

PROCEDURES AND GUIDELINES FOR THE REGIONAL CLINICAL LABORATORY AND BLOOD BANK INSPECTION TEAMS OF THE REGIONAL LICENSING UNITS

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SECTION 1. Title . — These Procedures and Guidelines shall be known as "Procedures and Guidelines for the Regional Clinical Laboratory and Blood Bank Inspection Teams of the Regional Licensing Units".

SECTION 2. Authority . — These are being issued to implement R.A. 4688 (Clinical Laboratory Law) with its Revised Rules and Regulations (A.O. #49-B, s. 1988) and R.A. 1517 (Blood Bank Law) with its Revised Rules and Regulations (A.O. #57, s. 1989) consistent with E.O. 119 (Reorganization Act of the Ministry of Health). These guidelines are issued pursuant to Department Circular 6-A, s. 1989 (Consolidation of Licensing Activities and Functions Under the Office of the Assistant Regional Director)

SECTION 3. Purpose . — To facilitate the application and licensing of clinical laboratories and blood banks in the Regions in accordance with the Laws and their implementing Revised Rules and Regulations.

SECTION 4. Functions of the Regional Licensing Units . —

- 4.1 To issue and accept applications for licenses to operate clinical laboratories and blood banks.
- 4.2 To inspect primary and secondary category hospital-based clinical laboratories and primary category hospital-based blood banks.
- 4.3 To assist and guide applicant laboratories and blood banks so that deficiencies are corrected within the period set by the Bureau of Research and Laboratories.
- 4.4 To submit completed reports to the Bureau of Research and Laboratories, Division of Laboratory Regulation and Development.
- 4.5 To accept and issue approved licenses to operate and open clinical laboratories and blood banks.
- 4.6 To be liaison between the central regulatory body (BRL) and the regional clinical laboratories and blood banks in the task of maintaining the high standards of Laboratory and Blood Bank Services.

SECTION 5. Regional Licensing Procedures and Guidelines . —

5.1 Application to operate CL/BB

5.1.1 The Regional Licensing Unit (RLU) specifically the Clinical Laboratory and Blood Bank Inspection Team headed by the Chief of the Regional Clinical Laboratory and the Medical Technologist Inspector shall accept records and file applications submitted in duplicate to operate Clinical Laboratories and Blood Banks and assign each application a number.

5.1.2 Postal Money Orders addressed to the Bureau of Research and Laboratories shall be forwarded together with duplicate copies of application forms and documents to the BRL in Manila within one week with the following information:

- a. Date PMO and application is received by the RLU and reference number.

- b. Information re: New or Renewal Application
- c. Category of Laboratory and Blood Bank to be licensed

5.1.3 Deficiencies noted in the application forms are communicated by RLU to the applicant and should be corrected within 45 days of date of application.

5.2 Inspection

5.2.1 In inspection of the Clinical Laboratory or Blood Bank is made within 60 days of the date of receipt of application.

5.2.2 Initial licensure inspections are announced because they are basically to verify capability of laboratories or blood banks to deliver services applied for and to help the staff comply with administrative and technical documentation now required by law. Subsequent inspections may be announced.

5.2.3 The Inspection visit includes:

- a. A brief meeting with the Head or Pathologist, Chief Medical Technologist and if convenient with the laboratory owner before and at the end of the inspection.
- b. Completion of the inspection which aims to be an objective assessment of physical, technical, administrative and manpower capabilities of the laboratory.
- c. The summation or post-inspection conference is a sharing and teaching session and may be chaired by the Physician Head of the Team or one of the Medical Technologist inspectors capable of guiding the discussion. To be taken up (a) Noted deficiencies; (b) Ways of correcting these deficiencies explained and discussed.

5.2.4 A written copy of the deficiencies is left with the staff and both staff and inspectors sign documents attesting to knowledge of inspection findings going into the report; certificates of appearance are also signed.

5.2.5 The laboratory staff are told where to present or mail evidence of deficiencies corrected or whom to call if a repeat inspection is required.

5.2.6 The laboratory is given two (2) deficiency letters, one on the day of inspection and a follow-up in case deficiencies have not been corrected 30 days after. They are given 60 days after inspection to correct deficiencies.

5.3 Evaluation

5.3.1 The completed inspection report using BRL Inspection Forms with all deficiencies corrected are forwarded within 2 weeks of completion to the Office of the Assistant Regional Director to be sent to the Bureau of Research and Laboratories.

5.3.2 The Evaluation, Processing and eventual approval or (disapproval) and issuance of a License takes two weeks after receipt of the above completed inspection report.

5.3.3 Licenses are sent to the Office of the Assistant Regional Director for issuance to the applicant Clinical Laboratories and Blood Banks.

SECTION 6. Liaison . —

6.1 Applications for licenses to operate tertiary category hospital-based and all categories of free-standing clinical laboratories; secondary, tertiary categories and all categories of free-standing blood banks shall be forwarded to the Bureau of Research and Laboratories for processing.

6.2 Monthly Reports of Accomplishments are to be submitted to the BRL by the Clinical Laboratory and Blood Bank Inspection Teams through the Office of the Assistant Regional Director using the attached form.

This Bureau Order takes effect immediately.

Adopted: 16 Jan. 1990

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Officer-In-Charge

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