LICENSING STANDARDS FOR CLINICAL LABORATORY

I. PHYSICAL PLANT

Every clinical laboratory (CL) shall have an adequate space for its operation to safely, effectively and efficiently provide services to clients.

A. The CL shall conform to all applicable local and national regulations for the construction, renovation, maintenance and repair of CL.

B. The laboratory shall conform to the required space for the conduct of its activities/service. Personnel, fixtures, equipment, sink among others shall also be considered. See Revision 01 Annex D for the space/area requirements.

C. There shall be well-ventilated, lighted, clean, safe and functional areas based on the services provided.

D. There shall be a program of proper maintenance and monitoring of physical plant and facilities.

E. There shall be policy guidelines on laboratory biosafety and biosecurity which includes risk assessment that will serve as the basis of biosafety level required for the specific CL.

F. There shall be an area for the conduct of confirmatory testing for rapid HIV diagnostic algorithm (CrCL) and Glucose-6-Phosphate Dehydrogenase (G6PD) Deficiency which may be a section, unit, or division integrated in a DOH licensed CL, if applicable.

II. PERSONNEL

Every CL shall have an adequate number of trained personnel, depending on the workload, to provide safe, effective and efficient services to clients.

A. **Head of the Laboratory (HOL)**

1. The HOL shall be a competent and experienced clinical pathologist, with a specialized skill set related to and proportionate to the CL classification, to ensure that the laboratory runs efficiently. The HOL is essentially responsible for the operation of the entire laboratory, its personnel, functions, and data, all of which shall meet the quality assurance criteria and regulatory requirements.

2. The HOL shall oversee the operation of the CL and have administrative and technical supervision of the activities including the mobile clinical laboratories (MCL), remote collection activities, and point of care testing (POCT), if applicable.

3. The HOL shall supervise the staff in accordance with the standards set by the Philippine Society of Pathologists (PSP).

4. The HOL shall visit once a month and at least twice a week of supervisory calls and/or videoconferencing OR at least once a week physical visit. For hospital based DOH licensed CL, it shall be once a week physical visit by the **HOL or his/her associate pathologist.** The visits shall have to be well documented and recorded.

5. For Geographically Isolated and Disadvantaged Areas (GIDAs) **or other areas** with no clinical pathologists, as certified by the PSP, board certified anatomic pathologists or physicians with complete training in Clinical Laboratory Medicine, Quality Assurance and Laboratory Management, may head one primary DOH licensed CL.

6. **The HOL or his/her associate pathologist shall sign all the official results issued by the CL, including the POCT, SCL and MCL as applicable.**

B. **Registered Medical Technologist (RMT)**

1. There shall be an adequate number of full-time RMT to conduct the laboratory procedures, including those assigned in MCL as stipulated in Revision 01 Annex B1. An increase in workload shall require a corresponding increase in the number of personnel.

2. There shall be staff development and continuing education program at all levels of organization to upgrade the knowledge, attitude and skills of staff.

3. There shall be a designated Biosafety and Biosecurity Officer in-charge primarily of the risk assessment of the DOH licensed CL.

4. **All official results, including that of the point of care test, shall be signed by the RMT analyst who performed the test.**

5. **The RMT analyst shall have the appropriate training as required in Revision 01 Annex B1. HIV proficient RMT shall be required for Medical Facility for Overseas Workers and Seafarers (MFOWS) CL offering HIV screening test.**

C. **Support Staff**

1. There shall be an adequate number of support staff such as, but not limited to laboratory technician, laboratory aide, encoders, and receptionists when applicable.

2. **There shall be a designated trained HIV Counselor for CL offering HIV tests.**

D. **POCT Coordinator – if applicable**

1. A senior **RMT staff** from the CL shall be designated as a POCT coordinator who shall have the following functions, but not limited to:
   a. Recommends procedures that will ensure the quality of results of POCT in consultation with the pathologist.
   b. Ensures that POCT machines/device and kits are properly maintained.
   c. Supervises the operators of POCT device/machine.
   d. Ensures that the operators have appropriate trainings and checks the competency of the operators regularly.

e. Ensures that quality control (QC) is implemented and reviews POCT QC results periodically, depending on the number of tests.

E. **POCT Operator – if applicable**

1. The designated operator of the POCT device/machine and testing kits shall have the following functions, but not limited to:
   a. Ensures accurate results of POCT.
   b. Ensure that POCT machines/device and kits are properly maintained and stored.
   c. Run tests on quality control at least once each day or as recommended by the manufacturer.
   d. Initially, implements quality assurance program or contact the manufacturer's application specialist for assistance, when a POCT machine/device is not properly functioning or the control sample is in out of control range.
   e. Reports to the supervising CL any untoward incidents or problems concerning POCT.

F. **MCL Personnel**

1. MCL shall has its own set of personnel, which includes the following but not limited to:
   a. Registered Medical Technologist – number will depend on the anticipated workload.
   b. Support staff such as, but not limited to, driver and laboratory technician.

III. EQUIPMENT, INSTRUMENTS, GLASSWARES, REAGENTS AND SUPPLIES

Every CL shall have an adequate equipment, instruments, reagents, glassware and supplies which are all in good working condition and sufficient for the operations.

A. There shall be available and operational equipment/machines/devices to provide the laboratory examination that the laboratory is licensed for.

B. There shall be a calibration, preventive maintenance and repair program for every equipment/machines/instruments/devices in the DOH licensed CL.

C. There shall be a contingency plan in case of equipment/machines/devices breakdown and malfunction.

D. There shall be adequate available reagents, glassware and supplies for the laboratory examinations. The reagents and supplies shall be handled properly and stored at the required conditions/temperatures

E. There shall be a documented inventory control of the equipment, instruments, reagents, glassware and supplies.

F. The reagents, glassware and supplies shall be properly stored under the required conditions.

G. The machines/devices, reagents and test kits that are used in the CL, SCL, MCL as well as POCT shall be approved by the Philippine Food and Drug Administration and validated by the proper government institutions (e.g., National Reference Laboratory) as applicable.

H. The MCL shall have its own set of functional, and operational equipment, as well as its own set of supplies. **The proper transport, handling and packaging of the equipment such as, but not limited to centrifuge and microscope, shall be ensured following the manufacturer's manual and/or standard operating procedures (SOP) of the CL.**

I. **All machine, devices and equipment used in the CL, and its SCL and MCL if applicable, shall be properly maintained and regularly calibrated.**

IV. SERVICE DELIVERY

The services provided by the CL shall ensure quality and safety to clients, to its personnel and to the general public.

A. All CL shall ensure that the service being delivered to patients must comply with the licensing standards and requirements and other related relevant issuances.

B. **All other service capability not part of the minimum services per CL category shall be reflected in the DOH-LTO as an additional service (add-on).**

C. Mobile Clinical Laboratory

1. The collection site/area for MCL shall be located within the same region, at a maximum distance of one hundred (100) kilometer from the main CL.

2. Aside from specimen collection for different tests within the service capability of the main CL, the MCL shall be allowed to perform the following on-site tests which shall be declared in the LTO of the main CL:
   a. Urinalysis
   b. Fecalysis
   c. Pregnancy Test (lateral flow)
   d. Tests using portable devices such as glucometer for random blood sugar and hemoglobinometer for hemoglobin
   e. Any rapid lateral flow serological or immunological diagnostic test (e.g., dengue, RPR, Hepa-B and HIV screening)

3. **Specimen collected for other tests (i.e., chemistry and hematology) not mentioned above (Section IV. B. 2), shall be properly handled, transported and be processed to the main CL, following the standard operating procedures (SOP) for each test and shall be within the prescribed handling and processing periods.**

4. **The vehicle to be used for MCL shall follow the protocols, as reflected in the SOP of the CL, at all times.**

D. **For guidelines in remote collection activities, refer to Revision 01 Annex E.**

V. INFORMATION MANAGEMENT

Every CL shall maintain a system of communication, recording, reporting and releasing of results.

A. **Administrative and Technical Policies and Procedures**

1. The CL shall have written policies and procedures for the provision of laboratory services, the operation and maintenance of the CL, which includes SCL, MCL and POCT, and shall include the accountabilities of every personnel working in the laboratory.

2. There shall be documented technical procedures for services provided in each section of the laboratory, including MCL SCL, and POCT, which shall ensure the quality of laboratory results.

3. There shall be policy on laboratory biosafety and biosecurity which also includes risk assessment and management for every section in the CL.

4. There shall be procedures for quality control, inventory control and related processes.

B. **Communication and Records Management**

1. The CL shall maintain and ensure the confidentiality of all records.

2. There shall be procedures for the receipt of samples, performance of laboratory examinations and reporting/releasing of results of routine and STAT requests for laboratory examinations, including critical values that would impact on patient care.

3. All results shall be released in accordance with DOH guidelines.

4. All laboratory reports **and official results to be issued** on various laboratory examinations of specimens shall bear the name, PRC registration number, and original or **digital** signature, **as applicable,** of the RMT who performed the laboratory examination/s, and the HOL or his/her associate pathologist who shall be accountable for the reliability of the results.

5. There shall be a policy guideline on the use of digital signature. The use of digital signature for laboratory results shall be permitted only if properly authenticated by the Department of Information and Communications Technology-Philippine National Public Key Infrastructure. The use of digital signature shall be in accordance with the provisions of the E-Commerce Law.

6. There shall be procedures for the reporting of workload, work schedule and assignments. The operating hours of the CL shall be known to its clients.

7. There shall be procedures for the reporting and analysis of incidents, adverse events, and in handling complaints.

8. The retention of laboratory documents, records, slides and specimens shall be in accordance to the standards promulgated by the DOH or by competent authorities for such purposes.

9. The CL which supervises the POCT shall have a master list of the following, but not limited to:
   a. Name and designation of operators, and,
   b. POCT machines, instruments and kits.

VI. QUALITY IMPROVEMENT ACTIVITIES

Every CL shall establish and maintain a system for continuous quality improvement activities.

A. There shall be an internal quality assurance program (QAP) which shall include:
   1. Internal quality control program for technical procedures.
   2. Internal QAP for inputs, processes and outputs.
   3. A continuous quality improvement program covering all aspects of laboratory performance.

B. The CL shall participate in External Quality Assessment Program (EQAP) that may be administered by a designated NRL or other local and international EQAP approved by the DOH.

C. A periodic assessment shall be conducted by representatives from the top management, clinical laboratory, clinical departments and nursing service, to evaluate the policy of the CL on POCT.

VII. REFERRAL OF LABORATORY EXAMINATIONS

Every CL shall ensure the quality of services provided through an agreement, or its equivalent, with a DOH licensed CL performing the laboratory services needed.

A. **Referral of examinations to other DOH-licensed CL are only permitted if referral of laboratory test is part of the contingency plan, such as in cases of equipment breakdown and power interruption, of the referring CL. This shall be for a certain limited period of time only and shall not last for more than 3 months. The referral shall be properly recorded and documented.**

B. **The referral laboratory must be a DOH-licensed CL. They shall have a Memorandum of Agreement (MOA), prescribing the accountability of each party, with the referring CL as responsible for the collection, transport and processing of specimen/s, and releasing of result/s.**

VIII. OUTSOURCING OF LABORATORY EXAMINATIONS

A. **Only the tests which are not required as minimum service for the specific CL category shall be allowed to be outsourced.**

B. **The CL where the tests will be outsourced must be DOH licensed. They shall have MOA, prescribing the accountabilities of each party, with the referring CL as responsible for the collection, transport and processing of specimens, and releasing of results.**

IX. ENVIRONMENTAL MANAGEMENT

Every CL shall ensure that the environment is safe for its patients and staff, including the general public.

A. The CL shall have a written plan and program of proper disinfection and preventive maintenance of the facility.

B. **The CL shall have appropriate signage, and that only authorized personnel shall be allowed entry.**

C. There shall be procedures for proper disposal of infectious wastes and toxic and hazardous substances in accordance with Republic Act No. 6969, also known as "Toxic Substances and Hazardous and Nuclear Wastes Control Act of 1990" and other related policy guidelines and/or issuances (e.g., DOH Healthcare Waste Management Manual).

D. There shall have a "No smoking policy" and that the same shall be strictly enforced.

E. There shall be a contingency plan in case of accidents and emergencies.

F. There shall be a policy for biosafety and biosecurity and environmental guidelines on infection prevention and control **and shall observe the use of personal protective equipment.**

G. **The CL shall have MOA/Memorandum of Understanding (MUA) with infectious waste and toxic and hazardous substances hauler or EMB certificate, as applicable.**