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QUIZ – UNDERSTANDING ISO/IEC 17025

Name: _____ Place: _____

Date: _____

Section 1 – True/False

Each question is worth 1 mark

The quiz questions below are to be answered with a **T** (True) or **F** (False) in the box provided.

		Answer
1.	Conformity of Process is one of the principles behind ISO/IEC 17025	
2.	A quality system that conforms to ISO/IEC 17025 includes a program for continual improvement.	
3.	The aim of Clause 8.3, - Document Control, is to minimize unnecessary distribution of procedures.	
4.	Document control puts the right document into the right hands.	
5.	Records do not need to be controlled – only documents.	
6.	Continual improvement requires a laboratory to identify and track corrective action.	
7.	All parts of a laboratory quality system must be documented	
8.	Opportunities for improvement do not need to be identified or tracked.	
9.	Preventive action and corrective action can follow the same approach	
10.	Continual improvement includes procedures for conducting internal audits	
11.	Management review does not need the input of top management	
12.	Internal audits are only necessary for the years the laboratory is not assessed.	
13.	Accommodations and equipment must always be monitored to prevent invalidation of test results	
14.	Samples do not need to be tracked throughout the laboratory	
15.	It is not possible to specify how a client must conduct sampling	
16.	If the method has been published in a standard, it does not need to be validated.	
17.	Uncertainties must be estimated for all non-numerical measurements.	
18.	Laboratories can estimate uncertainties using statistical methods.	
19.	“Uncertainty” is not a component of the Decision Rule.	
20.	Auditors and assessors should have access to all personnel records during the conduct of their audits/assessments.	

Section 2 – Multiple Choice

Each question is worth 1 mark

Circle the correct answer for each question in this Section. There is only **one correct** answer for each question.

21. A quality manager (or management representative) is a staff member who has responsibility for the laboratory quality system, its implementation and who, in this capacity:

    a. Approves internal audit schedules.
    b. Arranges for the training of auditors.
    c. Sets laboratory quality objectives.
    d. Reports directly to top management.

22. A master document list is required to record the following:

    a. Location and status of only lab documents
    b. Identification and approval of all external documents
    c. Determine the expected duration of the validity of a document
    d. Location and status of all documents used in the lab that are referenced in the quality system

23. The following feedback mechanisms are required in 17025:

    a. Publish all feedback on the website.
    b. Record all feedback
    c. Respond to all feedback
    d. Ignore all feedback

24. Management review, according to ISO/IEC 17025, requires examination of how many different issues/items:

    a. 7
    b. 13
    c. 11
    d. 19

25. Which requirement specifically states the frequency of laboratory internal audits?

    a. 17025 does not specify a frequency for internal audits.
    b. Clause 8.8 of ISO/IEC 17025
    c. Clause 8.7 of ISO/IEC 17025
    d. Our accreditation body interprets APLAC TC 002 to require labs to undertake internal audit every year

26. What are some of the considerations in metrological traceability?

    a. Specification of the measurand, unbroken chain of measurement, use of appropriate methods.
    b. Systematic error, use of appropriate decision rule, use of OIML R 111 class weights.
    c. Self-declaration of competence, unbroken chain of measurement, specification of the measurand.
    d. CIPM MRA, Joint Declaration on Legal Metrology, unbroken chain of measurement.

27. Why is the standard called ISO/IEC 17025 and not ISO 17025?

    a. IEC paid money to the ISO to publish it
    b. IEC participates with ISO in its development as part of CASCO
    c. ISO is not the real copyright holder of ISO/IEC 17025
    d. ILAC insisted that ISO allow the IEC name to appear in the standard

28. What is the meaning of the term ISO?

    a. It is an acronym for the International Standardization Organization.
    b. It is the acronym for the International Standards Organization
    c. It is the Greek for “the same” or “equal.”
    d. It means that the organization is really isolated from government influence

29. What is the aim of ISO/IEC 17025?

    a. It is to allow governments to accredit laboratories
    b. It is to provide the tools that allow laboratories to produce consistent, technically valid results.
    c. It is to allow laboratories to enter foreign markets
    d. It is to force laboratories to use quality systems

30. Traceability of measurement applies to:

    a. calibration laboratories only
    b. only physical measurement devices only
    c. all measurement devices and certified reference materials and standards
    d. all equipment which contributes to the overall uncertainty of the measurement.

31. ISO/IEC 17025 contains the following types of requirements:

    a. Management system and technical requirements
    b. Management system and process requirements
    c. Quality system and technical requirements
    d. Leadership and management requirements

32. Accreditation bodies conduct laboratory assessments:

    a. Against ISO/IEC 17025 alone
    b. Against ISO 9001 alone
    c. Against ISO/IEC 17011 and ISO/IEC 17025
    d. Against ISO/IEC 17025 and other accreditation requirements documents

33. The Principle of “Capacity” is described as:

    a. The people with the skills and knowledge,
    b. The environment with the facilities and equipment
    c. The quality control and the procedures
    d. All of the above.

34. Traceability includes three components for each step in the traceability chain:

    a. Uncertainty, calculation, documentation
    b. Calibration, uncertainty, traceability
    c. Documentation, registration, reference to the SI
    d. Calibration, uncertainty, competence

35. Documents and records acquired or created during testing and calibration work:

    a. Are the property of the client.
    b. Are to be retained for future reference by the assessors.
    c. Are to be sent to the accreditation body
    d. Are to demonstrate conformance to laboratory procedures.

36. Once a non-conforming condition is **observed**, the laboratory should first:

    a. Determine the level of conformance of the process when compared to requirements
    b. Find as many non-conformances as possible
    c. Understand the process under review as it is understood by the person responsible for it
    d. Allocate blame for the non-conformance

37. Infernal audits are conducted to determine:

    a. The conformance of laboratory operations to its own QMS and 17025
    b. The conformance of laboratory operations with ISO 9001
    c. The financial stability of the laboratory
    d. The best suppliers of reference materials

38. The following are Principles behind ISO/IEC 17025:

    a. Impartiality of Conduct, Objectivity of Results, Transparency, Process Approach
    b. Scientific Method, Capacity, Customer Focus, Objectivity of Results,
    c. Involvement of People, Exercise of Responsibility, Transparency, Traceability of Measurement
    d. Scientific Method, Objectivity of Results, Transparency, Traceability of Measurement

39. The VIM definition of Measurement Traceability includes the following components:

    a. Uncertainty of measurement, calculation, reference to the SI, documentation
    b. Calibration intervals, uncertainty of measurement, unbroken chain of comparisons, competence
    c. Documentation, registration, reference to the SI, calibration intervals
    d. Reference to the SI, calibration intervals, resolution of measurement, competence

40. The object of the Decision Rule is:

    a. Determine the level of conformance of the object of testing/calibration to the specification
    b. Relieve the client of responsibility in making compliance statements
    c. Explain the lab result to a person not knowledgeable of the science
    d. Protect the health, safety, and welfare of users of the object of testing/calibration.