Answer Key.

Technical Asst. (Instrumb) A-B.
Quality Cell.

SREE CHITRA TIRUNAL
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BIOMEDICAL TECHNOLOGY WING
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Technical Assistant (Instruments) A to B **Time : 60 Min**

Choose the most appropriate answer and write it as capital A, B, C, D in the answer sheet provided.
There is NO negative marking.

S. No	Question	Answer
1	Clause 7.7 of ISO/IEC 17025 relates to: A. sampling B. ensuring the validity of results C. complaints D. control of data and information management	B
2	Clause 6.2 of ISO/IEC 17025 relates to: A. personnel B. equipment C. metrological traceability D. externally provided products and services	A
3	ISO/IEC 17025 requires that management reviews: A. must be held at least annually B. must take place in a meeting attended by top management C. are chaired by the Quality Manager D. determine whether current policies are effective in helping the organisation to achieve its objectives	D
4	First edition of ISO 17025 was in the year A. 1998 B. 1999 C. 2000 D. 2005	B
5	ISO/IEC 17025: A. requires that every item of measurement and test equipment is calibrated B. requires all measuring equipment to carry clear calibration labels physically on it C. allows non-calibrated equipment to be used for indication purposes (e.g. electric light bulb test) D. requires regular eye tests for all personnel carrying out visual inspection	C
6	According to ISO/IEC 17025 A. all methods shall be fully validated by the laboratory B. method validation or verification is not required for methods published by reputable external organisations (e.g. ISO, ASME, ASTM etc.) C. all methods shall be validated using traceable reference standards	D

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	D. non-standard methods are required to be validated	
7	What does 'PDCA' stand for? A. Plan, Do, Check, Act B. Plan, Design, Confirm, Action C. Plan, Do, Critique, Appraisal D. Prepare, Do, Critique, Analyse	A
8	Adequacy audit is A. to check that any documented policies, quality manual and procedures meet the requirements B. to check whether the equipments are calibrated C. to check whether the system is in place D. to check whether the test reports meet the requirements	A
9	What does ISO 9000:2015 describe? A. The fundamental concepts, principles and vocabulary of quality management B. How ISO 9001:2015 should be applied within an organisation C. How an organisation can achieve sustained success by a quality management approach D. None of the above	A
10	Where the evaluation indicates that the nonconforming work could reoccur, or that there is doubt about the conformity of the laboratory operations within its own management system, the laboratory shall ... A. implement corrective action B. complete a written detailed report C. raise an issue log D. escalate to UKAS	A
11	Evaluation of measurements or tests on the same or similar items within the same laboratory is A. Interlaboratory comparison B. Intralaboratory comparison C. Proficiency testing D. Validation	B
12	ISO/IEC 17025 Clause 7.1.1 requires that work may only be conducted by an external provider (subcontracted): A. if the customer has been notified B. if the provider is ISO/IEC 17025 accredited C. in emergencies D. if it is cost-effective to do so	A
13	What can compromise impartiality within a laboratory? A. Business relationships between the laboratory and the client B. Financial pressures C. Pressures from personnel D. All of the above	D
14	Clause 7.6 of ISO/IEC 17025 relates to: A. evaluation of measurement uncertainty B. technical records C. ensuring the validity of results D. reporting of results	A

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15	A control limit A. Indicates the boundary of the bell curve in a normal distribution B. Indicates that a process event or measurement is likely to fall within that limit C. Indicates that a process event or measurement is likely to fall outside that limit D. Indicates the customer's desired upper or lower performance limits	B
16	Who accredits laboratories? A. UKAS B. Certification Bodies (e.g. BSI, LR, SGS) C. Companies D. Other	A
17	The latest revision of ISO 17025 is A. First edition B. Second edition C. Third edition D. Fourth edition	C
18	Within ISO/IEC 17025, 'impartiality' is defined as; A. presence of objectivity' B. equal treatment to all evidence provided' C. unbiased to results presented' D. free of judgement'	A
19	The main section in ISO/IEC 17025:2017 refers to ..... A. Structural mainly on organization structure B. Resource requirements on what is needed for good operation C. Management requirements related to the operation and effectiveness of the quality management system D. Process requirements E. All Of The Above	E
20	"Duties & responsibilities of all staff MUST be documented Must be signed by the immediate Superior & staff Updated at least once a year subjected to organizational changes Written in an easy to understand and simple language" **The above statements refer to which of the following document in a Laboratory Quality Management System?** A. Lab Quality Manual B. Lab Quality Policy C. Lab SOP D. Lab personnel Job Description (JD)	D
21	Comparison of an item to a standard that is closer to SI, also known as a higher level standard. Third party laboratories will issue a certificate which is normally valid for a period of one year. Done by external third party service provider. A sticker is issued by the third party provider that is pasted on the equipment. **The above statements refer to which of the following activity in a Laboratory Quality Management System?** A. Verification B. Calibration C. Preventive Maintenance D. Breakdown servicing & repair	B

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22	Organization need to develop processes and establish documented procedure to control externally provided products and services. This control can be achieved by the following means EXCEPT ..... A. Documenting the process in a SOP B. Supplier/Vendor Quality Survey Questionnaire C. Outgoing Finished Product Testing D. Supplier/Vendor Audit	C
23	Frequency based on equipment usage such as daily or weekly. Typically performed by internal lab personnel. No sticker is issued or pasted on equipment. Recorded manually in log book or in PC. 3-5 data per measurement for averaging. **The above statements refer to which of the following activity in a Laboratory Quality Management System?** A. Verification B. Calibration C. Preventive Maintenance D. Breakdown servicing & repair	A
24	A pictorial diagram showing possible causes (process inputs) for a given effect (process outputs) A. Yoshida diagram B. Fishbone diagram C. Random Experiment diagram D. Scatter Diagram	B
25	Training record for lab personnel must also include assessment on effectiveness of training conducted such as _____ A. Written assessment or exam B. Observation by Supervisor on improvement post training C. Verbal Quiz during class D. All of the above	D
26	What is the purpose of ISO/IEC 17025:2017 A. It is to allow government to accredit laboratories B. It is to allow laboratories to enter foreign market C. It is to force laboratories to use quality system D. Iy is to provide the tool that allow laboratories to produce consistent, technically valid results	D
27	Master schedule contains A. List of SOPs in the laboratory B. List of equipments in the laboratory C. List of all ongoing studies in the laboratory D. List of all personnel working in the laboratory	C
28	Measurement accuracy is attained when A. Different people get the same result when measuring the same item or characteristic. B. The same person taking multiple measurements on the same item or characteristic gets the same results every time. C. The measured value has little deviation from the actual value. D. When the resolution of the measurement instrument can give at least 5 distinct values in the range being measured.	C

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29	Risk management is the process of _____risk and developing methods to mitigate and manage it. A. Increasing B. Identifying C. Eliminating D. Creating	B
30	The main changes in the latest ISO 17025 compared to the previous edition is A. Risk based thinking is removed B. Definition of "laboratory" has been deleted C. Lesser flexibility in the requirements for processes and procedures D. Greater flexibility in the requirements for documented information and organizational responsibilities	D
31	The concept metrology traceability in 17025:2017 applies to A. Only physical measurement devices B. Calibration laboratories only C. Only measurement devices and certified reference materials and standards D. All equipments which contribute to the overall uncertainty of the measurement results	D
32	ISO/IEC 17025 contains the following types of requirements: A. Structural B. Process C. Resources D. All of the above	D
33	Organogram shows the A. Detailed floor plan of the organization B. Structure of an Organisation and the relationships and relative ranks of its parts and positions/jobs C. Audit schedule in detail D. Position of organization with respect to other organisation	B
34	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.	D
35	A successful TQM program incorporates all of the following **except** A. Continual improvement B. Employment involvement C. Centralized decision making authority D. Benchmarking	C
36	The following feedback mechanisms is not listed in 17025 A. Publish all feedback on the website B. Record all feedback C. Respond to all feedback D. Collect only positive feedback	D
37	Which is NOT true regarding internal audits A. Define audit criteria and scope for each audit B. ISO 19011 do not provide guidance for internal audits C. Ensure that the results are reported to relevant management D. Take corrective actions without undue delay	B

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38	The number of management system requirements in the latest ISO17025 (A) 6 (B) 9 (C) 5 (D) 12	B
39	When it is necessary to issue a new test report A. It shall be uniquely identified and reference to the original B. It shall retain the same identity as the original C. The original is returned to the lab D. Give as a supplementary report	A
40	Control of document referred as A. Documents are identified, authorized and reviewed B. Ways to reduce paper C. Supervisor will maintain all SOPs D. All will be kept in Quality Cell	A
41	Internal 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	A
42	A clause which is not practiced in BMT wing A. Improvement B. Service to customer C. Complaints D. Sampling	D
43	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	A
44	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.	D
45	Traceability includes three components for each step in the traceability chain A. Documentation, registration, reference to the SI B. Calibration, uncertainty, traceability C. Uncertainty, calculation, documentation D. Calibration, uncertainty, competence	C
46	Quality Management System can be defined as A. Management system to direct and control an organization with regard to quality B. Management system to direct an organization with regard to quality C. Management system to control an organization with regard to quality D. Management system to run any organisation	A
47	Management review will **NOT** review A. Complaints B. Internal audit reports C. External audit reports D. Raw data	D

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48	As per ISO 17025 which is NOT true A. Every test report should contain interpretation of result B. only personnel authorized should release the respective statement of interpretation C. Interpretation expressed should be based on results obtained D. When interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.	A
49	Supplies of critical consumables, supplies, and services which affect quality must be: A. Insured B. ISO 9001 certified C. Evaluated and approved by laboratory D. NABL accredited	C
50	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	A

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