outlined in a MSDS by manufacturers involved in production of laboratory chemicals. (5 marks)

c) Explain your understanding on the terms Internal Quality Assessment and External Quality Assessment. Explain the three methods used to elaborate EQA. (9 marks)

QUESTION FIVE (20 MARKS)

a) Explain what you understand by the terms accreditation and certification as used by standardization bodies (4 marks)

b) Name three standardization bodies/organizations recognized for accreditation and certification purposes (3 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 (5 marks)

d) What do you understand by the term competency assessment as applied in the laboratory? (2 marks)

e) 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 six ways which can be used to obtain customer satisfaction (6 marks)