

Licensing, Norms, and Accreditation of Clinical Laboratories

Medical Laboratory Science · Practice Test · 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