

Licensing, Norms, and Accreditation of Clinical Laboratories

Medical Laboratory Science · Answer Key · 20 Questions

1. What is the primary purpose of licensing a clinical laboratory?

- A) To grant formal recognition of competence
- B) To confirm conformity to specific requirements
- C) To authorize a laboratory to legally operate**
- D) To provide national/international recognition

2. Who is mandated to issue the License to Operate (LTO) for clinical laboratories in the Philippines?

- A) Accreditation Bodies
- B) Professional Organizations
- C) Department of Health (DOH)**
- D) International Organization for Standardization (ISO)

3. What does DOH AO 2021-0037 primarily govern?

- A) International laboratory standards
- B) Revised rules for laboratory licensure
- C) New rules and regulations for clinical laboratory regulation**
- D) Guidelines for laboratory accreditation

4. Which of the following is NOT a typical licensing requirement for clinical laboratories according to the DOH Tool?

- A) Adequate physical plant and personnel
- B) Proper reagents and equipment
- C) Demonstrated technical competence for specific tests**
- D) A functional quality improvement program

5. What is the validity period of a DOH-LTO?

- A) Three years
- B) Five years
- C) One year**
- D) Indefinite

6. Accreditation is a procedure that provides formal recognition of what aspect of a laboratory?

- A) Legal authorization to operate
- B) Conformity to management system requirements
- C) Competence to carry out specific tasks**
- D) Compliance with national policies

7. Which accreditation body uses a unique peer-inspection model with trained laboratory professionals?

- A) Joint Commission International (JCI)
- B) College of American Pathologists (CAP)**
- C) Philippine Accreditation Bureau (PAB)
- D) World Health Organization (WHO)

8. ISO 15189 is a standard specifically designed for:

- A) General testing and calibration laboratories
- B) Medical laboratories**
- C) Quality management systems in healthcare
- D) Biosafety cabinets

9. What is the main purpose of 'norms' in the context of laboratory operations?

- A) To provide specific, measurable requirements
- B) To define standards of proper or acceptable behavior and model principles**
- C) To grant permission to operate
- D) To formally recognize competence

10. When is accreditation typically considered mandatory?

- A) Always, for any laboratory operation
- B) When required by a regulator, contract, or organization**
- C) Only for international recognition
- D) When the laboratory seeks ISO 9001 certification

11. Certification provides written assurance that a product, process, or service conforms to:

- A) Minimum regulatory standards
- B) Designated competency levels
- C) Specific requirements**
- D) National laboratory leadership structure

12. Which of the following is a benefit of laboratory accreditation?

- A) Reduced need for personnel
- B) Increased operating costs
- C) Facilitates implementation of an effective quality system**
- D) Eliminates the need for licensing

13. What does the DOH Licensing Assessment Tool, specifically Annex B1, cover?

A) Only service capability of equipment and reagents

B) General assessment of the laboratory

C) Personnel training records only

D) Financial management systems

14. A 'normative statement' in an accreditation term uses which word to indicate a requirement?

A) May

B) Should

C) Shall

D) Could

15. What is a consequence of refusing inspection or monitoring visits by DOH?

A) Immediate accreditation

B) Stern warning only

C) Non-issuance or renewal of license

D) Mandatory participation in EQAP

16. Which of the following is a prohibited act that can lead to immediate revocation of a license?

A) Minor non-conformity in documentation

B) Using expired reagents for routine testing

C) Issuing fraudulent laboratory results

D) Having a slight delay in corrective actions

17. The DTI-Philippine Accreditation Bureau (PAB) accredits medical laboratories against which ISO standard?

A) ISO 9001

B) ISO/IEC 17025

C) ISO 15189

D) ISO 17011

18. What is the primary goal of a quality management system in a laboratory?

A) To solely focus on equipment maintenance

B) To address all aspects of laboratory operation to assure quality

C) To reduce the number of personnel

D) To exclusively manage financial systems

19. What is the role of stakeholders in the development of standards for clinical laboratories?

- A) They are solely responsible for enforcement
- B) They have no role in standard development
- C) They contribute to the development process**
- D) They only implement the standards

20. A non-conformity in accreditation can be categorized as major or minor based on:

- A) The number of standards violated
- B) The degree of failure to fulfill requirements**
- C) The opinion of the assessor
- D) The cost of the non-conformity