MFCP held on - 5/2/19
O/C

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY
Thiruvananthapuram.

MFCP Scientific Assistant (Instruments) Quality Cell

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

No.	Question
1.	What is a Quality Management System? (A) Management system to direct an organization with regard to quality (B) Management system to control an organization with regard to quality (C) Management system to direct and control an organization with regard to quality (D) Management system to run any organisation
2.	What is quality? (A) the degree to which the product meet standards (B) the degree to which a set of inherent characteristics fulfils requirement (C) the degree to which the product meet appearance (D) the degree to which the product meet durability
3.	Who is Responsible for Quality? (A) Top Management (B) Middle Management (C) Youngsters (D) Everyone
4.	ISO 17025 deals with standard for (A) Testing Laboratories (B) Calibration Laboratories (C) Testing and Calibration laboratories (D) Medical Devices
5.	PDCA cycle is also known as (A) Management Cycle (B) Deming Cycle (C) Ishikawa Cycle (D) Fleming Cycle
6.	First edition of ISO 17025 was in the year (A) 1998 (B) 1999 (C) 2000 (D) 2005

7.	The laboratory's quality system policies and objectives shall be defined in (A) Quality Policy (B) Quality Manual (C) Standard operating procedure (D) Work procedure
8.	Review of request is done in order to ensure that (A) no complaints occur (B) the test was not conducted earlier (C) client is good (D) the laboratory has the capability and resources to meet the requirements
9.	The procedure for Corrective action shall start with (A) person who did it (B) reaction to the problem (C) an investigation to determine the root cause of the problem (D) environmental conditions lead to the problem
10.	The quality policy statement shall be issued under the authority of (A) Quality Manager (B) Top management (C) Study Director (D) Scientist-in-charge
11.	The accreditation is done by (A) First Party (B) Second party (C) Third party (D) Fourth party
12.	The non-fulfillment of a specified requirement is called a (A) Lacunae (B) Nonconformity (C) Corrective action (D) Concession
13.	Adequecy 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

14.	Service to the customer include (A) Permitting them to witness the test (B) Giving access to all areas of the laboratory (C) Revealing the addresses of all other customers (D) Allow to carry out the test or calibration by them
15.	Records shall be maintained as (A) Hard copies (B) Soft copies (C) Hard copies or soft copies (D) Both hard and soft copies
16.	Evaluation of measurements or tests on the same or similar items within the same laboratory is (A) Interlaboratory comparison (B) Intralaboratory comparison (C) Proficieny testing (D) Validation
17.	Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement is (A) Verification rule (B) Validation rule (C) Decision rule (D) Thumb rule
18.	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.
19.	An improvement process in which a company measures its performance against that of best-in-class companies, determines how those companies achieved their performance levels, and uses the information to improve its own performance (A) Control Chart (B) Six Sigma (C) Benchmarking (D) Cause and Effect Diagram

20.	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
21.	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
22.	The middle value of a data set when the values are arranged in either ascending or descending order is (A) Median (B) Mode (C) Mean (D) Discrete Data
23.	Risk management is the process of _____risk and developing methods to mitigate and manage it. (A) Recognizing (B) Increasing (C) Eliminating (D) Creating
24.	However risk management involves a process of steps to be taken in order. This order is: (A) risk identification, risk treatment, risk analysis, risk monitoring and review (B) risk analysis, risk identification, risk treatment, risk monitoring and review (C) risk identification, risk analysis, risk monitoring and review, risk treatment (D) risk identification, risk analysis, risk treatment, risk monitoring and review
25.	Master schedule contains (A) List of SOPs in the laboratory (B) List of all ongoing studies in the laboratory (C) List of equipments in the laboratory (D) List of all personnel working in the laboratory
26.	The latest revision of ISO 17025 is (A) First edition (B) Second edition (C) Third edition (D) Fourth edition

27.	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
28.	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
29.	When the sample measurement falls inside the control limits, it means that (A) Each unit manufactured is good enough to sell (B) The process limits cannot be determined statistically (C) The process output exceeds the requirements (D) If there is no other pattern in the samples, the process is in control
30.	The process improvement technique that sorts the 'vital few' from the 'trivial many' is (A) Taguchi analysis (B) Pareto analysis (C) Benchmarking (D) Yamaguchi analysis
31.	A successful TQM program incorporates all of the following **except** (A) Continual improvement (B) Employment involvement (C) Centralized decision making authority (D) Benchmarking
32.	Which is **NOT** among the 5Ms of Management (A) Man (B) Machinery (C) Maintenance (D) Method
33.	In PDCA, C stands for (A) Control (B) Check (C) Continuous (D) Characteristic
34.	A clause which is not practiced in BMT wing (A) Improvement (B) Service to customer (C) Complaints (D) Sampling

35.	Management review will **NOT** review (A) Complaints (B) Internal audit reports (C) External audit reports (D) Raw data
36.	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.
37.	The philosophy of zero defect is (A) Unrealistic (B) Prohibitively costly (C) An ultimate goal; in practice, 1 to 2% defects is acceptable (D) Consistent with the commitment to continuous improvement
38.	Which is NOT true regarding internal audits (A) Define audit criteria and scope for each audit (B) Ensure that the results are reported to relevant management (C) Take corrective actions without undue delay (D) ISO 19011 do not provide guidance for internal audits
39.	Which of the following is **True** as per ISO (A) A laboratory cannot do sampling (B) A laboratory cannot do subcontracting (C) A laboratory should have legal identity (D) A laboratory should not give interpretation of test results
40.	Technical Auditor cannot be the Lead Auditor (A) True (B) False
41.	Which is **NOT** true about internal audits (A) Periodic with a predetermined schedule (B) Fact finding mission and not a fault finding mission (C) Based on subjective evidence and not on objective evidence (D) Pre audit meetings can be conducted
42.	The number of management system requirements in the latest ISO17025 (A) 10 (B) 7 (C) 8 (D) 9

43.	There is a standard for the risk management to medical devices (A) True (B) False
44.	What is the definition of the term "Impartiality" as per ISO 17025? (A) Conflict of interest (B) Prejudice (C) Presence of objectivity (D) Bias
45.	Provision of objective evidence that a given item fulfils specified requirements is (A) Validation (B) Control chart (C) Verification (D) Quality
46.	Document control means (A) Ways to reduce paper (B) Supervisor will maintain all SOPs (C) Documents are identified, authorized and reviewed (D) All will be kept in Quality Cell
47.	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
48.	Which of the following is NOT true (A) A laboratory performing calibrations shall evaluate the measurement uncertainty. (B) A laboratory performing calibrations shall evaluate the measurement uncertainty, including of its own equipment. (C) The laboratory shall identify the contributions to measurement uncertainty. (D) When evaluating measurement uncertainty, all contributions that are of significance, excluding those arising from sampling, shall be taken into account.
49.	Training records are essential for (A) Job description (B) Biodata (C) Job satisfaction (D) Ensure competence and authorize personnel
50.	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

KEY MFCP Scientific Assistant (QUALITY CELL)

1	C
2	B
3	D
4	C
5	B
6	B
7	B
8	D
9	C
10	B
11	C
12	B
13	A
14	A
15	C
16	B
17	C
18	C
19	C
20	B
21	B
22	A
23	A
24	D
25	B

26	C
27	D
28	B
29	D
30	B
31	C
32	C
33	B
34	D
35	D
36	A
37	D
38	D
39	C
40	B
41	C
42	D
43	A
44	C
45	C
46	C
47	C
48	D
49	D
50	A