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

ASSESSMENT TOOL FOR LICENSING A NEWBORN SCREENING CENTER

Name of Laboratory:_____

Address:_____
Number & Address Barangay/ Municipality

_____
Province/City Region

Contact No./ Fax No./ E-mail Address:_____

Application for: ☐ Initial

☐ Renewal

GENERAL INFORMATION

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

Name of Head of Laboratory: _____

Classification according to:

Ownership: ☐ Government ☐ Private

Institutional Character: ☐ Institution-based ☐ Freestanding

Instructions:

1. Check **Yes** ☐ if item indicated is present, **No** ☐ if item indicated is absent, and **N/A** ☐ if item does not apply.
2. All items with (*) must be posted in a conspicuously designated area.
3. The Regulatory Officer will use this checklist during inspection/monitoring prior to issuance of accreditation (initial/renewal)
4. This checklist should also serve as a guide for self-assessment of the facility in preparation for inspection/monitoring visits

STANDARDS	FINDINGS Yes	No	N/A	COMMENTS

1. MANAGEMENT STANDARDS

1.1 Application Documents

All application documents are valid and complete.

Documentary Requirements:

List of personnel available including the following:

- ❖ Name ☐ ☐ ☐ _____
- ❖ Position ☐ ☐ ☐ _____
- ❖ License number (if appropriate) and validity ☐ ☐ ☐ _____
- ❖ Status: Permanent or Temporary ☐ ☐ ☐ _____
- ❖ Educational Attainment (documentation available) ☐ ☐ ☐ _____
- ❖ Job Description ☐ ☐ ☐ _____
- ❖ Training (documentation available) ☐ ☐ ☐ _____
- ❖ Signature ☐ ☐ ☐ _____

List of equipment/instruments including:

- ❖ Name of Equipment and Manufacturer ☐ ☐ ☐ _____
- ❖ Date acquired with proof of purchase ☐ ☐ ☐ _____
- ❖ Quantity ☐ ☐ ☐ _____
- ❖ Functional Status ☐ ☐ ☐ _____

Floor Plan available including the following:

- ❖ Properly labeled areas with adequate scaling to include spatial relationship of adjacent rooms if present. ☐ ☐ ☐ _____
- ❖ Valid signature and seal of architect or engineer. ☐ ☐ ☐ _____

Certificates and Permits:

The laboratory must comply with the following certificates and permits, which should be valid, current, and posted conspicuously in the reception area:

- ❖ Fire Safety Inspection Certificate ☐ ☐ ☐ _____
- ❖ DTI/SEC registration/Enabling Act Resolution ☐ ☐ ☐ _____
- ❖ Mayor's Permit ☐ ☐ ☐ _____
- ❖ Annual Building Inspection Certificate ☐ ☐ ☐ _____
- ❖ PRC Board Certificate for the following:
  - Physician Head of Program ☐ ☐ ☐ _____
  - Head of Laboratory ☐ ☐ ☐ _____

-	Technical Staff	☐	☐	☐	
-	Nurse Follow-up Coordinator	☐	☐	☐	
❖	Proficiency Testing Program Participation (for renewal)	☐	☐	☐	
1.1.1.5	Quality Assurance Program Plan	☐	☐	☐	
1.1.1.6	Manual of Procedures/Operations	☐	☐	☐	

2.2 MANAGEMENT RESPONSIBILITY

The laboratory shall be managed effectively, efficiently and in accordance with its mission, vision and objectives.

Mission, Vision and Objectives

Mission, vision and objectives exist in accordance with RA 9288 "Newborn Screening Act"	☐	☐	☐	
Mission, vision and objectives are known and understood by all personnel.	☐	☐	☐	

Management/Staff Meetings

Documentation of staff meetings occurring at least once monthly or as needed including proof of attendance.	☐	☐	☐	
Meeting minutes exist and are properly filed.	☐	☐	☐	

Continuing Program for Staff Development and Training

A policy/program for continuing program on staff development and training exists.	☐	☐	☐	
Proof of training exists (certificates, memos, written reports, budgetary allocations, etc.	☐	☐	☐	

Quality Plan

A written program/plan of management to assure competence, integrity of newborn screening exists.	☐	☐	☐	
An indication of the status of program plan Implementation exists.	☐	☐	☐	

Procedures for handling internal complaints and accidents

A written protocol for handling internal complaints exists.	☐	☐	☐	
A written protocol for handling laboratory accidents exists.	☐	☐	☐	
A record of complaints and accidents exists.	☐	☐	☐	

Client Inquiries and Feedback

A written protocol for handling inquiries exists. ☐ ☐ ☐ _____

A written protocol for handling requests for adding or changing information contained in patient records exists ☐ ☐ ☐ _____

Records of record changes exist. ☐ ☐ ☐ _____

3.3 MANPOWER

Personnel and practices shall be in place to ensure the achievement of the mission of the laboratory

Staffing

An organizational chart exists that includes pictures of employees and clearly identifies positions and lines of authority. ☐ ☐ ☐ _____

Written job descriptions exist that describe duties responsibilities, and performance expectations. ☐ ☐ ☐ _____

Physician Program Head

Proofs of qualifications. Examples:

- ❖ Licensed Physician ☐ ☐ ☐ _____
- ❖ PRC Board Certificate ☐ ☐ ☐ _____
- ❖ Subspecialty Certification ☐ ☐ ☐ _____
- ❖ Etc. ☐ ☐ ☐ _____

Proof of training.

- ❖ Certificate of 1 year training/orientation/experience in running a NBS program or 3 years of experience in related field. ☐ ☐ ☐ _____

1.3.2.3 Proof of employment exists. ☐ ☐ ☐ _____

Laboratory Head

Proofs of qualifications. Examples:

- ❖ Licensed biochemist, chemist, medical technologist or microbiologist ☐ ☐ ☐ _____
- ❖ PRC ID (valid) ☐ ☐ ☐ _____
- ❖ PRC Board Certificate ☐ ☐ ☐ _____

Proof of training.

- ❖ Certificate of 1 year training in NBS Laboratory Management or 3 years of experience in related field. ☐ ☐ ☐ _____

Proof of employment exists. ☐ ☐ ☐ _____

Technical Staff (at least 3)

Proofs of qualifications.

- ❖ Licensed biochemist, chemist, medical technologist ☐ ☐ ☐ _____
- ❖ or microbiologist.
- ❖ PRC ID (valid) ☐ ☐ ☐ _____
- ❖ PRC Board Certificate ☐ ☐ ☐ _____

Proof of training.

- ❖ Certificate of at least 3 months training in laboratory testing experience in performing the tests specified or 1 year of equivalent testing experience in a clinical laboratory. ☐ ☐ ☐ _____

Proof of employment exists. ☐ ☐ ☐ _____

Administrative staff

Proofs of qualifications

- ❖ Licensed nurse ☐ ☐ ☐ _____
- ❖ PRC ID (valid) ☐ ☐ ☐ _____
- ❖ PRC Board Certificate ☐ ☐ ☐ _____

Proof of training. ☐ ☐ ☐ _____

- ❖ Certificate of at least 3 months of experience working/training in NBS or six (6) months of equivalent experience in a public health case Management program. ☐ ☐ ☐ _____

Proof of employment exists. ☐ ☐ ☐ _____

Personnel Records

All records should be within the lab premises.

Curriculum vitae for all employees exist containing: ☐ ☐ ☐ _____

- ❖ Personal background
- ❖ Education
- ❖ Training & Experience

A medical /health certificate is present for each employee. ☐ ☐ ☐ _____

Monthly schedule of office hours and duty assignments are present and posted within the laboratory. ☐ ☐ ☐ _____

Policies for Hiring, Orientation and Promotion

1.3.6.1 A written policy for hiring, orientation and promotion exists for all levels of personnel. ☐ ☐ ☐ _____

Policies for Violations/Suspension/Terminations

Written policies for violations/suspensions/terminations exist for all levels of personnel. ☐ ☐ ☐ _____

Written documentation of errors potentially affecting patient results exist with reason for occurrence and corrective actions to prevent recurrence. ☐ ☐ ☐ _____

Records of memoranda related to policy infractions exist. ☐ ☐ ☐ _____

4.4 PHYSICAL FACILITY

Adequate facility shall be in place for the safe and efficient operation of the laboratory.

General Floor Area

Overall working floor area is 100 sqm. or more. ☐ ☐ ☐ _____

A specimen collection area/drying area of samples exist. ☐ ☐ ☐ _____

Five (5) work-benches to run the five (5) tests. Each work bench approximately three (3) ft. wide and (5) ft. long. ☐ ☐ ☐ _____

Laboratory Facilities

Proper ventilation exists. ☐ ☐ ☐ _____

Adequate lighting exists. ☐ ☐ ☐ _____

An adequate water supply exists(free flowing water from the faucet in the work area and in the hand washing area). ☐ ☐ ☐ _____

Waste Facility

A written protocol for waste management following universal guidelines exists. ☐ ☐ ☐ _____

Evidence of protocol implementation exists. ☐ ☐ ☐ _____

Waste segregation is practiced. ☐ ☐ ☐ _____

5.5 EQUIPMENT (S) AND SUPPLIES

The facility should contain adequate equipment in good working order and sufficient supplies to provide uninterrupted operation.

Reagents

A sufficient supply of reagents to perform all required testing should exist. Tests include: ☐ ☐ ☐ _____

- ❖ TSH
- ❖ 17-OHP
- ❖ PHE
- ❖ GAL
- ❖ G6PD

All reagent containers are labeled with contents and ☐ ☐ ☐ _____

date opened.

All date sensitive reagents/kits are fresh (i.e. "in date").	☐	☐	☐	
Equipment (s)				
Refrigerator/Freezer is present and operational.	☐	☐	☐	
❖ A daily temperature record is posted on each unit.	☐	☐	☐	
❖ Food is not stored in reagent refrigerators.	☐	☐	☐	
❖ Maintenance records exist.	☐	☐	☐	
Manual/automated puncher is present and operational.	☐	☐	☐	
❖ Daily, weekly, monthly maintenance records exist and are posted on or near automated puncher.	☐	☐	☐	
Fume hood is functioning properly.	☐	☐	☐	
❖ Air flow is operating and records indicating flow has been regularly checked exist.	☐	☐	☐	
❖ Work area is uncluttered and safe.	☐	☐	☐	
Equipment necessary for the required tests is present and sufficient to perform the following tests:				
❖ TSH	☐	☐	☐	
❖ 17OHP	☐	☐	☐	
❖ PHE	☐	☐	☐	
❖ GAL	☐	☐	☐	
❖ G6PD	☐	☐	☐	
Database system is operational and compatible with NSRC.	☐	☐	☐	
2 Appropriate system maintenance records exist.	☐	☐	☐	
3 An operations manual is present and sufficient.	☐	☐	☐	
4 A system of daily back-up is in place.	☐	☐	☐	
Other supplies and fixtures				
Cabinets are orderly and safe.	☐	☐	☐	
5 Cabinets are secure where needed for records and supplies.	☐	☐	☐	
6 Tables and chairs are sufficient for the number of personnel.	☐	☐	☐	
7 A functional calculator is present and operational.	☐	☐	☐	
8 A supply of filter paper cards exists and storage meets NSRC requirements.	☐	☐	☐	
9 A supply of lancets exists and storage is safe.	☐	☐	☐	
10 A drying rack(s) is present and properly used.	☐	☐	☐	
11 Residual specimen cards are stored in an appropriate space in an orderly fashion.	☐	☐	☐	
12 A supply of gloves for employee use exists and	☐	☐	☐	

are appropriately used. ☐ ☐ ☐ _____

13 An appropriate supply of pipettes exists. ☐ ☐ ☐ _____

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2.0 TECHNICAL STANDARDS

2.1 LABORATORY FORMS/RECORDS

2.1.1 Individual result records for abnormal test results are in use ☐ ☐ ☐ _____

- ❖ Individual reports contain results obtained, expected range or result, and suggested action. ☐ ☐ ☐ _____
- ❖ Reported results are traceable to data showing the procedure used, accurate assay controls, and proper use of standard curve (if appropriate). ☐ ☐ ☐ _____

2.1.2 A summary form for reporting normal, elevated and unsatisfactory sample results is in use. Minimum data fields: ☐ ☐ ☐ _____

- ❖ Name of patient ☐ ☐ ☐ _____
- ❖ Date of birth ☐ ☐ ☐ _____
- ❖ Date of collection ☐ ☐ ☐ _____
- ❖ Hospital of birth ☐ ☐ ☐ _____
- ❖ Hospital of collection ☐ ☐ ☐ _____
- ❖ Attending physician ☐ ☐ ☐ _____
- ❖ Laboratory accession number ☐ ☐ ☐ _____

2.2 TECHNICAL PROCEDURES

The facility must include an integrated system for specimen collection, receipt of externally collected specimens, sorting, accessioning, releasing specimen results, and handling program finances.

2.2.1 Procedure for specimen collection

2.2.1.1 A written procedure for specimen collection at the facility must exist and comply with the procedure of the NSRC. ☐ ☐ ☐ _____

2.2.2 Procedure for receiving, accessioning and releasing results

- ❖ A written procedure for receiving specimens, and determining analytical acceptability, exists. ☐ ☐ ☐ _____
- ❖ A written procedure for assigning laboratory accession numbers exists and is routinely followed. ☐ ☐ ☐ _____
- ❖ A written procedure for entering and checking demographic information exists and is followed. ☐ ☐ ☐ _____
- ❖ A written procedure for entering and checking ☐ ☐ ☐ _____

analytical results exists for each procedure.

- ❖ A written procedure for releasing results exists. ☐ ☐ ☐
- ❖ A written procedure for correcting results or demographics when errors are reported exists and appropriate documentation of changes exists. ☐ ☐ ☐

2.2.3 Operating procedures for the analytical procedures

2.2.3.1 Written procedures exist which provide specific testing procedures for each of the following procedures exists: ☐ ☐ ☐

- ❖ TSH ☐ ☐ ☐
- ❖ 17-OHP ☐ ☐ ☐
- ❖ PHE ☐ ☐ ☐
- ❖ GAL ☐ ☐ ☐
- ❖ G6PD ☐ ☐ ☐

2.2.3.2 Criteria for determining analytical unacceptability exist for each testing procedure. ☐ ☐ ☐

2.2.3.3 Mechanism of Reporting Results ☐ ☐ ☐

- ❖ Flowchart reflecting mechanism of reporting results. ☐ ☐ ☐
- ❖ File copy of computer-generated results ☐ ☐ ☐
- ❖ Transmission of results to participating hospitals ☐ ☐ ☐

2.3 QUALITY ASSURANCE PROGRAM

The newborn screening laboratory shall practice quality assurance program.

2.3.1 Internal Quality Assurance Program ☐ ☐ ☐

- ❖ Protocol for Internal QA ☐ ☐ ☐
- ❖ Controls/ Standards/ Blind samples ☐ ☐ ☐
- ❖ Logbook/Record of QC results ☐ ☐ ☐

2.4 External Quality Assurance Program (for renewal) ☐ ☐ ☐

- ❖ Application for proficiency testing ☐ ☐ ☐
- ❖ Record of receipt of samples from NSRC ☐ ☐ ☐
- ❖ Logbook/Record of PT results ☐ ☐ ☐
- ❖ Record of results received from NSRC ☐ ☐ ☐
- ❖ Certificate of PT ☐ ☐ ☐
- ❖ Record of corrective action taken when evaluation of performance is below satisfactory. ☐ ☐ ☐

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Name of Facility: _____

Date of Inspection: _____

RECOMMENDATIONS:

A. For Licensing Process:

[ ] For issuance of Certificate of Accreditation as Newborn Screening Center.

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
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Name of Laboratory:

Date of Monitoring:

RECOMMENDATIONS:

A. **For Monitoring Process**:

[ ] For 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 _____