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ADMINISTRATIVE STANDARD OPERATING PROCEDURES FOR APPLICATION AND LICENSURE OF CLINICAL LABORATORIES AND BLOOD BANKS

KPL BUREAU ORDER NO. 6, January 16, 1990

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SECTION 1. Title . — These Administrative Standard Operating Procedures shall be known as "Administrative Standard Operating Procedures for Application and Licensure of Clinical Laboratories and Blood Banks".

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).

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

SECTION 4. Application for a License . — Applicant submits a properly accomplished application, the required supporting documents and pays the corresponding license fee.

1. Forms may be secured in person or requested by mail, from the Licensure Section, Division of Laboratory Regulation and Development of the Bureau of Research and Laboratories, San Lazaro Compound, Sta. Cruz, Manila or from Regional Health Office where the clinical laboratory/blood bank is located.

1.1. New application: BRL/CL/BB Forms Nos. 1, 2, 3.

1.2. Renewal application: BRL/CL/BB Forms Nos. 2&3

2. The following supporting papers and documents are required for every new application filed:

2.1. Xerox copy of proficiency certificate of the pathologist or head of the CL/BB.

2.2. Xerox copy of current hospital license (except for new hospitals which are not yet licensed).

2.3. Xerox copy of Certificate of Registration of Business Name from the Bureau of Domestic Trade.

2.4. Notarized certification of compliance with other business requirements.

SECTION 5. Filing of Application . — Application is filed either in person or by mail to the Bureau of Research and Laboratories or to the Regional Licensing Unit of the Regional Health Office were the CL/BB is located.

I
Application Filed at the BRL

A. In person —

1. Applicant or his authorized representative submits the completed application with required supporting documents to the Licensure Section of the Division of Laboratory Regulation and Development (DLRD) in the Bureau of Research and Laboratories (BRL), Department of Health, San Lazaro Compound, Sta. Cruz, Manila.

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2. The license fee, usually in cash or postal money order paid to the Bureau of Research and Laboratories is paid to the Cashier of BRL using a charge slip issued by the Licensure Section. Penalties and other charges are likewise paid at this time.

3. Copy of the charge slip and the official receipt (OR) is brought back to the Section where the OR number is recorded on the application form and countersigned by the applicant or his representative.

4. Applicant keeps the OR while the copy of charge slip is filed by the Section.

5. Only completed and supported application are processed.

B. By mail —

1. Application together with the license fee in postal money order (PMO) payable to the Bureau of Research and Laboratories, is mailed to the BRL thru Registered Mail.

2. Upon receipt of application at the Licensure Section, a charge slip is issued and the PMO paid to Cashier of BRL.

3. The OR number is recorded on the application; charge slip is filed.

4. Receipt of the application is acknowledged by mail. Deficiencies in the application or documentation plus any penalties and charges are likewise communicated in the letter of acknowledgement. The OR is enclosed in the letter.

Application Filed in Region

1. Applicant files the application and supporting documents all in duplicate the Regional Licensing Unit of the Regional Health Offices where the CL/BB is located.

2. License fees and other charges are paid through a PMO to the Bureau of Research and Laboratories.

3. The Postal Money Order and notice and date of receipt of application and one copy of application and document is forwarded by mail or messenger to the BRL, Licensure Section, DLRD, before PMO expires.

4. The PMO is paid to the Cashier by Licensure Section using a charge slip.

5. Receipt of the application and license fee is acknowledged thru a letter with the OR enclosed.

6. Application is processed and evaluated.

SECTION 6. Recording . —

1. New application received is assigned a number and filed in individual folder. For renewal, it is filed in its assigned folder.

2. Application is recorded in the In-Coming Record Book.

3. A letter acknowledging the receipt of the application with the OR enclosed is sent to the applicant. Applicant is informed of deficiencies in the application, if any.

SECTION 7. Inspection. — Inspection is to determine and evaluate compliance with the Rules and Regulations and technical standards prescribed which include: the address, the physical plant, number and names of laboratory personnel, service capabilities, equipment/instruments, reagents, glasswares, supplies, laboratory records, schedule of duties, rates, procedures, quality control program, etc.

1. Inspection is authorized by the Chief of the DLRD and the Director of BRL (or Regional Director/Assistant Regional Director) through Travel Order or Letter-Request.

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2. Ocular inspection of the facility is done within 60 days of application unless the convenience of a single inspection trip dictates an early inspection. Usually the date of inspection is communicated first to the applicant who in turn replies to confirm his readiness and availability for the inspection on the scheduled date.

3. The prescribed Inspection Form is used for inspection.

4. BRL Inspection Team conducts inspection of all categories of clinical laboratories and blood banks in the National Capital Region. In the Regions, the Team inspects all free-standing and tertiary category of hospital laboratories and all free-standing, secondary and tertiary categories of hospital blood banks.

5. Regional Inspection Teams inspect primary and secondary categories hospital laboratories and primary category hospital blood banks.

SECTION 8. Evaluation of Inspection . —

1. The Inspection Team submits the duly accomplished and signed inspection report to the Chief of Division within a week after the inspection.

2. In the Regions, completed report is forwarded to BRL only when deficiencies have been corrected. After designated period, inspection report is forwarded irregardless of deficiencies.

3. The Chief of Division evaluates the data gathered.

SECTION 9. Preparation of the License . —

1. When compliance with the Rules and Regulations is verified, the Chief of the Division approves the preparation of the license.

2. Otherwise, the deficiencies noted is informed to the applicant for corrections while the processing of the license is held in abeyance.

SECTION 10. Approval of License . —

1. The prepared license is sent to the Director who in turn recommends its approval to the Undersecretary of Health for Standards and Regulation.

2. The Undersecretary of Health approves the license.

SECTION 11. Releasing of License . —

1. For CL/BB located in NCR, the original of the license is sent or mailed to the applicant while the duplicate is filed in the Section.

2. For those in the Regions, the original of the approved licensed is sent to the Regional Licensing Unit, c/o The Assistant Regional Health Director, for mailing to the applicant while the duplicate is filed in the BRL.

SECTION 12. Terms and Conditions of License . —

1. The license is granted on the basis of specific conditions and limitation is established during the inspection.

2. The license granted as well as any right under the license shall not be assigned or transferred to an authorized party.

3. If the owner desires to transfer the laboratory to another place he shall inform the BRL in writing fifteen (15) days after the transfer. The laboratory in its new location is subject to inspection.

4. If there is a change in the personnel or the head, this is likewise reported in writing to the BRL within fifteen (15) days. Failure to do so may be the basis for suspension or revocation of the license.

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SECTION 13. Modification and Revocation of License . —

1. The license may be revoked, suspended or modified in full or in part if:

1.1. Any material false statement in the application as revealed by the record of inspection.

1.2. For failure to observe any of the terms and provisions of the Rules and Regulations.

1.3. Except in willful or repeated violations hereof or where public interest or safety requires otherwise, no license is modified, suspended or revoked unless prior notice has been made and corresponding investigation is conducted.

SECTION 14. Investigation of Charges and Complaints. —

1. Only written and/or duly sworn complaint is entertained.

2. The following steps may be done:

2.1. A letter is sent to the pathologist and/or owner against whom the complaint was filed: informing them of the charges and requesting for comments and explanations.

2.2. An inspection is conducted to look into the veracity of the complaint by gathering data pertinent to the case.

3. Data gathered is analyzed and evaluated by the Chief of the Division and the Director of BRL.

4. If the person(s) is found to be guilty of the charges, the Undersecretary of Health shall suspend, cancel or revoke the license without prejudice to taking the case to judicial authorities (thru the Legal Division of DOH) for criminal action.

SECTION 15. Exhibition of License . —

1. The following is placed in a conspicuous place within the clinical laboratory/blood bank:

1.1. License to Open and Operate

1.2. Certificate of Proficiency of the Pathologist of Head of the entity.

2. A copy of the Rules and Regulations for CL and/or BB is made readily available.

SECTION 16. List of Licensed Clinical Laboratories/Blood Banks (Publication). — The list of licensed clinical laboratories and blood banks and the results of the quality control test is sent to all concerned for legitimate purposes.

This Bureau Order takes effect immediately.

Adopted: 16 Jan. 1990

(SGD.) TOMAS P. MARAMBA, JR.
Officer-In-Charge

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