RULES AND REGULATIONS GOVERNING THE ACCREDITATION OF CLINICAL LABORATORIES FOR TRAINING OF MEDICAL TECHNOLOGY INTERNS

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SECTION 1. Title - These rules and regulations shall be known as the "Rules and Regulations Governing the Accreditation of Clinical Laboratories for Training of Medical Technology Interns".

SECTION 2. Authority - These rules and regulations are issued in accordance to Section 13 of Republic Act 5527 (Medical Technology Act of 1969) and consistent with Executive Order 119 (Reorganization Act of the Ministry of Health) and R.A. 4688 (Clinical Laboratory Law), and R.A. 1517 (Blood Bank Law).

SECTION 3. Purpose - These rules and regulations are promulgated to upgrade the training of medical technology interns to maintain the quality of laboratory services, and to properly utilize the medical technology interns during their training. Only those laboratory which are accredited for training shall be utilized for the affiliation of medical technology interns.

SECTION 4. Scope - The rules and regulations embodied herein shall apply to all clinical laboratories performing examinations for the diagnosis of diseases or for public health purposes as defined in R.A. 4688 and utilized as training laboratories for medical technology interns from universities and colleges offering medical technology courses.

SECTION 5. Regulatory Authority - The accreditation of training laboratories for medical technology interns under these rules and regulations shall be exercised by the Department of Health, through the Bureau of Research and Laboratories in the Office for Standards and Regulation.

SECTION 6. Accreditation Requirements for a Training Laboratory for Medical Technology Interns -

Technical Standards

6.1 All clinical Laboratories must be required to demonstrate compliance with the following technical standards as requirements for accreditation.

6.1.1

The Clinical Laboratory shall be duly licensed by the Bureau of Research and Laboratories (BRL).

6.1.2

The laboratory shall be headed by and under the supervision of a duly licensed physician who is certified by the Philippine Board of Pathology.

6.1.3

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The laboratory shall be staffed by at least one (1) medical technologist, duly registered with the Board of Medical Technology for each of the sections of Clinical Chemistry, Clinical microscopy, microbiology, hematology, blood banking and serology and histopathology.

6.1.4

The physical plant shall have adequate laboratory space to accommodate both laboratory staff and medical technology interns.

6.1.5

There should be sufficient equipment and supplies necessary depending on the volume and type of examinations as well as the number of interns to be trained by the laboratory.

6.1.6

A section of the laboratory can be utilized for training only if it has a sufficient volume of laboratory examination adequate for training of at least one Medical Technology Intern.

6.1.7

The laboratory should have a written training program for the Medical Technology interns.

6.2 The BRL shall evaluate compliance to the technical standards in accordance with the requirements including the minimum number of examination of samples required of each section as the BRL may promulgate.

SECTION 7. Training Program - The training program for Medical Technology interns should include the following:

7.1 The person responsible for the training program must be a duly licensed physician certified by the Philippine Board of Pathology. He shall be assisted by a registered medical technologist with previous experience in training medical technology interns.

7.2 The program shall provide for an objective measure or evaluation of the baseline skills and knowledge prior to allowing or utilizing interns to handle actual specimens from patients.

7.3 The program shall include the (1) objectives of training, (2) laboratory methods or procedures to be taught, (3) principles and clinical applications of the laboratory procedures, (4) right work attitudes and ethical values, (5) required quota of tests to be performed to develop accuracy and precision, (6) objective evaluation of performance in each section, (7) time schedule, (8) lecture seminars and conferences, and (9) methodology of training.

7.4 Not more than 20% of the number of Medical Technology interns but not to exceed ten (10) interns shall be allowed to train during the night shift. Provided further that no intern shall be allowed to train without a registered Medical Technologist on duty to supervise them.

7.5 There should be at least one (1) registered Medical Technologist with adequate skills and expertise in training for every group of interns not exceeding five (5) in each section.

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7.6 The staff and personnel of the laboratory shall be assisted by a laboratory instructor who must be a registered Medical Technologist from the sending university or school especially tasked to monitor individual attendance, behavior and performance of students.

7.7 A monthly conference by the pathologist, laboratory staff and laboratory instructor of the school shall be held to evaluate the implementation of the program, the problems that have been encountered and changes that have been instituted.

SECTION 8. Reporting - Each accredited clinical laboratories shall render an annual report of the number of Medical Technology interns training, the number of examinations performed and other activities in accordance with the format prescribed of the BRL.

SECTION 9. Affiliation of Medical Technology Interns from Universities, Colleges and Schools of Medical Technology - Accredited clinical laboratories shall be allowed to accept for affiliation Medical Technology interns from universities, schools or colleges of Medical Technology who have met the requirements specified in the Department of Health Administrative Order No. 70-A, s. 1989.

SECTION 10. Basic Accreditation Requirements - Any clinical laboratory desiring to train Medical Technology interns shall submit to BRL a sworn petition/application on the prescribed form containing/attaching among others:

10.1 Name of establishment

10.2 Place, municipality and province where it is to be established

10.3 Name, citizenship and domicile of the head of the Clinical Laboratory

10.4 Name, citizenship and domicile of owner

10.5 Copy of a valid permit to operate a clinical laboratory or blood bank from the Department of Health

10.6 The training program for Medical Technology interns

10.7 Volume of examinations performed in the previous year for each section.

SECTION 11. Application for Accreditation -

11.1 An application for accreditation shall be filed in a form "Application for Accreditation of Laboratories for Training Medical Technology Interns" with the Office of the Bureau of Research and Laboratories for screening and approval.

11.2 Each application shall be signed under oath or affirmation by the owner or a person duly authorized to act for and on his behalf.

11.3 Within sixty (60) days after receipt of said application together with the accreditation fee, an inspector from the Bureau of Research and Laboratories shall inspect the establishment and verify if the applicant has complied with the requirements prescribed in these regulations.

11.4 Any material false statement in the application or failure to comply with the requirements may serve as basis of the Director of the Bureau of Research and Laboratories to refuse recommending the issuance of a certificate of accreditation.

SECTION 12. Accreditation Fees -

12.1 A non-refundable fee shall be charged for every application for accreditation for the training of Medical

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Technology interns for government and private laboratories.

12.2 A non-refundable fee is charged on application of renewal of accreditation if filed at least sixty (60) days before the accreditation expires.

12.3 All fees shall be payable to the Bureau of Research and Laboratories in accordance with the following schedule:

For initial application P500.00
For renewal of accreditation P250.00

12.4 A penalty of P200.00 for late renewal shall be charged in addition to the renewal fee when filed within ninety (90) days after expiration of accreditation.

12.5 Ninety (90) days after expiration of accreditation, unrenewed certificates shall be considered lapsed, and a new certificate shall be applied for (initial application).

SECTION 13. Inspection - Clinical Laboratory for training of Medical Technology interns facilities and records shall be subject to regular inspection to determine compliance with the above regulations.

13.1 The Director of Bureau of Research and Laboratories or his duly authorized representative(s) shall be given reasonable time and opportunity to inspect the premises and facilities wherein the training of Medical Technology interns is being performed.

13.2 Each laboratory shall make available to the Director of the Bureau of Research and Laboratories or his duly authorized representative all records kept pursuant to these regulations for inspection.

13.3 The Director of the Bureau of Research and Laboratories or his representative may be assisted by duly designated experts from professional associations in such inspections.

13.4 Directors of Regional Health Offices, Provincial, City and Municipal Health Officers are hereby directed to report to the Bureau of Research and Laboratories the existence of unaccredited clinical laboratories training Medical Technology interns or any private party performing such training without a proper accreditation certificate.

SECTION 14. Issuance and Exhibition of Certificate of Accreditation -

14.1 The certificate shall be issued and signed by the Undersecretary of Health for Standards and Regulation upon compliance with the requirements prescribed herein and provided the corresponding fees are duly paid.

14.2 The accreditation certificate should be placed in a conspicuous place within the laboratory. A copy of the rules and regulations shall be readily available for the guidance of the staff in the laboratory.

SECTION 15. Terms and Conditions of Accreditation -

15.1 The certificate as herein granted or any right under the certificate shall not be assigned or otherwise transferred directly or indirectly to an unauthorized party.

15.2 The owner or manager of any clinical laboratory training Medical Technology interns desiring to transfer to another place shall inform the Bureau of Research and Laboratories in writing, stating the new place and site of establishment within fifteen (15) days after such transfer. The new facilities shall be subject to re-inspection before it can resume operation.

15.3 Any laboratory desiring to cease training Medical Technology interns should notify the Bureau of Research

and Laboratories stating the said date of termination.

15.4 Any pathologist who decides to terminate his services or transfer supervision should inform the Bureau of Research and Laboratories within fifteen (15) days after such termination or transfer.

15.5 Failure to report in writing within fifteen (15) days any change in conditions of Accreditation will be a cause for suspension or revocation of the certificate of accreditation of the laboratory.

SECTION 16. Expiration of Accreditation Certificate - Each accreditation certificate shall expire two years after the date of approval which is indicated in the upper right hand corner of the certificate.

SECTION 17. Renewal - Application for renewal of certificate shall be filed at least sixty (60) days before its expiration. The Bureau of Research and Laboratories shall process applications for renewal immediately upon receipt thereof subject to inspection upon the discretion of the Director; provided, however, that such clinical laboratory may continue operation pending action on their application, unless otherwise advised or ordered by the Director, of the Bureau Research and Laboratories or his duly authorized representative to cease operation.

SECTION 18. Publication of List of Accredited Laboratories -

18.1 A list of laboratories and blood banks accredited for training Medical Technology interns under these rules and regulations shall be published periodically and be made available to any person, agency or organization for legitimate purposes.

SECTION 19. Modification and Revocation of Certificates - The terms and conditions of each certificate shall be subject to amendment or modification as may be provided by any amendments to these regulations as the Secretary of Health may deem necessary. Except in cases of willful, or repeated violations hereof, or where public health interest or safety requires otherwise, no certificate shall be modified, suspended or revoked unless prior notice has been made and the corresponding investigation conducted.

SECTION 20. Violation -

20.1 The certificate of accreditation of a laboratory to train Medical Technology interns shall be suspended or revoked by the Undersecretary of Health for Standards and Regulation for any violation of these Rules and Regulations, including the following acts:

20.1.1 Training Medical Technology interns without a qualified pathologist or medical technologist.

20.1.2 Any material false statement in the application.

20.1.3 Failure to correct deficiencies a reasonable time after due notice from the Bureau of Research and Laboratories.

20.1.4 Refusal to allow inspection of the laboratory by persons authorized by the Bureau of Research and Laboratories during reasonable hours.

20.1.5 Repeated failure to submit an annual report to the Bureau of Research and Laboratories.

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20.2 Any clinical laboratory that violates these rules and regulations shall be liable under the Medical Technology Act (R.A. 5527) and Clinical Laboratory Law (R.A. 4688), and shall suffer penalties provided for in these laws and the Revised Rules and Regulations issued pursuant to such laws. Such violations shall be the basis for sanctions including suspension or revocation of the license to operate the Clinical Laboratory.

SECTION 21. Upon the filing of a complaint or charge duly sworn to by any person or interested party against a clinical laboratory or of any of its personnel for violating any provisions of this regulations, the Undersecretary or his duly authorized representative(s) shall investigate the complaint or charges and verify if the laboratory concerned or any of its personnel is guilty of the charges. If upon investigation, a person or persons are found violating any of the provisions of these rules and regulations, the Undersecretary of Health for Standards and Regulation shall suspend for a definite or indefinite period of time or cancel or revoke the accreditation of the laboratory without prejudice to taking the case to judicial authorities for criminal action.

SECTION 22. Separability and Repealing Clauses -

22.1 In the event that any rule, section, paragraph, sentence, clause or word of this Order is declared invalid for any reason, the other provisions thereof shall not be affected thereby.

22.2 All pertinent rules and regulations which are inconsistent with the provisions of this Order are hereby repealed or amended accordingly.

SECTION 23. Effectivity - These rules and regulations shall take effect within fifteen (15) days after its publication in the Official Gazette or in a newspaper of general circulation.

Adopted: 6 Mar. 1992

(SGD.) ANTONIO O. PERIQUET, M.D.
Secretary of Health

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