CLINICAL LABORATORY LAW

RA 4688

- Clinical Laboratory Law
- Approval date: June 18, 1966

AO 59s 2001

- “Rules and Regulations Governing the Establishment, Operation and Maintenance of Clinical Laboratories in the Philippines;”
- Contains implementing guideline of RA 4688
- Bureau of Health Facilities and Services (BHFS)
  - regulatory functions under these rules and regulations
- Section 3. Purpose
  - To protect and promote the health of the people
  - Ensure availability of clinical laboratories that are properly managed with adequate resources
  - Ensure effective and efficient performance through compliance with quality standards
- Section 4. Scope
  - DOES NOT INCLUDE (if gov’t based):
    - Acid Fast Bacilli microscopy
    - Malarial screening
    - Cervical cancer screening
  - Regulations apply to free standing laboratories
- Section 5. Classification of Laboratories
  - Function
    - Clinical Pathology
    - Anatomic Pathology
  - Institutional Character
    - Hospital-based laboratory
    - Non-hospital based laboratory
  - Service capability
    - Primary
      - Routine hematology
      - Routine urinalysis
      - Routine fecalysis
      - Blood typing
      - Quantitative platelet determination
    - Secondary
      - Routine clinical chemistry
    - Cross matching
    - Tertiary
      - Special chemistry
      - Special hematology
      - Immunology/serology
      - microbiology
TRAINING OF MEDICAL TECHNOLOGY INTERNS

Introduction

- Medtech training lab – tertiary category hospital-based and institution-based clinical laboratory
- Licensed to operate by the BHFS and DOH
- Accredited by CHED

RA 7722

- Higher Education Act of 1994
- Approval date: May 18, 1994

CMO No. 6s 2008

- Approval date: March 31, 2008
- Guideline for the Accreditation of Clinical Laboratories involved in the Training of Medical Laboratory Science/Medical Technology Interns
CHAPTER VII – NATIONAL VOLUNTARY BLOOD SERVICES ACT

RA 1517
- Blood Banking Law
- Blood Bank Act of 1956
- June 16, 1956 – approval date

RA 7719
- Repealed previous RA
- National Blood Services Act of 1994
- May 5, 1994 – Approval date

Section 2. Declaration of Policy
- To promote and encourage blood donation
- Blood transfusion is a professional medical service, not a commodity
- To provide adequate, safe, affordable and equitable supply of blood and blood products
- To inform the public of the need for voluntary blood donation
- To teach the benefits and rationale of voluntary blood donation in public/private high schools, college, non-formal education
- To mobilize all sectors to participate in voluntary & non-profit blood collection
- To mandate the DOH to establish and organize a National Blood Transfusion Service Network
- To provide adequate assistance to institutions promoting non-profit blood services
- To require all blood collection units and BB centers to operate on a non-profit basis

Section 3. Definition of Terms
- Secretary of Health – carry out provision of this Act
- Commercial Blood Bank – bb that exists for profit
- BCU – institution or facility authorized by DOH to recruit and screen donor, and collect blood
- BB/center – lab or institution with the capability to recruit and screen blood donors, collect, process, store, transport and issue blood for transfusion, provide information/education on blood transfusion transmissible disease
- Walking blood donor – ready to donate blood when needed in his/her community

Section 4. Promotion of Voluntary Blood Donation
a. Public education – nationwide educational campaign by DOH:
   - Philippine National Red Cross (PNRC)
   - Philippine Blood Coordinating Council (PBCC)
b. Promotion in Schools
c. Professional Education – PSHTB, PSP, PMA, PAMET, PNA
d. Establishment of Blood Service Network – established in every province and city nationwide
e. Walking blood donors

Section 5. National Voluntary Blood Services Program
- in cooperation with PNRC & PBCC
- funded by:
  o PCSO (25M)
  o PAGCOR (20M)
  o Duty Free Philippines (20M)

Section 7. Phase out of Commercial Blood Bank
- 2 years – grace period

Section 8. Non-Profit Organization
- All BB/centers shall operate on a non-profit basis

Section 9. Regulation of Blood Services*
- May collect fees not greater than the maximum amount prescribed by the DOH

Emergency Blood Transfusion
- Patient’s life is at risk
- Done under direct supervision
- Screening tests are done
- Required tests are done

Section 10. Importation of Blood Bank Equipment, Blood Bags and Reagents
- Shall be imported TAX and DUTY-FREE by the PNRC in consultation and coordination with Department of Finance

Section 12. Penalties
- 1month to 6 mos (5k to 50k) – collecting charges and fees greater than the maximum
- 12 yrs to 20 yrs imprisonment (50k to 500k) – operating a blood bank w/o any license
- 10 yrs imprisonment – failure to dispose contaminated blood within 48 hours

AO 9s 1995
- “Rules and Regulation” Implementing RA 7719 otherwise known as “National Blood Services Act of 1994”
- April 28, 1995 – Approval date

Blood Service Facilities
a. Blood Bank/Center
b. Blood Collection Unit – authorized by DOH to recruit and screen donors and collect blood
c. Blood Station – not licensed but authorized by the DOH to store and issue blood and blood product, perform compatibility testing

National Voluntary Blood Service Program Committee
- Secretary of Health – Chairperson
- Composed of Heads of:
  o DECS, DILG, DOF, DSWD, PRC, PNRC, PBCC, PSHBT, PSP, PMA, PHA, PAMET, Representatives from other societies
- Functions
  o Formulation of a 5-year directional/strategic plan
  o Operationalization and institutionalization of NVBSP including budgetary allocations for program activities
  o Monitoring and evaluation of activities
  o Creation of multi-sectoral sub-committees
  o Generation of multi-sectoral and inter-disciplinary support for national activities focused on blood services
- Conducts meetings at least quarterly

Regional Health Director – Field representative of NVBSP, coordinate the program activities in the region

Composition and Function of Hospital Blood Transfusion Committee
- Physicians from Department of Pediatrics, Medicine, Surgery, Obstetrics and Gynecology, and Pathology
- Hematology consultant
- Representative from nursing service
Hospital Medical Training Officer
Blood Service Quality Assurance Officer

Functions of National Blood Center
- Preparation of Special Plasma Derivative
- Performance of Special Confirmatory and reference blood tests
- Conduct of highly technical specialist on the job training courses
- Conduct of research and special studies

Functions of Regional Blood Center
- Preparation and distribution of blood components
- Training and supervisory functions over the BBC (Blood Coordinating Council)
- Research

Authorization of Blood Collection Units
- 1 registered physician & 1 RMT
  - Valid license
  - 1 month training on voluntary donor recruitment
- Adequate and proper equipment and supplies
- May be static or mobile
- Clearly attached to a network of one BB center
- BCU shall submit its schedule of bleeding and target area of donor recruitment
- Shall express agreement to submit the blood bags collected
- Shall be visited once a year by the head of BB center
- Authorization as a BCU shall be renewed yearly
- ATO of BCU shall be revoked by the RHD

Authorization of Blood Stations
- May be located only within hospital premises
- Shall be under the responsibility of a RMT
- Have at least one blood refrigerator
- Have a regular schedule, and a written record of maintenance and service
- ATO a Blood Station shall be renewed yearly

Penalties
- 5k – fails to submit the application for renewal
- 3k – operate without securing authorization

Violations in Revocation/ Suspension of BBC
- Misinterpretation of facts of documents or records
- Refusal of entry for inspection
- Refusal to make available its books, accounts and records of operation
- Failure to inform the BRL about change in BBC

Terms and Conditions of License
- Shall be signed by the Undersecretary of health for health facilities
- License is valid for 1 year
- License is non- transferable
- License must be displayed within BBC
- Linked within Blood Services Network
Chapter VIII

RA 8504

- Philippine HIV/AIDS Law

Penalties

- 6yrs to 12yrs – unsafe practices and procedures
- 2months to 2yrs – misleading information
- 6months to 4yrs – violations of confidentiality, discriminatory acts and policies

Exception to the Prohibition on Compulsory Testing

- Charged with any of the crimes under Revised Penal Code
- Determination of the HIV status is necessary to resolve relevant issues under Family Code of the Phil.
- Complying with the provisions of RA 7170 & RA 7719

Exceptions to the Mandate of Confidentiality

- Complying with reportorial requirements of AIDSWATCH
- Needed for the treatment or care of a person with HIV
- When responding to a subpoena duces tecum and subpoena ad testificandum
- As authorized by the judge of the court

Release of HIV/AIDS Results

- Patient himself/herself
- Parent of minor child
- Legal guardian of insane person/orphan
- Authorized person of AIDSWATCH
- Justice of the Court of Appeals/Supreme Court

Discriminatory Acts and Policies

- Discrimination in the workplace
- Discrimination in schools
- Restrictions on travel and habitation
- Inhibition from public service
- Discrimination in hospitals
- Denial of Burial Service

Membership and Composition of the Council (26)

- DEPED
- CHED
- TESDA
- DOLE
- DSWD
- DILG

Chapter IX – Philippine Dangerous Drugs Law

Classification of Drug Testing Lab Acc:

Ownership

- Government
- Private

Institutional Character

- Institutional-based
- Free-standing

Service Capability

- Screening Lab – 20fl by 10wa
- Confirmatory Lab – 60fl by 30wa

Mandatory Drug Testing

- Driver’s License
- Firearm’s License
- Officers and members of the military police
- Persons charged for imprisonment not less than 6yrs

- Candidates for public office
- Persons apprehended or arrested for violating this act

Required Documentation:

- Training records on all individuals that have access to samples
- Chain of custody forms
- Quality assurance/quality control records
- Data inc. calibration curves
- Reports
- Records of performance testing & comp. generated data

Information on the Chain of Custody Forms

- Information identifying the specimen
- Date and time of collection
- Name of testing lab
- Name and signature of individuals who had custody sample

Calibrators and Control

- Pure reference standards
- Stock standard solutions
- Purchased Standards

Authorization of Blood Stations

Documents Needed for LTO A Drug Testing Lab

- BHFS application form
- Letter of indorsement to the Bureau Director
- DTI/SEC registration
- Enabling Act
- Approved Board Resolution
- Mayor’s Permit
- Contract of Lease

Requirements for Certificate of Accreditation

- BHFS Application form
- Letter of Endorsement to the Bureau Director
- Copy of DOH LTO
- Record of lab personnel
- Documentation of chain of custody
- Quality Control Program
- Procedure Manual
- Proficiency Testing Result

Renewal for License to Operate

- Notarized: application for Renewal of License
- Notarized List Personnel
- List of Equipment/Instrument
- Current Certificate of Accreditation
- Current Mayor’s Permit

 Renewal for Certificate of Accreditation

- Current LTO
- Current Certification for Quality Standard System
- Current Proficiency Test Result

Violations

- False drug test results
- Failure to protect confidentiality of results
- Failure to participate in a proficiency testing
- Failure to refer the positive result to confirmatory lab
- Refusal to allow survey, monitoring of lab by Bureau of CHD