Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

ASSESSMENT TOOL FOR LICENSING A GENERAL CLINICAL LABORATORY

INSTRUCTIONS:

1. *Check to make sure that you have the complete tool with a total of thirteen **(13)** pages with* Annex A- Service Capability (I-VII) that serve as reference for Equipment, Reagents & Supplies per Category.
2. *Assign sections of the tool to corresponding team members.*
3. *To properly fill-out this tool, the Licensing Officer shall make use of: INTERVIEWS, REVIEW OF DOCUMENTS, OBSERVATIONS and VALIDATION of findings.*
4. *If the corresponding items are present, available or adequate, place a ✓on each of the appropriate spaces under the FINDINGS column or space provided alongside each corresponding item. If not, put an* **X** *instead.*
5. *The REMARKS column shall document relevant observations for Quality Improvement.*
6. *Make sure to fill-in the blanks with the needed information. Do not leave any items blank; write (*N/A) not applicable *or* **---** *if needed.*
7. ■ *(Shaded cell) means that specific items are not applicable to the laboratory category. With (*****) asterisk–policies incorporated in One Stop Shop facility are acceptable.*
8. *The Team Leader shall at the end of the ocular visit, make sure that the team members complete their respective tool section.*
9. *The Team Leader shall ensure that all team members write down their printed names, designation and affix their signatures and indicate the date of inspection/monitoring, all at the last page of the tool.*
10. *The Team Leader shall make sure that the Head of the facility or, when not available, the next most senior or responsible officer likewise affix his/her signature on the same aforementioned pages, to signify that the inspection/monitoring results were discussed during the exit conference and a duplicate copy also received.*

I. GENERAL INFORMATION:

Name of Facility: _____

Address: _____
(Number & Street)(Barangay/District) (Municipality/City)

_____
(Province & Region)

Telephone/ Fax No ._____E-mail Address: _____

Initial: ___

Renewal: ___License No: _____ Date Issued: _____ Expiry Date: _____

Name of Owner or Governing Body (if corporation): _____

Name of Head of Laboratory: _____

Classification According to: Ownership: __ Government __ Private
Function: __ Clinical Pathology __ Anatomic Pathology
Institutional- __ Inst.-based (specify) _____
Character: __ Free-Standing
Service Capability: __ Primary __ Secondary
__ Tertiary __ Limited

Standards and Requirements *A.O.No.2007-0027*	Indicators/ Verifiers	Findings	Remarks (Quality Improvement)
1. MANAGEMENT RESPONSIBILITY *Sec. VI B. 1(a) v. (p.5)*	**The clinical laboratory shall be managed effectively and efficiently and in accordance with its vision, mission, and objectives.**		
Mission, vision and objectives shall be in accordance with RA 4688	• Posted / displayed mission, vision and objectives in a conspicuous area visible to client		
License to operate/ accreditation Certificate and other documents	• Valid licenses/Certificates posted in a conspicuous area visible to client • Compilation of Clinical Laboratory AOs, Report of Inspection/Monitoring • Copy of lab floor layout • Notarized MOA with clinicians for inst.-based laboratory **(if applicable**)		
Policy on continuing program for staff development and training*	• Documented Policy/ Program • Proof of training through relevant certificates, memos, written reports, budgetary allocations		
Policy for hiring, orientation and promotion for all levels of personnel *	• Documented procedure/ process on hiring, orientation and promotion of personnel at all levels		
Policy for discipline, suspension, demotion and termination of personnel at all levels*	• Documented procedure/ process on discipline, suspension, demotion and termination of personnel at all levels		
Policy on Management Review *	• Conduct of regular staff meetings held at least twice a year or as needed. • Documented minutes of meeting (reflecting the date, time, attendance, agenda and action taken signed by head of laboratory) shall be present and properly filed up		

Standards and Requirements *A.O.No.2007-0027*	Indicators/ Verifiers	Findings	Remarks (Quality Improvement)
Procedures for handling complaints and client feedback*	• Written protocol for handling complaints/ client feedback. • Forms for complaints/ client feedback • Suggestion box visible to clients • Records of complaints/ client feedback and actions taken		

2. MANPOWER	The clinical laboratory shall be organized to provide effective and efficient laboratory services		
The organizational chart shall be clearly structured. ***Sec. VI B. 1(a) (p.5)***	• Updated organizational chart indicating the **names with latest pictures(at least passport size)and designation**, reflecting lines of authority, accountability, communication, inter-relationship, hierarchy of functions and flow of referrals		
Duties and responsibilities shall be clearly spelled out. ***Sec. VI B. 1(a) (p.5)***	• Documented duties and responsibilities of all general laboratory personnel		
Adequate number of qualified personnel with documented training and experience to conduct the laboratory procedures performed. ***Sec. VI B. 1(a) iii – iv. (p.5)***	• List of Personnel with designation (other functions or special assignments) • Area of assignments indicated in the **posted work schedule signed and approved by head of laboratory** • **Proof of attendance** • Proof of qualifications: Updated copy of 201 File: ➢ Resume ➢ PRC ID and Certificate ➢ PSP Board Certificate (Head) ➢ Notarized Employment contract ➢ Training Certificates ➢ Annual Health status (Latest Medical Certificate)		
Authority to practice (if applicable) ***(AO# 92 S. 2003)***	• Copy of certificate signed by the head of the **Government facility**		

Standards and Requirements *A.O.No.2007-0027*	Indicators/ Verifiers	Findings	Remarks (Quality Improvement)
The general laboratory shall be headed and managed by a Clinical and/or Anatomic Pathologist certified by the Philippine Board of Pathology (PBP) ***Sec. VI B. 1(a) i.-iii. (p.5)*** This shall apply to all general laboratories be they government or private, institution based or free standing			
The head shall have administrative and technical supervision of the activities in the laboratory ***Sec. VI B. 1(a) i.-iii. (p.5)***	• Documented proof of Supervisory visit at least **once a month** or as needed		

Qualification of head of laboratory:	Category			Remarks (Quality Improvement)
	Primary	Secondary	Tertiary	
1. No Pathologist in the area				
• Physicians with complete training in Clinical Laboratory Medicine, Q. A., and Lab. Mgt. by BRL, CHD or PSP certified by BHFS (Certification from PSP that there is no pathologist in the area) ***may handle only (1) clinical laboratory**				
2. No Clinical Pathologist certified by PSP				
• Anatomic Pathologist with 2 yrs. training in Clinical Pathology • Anatomic Pathologist with no training in Clinical Pathology • Licensed physician with residency training in Clinical Pathology for at least2 yrs.				
3. In laboratories offering Clinical Pathology services only				
• Clinical Pathologist • Both CP & AP • AP & Associate CP				
4. In laboratories offering both Anatomic & Clinical Pathology				
• Both AP & CP • CP & Associate AP • AP & Associate CP				

Standards and Requirements *A.O.No.2007-0027*	Indicators/ Verifiers	Findings	Remarks (Quality Improvement)
There shall be an adequate number of medical technologists and other health professionals with documented training and experience to conduct laboratory procedures ***Sec. VI B. 1(a) i.-iv. (p.5)***			
Medical Technologist staff **(**additional proof of qualifications - **as applicable)**	• Valid HIV-trained RMT for lab with HIV Services (Required full time RMT for OFW facility) • Certificate of training on DSSM for lab with AFB services • Certificate of Training on Bacteriology **(Tertiary category)**		

MINIMUM NUMBER OF PERSONNEL

SERVICES	PRIMARY		SECONDARY		TERTIARY		Findings	Remarks (Quality Improvement)
	24 hour duty		24 hour duty		24 hour duty			
	8 hours	12 hours	8 hours	12 hours	8 hours	12 hours		
	Minimum		Minimum		Minimum			
Microscopy	1	1	1	1	1	1		
Hematology					1	1		
Clinical Chemistry			1	1	1	1		
Immunology					1	1		
Microbiology					1	1		
Histopathology	Optional except in Level III Hospital				1	1		
TOTAL	4	3	6	5	14	11		

- ❖ Total number of staff include reliever/s
- ❖ Free standing laboratory – actual number of staff per section
- ❖ Rotation of 24 hour duty
  - For tertiary laboratory, only three sections namely Microscopy, Hematology & Clinical Chemistry, function during PM and night shifts.
- ❖ Working hours: Minimum of 8 hours, Maximum of 12 hours
- ❖ Additional staff depends on workload: (10 minutes/ test)
  - Manual testing: 50 tests/RMT/8 hours
  - Manual testing: 75tests/RMT/12 hours
  - Automated testing: 100 tests/RMT/8 hours
  - Automated testing: 150 tests/RMT/12 hours
- ❖ Additional staff for other duties will be determined by the head of lab.

Standards and Requirements *A.O.No.2007-0027*	Indicators/ Verifiers	Findings	Remarks (Quality Improvement)
3. PHYSICAL PLANT/ FACILITIES/WORK ENVIRONMENT	Adequate facilities shall be in place for the safe & efficient operation of the clinical laboratory		
Program of proper maintenance and monitoring of physical plant and facilities ***Sec. VI B.1 (h) iv. (p6)***	• Documented program for the proper maintenance and monitoring of physical plant and facilities • Proposed schedule for preventive maintenance • Updated proof of actual implementation of maintenance as to structure, ventilation, lighting & water supply		
Policy guidelines on laboratory biosafety and biosecurity ***Sec. VI B.1 (h) v. (p6)***	• Documented procedure/ process on laboratory biosafety and biosecurity • Good Laboratory Practice that includes use of PPE and other precautionary measures		
Procedures for the proper disposal of waste and hazardous/infectious substances that shall conform to the standards set by the DOH ***Sec. VI B.1 (h) vi. (p6)***	• Documented policy on disposal of wastes that conform with Healthcare/ Waste Management Manual • Proof of proper management of wastes from point of generation, segregation(color-coded waste bins), disinfection …up to the final disposal		

REQUIRED AREA	Category			Remarks (Quality Improvement)
	Primary	Secondary	Tertiary	
Technical Working Area (minimum) **As per DM No. 148s. 2003**	10 sq. meters	20 sq. meters	60 sq. meters	**(To be implemented on 2016 to all new & 2017 for existing clinical laboratory)**
***Sections include**:*				
Microscopy				
Hematology				
Clinical Chemistry				
Immunology/Serology		Optional		
Microbiology*(Processing &Media Preparation room)*			*(Room Type)*	
Histopathology *(Level III Hospital based only)*	Optional		*(Room Type)*	
Other area to be provided:				
Extraction Area				
Pathologist Area	(Cubicle within the technical working area)		(Room Type)	
Toilet (**Staff** - adjacent or within the laboratory) (**Patient** - adjacent to laboratory or within premises)			(w/ Exhaust fan)	
Optional for One Stop Shop (OSS) facility				
Waiting Area				
Reception (Receiving of specimen/ Releasing of Laboratory Results)				
Storage Area (Supplies/Records)				
Pantry				
Conference Room	Level III Hospital			
Autoclave/Washing Area				
• Space components of the laboratory complex are required to be adjacent with one another in view of functional relationship, human traffic and efficient conduct of operations with **signage per area**				
• Required flooring: Use ceramic non-skid tiles or approved equivalent				
• Required working counter with at least 0.40 meter wainscoting as applicable: Counter top with laminated, ceramic, granite or approved equivalent and provided with stainless sink with a depth of at least 8 inches and goose-neck faucet				
• Required ventilation for technical working area: artificial means (ie. Exhaust fan/fume hood, air condition)				
• For tertiary level laboratories, microbiology and histopathology sections shall be provided separate exhaust fans each. However, for primary and secondary level laboratories, common exhaust fan can be used.				
• Room width should be at least 3 meters				

Standards and Requirements *A.O.No.2007-0027*	Indicators/ Verifiers	Findings	Remarks (Quality Improvement)
4. EQUIPMENT /INSTRUMENTS	Adequate equipment shall be in good working order.		
Adequate number of operational equipment to provide the laboratory examinations that the laboratory is licensed for. ***Sec. VI B.1 (b) i. (p5)***	• Equipment listed available in the laboratory • Equipment are operational • Provision for personal protective equipment ✚ *Specifications: **long Sleeved** (if applicable) laboratory gown with name or ID, closed shoes for laboratory use only, goggle, gloves, mask)*		
Program for calibration, preventive maintenance and repair for the equipment. ***Sec. VI B.1 (b) ii. (p5)***	• Record of schedule and updated certificate of calibration and maintenance of equipment • Record of reports of preventive maintenance and repair		
Contingency plan in case of equipment breakdown ***Sec. VI B.1 (b) iii. (p5)***	• Documented contingency plan in case of equipment breakdown		
5. **REAGENTS AND SUPPLIES**	Adequate reagents and supplies shall be in good working order.		
Adequate supply of properly stored and inventoried reagents and supplies for the laboratory examinations to be provided. ***Sec. VI B.1 (c) i.-ii. (p5)***	• Quality records of supplies /reagents with **expiration date**, their **usage/ consumption** and disposal are available • Certificate of Product Registration and evaluation of National Reference Labs.(NRL), Food & Drug Administration (FDA) etc.(If applicable)		
Reagents and supplies are stored under the required conditions. Adequate storage facilities such as refrigerators for perishable reagents and supplies. ***Sec. VI B.1 (c)iii. (p5)***	• Temperature monitoring records as follow: ❖ Room temperature reading ❖ Reagent storage refrigerator reading		
Appropriate storage area/technique for flammable, combustible and hazardous chemical/reagents ***Sec. VI B.1 (h) v.-vi. (p6)***	• Material Safety Data Sheet (MSDS) available for all reagents/supplies and accessible to all personnel at all times ❖ Organized per section with **National Fire Protection Association** (NFPA) Label 		

Standards and Requirements *A.O.No.2007-0027*	Indicators/ Verifiers	Findings	Remarks (Quality Improvement)
6. POLICIES AND PROCEDURES			
Administrative policies & procedures for provision of laboratory services and for the operation and maintenance of the laboratory ***Sec. VI B.1 (d) (p5)***	• Documented policies, protocols, procedures signed and approved by the head of laboratory • Guidelines in the operation and maintenance of the laboratory including **policy on security of supplies, specimens and confidentiality of records** • Documented policies, procedures and quality assurance program on Point of Care Testing (***if hospital based***) with **list of apparatus & calibration record**		
Technical procedures of services provided in each section are available ***Sec. VI B.1 (e) (p6)***	• Documented technical procedures provided in each section		
a. Communication and Records			
Procedures for the receipt and performance of routine and STAT requests for laboratory examinations (If applicable) ***Sec. VI B.1 (g) i (p6)***	• Documented procedures for receipt and performance of routine and STAT requests for laboratory examinations.		
Procedures for reporting of results of routine and STAT laboratory examinations (If applicable) ***Sec. VI B.1 (g) ii. (p6)***	• Documented procedures for reporting of results of routine and STAT laboratory examinations.		
All laboratory reports on various examinations of specimens shall bear the name of the pathologist or designated associate who shall be responsible for the reliability of the results. The reports shall bear the name of the registered medical technologist(s) who performed the examinations and duly signed by that person(s). Electronic signatures will be permitted in accordance to the E-commerce law. ***Sec. VI B.1 (g)iii. (p6)***	• Laboratory report forms bearing the name of the head or associate and facsimile signature with PRC ID No. • Laboratory reports bearing the name of RMT and original signature with PRC ID No. who performed the examinations • Updated records of result (logbooks/ electronically stored data with back up) including entry, releasing & endorsement records Policy for **Laboratory Information System** (LIS) (if available)		

Standards and Requirements *A.O.No.2007-0027*	Indicators/ Verifiers	Findings	Remarks (Quality Improvement)
Procedures for reporting of work load, quality control, inventory control, etc. ***Sec. VI B.1 (g) iv (p6)***	• Documented procedures for reporting of work load, quality control, inventory control, etc. • Updated reports, documents (Hard or soft copy with back up) • Worksheets/ machine print out per section as proof of actual performance		
Procedure for reporting and analysis of incidents, adverse events, etc. ***Sec. VI B.1 (g) v (p6)***	• Documented procedures for reporting and analysis of incidents, adverse events, etc • Compilation of written reports with resolutions		
The retention of records of the laboratory shall follow standards promulgated by the Department of Health **(DC# 70 s. 1996)** and/or competent professional Organizations ***Sec. VI B.1 (g).vi. (p6)***	• Documented procedure for the retention of records which follows standards promulgated by the Department of Health		
b. Quality Assurance Program			
Policy on Quality Assurance Program and Continuous Quality Improvement ***Sec. VI B.1 (f).i. (p6)***	• Documented Internal Quality Assurance Program including Internal Quality Control and Continuous Quality Improvement • Updated QC reports conducted • Availability of reference materials and appropriate reagents & equipment used • Results/findings of Quality Assurance audits/ assessments		

Standards and Requirements *A.O.No.2007-0027*	Indicators/ Verifiers	Findings	Remarks (Quality Improvement)
Participation in an External Quality Assessment Program (EQAP) administered by the designated National Reference Laboratories (NRL) or other EQAP approved by the BHFS-DOH ***Sec. VI B.1 (f).ii. (p6)***	• Documented procedure in the actual performance of EQAP activities administered by the NRLs (**after 1 year of operation**) • Certificate of participation of the laboratory administered by the NRLs: ❖ NRL - NKTI (Hematology) Year _____ ❖ NRL - LCP(Chemistry) Year _____ ❖ NRL - SLH/SACCL (Immunology/Serology) Year _____ ❖ NRL - RITM (Parasitology & Microbiology) Year _____		
c. Referral of Examinations Outside of the Clinical Laboratory	When laboratory examinations are referred to and provided by an outside clinical laboratory, the referring clinical laboratory shall obtain assurance of the quality of services provided through an agreement or its equivalent with a licensed clinical laboratory performing the laboratory services needed		
Policy on referral and outsourcing of examinations. ***Sec. VI B.1.i. (p6)***	• Documented Procedures on referral and outsourcing of examinations to other licensed clinical laboratory • Records of outsourced examinations • MOA, DOH license or its equivalent on referral of laboratory services to outside duly licensed laboratory (**With special/ higher service capability than the referring laboratory)**		
Note: For the presence of other laboratories in the vicinity: If any, indicate the kind of laboratory & provide details			
[ ] Research Lab [ ] Special Clinical Laboratory [ ] Teaching Lab [ ] Others, specify: _____			

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Name of Facility: _____

Date of Inspection: _____

RECOMMENDATIONS:

A. For Licensing Process:

[ ] For issuance of License as General Clinical Laboratory.

Validity from _____ to _____

[ ] Issuance depends upon compliance to the recommendations given and submission of the following within _____ days from the date of inspection:

_____

_____

_____

_____

[ ] Non-Issuance: Specify reason/s. _____

_____

_____

_____

_____

Inspected by:

Printed Name	Signature	Position/Designation

Received by:

Signature _____
Printed Name _____
Position/Designation _____
Date _____

Republic of the Philippines
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HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Name of Health Facility: _____

Date of Monitoring: _____

RECOMMENDATIONS:

B. For Monitoring Process:

[ ] Issuance of Notice of Violation

_____

_____

_____

[ ] Non-issuance of Notice of Violation

_____

_____

_____

_____

[ ] Others (Specify) _____

_____

_____

_____

Monitored by:

Printed Name	Signature	Position/Designation

Received by:

Signature _____
Printed Name _____
Position/Designation _____
Date _____