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University Examinations 2024/2025

FOURTH YEAR FIRST SEMESTER EXAMINATION FOR THE DEGREE OF BACHELOR OF MEDICAL LABORATORY SCIENCES

HML 3415: LABORATORY QUALITY SYSTEMS

DATE: JANUARY 2025 **TIME: 3 HOURS**

INSTRUCTIONS:
Answer ***All*** *questions*
Ensure that all your answers are properly numbered
Part I multiple Choice Questions (MCQ): Write the correct answer on the space provided in the answer booklet. Each MCQ is one mark
Part II: Short Answer Questions – Answer questions following each other on the answer booklet
Part III: Long Answer Questions – Answer each question on the answer booklet

SECTION A: MULTIPLE CHOICE QUESTIONS (20 marks)

1. In order to determine if an employee can perform a particular examination correctly in the laboratory, the manager should:

a. Write a job description
b. Orient the employee in the laboratory's processes and procedures
c. Review the employee's qualifications
d. Perform a competency assessment

2. The role of the quality manager usually includes:
   a. Running quality control samples as a part of the testing process
   b. Monitoring all aspects of the quality system
   c. Assuring that adequate resources are available for quality system processes and procedures
   d. Hiring highly competent staff for the laboratory
3. All of the following statements are true EXCEPT:
   a. Confidentiality of patient information is a goal of quality management
   b. Information management always requires a computerized system
   c. Managing patient information using a computerized system requires frequent backup of data
   d. A test report should include special information about any irregularities with the sample
4. The probability that a given control value will fall within + 2 SD of the established mean is:
   a. 68.2%
   b. 99.7%
   c. 95.5%
   d. 92.5%
5. Written policies, processes, and procedures are necessary for all of the following reasons EXCEPT:
   a. Verbal instructions may be misunderstood
   b. Laboratory inspectors require it
   c. They record data or information about what happened, and are not revised or modified
   d. Reproducibility of results is improved
6. The source of Plan, Do, Check, Act as a means of process improvement was:
   a. ISO 15189
   b. W. Edwards Deming

c. CLSI

d. Six Sigma

7. In the context of quality management, an occurrence is defined as:

a. Every process in which the laboratory is involved

b. Any negative event that can lead to a laboratory error

c. Any positive event that leads to laboratory improvement

d. A problem in the testing process

7. Who among the following is not an immediate customers of the medical laboratory

a. Patient

b. Health care provider / physician

e. Public health officials

d. School

8. In order to determine if an employee can perform a particular examination correctly in the laboratory, the manager should:

a. Write a job description

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9. Which of the following statements is true?

a. Standards organizations can never serve as accrediting bodies

b. Certification is the procedure by which an independent body gives written assurance that a product, process or service conforms to specific requirements

c. Most standards for laboratory practice are developed by local government agencies

d. Only one international standards organization is recognized by all countries for quality management of laboratories

10. All of the following are external quality assurance methods EXCEPT:
    a. Proficiency testing
    b. On-site evaluations from an external agency
    c. Quality control of quantitative testing
    d. Retesting or rechecking samples exchanged between laboratories
11. When conducting an external assessment, auditors will:
    a. Only assess the processes related to the examination phase of testing.
    b. Compare the laboratory's practices with established standards
    c. Keep their results secret until they file a report to the health department
    d. Always audit the entire laboratory processes and procedures
12. Qualitative examinations are those that:
    a. Use methods with little likelihood of error
    b. Produce non-numerical results
    c. Use statistical tools to establish normal ranges
    d. Are only found in textbooks
13. Calibrators have the following characteristics/functions:
    a. Contain a known amount of the analyte being tested
    b. Monitor the quality of reagents
    c. Monitor the quality of the sample
    d. Prevent equipment failure
14. One of the most difficult aspects of the sample management process for the laboratory to monitor is:
    a. Patient identification
    b. Preservation of samples
    c. Controlling time of collection of sample
    d. Reporting results

15. When developing policies and procedures for purchasing and inventory, which of the following is a true statement:
    a. Store the latest shipment of reagents at the front of the shelves to ensure the freshest reagents are used first.
    b. Materials used should be tracked to individual patients in case repeat testing is required
    c. Since everyone is responsible for maintaining supplies, it is not necessary to assign one person to manage the inventory
    d. Computerized inventory methods are always better than paper systems
16. When selecting laboratory equipment, important factors to consider are (check all that apply):
    a. Ease of operation
    b. Performance specifications
    c. Repair cost
    d. Aesthetics
17. Why is it important to know the pathway of the sample through the laboratory?
    a. To make sure it doesn't get lost
    b. To identify where improvements in laboratory design may be needed
    c. To assess laboratory workload
    d. To identify staff that need additional training
18. The rationale for implementing an overall quality management system in the laboratory is to:
    a. Prevent any possibility of testing error
    b. Differentiate between qualitative and quantitative methods
    c. Prevent potential errors in the laboratory's path of workflow
    d. Help to ensure that testing performed by the laboratory is accurate and reliable
19. A rule of thumb in equipment maintenance and management is:
    a. Always purchase the least expensive equipment

b. Develop criteria for troubleshooting, service, and repair

c. Only train managers in calibration of equipment

d. Perform all function checks daily

20. Sources of continuing education of laboratory employees should include:

a. Only internal laboratory resources

b. Only external laboratory experts

c. Both internal and external resources

d. Only manufacturer's technical representatives

SECTION B: SHORT ANSWER ALL QUESTIONS (40 MARKS)

1. List the implementation steps for an inventory management programme (5 marks).
2. Briefly explain how you will be determining the quantity of laboratory consumables to order when you become a laboratory manager (5 marks).
3. Define the following terms in the context of laboratory quality management systems (5 marks)

   a) Calibration

   b) Precision

   c) Accuracy

   d) Internal quality control

   e) External quality assurance
4. Briefly explain with an illustration the use of Levey-Jennings chart in quality control (5 marks).
5. Describe the characteristics of a control material (5 marks).
6. Describe the need for laboratory norms and standards (5 marks)
7. Give five parameters used to verify microbiological media performance (5 marks).

8. List the steps of orienting a new hire into the medical laboratory to promote quality management (5 marks)

SECTION C: LONG ANSWER TWO QUESTIONS (40 MARKS)

1. Discuss the 12 quality system essentials in the quality management system model that must be addressed to produce accurate, reliable, and timely laboratory results in a medical laboratory (20 marks)
2. Explain with examples the role of international standards organizations for laboratories in promoting quality in medical laboratories (20 marks)
3. Explain with illustrations the implementation steps for quantitative and qualitative quality control in a medical laboratory (20 marks)